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To: Ms. Jennifer Klein
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Message/ Instructions: Medical necessity

Date: 8/31/94
Time: 4:30 pm
Total Pages: 13
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WILLIAM M. MERCER
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Linda A Bergthold, PhD
Principal

September 1, 1994

TO: Nan Hunter, HHS
Lisa Simpson, HHS
Jennifer Klein, The White House
Bob Valdez, HHS

FROM: Linda Bergthold, William M. Mercer
RE: The Latest on Medical Necessity

I am sending you the following updated spreadsheet on the various definitions of medical necessity currently in the marketplace, including the one which the Mainstream Coalition had proposed to include as of last week.

I have been in touch with most of the Senate staffers who are knowledgeable about this issue (Karen Hein - Finance; John Ratner -minority staff of Finance; Drew Littman, Boxer; Oliver Fein, Mitchell; Mary Beth Fiske, Kennedy; Robyn Lipner, Mikulski). However, since the Mainstream Proposal language now seems sure to include Susan Foote's definitional language, Democratic staffers are not sure they can affect the outcome. It looks as if the terminology will include "medical necessity or appropriateness" and use the term "enrollee". Nothing in the Durenberger/Foote language as it appeared in the 8/22 version would prevent abortion from being covered as a treatment for the condition of pregnancy. But they have added a very broad definition of health outcomes that includes "alleviation of fatigue" and they still have their "safe and effective" criteria. They have also added Christian Science practitioners to covered providers, allowing them to determine their own definition of medical necessity.

I have made some suggestions to the staffers about how they could mitigate the effects of Susan's definition (e.g. using "may" instead of "must"), but if we get legislation this year, and if it is built on the Mainstream proposal, it looks like it will include the terms and a set of criteria for applying them in statute. The only hope in getting it taken out is the negotiation currently going on, as well as the prospect of some lobbying of Durenberger by managed care organizations.

Please keep in touch.

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MEDICAL NECESSITY

DEFINITIONS OF MEDICAL NECESSITY IN LEGISLATION AND PRIVATE PLANS

LINDA A. BERGTHOLD, Ph.D.

DRAFT (9/1/94)

I. DEFINITIONS IN EXISTING LEGISLATION

A.MEDICARE

Section 1862(2)(1)(A) of the Social Security Act: Prohibits Medicare payment for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." The act specifically excludes certain services from coverage (e.g. cosmetic surgery and routine dental care), but it does not provide a comprehensive list of services and equipment that are either covered or excluded. The Act gives the Secretary of Health and Human Services the discretionary authority to identify medical services that are not medically reasonable and necessary for the treatment of illness or injury. (42 U.S.C. § 1395y(a)(1) (1988).

B. MEDICAID

The Medicaid statute has been construed similarly to require states to cover all "medically necessary services".

Examples of state definitions of medically necessary:

Florida: Covered outpatient services must be medically necessary, preventive, diagnostic, therapeutic or palliative services (Fla Admin. Code Ann. r. 10C-7.040(1992)). Requested service must be reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that threaten life, cause suffering or pain, result in illness or infirmity, or threaten to cause or aggravate a handicap, physical deformity, or malfunction, and there is no equally effective, more conservative or less costly course of treatment available.

Minnesota: Covered services must "(A) be determined by prevailing community standards or customary practice and usage to: (1) be medically necessary; (2) be appropriate and effective for the medical needs of the recipient; (3) meet quality and timeliness standards; (4) be the most cost effective health service available for the medical needs of the recipient; (B) represent an effective and appropriate use of medical assistance funds." (Minn. R. 9505.0210)

South Dakota: To be medically necessary, the covered service must meet the following conditions: (1) It is consistent with the recipient's symptoms, diagnosis, condition, or injury; (2) It is recognized as the prevailing standard and is consistent with generally accepted professional medical standards of the provider's peer group; (3) It is provided in response to a life-threatening condition; to treat pain, injury, illness or infection; to treat a condition that could result in physical or mental disability; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; (4) It is not furnished primarily for the convenience of the recipient or the provider; and (5) There is no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly. (S.D. Admin. R. 67: 16:01:06.02)

C. FEDERAL EMPLOYEES HEALTH BENEFIT PROGRAM (FEHBP) "PROTOTYPE" DEFINITION OF MEDICAL NECESSITY

Plans can negotiate a different definition.

Medical necessity means that services, supplies, or equipment provided by a hospital or provider of health care services associated with a particular plan:

1. are appropriate to the diagnosis or treatment of a patient's condition, illness or injury;
2. are consistent with the standards of good medical practice in the United States;
3. are not primarily for the personal comfort or convenience of the patient, family, or provider;
4. are not a part of or associated with scholastic education or vocational training of the patient;
5. in the case of inpatient care, cannot be provided safely on an outpatient basis.

The fact that a covered provider has prescribed, recommended or approved a service, supply, or equipment, does not, in itself, make it medically necessary.

II. TREATMENT OF MEDICAL NECESSITY IN PROPOSED LEGISLATION (1994)

A. LEGISLATION IN WHICH MEDICAL NECESSITY IS DEFINED SPECIFICALLY:

1. COOPER/BREAUX HR 3222

Sec.1302 SPECIFICATION OF UNIFORM SET OF EFFECTIVE BENEFITS
(a)(2) SPECIFICATION OF ALL MEDICALLY APPROPRIATE TREATMENTS
(a) **MEDICALLY APPROPRIATE TREATMENTS** -- The uniform set of effective benefits submitted under paragraph (1) shall include such categories of health care services that the Commission determines will provide for the delivery of medically appropriate treatment by the AHP.

(D) ADDITIONAL COVERAGE - Nothing in this paragraph shall be construed as preventing a plan from providing coverage of treatment that has not been determined (under subsection (b)) by the Commission to be medically appropriate for the purposes of this paragraph.

(b) **CRITERIA FOR DETERMINATION OF MEDICALLY APPROPRIATENESS FOR BENEFIT COVERAGE**
(1) IN GENERAL - An AHP is required to provide for coverage of the uniform set of effective benefits only for treatments and diagnostic procedures that are medically appropriate... a treatment (as defined in paragraph (6) (A) or diagnostic procedure is considered to be "medically appropriate" if the following criteria are met (as interpreted by the Commission):

(A) TREATMENT OR DIAGNOSIS OF MEDICAL CONDITION

(I) IN GENERAL - The treatment or diagnostic procedure is for a medical condition.

(ii) MEDICAL CONDITION DEFINED - The Term "medical condition" means a disease, illness, injury, or biological or psychological condition or status for which treatment is indicated to improve, maintain, or stabilize a health outcome (as defined in paragraph (6) (B)), or which, in the absence of treatment could lead to an adverse change in health outcome.

(iii) ADVERSE CHANGE IN HEALTH OUTCOME DEFINED - In clause (ii), an adverse change in a health outcome occurs if there is a biological or psychological decremental change in a health status or if the original endowment for a feature lies outside the normal range.

(B) NOT INVESTIGATIONAL - There must be sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcome resulting from the treatment or diagnostic procedure compared with the best available alternative (or with no treatment or diagnostic procedure if no alternative treatment or procedure is available).

(C) EFFECTIVE AND SAFE - The evidence must demonstrate that the treatment or diagnostic procedure can reasonably be expected to produce the intended health result or provide intended health information and is safe and the treatment or diagnostic procedure provides a clinically meaningful benefit with respect to safety and effectiveness in comparison to other available alternatives.

(2) TREATMENT OR DIAGNOSTIC PROCEDURE CONSISTENT WITH PRACTICE GUIDELINES - A treatment or diagnostic procedure that is provided consistent with a practice guideline established under Section 1309 (or its predecessor) is deemed to be medically appropriate.

2. CHAFEE/THOMAS - S.1770

Sec. 1301 - OFFERING OF BENEFIT PACKAGES

(b) Covered Items and Services - Subject to the procedures for clarification and modification described in Part II, covered items and services consist of the following items and services, but only when the provision of the item or service is **medically necessary or appropriate.**

(d) CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY AND APPROPRIATENESS

SAME AS COOPER/BREAUX except for the introduction of the phrase "medically necessary or appropriate."

(1) IN GENERAL - A qualified health plan shall provide for coverage of the items and services described in subsection 9(b) only for treatments and diagnostic procedures that are medically necessary or appropriate. In the case of a dispute concerning a determination of medical necessity or appropriateness and subject to the succeeding provisions of this subsection, for purposes of this title, a treatment, (as defined in subparagraph (6)(A) or diagnostic procedure shall be considered to be medically necessary or appropriate if the following criteria are met

PART II - BENEFITS COMMISSION

Allows the Commission to develop and submit to Congress the clarification of covered items and services under Section 1301(b) - the Commission may propose to eliminate a category of items or services, but may <u>not</u> specify particular treatments or procedures to be covered.

Chafee version also introduces section (f) "Freedom to Offer Benefits " - Nothing in this section shall be construed to prohibit a health plan that is not a qualified health plan from offering any health care benefits.

3. ALTERNATIVE PROPOSALS IN WHICH THE TERMS ARE DEFINED:

A. MAINSTREAM COALITION (SENATE FINANCE) (6/27/94):

E4 - BENEFIT PACKAGES - MEDICALLY NECESSARY OR APPROPRIATE

"A Qualified Health Plan shall provide for coverage of the categories of benefits described in this section for treatment and diagnostic procedures that are **medically necessary or appropriate.**

An item or service is **"medically necessary or appropriate"** if, consistent with prevailing medical standards, it is:

a. For treatment of a medical condition;
b. Safe and effective (i.e., there is sufficient evidence to demonstrate that the item can reasonably be expected to produce the intended health outcome or provide the intended information).
c. Medically appropriate for a specific patient (i.e., it can reasonably be expected to provide a clinically meaningful benefit if furnished in a setting commensurate with the patient's needs).

Criteria for determination of medically necessary or appropriateness are set forth. QHPs shall make all coverage decisions under these criteria. The Commission can, in limited circumstances, issue interim coverage recommendations.

B. THE MAINSTREAM PROPOSAL (8/22/94)

SUBTITLE C - BENEFITS AND COST SHARING
PART 1 -STANDARD BENEFITS PACKAGES - SEC. 2202 - Description of Categories of Covered Benefits
(b) MEDICAL NECESSITY OR APPROPRIATENESS

(1) IN GENERAL - Health care interventions (as defined in subsection (d) in the categories described in subsection (a)) shall be covered by a benefits package when medically necessary or appropriate. A standard health plan may, but is not required to, exclude health care interventions that are not medically necessary or appropriate.

(2) CRITERIA FOR DETERMINATIONS - In making a determination of medical necessity or appropriateness, a standard health plan must apply the following criteria:

(A) MEDICAL CONDITION

(i) IN GENERAL - The health care intervention shall be for a medical condition.

(ii) MEDICAL CONDITION DEFINED - The term "medical condition" means a disease, illness, injury, genetic defect, or biological or psychological condition or status for which health care intervention is indicated to improve, maintain, restore, or stabilize a health outcome (as defined in subsection (d) or which, in the absence of such intervention, could lead to an adverse change in health outcome.

(iii) ADVERSE CHANGE IN HEALTH OUTCOME DEFINED - In subclause (i), an adverse change in health outcome occurs if there is a biological or psychological decremental change in a health status.

(B) SAFETY AND EFFECTIVENESS --

(i) IN GENERAL - The health care intervention shall be safe and effective.

(ii) WHEN SAFE AND EFFECTIVE - A health care intervention is safe and effective if there is sufficient evidence to demonstrate that such health care intervention can reasonably be expected to produce the intended health outcome and if the expected benefit of the health care intervention outweighs any potential harm.

(C) INDICATED FOR SPECIFIC ENROLLEE -

(i) IN GENERAL - The health care intervention shall be indicated for the specific enrollee.

(ii) WHEN INDICATED - A health care intervention is indicated for a specific enrollee if, with respect to that enrollee's medical condition, and in consideration with other available options, the health care intervention is appropriate and can reasonably be expected to provide a clinically meaningful benefit.

3. BASIS FOR DETERMINATIONS -

(A) IN GENERAL - In determining whether a health care intervention is medically necessary or appropriate, a standard health plan shall consider --

(i) presumptions established by subparagraphs (B) through (E) of this paragraph;

(ii) published peer-reviewed medical literature;

(iii) opinions of medical specialty groups;

(iv) evidence of general acceptance in the medical community; and

(v) recommendation of the Board pursuant to this section.

(B) FDA-APPROVED DRUGS AND BIOLOGICS - A drug or biologic which is approved for marketing by the Food and Drug Administration is deemed to be safe and effective if such drug or biologic is furnished for treatment of a medically accepted indication (as defined in section 1927(k)(6) of the Social Security Act).

(C) FDA-APPROVED DEVICES - a medical device that has been cleared for marketing by the Food and Drug Administration is deemed safe and effective when used for the conditions, purposes, or uses prescribed, recommended, or suggested in the labeling of the device.

(D) PRACTICE GUIDELINES - A health care intervention furnished to an enrollee consistent with practice guidelines developed or certified by the Agency for Health Care Policy and Research under Section 912 of the Public Health Service Act is deemed to be safe and effective, but the omission of an item or procedure from a practice guidelines does not give rise to a presumption that an item or procedure is not safe and effective.

(d) DEFINITIONS - For purposes of this subtitle:

(1) HEALTH CARE INTERVENTION - The term "health care intervention" means any item or service provided, with respect to a specific indication, to diagnose, improve, maintain, restore, or stabilize a health outcome or to prevent or mitigate an adverse change in a health outcome.

(2) HEALTH OUTCOME - The term "health outcome" means an outcome that affects the length or quality of an enrollee's life. Improved quality of life includes ability to perform activities of daily living, ability to work, relief from discomfort or pain, alleviation of fatigue, and improved cognitive, social, or emotional functioning and wellbeing.

(3) HEALTH PROFESSIONAL SERVICES - ...professional services that are lawfully provided by a physician or another health professional who is legally authorized to provide such services in the State in which the services are provided.

(4) QUALIFIED INVESTIGATIONAL TREATMENT - ...an investigational treatment that is part of a peer-reviewed and approved research program (as defined by the Secretary) or research trials approved by the Secretary. A research trial is deemed to be approved for purposes of this paragraph if such trial is approved by one or more of the following: The NIH, the FDA..., the Department of Veterans Affairs, the Department of Defense, or by a qualified nongovernmental research entity as defined in guidelines issued by one or more of the NIH, including guidelines for cancer centers...

C. THE CHAIRMAN'S MARK OF THE SENATE FINANCE COMMITTEE (6/29/94)

IV. BENEFITS AND THE NATIONAL HEALTH BENEFITS BOARD

B. "Health plans would be required to offer a standardized set of covered services. Categories of covered services would be specified in statute. A National Health Benefits Board would be directed to refine covered services by reference to standards of medical necessity or appropriateness. **Medically necessary or appropriate treatments** would be defined by law as those intended to maintain or improve the biological or psychological condition of the enrollee or to prevent or mitigate an adverse health outcome to the enrollee."

AS AMENDED 7/3/94: "Qualified health plans would provide coverage for categories of services that are medically necessary or appropriate for the enrollee. Criteria for determination of medically necessary or appropriate treatments would be set forth (by the National Health Benefits Board)." (Term now used but not defined)

16. Investigational treatments, including routine care provided in research trials by the Secretary of HHS, the Directors of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity as defined in guidelines of the NIH, including guidelines for National Cancer Institute-designated cancer center support grants; or a peer-reviewed and approved research program as defined by the Secretary of HHS.

B. PROPOSED LEGISLATION IN WHICH THE TERMS WERE USED BUT NOT DEFINED

1. CLINTON - S.1757

PART 4 - EXCLUSIONS

Sec. 1141 - EXCLUSIONS

(A) MEDICAL NECESSITY - The comprehensive benefit package does not include -

(1) an item or services that is **not medically necessary or appropriate; or**

(2) an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under Section 1154.

2. CHAIRMAN OF SENATE LABOR AND HUMAN RESOURCES COMMITTEE EDWARD KENNEDY'S MARK
(Same as Clinton language)
Part 4 - EXCLUSIONS
Section 1141. EXCLUSIONS
(a) MEDICAL NECESSITY - The comprehensive benefit package does not include -
(1) an item or services that is **not medically necessary or appropriate**; or
(2) an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under Section 1154.

3. NICKLES - S.1743
Sec. 112. Family Security Benefits Package
(a) IN GENERAL - The requirements of this section are met, if the health insurance plan --
(1) provides coverage for **all medically necessary acute medical care** described in subsection (b),
(2) does not exclude coverage for selected illnesses or selected treatments if consistent with medically accepted practices, and
(3) meets the patient cost sharing requirements of subsection (c).

Nickles specifically excludes abortion services.

4. MCDERMOTT - H.R. 1200
Sec. 201 - COMPREHENSIVE BENEFITS
(a) IN GENERAL - subject to the succeeding provisions of this title, individuals enrolled for benefits under this Act are entitled to have payment made under a State health security program for the following items and services **if medically necessary and appropriate** for the maintenance of health or for the diagnosis, treatment or rehabilitation of a health condition.

5. ROWLAND - H.R. 3955
(3) EXCEPTIONS - Paragraph (1) shall not be construed as requiring a plan to include payment for--
(A) items and services that are **not essential and medically necessary;**
(B) routine physical examinations or preventive care (other than care and services described in subparagraph (D) of paragraph (1); or
(C) experimental services and procedures.

6. MICHEL- H.R. 3080

SEC. 1102 - PLAN DEFINED

(a)(1)(B) the plan includes **only essential and medically necessary services,** including medical, surgical, hospital, and preventive services; except that no specific procedure or treatment, or classes thereof, is required to be covered in such a plan, by this act or through regulations.

7. SENATORS DOLE AND PACKWOOD S.2374 (8/9/94)

SUBTITLE B - STANDARDS FOR REFORM

PART II - INSURANCE REFORM STANDARDS APPLICABLE TO HEALTH PLANS

Sec. 21115- BENEFITS OFFERED (related to FEDMED benefits package)

(3) Medical Necessity or Appropriateness

(A) DETERMINATIONS BY HEALTH PLANS

(i) IN GENERAL - The determination of medical necessity or appropriateness of specific treatments or procedures shall be made by individual health plans with reference to criteria established under subparagraph (B).

(ii) NEW PROCEDURES AND TECHNOLOGIES - Health plans may make coverage decisions regarding new procedures and technologies with reference to the criteria established by the Secretary under subparagraph (B).

(B) CRITERIA ESTABLISHED - The Secretary shall establish general criteria for determining whether an item or service specified by the Secretary under paragraph (2)(B) is medically necessary or appropriate.

III. TREATMENT OF MEDICAL NECESSITY IN PRIVATE PLANS (Five examples)

1. **"Medically necessary"** means services or supplies, provided by a Provider Facility or Provider Individual, which are required for treatment of illness, injury, diseased condition, or impairment, (one plan includes **"pregnancy related condition"** in this list) and are:

a. consistent with the patient's diagnosis or symptoms, and
b. appropriate treatment according to generally accepted standards of medical practice, and
c. not provided only as a convenience to the patient or Provider, and
d. not investigational or unproven, and
e. not excessive in scope, duration, or intensity to provide safe, adequate, and appropriate treatment to the insured. Any service or supply provided at a Provider Facility will not be considered Medically Necessary if the Insured's symptoms or condition indicate that it would be safe to provide the service or supply in a less comprehensive setting.

2. "**Medically Necessary**" means services or supplies (the Plan) determines to be:

a. appropriate and necessary for the symptoms, diagnosis or treatment of a medical condition, and
b. provided for the diagnosis or direct care and treatment of the medical condition, and
c. within standards of good medical practice within the organized medical community, and
d. not primarily for the convenience of the patient, the patient's physician or another provider, and
e. the most appropriate supply or level of service which can safely be provided.

3. "**Medically Necessary**" means that, according to generally accepted medical practice, the service or supply must be:

a. consistent with and appropriate for the treatment of the member's symptoms, illness, or injury;
b. **of proven value or usefulness;**
c. the most appropriate and cost effective level of service or supply which can safely be provided to the member as determined by the plan.
d. not primarily for the convenience of the member, his or her family, or the provider.

4. **"Medically Necessary"** means that a procedure, service or supply is <u>all</u> of the following:

a. appropriate and necessary for the diagnosis and treatment of your illness or injury;
b. consistent with professionally recognized standards of health care determined within the State and given at the right time and in the right setting.
c. **not more costly than alternative services that would be effective for the diagnosis and treatment of your condition.**
d. enables a patient to make reasonable progress in treatment.

5. A service is considered **"medically necessary"** if it is:

a. appropriate and consistent with the diagnosis and **could not have been omitted without adversely affecting the patient' condition or the quality of medical care rendered;**
b. compatible with the standards of accepted medical practice in the United States;
c. provided not solely for your convenience or the convenience of the doctor or hospital;
d. not primarily **custodial care; and**
e. the **least costly** level of service that can be safely provided.

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Fax Transmittal

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Message/ Instructions: Attached is a "washed", more moderate version of the memo I gave you plus an updated spreadsheet that includes Dole, Mojiba + Reimp.

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June 30, 1994

TO: Lisa Simpson, HHS
Jennifer Klein, The White House

FROM: Linda Bergthold

RE: Information on Medical Necessity/appropriateness

I am attaching a short memo/paper that I have sent to Sheila Burke, Karen Hein, John Ratner, and other staff on the Senate Finance Committee. I updated my draft spreadsheet of existing language to include the "Mainstream" proposal, Dole's proposal and the Moynihan mark.

I think there is an emerging middle ground for no definitions in statute, coming from both Moynihan's staff (who have proposed a very spare definition but would probably give it up if a NHB could define it) and Dole's proposal. Only Durenberger and the "mainstream" group still seem to want the terms defined and now they have a worse definition than before. Someone suggested to me that a vague definition such as the"mainstream" proposal would most definitely benefit companies like 3M (--hmm--now where is that located? Minnesota?) which produce and sell medical products. That may help explain Susan Foote's dedication to defining these terms.

ISSUES IN DEFINING MEDICAL NECESSITY OR APPROPRIATENESS

At the core of all clinical decision-making is the determination of what is the appropriate treatment for any given patient's condition. These decisions are generally made by physicians, sometimes in consultation with patients, and occasionally overruled by health plan administrators. What is medically necessary or appropriate? Who should decide what is necessary? Who should arbitrate if there is conflict among the parties to the decision? Should federal legislation specify these definitions or leave them to health plans?

There are dozens of definitions of medical necessity being applied by health plans and several definitions circulating in proposed legislation (see Attachment A). Medicare has one of the most illness and injury oriented definitions; Medicaid has different definitions in every state, some of which are surprisingly innovative (e.g. South Dakota); private plans, including HMOs, rarely publish their definitions for consumers or policymakers. Lawsuits tend to be the mechanism for bringing these definitions into the public domain.

All existing definitions of medical necessity have some elements in common: they rely on the judgment of medical practitioners and "prevailing standards" of care; they tend to focus on curing illness rather than maintaining health; they leave final interpretation up to the administrators of the health plans. Patients and physicians are often left out of the decision making process.

In attempting to craft consensus legislation, you need to ask and answer the following questions:

1. Should any terms be specified in statute? Why or why not?

The status quo is that most programs (i.e. Medicare, Medicaid, HMO Act, state level legislative language) identify (but do not define) terminology by which treatment coverage can be defined.

Most plan administrators believe that unless there is some benchmark by which health plans can define appropriate treatments for individual patients, there will be hopeless confusion and unacceptable variation

among plans as to what is covered and what is not. Some terminology should be mentioned in legislation to prevent chaos in the marketplace and in the courts.

2. If terms are used, what should they be?

The most common term currently used is "medically necessary." As Attachment A reveals, the Medicare definition is illness and injury oriented. Nevertheless, this definition has been the basis of a number of court cases and a certain amount of case law has been developed around this definition. Some would argue that we should stick with a known definition of "medical necessity"; to do otherwise would throw the legal system into chaos. Others would argue that the system will be thrown into chaos anyway, as new rules for health plans are embedded in national legislation. A completely new term, such as "medically appropriate," might avoid the lawsuits and arguments surrounding the old language.

The fact that each state defines "medical necessity" for Medicaid in a different way, would argue for a broad federal framework with somewhat less state discretion than Medicaid. As demonstrated in the examples in Attachment A, Minnesota does not consider cost in its coverage determinations; South Dakota does.

To broaden the application of the term, some experts have introduced new terminology, "medically appropriate". This terminology, however, has not been tested in the courts and no consensus definition exists. Because no consensus definition exists, it should NOT be defined in statute at this time. If used in the health reform legislation, some definable entity should be made responsible for developing criteria for this new terminology within a given period of time.

3. Should these terms be defined in statute or left to other entities? If so, what entities should define them?

There is some consensus in the benefits, insurance and managed care community that the definition of these terms should <u>not</u> be put in statute but given to a benefits board or commission or to the Secretary of HHS.

The only interests that would profit by a vaguely worded definition of terms in statute are companies that produce medical products or discover new treatments that they want instantly or easily covered. Some physicians may support a vague definition because it offers them greater latitude in prescribing and treating patterns within their health plans. Most physicians, however, and most health plan administrators would like some responsible guidance from experts on how to apply these terms.

There are only two basic approaches to the definition of medical necessity in proposed legislation: 1) the term(s) are proposed but not defined (e.g. Clinton, Kennedy mark, McDermott/Wellstone, Stark, Nickles, Dole Alternative proposal); or 2) the term is defined but changed to "medically appropriate" (e.g. Cooper/Breaux) or "medically necessary or appropriate" (e.g. Chafee).

Most of the currently proposed definitions spring from the Jackson Hole definitions described originally by Dr. David Eddy. Dr. Eddy's definition, as outlined in Cooper/Breaux ("medically appropriate") and Chafee ("medically necessary or appropriate") has been repudiated by Eddy for a number of reasons : without any way to bring cost considerations into the determinations of medical necessity, Eddy believes that any other definition would cause more harm than good. Furthermore, Eddy objects to the use of "safe and effective" (since as he points out, most medical interventions would not pass the test), "prevailing standards" (since that would return us to the lowest common denominator of medical standards), and he points out that joining the terms "necessary" and "appropriate" with the conjunction "and, " absent any definition of "appropriate", would open health plans to a variety of interpretations, most of which would drive costs upward. Eddy concludes that unless his complete definition of "medically appropriate" is adopted, it would be better policy if no definition were defined in legislation, leaving the issue to a National Health Board of experts.

4. What would a consensus solution look like?

Because this issue is so complex and has a myriad of unintended consequences for the delivery of health care, the following recommendations seem practical. Final health care reform legislation

should include the following:

1.) Reference to a term such as "medically appropriate" in statute, by which plans can make decisions about the coverage of specific treatments;

2.) A definition of this term, with criteria by which it can be applied, by a National Health Board, benefits commission, or the Secretary of HHS;

3.) Implementation and interpretation of this term left to individual health plans;

4.) A process for resolving disputes about coverage at the health plan level that includes patients.

DEFINITIONS OF MEDICAL NECESSITY IN EXISTING AND PROPOSED LEGISLATION

MEDICARE

Section 1862(2)(1)(A) of the Social Security Act: Prohibits Medicare payment for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." The act specifically excludes certain services from coverage (e.g. cosmetic surgery and routine dental care), but it does not provide a comprehensive list of services and equipment that are either covered or excluded. The Act gives the Secretary of Health and Human Services the discretionary authority to identify medical services that are not medically reasonable and necessary for the treatment of illness or injury. (42 U.S.C. § 1395y(a)(1) (1988).

MEDICAID

The Medicaid statute has been construed similarly to require states to cover all "medically necessary services."

Examples of state definitions of medically necessary:

Florida: Covered outpatient services must be medically necessary preventive, diagnostic, therapeutic or palliative services (Fla Admin. Code Ann. r. 10C-7.040(1992)). Requested service must be reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that threaten life, cause suffering or pain, result in illness or infirmity, or threaten to cause or aggravate a handicap, physical deformity, or malfunction, and there is no equally effective, more conservative or less costly course of treatment available.

Minnesota: Covered services must "(A) be determined by prevailing community standards or customary practice and usage to: (1) be medically necessary; (2) be appropriate and effective for the

medical needs of the recipient; (3) meet quality and timeliness standards; (4) be the most cost effective health service available for the medical needs of the recipient; (B) represent an effective and appropriate use of medical assistance funds." (Minn. R. 9505.0210)

South Dakota: To be medically necessary, the covered service must meet the following conditions: (1) It is consistent with the recipient's symptoms, diagnosis, condition, or injury; (2) It is recognized as the prevailing standard and is consistent with generally accepted professional medical standards of the provider's peer group; (3) It is provided in response to a life-threatening condition; to treat pain, injury, illness or infection; to treat a condition that could result in physical ormental disability; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; (4) It is not furnished primarily for the convenience of the recipient or the provider; and (5) There is no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly. (S.D. Admin. R. 67: 16:01:06.02)

FEHBP "PROTOTYPE" DEFINITION OF MEDICAL NECESSITY

Plans can negotiate a different definition.

Medical necessity means that services, supplies, or equipment provided by a hospital or provider of health care services associated with a particular plan:

1. are appropriate to the diagnosis or treatment of a patient's condition, illness or injury;

2. are consistent with the standards of good medical practice in the United States;

3. are not primarily for the personal comfort or convenience of the patient, family, or provider;

4. are not a part of or associated with scholastic education or vocational training of the patient;

5. in the case of inpatient care, cannot be provided safely on an outpatient basis.

The fact that a covered provider has prescribed, recommended or approved a service, supply, or equipment, does not, in itself, make it medically necessary.

TREATMENT OF MEDICAL NECESSITY IN PROPOSED LEGISLATION

I. LEGISLATION IN WHICH MEDICAL NECESSITY IS DEFINED SPECIFICALLY:

A. COOPER/BREAUX HR 3222

Sec.1302 SPECIFICATION OF UNIFORM SET OF EFFECTIVE BENEFITS
(a)(2) SPECIFICATION OF ALL MEDICALLY APPROPRIATE TREATMENTS
(a) MEDICALLY APPROPRIATE TREATMENTS -- The uniform set of effective benefits submitted under paragraph (1) shall include such categories of health care services that the Commission determines will provide for the delivery of medically appropriate treatment by the AHP.
(D) ADDITIONAL COVERAGE - Nothing in this paragraph shall be construed as preventing a plan from providing coverage of treatment that has not been determined (under subsection (b)) by the Commission to be medically appropriate for the purposes of this paragraph.

(b) **CRITERIA FOR DETERMINATION OF MEDICALLY APPROPRIATENESS FOR BENEFIT COVERAGE**

(1) IN GENERAL - An AHP is required to provide for coverage of the uniform set of effective benefits only for treatments and diagnostic procedures that are medically appropriate... a treatment (as defined in paragraph (6) (A) or diagnostic procedure is considered to be "medically appropriate" if the following criteria are met (as interpreted by the Commission):

(A) TREATMENT OR DIAGNOSIS OF MEDICAL CONDITION

(I) IN GENERAL - The treatment or diagnostic procedure is for a medical condition.

(ii) MEDICAL CONDITION DEFINED - The Term "Medical condition" means a disease, illness, injury, or biological or psychological condition or status for which treatment is indicated to improve, maintain, or stabilize a health outcome (as defined in paragraph (6) (B), or which, in the absense of treatment could lead to an adverse change in health outcome.

(iii) ADVERSE CHANGE IN HEALTH OUTCOME DEFINED - In clause (ii), an adverse change in a health outcome occurs if there is a biological or psychological decremental change in a health status or if the original endowment for a feature lies outside the normal range.

(B) NOT INVESTIGATIONAL - There must be sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcome resulting from the treatment or diagnostic procedure compared with the best available alternative (or with no treatment or diagnostic procedure if no alternative treatment or procedure is available).

(C) EFFECTIVE AND SAFE - The evidence must demonstrate that the treatment or diagnostic procedure can reasonably be expected to produce the intended health result or provide intended health information and is safe and the treatment or diagnostic procedure provides a clinically meaningful benefit with respect to safety and effectiveness in comparison to other available alternatives.

(2) TREATMENT OR DIAGNOSTIC PROCEDURE CONSISTENT WITH PRACTICE GUIDELINES - A treatment or diagnostic procedure that is provided consistent with a practice guideline established under Section 1309 (or its predecessor) is deemed to be medically appropriate.

B. CHAFEE/THOMAS - S.1770

SEC. 1301 - OFFERING OF BENEFIT PACKAGES

(b) Covered Items and Services - Subject to the procedures for clarification and modification described in Part II, covered items and services consist of the following items and services, but only when the provision of the item or service is **medically necessary or appropriate.**

(d) CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY AND APPROPRIATENESS

SAME AS COOPER/BREAUX except for the introduction of the phrase "medically necessary or appropriate."

(1) IN GENERAL - A qualified health plan shall provide for coverage of the items and services described in subsection 9b) only for treatments and diagnostic procedures that are medically necessary or appropriate. In the case of dispute concerning a determination of medical necessity or appropriateness and subject to the succeeding provisions of this subsection, for purposes of this title, a treatment, (as defined in subparagraph (6)(A) or diagnostic procedure shall be considered to be medically necessary or appropriate if the following criteria are met

PART II - BENEFITS COMMISSION

Allows the Commission to develop and submit to Congress the clarificaiton of covered items and services under Section 1301(b) - the Commission may propose to eliminte a category of items or services, but may not specify particular treatments or procedures to be covered.

Chafee version also introduces section (f) "Freedom to Offer Benefits " - Nothing in this section shall be construed to prohibit a health plan that is not a qualified health plan from offering any health care benefits.

C. ALTERNATIVE PROPOSALS IN WHICH THE TERMS ARE DEFINED:

1. MAINSTREAM COALITION (SENATE FINANCE) (6/27/94):

E. 4 BENEFIT PACKAGES -MEDICALLY NECESSARY OR APPROPRIATE

"A Qualified Health Plan shall provide for coverage of the categories of benefits describedin this section for treatment and diagnostic procedures that are **medically necessary or appropriate.**

An item or service is **"medically necessary or appropriate"** if, consistent with prevailing medical standards, it is:

a. For treatment of a medical condition;

b. Safe and effective (i.e., there is sufficient evidence to demonstrate that the item can reasonably be expected to produce the intended health outcome or provide the intended information).

c. Medically appropriate for a specific patient (i.e., it can reasonably be expected to provide a clinically meaningful benefit if furnished in a setting commensurate with the patient's needs).

Criteria for determination of medically necessary or appropriate are set forth. QHPs shall make all coverage decisions under these criteria. The Commission can, in limited circumstances, issue interim coverage recommendations.

2. THE CHAIRMAN'S MARK OF THE SENATE FINANCE COMMITTEE (6/29/94)

IV. BENEFITS AND THE NATIONAL HEALTH BENEFITS BOARD

B. "Health plans would be required to offer a standardized set of covered services. Categories of covered services would be specified in statute. A National Health Benefits Board would be directed to

refine covered services by reference to standards of medical necessity or appropriateness. **Medically necessary or appropriate treatments** would be defined by law as those intended to maintain or improve the biological or psychological condition of the enrollee or to prevent or mitigate an adverse health outcome to the enrollee. "

16. Investigational treatments, including routine care provided in research trials by the Secretary of HHS, the Directors of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity as defined in guidelines of the NIH, including guidelines for National Cancer Institute-designated cancer center support grants; or a peer-reviewed and approved research program as defined by the Secretary of HHS.

II. LEGISLATION IN WHICH THE TERMS ARE USED BUT NOT DEFINED

A. CLINTON - S.1757
PART 4 - EXCLUSIONS
Sec. 1141 - EXCLUSIONS
(A) MEDICAL NECESSITY - The comprehensive benefit package does not include -
(1) an item or services that is not **medically necessary or appropriate**; or
(2) an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under Section 1154.

B. CHAIRMAN OF SENATE LABOR AND HUMAN RESOURCES COMMITTEE EDWARD KENNEDY'S MARK
(Same as Clinton language)
Part 4 - EXCLUSIONS
Section 1141. EXCLUSIONS

(a) MEDICAL NECESSITY - The comprehensive benefit package does not include -

(1) an item or services that is **not medically necessary or appropriate**; or

(2) an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under Section 1154.

C. NICKLES - S.1743

Sec. 112. Family Security Benefits Package

(a) IN GENERAL - The requirements of this section are met, if the health insurance plan --

(1) provides coverage for **all medically necessary acute medical care** described in subsection (b),

(2) *does not exclude coverage for selected illnesses or selected treatments if* consistent with medically accepted practices, and

(3) meets the patient cost sharing requirements of subsection (c).

Nickles specifically excludes abortion services.

D. MCDERMOTT - H.R. 1200

Sec. 201 - COMPREHENSIVE BENEFITS

(a) IN GENERAL - subject to the succeeding provisions of this title, individuals enrolled for benefits under this Act are entitled to have payment made under a State health security program for the following items and services **if medically necessary and appropriate** for the maintenance of health or for the diagnosis, treatment or rehabilitation of a health condition.

E. ROWLAND - H.R. 3955

(3) EXCEPTIONS - Paragraph (1) shall not be construed as requiring a plan to include payment for--

(A) items and services that are **not essential and medically necessary;**

(B) routine physical examinations or preventive care (other than care and services described in subparagraph (D) of paragraph (I); or

(C) experimental services and procedures.

F. MICHEL- H.R. 3080

SEC. 1102 - MEDACCESS PLAN DEFINED

(a)(1)(B) the plan includes **only essential and medically necessary services**, including medical, surgical, hospital, and preventive services; except that no specific procedure or treatment, or classes thereof, is required to be covered in such a plan, by this act or through regulations.

G. KASSEBAUM AMENDMENT INTRODUCED IN SENATE LABOR AND HUMAN RESOURCES AND DEFEATED (proposed Durenberger amendment is very similar)

The amendment is the same language as in Chafee and Cooper/Breaux. The terms "medically necessary or appropriate" are used in the body of the amendment; the title of the amendment uses "and" (CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY AND APPROPRIATENESS)

Kassebaum also uses term "community rated health plan" instead of "qualified" health plan as in Chafee.

H. SENATOR DOLE'S ALTERNATIVE HEALTH REFORM PROPOSAL (6/29/94)

C.3.g. (relating to subsidized coverage): Coverage decisions about new procedures and technologies are made by health plans, using criteria for **medical appropriateness** developed by the Secretary.

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to: Jennifer Klein

fax #: 456-2878

from: Lisa Simpson

date:

re:

pages: , including this cover sheet

NOTES:

TO: JUDY FEDER
NAN HUNTER
JENNIFER KLEIN
PHIL LEE
BOB VALDEZ

~~CONFIDENTIAL~~

NOTE RE: ATTACHMENT

Attached are three versions of possible approaches to medical necessity in legislation. These versions incorporate comments made on earlier drafts by Bob Valdez, Jennifer Klein, Phil Lee, and Jeff Clair.

In each of the versions, I have noted remaining questions I have in italics. In addition there are some broad comments/questions on each approach.

I have also attached a copy of the Senate Finance Chairman's Mark definition of medical necessity.

I am hoping to get a next version of these done by Friday, July 8.

~~CONFIDENTIAL~~

Option 1 - Defining the Role of the National Health Board

This approach is the closest to the HSA and simply provides the Board guidance as to the process to follow in addressing medical necessity. Hence, no dimensions of care, etc... are incorporated. This is intended to be extremely broad.

- Should the charge to the Board include explicit authority over investigational treatment decisions or the passage of treatments from investigational/experimental to medically necessary or appropriate?

- Should there be an appeals process at the Board level - i.e. if the Board were to decide that a service was not medically necessary or appropriate, what rights of appeals would plans, manufacturers, or providers have?

- Should States have a role in these determinations? Given that States are responsible for assuring access to the comprehensive benefit package and certifying plans based on this, should they have authorities in this area? [Especially in light of the fact that some States, e.g. California, are moving ahead on these issues].

Option 2 - Defining in statute the parameters of medical necessity

This version incorporates portions of Durenberger/Eddy/Bergthold approaches to the issue. Where possible, the HSA language has been used and the broadest possible terms definitions to address concerns that many accepted practices would be excluded if "evidence" of effectiveness were needed. This also assures that prevention, palliation, functioning, and other less "medical model" dimensions of health care are incorporated.

Option 3 - Further definition, including more Durenberger language

This version simply incorporates the "presumptions section" of the Durenberger amendment, in case more compromise is desired. However, a number of persons have pointed out problems with this section.

OPTION 1 - MEDICAL NECESSITY OR APPROPRIATENESS

Section 1154. ESTABLISHMENT OF STANDARDS REGARDING MEDICAL NECESSITY.

(a) MEDICAL NECESSITY OR APPROPRIATENESS.-

(1) IN GENERAL. - The comprehensive benefit package shall provide coverage for health care items, services, or interventions that are medically necessary or appropriate.

(2) THE ROLE OF THE NATIONAL HEALTH BOARD. -

(A) IN GENERAL - The National Health Board shall promulgate such regulations or establish such guidelines as may be necessary to ensure uniformity of application of the benefits package across all health plans and to carry out section 1141(a)(2) (relating to the exclusion of certain services which are not medically necessary or appropriate).

(B) CRITERIA FOR ESTABLISHMENT OF STANDARDS - In establishing standards for medical appropriateness, the National Health Board:

(i) may consult with health plans, health professionals, consumers or their representatives, and experts in the fields of medical care, health services research, quality and outcomes research, biomedical and behavioral research, ethics, and benefits management;

or could delete list of experts completely.

(ii) shall address at least the following:

(I) the role of the health plan in decisions of medical necessity or appropriateness;
(II) the role of health care providers in decisions of medical necessity or appropriateness; and
(III) the role of the enrollee in decisions of medical necessity or appropriateness to ensure that there is enrollee participation and that enrollee preferences are taken into account.

OPTION 2 - MEDICAL NECCESITY OR APPROPRIATENESS

Section 1154. ESTABLISHMENT OF STANDARDS REGARDING MEDICAL NECESSITY

(a) MEDICAL NECESSITY OR APPROPRIATENESS.-

(1) IN GENERAL. - The comprehensive benefit package shall provide coverage for health care items, services, or interventions that are medically necessary or appropriate.

(2) THE ROLE OF THE NATIONAL HEALTH BOARD. -

(A) IN GENERAL - The National Health Board shall promulgate such regulations or establish such guidelines as may be necessary to ensure uniformity of application of the benefits package across all health plans and to carry out section 1141(a)(2) (relating to the exclusion of certain services that are not medically necessary or appropriate).

(i) CONSULTATION - The National Health Board may consult with health plans, health professionals, consumers or their representatives, and experts in the fields of medical care, health services research, quality and outcomes research, biomedical and behavioral research, ethics, and benefits management.

(B) COVERAGE DECISIONS. -

(i) IN GENERAL - Each health plan shall provide for coverage of all medically necessary or appropriate items and services in the comprehensive benefit package.

(ii) DETERMINATION - In general, health plans will determine medically appropriate any item or service which represents a health care intervention that:

(I) is covered in the comprehensive benefit package;
(II) is undertaken with respect to a specific indication as defined in section 1154(D)(i) and 1154(D)(ii); and
(II) is effective and beneficial.

(D) DEFINITIONS. -

(i) HEALTH INTERVENTION - A health intervention is any item or service undertaken for a specific indication to promote health and development; prevent disease, injury, or disability; diagnose, improve, maintain, restore or stabilize a health outcome; or maximize functioning.

these don't mesh.

(ii) INDICATION. - An indication designates any feature of the enrollee or delivery setting that could reasonably be expected to affect the health outcomes

of a health intervention. Any reference to a health intervention is assumed to apply to a specific indication for that item or service.

The use of "indication" comes from the Eddy language [attached] and functionally addresses the parameters outlined in the Bergthold/Valdez version. [also attached]

(iii) HEALTH OUTCOME. - A health outcome means a condition that affects the length or quality of an enrollee's life or maximize an enrollee's ability to achieve full developmental potential and functioning.

(I) QUALITY OF LIFE AND FUNCTIONING. - These include the ability to perform activities of daily living commensurate with the enrollee's age or developmental status; the ability to work or function in society appropriate to the enrollee's age or developmental status; the relief from discomfort or pain; the alleviation of fatigue, and the maximization of cognitive, behavioral, social, psychological or emotional functioning and well-being.

(iv) EFFECTIVE. - A health intervention is effective when in the judgment of the provider at the time the intervention is provided the benefits to the enrollee of the intervention outweigh its risks.

There is seemingly no limitation here.

These two definitions get us away from any reference to evidence which might limit the coverage of many treatments now used.

(v) BENEFICIAL. - A health intervention is beneficial when, in the judgment of the enrollee at the time the intervention is provided, the benefits of the intervention outweigh its risks; provided that emergency treatment administered to the enrollee shall be deemed to be beneficial.

(E) COVERAGE OF INVESTIGATIONAL TREATMENTS IN APPROVED RESEARCH TRIALS. -

I have revised this section to make it consistent with the Health Security Act. However I raise the question of what happens to investigational treatments that are not "qualifying" i.e. the patient is not in an approved research trial - then, is no care covered at all?

(i) IN GENERAL. - Coverage of the enrollee care costs (as defined in clause (iii)), associated with the delivery of qualifying investigational treatments (as defined in clause (ii)), are considered to be medically necessary or appropriate only if the treatment for the enrollee is part of an approved research trial (as defined in clause (iv)).

In general I have substituted "enrollee" everywhere for patient.

(ii) QUALIFYING INVESTIGATIONAL TREATMENT DEFINED. - In clause (i), the term "qualifying investigational treatment" means a health care intervention the effectiveness of which has not been determined and that is under clinical investigation as part of an approved research trial.

(iii) ENROLLEE CARE COSTS DEFINED. - In clause (i), the term "enrollee care costs" means the cost of health services required to provide treatment according to the design of the trial, except those costs normally paid for by other funding sources (as defined by the Secretary), such as the cost of the investigational drug, technology, or procedure, the costs of any nonhealth services that might be required for a person to receive the treatment, or the costs of managing the research. Items or services subject to this exception may be covered in addition to enrollee care at the discretion of the health plan.

I have included investigational technologies and procedures under the exceptions in this draft - the Durenberger language only leaves optional the coverage of investigational drugs.

iv) APPROVED RESEARCH TRIAL DEFINED. - In clause (i), the term "approved research trial" means a trial –

(I) conducted for the primary purpose of determining whether or not a health care intervention is safe, effective, or having any other characteristic of a health care intervention which must be demonstrated in order for the health care intervention to be medically necessary or appropriate; and

(II) approved by the Secretary of Health and Human Services.

A trial is deemed to be approved under subclause (II) if such trial is approved the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration (through an investigational new drug exemption), the Secretary of Veterans Affairs, the Secretary of Defense, or by a qualified non-governmental research entity (as defined in guidelines of the National Institutes of Health).

not included in this definition, and in HSA, are peer-reviewed and Secretary approved research programs.

Why leave out?

OPTION 3 - MEDICAL NECCESITY OR APPROPRIATENESS

Section 1154. ESTABLISHMENT OF STANDARDS REGARDING MEDICAL NECESSITY

(a) MEDICAL NECESSITY OR APPROPRIATENESS.-

(1) IN GENERAL. - The comprehensive benefit package shall provide coverage for health care items, services, or interventions that are medically necessary or appropriate.

(2) THE ROLE OF THE NATIONAL HEALTH BOARD. -

(A) IN GENERAL - The National Health Board shall promulgate such regulations or establish such guidelines as may be necessary to ensure uniformity of application of the benefits package across all health plans and to carry out section 1141(a)(2) (relating to the exclusion of certain services that are not medically necessary or appropriate).

(i) CONSULTATION - The National Health Board may consult with health plans, health professionals, consumers or their representatives, and experts in the fields of medical care, health services research, quality and outcomes research, biomedical and behavioral research, ethics, and benefits management.

(B) COVERAGE DECISIONS. -

(i) IN GENERAL - Each health plan shall provide for coverage of all medically necessary or appropriate items and services in the comprehensive benefit package.

(ii) DETERMINATION - In general, health plans will determine medically appropriate any item or service which represents a health care intervention that:

(I) is covered in the comprehensive benefit package;
(II) is undertaken with respect to a specific indication as defined in section 1154(D)(i) and 1154(D)(ii); and
(II) is effective and beneficial.

(iii) PRESUMPTIONS. -

(I) A drug or biologic which is approved for marketing by the Food and Drug Administration is deemed to be effective, beneficial, and not investigational if such drug or biologic is furnished for the treatment of a medically accepted indication (as defined in section 1122(a)(1)).

(II) A medical device that has been cleared for marketing by the Food and Drug Administration is deemed effective, beneficial, and not

investigational when used for the conditions prescribed, recommended, or suggested in the labeling of the device.

(III) An item or service furnished to an enrollee consistent with a practice guideline developed by the Agency for Health Care Policy and Research under section 912(a) of the Public Health Service Act or certified under section 912(g) of the Public Health Service Act is deemed effective, beneficial and not investigational, but the omission of an item or procedure from a practice guideline does not give rise to a presumption that an item or procedure is not effective, beneficial or investigational.

Jeff has brought up concerns with these presumptions - Jeff - please elaborate in writing.

(D) DEFINITIONS. -

(i) HEALTH INTERVENTION - A health intervention is any item or service undertaken for a specific indication to promote health and development; prevent disease, injury, or disability; diagnose, improve, maintain, restore or stabilize a health outcome; or maximize functioning.

(ii) INDICATION. - An indication designates any feature of the enrollee or delivery setting that could reasonably be expected to affect the health outcomes of a health intervention. Any reference to a health intervention is assumed to apply to a specific indication for that item or service.

The use of "indication" comes from the Eddy language [attached] and functionally addresses the parameters outlined in the Bergthold/Valdez version. [also attached]

(iii) HEALTH OUTCOME. - A health outcome means a condition that affects the length or quality of an enrollee's life or maximize an enrollee's ability to achieve full developmental potential and functioning.

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(iv) EFFECTIVE. - A health intervention is effective when in the judgment of the provider at the time the intervention is provided the benefits to the enrollee of the intervention outweigh its risks.

These two definitions get us away from any reference to evidence which might limit the coverage of many treatments now used.

(v) BENEFICIAL. - A health intervention is beneficial when, in the judgment of

the enrollee at the time the intervention is provided, the benefits of the intervention outweigh its risks; provided that emergency treatment administered to the enrollee shall be deemed to be beneficial.

(E) COVERAGE OF INVESTIGATIONAL TREATMENTS IN APPROVED RESEARCH TRIALS. -

I have revised this section to make it consistent with the Health Security Act. However I raise the question of what happens to investigational treatments that are not "qualifying" i.e. the patient is not in an approved research trial - then, is no care covered at all?

(i) IN GENERAL. - Coverage of the enrollee care costs (as defined in clause (iii)). associated with the delivery of qualifying investigational treatments (as defined in clause (ii)), are considered to be medically necessary or appropriate only if the treatment for the enrollee is part of an approved research trial (as defined in clause (iv)).

In general I have substituted "enrollee" everywhere for patient.

(ii) QUALIFYING INVESTIGATIONAL TREATMENT DEFINED. - In clause (i), the term "qualifying investigational treatment" means a health care intervention the effectiveness of which has not been determined and that is under clinical investigation as part of an approved research trial.

(iii) ENROLLEE CARE COSTS DEFINED. - In clause (i), the term "enrollee care costs" means the cost of health services required to provide treatment according to the design of the trial, except those costs normally paid for by other funding sources (as defined by the Secretary), such as the cost of the investigational drug, technology, or procedure, the costs of any nonhealth services that might be required for a person to receive the treatment, or the costs of managing the research. Items or services subject to this exception may be covered in addition to enrollee care at the discretion of the health plan.

I have included investigational technologies and procedures under the exceptions in this draft - the Durenberger language only leaves optional the coverage of investigational drugs.

iv) APPROVED RESEARCH TRIAL DEFINED. - In clause (i), the term "approved research trial" means a trial --

(I) conducted for the primary purpose of determining whether or not a health care intervention is safe, effective, or having any other characteristic of a health care intervention which must be demonstrated in order for the health care intervention to be medically necessary or appropriate; and

(II) approved by the Secretary of Health and Human Services.

A trial is deemed to be approved under subclause (II) if such trial is approved the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration (through an investigational new drug exemption), the

Secretary of Veterans Affairs, the Secretary of Defense, or by a qualified non-governmental research entity (as defined in guidelines of the National Institutes of Health).

not included in this definition, and in HSA, are peer-reviewed and Secretary approved research programs.

CRITERIA FOR MEDICAL APPROPRIATENESS FOR BENEFIT COVERAGE

1. A health plan is required to provide for coverage of the comprehensive benefit package only for health interventions that are "medically appropriate." A health intervention is considered to be "medically appropriate" if all of the following criteria are met.

   A. Medical Condition. The health intervention must be for a medical condition. A "medical condition" is a disease, an illness, an injury, a genetic defect, or a biological or psychological condition that if not treated could result in a disease, an illness or an injury.

      i. Health Intervention. A "health intervention " is any activity undertaken for a specified indication for the primary purpose of preventing, stabilizing, restoring, or improving a decrement in health outcomes caused by a medical condition. "Health interventions" include primary prevention, screening, diagnosis, treatments (including drugs, biologicals, devices, and procedures), support care, rehabilitation, and reconstruction. "Health intervention" does not include social activities that might have an indirect effect on health, such as housing, crime, education and employment. Nor does it include health interventions that occur as a normal condition of existence, such as food.

      ii. Indication. An "indication" designates any feature of the patient or delivery-setting that could reasonably be expected to affect the health outcomes of a health intervention. Any reference to a health intervention is assumed to apply to a specific indication for that treatment or diagnostic procedure.

      iii. Health Outcomes. A "health outcome" is an outcome that directly affects the length and/or quality of a person's life.

      iv. Decrement in Health Outcomes. A "decrement" in health outcomes is said to exist for an individual if either (1) there is a decremental change in a health-related feature for the individual caused by a medical condition, or (2) the individual's original endowment for a feature lies outside the normal range to an extent that any reasonable person would call abnormal.

services," but without any definition. (4) Pick terms that are neutral in the sense that they do not have any current medical connotations that might confuse their interpretation. The Clinton plan uses "items and services". Although in the past, for other purposes, I have used the third approach and called all things "treatments" (followed by a three-line definition), I agree that that word could be misleading if it got separated from its definition. Thus if I were you I would either use a more general word like "health intervention," "practice," or "service" and define it to be very inclusive (as I did in (2) above), or use "items and services," as in the Clinton plan. For convenience, in my outline, I use the words "health intervention" as a place holder for whatever you decide to use.

5. Whatever term(s) you use for the things that will be covered, you will need to make it clear that the criteria and any resulting coverage decisions or guidelines are to be applied not to the health interventions themselves but to the application of the health interventions *for specific patient indications*. This is necessary because, as you know, a health intervention in the abstract (eg, an MRI) does not have *an* effectiveness or a harm, or even a cost, as though these were properties of the health intervention. Rather, the effectiveness (or harms or costs) of a health intervention depends acutely on the indication for which it is used. MRIs have high value for suspected brain tumors, but little value for diagnosing chest pain. Appendectomies have high value for patients with classic signs and symptoms of appendicitis, but little value for patients with diarrhea. The way plans will try to handle this is to either (1) cover the health intervention *only* if it is for specified indications that meet the criteria of noninvestigational, effective, and so forth; or (2) cover the health intervention for all indications, but design guidelines that discourage its use for inappropriate indications. To enable them to do either of these, we need to make it clear that a coverage decision, whether it is positive or negative, is *not* a decision about every possible use of the health intervention. You can see how I try to accomplish this in my outline. If that does not work, let me know, because this is important.

6. I left the definition of "investigational" unchanged. (The Cooper-Breaux language is very close to what I wrote for the Task Force.) The important elements to be certain to retain are:

   a. The existence of this criterion puts the burden of proof where it should be—consistent with "first, do no harm," the scientific method, and the Food, Drug and Cosmetic Act. This is a stricter burden of proof than we have traditionally applied to procedures and other

APPENDIX B

COVERAGE OF TREATMENTS

Note: These provisions are intended to determine coverage of specific treatments potentially included in the enumerated categories of services within the nationally guaranteed benefit package. They are not intended to expand the scope of services beyond those enumerated categories. Inclusion of these provisions in the Act is necessary to facilitate the development of integrated delivery systems by making clear to providers and enrollees which services will be covered. It should be noted that these provisions govern coverage of health services, not their use, and do not affect the legality of delivering those services (including the ability of a given type of provider to deliver them), which is intended to remain subject to applicable state and federal law.

I. Treatments that are medically appropriate shall be covered.

A. A **"treatment"** is an intervention intended to improve ~~significantly~~ the physical or psychological condition of the enrollee or to prevent or mitigate an adverse health outcome for the enrollee.

Note: The term "treatment" is intended to encompass a variety of interventions, in addition to therapy for acute illness or injury, that provide physical or psychological benefit to the enrollee, including preventive care, care for disabilities and reproductive care.

1. **"Intervention"** means a diagnostic, therapeutic or other health-related procedure or service described by the following parameters: (i) the physical or psychological characteristics of the enrollee to whom the intervention is applied; (ii) the technical method of applying the intervention; (iii) the type of provider applying the intervention; and (iv) the setting in which the intervention is applied.

Note: "Intervention" is intended to include diagnosis, prevention and other health services as well as therapy. Defining interventions along certain specified dimensions is not intended to expand or restrict coverage but to allow treatments to be evaluated for medical appropriateness. For example, "a mammogram in a healthy woman under 30 with no family history" is clearer than "a mammogram"; "a decongestant for childhood otitis media" is more specific than "a decongestant"; "pre-anesthesia evaluation by a physician assistant" is more informative than "pre-anesthesia evaluation"; and "home antibiotic therapy for endocarditis" is more helpful than "antibiotic therapy for endocarditis." However, this provision should not be read as establishing, in federal law, any particular level of documentation as a prerequisite to coverage.

2. **"Adverse health outcome"** means a physical or psychological condition that constitutes a ~~significant~~ adverse change or a physical or psychological condition that lies outside the normal range.

Note: A "treatment" should be administered with the intent of affecting the enrollee's health to a significant degree; for example, cholesterol-lowering drugs should be given in order to reduce the risk of cardiovascular disease, not merely to alter the measured value of serum cholesterol. In addition, conditions being corrected should be disabilities, not normal variations. Reconstructive surgery for a cleft palate is a "treatment," while cosmetic facial surgery is not. Similarly, prevention of a significant change in health, such as the development of cancer, is a "treatment," while an attempt to prevent normal aging is not.

TALKING POINTS ON MEDICAL NECESSITY

- In any benefit package, coverage is provided for items and services that are deemed medically necessary or appropriate. These **decisions are best left up to the physician and patient**, working together to select the best care. Defining this in statute would be perceived as an infringement on the practice of medicine and would likely meet with strong opposition.

- We must not define medical necessity in terms that will fix in stone the medical model which we are trying to move our system away from. Health care today, and in the future, is about **much more than the treatment of medical conditions.** Three key dimensions of health care are not captured by the language for medical necessity being proposed:

  - **Health promotion and disease prevention** - medical care goes beyond treatment of diseases and injuries. Preventive services which must be covered include risk assessment, tests for the monitoring of disease conditions, health promotion and patient education, training in self care and the management of chronic diseases.

  - **Functioning** is an essential dimension of health care. This goes beyond ability to perform activities of daily living or ability to work, which are criteria used by SSI and have been shown to discriminate against children. Health care must maximize functioning.

  - **Patient preference** - the choice of care management goes beyond what is clinically beneficial and must incorporate patient preferences and cultural acceptability.

- Defining medical necessity in statute is **particularly problematic for children's health care** as the criteria used are so different from adults. A recent and vivid example is the 1990 Zebley decision that showed that SSI was inappropriately using adult criteria to judge disability in children. Interventions for children are particularly important as they can dramatically alter the future potential and functioning of that person.

- The benefit package must be defined in statute to create and maintain a market with a level playing field where the consumer uses comparable information about a standard benefit package to choose plans and providers. If health plans are allowed to exclude services based on varying interpretations of medical necessity that rely on medical model interpretations of health interventions, they will continue to game the system through fine print and risk avoidance.

- To ensure not only the quality of medical care, but also equity in the distribution of services, a more appropriate strategy is to build and make available the information about best practices so that physicians and patients can make better choices.

- Currently, **medical necessity is not detailed in most private health insurance.** Therefore to define it in legislation does not build on current practices in the insurance market.

- Medicine and science change over time and what is today perceived as the domains of medical necessity and reflecting best practices may not be so ten or twenty years from now. We want to preserve the innovation and adaptability of the American health care system and legislative definition of medical necessity could have unforeseen negative consequences.

- Health care interventions are not only for medical conditions as proposed. The presence of a medical condition implies the *absence* of health and therefore is only one domain of health care. Medical care and interventions also include the promotion of health and the maximizing of functioning.

- Not all health care interventions or treatment options will affect the *outcome* of care. In other words, services may affect such things as the length of illness, patient satisfaction, or the cost of care but not change the ultimate outcome. Therefore, defining an item or service as medically necessary only if it affects a health *outcome* is very limiting.

- Defining an adverse change in a health outcome only in terms of biological or psychological domains does not capture the full range of medical care interventions. For example, children with learning disability may benefit from drug treatment to improve their *behavior* and therefore their learning ability. This is a change in behavioral health status, not biological or psychological. Another example, providing a wheelchair to a disabled person does not change their biology or psychology, it assists their *functioning*. Similarly, eyeglasses and hearing aids assist or maximize functioning.

- In decisions related to appropriateness for a specific patient it is important to ensure that patient preferences in care be respected. One therapy may be superior to another in terms of "clinically meaningful benefit" but be unacceptable to the patient in terms of risks, discomfort, or cultural acceptability. For example, a cancer patient may choose the less "clinically beneficial" treatment - in terms of cancer eradication - because it provides the best quality of life for the remaining weeks or months.

- Coverage decisions by health plans should be, to the extent possible, based on science. It is important however to realize that the scientific literature often includes conflicting evidence as to benefit or appropriateness, especially for new therapies. Allowing plans to use all literature or prevailing practice could mean that any single report of lack of effectiveness could be used to exclude treatments.

MEDICAL NECESSITY OR APPROPRIATENESS -

(a) MEDICAL NECESSITY OR APPROPRIATENESS.-

(1) IN GENERAL. - The comprehensive benefit package shall provide coverage for health care items, services, or interventions that are medically necessary or appropriate.

(2) THE ROLE OF THE NATIONAL HEALTH BOARD. -

(A) IN GENERAL - The National Health Board shall promulgate such regulations or establish such guidelines as may be necessary to ensure uniformity of application of the benefits package across all health plans and to carry out section 1141(a)(2) (relating to the exclusion of certain services that are not medically necessary or appropriate).

(B) CRITERIA FOR ESTABLISHMENT OF STANDARDS - In establishing standards for medical appropriateness, the National Health Board:

(i) may consult with health plans, health professionals, consumers or their representatives, and experts in the fields of medical care, health services research, quality and outcomes research, and benefits management;

(ii) shall address at least the following:

(I) the role of the health plan in decisions of medical appropriateness consistent with (C) below;
(II) the role of the physician or other health care provider in decisions of medical appropriateness; and
(III) the role of the patient in decisions of medical appropriateness to ensure that there is patient participation and that patient preferences are taken into account.

(C) ROLE OF THE HEALTH PLAN. - Each health plan shall provide for coverage of all medically appropriate items and services within the comprehensive benefit package. Except as established in any regulations pursuant to subsection (A) above, a health plan may, but is not required to, exclude items or services that the health plan determines are not medically appropriate consistent with the standards established by the National Health Board.

necessary or

MEDICAL NECCESITY OR APPROPRIATENESS - VERSION 2

(a) MEDICAL NECESSITY OR APPROPRIATENESS.-

(1) IN GENERAL. - The comprehensive benefit package shall provide coverage for health care items, services, or interventions that are medically necessary or appropriate.

(2) THE ROLE OF THE NATIONAL HEALTH BOARD. -

(A) IN GENERAL - The National Health Board shall promulgate such regulations or establish such guidelines as may be necessary to ensure uniformity of application of the benefits package across all health plans and to carry out section 1141(a)(2) (relating to the exclusion of certain services that are not medically necessary or appropriate).

(B) COVERAGE DECISIONS. -

? (i) IN GENERAL - Each health plan shall provide for coverage of all medically necessary or appropriate items and services in the comprehensive benefit package.

(ii) DETERMINATION - In general, health plans will determine medically (nec or) appropriate any item or service which represents a health care intervention that:

(I) is covered in the comprehensive benefit package;
(II) is undertaken with respect to a specific indication as defined in section 11..(D)(i); and
(II) is effective and beneficial.

(ii) PRESUMPTIONS. -

What about for the particular patient?

(I) A drug or biologic which is approved for marketing by the Food and Drug Administration is deemed to be effective, beneficial, and not investigational if such drug or biologic is furnished for the treatment of a medically accepted indication (as defined in section 1122(a)(1)).
(II) A medical device that has been cleared for marketing by the Food and Drug Administration is deemed effective, beneficial, and not investigational when used for the conditions prescribed, recommended, or suggested in the labeling of the device.
(III) An item or service furnished to a patient consistent with a practice guideline developed by the Agency for Health Care Policy and Research under section 912(a) of the Public Health Service Act or certified under section 912(g) of the Public Health Service Act is deemed effective, beneficial and not investigational, but the omission of an item or procedure from a practice guideline does not give rise to a presumption that an item or procedure is not effective, beneficial or investigational.

Jeff has brought up concerns with these presumptions - Jeff - please elaborate in writing.

(D) DEFINITIONS. -

(i) HEALTH INTERVENTION - A health intervention is any item or service undertaken for a specific indication to promote health and development; prevent disease, injury, or disability; diagnose, improve, maintain, restore or stabilize a health outcome; or maximize functioning.

(ii) INDICATION. - An indication designates any feature of the enrollee or delivery setting that could reasonably be expected to affect the health outcomes of a health intervention. Any reference to a health intervention is assumed to apply to a specific indication for that item or service.

(iii) HEALTH OUTCOME. - A health outcome means a condition that affects the length or quality of an enrollee's life or maximize an enrollee's ability to achieve full developmental potential and functioning.

(I) QUALITY OF LIFE AND FUNCTIONING. - These include the ability to perform activities of daily living commensurate with the enrollee's age or developmental status; the ability to work or function in society appropriate to the enrollee's age or developmental status; the relief from discomfort or pain; the alleviation of fatigue, and the maximization of cognitive, behavioral, social, psychological or emotional functioning and well-being.

Isn't this too broad?

(iv) EFFECTIVE. - A health intervention is effective when in the judgment of the provider at the time the intervention is provided the benefits to the enrollee of the intervention outweigh its risks.

(v) BENEFICIAL. - A health intervention is beneficial when, in the judgment of the enrollee at the time the intervention is provided, the benefits of the intervention outweigh its risks; provided that emergency treatment administered to the enrollee shall be deemed to be beneficial.

(E) COVERAGE OF INVESTIGATIONAL TREATMENTS IN APPROVED RESEARCH TRIALS. -

(i) IN GENERAL. - Coverage of the patient care costs (as defined in clause (iii)), associated with the delivery of investigational treatments (as defined in clause (ii)), are considered to be medically appropriate only if the treatment for the patient is part of an approved research trial (as defined in clause (iv)).

nec. or

(ii) INVESTIGATIONAL TREATMENT DEFINED. - In clause (i), the term "investigational treatment" means health care intervention for which there is not sufficient evidence to establish that such intervention is effective and beneficial as determined under subparagraph (D)(.

(iii) PATIENT CARE COSTS DEFINED. - In clause (i), the term "patient care

costs" means the cost of health services required to provide treatment according to the design of the trial, except those costs normally paid for by other funding sources (as defined by the Secretary), such as the cost of the investigational drug, the costs of any nonhealth services that might be requiredfor a person to receive the treatment, or the costs of managing the research. Items or services subject to this exception may be covered in addition to patient care at the discretion of the health plan.

(iv) APPROVED RESEARCH TRIAL DEFINED. - In clause (i), the term "approved research trial" means a trial --

(I) conducted for the primary purpose of determining whether or not a health care intervention is safe, effective, or having any other character of a health care intervention which must be demonstrated in order for the health care intervention to be medically necessary and appropriate, and

or

(II) approved by the Secretary.

A trial is deemed to be approved under subclause (II) if such trial is approvied the National Institutes of Health, the Food and Drug Administration (through an investigational new drug exemption, the Department of Veterans Affairs, the Department of Defense, or by a qualified non-governmental research entity (as identified in guidelines issued by one or more of the National Institutes of Health).

DRAFT - Medically Necessary and Appropriate Report Language

[SEC. 1141. EXCLUSIONS]

The Committee expects that the National Health Board will consider guidelines or regulations regarding coverage decisions relating to medical appropriateness or necessity. [Treatments that are consistent with standard medical practice at the time of enactment of this legislation should be assumed to be medically appropriate unless or until shown otherwise or unless or until such treatments cease to be consistent with standard medical practice.]

The Committee intends that any determinations of the medical necessity or appropriateness of a covered service or item for an individual under age 21 shall be consistent with the factors that enter into clinical judgments on behalf of individuals in that age group. These factors include but are not limited to healthy growth and development of an individual patient. By childhood development, the committee means the maturing of an individual's physical emotional and intellectual capacities from birth to adulthood.

[SEC. 1154. ESTABLISHMENT OF STANDARDS REGARDING MEDICAL NECESSITY]

The Committee intends that health plans will provide to enrolled individuals all medically necessary or appropriate items, treatments, or services within the comprehensive benefits package. The Committee recognizes that decisions regarding medical necessity or appropriateness of care are first addressed by the health provider and individual enrollee. The Committee further recognizes that while health plans have flexibility in implementing delivery of care, they are responsible for providing the benefits under this Act in a manner consistent with any guidelines or regulations established by the National Health Board under this Act.

The Committee expects such guidelines to reflect current professionally accepted standards of care. Such standards of care may be derived from peer reviewed publications, expert opinion, as well as those broadly accepted within the community of practicing health professionals.

The Committee intends that any regulations issued by the board for the purpose of determining services that are medically necessary or appropriate for individuals under 21 shall be consistent with clinical factors in the health care of individuals in this age group. The factors shall be those that determine reasonable standards of medical practice for individuals under age 21, as determined by the Board after consultation with recognized medical organizations involved in child health care. Such factors include but are not limited to healthy childhood growth and development.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
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fax transmittal

to:	Jennifer Klein
fax #:	456-2878
from:	Lisa Simpson, MB, BCh, MPH
date:	6/24/94
re:	medical necessity
pages:	7, including this cover sheet

NOTES: Here are the two versions - I am also giving them to Jeff and Bob - call when you want to talk....

MEDICAL APPROPRIATENESS - VERSION I

(a) MEDICAL APPROPRIATENESS.-

(1) IN GENERAL. - The comprehensive benefit package shall provide coverage for health care items, services, or interventions that are medically appropriate. or ncc.

I used appropriateness rather than necessary given Eddy's point about the significant amount of case law that exists regarding "necessary".

(2) THE ROLE OF THE NATIONAL HEALTH BOARD. -

(A) IN GENERAL - The National Health Board shall promulgate such regulations or establish such guidelines as may be necessary to ensure uniformity of application of the benefits package across all health plans. This includes but is not limited to:

(i) establishment of standards for medical appropriateness. - as defined in subsection (B) below;

Highlight this ?

(ii) making specific determinations about whether particular health interventions are medically appropriate and requiring health plan coverage of these interventions;

(iii) excluding items or services from coverage by health plans that the Board determines are not medically appropriate;

(B) CRITERIA FOR ESTABLISHMENT OF STANDARDS - In establishing standards for medical appropriateness, the National Health Board ~~shall~~: may

(i) may consult with health plans, health professionals, consumers or their representatives, and experts in the fields of medical care, health services research, quality and outcomes research, and benefits management;

just a first pass list - any suggestions?

(ii) shall address at least the following:

(I) the role of the health plan in decisions of medical appropriateness consistent with (C) below;
(II) the role of the physician or other health care provider in decisions of medical appropriateness;
(III) the role of the patient in decisions of medical appropriateness to ensure that there is patient participation and that patient preferences are taken into account; and
(IV) the remedies available to patients and providers in instances where there is disagreement as to the medical necessity or appropriateness of a particular item or service *[cross reference here the sections on rights and remedies in the HSA]*;

Reserve

(C) ROLE OF THE HEALTH PLAN. - Each health plan shall provide for coverage of all medically appropriate items and services within the comprehensive benefit package. Except as established in any regulations pursuant to subsection (A) above, a health plan may, but is not required to, exclude items or services that the health plan determines are not medically appropriate consistent with the standards established by the National Health Board.

MEDICAL APPROPRIATENESS - VERSION 2

(a) MEDICAL APPROPRIATENESS.-

(1) IN GENERAL. - The comprehensive benefit package shall provide coverage for health care items, services, or interventions that are medically appropriate.

(2) THE ROLE OF THE NATIONAL HEALTH BOARD. -

(A) IN GENERAL - The National Health Board shall promulgate such regulations or establish such guidelines as may be necessary to ensure uniformity of application of the benefits package across all health plans. This includes but is not limited to:

(i) establishment of standards for medical appropriateness. - as defined in subsection (B) below;

(ii) making specific determinations about whether particular health interventions are medically appropriate and requiring health plan coverage of these interventions;

(iii) excluding items or services from coverage by health plans that the Board determines are not medically appropriate;

(B) CRITERIA FOR ESTABLISHMENT OF STANDARDS - In establishing standards for medical appropriateness, the National Health Board shall:

(i) consult with health plans, health professionals, consumers or their representatives, and experts in the fields of medical care, health services research, quality and outcomes research, and benefits management;

(ii) address at least the following:

(I) the role of the health plan in decisions of medical appropriateness consistent with (C) below;
(II) the role of the physician or other health care provider in decisions of medical appropriateness;
(III) the role of the patient in decisions of medical appropriateness to ensure that there is patient participation and that patient preferences are taken into account; and
(IV) the remedies available to patients and providers in instances where there is disagreement as to the medical necessity or appropriateness of a particular item or service *[cross reference here the sections on rights and remedies in the HSA]*;

(C) APPLICATION OF STANDARDS IN COVERAGE DECISIONS. -

(i) IN GENERAL - Each health plan shall provide for coverage of all medically appropriate items and services within the comprehensive benefit package.

(ii) ROLE OF HEALTH PLAN.- Except as established in any regulations pursuant to subsection (A) above, a health plan may, but is not required to, exclude items or services that the health plan determines are not medically appropriate consistent with the standards established by the National Health Board.

(ii) DETERMINATION - In general, health plans will determine medically appropriate any item or service which represents a health care intervention that is:

(I) undertaken with respect to a specific indication to promote health and development; prevent disease, injury, or disability; diagnose, improve, maintain, restore or stabilize a health outcome; or maximize functioning;
(II) is effective, beneficial and judicious; and
(III) is not investigational.

Are these too many tests for a treatment?

(iii) PRESUMPTIONS. -

(I) A drug or biologic which is approved for marketing by the Food and Drug Administration is deemed to be effective, beneficial, and not investigational if such drug or biologic is furnished for the treatment of a medically accepted indication (as defined in section 1122(a)(1)).
(II) A medical device that has been cleared for marketing by the Food and Drug Administration is deemed effective, beneficial, and not investigational when used for the conditions prescribed, recommended, or suggested in the labeling of the device.
(III) An item or service furnished to a patient consistent with a practice guideline developed by the Agency for Health Care Policy and Research under section 912(a) of the Public Health Service Act or certified under section 912(g) of the Public Health Service Act is deemed effective, beneficial and not investigational, but the omission of an item or procedure from a practice guideline does not give rise to a presumption that an item or procedure is not effective, beneficial or investigational.

(D) DEFINITIONS. -

(i) HEALTH INTERVENTION - A health intervention is any item or service undertaken for a specific indication to promote health and development; prevent disease, injury, or disability; diagnose, improve, maintain, restore or stabilize a ~~[an adverse]~~ health outcome; or maximize functioning.

I prefer not putting in the "adverse" part and then one avoids defining it below.

(I) INDICATION. - An indication designates any feature of the enrollee or delivery setting that could reasonably be expected to affect the health outcomes of a health intervention. Any reference to a health intervention is assumed to apply to a specific indication for that item or service. *[Is this second sentence necessary?].*

(II) PARAMETERS. - Any health intervention is described by the following parameters:

(..) the characteristics of the enrollee to whom the intervention is provided;
(..) the technical method of providing the intervention;
(..) the type of provider applying the intervention;
(..) the setting in which the intervention is provided.

This parameters section seems overly detailed - I would tend to leave it out - What is gained by it?

(ii) HEALTH OUTCOME. - A health outcome means a condition that affects the length or quality of an enrollee's life or maximize enrollees' ability to achieve their full developmental potential and functioning.

(I) QUALITY OF LIFE AND FUNCTIONING. - These include the ability to perform activities of daily living commensurate with the individual's age or developmental status; the ability to work or function in society appropriate to the individual's age or developmental status; the relief from discomfort or pain; the alleviation of fatigue, and the maximization of cognitive, behavioral, social, psychological or emotional functioning and well-being.

(iii) ADVERSE HEALTH OUTCOME. - An adverse health outcome is said to exist for an individual if either there is an adverse change in a characteristic of the individual or the individual's original endowment for a feature lies outside the normal range.

I would prefer to not use the direction of adverse health outcome, as it perpetuates the disease and treatment construct, and we do not have a similar definition for the health promotion side. I am also not sure about the second part of this definition - It seems to address pediatric concerns for conditions that are not a decrease in health status but the test of "normality" may be too rigorous. For example, "normal" compared to what, and for whom - i.e. does it get to population differences?

(iv) EFFECTIVE. - A health intervention is effective when in the judgment of the provider at the time the intervention is provided, sufficient evidence exists to conclude that the benefits to the enrollee of the intervention outweigh its risks.

What about linking effectiveness to intended health result as Eddy does, comparing to no intervention? I have also deleted the "reasonable" qualifier on judgment as well as the "subjective" qualifier for enrollees below. Why should judgments be any different for provider and patient?

(iv) BENEFICIAL. - A health intervention is beneficial when, in the judgment of the enrollee at the time the intervention is provided, the benefits of the intervention outweigh its risks; provided that emergency treatment administered to the enrollee shall be deemed to be beneficial.

What about the Eddy concept of comparison of effects to NO treatment as opposed to its inherent risks?

(v) JUDICIOUS. - A health intervention is judicious unless, in the judgment of the plan before the intervention is administered, another medically appropriate

intervention is available that would be substantially as effective for the enrollee and significantly *[substantially?]* less costly to the plan.

(vi) NOT INVESTIGATIONAL. - There must be sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcomes resulting from the health intervention compared with the best available alternative, or with no health intervention if no alternative health intervention is available.

(E) COVERAGE OF INVESTIGATIONAL TREATMENTS IN APPROVED RESEARCH TRIALS. - *this part is the Durenberger language*

(i) IN GENERAL. - Coverage of the patient care costs (as defined in clause (iii)), associated with the delivery of investigational treatments (as defined in clause (ii)), are considered to be medically appropriate only if the treatment for the patient is part of an approved research trial (as defined in clause (iv)).

(ii) INVESTIGATIONAL TREATMENT DEFINED. - In clause (i), the term "investigational treatment" means health care intervention for which there is not sufficient evidence to establish that such intervention is effective and beneficial as determined under subparagraph (D)(.

(iii) PATIENT CARE COSTS DEFINED. - In clause (i), the term "patient care costs" means the cost of health services required to provide treatment according to the design of the trial, except those costs normally paid for by other funding sources (as defined by the Secretary), such as the cost of the investigational drug, the costs of any nonhealth services that might be requiredfor a person to receive the treatment, or the costs of managing the research.
Items or services subject to this exception may be covered in addition to patient care at the discretion of the health plan.

(iv) APPROVED RESEARCH TRIAL DEFINED. - In clause (i), the term "approved research trial" means a trial --

(I) conducted for the primary purpose of determining whether or not a health care intervention is safe, effective, or having any other character of a health care intervention which must be demonstrated in order for the health care intervention to be medically necessary and appropriate, and

(II) approved by the Secretary.

A trial is deemed to be approved under subclause (II) if such trial is approvied the National Institutes of Health, the Food and Drug Administration (through an investigational new drug exemption, the Department of Veterans Affairs, the Department of Defense, or by a qualified non-governmental research entity (as identified in guidelines issued by one or more of the National Institutes of Health).

From:

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Number of Pages: 5

Date: 6/23/94-11:23:49 AM

Subject: Hein memo

Notes:

This is a copy of the memo I sent to Karen Hein last night. It refers to the documents I gave you at the meeting. Please keep in touch.

June 22, 1994

TO: KAREN HEIN, MD
PROFESSIONAL STAFF TO THE SENATE FINANCE COMMITTEE

FROM: LINDA BERGTHOLD, PhD

RE: HEALTH BENEFITS IN THE CHAIRMAN'S MARK

You asked for my reaction to the language in the 6/21 draft. I have several reactions, including some comments on an earlier version of this same document that I received from a local law firm.

1. COVERED SERVICES: The first three sentences all seem fine. I like the standardized set of benefits, categories which are defined in statute, and a NHB to refine the list. It is good that the term is "or" not "and"; and it is critical that you refer to the "enrollee" not the patient or individual for the reasons we have discussed.

There needs to be additional language to clarify the difference between defining categories of covered services in statute and determining which treatments within those coverage categories might be included or excluded by standards of medically necessary or appropriate.

PROPOSED CHANGES IN LANGUAGE (changes in bold and underlined):
Categories of services would be defined in statute. A National Health Benefits Board would be directed by statute to refine the list of covered services **and treatments within service categories** by reference to standards of medical necessity or appropriateness. (Option 1:) **These standards will be defined by the National Health Board.** (Option 2:) Medically necessary or appropriate treatments would be defined ... as those intended to maintain or improve the **physical** or **psychological** condition of the enrollee or to prevent or mitigate an adverse health outcome to the enrollee.

I still believe that you should not define medically necessary or appropriate at all, even with regard to treatments (and by the way, if you do include this one sentence definition, make "biologic" into "biological", etc. That is Eddy's original term and it is awkward and pedantic.) One

reason for leaving it undefined is that you must then define every word: what does "maintain" mean? "Adverse health outcome"? etc.

Regarding the sentences relating to individuals under 22 years of age, I believe it is best to insert this language into a specific category of services for children under the age of 22 which includes its own language related to functional capacity, etc. in statute. You could include it under section (o) in the next section before you describe the special services, i.e., vision, hearing aids, etc. for individuals in this age group. Another alternative would be to fold the concepts of coverage for children into the general coverage for adults. A disadvantage of a separate sentence is that it invites the addition of other sentences addressing special provisions for disabled adults and makes the concepts even more vulnerable to complete deletion.

If you wish to provide special consideration for children, you could simply say, "For individuals under 22 years of age, the Board would be directed to give special consideration to age and health status in the definition of covered services."

Why is the age limit 22? Why not 18 or 21 or 24?

2. In the first section, ACTUARIAL VALUE AND COST SHARING, I would strongly recommend that you price out an option for the high cost sharing plan that would include primary care services as well as preventive services in the category that excludes copayments, coinsurance and deductibles. (e.g. "for services other than clinical preventive and primary care services.") As you know, research shows that people postpone necessary primary care when that care is subject to deductibles, leading to expensive and inappropriate utilization of emergency rooms and more serious illness resulting from neglect of early detection. This provision should definitely apply to the catastrophic "non-certified" plan. Unfortunately, the savings in catastrophic coverage have come from keeping people from utilizing any medical care at all and shifting costs of coverage and risk to enrollees.

You asked for some information on values of catastrophic plans: The word from our actuaries is that a "benchmark" rule of thumb regarding catastrophic plans is that they tend to be 60% to 65% of the premium of a comprehensive plan. (That is, 30 to 40% less expensive than a

comprehensive plan.) Catastrophic plans are defined as plans that range from $1000 to $3000 individual deductibles, 60 to 70% coinsurance (i.e. the enrollee pays 30 to 40% for out of network services)and $5000 to $8000 out of pocket annual maximum. This would compare with a typical HMO plan or an indemnity plan with a $250 individual deductible, a 80/20 coinsurance and $2000 to $3000 out of pocket maximum.

3. The service category definitions in the version I have seen generally good. I suggest the following modifications (**changes in bold**):

(e) mental illness and substance abuse services. Paragraph 2. "Treatments covered in the inpatient setting would be covered according to standards of medical necessity or appropriateness."

(g) hospice care services. Here is an important opportunity to correct an advertent error in the Clinton plan, caused by a clerical mistake. Hospice services as defined in Medicare do not include any respite care. A limited amount of respite services were included in our original Clinton draft but were put in another category of services by mistake. Hospice providers say that the Medicare benefit is generally a good benefit, but that respite care would really add value to the service. You could add "up to 8 hours a month" of respite care services without substantial cost implications. In fact, if the benefit is capped, as it is in Medicare, the respite care could be folded in at no additional cost to the payor. I suggest you contact Lisa Simpson at HHS for specifics on this.

(h) home health care services. "these services would be an alternative to more costly settings such as inpatient treatment in a hospital and would be reevaluated for continuation subject to standards of "medically necessary or appropriate" after each 60 day period.

(i) extended care services. I believe that Medicare limits extended care to a number of days. These services should also be extendable if medically necessary or appropriate as determined by a provider who is responsible for care management.

(m) outpatient rehabilitation services. I am not comfortable with the evaluation of extension being provided by the person primarily responsible for providing the services -- unless the payment is capitated. Otherwise, there is a strong incentive to keep the patient in rehabilitation unnecessarily. If you are worried about financial incentives in the opposite direction, you could designate a third party to evaluate the need for continuing care who has no financial stake in the continuation of treatment.

(p) investigational treatments. It is best to leave this term without definition. Once you start thinking about "effectiveness" and "benefit" you have to define those terms as well, so it may be best to leave it as it is. There is consensus among health plans that there is no important difference between the terms "experimental" and "investigational."

4. National Health Benefits Board. The argument my Republican colleagues give me for putting the NHB within HHS is that it would not create a new agency or entity, it would contain its power within the HHS, and it would be cheaper since salaries for Board members could be lower than they would be if the Board were like the Federal Reserve Board. However, the Board would be more independent and insulated, both from politics and norms of bureaucratization, if it were free-standing.

I would change "refine the statutory definition of medical necessity or appropriateness" to **"define the criteria by which standards of medical necessity or appropriateness would be applied in health plans."**

I am happy to provide further input if you need it. Good luck.

APPENDIX A

DEFINITIONS OF MEDICAL NECESSITY IN EXISTING AND PROPOSED LEGISLATION

MEDICARE

Section 1862(2)(1)(A) of the Social Security Act: Prohibits Medicare payment for services that "are not reasonable and necessary for **the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.**" The act specifically excludes certain services from coverage (e.g. cosmetic surgery and routine dental care), but it does not provide a comprehensive list of services and equipment that are either covered or excluded. The Act gives the Secretary of Health and Human Services the discretionary authority to identify medical services that are not medically reasonable and necessary for the treatment of illness or injury. (42 U.S.C. § 1395y(a)(1) (1988).

MEDICAID

The Medicaid statute has been construed similarly to require states to cover all "medically necessary services."

Examples of state definitions of medically necessary:

Florida: Covered outpatient services must be medically necessary **preventive, diagnostic, therapeutic or palliative services** (Fla Admin. Code Ann. r. 10C-7.040(1992)). Requested service must be reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that threaten life, cause suffering or pain, result in illness or infirmity, or threaten to cause or aggravate a handicap, physical deformity, or malfunction, and there is no equally effective, more conservative or less costly course of treatment available.

Minnesota: Covered services must "(A) be determined by prevailing community standards or customary practice and usage to: (1) be medically necessary; (2) be appropriate and effective for the medical needs of the recipient; (3) meet quality and timeliness standards; (4) be the most cost

effective health service available for the medical needs of the recipient; (B) represent an effective and appropriate use of medical assistance funds." (Minn. R. 9505.0210)

South Dakota: To be medically necessary, the covered service must meet the following conditions: (1) It is consistent with the recipient's symptoms, diagnosis, condition, or injury; (2) It is recognized as the prevailing standard and is consistent with generally accepted professional medical standards of the provider's peer group; (3) It is provided in response to a life-threatening condition; to treat pain, injury, illness or infection; to treat a condition that could result in physical ormental disability; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; (4) It is not furnished primarily for the convenience of the recipient or the provider; and (5) There is no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly. (S.D. Admin. R. 67: 16:01:06.02)

FEHBP "PROTOTYPE" DEFINITION OF MEDICAL NECESSITY

Plans can negotiate a different definition.

Medical necessity means that services, supplies, or equipment provided by a hospital or provider of health care services associated with a particular plan:

1. are appropriate to the diagnosis or treatment of a patient's condition, illness or injury;

2. are consistent with the standards of good medical practice in the United States;

3. are not primarily for the personal comfort or convenience of the patient, family, or

provider;

4. are not a part of or associated with scholastic education or vocational training of the patient;

5. in the case of inpatient care, cannot be provided safely on an outpatient basis.

The fact that a covered provider has prescribed, recommended or approved a service, supply, or equipment, does not, in itself, make it medically necessary.

TREATMENT OF MEDICAL NECESSITY IN PROPOSED LEGISLATION

I. LEGISLATION IN WHICH MEDICAL NECESSITY IS DEFINED SPECIFICALLY:

A. COOPER/BREAUX HR 3222

Sec.1302 SPECIFICATION OF UNIFORM SET OF EFFECTIVE BENEFITS
(a)(2) SPECIFICATION OF ALL MEDICALLY APPROPRIATE TREATMENTS
(a) **MEDICALLY APPROPRIATE** TREATMENTS -- The uniform set of effective benefits submitted under paragraph (1) shall include such categories of health care services that the Commission determines will provide for the delivery of medically appropriate treatment by the AHP.
(D) ADDITIONAL COVERAGE - Nothing in this paragraph shall be construed as preventing a plan from providing coverage of treatment that has not been determined (under subsection (b)) by the Commission to be medically appropriate for the purposes of this paragraph.

(b) **CRITERIA FOR DETERMINATION OF MEDICALLY APPROPRIATENESS FOR BENEFIT COVERAGE**

(1) IN GENERAL - An AHP is required to provide for coverage of the uniform set of effective benefits only for treatments and diagnostic procedures that are medically appropriate... a treatment (as defined in paragraph (6) (A) or diagnostic procedure is considered to be "medically appropriate" if the following criteria are met (as interpreted by the Commission):

(A) TREATMENT OR DIAGNOSIS OF MEDICAL CONDITION

(I) IN GENERAL - The treatment or diagnostic procedure is for a medical condition.

(ii) MEDICAL CONDITION DEFINED - The Term "Medical condition" means a disease, illness, injury, or biological or psychological condition or status for which treatment is indicated to improve, maintain, or stabilize a health outcome (as defined in paragraph (6) (B), or which, in the absense of treatment could lead to an adverse change in health outcome.

(iii) ADVERSE CHANGE IN HEALTH OUTCOME DEFINED - In clause (ii), an adverse change in a health outcome occurs if there is a biological or psychological decremental change in a health status or if the original endowment for a feature lies outside the normal range.

(B) NOT INVESTIGATIONAL - There must be sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcome resulting from the treatment or diagnostic procedure compared with the best available alternative (or with no treatment or diagnostic procedure if no alternative treatment or procedure is available).

(C) EFFECTIVE AND SAFE - The evidence must demonstrate that the treatment or diagnostic procedure can reasonably be expected to produce the intended health result or provide intended health information and is safe and the treatment or diagnostic procedure provides a clinically meaningful benefit with respect to safety and effectiveness in comparison to other available alternatives.

(2) TREATMENT OR DIAGNOSTIC PROCEDURE CONSISTENT WITH PRACTICE GUIDELINES - A treatment or diagnostic procedure that is provided consistent with a practice guideline established under Section 1309 (or its predecessor) is deemed to be medically appropriate.

B. CHAFEE/THOMAS - S.1770

SEC. 1301 - OFFERING OF BENEFIT PACKAGES

(b) Covered Items and Services - Subject to the procedures for clarification and modification described in Part II, covered items and services consist of the following items and services, but only when the provision of the item or service is **medically necessary or appropriate.**

(d) CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY AND APPROPRIATENESS

SAME AS COOPER/BREAUX except for the introduction of the phrase "medically necessary or *appropriate.*"

(1) IN GENERAL - A qualified health plan shall provide for coverage of the items and services described in subsection 9b) only for treatments and diagnostic procedures that are medically necessary or appropriate. In the case of dispute concerning a determination of medical necessity or appropriateness and subject to the succeeding provisions of this subsection, for purposes of this title, a treatment, (as defined in subparagraph (6)(A) or diagnostic procedure shall be considered to be medically necessary or appropriate if the following criteria are met

PART II - BENEFITS COMMISSION

Allows the Commission to develop and submit to Congress the clarificaiton of covered items and services under Section 1301(b) - the Commission may propose to eliminte a category of items or services, but may <u>not</u> specify particular treatments or procedures to be covered.

Chafee version also introduces section (f) "Freedom to Offer Benefits " - Nothing in this section shall be construed to prohibit a health plan that is not a qualified health plan from offering any health care benefits.

II. LEGISLATION IN WHICH THE TERMS ARE USED BUT NOT DEFINED

A. CLINTON - S.1757
PART 4 - EXCLUSIONS
Sec. 1141 - EXCLUSIONS
(A) MEDICAL NECESSITY - The comprehensive benefit package does not include -
(1) an item or services that is **not medically necessary or appropriate; or**
(2) an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under Section 1154.

B. CHAIRMAN OF SENATE LABOR AND HUMAN RESOURCES COMMITTEE EDWARD KENNEDY'S MARK
(Same as Clinton language)
Part 4 - EXCLUSIONS
Section 1141. EXCLUSIONS
(a) MEDICAL NECESSITY - The comprehensive benefit package does not include -
(1) an item or services that is **not medically necessary or appropriate;** or
(2) an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under Section 1154.

C. NICKLES - S.1743
Sec. 112. Family Security Benefits Package
(a) IN GENERAL - The requirements of this section are met, if the health insurance plan --
(1) provides coverage for **all medically necessary acute medical care** described

in subsection (b),

(2) does not exclude coverage for selected illnesses or selected treatments if consistent with medically accepted practices, and

(3) meets the patient cost sharing requirements of subsection (c).

Nickles specifically excludes abortion services.

D. MCDERMOTT - H.R. 1200

Sec. 201 - COMPREHENSIVE BENEFITS

(a) IN GENERAL - subject to the succeeding provisions of this title, individuals enrolled for benefits under this Act are entitled to have payment made under a State health security program for the following items and services **if medically necessary and appropriate** for the maintenance of health or for the diagnosis, treatment or rehabilitation of a health condition.

E. ROWLAND - H.R. 3955

(3) EXCEPTIONS - Paragraph (1) shall not be construed as requiring a plan to include payment for--

(A) items and services that are **not essential and medically necessary;**

(B) routine physical examinations or preventive care (other than care and services described in subparagraph (D) of paragraph (!); or

(C) experimental services and procedures.

F. MICHEL- H.R. 3080

SEC. 1102 - MEDACCESS PLAN DEFINED

(a)(1)(B) the plan includes **only essential and medically necessary services,** including medical, surgical, hospital, and preventive services; except that no specific procedure or treatment, or classes thereof, is required to be covered in such a plan, by this act or through regulations.

G. KASSEBAUM AMENDMENT INTRODUCED IN SENATE LABOR AND HUMAN RESOURCES AND DEFEATED (proposed Durenberger amendment is very similar)

The amendment is the same language as in Chafee and Cooper/Breaux. The terms "medically necessary or appropriate" are used in the body of the amendment; the title of the amendment uses "and" (CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY AND APPROPRIATENESS)

Kassebaum also uses term "community rated health plan" instead of "qualified" health plan as in Chafee.

APPENDIX B

COVERAGE OF TREATMENTS

Note: These provisions are intended to determine coverage of specific treatments potentially included in the enumerated categories of services within the nationally guaranteed benefit package. They are not intended to expand the scope of services beyond those enumerated categories. Inclusion of these provisions in the Act is necessary to facilitate the development of integrated delivery systems by making clear to providers and enrollees which services will be covered. It should be noted that these provisions govern coverage of health services, not their use, and do not affect the legality of delivering those services (including the ability of a given type of provider to deliver them), which is intended to remain subject to applicable state and federal law.

I. Treatments that are medically appropriate shall be covered.

A. A **"treatment"** is an intervention intended to improve ~~significantly~~ the physical or psychological condition of the enrollee or to prevent or mitigate an adverse health outcome for the enrollee.

Note: The term "treatment" is intended to encompass a variety of interventions, in addition to therapy for acute illness or injury, that provide physical or psychological benefit to the enrollee, including preventive care, care for disabilities and reproductive care.

1. **"Intervention"** means a diagnostic, therapeutic or other health-related procedure or service described by the following parameters: (i) the physical or psychological characteristics of the enrollee to whom the intervention is applied; (ii) the technical method of applying the intervention; (iii) the type of provider applying the intervention; and (iv) the setting in which the intervention is applied.

Note: "Intervention" is intended to include diagnosis, prevention and other health services as well as therapy. Defining interventions along certain specified dimensions is not intended to expand or restrict coverage but to allow treatments to be evaluated for medical appropriateness. For example, "a mammogram in a healthy woman under 30 with no family history" is clearer than "a mammogram"; "a decongestant for childhood otitis media" is more specific than "a decongestant"; "pre-anesthesia evaluation by a physician assistant" is more informative than "pre-anesthesia evaluation"; and "home antibiotic therapy for endocarditis" is more helpful than "antibiotic therapy for endocarditis." However, this provision should not be read as establishing, in federal law, any particular level of documentation as a prerequisite to coverage.

2. **"Adverse health outcome"** means a physical or psychological condition that constitutes a ~~significant~~ adverse change or a physical or psychological condition that lies outside the normal range.

Note: A "treatment" should be administered with the intent of affecting the enrollee's health to a significant degree; for example, cholesterol-lowering drugs should be given in order to reduce the risk of cardiovascular disease, not merely to alter the measured value of serum cholesterol. In addition, conditions being corrected should be disabilities, not normal variations. Reconstructive surgery for a cleft palate is a "treatment," while cosmetic facial surgery is not. Similarly, prevention of a significant change in health, such as the development of cancer, is a "treatment," while an attempt to prevent normal aging is not.

B. A treatment is **"medically appropriate"** if it is effective, beneficial and judicious.

1. **"Effective"** means that, in the reasonable judgment of the provider at the time the treatment is administered, sufficient evidence exists to conclude that the benefits to the enrollee of the treatment outweigh its risks.

Note: By setting a reasonableness standard, "effective" is intended to require objective, scientific evidence of net benefit to the enrollee. Because it is not possible to weigh the risks and benefits of experimental or investigational treatments, it is intended that such treatments not be considered effective. For treatments developed in the future, nationally sponsored or approved clinical research will assist providers in determining effectiveness. Additionally, in the definitions of "effective" and of "beneficial," below, it is intended that the term "risks" encompass all outcomes harmful or adverse to the enrollee (e.g., side effects).

2. **"Beneficial"** means that, in the subjective judgment of the enrollee at the time the treatment is administered, the benefits of the treatment outweigh its risks; provided, however, that emergency treatment administered to the enrollee shall be deemed to be beneficial.

Note: "Beneficial" is intended to emphasize the importance of the enrollee in the decision to administer a treatment. Because these provisions govern coverage, not legitimacy, "beneficial" is not intended to correspond precisely to prevailing medical ethics or the law of informed consent (to which plans will be subject under enterprise liability). It is intended that emergency treatments be deemed beneficial, and that treatments administered to persons subject to legal guardianship the applicable law of informed consent be judged beneficial by the guardian. However, treatments that are not judged "beneficial" should not be administered by providers with the expectation of payment.

3. A treatment is **"judicious"** unless, in the reasonable judgment of the plan before the treatment is administered, another medically appropriate treatment is available that would be (i) substantially as effective for the enrollee and (ii) significantly less costly to the plan.

Note: "Judicious" is intended to allow and encourage plans to develop practice guidelines that will permit the delivery of high-quality care within a budget. In order to avoid covering an injudicious treatment, a plan must bear the burden of showing, in advance of the treatment, that it offers a significantly less costly alternative that is substantially as effective. It is intended that "judiciousness" be established for specific treatments through scientific guidelines at the plan level, not through retrospective claims denial or through cost-benefit decisions by individual providers.

II. Treatments that are not medically appropriate shall be excluded from coverage.

Note: Plans should not be permitted to cover medically inappropriate treatments. Any additional resources should be devoted to improving the quality of covered benefits.