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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 13 - 1-98

Subject: Definitions of "Screening" and "Medical Necessity"
(Resolution 719, A-98)

Presented by: Kay K. Hanley, MD, Chair

Referred to: Reference Committee G
(Richard W. Whitten, MD, Chair)

At the 1998 Annual Meeting, the House of Delegates referred Resolution 719 to the Board of Trustees. Introduced by the Oklahoma delegation, the resolution calls for the AMA to adopt the following definitions of "screening" and "medical necessity":

Screening, which is a term referring solely to examinations of asymptotic, apparently healthy individuals with no signs or symptoms of disease, typically undertaken to provide the individual examined with reassurances of his/her good health, shall not be considered the examination for asymptotic individual with signs or symptoms of disease for whom a process of diagnosis or treatment is being undertaken by his/her physician.

The term "medical necessity" or "medically necessary" when used in reference to the evaluation and/or treatment of a patient by a medical doctor or doctor of osteopathy shall mean any evaluation provided by or at the direction of an MD or DO, or treatment, which in the professional opinion of the MD or DO in consultation with and concurrence of the patient or his/her legal representative will provide functional, psychological, or health benefits to the patient.

The Board of Trustees referred Resolution 719 (A-98) to the Council on Medical Service for study and a report back to the House at the 1998 Interim Meeting.

The following report describes use of the term "medical necessity" in the Medicare program and the private sector, summarizes AMA policy on medical necessity determinations, and presents a number of policy recommendations.

"MEDICAL NECESSITY" IN THE MEDICARE PROGRAM

Since its inception in 1965, the Medicare program has only paid for those health care items and services that are considered to be medically necessary and relevant to improving or maintaining the health of a beneficiary. In particular, Section 1862(a)(1) of the Social Security Act prohibits payment for services or procedures that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member." Accordingly, Medicare carriers have generally used the following criteria to determine the medical necessity of specific items and services:

- 1 • Consistent with the symptoms or diagnoses of the illness or injury under treatment.
- 2
- 3 • Necessary and consistent with generally accepted professional medical standards (i.e., not
- 4 experimental or investigational).
- 5
- 6 • Not furnished primarily for the convenience of the patient, the attending physician, or another
- 7 physician or supplier.
- 8
- 9 • Furnished at the most appropriate level that can be provided safely and effectively to the
- 10 patient.
- 11

12 The Medicare program also specifies a number of items and services that are not covered,
13 including glasses, hearing aids, routine foot care, dental services, cosmetic surgery, custodial care,
14 and routine checkups. Such checkups usually involve examinations that are unrelated to the
15 treatment or diagnosis for a specific illness, symptom, complaint or injury.

16 "MEDICAL NECESSITY" IN THE PRIVATE SECTOR

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18
19 Over the years, most private insurers and third-party payers have viewed "medical necessity" as
20 those health care products or services provided in accordance with "prevailing standards of care" or
21 "generally accepted standards of medical practice." Accordingly, medical necessity determinations
22 have typically been made using specified review criteria and processes that afford clinical peer-to-
23 peer review. More recently, however, increasing concern has been raised regarding changing
24 health plan interpretations of the term "medical necessity."

25
26 Reviews of managed care contracts conducted by the AMA during the past year have revealed that
27 language imposing "lowest cost" criteria has been included in the definition of medical necessity in
28 some contracts. An example of such language is as follows:

29
30 Medical necessity means the shortest, least expensive, or least intense level of treatment,
31 care or service rendered, or supply provided, as determined by us [health plan], to the
32 extent required to diagnose or treat an injury or sickness. The service or supply must be
33 consistent with the insured person's medical condition at the time the service is rendered,
34 and is not provided primarily for the convenience of the insured person or doctor.

35
36 The use of "lowest cost" language in contractual definitions of medical necessity clearly raises the
37 question as to whether some health plans and third-party payers are basing their medical necessity
38 determinations on a standard that affords patients a far lower standard of care than most physicians
39 would provide without such interference.

40 CURRENT AMA POLICY

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42
43 The AMA has established a comprehensive, long-standing policy base on medical review and, in
44 particular, on the processes that health plans and third-party payers should adhere to in making
45 medical necessity determinations. The most relevant of these policies are listed below:

- 1 • The medical protocols and review criteria used in any utilization review or utilization
2 management program must be developed by physicians (Policy H-285.998[5], AMA Policy
3 Compendium).
- 4
- 5 • Public and private payors should be required to disclose to physicians on request the screening
6 and review criteria, weighting elements, and computer algorithms utilized in the review
7 process, and how they were developed (Policies H-285.998[5] and H-320.968[2a]).
- 8
- 9 • Third-party methodologies for determining "medical necessity" should be made available to
10 medical societies and to individual physicians, as well as listings of those specific situations
11 (such as the ordering of either experimental or outdated procedures or questionable hospital
12 admissions) where additional data may be required (Policy H-320.995[2c]).
- 13
- 14 • A physician of the same specialty must be involved in any decision by a utilization
15 management program to deny or reduce coverage for services based on questions of medical
16 necessity (Policies H-285.998[5], H-320.965, H-320.968[2b], and H-320.982[3]).
- 17
- 18 • Any physician who makes judgments or recommendations regarding the necessity or
19 appropriateness of services or site of services should be licensed to practice medicine and
20 actively practicing in the same jurisdiction as the practitioner who is proposing or providing the
21 reviewed service and should be professionally and individually accountable for his or her
22 decisions (Policies H-285.998[5] and H-320.968[2d]).
- 23
- 24 • A physician whose services are being reviewed for medical necessity should be provided the
25 identity of the reviewing physician on request (Policy H-285.998[5]).
- 26
- 27 • All health plans conducting utilization management or utilization review should establish an
28 appeals process whereby physicians, other health care providers, and patients may challenge
29 policies restricting access to specific services and decisions to deny coverage for services, and
30 have the right to review any coverage denial based on medical necessity by a physician
31 independent of the health plan who is of the same specialty and has appropriate expertise and
32 experience in the field (Policies H-285.998[5] and H-320.968[2c]).
- 33
- 34 • In "medical necessity" decisions where the determination may be modified by additional
35 medical evidence, there should be an opportunity for the treating physician to provide such
36 evidence before a final decision not to pay is made (Policy H-320.995[2d]).
- 37

38 DISCUSSION

39

40 The medical review policies cited in this report have served the AMA well during the past 10
41 years. Many of these policies have been included in a variety of state laws regulating the
42 utilization review industry. Similarly, many of the policies have been included in state patient
43 protection legislation. Through its active participation on the American Accreditation HealthCare
44 Commission (AAHCC)/URAC, the AMA has succeeded in having many of the policies included in
45 the Commission's utilization management standards. Twenty states currently incorporate the
46 AAHCC/URAC utilization management standards in their regulatory process, either through
47 "deemed status" in lieu of the utilization review requirements in their states, or by requiring entities
48 performing utilization review to be AAHCC/URAC accredited. In addition, AMA medical review

1 policy has provided much of the underlying basis for the Advocacy Resource Center's ongoing
2 campaign to promote physician control of medical decision-making.

3
4 At the same time, neither AMA policy nor AMA model state legislation is explicit as to what
5 standard of "medical necessity" should apply during the review process. Accordingly, the Council
6 on Medical Service commends the Oklahoma delegation for bringing forth Resolution 719 (A-98)
7 with the intent of strengthening the AMA's policy base on medical review. Although specific
8 definitions are codified only occasionally in AMA policy, the Council believes the inclusion of
9 definitions of "screening" and "medical necessity" are warranted at this time. It also should be
10 noted that the House of Delegates previously adopted Council recommendations regarding
11 definitions of "emergency services" (Policy H-130.970[1]) and "principal care" (Policy H-
12 160.943).

13
14 With respect to the issue of screening, the Council notes that the Health Care Financing
15 Administration, in its interpretive guidelines for the Emergency Medical Treatment and Active
16 Labor Act (EMTALA), defines a "medical screening examination" as "the process required to
17 reach with reasonable clinical confidence, the point at which it can be determined whether a
18 medical emergency does not exist." While the Council acknowledges that this definition has
19 particular relevance for the implementation of EMTALA, it concurs with the sponsor of Resolution
20 719 (A-98) that the intent of the resolution was a different, more frequent use of the term
21 "screening." In this context, the Council believes that screening most commonly refers to a
22 "routine" physical examination or test that is unrelated to the diagnosis or treatment of a specific
23 illness, symptom, complaint, or injury, and which often is a noncovered service under many private
24 and public sector health plans.

25
26 Medical necessity, on the other hand, most commonly refers to those health care products or
27 services that are directly related to the diagnosis or treatment of a specific illness, symptom,
28 complaint, or injury. In developing its definition, the Council carefully reviewed the Medicare
29 statute, as well as the language contained in the 10 state laws that currently define "medical
30 necessity." In general, the definitions address what is provided (i.e., health care services), the
31 purpose (i.e., to diagnose or treat an illness or injury), and a varying level of standards (i.e., in
32 accordance with generally accepted standards of practice). The definition proposed in this report
33 includes what the Council believes are the most important factors for making medical necessity
34 determinations.

35
36 The Council believes that these definitions, combined with key existing policies on the
37 qualifications of those making medical necessity determinations, will enhance the advocacy efforts
38 of the AMA and members of the Federation. The Council also believes that these definitions will
39 help to empower physicians in the contracting process with managed care organizations and other
40 health plans. In addition, the Council recommends that these policies continue to be strongly
41 advocated to government agencies, managed care organizations, third-party payers, and private
42 sector health care accreditation organizations.

43 44 RECOMMENDATIONS

45
46 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
47 719 (A-98), and the remainder of the report be filed:

1 1. That the AMA adopt the following definition of "screening":

2
3 Health care services or products provided to an individual without apparent signs or
4 symptoms of an illness, injury or disease for the purpose of identifying or excluding an
5 undiagnosed illness, disease, or condition.
6

7 2. That the AMA recognize that federal law (EMTALA) includes the distinct use of the word
8 screening in the term "medical screening examination":
9

10 "The process required to reach, with reasonable clinical confidence, the point at
11 which it can be determined whether a medical emergency does or does not exist."
12

13 3. That the AMA adopt the following definition of "medical necessity":
14

15 Health care services or products that a prudent physician would provide to a patient for the
16 purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in
17 a manner that is: (1) in accordance with generally accepted standards of medical practice;
18 (2) clinically appropriate in terms of type, frequency, extent, site, and duration; and (3) not
19 primarily for the convenience of the patient, physician, or other health care provider.
20

21 4. That the AMA incorporate its definition of "medical necessity" in relevant AMA advocacy
22 documents, including its "Model Managed Care Services Agreement." Usage of the term
23 "medical necessity" must be consistent between the medical profession and the insurance
24 industry. Carrier denials for non-covered services should state so explicitly and not
25 confound this with a determination of lack of "medical necessity."
26

27 5. That the AMA encourage physicians to carefully review their health plan medical services
28 agreements to ensure that they do not contain definitions of medical necessity that
29 emphasize cost and resource utilization above quality and clinical effectiveness.
30

31 6. That the AMA urge private sector health care accreditation organizations to develop and
32 incorporate standards that prohibit the use of definitions of medical necessity that
33 emphasize cost and resource utilization above quality and clinical effectiveness.
34

35 7. That the AMA advocate that determinations of medical necessity shall be based only on
36 information that is available at the time that health care products or services are provided.
37

38 8. That the AMA reaffirm Policies H-320.982(5) and 320.968(2b) which emphasize that a
39 physician of the same specialty must be involved in any decision to deny or reduce
40 coverage for services based on questions of medical necessity.
41

42 9. That the AMA reaffirm Policies H-285.998(5) and 320.965 which emphasize that any
43 physician who makes judgments or recommendations regarding the necessity or
44 appropriateness of services should be licensed to practice medicine and actively practicing
45 in the same jurisdiction as the practitioner who is proposing or providing the reviewed
46 service.

- 1 10. That the AMA continue to advocate its policies on medical necessity determinations to
- 2 government agencies, managed care organizations, third-party payers, and private sector
- 3 health care accreditation organizations.

FAX

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Memo: DOL staff draft position paper

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REMEDIAL SCHEME POLICY ISSUES - Internal Discussion Draft

I. Internal Claims Review:

A proposal requiring internal review of benefit disputes could be modeled on the policies outlined in the recently proposed claims procedure regulation.

II. Independent External Review:

Any proposal providing external review should include the following elements:

Exhaustion: If participants are required to exhaust their external review procedures before pursuing judicial remedies, exhaustion should not be required in cases where:

1. The external review entity or plan/issuer has not complied with the required time frames;
2. The participant has already been injured by a denial or delay of claim and is not seeking the benefit that was denied; [*Note:* This approach could mean that an individual who is injured by a denial, but who is still seeking the benefit they were denied, would be forced to exhaust the external review process before seeking damages in court.]
3. The participant can show that pursuing external review would be futile (e.g., the plan has exhibited such bias or hostility in its dealings with the claimant that it is clear that pursuing internal review would be fruitless);
4. An emergency situation which precludes the participant from pursuing normal procedures (e.g., the external review entity cannot respond in a timely manner to the claimant's need of immediate emergency care); or **(HHS is concerned that this exception may be too broad.)**
5. The court determines in its discretion that the participant would suffer a severe hardship if review were denied (e.g., the individual becomes injured after the time period for bringing an external appeal has expired.).

Timeframes for Review: There should be explicit timeframes for completion of external review determinations that are both timely and reasonable given the requirements (e.g., Medicare+Choice regulations require routine determinations within 30 days and expedited determinations within 72 hours).

Expedited Review: There must be some process providing expedited external review for claims involving urgently needed care.

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Standard and Scope of Review: The external review entity should be required to review all benefit disputes *de novo*. External reviewers should not be permitted to defer to the plans'/issuers' decision. In addition, new evidence which was not considered during the internal review process should be admissible.

Access to Review:

Types of Claims: External review should be available for all adverse benefit determinations that meet any of the following criteria:

1. The appeal is supported by the claimant's treating physician [*Note:* physician should not have to be employed by plan]; **(HHS would prefer not to have this as a separate avenue of access to external review)**
2. There is a significant financial amount in controversy (as defined by the statute or by regulations); or
3. The reviewing entity determines that the case involves a determination that could seriously jeopardize the participant's life, health, ability to regain or maintain maximum function, or (for children) development.

Query: If a claim does not qualify for external review, should it be permitted to go straight to court? Should it be subject to an arbitrary and capricious standard of review?

Minimum Time Limits for Participants to Seek External Review: Any limits on a participant's ability to seek external review should provide that they have at least 180 days to seek review of a benefit dispute. [*Note:* The Republican bills raised this issue by including time limits that seemed unreasonably short (e.g., 30 days). Short time frames would preclude participants from seeking damages if they do not bring their claim within the required time frames and there is no exception to the exhaustion requirement for hardship. (See *Exhaustion*, above.)]

Financial Barriers: The plan/issuer should bear the cost of external review. The process should not impose administrative fees upon participants that would inhibit them from exercising their rights to external review.

Quasi-Judicial Process: Participants should be guaranteed the rights to use assistance or representation, to present relevant evidence, and make an oral presentation as part of the decisionmaking process. The plan or issuer should be required to provide timely access to all provisions of the plan and other documents relevant to the dispute. [*Note:* Should the participant be empowered to compel testimony by the plan?]

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Determination Binding on Plan/Participant: Judicial review of the external review entity's decision should be limited for both the plan/issuer and participant. [Note: Because of policy concerns about a plan's/issuer's greater resources to unilaterally appeal adverse external review decisions, there may be a need for some provision which deters plans/issuers from exercising their right to judicial review or addresses this imbalance in resources. (E.g., judicial review could be more deferential to the external reviewers determination in cases where the plan/issuer makes the appeal; plans/issuers who appeal could be required to pay the attorney's fees and court costs for the participants, regardless of the outcome.))]

External Review Entity Requirements:

Independence of Decisionmaking: There must be specific protections to assure the independence of external review, including protections relating to the independence of the reviewers and the entity, and protections assuring there will be no incentive for bias resulting from the plans'/issuers' ability to select an entity. **(HHS would prohibit contractual agreements between the plan and the external review entity)**

Certification Authority: There should be some oversight authority responsible for certifying the qualifications and independence of external review entities. [There are several options regarding whether the certification authority should be state, federal, both, or some combination that also coordinates with private entities. If both federal and state agencies are designated as certification authorities, there should be standards that will assure uniformity and coordination requirements.]

Eligibility to Serve as an Entity: [This gets at whether the bill should make specific requirements regarding whether the entity is a public or private entity, or whether the state external review programs could be preserved as long as certain standards are met.]

Application based on Insured Status **HHS would apply different requirements based on whether the plan was self-funded or fully insured.**

III. Remedies for Benefit Disputes:

Participants and beneficiaries of ERISA-covered group health plans who are injured due to an unreasonable delay or denial of a benefit would have a federal remedy. Changes to ERISA that would make the full array of compensatory damages available to those who are harmed, provide for civil penalties in egregious cases, and provide other new procedural rights. These new remedies would be available for all claims of unreasonable delay or denial of a claim resulting in

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injury, not simply those involving determinations of medical necessity.¹

Such a proposal should include all of the following elements:

Damages: Allow participants and beneficiaries harmed by an unreasonable delay or denial of a claim to sue plan fiduciaries and obtain damages for personal injury (whether physical or mental) and financial injury. We note that the availability of damages may result in a jury trial right not generally considered to be available under ERISA. Damages would include the following:

compensatory damages (both economic and non-economic); no caps [*Note:* Non-economic damages includes emotional distress, pain and suffering, etc.]

no punitive damages (**HHS recommends punitive damages except where the denial was upheld by the external review panel**)

attorneys' fees, court costs, and expert witness fees for prevailing plaintiff (both for external and judicial review)

Civil Penalties in Certain Cases: Two civil monetary penalties should be available where a plan or issuer has engaged in egregious behavior in delaying or denying a claim:

One enforceable by, and payable to, a participant or beneficiary who brings an action for reasonable delay or denial of a claim. An individual could obtain a civil penalty starting at \$10,000 and up to \$50,000 for each violation.

Another enforceable by, and payable to, the Secretary for a pattern or practice of unreasonable claims delays or denials. The Secretary could obtain a civil penalty of up to \$2 million per pattern or practice of conduct. [*Note:* Is this amount feasible? If not, is there some other way to structure this that would look more feasible but reach the same result? An alternative option would be to omit any figures and instead include criteria for the court to use in making its determination.]

Standing to Sue: A suit for damages could be brought by a participant, beneficiary, or the survivor or estate of a participant or beneficiary.

¹ The remedies available for benefit delays or denials that were merely erroneous (as opposed to unreasonable) would remain as they are under current law: equitable relief would be available. However, technical adjustments may be needed to assure claimants further procedural protections than are available under current law (e.g., the standard of review is less deferential).

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De Novo Standard of Review: Judicial review should be available for all cases where the plaintiff alleges unreasonable benefit delays or denials. A *de novo* standard of review should be applied for judicial determinations as to whether the benefit is owing, except where a claim has gone through *de novo* external review. In this circumstance, an arbitrary and capricious standard should apply. A *de novo* standard of review means review without deference to the decision of the plan where there is opportunity to introduce new evidence that was not before the internal claims reviewer.

Where An Action is Brought/Removal: For claims valued under \$50,000 (including compensatory damages), the individual could bring their federal claim to a state tribunal for a decision and an award of damages. These smaller claims could not be removable to federal court. Claims valued over \$50,000 would stay in federal court. [Note: Employer groups and unions will oppose provisions preventing removal from state court.]

Who is Liable: The fiduciary responsible for the unreasonable delay or denial of the claim should be liable for participants' actions. Two exceptions could be created:

Employer/Issuer Exception: This would exempt employers/issuers from liability where they have contracted with a third party to make claims review decisions. Employers/Issuers could retain final authority for decisionmaking without incurring liability where, under certain conditions, they follow the recommendation of a third party (who is contractually liable). There would need to be language to ensure that employers do not contract away this responsibility to shell organizations.

Taft-Hartley Exception: Trustees of Taft-Hartley plans could be exempt from liability under certain circumstances, transferring the liability to the plan itself.

IV. Remedies for Violation of Patient Protections/HIPAA:

It is expected that health care reform legislation will include certain specific patient protections guaranteeing access to such benefits as emergency treatment, specialist care, and a patient's right to have a gynecologist be her primary care physician. In addition, prohibitions against improper incentive compensation arrangements and gag clauses may be enacted. Enforcement of such substantive provisions is a novel issue which has not been thoroughly discussed within the Department. There are several options which address this issue. The following options are not mutually exclusive:

Option 1: Amend the current HIPAA enforcement scheme for violations of the substantive patient protection provisions and HIPAA (part 7) protections (with the exception of the provisions relating to internal claims processing procedures) to enable greater enforcement authority by HHS and DOL.

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The current scheme for enforcement of HIPAA includes the following:

DOL, and plan participant enforcement of the substantive patient protection provisions against that are incorporated into title I of ERISA. Such enforcement is limited to group health plans. DOL may not enforce these provisions against health insurance issuers. The available remedies are generally limited to equitable relief. [Note: CMPs of up to \$110 per day are available for information disclosure violations.]

The IRS may assess excise taxes against group health plans for violations HIPAA

States may assess civil money penalties against health insurance issuers.

HHS enforces as a fallback where states fail to substantially enforce and enforces directly against nonfederal governmental self-insured plans that have not opted out of HIPAA's requirements.

This scheme would be amended to give both HHS and DOL equivalent authority to enforce the substantive health care requirements, including the authority to impose CMPs, equitable relief, and the powers necessary to conduct investigations (e.g., subpoena power, etc.) **(Note: See Specific HHS recommendations in this area)**

Option 2: Adopt specific monetary penalty authority to enable enforcement by federal agencies (DOL for group health plans and HHS for issuers) and participants.

E.g.: A two-part penalty scheme made up of :

(1) A civil money penalty ordered by a court, in a suit brought by a participant or beneficiary against the plan for a substantive violation. The minimum penalty would be \$10,000 and the maximum would be \$50,000. The penalty would be payable to the participant or beneficiary.

(2) A civil money penalty ordered by a court in suit brought by the Secretary against plan for a pattern and practice of substantive violations. The maximum penalty would be \$2 million. The penalty would be payable to the government.

(HHS would prefer to allow the federal agencies to obtain civil money penalties for individual violations in addition to pattern/practice violations.)

Option 3: Instead of requiring the Secretary to go to court for a civil penalty (as in paragraph (2) of Option 3) allow the Secretary to assess the penalty administratively.

(Note: HHS appears to support such an option and proposes an administrative scheme this penalty and for this penalty and the participant's civil penalty as well, at least where no damages are sought.)

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Note: The purpose of the penalty scheme would be to provide some incentive to participants to bring suits for substantive violations without giving rise to the argument that the scheme unnecessarily encourages litigation. Only the Secretaries would have the authority to pursue the largest cases.

Question: What do we do about situations where the same facts raise a benefits dispute and a substantive violation of the patient protections? Need to avoid requiring participants to have to press their cases in two different tribunals at the same time. For this reason, it may be best to have the civil money penalty for substantive violations decided in the same court that a participant uses for appealing external review decisions.

V. Medical Necessity Determinations:

Meaningful review of determinations that require the exercise of medical judgment may require creation of a statutory standard for such decisions. Many plan documents provide that certain benefits will be provided when they are "medically necessary" or "medically appropriate." Similar plans often exclude "experimental," "investigational," "cosmetic," or "dental" services or treatments. The plans have great leeway in deciding what these terms mean in any given context, opening the door to arbitrariness. A statutory standard would assure that medical judgments are excised in a manner that is at least consistent with prevailing medical practice.

Under such a standard, plans' and issuers' coverage determinations that involve an exercise of medical judgment (including determinations of medical necessity) must be consistent with generally accepted principles of medical practice. Plans and issuers would generally defer to the recommendation of a treating physician unless they can show by a preponderance of the evidence that the physician's recommendation is inconsistent with such principles or that there is an alternative treatment that is at least as, or more, medically effective.

The purpose of this approach is to provide an informed, fair review of medical necessity determinations at all levels of review to reduce improper benefit denials. This approach has been criticized as an approach that will lead to the application of varying local standards of practice that are outmoded and do not result in the best quality care. However, a federal standard should be designed to be flexible and informed by current medical science, not simply by relevant local practice or industry protocols.

Although further analysis and development of this approach is warranted, the Department supports the following basic elements as an addition to our remedies framework:

Application of the Standard: The standard should apply not simply to coverage determinations that involve defining the term "medical necessity," but include any coverage decision where medical judgment is exercised.

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Standard of Determination: In general, plan coverage determinations should be based on an objective, flexible standard such as “generally accepted principles of medical practice” or a similar standard. There could be a special standard incorporated into the “generally accepted principles of medical practice” standard for new innovative treatments that are not yet “generally accepted” but may be proven to be more effective than alternative treatments. Ultimately the plan or issuer must be able to show that a particular benefit was not medically indicated based on an objective standard, not industry protocols or practices that do not track what is the most effective medical practice.

Deferral to Treating Physician: If the treating physician’s recommendation is consistent with generally accepted principles of medical practice, that recommendation should prevail unless the plan can show, by a preponderance of the evidence that its preferred course of treatment is at least as (more?) medically effective.

Procedural Requirements: The following procedural requirements should apply at least at an external review level, and during judicial review of claims that have not been reviewed by an external review entity.

Burden of Proof - It should be up to the claimant to challenge a plan’s decision regarding medical necessity by producing evidence that shows that the denied benefit was medically necessary. This could be done by merely presenting the recommendation of a treating physician that the denied care be provided. The burden then shifts to the plan to show either that the physician’s recommendation is not consistent with general principles of medical practice or that there is an alternative covered treatment that is just as effective.

Admissible Evidence - Any decision maker must evaluate all relevant evidence, not simply evidence relied on by a plan or issuer during an internal appeal. Admissible evidence could include peer reviewed studies and the opinions of qualified experts. The legislation would not set out an exhaustive list of admissible evidence, but would merely set out examples of evidence that could be admissible. It is up to the decision maker to ultimately determine what evidence is relevant.

The purpose of this approach is to provide an informed, fair review of determinations involving medical judgment to reduce improper benefit denials. This approach has been criticized as an approach that will lead to the application of varying local standards of practice that are outmoded and do not result in the best quality care. However, the federal standard of determination set out above is designed to be flexible and informed by current medical science, not simply by relevant local practice or insurance industry protocols.

This approach does have one significant limitation. The basic purpose behind these provisions is that a plan should generally abide by a treating physician’s decision on medical

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necessity unless they can show that the physician's decision is against generally accepted medical principles. This approach assumes that all physicians can and will exercise objective medical judgement. In today's incentivized managed care arrangements this is not always the case. A health plan's control over the physician's in its network cannot be underestimated. We may not wish to link a patient's ability to challenge a determination involving medical judgement to the concurrence of the patient's treating physician.

We also caution that this approach is not a substitute for providing adequate remedies under ERISA. Although it may reduce the number of improper benefit decisions that are made, it does not provide any recourse for those who are harmed by improper delays or denial of care.

HHS proposes an alternative option which would address this issue as part of the external reviewer's standard of review rather than as an express standard for medical decisionmaking for use by plans. Under this alternative option, a plan's benefit denial would be upheld if supported by any "reasonable evidence" that the treatment offered by the plan is at least as or more medically effective than the treatment requested by the claimant. In DOL's view, this option, as stated, is unacceptable, because it amounts to a codification of the current arbitrary and capricious standard.

DHHS
by Fax

To: Devora Adler
Fr: Lisa Rovin
Re: Materials for Monday's 3:00
Number of pages (including cover): 14
CC: Bill Taylor

Devora:

Here is the mark-up of the DoL paper, as requested. We have provided additional material:

- on issues where DoL refers to our recommendations without further explanation
- to raise issues not raised in the DoL paper
- to provide the Options paper requested by Chris on the Medical Necessity issue. (We are presenting for discussion an alternative that could create a greater ability to compromise in the future, and are aware that this approach has risks. We look forward to a full airing of the risks and opportunities of both approaches.)

We tried to keep the extra paper to a minimum, and apologize that you and Chris will have so much to read.

-lr

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REMEDIAL SCHEME POLICY ISSUES - Internal Discussion Draft**I Internal Claims Review:**

A proposal requiring internal review of benefit disputes could be modeled on the policies outlined in the recently proposed claims procedure regulation.

II Independent External Review:

Any proposal providing external review should include the following elements:

Exhaustion: If participants are required to exhaust their external review procedures before pursuing judicial remedies, exhaustion should not be required in cases where:

- Can be handled with well crafted "futility" exception, see Recommended Change #2.
1. The external review entity or plan/issuer has not complied with the required time frames;
 2. The participant has already been injured by a denial or delay of claim and is not seeking the benefit that was denied; [Note: This approach could mean that an individual who is injured by a denial, but who is still seeking the benefit they were denied, would be forced to exhaust the external review process before seeking damages in court.]
 3. The participant can show that pursuing external review would be futile (e.g., the plan has exhibited such bias or hostility in its dealings with the claimant that it is clear that pursuing internal review would be fruitless);
 4. An emergency situation which precludes the participant from pursuing normal procedures (e.g., the external review entity cannot respond in a timely manner to the claimant's need of immediate emergency care); or ~~(HHS is concerned that this exception may be too broad.)~~
 5. The court determines in its discretion that the participant would suffer a severe hardship if review were denied (e.g., the individual becomes injured after the time period for bringing an external appeal has expired.).

Timeframes for Review: There should be explicit timeframes for completion of external review determinations that are both timely and reasonable given the requirements (e.g., Medicare+Choice regulations require routine determinations within 30 days and expedited determinations within 72 hours.).

Expedited Review: There must be some process providing expedited external review for claims involving urgently needed care.

HHS views this as unnecessary and dangerous.

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Standard and Scope of Review: The external review entity should be required to review all benefit disputes *de novo*. External reviewers should not be permitted to defer to the plans'/issuers' decision. In addition, new evidence which was not considered during the internal review process should be admissible.

Access to Review:

Types of Claims: External review should be available for all adverse benefit determinations that meet any of the following criteria:

1. The appeal is supported by the claimant's treating physician [Note: physician should not have to be employed by plan]; (HHS would prefer not to have this as a separate avenue of access to external review)
2. There is a significant financial amount in controversy (as defined by the statute or by regulations); or
3. The reviewing entity determines that the case involves a determination that could seriously jeopardize the participant's life, health, ability to regain or maintain maximum function, or (for children) development.

Query: If a claim does not qualify for external review, should it be permitted to go straight to court? Should it be subject to an arbitrary and capricious standard of review?

Minimum Time Limits for Participants to Seek External Review: Any limits on a participant's ability to seek external review should provide that they have at least 180 days to seek review of a benefit dispute. [Note: The Republican bills raised this issue by including time limits that seemed unreasonably short (e.g., 30 days). Short time frames would preclude participants from seeking damages if they do not bring their claim within the required time frames and there is no exception to the exhaustion requirement for hardship. (See *Exhaustion*, above.)]

Financial Barriers: The plan/issuer should bear the cost of external review. The process should not impose administrative fees upon participants that would inhibit them from exercising their rights to external review.

Quasi-Judicial Process: Participants should be guaranteed the rights to use assistance or representation, to present relevant evidence, and make an oral presentation as part of the decisionmaking process. The plan or issuer should be required to provide timely access to all provisions of the plan and other documents relevant to the dispute. [Note: Should the participant be empowered to compel testimony by the plan?]

NHS
says NO. →
The process should
be as informal
as possible.

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HHS
supports
HR3605
approach,
binding on
plan.

Determination Binding on Plan/Participant: Judicial review of the external review entity's decision should be limited for both the plan/issuer and participant. [Note: Because of policy concerns about a plan's/issuer's greater resources to unilaterally appeal adverse external review decisions, there may be a need for some provision which deters plans/issuers from exercising their right to judicial review or addresses this imbalance in resources. (E.g., judicial review could be more deferential to the external reviewers determination in cases where the plan/issuer makes the appeal; plans/issuers who appeal could be required to pay the attorney's fees and court costs for the participants, regardless of the outcome.))]

External Review Entity Requirements:

Independence of Decisionmaking: There must be specific protections to assure the independence of external review, including protections relating to the independence of the reviewers and the entity, and protections assuring there will be no incentive for bias resulting from the plans'/issuers' ability to select an entity. (HHS would prohibit contractual agreements between the plan and the external review entity)

Certification Authority: There should be some oversight authority responsible for certifying the qualifications and independence of external review entities. [There are several options regarding whether the certification authority should be state, federal, both, or some combination that also coordinates with private entities. If both federal and state agencies are designated as certification authorities, there should be standards that will assure uniformity and coordination requirements.]

Eligibility to Serve as an Entity: [This gets at whether the bill should make specific requirements regarding whether the entity is a public or private entity, or whether the state external review programs could be preserved as long as certain standards are met.]

Application based on Insured Status HHS would apply different requirements based on whether the plan was self-funded or fully insured. ← See

III Remedies for Benefit Disputes:

Participants and beneficiaries of ERISA-covered group health plans who are injured due to an unreasonable delay or denial of a benefit would have a federal remedy. Changes to ERISA that would make the full array of compensatory damages available to those who are harmed, provide for civil penalties in egregious cases, and provide other new procedural rights. These new remedies would be available for all claims of unreasonable delay or denial of a claim resulting in

Recommended Change
6.

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injury, not simply those involving determinations of medical necessity.¹

Such a proposal should include all of the following elements:

Damages: Allow participants and beneficiaries harmed by an unreasonable delay or denial of a claim to sue plan fiduciaries and obtain damages for personal injury (whether physical or mental) and financial injury. We note that the availability of damages may result in a jury trial right not generally considered to be available under ERISA. Damages would include the following:

compensatory damages (both economic and non-economic); no caps [Note: Non-economic damages includes emotional distress, pain and suffering, etc.]

no punitive damages (HHS recommends punitive damages except where the denial was upheld by the external review panel)

attorneys' fees, court costs, and expert witness fees for prevailing plaintiff (both for external and judicial review)

HHS Concerns: *Civil Penalties in Certain Cases:* Two civil monetary penalties should be available where a plan or issuer has engaged in egregious behavior in delaying or denying a claim:

- This confuses government enforcement with individual benefits claims

One enforceable by, and payable to, a participant or beneficiary who brings an action for reasonable delay or denial of a claim. An individual could obtain a civil penalty starting at \$10,000 and up to \$50,000 for each violation.

- The \$10,000/\$50,000 scheme is too small to be an effective substitute for punitives, and it looks too much like capped damages

Another enforceable by, and payable to, the Secretary for a pattern or practice of unreasonable claims delays or denials. The Secretary could obtain a civil penalty of up to \$2 million per pattern or practice of conduct. [Note: Is this amount feasible? If not, is there some other way to structure this that would look more feasible but reach the same result? An alternative option would be to omit any figures and instead include criteria for the court to use in making its determination.]

- Proposing a "CMP" substitute for punitives could

Standing to Sue: A suit for damages could be brought by a participant, beneficiary, or the survivor or estate of a participant or beneficiary.

out compensatory damages + risk.

The remedies available for benefit delays or denials that were merely erroneous (as opposed to unreasonable) would remain as they are under current law: equitable relief would be available. However, technical adjustments may be needed to assure claimants further procedural protections than are available under current law (e.g. the standard of review is less deferential).

Not tied to level of harm.

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De Novo Standard of Review: Judicial review should be available for all cases where the plaintiff alleges unreasonable benefit delays or denials. A *de novo* standard of review should be applied for judicial determinations as to whether the benefit is owing, except where a claim has gone through *de novo* external review. In this circumstance, an arbitrary and capricious standard should apply. A *de novo* standard of review means review without deference to the decision of the plan where there is opportunity to introduce new evidence that was not before the internal claims reviewer.

Where An Action is Brought/Removal: For claims valued under \$50,000 (including compensatory damages), the individual could bring their federal claim to a state tribunal for a decision and an award of damages. These smaller claims could not be removable to federal court. Claims valued over \$50,000 would stay in federal court. [Note: Employer groups and unions will oppose provisions preventing removal from state court.]

Who is Liable: The fiduciary responsible for the unreasonable delay or denial of the claim should be liable for participants' actions. Two exceptions could be created:

Employer/Issuer Exception: This would exempt employers/issuers from liability where they have contracted with a third party to make claims review decisions. Employers/Issuers could retain final authority for decisionmaking without incurring liability where, under certain conditions, they follow the recommendation of a third party (who is contractually liable). There would need to be language to ensure that employers do not contract away this responsibility to shell organizations.

Taft-Hartley Exception: Trustees of Taft-Hartley plans could be exempt from liability under certain circumstances, transferring the liability to the plan itself.

IV. Remedies for Violation of Patient Protections/HIPAA:

It is expected that health care reform legislation will include certain specific patient protections guaranteeing access to such benefits as emergency treatment, specialist care, and a patient's right to have a gynecologist be her primary care physician. In addition, prohibitions against improper incentive compensation arrangements and gag clauses may be enacted. Enforcement of such substantive provisions is a novel issue which has not been thoroughly discussed within the Department. There are several options which address this issue. The following options are not mutually exclusive:

Option 1: Amend the current HIPAA enforcement scheme for violations of the substantive patient protection provisions and HIPAA (part 7) protections (with the exception of the provisions relating to internal claims processing procedures) to enable greater enforcement authority by HHS and DOL.

Why this exception?

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The current scheme for enforcement of HIPAA includes the following:

DOL, and plan participant enforcement of the substantive patient protection provisions against that are incorporated into title I of ERISA. Such enforcement is limited to group health plans. DOL may not enforce these provisions against health insurance issuers. The available remedies are generally limited to equitable relief. [Note: CMPs of up to \$110 per day are available for information disclosure violations.]

The IRS may assess excise taxes against group health plans for violations HIPAA

States may assess civil money penalties against health insurance issuers.

HHS enforces as a fallback where states fail to substantially enforce and enforces directly against nonfederal governmental self-insured plans that have not opted out of HIPAA's requirements.

This scheme would be amended to give both HHS and DOL equivalent authority to enforce the substantive health care requirements, including the authority to impose CMPs, equitable relief, and the powers necessary to conduct investigations (e.g., subpoena power, etc.) (Note: See Specific HHS recommendations in this area)

See "Open Issues" # 2

Option 2: Adopt specific monetary penalty authority to enable enforcement by federal agencies (DOL for group health plans and HHS for issuers) and participants.

E.g.: A two-part penalty scheme made up of:

(1) A civil money penalty ordered by a court, in a suit brought by a participant or beneficiary against the plan for a substantive violation. The minimum penalty would be \$10,000 and the maximum would be \$50,000. The penalty would be payable to the participant or beneficiary.

(2) A civil money penalty ordered by a court in suit brought by the Secretary against plan for a pattern and practice of substantive violations. The maximum penalty would be \$2 million. The penalty would be payable to the government.

(HHS would prefer to allow the federal agencies to obtain civil money penalties for individual violations in addition to pattern/practice violations.)

Option 3: Instead of requiring the Secretary to go to court for a civil penalty (as in paragraph (2) of Option 3) allow the Secretary to assess the penalty administratively. (Note: HHS appears to support such an option and proposes an administrative scheme this penalty and for this penalty and the participant's civil penalty as well, at least where no damages are sought.)

HHS does not understand what this means. We wish to put

on the table for discussion the possibility of creating an informal mechanism for individuals who are not seeking damages to obtain statutory compliance. If this option is pursued, there are several difficult issues to resolve regarding how this mechanism would interact with the external appeals mechanism.

See "Open Issues" # 4.

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Note: The purpose of the penalty scheme would be to provide some incentive to participants to bring suits for substantive violations without giving rise to the argument that the scheme unnecessarily encourages litigation. Only the Secretaries would have the authority to pursue the largest cases.

Question: What do we do about situations where the same facts raise a benefits dispute and a substantive violation of the patient protections? Need to avoid requiring participants to have to press their cases in two different tribunals at the same time. For this reason, it may be best to have the civil money penalty for substantive violations decided in the same court that a participant uses for appealing external review decisions.

V. Medical Necessity Determinations: HHS sees 2 options for this issue. They are presented at "Open Issue" #1

Meaningful review of determinations that require the exercise of medical judgment may require creation of a statutory standard for such decisions. Many plan documents provide that certain benefits will be provided when they are "medically necessary" or "medically appropriate." Similar plans often exclude "experimental," "investigational," "cosmetic," or "dental" services or treatments. The plans have great leeway in deciding what these terms mean in any given context, opening the door to arbitrariness. A statutory standard would assure that medical judgments are excised in a manner that is at least consistent with prevailing medical practice.

Under such a standard, plans' and issuers' coverage determinations that involve an exercise of medical judgment (including determinations of medical necessity) must be consistent with generally accepted principles of medical practice. Plans and issuers would generally defer to the recommendation of a treating physician unless they can show by a preponderance of the evidence that the physician's recommendation is inconsistent with such principles or that there is an alternative treatment that is at least as, or more, medically effective.

The purpose of this approach is to provide an informed, fair review of medical necessity determinations at all levels of review to reduce improper benefit denials. This approach has been criticized as an approach that will lead to the application of varying local standards of practice that are outmoded and do not result in the best quality care. However, a federal standard should be designed to be flexible and informed by current medical science, not simply by relevant local practice or industry protocols.

Although further analysis and development of this approach is warranted, the Department supports the following basic elements as an addition to our remedies framework:

Application of the Standard: The standard should apply not simply to coverage determinations that involve defining the term "medical necessity," but include any coverage decision where medical judgment is exercised.

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Standard of Determination: In general, plan coverage determinations should be based on an objective, flexible standard such as "generally accepted principles of medical practice" or a similar standard. There could be a special standard incorporated into the "generally accepted principles of medical practice" standard for new innovative treatments that are not yet "generally accepted" but may be proven to be more effective than alternative treatments. Ultimately the plan or issuer must be able to show that a particular benefit was not medically indicated based on an objective standard, not industry protocols or practices that do not track what is the most effective medical practice.

Deferral to Treating Physician: If the treating physician's recommendation is consistent with generally accepted principles of medical practice, that recommendation should prevail unless the plan can show, by a preponderance of the evidence that its preferred course of treatment is at least as (more?) medically effective.

Procedural Requirements: The following procedural requirements should apply at least at an external review level, and during judicial review of claims that have not been reviewed by an external review entity.

HHS is concerned
that this is too
judicial. The
process should be
as informal as
possible, and
should avoid
putting formal
evidentiary burdens
on the enrollee.

Burden of Proof - It should be up to the claimant to challenge a plan's decision regarding medical necessity by producing evidence that shows that the denied benefit was medically necessary. This could be done by merely presenting the recommendation of a treating physician that the denied care be provided. The burden then shifts to the plan to show either that the physician's recommendation is not consistent with general principles of medical practice or that there is an alternative covered treatment that is just as effective.

Admissible Evidence - Any decision maker must evaluate all relevant evidence, not simply evidence relied on by a plan or issuer during an internal appeal. Admissible evidence could include peer reviewed studies and the opinions of qualified experts. The legislation would not set out an exhaustive list of admissible evidence, but would merely set out examples of evidence that could be admissible. It is up to the decision maker to ultimately determine what evidence is relevant.

The purpose of this approach is to provide an informed, fair review of determinations involving medical judgment to reduce improper benefit denials. This approach has been criticized as an approach that will lead to the application of varying local standards of practice that are outmoded and do not result in the best quality care. However, the federal standard of determination set out above is designed to be flexible and informed by current medical science, not simply by relevant local practice or insurance industry protocols.

This approach does have one significant limitation. The basic purpose behind these provisions is that a plan should generally abide by a treating physician's decision on medical

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necessity unless they can show that the physician's decision is against generally accepted medical principles. This approach assumes that all physicians can and will exercise objective medical judgement. In today's incentivized managed care arrangements this is not always the case. A health plan's control over the physician's in its network cannot be underestimated. We may not wish to link a patient's ability to challenge a determination involving medical judgement to the concurrence of the patient's treating physician.

We also caution that this approach is not a substitute for providing adequate remedies under ERISA. Although it may reduce the number of improper benefit decision that are made, it does not provide any recourse for those who are harmed by improper delays or denial of care.

HHS proposes an alternative option which would address this issue as part of the external reviewer's standard of review rather than as an express standard for medical decisionmaking for use by plans. Under this alternative option, a plan's benefit denial would be upheld if supported by any "reasonable evidence" that the treatment offered by the plan is at least as or more medically effective than the treatment requested by the claimant. In DOL's view, this option, as stated, is unacceptable, because it amounts to a codification of the current arbitrary and capricious standard.

There appears to be some mis-
understanding regarding Option 2.

HHS Staff Recommendations for Modification of HR3605 External Review and Medical Necessity Provisions¹

1. Scope of External Appeals: Allow contractual disputes to go to the external panel. As a fall-back position, allow the medical component of contractual disputes to go to the panel.
2. Exhaustion of External Appeals. HR3605 does not require exhaustion of the external appeals prior to judicial action. The bill should require such exhaustion unless doing so would be "futile." Each of the following should, by statutory definition, constitute "futile:"
 - the enrollee has been injured and is no longer seeking the benefit
 - the external appeal entity has failed to meet its deadlines
 - the enrollee suffered or discovered harm after the plans's deadline for appeal has passed
3. Eliminate the Contract Between the Plan and the External Panel
4. Prohibited Unreasonably Short Deadlines for Enrollee Appeals (both internal and external). The OPM 180 limit is a good starting point.
5. Modification to ERISA Judicial Review. While it was the intent last session that, for external appeals from group health plans, the court would review the external appeals panel's decision (not the plan's decision), the necessary ERISA amendments were not included in the HR3605. These changes should be included in the new bill. As part of these amendments, the standard of review for appeals from the external panel should be "arbitrary and capricious," and the standard of review for cases that did not go through external review should be "de novo."
6. Clarify Regulatory Authority for Group Health Plan External Appeals. HR3605 is unclear. We think the intent is that DoL set the rules for self-funded plans, states set the rules for issuers in fully-funded arrangements, and DoL set the rules for group health plans in fully funded arrangements. If a fully-funded ERISA plan has contracted for its issuers to handle external appeals, those issuers must abide by the state's rules. If the fully-funded plan administers the external appeals itself, it must abide by the DoL rules. Clarifications to HR3605 would include the addition of a requirement that the plan and issuer specify in the plan documents where the responsibility for external appeals lies.
7. Medical Necessity Related Modifications. One of the Open Policy Issues is a potential alternative approach to the "medical necessity" issue. If the alternative approach is chosen, numerous amendments to HR3605 would be required. In addition to changing the External Appeals provisions, the HR3605 denial notice requirement could be made more detailed, to specify that the plan must include all clinical criteria on which the denial is based.

1

This addresses only significant changes. Staff are also working with Hill staff on reconciling smaller issues, such as claims and appeals deadlines.

Open Policy Issues

1. Strategy on Improvements to HIPAA Enforcement. How and when should the general HIPAA enforcement issues be joined with the Bill of Rights debate? Policy decisions regarding HIPAA enforcement are linked to issues regarding internal and external appeals.

2. New Civil Monetary Penalty Structure for Enforcing HIPAA (including PBOR).

HHS supports changing the CMP authority for Departmental enforcement of HIPAA under the PHSA, to move from a per day to a per violation structure.

- Change HIPAA CMPs to maximums per violation (\$250,000) with factors (such as whether pattern/practice, severity, plan's compliance history, etc) that would be considered by HHS in proposing, and an ALJ in affirming, a fine.
- Give HHS authority to seek injunction, order equitable relief (similar to current ERISA)
- Increase investigative authority of HCFA (similar to current ERISA)

HHS should have the authority to bring an action for a single violation.

Issues: (1) Should this Administrative enforcement be sought as part of a broader set of HIPAA insurance reforms, or as part of the Patient Bill of Rights debate? (2) If DoL does not want to alter the CMP structure currently in ERISA, are we prepared to ask for this enforcement authority for the PHSA side of HIPAA, but not the ERISA side?

3. Medical Necessity. HR3605 and the Chafee bill included a definition of "medical necessity" and some additional language restricting arbitrary medical decision making by health plans. The goal of these provisions is to prevent arbitrary coverage decisions by health plans. We see two options.

- First, continue the approach taken by HR3605 and Chafee: define medical necessity and include language which directly prohibits certain arbitrary decision making by health plans. Under this approach, the standard of review and decision rule for the external panel could be left as is or stated in more detail.
- Second, include a definition of the standard of review and decision rules for the external panel that can substitute for direct legislative statements on medical necessity and medical decision-making. The standard of review could be set at any level.

Each of these approaches creates policy and political risks. Attachment A is the Options paper requested on these issues.

4. Private Right of Action for Violation of HIPAA/PBOR Where Damages Are Not Sought
Do we want to develop a simplified administrative mechanism for people seeking statutory enforcement, but not damages? Attachment B describes the options and issues.

5. Private Right of Action for Violation of HIPAA/PBOR Where Damages Are Sought
Do we want to create a judicial private right of action for violations of HIPAA? If principals wish to pursue this, staff will provide Options for specifics such as the standard of review (e.g., any statutory violation, "knowing" violations, "wilful" violations, etc) and the available damages.

ATTACHMENT A – "Medical Necessity" Options

Option 1: Continue the HR3605/Chafee Approach

Under this option, the federal legislation defines 'medical necessity' and includes a direct prohibition on arbitrary medical decision making.

Standard of review in "medical necessity" cases

For cases involving medical necessity, the federal law would require that the external panel determine *de novo* whether the sought treatment is "medically necessary," under the federal statutory definition of that term. (Neither HR3605 or S.2416 provided further definition of *de novo*.)

The external appeal entity would look at all the evidence and make its own, independent judgement about whether the evidence meets the statutory definition of "medically necessary." It would not defer to the plan's decision, it would look at all the evidence and would not take into account any plan definition of "medical necessity." As currently drafted, if both the plan's and enrollee's approach meet the definition of "medically necessary," we think the enrollee is upheld (this is ambiguous).

Analysis

Under this approach, the plan is governed by a federal definition of medical necessity for the initial coverage determination and internal appeal. While an external appeal would be required to enforce the definition, having the definition applicable at this stage could reduce the likelihood that plans would make arbitrary decisions on the assumption that most enrollees won't appeal.

This approach arguably impairs the ability of plans to make coverage determinations based on new evidence or practice guidelines, even where there is reasonable evidence that the plan's choice does not make the patient less well off medically. (It is not clear how often plans actually try to do this today.) This approach puts into federal legislation a definition for a concept ("medical necessity") that is used in many ways and many contexts, creating a risk of unintended consequences. CBO scored the HR3605 medical necessity clause at roughly 1% of premium.

The political debate surrounding this Option has focused on allegations that it would "end managed care," "federalize medicine," and would "stop medical progress." To date, compromise positions have not emerged.

Option 2: Define the Standard of Review in Detail, Instead of "medical necessity"

Under this option, the standard of review is stated in such a way that it can substitute for a statutory definition of "medical necessity" as well as for statutory prohibitions on arbitrary decisions. The standard of review is used to prevent arbitrary health plan decisions.

Standard of review in "medical necessity" cases

For cases involving medical necessity the federal law would require that the plan's decision be

Attachment B – Options for Administrative "private action" for statutory enforcement where no damages are sought.

1. **New Administrative Mechanism.** The Clean Air and Clean Water Acts provide a simplified process for small violations (defined by a limit on the proposed fines). Under this process, the enforcing agency does not have to comply fully with the Administrative Procedures Act; rules of evidence, etc., are simpler and disputes are decided by a hearing officer, who is usually a senior attorney in EPA (under these statutes, only the government can bring an action, though individuals are permitted to participate in the proceedings).
2. **Combine Statutory Enforcement with the External Appeals Panel.** It may be possible to use the PBOR external appeals panel for this purpose. As drafted in HR3605, specified violations of the PBOR go to the panel (if they meet an unspecified "significant" money threshold or if the life or health of the enrollee is jeopardized as a consequence of the decision). This could be expanded to include any HIPAA violation. Thus, the external review mechanism would serve as both the forum for wrongful denial of benefits, and as an administrative "private right of action" for enforcing HIPAA violations.
 - A combined approach provides individuals with one place to take any dispute. Benefits disputes and allegations of statutory violations may regularly arise from the same set of facts (particularly pre-existing condition disputes, and allegations of violations of Bill of Rights provisions that govern clinical care such as access to specialists).
 - However, including significant statutory disputes in the external panel's responsibilities could require creating a more complicated process than necessary for just benefits disputes. Creating a fast and easy way for individuals to resolve benefits disputes is the policy priority, and we are concerned that combining this with statutory enforcement could compromise that priority.

Significant issues:

- If the processes for handling statutory and benefits/coverage issues are separate (i.e., there is a separate simplified administrative process for certain kinds of disputes and external appeals for others), how do we define these terms, and what happens to cases that may involve both?
- If the external appeals entity can hear statutory cases, are there circumstances under which an individual can bypass the internal review procedure? (For example, it may not make sense for an internal appeals review of a dispute involving a certificate of coverage, guaranteed issuance, or whether a plan is in conformance with the mental health parity exemption claim.)
- Should the same processes apply to PHS and ERISA cases?
- Could the panel order the payment of medical expenses incurred during the violation, such as improper enrollment, occurred, or would this be considered "damages" and be unavailable?

upheld if, in the eyes of an independent panel, there is "reasonable evidence" that the plan's approach is "as medically effective" (or "more medically effective," or "substantially as medically effective," etc) for this particular enrollee as what the enrollee is asking for. "Reasonable evidence" would be defined in statute to include a variety of clinical evidence (whether "generally accepted medical practice" should be part of "reasonable evidence" requires discussion).

The external appeal entity would look at all the evidence and make its own, independent judgement about this whether there is "reasonable evidence" in support of the plan -- it would not defer to the plan's decision nor to the evidence available to the plan, and would not take into account any plan definition of "medical necessity." In this way, any arbitrary plan definition of medical necessity would be ignored, but at the same time the plan's decision would be upheld if it is at least as good (or is better, depending on where the standard is set) for the patient. If neither the plan nor the enrollee are supported by "reasonable evidence," the legislation could either call the tie in favor of the enrollee or defer to generally accepted medical practice. If both the plan and enrollee's approach are supported by reasonable evidence, HHS staff recommend upholding the health plan, while DoL staff recommend upholding the enrollee.

Analysis

If a standard of review is stated in this way, it is not clear what a definition of "medical necessity" would add to the legislation that would outweigh the political freight this term carries. Under such an approach, the plan is not explicitly governed by a federal definition of medical necessity for the initial coverage determination and internal appeal and so could legally act arbitrarily at this stage. The threat of external review and litigation should minimize this risk. In practice, the standard of review should become the definition of medical necessity, but without having to legislate it. Modifying the HR3605 denial notice requirement to include a requirement that the relevant clinical criteria also be disclosed will also help avoid arbitrariness at this stage.

This approach would avoid legislating a federal definition for a concept that is used in many contexts. Whether this option could result in a lower CBO score than HR3605 would depend on which standard of review is chosen.

Changing the terms of the debate from the meaning of "medical necessity" to a debate about what a plan has to show to prove that its decision is not arbitrary creates a well understood area for a final compromise. The debate would likely be over the whether a plan would have to show reasonable evidence that its approach is "just as" medically effective as the enrollee's request, "more" effective, or some other standard. There would likely also be a debate over evidentiary standards: while the above formulation does not include an explicit evidentiary burden, there would likely be proposals that the plan show it is more medically effective by "a preponderance" of the evidence, or that it is "more likely than not" that the plan's approach is as medically effective, and the like. Some may suggest that the legislation define certain evidence as automatic proof that the plan's approach be upheld, or that the legislation define certain evidence as necessary in order for a plan's decision to be upheld.

LRM ID: MNB3

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Thursday, January 14, 1999

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below
FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
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SUBJECT: LABOR Testimony on Processing of Benefit Claims under ERISA
DEADLINE: 10 a.m. Tuesday, Jan. 19, 1999

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: To follow is testimony to be delivered by Leslie Kramerich (PWBA) before the Senate Helath, Education, Labor, and Pensions Committee (the renamed Senate Labor and Human Resources Committee) the morning of Wednesday, January 20th.

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**TESTIMONY OF LESLIE KRAMERICH
DEPUTY ASSISTANT SECRETARY FOR POLICY
PENSION AND WELFARE BENEFITS ADMINISTRATION
UNITED STATES DEPARTMENT OF LABOR
BEFORE THE
UNITED STATES SENATE
COMMITTEE ON LABOR AND HUMAN RESOURCES**

JANUARY 20 , 1999

Chairman Jeffords and Members of the Committee, thank you for the opportunity to testify this morning about the Department of Labor's efforts to ensure that American workers are afforded full and fair reviews of their benefit claims. We appreciate the leadership of the Chairman, Ranking Member, and other Committee Members for focusing early in this new Congress on these issues, which are so important to the millions of Americans and their families who receive their health care coverage through employment-based plans.

I am Leslie Kramerich, Deputy Assistant Secretary for Policy for the Pension and Welfare Benefits Administration (PWBA). PWBA administers Title I of the Employee Retirement Income Security Act (ERISA), the primary federal statute governing employment-based pension and welfare plans. Currently, ERISA governs an estimated 700,000 pension plans, covering approximately 87 million participants and an estimated 6 million welfare plans (including 2.6 million group health plans) covering approximately 72 million participants.

The regulatory efforts that I will discuss this morning represent an important step towards improving the fairness and effectiveness of the processes by which health and

other benefit determinations are made by employee benefit plans subject to ERISA. Although we are working to achieve these goals, we do not have the authority under ERISA to address all the related needs of American workers, such as the need to be able to obtain independent external reviews of denied health benefit claims and meaningful remedies for wrongful delays or denials of those claims. In this regard, legislation is required to ensure that fundamental patient protections are extended to the millions of Americans covered by ERISA plans. We believe American workers not only need, but deserve, a strong and enforceable Patients' Bill of Rights.

We also thank you, Mr. Chairman and Members of the Committee, for your leadership in the nation's continuing efforts to improve the health care rights of American workers. We welcome the opportunity to work with you and Members of the Committee in addressing these issues so important to millions of Americans.

CURRENT LAW PROCEDURAL PROTECTIONS FOR BENEFIT CLAIMANTS

ERISA sets out the broad contours of procedural fairness for benefit claims of plan participants. It simply states that all plans must provide a claimant with an adequate written notice when a claim for benefits is denied in whole or in part. The notice must give specific reasons for the denial and be written in a manner calculated to be understood by the claimant. Finally, the claimant must be afforded a reasonable opportunity to obtain a full and fair review of the denial by an appropriate named fiduciary of the plan. ERISA gives the Department of Labor the authority to promulgate regulations to give substance to these general rights.

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In 1977, early in ERISA's history, the Department issued a regulation to implement these basic requirements. The 1977 regulation, which applies uniformly to both pension and welfare plans (including group health plans), sets a number of specific, basic standards, such as requiring that the plan's claims procedures be set forth in the plan's summary plan description — a document commonly referred to as the SPD. The SPD is the principal document by which ERISA participants and beneficiaries are notified of their rights under their plans. They should receive it when they join the plan, and they should receive summaries of material changes within time frames set out in the statute and regulations.

The 1977 regulation also provides that when a plan denies a claim, it must notify the claimant in writing, stating the reasons for the denial and references to the relevant plan provisions. This notice must also describe any additional material or information necessary for the claimant to perfect the claim. Finally, the notice must include appropriate information on how the claimant may seek review of this denial. A claimant must have the right to inspect pertinent documents and to submit issues and comments in writing to the plan.

ERISA and the 1977 regulation set requirements for an initial decision and a review by an appropriate named fiduciary. The 1977 regulation sets maximum time frames for completing this two-stage process: the initial written denial must be provided within a reasonable period of time, but not later than 90 days after receipt of the claim (if special circumstances require additional time, up to 90 more days is allowed, for a total of 180 days); a claimant must be given at least 60 days after a denial in which to request a review of the decision; a decision on appeal of a denial must be made ordinarily within 60

days after the review request (if there are special circumstances, the appeal can take up to an additional 60 days, for a total of 120 days). The 1977 regulation also allows a plan to take even longer to complete a review where the named fiduciary is a group that holds regularly scheduled meetings at least quarterly. If a review decision is not made within the 1977 regulation's time frames, the claimant can deem the claim to be denied and can file suit for court review. While these time frames may have been appropriate when this regulation was promulgated, they obviously are no longer responsive to the needs of participants today. These standards are so out-of-date that they provide little protection in any benefit dispute. In particular, they do not provide any meaningful protection for participants and beneficiaries of group health plans, where patients must obtain pre-approvals for tests, treatments, hospitalizations, and referrals to specialists.

DEVELOPMENTS LEADING TO THE PROPOSED REGULATION

In 1977, when most health plans operated on a traditional fee-for-service basis and most health benefits were fully insured, the maximum time frames set by the 1977 regulation may have been appropriate, because the matter at issue was simply whether or how much the plan would pay for a service that already had been rendered. Times have changed. The overwhelming rise in health care costs over the last twenty years has placed enormous pressures on employers, health care entities, insurance providers, and individuals to reduce costs and has created a revolution in the methods of financing employer-provided health care coverage. A large proportion of group health plans are now "self-insured," that is, the employer pays for the benefit claims out of its own assets, without recourse to insurance. The health care industry has developed, and is continuing to develop, creative methods of reducing its costs by adopting a variety of techniques to

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“manage” health care, many of which limit patient access to care. In today’s health care environment, an outside limit of 90-days to decide, for example, whether to pre-approve a request to see a specialist or to have a diagnostic test is unnecessarily long and unreasonable. In most respects, the 1977 regulation’s requirements simply do not provide plans or participants with an appropriate framework for timely decision-making while the claimant's health -- potentially life -- hangs in the balance.

Far reaching changes in the delivery and financing of medical services, particularly the growth of managed care systems and the requirement of pre-approval for major medical expenses under fee-for-service plans, have occurred since the 1977 regulation was issued and have accelerated in recent years. Accordingly, the Department initiated a project in mid-1997 to consider whether, and to what extent, to change the framework set by the 1977 regulation.

The need to bring claims adjudication procedures up to date, particularly with respect to health claims, has been widely recognized. For example, during the period in which the Department developed its current benefit claims procedure proposal, the Health Care Financing Administration (HCFA) was in the process of amending its regulations relating to Medicare beneficiary appeals for managed care plans. The amendments adopted by HCFA established an expedited review process in situations where the time required for the standard review process could seriously jeopardize the life or health of the Medicare beneficiary or the beneficiary’s ability to regain maximum function. The new Medicare expedited procedure rule also provides that a decision to discontinue services that are currently being provided may also be subject to the expedited review process. In addition, the National Association of Insurance Commissioners (NAIC) has

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developed several model acts that address the need for more detailed health benefit claims procedure regulation, especially with respect to claims that are subject to utilization review. Two of the NAIC's model acts provide specific requirements comparable to the Department's proposal, including expedited time frames in urgent care circumstances and independence of the decision-maker on review of denied claims.

Because we seek to ensure that the development of any new procedural standards is based on sound information, the Department published in the Federal Register, on September 8, 1997, a Request for Information (RFI) inviting the views of the public on the advisability of amending the 1977 regulation. The RFI invited comments on a series of questions, focusing primarily on benefit claims standards and practices of group health plans. The RFI also invited comments on the extent to which the standards set by the NAIC model acts and by HCFA with respect to Medicare beneficiaries would be applicable to ERISA-covered group health plans.

We received over ninety comments in response to the RFI. While they were far from unanimous in their descriptions or views, they presented strong support for the need to update the 1977 regulation, especially as it applies to health and disability benefit claims. Even those commenters who opposed revision of the regulation asserted that health benefit claims disputes are usually resolved in much shorter time frames than currently permitted under the 1977 regulation. Other comments stated that many plans fail to provide claims processing that meets the standards of the 1977 regulation and that claimants are not well-informed about their rights or the procedures that govern their claims disputes.

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In November of 1997, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry issued its report entitled *Consumer Bill of Rights and Responsibilities*. One of the rights identified by the Commission was the right of consumers to receive accurate, easily understood information relating to their health plans. Another right identified by the Commission was the right of all consumers "to a fair and efficient process for resolving differences with their health care providers . . . including a rigorous system of internal review and an independent system of external review" after the internal review has been exhausted. The President embraced the Commission's recommendations and directed the Department of Labor, among other agencies in the Administration, to report to him on how it could act within its jurisdiction to effectuate the recommendations. In its February 1998 report to the President, the Department fully supported the Commission's recommendations, but explained the limits of the Department's authority under ERISA to implement many of those recommendations.

In its report, the Department outlined a series of specific regulatory reforms it could undertake within its authority. One of these reforms involved the issuance of proposed regulations clarifying the information required to be contained in the summary plan description, the principal document furnished to participants and beneficiaries describing their rights, benefits and obligations under the plan. On September 9, 1998, the Department proposed amendments to the summary plan description requirements requiring the clarifications identified in the Department's report. These amendments make clear that the summary plan description of group health plans must set forth a description of benefits and limits on coverage, the extent to which preventive services are covered, provider network composition and coverage of out-of-network services, among

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other things. We are currently reviewing comments submitted in response to those proposed regulations.

The Department also identified in its report to the President a number of actions it could take to strengthen the claims review procedures under ERISA. The Department's proposed claims procedure regulation incorporates the reforms identified in the Department's report. The proposal also reflects the Department's consideration of the RFI comments, the Commission's findings, and the actions taken by other regulatory and governmental bodies, and it has been published as a proposal subject to further consideration to reflect public comment.

THE PROPOSED REGULATION

On September 9, 1998, the Department published in the Federal Register a proposed regulation that would revise the minimum standards relating to benefit claims procedures for all employee benefit plans covered by ERISA. This proposed regulation would change the benefit claims procedures that must be provided under both pension plans and welfare plans (including group health plans). While the proposal would make substantial changes to the processing of all benefit claims, the most significant changes in the proposed regulation concern the standards that would be applicable to group health plans.

Among the significant proposed changes are the following: The proposal would require that group health plans process routine claims within a reasonable period of time, not to exceed 15 days, and that appeals of such claims be resolved not later than 30 days.

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In the case of claims requiring expedited processing because the health of the claimant is at risk, described as "urgent care" claims, the proposal would require a decision on the claim as soon as possible, but not later than 72 hours. The proposal also would require that appeals of "urgent care" claims be resolved not later than 72 hours. The proposal would also establish special time limits for resolving disability benefit claims. Under the proposal, disability benefit claims would have to be resolved within 30 days and appeals of adverse determinations on such claims resolved within 45 days. In addition to establishing shorter processing time frames for health and disability plans, the proposal would require for group health plans that, in appeals of any adverse benefit determination involving a medical judgement, the deciding fiduciary of the plan consult with an independent health care professional who has appropriate training and expertise in the relevant field of medicine.

As stated earlier, the proposal would also make some changes to claims processing that are applicable more generally to all plans. Under the proposal, for example, all covered plans, including pension plans, would be required to notify participants and beneficiaries when the participant or beneficiary makes a request for benefits, but fails to follow the plan's claim filing procedures, or where a properly filed claim is determined to be incomplete. Additionally, the plan fiduciary who reviews a denied claim would have to be different from, and not subordinate to, the initial decision maker, and would be required to make a *de novo* finding, not giving deference to the initial decision, and to consider any new evidence the claimant submits. In considering the application of such changes to all employee benefit plans, the Department concluded that these changes represent such fundamental components of a fair claims process that the principles must

be applied uniformly to all benefit plans subject to ERISA, whether they provide health, pension, or other benefits.

The proposed regulation is intended to ensure that American workers and their families are afforded full and fair review of their benefit claims. Since the publication of the proposed regulation in early September 1998, the Department has received more than 600 public comments. Many commenters, including plan sponsors, trade associations and others, express concerns about increases in the cost of providing benefits that may result from compliance with the proposed rules. On the other hand, commenters representing employees and patients overwhelmingly support the proposal. Mr. Chairman our deliberative process will be continued through a public hearing on the proposed regulation scheduled to take place beginning on February 17, 1999. The purpose of the public hearing is to obtain further information on the proposed regulation so that the Department can better assess whether, and to what extent, the proposed regulation should be modified before the adoption of a final rule.

I can assure you that the Department will give thorough consideration to all of the issues raised by the commenters and expects to gain further understanding through the testimony that will be presented at the public hearing. Any final regulation promulgated through this process will reflect a balance of the burdens imposed on employers and other sponsors of employee benefit plans with the needs of participants and beneficiaries for procedural fairness in the process of resolving benefit claims.

LEGISLATIVE PROPOSALS

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The Committee has requested that we specifically address provisions of two health care bills introduced in the last Congress, S. 1890 and S. 2330. The Committee has asked the Department to explain how the standards of the proposed regulation compare to the internal claims and appeals provisions in S. 1890 and S. 2330. In general, these bills called for the establishment of new minimum standards and requirements for processing claims under all group health plans subject to ERISA. They required plans to provide for accelerated procedures that take into account medical exigencies, for increased disclosure of information relating to the claims and appeals process, and for some kind of "independent" internal appeals process conducted by a doctor or other individual with appropriate expertise.

Many of the principal requirements of our proposal are comparable to the internal claims and appeals provisions of S. 1890 and S. 2330. All three proposals include provisions requiring:

- expedited review of claims involving urgent care within comparable time frames (up to 72 hours for the Department's proposal and S. 2330; 3 business days for S. 1890);
- notice provisions requiring plans to provide more information to participants when claims are denied, including an explanation of why the claim was denied, notice of the participant's right to appeal, and information about the plan's appeal process; and

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- independent internal review conducted by, or in consultation with, a doctor, health care professional, or some other person with appropriate medical expertise.

There are also some important differences between our proposal and the legislative proposals that warrant discussion. First, there are a number of provisions which were included in our proposal that were not addressed in one or both of the legislative proposals. These include: (1) a timely notification requirement for situations in which the plan needs more information to determine whether a benefit is covered; (2) provisions protecting participants from being subjected to multiple levels of internal review; (3) provisions extending the minimum period within which plans must permit participants to initiate appeals; (4) requirements that the review upon appeal be conducted *de novo*, meaning that the reviewer will not defer to the initial determination and will allow new evidence to be submitted; and (5) provisions allowing the participant to seek immediate judicial review where the plan has failed to establish or comply with procedures consistent with the proposed regulation.

There are also important differences in the way the time frame requirements are structured in the legislative proposals, as compared with our proposal. First, our proposal imposes time frame requirements in terms of calendar days, rather than "business" days, as S. 1890 does. Next, our proposal provides a standard that determines time frame requirements on the basis of the urgency of the need for care. Both S. 1890 and S. 2330 further delineate benefit determination time frame requirements on the basis of whether the claim involves prospective, concurrent, or retrospective review.

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In addition to provisions addressing the internal claims review process, both bills provided for an external claims review process. We believe that the establishment of a system for providing an independent external review of benefit claims is critical to providing participants and beneficiaries a fair and efficient claims review process. We note that the establishment of an independent system for external review of benefit claims was advocated by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry in their *Consumer Bill of Rights and Responsibilities*.

The Department, however, does not have the authority under current law to establish through regulations a system for independent, external benefit reviews. Accordingly, we strongly support legislative efforts to establish such a review system for participants and beneficiaries in ERISA-covered group health plans. We believe that any legislative proposal establishing an external review process must, at a minimum:

- Ensure that the reviewing person or entity is independent of the party who decided the appealed claim and is not operating under any conflict of interest (including an objective procedure for selecting the reviewer);
- Ensure that the reviewing person or entity possesses the medical or other expertise necessary to perform the required review;
- Establish a certification and oversight process to ensure independence and qualifications of reviewers;

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- Provide that external reviews will be *de novo*, i.e., reviews that afford no deference to original decisions and permit the claimant to submit new evidence pertinent to his or her claim;
- Establish specific time-frames within which routine and "urgent care"-type claims must be determined, providing expedited review of claims involving urgent care;
- Provide for decisions on review to be binding on the plan; and
- Preserve the legal rights of participants and beneficiaries to pursue their claims in court.

AN IMPROVED INTERNAL CLAIMS PROCEDURE IS NOT ENOUGH

As I noted earlier, American workers need and deserve a strong and enforceable Patients' Bill of Rights. Because the Department lacks the authority under current law to do more than reform the standards applicable to internal benefit claims processing, however, reform measures must come through legislation. In this regard, as I have already stated, we strongly support the Health Care Commission's recommendations for an external review of plan decisions. The absence of any independent, *de novo* review for claims determinations is a serious weakness in the protections offered by the existing statutory scheme.

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In our view, stronger remedies are needed to assure compliance with the enhanced procedural protections. Under current law, when a consumer suffers harm due to the wrongful delay or denial of a claim for benefits, ERISA provides only for the benefit that the individual should have received to begin with; no additional medical costs or other compensation is available. As a result, a plan fiduciary who fails to assure compliance with the time limits or notice provisions of our current regulation is not accountable to individual participants for that failure. At best, an aggrieved participant may treat the claim as denied and proceed to court, possibly without the benefit of a clear explanation of his denial or access to pertinent documents that might help him evaluate or prove his claim. A participant may find himself in court with his health already injured and his need for treatment mooted by the progress of his illness, or even the possibility of death. If the plan's delay in providing a decision or critical information causes injury, the participant has no legal recourse, and the responsible fiduciary suffers no consequences.

DRAFT**CONCLUSION**

In May of 1998, then Assistant Secretary Olena Berg testified before this Committee on the Department's efforts to address deficiencies in the benefit claims procedure processes and the limited ability of the Department to provide for the essential consumer protections listed in the Health Care Commission's *Consumer Bill of Rights*. While the Department has since that time taken steps to strengthen the internal claims review processes followed by plans, legislation is needed to provide the important patient protections American workers need and deserve. Merely rewriting our claims procedure regulation is a good start, but is simply not enough.

Millions of American workers are looking to Congress to address these critical issues through bipartisan legislation. In this regard, I reiterate our willingness to work with the Members of this Committee in developing a Patients' Bill of Rights in which we all can take great pride.

In closing, I want to thank the Members of this Committee for their leadership and for affording us the opportunity to testify this morning. I would be pleased to answer any question you might have.

h:\plan1.wpd (January 13, 1999)

"It's Time to Pass a Real Patients' Bill of Rights"

By Donna E. Shalala

Secretary of Health and Human Services

When I was a kid growing up in Cleveland, my friends and I would often play a pickup game of softball. Every once in a while someone would hit a ball that was so close to the line that we would argue about whether it fair or foul. After the argument had gone on long enough, we would agree to what was called a "do-over." After a year of bitter partisan wrangling over a Patients' Bill of Rights, Congress now has a chance at a do-over. The only question is, will the outcome be any better this time?

The need for managed care reform is very clear. American consumers are losing faith in the ability of the health care system to meet their health care needs. A national poll conducted by the Harvard School of Public Health found that 57 percent of Americans have had a problem with their health plan in the last year. Among the problems cited were: less time with doctors (64%); difficulty seeing specialists (62%); and decreased quality of care (56%). Perhaps most troubling, 59 percent of Americans said they were "very worried" or "somewhat worried" that their health plan would be more concerned about saving money than doing what's best for the patient. It is no wonder that an overwhelming majority of Americans are calling for tougher oversight of managed care.

Don't get me wrong. Managed care, when it's managed well, can work to improve people's health. The commitment to prevention and care coordination in a good managed care operation can meet or exceed the quality of traditional fee-for-service insurance. In fact, I first joined an HMO 25 years ago and was very happy with the care I received. But it is clear that not all managed care plans are run well and some are cutting too many corners. Just as disturbing, despite the promises of a slick marketing campaign, the managed care industry has not stepped up to the plate to police itself in the face of these public concerns and complaints.

That's why almost two years ago, President Clinton named a bipartisan commission to study this issue and make recommendations to him to protect consumers and improve health care quality. In November of 1997, the Quality Commission recommended the creation of a Patients' Bill of Rights that would assure every American of the following:

many protections, including

- Comprehensive easy-to-read information about their health plans;
- Access to emergency care when and where the need arises;
- Direct access to medical specialists for patients in need of treatment for severe conditions like cancer and heart disease;
- Continuity of care for pregnant women and other patients whose care is disrupted by a health plan's decision to drop a doctor from its approved network;
- Direct access for women to obstetricians and gynecologists for routine and preventive care;
- Information about all of the treatment options available to them — not just those that are the cheapest;

- ~~• Confidentiality of their health care records and information;~~
- ~~• Respect and nondiscrimination in their care and in the marketing and enrollment practices of health plans; and,~~
- Access to an independent system of external review of any decision by a health plan to deny or limit care.

The President and his Administration moved quickly to assure these rights to the more than 80 million Americans who are covered in public health programs like Medicare, Medicaid, the Department of Veterans Affairs, and military health programs. And, he asked Congress to work with him to enact legislation to assure these rights for all Americans.

Leaders from both political parties including Senators Tom Daschle (D-SD) and Edward Kennedy (D-MA) and Congressmen John Dingell (D-MI) and Greg Ganske (R-IA) incorporated the Commission's recommendations into bipartisan legislation. They added important provisions to make sure that the rights being provided would be legally enforceable.

Sadly, the Patients' Bill of Rights fell victim to the bitter partisan wrangling of 1998. The House passed a wholly inadequate, partisan bill and the Senate wouldn't even allow the plan to come to a vote. But today is a new day and we have a new Congress. Last year's election results made it clear that the American people want their legislators to address the very real problems with managed care and to do so in a bipartisan way. In his State of the Union address, President Clinton offered to work with Congress and pass a bipartisan Patients' Bill of Rights early this year. The new Speaker of the House, Dennis Hastert (R-IL), and Senate Majority

Leader Trent Lott (R-MS) have made similar promises.

It's time to turn those promises into reality. The elements of a bipartisan Patients' Bill of Rights are already on the table. In fact, just two years ago Congress voted to extend many of these same protections to the nearly 40 million Americans in Medicare. Now we must work together to ensure that all Americans have the same legal protections. Let's not waste this do-over. Let's hit a home run.

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THE IMPACT ON PATIENTS OF DELAYS IN PASSING A PATIENTS' BILL OF RIGHTS: A SENATE HEALTH, EDUCATION, LABOR AND PENSIONS COMMITTEE MINORITY STAFF STUDY

Delays in passing legislation to curb insurance company abuse result in injury to thousands of patients daily and millions of patients annually. Drawing on two prior studies on the incidence of abusive health plan practices, this report looks at the number of patients affected daily, weekly, monthly and yearly.

The estimates are based on patient self-reports of experiences with health plans and on physicians' reports of the frequency of various abuses and the seriousness of injuries sustained by the patients they see in their own practices.

Highlights:

According to patient reports, every day, as the result of actions of their health plan:

- 59,000 patients experience added pain and suffering
- 41,000 patients experience a worsening of their condition
- 35,000 patients have needed care delayed
- 35,000 patients have a specialty referral delayed or denied
- 31,000 patients are forced to change doctors
- 18,000 patients are forced to change medications

did not use

According to physician reports, every day:

- 14,000 physicians see patients whose health has seriously declined because an insurance plan refused to provide coverage for a prescription drug
- 10,000 physicians see patients whose health has seriously declined because an insurance plan did not approve a diagnostic test or procedure

7,000 physicians see patients whose health has seriously declined because an insurance plan did not approve referral to a medical specialist

used

- 6,000 physicians see patients whose health has seriously declined because an insurance plan did not approve an overnight hospital stay
- 6,000 physicians see patients whose health has seriously declined because an insurance plan did not approve a referral for mental health or substance abuse treatment.

Table 1 shows the incidence of plan restrictions on care and patient injuries resulting from plan actions by day, week, month, and annually, as reported in the survey of patients. Table 2 shows the number of physicians seeing plan abuses that result in serious declines in patient health each day, month, week, and year.

Table 1. Patient Survey *DID NOT USE*

<u>Health Plan Abuse</u>	<u>Number of Patients Affected Per Year</u>	<u>Number of Patients Affected Per Month</u>	<u>Number of Patients Affected Per Week</u>	<u>Number of Patients Affected Per Day</u>
Delay in Needed Care	12,880,000	1,073,000	247,000	35,000
Delay or Deny Specialty Referral	12,880,000	1,073,000	247,000	35,000
Forced to Change Doctors	11,270,000	939,000	216,000	31,000
Forced to Change Medications	6,440,000	537,000	124,000	18,000
<u>Results of Health Plan Abuse</u>				
Added Pain and Suffering	21,638,000	1,803,000	415,000	59,000
Worsening of Condition	14,876,000	1,240,000	285,000	41,000

Source: Committee Analysis Based on Helen H. Schauffler's "California Managed Health Care Improvement Task Force Survey of Public Perceptions and Experiences with Health Insurance Coverage." U.C. Berkeley School of Public Health and Field Research Corporation, September, 1997, reported in Improving Managed Health Care in California. Findings and Recommendations, Volume Two, January 1998, tables 4 and 19, projected to the national level.

USED

<u>Health Plan Abuse</u>	<u>Number of Doctors Each Year Seeing Patients with Serious Decline in Health from Plan Abuse</u>	<u>Number of Doctors Each Month Seeing Patients with Serious Decline in Health from Plan Abuse</u>	<u>Number of Doctors Each Week Seeing Patients with Serious Decline in Health from Plan Abuse</u>	<u>Number of Doctors Each Day Seeing Patients with Serious Decline in Health from Plan Abuse</u>
Denied coverage of recommended prescription drug	137,000	111,000	71,000	14,000
Denied coverage of needed diagnostic test	149,000	100,000	51,000	10,000
Denied referral for needed specialty care	122,000	76,000	37,000	7,000
Denied overnight hospital stay	110,000	65,000	29,000	6,000
Denied referral for mental health or substance abuse treatment	116,000	63,000	30,000	6,000

Source: Committee Analysis Based on Kaiser Family Foundation and Harvard School of Public Health, "Survey of Physicians and Nurses," July, 1999.

METHODOLOGY

The data presented in this report was drawn from two sources. Patients' self-reports on difficulties with their health plans and illness and injury caused by actions of their health plans was drawn from a random sample survey of individuals in California with private health insurance conducted by the Center for Health and Public Policy Studies, School of Public Health, University of California at Berkeley. Helen Schaffler, Ph.D., was the principal investigator. The survey was conducted during September, 1997 for the Managed Care Improvement Task Force of the State of California, and reported in Improving Managed Health Care in California. Findings and Recommendations, Volume Two, January, 1998, Tables 4 and 19.

The survey asked whether the respondent experienced specific difficulties with a health plan. Those who experienced difficulties were asked about the impact of the difficulty on their health. The figures presented in this report assume that the incidence of such events is the same among the total U.S. population of privately insured individuals as it is among the privately insured population in California. Daily, weekly, and monthly figures were derived by dividing annual rates by 365, 52, and 12, respectively. All figures in the tables are rounded to the nearest 1,000 patients.

Data on physicians' reports of health plan practices and serious declines in health experienced by patients as the result of health plan actions were drawn from the 1999 Survey of Physicians and Nurses by the Kaiser Family Foundation and the Harvard School of Public Health. The survey was conducted between February 11 and June 5, 1999. Physicians were asked how frequently a set of plan practices occurred (weekly, monthly, every six months, yearly, never, or not applicable to my practice). Physicians who reported that the practice occurred were asked for the impact on the health of their patients.

The figures reported in the survey were converted into daily, weekly, monthly, and annual totals by adding the proportions seeing the specified event during the specified time period. For example, to derive a weekly total, the numbers of doctors reporting seeing such patients weekly was added to one-fourth of the doctors reporting seeing such patients monthly plus one-fifty-second of the doctors reporting seeing such patients annually. The proportions were then multiplied by the size of the sampling universe of 470,364 physicians. All figures reported in the table are rounded to the nearest 1,000 patients.

Note that the tables are not comparable, since one reports on numbers of patients affected, while the other reports on numbers of doctors seeing affected patients. Many doctors saw numerous affected patients. Moreover, judgements of doctors who attribute health declines to specific plan practices may not coincide with patients' own conclusions. Also, the doctor survey reports on patient injuries due to specific plan practices which are not identical with the problems identified in the patient survey.

Contact: Jim Manley, Office of Senator Kennedy, (202) 224-2633

75-177-1

Proposed Revision to the ERISA provision in the Patients' Bill of Rights

To break the log-jam over health plan liability that helped prevent enactment of patient protection legislation in the 105th Congress, here is a possible alternative:

1. Patients who feel their health plan denied them medically necessary care could appeal their case through an internal review mechanism.

Congress of the United States
House of Representatives
Washington, D.C. 20515

DEMOCRATIC STAFF

FAX COVER SHEET

DATE: _____

TO: Deborah

FROM: Amy

FAX NUMBER: 456 5557

NUMBER OF PAGES: 18
(Including Cover)

COMMENTS: is
3/9
70
289

(If there are problems with this transmission,
please phone 202-226-3400, Democratic Staff, 564 FHOB.)

REVISION OF SECTIONS 133 AND 302 AND RE-
LATED PROVISIONS) OF GANSKE/DINGELL
SUBSTITUTE FOR H.R. 3605

(previously in file \P5\HEALTH\H4250\H3605.SUB)

[revisions indicated by ~~strike out~~ for deletions and *italics*
for insertions]

1 SEC. 133. EXTERNAL APPEALS OF ADVERSE DETERMINA-
2 TIONS.

3 (a) RIGHT TO EXTERNAL APPEAL.—

4 (1) IN GENERAL.—A group health plan, and a
5 health insurance issuer offering group health insur-
6 ance coverage, shall provide for an external appeals
7 process that meets the requirements of this section
8 in the case of an externally appealable decision de-
9 scribed in paragraph (2), *for which a timely appeal*
10 *is made either by the plan or issuer or by the partici-*
11 *pant, beneficiary, or enrollee, or a representative of*
12 *any of them.* The appropriate Secretary shall estab-
13 lish standards to carry out such requirements.

14 (2) EXTERNALLY APPEALABLE DECISION DE-
15 FINED.—For purposes of this section, the term “ex-
16 ternally appealable decision” means an appealable
17 decision (as defined in section 132(a)(2)) if—

18 (A) the amount involved exceeds ~~a signifi-~~
19 ~~cant threshold~~ \$100; or

1 (B) the patient's life or health is jeopard-
2 ized as a consequence of the decision.

3 Such term does not include a denial of coverage for
4 services that are specifically listed in plan or cov-
5 erage documents as excluded from coverage.

6 (3) EXHAUSTION OF INTERNAL APPEALS PROC-
7 ESS.—A plan or issuer may condition the use of an
8 external appeal process in the case of an externally
9 appealable decision upon completion of the internal
10 review process provided under section 132, but only
11 if the decision is made in a timely basis consistent
12 with the deadlines provided under this subtitle.

13 (b) GENERAL ELEMENTS OF EXTERNAL APPEALS
14 PROCESS.—

15 (1) CONTRACT WITH QUALIFIED EXTERNAL AP-
16 PEAL ENTITY.—

17 (A) CONTRACT REQUIREMENT.—Subject to
18 subparagraph (B), the external appeal process
19 under this section of a plan or issuer shall be
20 conducted under a contract between the plan or
21 issuer and one or more qualified external appeal
22 entities (as defined in subsection (c)).

23 (B) RESTRICTIONS ON QUALIFIED EXTER-
24 NAL APPEAL ENTITY.—

1 (i) BY STATE FOR HEALTH INSUR-
2 ANCE ISSUERS.—With respect to health in-
3 surance issuers in a State, the State may
4 provide for external review activities to be
5 conducted by a qualified external appeal
6 entity that is designated by the State or
7 that is selected by the State in such a
8 manner as to assure an unbiased deter-
9 mination.

10 (ii) BY FEDERAL GOVERNMENT FOR
11 GROUP HEALTH PLANS.—With respect to
12 group health plans, the appropriate Sec-
13 retary may exercise the same authority as
14 a State may exercise with respect to health
15 insurance issuers under clause (i). Such
16 authority may include requiring the use of
17 the qualified external appeal entity des-
18 ignated or selected under such clause.

19 (iii) LIMITATION ON PLAN OR ISSUER
20 SELECTION.—If an applicable authority
21 permits more than one entity to qualify as
22 a qualified external appeal entity with re-
23 spect to a group health plan or health in-
24 surance issuer and the plan or issuer may

1 select among such qualified entities, the
2 applicable authority—

3 (I) shall assure that the selection
4 process will not create any incentives
5 for external appeal entities to make a
6 decision in a biased manner, and

7 (II) shall implement procedures
8 for auditing a sample of decisions by
9 such entities to assure that no such
10 decisions are made in a biased man-
11 ner.

12 (C) OTHER TERMS AND CONDITIONS.—

13 The terms and conditions of a contract under
14 this paragraph shall be consistent with the
15 standards the appropriate Secretary shall estab-
16 lish to assure there is no real or apparent con-
17 flict of interest in the conduct of external ap-
18 peal activities. Such contract shall provide that
19 the direct costs of the process (not including
20 costs of representation of a participant, bene-
21 ficiary, or enrollee) shall be paid by the plan or
22 issuer, and not by the participant, beneficiary,
23 or enrollee.

24 (2) ELEMENTS OF PROCESS.—An external ap-
25 peal process shall be conducted consistent with

1 standards established by the appropriate Secretary
2 that include at least the following:

3 (A) FAIR PROCESS; DE NOVO DETERMINA-
4 TION.—The process shall provide for a fair, de
5 novo determination. *In carrying out this sub-*
6 *paragraph, the determination of medical neces-*
7 *sity shall be made under the process without re-*
8 *gard to the definition used by the plan or issuer.*
9 *However, nothing in this sentence shall be con-*
10 *strued as providing for coverage of items and*
11 *services for which benefits are specifically ex-*
12 *cluded under the plan or coverage.*

13 (B) DETERMINATION CONCERNING EXTER-
14 NALLY APPEALABLE DECISIONS.—A qualified
15 external appeal entity shall determine whether a
16 decision is an externally appealable decision and
17 related decisions, including—

18 (i) whether such a decision involves an
19 expedited appeal;

20 (ii) the appropriate deadlines for in-
21 ternal review process required due to medi-
22 cal exigencies in a case; and

23 (iii) whether such a process has been
24 completed.

1 (C) OPPORTUNITY TO SUBMIT EVIDENCE,
2 HAVE REPRESENTATION, AND MAKE ORAL
3 PRESENTATION.—Each party to an externally
4 appealable decision (*directly or through an au-*
5 *thorized representative or representatives, any of*
6 *whom may be an attorney*)—

7 (i) may submit and review evidence
8 related to the issues in dispute,

9 (ii) may use the assistance or rep-
10 resentation of one or more individuals (any
11 of whom may be an attorney), and

12 (iii) may make an oral presentation.

13 (D) PROVISION OF INFORMATION.—The
14 plan or issuer involved shall provide timely ac-
15 cess to all its records relating to the matter of
16 the externally appealable decision and to all
17 provisions of the plan or health insurance cov-
18 erage (including any coverage manual) relating
19 to the matter.

20 (E) TIMELY DECISIONS.—A determination
21 by the external appeal entity on the decision
22 shall—

23 (i) be made orally or in writing and,
24 if it is made orally, shall be supplied to the
25 parties in writing as soon as possible;

1 (ii) be binding on the plan or issuer;

2 (iii) be made in accordance with the
3 medical exigencies of the case involved, but
4 in no event later than 60 days (or 72
5 hours in the case of an expedited appeal
6 or, in the case of an appeal involving emer-
7 gency circumstances, as soon as possible in
8 accordance with the medical exigencies of
9 the case, and in no event later than 24
10 hours) from the date of completion of the
11 filing of notice of external appeal of the de-
12 cision;

13 (iv) state, in layperson's language, the
14 basis for the determination, including, if
15 relevant, any basis in the terms or condi-
16 tions of the plan or coverage; and

17 (v) inform the participant, beneficiary,
18 or enrollee of the individual's rights (in-
19 cluding any limitation on such rights) to
20 seek further review by the courts (or other
21 process) of the external appeal determina-
22 tion.

23 (c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
24 TIES.—

1 (1) IN GENERAL.—For purposes of this section,
2 the term “qualified external appeal entity” means,
3 in relation to a plan or issuer, an entity (which may
4 be a governmental entity) that is certified under
5 paragraph (2) as meeting the following require-
6 ments:

7 (A) There is no real or apparent conflict of
8 interest that would impede the entity conduct-
9 ing external appeal activities independent of the
10 plan or issuer.

11 (B) The entity conducts external appeal
12 activities through clinical peers.

[Note: The term “clinical peer”, as defined in section
191(c)(2) of Dingell-Ganske, would be modified as fol-
lows:

(2) CLINICAL PEER.—The term “clinical peer”
means, with respect to a review or appeal, a physi-
cian (allopathic or osteopathic) or other health care
professional who holds a non-restricted license in a
State (*or, for purposes of section 133, in a State in
which the care is to be provided or in which the refer-
ral or recommendation for care is made*) and who is
appropriately credentialed in the same or similar
specialty as typically manages the medical condition,
procedure, or treatment under review or appeal and

includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment *recommended or rendered* by a physician.

1 (C) The entity has sufficient medical, legal,
2 and other expertise and sufficient staffing to
3 conduct external appeal activities for the plan
4 or issuer on a timely basis consistent with sub-
5 section (b)(3)(E).

6 (D) The entity meets such other require-
7 ments as the appropriate Secretary may im-
8 pose.

9 (2) CERTIFICATION OF EXTERNAL APPEAL EN-
10 TITIES.—

11 (A) IN GENERAL.—In order to be treated
12 as a qualified external appeal entity with re-
13 spect to—

14 (i) a group health plan, the entity
15 must be certified (and, in accordance with
16 subparagraph (B), periodically recertified)
17 as meeting the requirements of paragraph
18 (1) by the Secretary of Labor (or under a
19 process recognized or approved by the Sec-
20 retary of Labor); or

1 (ii) a health insurance issuer operat-
2 ing in a State, the entity must be certified
3 (and, in accordance with subparagraph
4 (B), periodically recertified) as meeting
5 such requirements by the applicable State
6 authority (or, if the States has not estab-
7 lished an adequate certification and recer-
8 tification process, by the Secretary of
9 Health and Human Services, or under a
10 process recognized or approved by such
11 Secretary).

12 (B) RECERTIFICATION PROCESS.—The ap-
13 propriate Secretary shall develop standards for
14 the recertification of external appeal entities.
15 Such standards shall include a specification
16 of—

17 (i) the information required to be sub-
18 mitted as a condition of recertification on
19 the entity's performance of external appeal
20 activities, which information shall include
21 the number of cases reviewed, a summary
22 of the disposition of those cases, the length
23 of time in making determinations on those
24 cases, and such information as may be nec-
25 essary to assure the independence of the

1 entity from the plans or issuers for which
2 external appeal activities are being con-
3 ducted; and

4 (ii) the periodicity which recertifi-
5 cation will be required.

6 (3) *LIMITATION ON LIABILITY OF REVIEWERS.—*

7 *No qualified external appeal entity having a contract*
8 *with a plan or issuer under this part and no person*
9 *who is employed by, or who has a fiduciary relation-*
10 *ship with, any such entity or who furnishes profes-*
11 *sional services to such entity, shall be held by reason*
12 *of the performance of any duty, function, or activity*
13 *required or authorized pursuant to this section, to*
14 *have violated any criminal law, or to be civilly liable*
15 *under any law of the United States or of any State*
16 *(or political subdivision thereof) if due care was exer-*
17 *cised in the performance of such duty, function, or ac-*
18 *tivity and there was no actual malice or gross mis-*
19 *conduct in the performance of such duty, function, or*
20 *activity.*

21 (d) *LIMITATION ON LEGAL RIGHTS.—*

22 (1) *IN GENERAL.—Subject to paragraph (2), the*
23 *determination by an external appeals entity under*
24 *this section is binding on the plan (and issuer, if*

1 any) involved and on the participant, beneficiary, or
2 enrollee involved and is not subject to judicial review.

3 (2) *EXCEPTION.*—The determination in an exter-
4 nal appeals entity under this section may be vacated
5 or modified by a court only under the same cir-
6 cumstances as the decision of an arbitrator may be
7 vacated or modified under sections 10 and 11 of title
8 9, United States Code.

9 (3) *LIMITATION ON PUNITIVE DAMAGES.*—If a
10 group health plan, or a health insurance issuer offer-
11 ing group health insurance coverage, follows the deter-
12 mination of an external appeals entity under this
13 subsection, the plan or issuer is not liable for any pu-
14 nitive damages in any subsequent legal action in re-
15 lation to the matter of such determination.

16 (4) *CONSTRUCTION.*—Nothing in this subsection
17 shall be construed to prohibit any person from bring-
18 ing an action in an appropriate court to enforce the
19 decision of an external appeals entity under this sec-
20 tion.

1 SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN
2 ACTIONS INVOLVING HEALTH INSURANCE
3 POLICYHOLDERS.

4 (a) IN GENERAL.—Section 514 of the Employee Re-
5 tirement Income Security Act of 1974 (29 U.S.C. 1144)
6 is amended by adding at the end the following subsection:

7 “(c) PREEMPTION NOT TO APPLY TO CERTAIN AC-
8 TIONS ARISING OUT OF PROVISION OF HEALTH BENE-
9 FITS.—

10 “(1) IN GENERAL.—Except as provided in this
11 subsection, nothing in this title shall be construed to
12 invalidate, impair, or supersede any cause of action
13 brought by a plan participant or beneficiary (or the
14 estate of a plan participant or beneficiary) under
15 State law to recover damages resulting from per-
16 sonal injury or for wrongful death against any per-
17 son—

18 “(A) in connection with the provision of in-
19 surance, administrative services, or medical
20 services by such person to or for a group health
21 plan (as defined in section 733), or

22 “(B) that arises out of the arrangement by
23 such person for the provision of such insurance,
24 administrative services, or medical services by
25 other persons; ;

1 *but only, in the case of a cause of action relating to*
2 *an externally appealable decision (as defined in sec-*
3 *tion 133(a)(2) of the Patients' Bill of Rights Act of*
4 *1999), if an external appeal was completed under sec-*
5 *tion 133 of such Act with respect to the decision. In*
6 *a cause of action described in the previous sentence*
7 *for which an external appeal was completed, the plan*
8 *or issuer is not liable for any punitive, exemplary, or*
9 *similar damages if the plan or issuer followed the rec-*
10 *ommendation of the qualified external appeal entity*
11 *involved. For purposes of this subsection, the term*
12 *'personal injury' means a physical injury and in-*
13 *cludes an injury arising out of the treatment (or fail-*
14 *ure to treat) a mental illness or disease.*

15 “(2) EXCEPTION FOR EMPLOYERS AND OTHER
16 PLAN SPONSORS.—

17 “(A) IN GENERAL.—Subject to subpara-
18 graph (B), paragraph (1) does not authorize—

19 “(i) any cause of action against an
20 employer or other plan sponsor maintain-
21 ing the group health plan (or against an
22 employee of such an employer or sponsor
23 acting within the scope of employment), or

24 “(ii) a right of recovery or indemnity
25 by a person against an employer or other

1 plan sponsor (or such an employee) for
2 damages assessed against the person pur-
3 suant to a cause of action under paragraph
4 (1).

5 “(B) SPECIAL RULE.—Subparagraph (A)
6 shall not preclude any cause of action described
7 in paragraph (1) against an employer or other
8 plan sponsor (or against an employee of such
9 an employer or sponsor acting within the scope
10 of employment) if—

11 “(i) such action is based on the em-
12 ployer’s or other plan sponsor’s (or em-
13 ployee’s) exercise of discretionary authority
14 to make a decision on a claim for benefits
15 covered under the plan or health insurance
16 coverage in the case at issue; and

17 “(ii) the exercise by such employer or
18 other plan sponsor (or employee) of such
19 authority resulted in personal injury or
20 wrongful death.

21 “(3) CONSTRUCTION.—Nothing in this sub-
22 section shall be construed as permitting a cause of
23 action under State law for the failure to provide an
24 item or service which is not specifically excluded
25 under the group health plan involved.”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall apply to acts and omissions occurring
3 on or after the date of the enactment of this Act from
4 which a cause of action arises.

In section 192(a), revise paragraph (1) as shown
below:

5 (1) IN GENERAL.—Subject to paragraph (2),
6 this title shall not be construed to supersede any
7 provision of State law which establishes, implements,
8 or continues in effect any standard or requirement
9 solely relating to health insurance issuers in connec-
10 tion with group health insurance coverage, except to
11 the extent that such standard or requirement pre-
12 vents the application of a requirement of this title,
13 *or which requires (in connection with any litigation*
14 *against a health insurance issuer) that the dispute be*
15 *first, or simultaneously, considered through an alter-*
16 *native dispute resolution system.*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

Date:

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS
TRANSMISSION TO THE FOLLOWING
PERSON AS SOON AS POSSIBLE:

Name(s): Sarah Bianchi

Department: _____

Phone#: _____

Fax#: 456-5557

FROM:

Terri Shaw @*Assistant Secretary for Planning & Evaluation*Number of pages being transmitted (including fax sheet): 17

COMMENTS:

Updated side by sidew/ Ganske + Chafee205-8681



UNITED STATES DEPARTMENT OF EDUCATION

THE DEPUTY SECRETARY

FEB 25 1999

Mr. Steve Malphrus
Financial Institutions Work Group
Federal Reserve System
Washington, D.C.

Dear Mr. Malphrus:

At last week's meeting agencies were asked whether they support the use of "early payments" as a Y2K risk mitigation strategy and were invited to comment on a draft report of the Task Force.

In general, we believe the "early payment" approach to Y2K risk mitigation is reasonable, prudent, and in line with GAO and Congressional guidance for Y2K risk mitigation. While it does have significant cash flow cost implications for the Government such costs can be limited by limiting the time frames involved or by limiting the types of payments involved.

As you know, agencies have been asked to identify means of avoiding Y2K problems not only in their own data systems, but also in those of key data exchange partners. In our case, many of our postsecondary institution partners participate in the delivery of Federal student aid and face their own Y2K challenge. Allowing the early advance of funds to schools would add significantly to preserving student aid delivery for the estimated 8 million Federal student aid recipients in year 2000 and add to the institution's individual confidence in making available funds in advance of the changeover.

Under the Department's early draw down strategy, we would allow schools to draw down Federal student aid funds in December, 1999 that they would normally draw down in January 2000. Further, we would allow schools to disburse those funds to students in December only by allowing the schools to credit those student school accounts. The disbursements could be used to satisfy school charges and to create credit balances. Actual payments to students for non-school charges would have to be made in accordance with the Department's regular disbursement rules.

To facilitate this approach, the Department would "waive"/not enforce on a temporary basis several of our cash management regulations that apply to participating schools. These include (1) the 3-day rule. A school would not have to disburse funds it receives within 3 days; (2) the 10-day rule. We would allow a school to credit a student's account earlier than 10 days before classes begin; and, (3) excess cash rules. The Department

Page 2 – Mr. Steve Malphrus

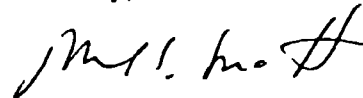
would allow schools to maintain excess balances without penalty. The early draw down of Federal student aid funds would be entirely at the school's option. We would limit to historical levels the amounts schools could draw down early, and would not allow any portion of the early advances to be disbursed directly to a student or parent. Thus, if a student does not begin classes as scheduled or for some reason becomes ineligible, we could recover the Federal aid funds from the school.

No statutory changes would be necessary to implement this Y2K risk mitigation strategy. Moreover, there is precedent for the temporary non-enforcement of our cash management regulations due to potential system difficulties. In March 1998, while implementing a new financial management data system, we instituted such an early draw down strategy. We issued a letter to participating schools announcing our intention to not enforce our cash management regulations for a temporary period. This strategy was successful and did not result in problems or abuse.

In considering the draft report, while we appreciate the need for not overly alarming the public about the Y2K issue, we consider the early payment of Federal benefits as removing or reducing the risk in case of unforeseen failures. Like other agencies represented at last week's meeting, we believe it more likely that the public would see these risk avoidance steps as a sign of the Government's prudence and seriousness about protecting the delivery of Federal program benefits to citizens who rely on them. In our case, this preference was reinforced by our partners at a recently conducted focus group of school and association representatives and viewed as a practical and reasonable risk mitigation action to reduce risk of disruptions.

Please let me know if you have any questions or need more information.

Sincerely,



Marshall S. Smith
Deputy Secretary (A)

cc: Mr. Oliver Ireland
Mr. John Koskinen

1

**COMPARISON OF CONSUMER PROTECTIONS:
PRESIDENT'S ADVISORY COMMISSION, MEDICARE + CHOICE, AND PROPOSED LEGISLATION**

PROVISION	Advisory Commission	Medicare+ Choice (Interim Final Reg.)	Daschle/Dingell (S6/HR358)	Ganske (HR719)	Chafee (S374)	Senate Republican (consumer protection provisions only) (S300)	House Republican (consumer protection provisions only) (HR448)
1. Entities Regulated	Recommendations apply to all health care consumers.	All plans participating in the Medicare + Choice program.	All group health plans, and health insurance issuers in both the group and individual markets (i.e., both where state rules are preempted by ERISA and where states could regulate).	All group health plans, and health insurance issuers in both the group and individual markets (i.e., both where state rules are preempted by ERISA and where states could regulate).	All group health plans, and health insurance issuers in both the group and individual markets (i.e., both where state rules are preempted by ERISA and where states could regulate).	Only where state rules are pre-empted by ERISA: All ERISA plans for Information Disclosure and Appeals, self-insured plans only for all other consumer protection provisions. For Privacy provisions, all plans, providers, schools, etc.	All group health plans, and health insurance issuers in the group market only (i.e., where state rules are preempted by ERISA, plus some but not all areas where states could regulate). For POS provisions, only issuers that are HMOs. For Privacy provisions, all plans, providers, schools, etc.
2. Information Disclosure	List of information to be disclosed automatically, additional information to be disclosed on request. Information should	List of information to be disclosed automatically, additional information to be disclosed on request. HHS provides information prior to	List of information to be disclosed automatically, additional information to be disclosed on request. Information must be issued at time of	List of information to be disclosed automatically, additional information to be disclosed on request. Information must be issued at time of	List of information to be disclosed automatically, additional information to be disclosed on request. Information must be issued at time of	List of information to be disclosed automatically, additional information to be disclosed on request. Disclosure is one time only, within a	List of information to be disclosed automatically, additional information to be disclosed on request. Uses existing SPD time frames. Does

**COMPARISON OF CONSUMER PROTECTIONS:
PRESIDENT'S ADVISORY COMMISSION, MEDICARE+CHOICE, AND PROPOSED LEGISLATION**

PROVISION	Advisory Commission	Medicare+Choice (Interim Final Reg.)	Daschle/Dingell (S6/HR358)	Ganske (HR719)	Chafee (S374)	Senate Republican (consumer protection provisions only) (S300)	House Republican (consumer protection provisions only) (HR448)
	be provided at "appropriate times (i.e. decision points)."	each open season, plans provide information at time of enrollment and updates at least annually.	enrollment and at least annually thereafter. Gives Secretary authority to require notice of changes be provided to enrollee before the effective date of the changes.	enrollment and at least annually thereafter. Gives Secretary authority to require notice of changes be provided to enrollee before the effective date of the changes.	enrollment and at least annually thereafter. Gives Secretary authority to require notice of changes be provided to enrollee before the effective date of the changes.	year of enactment. Does not fix current ERISA law that allows notice of material reductions in benefits to be provided after the effective date of the changes.	not fix current ERISA law that allows notice of material reductions in benefits to be provided after the effective date of the changes, except requires advance notice of exclusions from formulary.
3. Network Adequacy							
a. Basic standard for network adequacy	Yes	Yes	Yes	Yes	Yes	No	No
b. Enrollees go out of network if network not adequate for their particular needs	Yes, at no additional cost beyond that for participating providers.	Does not address situations where network is not adequate, but mandates coverage of out-of-network services in limited specified situations, at no additional cost	Yes, at no additional cost to enrollees beyond that for participating providers.	Yes, at no additional cost to enrollees beyond that for participating providers.	Yes, at no additional cost to enrollees beyond that for participating providers.	No	No

**COMPARISON OF CONSUMER PROTECTIONS:
PRESIDENT'S ADVISORY COMMISSION, MEDICARE+ CHOICE, AND PROPOSED LEGISLATION**

PROVISION	Advisory Commission	Medicare+ Choice (Interim Final Reg.)	Daschle/Dingell (S6/HR358)	Ganske (HR719)	Chafee (S374)	Senate Republican (consumer protection provisions only) (S300)	House Republican (consumer protection provisions only) (HR448)
		to enrollee.					
4. Direct Access to Specialists							
a. Complex/serious conditions requiring on-going care	Authorization should be "for an adequate number" of visits.	Treatment plans must provide an adequate number of visits.	Standing specialist referrals and specialists may serve as primary care physicians.	Standing specialist referrals and specialists may serve as primary care physicians with respect to the condition.	Standing specialist referrals and specialists may serve as primary care physicians.	No	No
b. Routine and preventive Ob/Gyn	Yes	Yes	Yes, and plan must allow Ob/Gyn to be designated as primary care physician.	Yes	Yes	Yes	Yes
c. Pediatricians	No	No	No. Plan must allow pediatrician to be designated as PCP.	No. Plan must allow pediatrician to be designated as PCP.	No	Yes	No. Plan must allow pediatrician to be designated as PCP.
5. Continuity of Care/ Transitional Care	When the provider is dropped from the plan or the employer changes	No provision for an enrollee to continue with managed care provider. Enrollee	When the provider is dropped from the plan or the employer changes health	When the provider is dropped from the plan or the employer changes health	When the provider is dropped from the plan or the employer changes health	When the provider is dropped from the plan.	No

TVA 02:01 PM

RR/GZ/ZN

4

**COMPARISON OF CONSUMER PROTECTIONS:
PRESIDENT'S ADVISORY COMMISSION, MEDICARE+CHOICE, AND PROPOSED LEGISLATION**

PROVISION	Advisory Commission	Medicare+Choice (Interim Final Reg.)	Daschle/Dingell (S6/HR358)	Ganske (HR719)	Chafee (S374)	Senate Republican (consumer protection provisions only) (S300)	House Republican (consumer protection provisions only) (HR448)
	health plans. For people in a course of treatment for a chronic or disabling condition (for 90 days) and pregnant women beyond their first trimester (through postpartum care).	can return to original Medicare (the ability to do this will be limited after 2001 and is further limited by lack of access to MediGap policies).	plans. For persons in a course of treatment (for 90 days), inpatients (through discharge), women past first trimester of pregnancy (through postpartum care), and terminally ill persons (for remainder of life).	plans. For persons in a course of treatment (for 90 days), inpatients (through discharge), women past first trimester of pregnancy (through postpartum care), and terminally ill persons (for remainder of life).	plans. For persons in a course of treatment (for 90 days), inpatients (through discharge), women past first trimester of pregnancy (through postpartum care), and terminally ill persons (up to 180 days).	For inpatients and terminally ill persons (for 90 days), for women past first trimester of pregnancy (through postpartum care).	
6. Mandatory POS Option	No	BBA permits, but does not mandate, a POS option.	Yes	Yes	No	Yes, with exception for small employers	Yes, with exception if POS premium will be more than 1% greater than the closed panel premium or if HMO would need new license.
7. Access to Emergency Services							
a. Bans prior authorization	Yes.	Yes	Yes	Yes	Yes	Yes	Yes

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requirements							
b. Bans in- network requirements	Yes	Yes	Yes	Yes	Yes	No	Yes
c. Prudent layperson standard for coverage of screening and stabilization	Yes	Yes	Yes	Yes	Yes	Yes	For screening exam only. Any additional emergency medical services covered under "prudent emergency medical professional" standard (unclear is this includes stabilization care).
d. Emergency medical condition includes "Severe Pain"	Yes	Yes	Yes	Yes	Yes	Yes	No
e. Post- stabilization care	Emergency department should contact the plan or provider to discuss post-stabilization care and promote	ER required to contact organization to obtain authorization for post-stabilization care; if the	Mandates process consistent with Medicare guidelines	Mandates process consistent with Medicare guidelines	Mandates process consistent with Medicare guidelines	Not addressed	Not addressed

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	continuity of care.	organization fails to respond or cannot be contacted within 1 hour, authorization is deemed.					
8. Limits on Physician Incentives	No	Prohibits specific payments to physicians "as an inducement to reduce or limit medically necessary services." Where physician is at substantial financial risk for services not provided by those physicians, requires stop loss coverage, disclosure, and surveys of enrollees and disenrollees.	Same as Medicare	Same as Medicare	Same as Medicare	No	No
9. Anti-Gag Rule							
a. Communication about	Yes	Yes	Yes	Yes	Yes	Yes	Yes, but only applies to direct contract between plan and

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condition and treatment							provider
b. Protection for advocating behalf of patient	Yes	No	Yes	Yes	Yes	No	No
10. Non-discrimination	Yes	Yes	Yes	No	Yes	No	No
11. Confidentiality of Health Information	Individually identifiable health information cannot be used without the written consent of the enrollee except for research, fraud investigations, and public health reporting. Consumers have the right to review, copy, and request amendments to their medical	A M+C organization must establish procedures to safeguard the privacy of any individually identifiable enrollee information.	Plan must safeguard the privacy of individually identifiable information, and allow timely access for individuals to their health information.	Plan must safeguard the privacy of individually identifiable information, and allow timely access for individuals to their health information.	Plan must safeguard the privacy of individually identifiable information.	Nothing in consumer protection provisions. A separate Privacy Title requires plans to safeguard the privacy of health information, and provide access for individuals to inspect, copy, and amend their health information.	Nothing in consumer protection provisions. A Separate Privacy Title requires plans to safeguard the privacy of health information, and provide access for individuals to inspect, copy, and amend their health information. The Title overrides many State protections without providing adequate Federal

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	records.						protection.)
12. Coverage determinations							
a. Deadline	"Timely"	Yes	For decisions covered by broad definition of UR	For decisions covered by broad definition of UR	For prior authorizations, continued care, and previously provided services.	For pre- and concurrent authorization.	Only for decision on physician's request for prior authorization for specialty care. Not for other determinations.
b. Expedited Process and/or tied to medical exigencies of the case	Yes	Yes	Yes	Yes	Yes	Yes (but plan decides), not tied to medical exigencies of case.	No*
13. Internal appeal							
a. Decisions that can be appealed	Denial of coverage, reduction or termination of services, or denial of payment for	Denial or discontinuation of benefits, payment, or services.	Denials or discontinuation of benefits, payment, or services, adverse UR determinations, certain violations of	Denials or discontinuation of benefits, payment, or services, adverse UR determinations, certain violations of	Adverse initial coverage determinations and imposition of prohibited manner or setting limitations.	Adverse initial coverage determinations - does not include failure to meet determination	Adverse benefit payment decisions, advance determinations of coverage, and required

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b. Deadline	services. "Timely"	Yes	the statute. Yes	the statute. Yes	Yes	deadlines, or disputes regarding items and services specifically listed as excluded in the coverage documents. Yes	determinations of medical necessity No*
c. Expedited process and/or tied to medical exigencies of the case	Yes ("consistent with Medicare")	Yes	Yes	Yes	Yes	Yes	No*
14. External appeal							
a. Decisions that can be appealed	Any decision to deny, reduce or terminate coverage or payment based on determination that treatment is experimental or not medically necessary.	Any determination which is, in whole or in part, adverse to the enrollee.	Same as internal appeals, but not including denials for services specifically listed in plan documents as excluded from coverage.	Same as internal appeals, but not including denials for services specifically listed in plan documents as excluded from coverage. Plan may request appeal.	Same as internal appeals.	Disputes re whether care meets plan's definition of medical necessity, and experimental treatment where there is significant risk to life or health.	Adverse re whether care meets plan's definition of medical necessity or experimental, and no ERISA §502 suit has been initiated.

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b. Failure to meet internal review deadline moves dispute to external review	"Timely"	Yes	Yes	Yes	Yes. If plan fails to meet deadline, must automatically forward case file to external reviewer.	No	In theory only, because internal "deadlines" can be indefinite.
c. Barriers / thresholds	For medical necessity decisions, a "significant threshold" unless the denial jeopardize life or health.	None -- all disputes not resolved wholly in favor of the enrollee are automatically forwarded to the external review entity.	A "significant threshold" unless the denial jeopardizes the life or health (including development, in the case of a child) of the patient.	\$100 unless the denial jeopardizes the life or health of the patient.	A "significant" threshold unless the denial jeopardizes the life or health or ability to regain or maintain maximum function (including development, in the case of a child under 6) of the patient.	For Medical Necessity disputes, the amount involved must exceed a significant financial threshold. Enrollee has only 30 days to appeal.	Non-Medicaid/CHIP enrollees may be required to pay a fee (the greater of the lesser of \$100 or 10% of the care under dispute or \$25). Enrollee has only 30 days to appeal.
d. Review entity selection	External review should be "independent" and "fair to all parties"	HCFA chooses entity	Selected either by appropriate authority, or by plan under rules developed by appropriate authority to prevent bias.	Selected either by appropriate authority, or by plan under rules developed by appropriate authority to prevent bias.	Selected either by appropriate authority, or by plan under rules developed by appropriate authority to prevent bias.	Plan chooses entity	Plan chooses intermediary, which chooses reviewing expert.
e. Protections	External review	Review entity	Certified by	Certified by	Certified by	Reviewers must not	Reviewers/entity

**COMPARISON OF CONSUMER PROTECTIONS:
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against reviewers' bias/ conflict of interest	should be "independent" and "fair to all parties"	chosen by HCFA, not plan.	appropriate authority as having no conflict of interest and meeting any other regulatory requirements. If more than one certified entity is available to a plan, rules of the applicable authority assure that the selection process creates no incentives for bias.	appropriate authority as having no conflict of interest and meeting any other regulatory requirements. If more than one certified entity is available to a plan, rules of the applicable authority assure that the selection process creates no incentives for bias.	appropriate authority as having no conflict of interest and meeting any other regulatory requirements. If more than one certified entity is available to a plan, rules of the applicable authority assure that the selection process creates no incentives for bias.	have any affiliation with the case, the enrollee, or the provider. Affiliation with plan or employer is not prohibited. Reviewers can receive only reasonable compensation not contingent on decisions.	must not be affiliated with any party to the dispute, receive only reasonable compensation not contingent on decisions, not be subject to retaliation from the plan, be free from conflict of interest as determined by regulation, and in some cases reviewer is blind to identify of plan and enrollee, and vice versa.
f. Deadline	"Timely"	Yes	Yes	Yes	No. Review entity establishes time frames similar to internal appeal time frames.	No	No*
g. Expedited process and/or tied to medical exigencies of	Yes ("consistent with Medicare")	Yes	Yes	Yes	No. Review entity establishes time frames similar to internal appeal time	No	No*

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PROVISION	Advisory Commission	Medicare + Choice (Interim Final Reg.)	Daschle/Dingell (S6/HR358)	Ganske (HR719)	Chafee (S374)	Senate Republican (consumer protection provisions only) (S300)	House Republican (consumer protection provisions only) (HR448)
the case					frames.		
h. Binding v. Advisory	Silent	Binding on plan	Binding on plan	Binding on plan	Binding on plan	Binding on plan	Advisory. If offered by plan, enrollee can agree to binding ADR in lieu of external appeals process.
i. De Novo standard	"Objective and credible"	Yes	Yes	Yes, without regard to plan's definition of medical necessity.	Yes	No, review based on plan's definition of medical necessity, and must take into consideration plan's guidelines	No, review based on plan's definition of medical necessity and experimental.
15. Quality Advisory Board	Commission recommends creation of the Advisory Council for Health Care Quality and the Forum for Health Care Quality Measurement and Reporting.	No	Creates Health Care Quality Advisory Board.	No	No	No, gives some of the relevant responsibilities to AHCPR.	No
16. Experimental	No	Medicare excludes coverage for	No coverage mandate. Plan must	No coverage mandate. Plan must	No coverage mandate. Plan must	No coverage mandate. Plan must	No coverage mandate. Plan must

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therapies		experimental therapies. M+C organizations may cover experimental therapies through supplemental benefits.	disclose how it decides if treatment is experimental.	disclose how it decides if treatment is experimental.	disclose how it decides if treatment is experimental.	disclose whether experimental therapies are covered.	disclose whether experimental therapies are excluded from coverage and the definitions it uses.
17. Clinical trial coverage mandate	No	No	Yes, if enrollee has a serious illness for which no standard treatment is effective plan must pay routine costs.	Yes, if enrollee has a serious illness for which no standard treatment is effective plan must pay routine costs.	Yes, if enrollee has a serious illness for which no standard treatment is effective plan must pay routine costs.	No	No
18. Enforcement	No	HHS/Department of Justice have authority to seek civil money penalties (\$10,000 - \$100,000, or \$25,000 per violation plus \$10,000 for each week the deficiency remains uncorrected), criminal penalties, intermediate	HIPAA enforcement provisions: Under PHSA, HHS may impose CMPs of up to \$100/day/violation. Under ERISA, DoL may impose CMPs of up to \$100/day for certain violations (generally limited to information disclosure violations); for other	HIPAA enforcement provisions: Under PHSA, HHS may impose CMPs of up to \$100/day/violation. Under ERISA, DoL may impose CMPs of up to \$100/day for certain violations (generally limited to information disclosure violations); for other	In addition to HIPAA enforcement provisions, grants HHS same investigative and injunctive relief authority as DoL has under ERISA. HHS and DoL may impose CMPs equal to the greater of \$250,000 for pattern and practice or \$50,000 per	Current ERISA enforcement provisions. DoL may impose CMPs against a fiduciary for a pattern or practice of 1) adverse coverage decisions in violation of the terms of the plan or bill, 2) violation of ERISA §503 notice of denied claim	HIPAA enforcement provisions: Beneficiaries under PHSA, HHS may impose CMPs of up to \$100/day/violation. Under ERISA, DoL may impose CMPs of up to \$100/day for certain violations (generally limited to information disclosure

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		sanctions (e.g., suspension of enrollment or marketing) and exclusion from the Medicare Program. A single violation may be prosecuted (i.e., a pattern or practice is not required).	ERISA violations, the IRS may impose excise taxes on group health plans.	ERISA violations, the IRS may impose excise taxes on group health plans.	individual for statutory violations that result in unreasonable denial or delay in benefits. For other statutory violations, CMPs equal to the greater of \$50,000 for pattern or practice or \$10,000 per individual. The maximum CMP is increased by \$10,000 for each week the problem remains uncorrected.	requirements, or 3) violation of ERISA §503 full and fair review requirements. Penalty may not exceed lesser of 5% of aggregate value of benefit or \$100,000. The fiduciary may be removed by court.	violations); for other ERISA violations, the IRS may impose excise taxes on group health plans.
19. Liability	No	Beneficiaries can sue M+C plans for damages for personal injury, wrongful death, breach of contract, and similar claims as allowed by state law. State law suits cannot be brought to obtain the actual	Amends ERISA (sec. 514) to permit suits for damages against plans for personal injury or wrongful death, as allowed by state law. Exempts employer, employees, and plan sponsor if they did not exercise	Amends ERISA (sec. 514) to permit suits for damages against plans for personal injury or wrongful death, as allowed by state law. Exempts employer, employees, and plan sponsor if they did not exercise	Amends ERISA (sec. 502(c)) to permit suits for economic damages against coverage decision-makers for personal injury resulting from coverage determinations not made on a timely	No change to ERISA pre-emption of state law suits. Adds failure to abide by decision of external reviewer to allowable actions under ERISA sec. 502(c)(1).	No change to ERISA pre-emption of state law suits. Tort reform provisions limit damages available in Federal and state law suits against health plans (and providers and others), including M+C plans, but not

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		Medicare benefit.	discretion to make a decision on the claim.	discretion to make a decision on the claim. No punitive damages when plan follows external appeal decision.	basis or in accordance with the terms of the plan or bill. Economic damages do not include punitives, pain and suffering, emotional distress, etc.		to claims under ERISA. Failure to follow external reviewer recommendation increases fiduciary liability if participant prevails in court under ERISA §502. In lieu of liability, adds civil money penalties under ERISA sec. 502, where court finds a benefit was delayed or denied against the recommendation of the external reviewer. The fiduciary may be required to pay to the participant a civil fine of \$500/day up to \$250,000.
20. Ombudsman/ Consumer	No recommendation, outlines desirable	Nothing in BBA. HHS funds Statewide Insurance	Yes, States (or federal if no State program). HHS to	Yes, States (or federal if no State program). HHS to	Yes, States (or federal if no State program). HHS to	No	No

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Assistance	characteristics of such programs.	Counseling and Assistance (ICA) programs, and the Administration on Aging operates a Nursing Home Ombudsman program.	award grants to States.	award grants to States.	award grants to States.		
21. Provider Protections	No	Plans must provide written notice of the rules of participation and of adverse participation decisions. Plans must provide a process for appealing decisions adverse to participating physicians.	Plan must provide written notice of rules of participation and of adverse participation decisions. Plans must provide a process for appealing adverse decisions of participation.	Plan must provide written notice of rules of participation and of adverse participation decisions. Plans must provide a process for appealing adverse decisions of participation.	Plan must provide written notice of rules of participation and of adverse participation decisions. Plans must provide a process for appealing adverse decisions of participation.	No	No

DATE: February 23, 1999

TO: Chris Jennings

FROM: Andie King

RE: Staff expected to participate in Friday's meeting

Aimee Occhetti, Rep. Clayton
Bill Vaughan, Ways and Means
Bridgett Taylor, Commerce
Cathy Hurwitt, Rep. Schakowsky
Cedric Hendricks, Education and Workforce
Courtenay Dusenbury, Rep. Berry
Curt Clifton, Rep. Wynn
Debbie Curtis, Rep. Stark/Ways and Means
Ellie Dehoney, Rep. S. Brown
Gayle Parker, Rep. John
Jerry Hartz, Whip
Karen Folk, Commerce
Karen Nelson, Rep. Waxman
Priscilla Ross, Rep. Cardin
Randolph Harrison, Rep. Capps
Steve Giuli, Rep. Pallone
Amy Droskoski, Commerce
Andie King, Dem. Leader Gephardt

This list represents staff from committees of jurisdiction, leadership, Caucus Health Care taskforce co-chairs, Dem. new Members, and other interested parties. We have been meeting as a group since last Fall, to keep a handle on the PBOR through all the changes and transitions that have occurred.

We would appreciate a frank discussion of where the President wants to go and how to get there; I also think it would be useful for you to hear where our Members are. The goal of all this is to keep everyone on the same page.

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February 28, 1999

In Denial: Managed Care's Other Problem -- It's Not What You Think

By MICHAEL M. WEINSTEIN

A woman suffering from breast cancer asks for a bone marrow transplant. Her health plan says no. A paraplegic needs a special wheelchair to achieve adequate mobility. The plan says no.

Rarely a week goes by without a health maintenance organization getting hammered in the press or in court for denying payment for the care of a gravely ill patient. Clearly, the anecdotal evidence suggests, the scandal of managed care is rampant denial of treatment.

But guess again. The media, courts and consumer advocates are overlooking a problem that is precisely the opposite of the one everybody's complaining about. That problem is too many medical treatments rather than too few.



Chris Maynard for The New York Times

After enrolling in managed care, Milagros Lebron visited Dr. James Sayegh in his Yonkers office.

For a variety of reasons -- fears of consumer backlash, legislative intervention or large jury awards -- managed-care plans appear to be denying little care, notwithstanding all the well-publicized horror stories and growing complaints as HMOs become commonplace in American society.

As a result, the cost savings that HMOs have already achieved are in jeopardy. Managed care also is not meeting its stated goal of improving the quality of treatment by second-guessing physicians who fail to follow the best medical practices.

Take a look at figures on care denial that New York and other states are just beginning to collect. While incomplete and problematic, they suggest that there have been few denials over the objections of enrollees or their doctors, raising the question of whether the persistent reports of callous behavior by HMOs provide a distorted picture.

For example, New York for the first time in 1997 required health plans to report each time patients or their physicians appealed a plan's denial of reimbursement for a physician-approved treatment. The plans reported a small number of appeals.

The Oxford Health Plans, covering more than a million New Yorkers in managed care, reported fewer than 1.5 appeals for every 1,000 enrollees. The six largest managed-care plans in the state averaged about 2.5 appeals per 1,000

patients.

Mainly, the HMOs denied coverage for specialists not part of the plan's network of physicians; treatments deemed unnecessary for a patient's recovery, and procedures that the plan deemed experimental -- lacking scientific evidence of safety or effectiveness.

A similar picture emerges from reports in other states. New Jersey and Connecticut, for example, keep track of appeals that are not resolved by the internal procedures of managed-care plans -- a smaller category than that reported for New York. For 1998, New Jersey reported 69 such appeals from about 2.5 million enrollees in managed care. Connecticut reported 39 appeals from about a million enrollees. Appeals are rare even in managed-care plans serving **Medicare**, despite the fact that appeals are automatic once the enrollee has exhausted the plan's internal review. Managed-care patients in general win between a quarter to a third of their appeals to federal and state authorities.

Could there be too **few** denials? Don't snicker. A presidential commission recently concluded that excessive procedures -- procedures that lack scientific justification -- could account for as much as 30 percent of the nation's medical bills. Surgeons perform mastectomies rather than breast-preserving surgery on **Medicare** patients 35 times more often in some parts of the country than in others, for no apparent medical reason. Roughly a quarter of the surgeries to implant tubes in children's ears are inappropriate.

There is, says Professor Alain Enthoven of Stanford University, an "urgent need for managed care to second-guess decisions by physicians to subject patients to needlessly risky surgery and needlessly costly tests."

Critics dismiss the self-reported New York data as unverified and unreliable. It is true that plans use different definitions of appeals and other grievances. Nor did some of the plans submit internally consistent or complete reports.

And it's not entirely clear how to interpret the low number of reported appeals. Most enrollees are healthy and present no occasion to deny care. Many denials never get appealed because patients give up easily or are unaware of legal options.

But before dismissing the data, take a close look at Empire Blue Cross and Blue Shield of New York. It reported twice as many appeals, about 38 per 1,000 patients, as any other plan, and about 15 times as many appeals as the largest plans. Upon re-examination, Empire has determined that it exaggerated the actual number because its accounting system tossed in non-medical complaints like protests of premium increases. When corrected, Empire says, its reported appeals will plummet. But is even its exaggerated estimate -- 7,300 appeals for about 200,000 patients -- an excessive figure?

A number of medical directors of large health plans say in private that fear of consumer and legal backlash has scared them from denying reimbursement even when they are convinced the treatment is ill advised. Dr. Gordon Norman of PacificCare of California, a large managed-care plan, points to another problem: "Doctors often prefer to bend to the wishes of patients, agreeing to request diagnostic tests or procedures that they may not feel are truly necessary." The doctors put the onus on the health plan to deny their requests, leaving them "in good graces with their patients, but making the plan look like the bad guy."

Aetna U.S. Healthcare identifies another way health plans keep the number of

denials and appeals low. Dr. Arthur Leibowitz, Aetna's medical director, calls it a "sentinel" effect, by which his staff keeps physicians well informed about Aetna's standards. Critics might call this bullying physicians to cut costs. That is no doubt part of the story.

But Leibowitz defends Aetna's practices by pointing to a side of managed care that the public rarely sees. It is the side that focuses on raising quality. It often tells doctors to do more, not less.

Besides pointing out ways doctors do too much, research also exposes ways they do too little. Physicians often fail to prescribe life-saving beta-blockers for heart attack victims or proper inhalers for asthma patients. Aetna issues reports to its doctors tracing how their care stacks up against their peers.

Empire made available short accounts of appeals for the first eight months of 1998. The names of the patients were stricken, though Empire contacted a random sample of the patients to ask whether they would take follow-up phone calls from a reporter. The picture that emerges is murky.

Empire refers appeals about experimental treatments like bone marrow transplants to outside panels of independent experts. That has virtually eliminated contentious legal challenges of this type of denial, raising the possibility that external review might blunt some of the consumer backlash over managed care. But Empire's other denials trigger a tug-of-war between a plan that tries to control costs and supervise care, and patients who demand the freedom to get the care they want.

Many of Empire's cases lie in a gray zone. Empire tells of financially strapped patients who skip paying premiums, then get hit with crushing medical bills. Employers switch health insurers, forcing employees to switch to Empire's doctors -- a traumatic experience for many chronically ill patients. One parent refused to take her child, who suffered from speech and other development problems, to a doctor who had once screamed at her, triggering nightmares. Empire agreed to let the child see any other doctor in the same medical office, but the parent balked. In another case, a patient insisted on seeing a physical therapist who, she decided for unspecified reasons, was uniquely qualified to treat her back problems. Empire overturns about 30 percent of its initial denials, often after physicians produce better evidence.

The point is not that managed care does not make callous medical decisions and aggravate patients. Even if appeals are infrequent, complaints to state officials about managed care are rising, though some of the trend can be explained by rising enrollment in managed-care plans, and many of the complaints involve nuisances like not answering the phone quickly or paying claims on time.

Managed-care plans sometimes deny care when they should not, and sometimes pay for care when they should not. Both mistakes pose dangers. Enthoven offers a caution. "The country risks making a terrible mistake if it overreacts and treats every denial as an assault on patients," he said. "Denials are a necessary feature of a well-run plan."