

To: Jennifer Klein
From: LB
Re: Boxer amendment
on MN/A

14 pages

P.S. I'll send you a copy
of my report.

These amendments are based on the first Mitchell bill
and are consistent with the second version released 8/11/94.

MITCHELL BILL AMENDMENTS CONCERNING COVERAGE

1. Section 1202, describing categories of health care items and services, is amended by striking "OF ITEMS AND SERVICES" and inserting "BENEFIT" before "CATEGORIES" in the title, and by inserting "benefit" before "categories" and striking "of health care items and services" in subsection (a).

2. Section 1202(b) is amended to read as follows:

1 "(b) MEDICAL NECESSITY OR APPROPRIATENESS.—

2 "(1) IN GENERAL. Health care interventions (as defined in this
3 subsection) in the categories described in subsection (a) shall be
4 covered in the benefit package when medically necessary or
5 appropriate, as defined in this subsection. A health plan may, but is
6 not required to, exclude health care interventions that are not
7 medically necessary or appropriate, as defined in this subsection.

8 "(2) CRITERIA FOR DETERMINATIONS.—In making a
9 determination of medical necessity or appropriateness a health plan
10 shall find a health care intervention (as defined in subparagraph
11 (5)(A)) to be "medically necessary or appropriate" if the following
12 criteria are met:

13 "(A) THE HEALTH CARE INTERVENTION IS FOR A MEDICAL
14 CONDITION.

15 "(i) MEDICAL CONDITION DEFINED.—The term
16 "medical condition" means a disease, illness, injury,
17 genetic defect, or biological or psychological condition or
18 status for which health care intervention is indicated to

SEP 04 10:20 20:00
AUG 11 '94 08:16 AM H & H 12E 400

Sep. 19. 1994 09:43 AM P03
AUG 12 '94 18:44 Nn.009 P.02
ETA ASSUM

DOCTORS AND PATIENTS SHOULD DETERMINE WHETHER A MEDICAL TREATMENT IS MEDICALLY NECESSARY

PROBLEM:

Under the Mitchell bill, a national board determines whether a particular medical service or procedure is medically necessary. This approach places too much power over medical care in the hands of a distant Federal bureaucracy with little public accountability.

IMPLICATIONS:

Under the proposed bill, the national board defines "medical necessity" and decides whether specific items and services meet the definition. The board is given virtually no statutory guidance in determining how to define the term or how to apply it to particular medical interventions or treatments. Thus, it is possible that promising new therapies will not be covered because a federal bureaucracy has a different view of whether a treatment is medically necessary than a patient's physician.

SOLUTION:

The pending bill should be amended to provide for a set of uniform national standards that guide the decision making process on determinations of medical necessity and provide that the implementation of these standards start with the decision maker closest to the patient. This set of amendments will mean that patients and their doctors/medical professionals will make decisions about medical necessity under rules set up by their own local health plans and that local health plans will have the initial responsibility for applying such definitions to given therapies.

The proposed amendment provides that within a uniform national benefits package, each health care plan would set up guidelines for physician decisions about which specific items and services are necessary to care for their enrollees, using a statutory definition of what is "medically necessary and appropriate" care, and taking into account peer reviewed medical literature, opinions of medical specialty groups and evidence of general acceptance in the medical community. The amendment also assures patients, physicians and other interested persons an opportunity to obtain and comment on any treatment guideline or utilization protocol or general coverage determination.

Such an approach is more consistent with current practice, both in private insurance and to a certain extent within Medicare. National standards with local decision making preserve patients' rights and expand physicians' options.

Under this amendment:**1. An item or service is "medically necessary and appropriate" if ..**

- it is for treatment of a medical condition (as defined in the amendment)
- it is 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).
- it is medically appropriate for a specific patient (i.e., it can be reasonably be expected to provide a clinically meaningful benefit and is furnished in a setting commensurate with the patient's medical needs).

2. The amendment creates certain presumptions regarding safety and efficacy..

- drugs and biologics approved for marketing by FDA are deemed safe and effective if furnished for treatment of a medically accepted indication (as defined elsewhere in the comprehensive benefit package)
- a medical device cleared for marketing by FDA is deemed safe and effective when used consistent with labeling
- an item or service furnished consistent with a practice guideline developed by the AHCPR or certified under the Public Health Service Act is deemed safe and effective.

3. Patient care costs associated with delivery of investigational treatments are medically necessary and appropriate if the treatment is part of an approved research trial (as defined in the amendment).

AUG-11-1994 18:56

DON WIRSON

381 262 7541 P.02

EXPLANATION OF AMENDMENT TO S.2357

Under the Mitchell bill, S.2357, a health plan may furnish to its enrollees only those treatments—including investigational treatments—that are medically necessary or appropriate. This in itself is not bad, but in determining what is medically necessary or appropriate the health plan is bound by criteria, procedures, regulations, and guidelines to be issued by a presidentially appointed central body, the National Health Benefits Board. The board, assisted by a staff of federal employees, is empowered to decide on a national basis which treatments a health plan must exclude from the bill's benefits packages on the grounds of lack of medical necessity.

NHBB rules thus have the dangerous potential of limiting patient access to advances in medical care, including improvements in diagnostic tests and therapies, even though they are found safe and effective by the Food and Drug Administration. In short, the board has the power to ration health care. That is not the kind of health care reform that Americans want.

For example, an osteoporosis test may soon be approved by FDA that relies on urine analysis rather than bone marrow examination. Similarly, a new test for breast cancer is now being investigated as a supplement to, or alternative for, mammography. If the NHBB were to require board certification of all new diagnostic tests, even though FDA-approved, before allowing reimbursement, women who require evaluation for osteoporosis or breast cancer will be unable to receive them as part of the benefits package for an indeterminate period after they become generally available.

This is the situation that now undermines the quality of medical care for medicare patients, who are denied access to treatments with new medical devices, because of long delays between the time that the Food and Drug Administration approves an investigational new medical device as safe and effective, and the time that the Health Care Financing Administration decides that the device is no longer "experimental".

To remedy this situation, the amendments would establish criteria under which the health plan itself would be empowered to make this determination, thereby preventing the board from rationing health care. The amendments would preserve the requirement that a health plan provide only those treatments that are medically necessary or appropriate. The intent of the amendment is to have these decisions made locally in the best medical interests of the patient, not by a board in Washington, D.C.

Under the amendments, a health plan could find a treatment to be "medically necessary or appropriate" if—

AUG-11-1994 10:57

DON HIRSCH

301 267 7541 P.03

- it is for a medical condition, as defined in the amendment);
- it is safe and effective, i.e., there is sufficient evidence to demonstrate that the treatment can reasonably be expected to produce the intended health outcome or provide the intended information;
- it is medically appropriate for a specific patient, i.e., it can reasonably be expected to provide a clinically meaningful benefit and is furnished in a setting commensurate with the patient's medical needs.

FDA-approved drugs, biologics, and devices are considered safe and effective when used, in the case of drugs or biologics, for the treatment of a medically accepted indication or, in the case of medical devices, under the terms of their labeling.

In addition, a health plan is not required to exclude a treatment that fails to meet the definition of medically necessary or appropriate.

The amendment would allow the individual health plan to exclude particular treatments from a benefits package (but not the mandated benefit, itself) through the use of a generally applicable treatment guideline or similar statement, but only through a process that ensures that the statement will be fully considered by the plan's providers and patients before its adoption.

The bill authorizes the NHB to clarify and refine items and services in the benefit package, with a special rule for preventive services. The amendment would substitute a provision that, instead, allows the NHB to recommend that the Agency for Health Care Policy and Research (AHCPR) undertake development of practice guidelines. The purpose here is to avoid a duplication of functions by the NHB and the AHCPR, and to move what is essentially a medical and scientific activity from a politically appointed body to a scientific agency.

In this last regard, the amendment strikes a dangerously flawed provision of the bill that would allow the AHCPR to perform its work—developing statistical data, performing technology assessments, preparing clinical practice guidelines—at the request of, and paid by, private parties, including insurance companies. AHCPR priorities, and the work that AHCPR does, should not be determined by what private companies are willing to pay for.

1 improve, maintain, restore, or stabilize a health outcome
2 (as defined in subparagraph (5)(B)) or which, in the
3 absence of such intervention, could lead to an adverse
4 change in a health outcome.

Not def.
of med.
condition

5 **"(ii) ADVERSE CHANGE IN HEALTH OUTCOME**

6 **DEFINED.**—In subclause (i), an adverse change in a health
7 outcome occurs if there is a biological or psychological
8 decremental change in a health status.

what
about
medical condition?

9 **"(B) THE HEALTH CARE INTERVENTION IS SAFE AND**

10 **EFFECTIVE.** A health care intervention is safe and effective if
11 there is sufficient evidence to demonstrate that such health
12 care intervention can reasonably be expected to produce the
13 intended health outcome or provide the intended health
14 information.

15 **"(C) THE HEALTH CARE INTERVENTION IS INDICATED FOR THE**

16 **SPECIFIC ENROLLEE.**—A health care intervention is indicated for
17 a specific enrollee if, with respect to that enrollee's medical
18 condition, the health care intervention can reasonably be
19 expected to provide a clinically meaningful benefit and such
20 health care intervention is furnished in a setting
21 commensurate with the enrollee's needs.

22 **"(8) BASIS FOR DETERMINATIONS.—**

23 **"(A) IN GENERAL.**—In determining whether a health care
24 intervention is medically necessary or appropriate, a health
25 plan shall consider—

26 **"(i)** presumptions established by subparagraphs
27 **(B) through (D) of this subsection;**

1 **"(A) IN GENERAL.—A plan at its discretion may, but is not**
2 **required to, exclude items or services through the use of a**
3 **treatment guideline, utilization protocol or determination of**
4 **general applicability, provided the plan follows the procedures**
5 **of this paragraph and applies the criteria set forth in**
6 **subsection (b).**

7 **"(B) REQUIREMENTS.—In the event a health plan has**
8 **established a treatment guideline or utilization protocol, or**
9 **has made a determination of general applicability that a**
10 **particular health care intervention is not available to the**
11 **plan's enrollees as part of the comprehensive benefits package,**
12 **the guideline, protocol, or determination and a written**
13 **statement of the basis thereof—**

14 **"(i) shall be provided at least 60 days prior to its**
15 **effective date to the certifying authority and to each**
16 **affected provider with which the plan has a contract;**

17 **"(ii) shall be provided upon request, within 30**
18 **days to any interested party;**

19 **"(iii) shall be revised as soon as practicable after**
20 **new evidence of the type described in subparagraph**
21 **(b)(3)(A) becomes available, but in no event shall a plan's**
22 **guideline, utilization protocol or determination remain**
23 **in effect for more than 1 year after the development of**
24 **new evidence without reevaluation and republication,**
25 **pursuant to this subparagraph, of the determination,**
26 **guideline, or protocol and a written statement of the**
27 **basis thereof, and**

- 1 "(ii) published peer-reviewed medical literature;
2 "(iii) opinions of medical specialty groups;
3 "(iv) evidence of general acceptance in the medical
4 community; and
5 "(v) recommendations of the Board pursuant to
6 this section.

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

13 "(C) **FDA-APPROVED DEVICES.**—A medical device that has
14 been cleared for marketing by the Food and Drug
15 Administration is deemed safe and effective when used for the
16 conditions, purposes or uses prescribed, recommended, or
17 suggested in the labeling of the device.

18 "(D) **PRACTICE GUIDELINES.**—A health care intervention
19 furnished to an enrollee consistent with a practice guideline
20 developed or certified by the Agency for Health Care Policy
21 and Research under section 912 of the Public Health Service
22 Act is deemed to be safe and effective, but the omission of an
23 item or procedure from a practice guideline does not give rise
24 to a presumption that an item or procedure is not safe and
25 effective.

26 "(4) **DETERMINATIONS OF GENERAL APPLICABILITY.**—

1 program (as defined by the Secretary) or research trials approved by
2 the Secretary. A research trial is deemed to be approved for
3 purposes of this paragraph if such trial is approved by one or more
4 of the National Institutes of Health, the Food and Drug
5 Administration (through an investigational new drug exemption
6 pursuant to 21 U.S.C. 355 or an investigational device exemption
7 pursuant to 21 U.S.C. 360j(g)), the Department of Veterans Affairs,
8 the Department of Defense, or a qualified nongovernmental research
9 entity as defined in guidelines issued by one or more of the National
10 Institutes of Health, including guidelines for cancer center support
11 grants designated by the National Cancer Institute."

4. Section 1213(a)(9) is renumbered as subsection "(c)". (renumbering
succeeding subsections, paragraphs, subparagraphs and clauses accordingly), and
inserting the following after "SERVICES.--" and before "(A) Parity."

1 "The Board shall promulgate such regulations or guidelines as may
2 be necessary to clarify the mental illness and substance abuse
3 services under paragraph 1202(a)(5)."

5. Section 1213(a) is amended to read as follows:

1 "(a) RECOMMENDATIONS FOR PRACTICE GUIDELINES.--

2 "(1) IN GENERAL.--The Board may recommend that the Agency
3 for Health Care Policy and Research undertake the development of a
4 practice guideline if the Board determines that health plans need
5 guidance for determination of coverage decisions for a health care
6 intervention.

7 "(2) PETITION FOR GUIDELINE.--Health plans, providers, or
8 citizens may petition the Agency for Health Care Policy and
9 Research to request the development of a guideline.

1 "(iv) shall reflect due consideration of comments
2 the plan may receive from providers and other interested
3 persons.

4 "(C) **ADDITIONAL REQUIREMENTS.**—Copies of all treatment
5 guidelines, utilization protocols, and determinations of general
6 applicability, and a description of the process for providers to
7 comment on such guidelines, protocols and determinations
8 and revisions thereto, shall be supplied to each provider
9 contracting with the plan to be a participating provider.

10 "(5) **HEALTH CARE INTERVENTION AND HEALTH OUTCOME**
11 **DEFINED.**—For purposes of this section:

12 "(A) The term "health care intervention" means any item
13 or service provided, with respect to a specific indication, to
14 diagnose, improve, maintain, restore, or stabilize a health
15 outcome or to prevent or mitigate an adverse change in a
16 health outcome.

17 "(B) The term "health outcome" means an outcome that
18 affects the length or quality of an enrollee's life. Improved
19 quality of life includes ability to perform activities of daily
20 living, ability to work, relief from discomfort or pain,
21 alleviation of fatigue, and improved cognitive, social, or
22 emotional functioning and well-being."

See pp 1-2
How
different
from (b)
(2)(1) etc?

3. Item (13) of section 1203, defining "qualified investigational treatment",
is amended to read as follows:

1 "(18) **QUALIFIED INVESTIGATIONAL TREATMENT.**—The term
2 "qualified investigational treatment" means an investigational
3 treatment that is part of a peer-reviewed and approved research

1 **"(3) GUIDELINE PRIORITIES. The Agency for Health Care Policy**
2 **and Research must consider all petitions under paragraph (2) as well**
3 **as recommendations of the Board in determining its priorities."**

6. *Section 1213(b) is amended to read as follows:*

1 **"(b) INTERIM COVERAGE RECOMMENDATIONS.—**

2 **"(1) In the absence of a relevant practice guideline or other**
3 **presumptions pursuant to paragraph 1202(b)(3), and taking into**
4 **account that the dissemination of new health care interventions**
5 **should be broad enough to allow for accurate assessments of their**
6 **safety and effectiveness, the Board may apply the criteria set forth**
7 **in subsection 1202(b) to issue a coverage recommendation for plans**
8 **if the Board determines that a health care intervention:**

9 **"(A) raises exceptionally significant issues of safety and**
10 **effectiveness;**

11 **"(B) on the basis of information received from health**
12 **plans is, or is likely to be, the subject of conflicting**
13 **determinations by health plans with respect to findings of**
14 **medical necessity or appropriateness; and**

15 **"(C) is used or is contemplated for use for a significant**
16 **number of enrollees.**

17 **"(2) Interim coverage recommendations shall be published**
18 **for notice and comment pursuant to the Administrative Procedure**
19 **Act [5 U.S.C. 553], shall be based on application of the criteria set**
20 **forth in section 21202(b) and may include:**

21 **"(A) interim guidelines, including recommendations**
22 **that plans include or exclude a health care intervention,**

From:

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Number of Pages:

3

Date:

8/13/94-11:48:05 AM

Subject:

BENEFITS ARGUMENTS

Notes:

August 13, 1994

TO: Jennifer Klein
FROM: Linda Bergthold
RE: Your question on benefits

You asked me to research the arguments that could be made regarding the thirty percent of plans that would offer richer benefits than what the Mitchell legislation proposes. I sent a message around to some of our actuaries and benefits consultants and received a few responses. I am sure you have already thought of most of these ideas, but let me summarize them:

1. We cannot afford to cover one hundred percent of the possible benefits for everyone. If we could, we would not be having the current debate. You have to draw the line somewhere. The question is, where do you draw the line and is it fair? And to whom is it fair? Is the seventieth percentile fair? And what would a person lose if their plan was "richer" than the basic or standard plan?

2. When we talk about "benefits", we actually roll two concepts into one: 1) the types of services that will be reimbursed; and 2) the levels of cost sharing that will be required. Most benefit packages, across the spectrum, include approximately the same "basic" services. That is, hospitalization, physician, lab, outpatient, etc. (See the charts I will fax you to accompany this memo.) The services that are covered by fewer than 50% of plans tend to be hospice, home health care, alcohol or drug rehab, and various types of preventive benefits.

3. Mitchell's plan covers sixteen categories of services, which will expand access for most Americans over what they currently have. It will establish a floor that is not only basic, but actually expands existing coverage.

4. Most of the variation in FEHBP plans, therefore, is not so much in the type of services that are offered but in the amount of deductibles and coinsurance -- the cost sharing -- that will be required. Thirty percent of plans could require slightly higher deductibles or coinsurance than current levels. That might mean a \$300 or \$400 deductible for the fee for service plan instead of a \$200 deductible.

5. The important point to make about increases in cost sharing is that consumers will have a CHOICE whether or not they want to pay more or not. Now, if an employer decides to change the deductibles, the employee has no recourse. In reform, the employer MUST offer a choice of plans with a choice of cost sharing options. We find that employees willingly go into managed care plans, at lower cost sharing levels, when offered a choice.

6. Many of the richest plans are collectively bargained plans. These plans are protected under reform. They cannot be changed until the plan is due for re-negotiation. Therefore, employees who have coverage under these plans will NOT lose their benefits. They will actually continue to have a higher level of benefits than other working Americans during the transition.

7. The trend in benefits over the past few years has been for employers to consistently reduce the level of services covered while increasing the cost sharing for the employee. It is important that we set a floor below which no package can sink. (Do you remember that Paul Simon song, "One Man's Ceiling is Another Man's Floor?")We must keep the level of benefits from falling any further, while ensuring that the most important services, e.g. primary care and prevention, are covered fully.

I hope this helps. By the way, our actuaries have been helping both House and Senate staffers work out the details of the mechanism by which abortion payments could be separately pooled, if that becomes a compromise approach. Please let me know if you need more details on that. I can put you in touch with the key people who have done that for some of our private sector clients.

From:

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Number of Pages:

6

Date:

8/15/94-10:25:57 AM

Subject:

DURENBERGER AMENDMENT MEMO

Notes:

**THIS REPLACES THE DRAFT I SENT YOU YESTERDAY. I JUST SENT THIS
TO LITTMAN.**

August 15, 1994

TO: Drew Littman
Chief of Staff to Senator Barbara Boxer

FROM: Linda Bergthold, Ph.D.

RE: **Medically Necessary/Appropriate Amendment**

I understand that Senator Durenberger will be introducing an amendment to the Mitchell language on Medical Necessity and benefits. From the materials I received, it seems he has several major goals: 1) He wants health plans and practitioners to have maximum flexibility to make decisions at the local level, but he still wants some uniformity and consistency; and 2) He wants to avoid setting up a new bureaucracy that would be costly and possibly prevent new treatments from being covered in a timely way.

Unfortunately, the language he proposes would accomplish the opposite of his intentions. I urge Senator Boxer to reject this amendment and support Mitchell's simpler, less prescriptive approach to these definitions. I find it odd that a Republican would want to tie the hands of private health plans, while Democrats seek to provide the market with maximum flexibility!

1.) ISSUE: WHETHER TO USE 'AND' OR 'OR' IN LINKING THE TERMS NECESSITY AND APPROPRIATENESS.

Although they use "or" in the amendment language, "and" appears in some of the other material. It is an important distinction that deserves emphasis. Linking the terms "medically necessary" and "appropriate" with "and" instead of "or" would mean that every health plan would have to cover not only services defined as medically necessary, but also services defined as appropriate, a far vaguer term with no case law to define its proper application. This would hold plans to an impossibly broad standard of coverage. It would also virtually eliminate the possibility of covering abortions (which would have to meet dual tests of "necessity" as well as "appropriateness"), something which Senator Boxer certainly would not support.

SOLUTION: Apply the phrase "medically necessary OR appropriate" in statute. That would allow health plans flexibility to use either the more commonly understood and defined "necessity" or apply the newer term "appropriate" to certain services which are not truly medical; i.e. prevention, rehabilitation, etc.

2.) ISSUE: WHETHER TO DEFINE THESE TERMS OR CRITERIA IN STATUTE.

Trying to define "medically necessary or appropriate" in statute or even establishing criteria in statute will almost surely result in language that makes it even harder for plans and practitioners to make good decisions. There are dozens of definitions of "medical necessity" in the marketplace and little consensus among practitioners as to which definitions are best. These definitions need and deserve sustained examination and debate, away from the political arena.

SOLUTION: Simply introduce the terms in statute (i.e. health plans may cover services that are medically necessary or appropriate). Leave the criteria development to the National Health Board, DHHS, or some other independent body. This approach should be generally supported by most Republicans, and it is part of Dole's bill as well as the mainstream's proposal.

3. ISSUE: PROBLEMS WITH SOME TERMS IN DURENBERGER'S PROPOSED DEFINITIONS

There are dozens of time bombs within these proposed definitions. The language that Susan Foote proposes is based on Dr. David Eddy's work, which originally came from the Jackson Hole group into Cooper-Breaux, then into Chafee's legislation and now into Durenberger's amendments on the Senate side. I expect Eddy will write you directly; however, I can assure you that the current version of his language does not accomplish what he had intended it to do. Here are some examples:

a. "safe and effective" - some treatments may be safe but not effective; does effective take into account "cost-effective"? Safe and effective compared to what? No treatment? Other alternatives? What is "safe"? Almost nothing we do in medicine is completely safe. A literal interpretation of this would mean almost nothing could be covered.

b. **“clinically meaningful benefit:”** --in what context? who in the world knows what that means? Very subjective and vague.

c. **“maintain, restore or stabilize a health outcome...”**
Although I personally believe that any definition should include maintenance as well as restorative outcomes, in practical terms, it means that plans would be required to cover treatment for all chronic conditions, including non-medical, social services (another consequence of the broader definition of “medical” in the other section). The Mitchell plan is currently priced by CBO as an “acute care” plan. If this amendment were passed, it is possible that this language could add billions to the cost of the bill.

d. The basis for determinations in (3)(A) (ii-iv) (**peer review, specialty opinion, etc.**) relies on “garden variety” medicine, not best practices. As you know, there is tremendous variety in the practice of medicine; this provision regresses medical practice to the mean, not to a higher standard of excellence and quality.

e. The definition of **“health outcome”** is incredibly broad. This would definition would have the effect of requiring plans to cover every headache, every visit to a psychotherapist, every cosmetic surgery treatment prescribed. Wouldn't we all have improved well being if we could have new bodies? The breadth of this definition would not be so troublesome if there were some provision for making determinations on the basis of cost effectiveness. However, there is no such provision in Mitchell, nor is there likely to be for political reasons i.e. fear of appearing to ration care.

4.) ISSUE: WHO SHOULD DETERMINE THE CRITERIA?

There are several answers to this question: 1) an independent national board or commission; 2) the Secretary of HHS or her designate (AHCPR?); 3) states; 4) health plans 5) each practitioner. While many providers would argue for leaving it entirely to plans and practitioners, the legal atmosphere is becoming increasingly contentious over this issue, and many providers would like a little guidance. Some states have begun to establish criteria. However, there is little rational support for the establishment of 50 different sets of criteria. Just look at Medicaid. It is far from a consistent program.

Clinton's original plan scared the Republicans (and some Democrats) by the power it gave to an independent national board. The Mitchell proposal retains a national board, but contrary to the Durenberger materials, it does not allow the Board to make determinations about individual treatments and procedures. It only allows the Board to establish criteria (e.g. the terminology Durenberger wishes to insert into statute) so that health plans can make the individual treatment decisions. The only controversial language in Mitchell would be in Section 1211 where it mentions (b) Determining Medical Necessity or Appropriateness, and gives the Board authority to establish "regulations or guidelines to be used in determining whether an item or service...is medically necessary or appropriate." It is the language of "item or service" that implies specific treatments.

SOLUTION: 1.) Create an independent commission, as I believe you support, but locate it within an existing agency for reasons of cost effectiveness and less bureaucracy. The Dole proposal allows the Secretary of HHS to designate the commission members within HHS. Allowing the President and the Congress to appoint members, and giving them a limited term, would provide greater accountability.

2.) Let the commission set up criteria by which plans may determine coverage and exclusions. Do not bind plans to mandatory guidelines. There will be considerable compliance simply from the fact that national guidelines are issued. And plans will have some protection in the courts for their decisions if they have followed criteria set up by the national board. I believe this solution would also have some bipartisan support. Durenberger's language in 1202(b) that says "a health plan may, but is not required to, exclude..." is not bad.

5. ISSUE: HOW SHOULD EXPERIMENTAL/INVESTIGATIONAL TREATMENTS BE DEFINED AND COVERED?

Giving authority to the Secretary or one of the other agencies to define what is a "qualified investigational treatment?" is fine, but neither Mitchell nor Durenberger's language is clear about who has access to these trials and what aspects of patient care are covered. Should the plan cover investigational devices themselves, even if the research trial already covers them? What about transportation for the enrollee to the center

which is doing the trial? What about transportation for the family? motels? meals? What happens if the enrollee is denied access to the trial, etc. etc.

SOLUTION: Clarify what portions of patient care will be covered and how enrollees will have access to these services. David Eddy can speak to how to do this.

6. ISSUE: WHETHER TO USE 'SERVICES' OR 'BENEFITS'

It's not clear to me why the term 'service' is not suitable. The word 'benefit' encompasses a broader category of meaning in the real world -- health benefits mean the covered services, the providers and the cost sharing attached to that coverage. The important thing about specifying categories of service coverage, not specific treatments for specific conditions, is that it is an approach that we already use. HMOs provide services within broad categories of mandated services specified in the HMO Act of 1973.

Please feel free to call me if you have further questions. I have a Washington D.C. phone and voice mail where you can leave messages (202-778-7830 - Fax: 202-463-8006). I will be in Santa Cruz, California this week. You can reach me there as well: 408-462-1334.

If it would be helpful, I will re-write the Mitchell language, incorporating the suggestions from Durenberger where they are "appropriate," and leaving what I think is good in Mitchell as it is.

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Date:

8/15/94-8:12:45 AM

Subject:

untitled

Notes:

August 15, 1994

TO: JENNIFER KLEIN
FROM; LINDA BERGTHOLD
RE: MED NEC AMENDMENT

The amendment and memo I sent you yesterday re. medical necessity is DURENBERGER's amendment, not Boxer's. I misunderstood. She was asked to sign onto it, and I will be revising my memo to send to Drew Littman right now. The arguments still stand, but the politics of my response will be different.