

## 1 SEC. 1128. INVESTIGATIONAL TREATMENTS.

2 (a) COVERAGE.—Subject to subsections (b) and (c),  
3 the items and services described in this section are—

- 4 (1) qualifying investigational treatments; and  
5 (2) routine medical costs associated with the  
6 delivery of a qualifying investigational treatment.

7 (b) DISCRETION OF SPONSOR.—A HSA plan sponsor  
8 may provide coverage for a qualifying investigational  
9 treatment at the discretion of the sponsor.

10 (c) ROUTINE MEDICAL COSTS.—If a HSA plan spon-  
11 sor elects under subsection (b) to provide coverage for a  
12 qualifying investigational treatment, the sponsor shall pro-  
13 vide coverage for the routine medical costs associated with  
14 the delivery of the investigational treatment. If such rou-  
15 tine medical costs include an item or service that is de-  
16 scribed in any other section of this part, then any limita-  
17 tion, deductible, cost sharing requirement, or provision re-  
18 lating to an out-of-pocket limit on cost sharing that other-  
19 wise would apply to the item or service shall apply even  
20 though the item or service is a part of routine medical  
21 costs described in this section.

22 (d) EFFECT OF QUALIFYING TREATMENT ON OTHER  
23 COVERAGE.—The decision by a HSA plan sponsor to  
24 cover or not to cover a qualifying investigational treatment  
25 may not affect the coverage provided by the sponsor to,  
26 or the limitations or cost sharing requirements imposed

1 by the sponsor on, an eligible individual with respect to  
2 an item or service that is described in any other section  
3 of this part, if such item or service—

4 (1) would have been medically necessary or ap-  
5 propriate for the individual even if the individual  
6 were not receiving (or had not received) an inves-  
7 tigational treatment (regardless of whether the in-  
8 vestigational treatment is a qualifying investigational  
9 treatment); or

10 (2) is medically necessary or appropriate for the  
11 individual solely because the individual is receiving  
12 or (or has received) a qualifying investigational  
13 treatment.

14 (e) NO COVERAGE FOR ITEMS REQUIRED SOLELY  
15 BECAUSE OF NONQUALIFYING TREATMENTS.—The com-  
16 prehensive benefit package does not include an item or  
17 service that is medically necessary or appropriate for an  
18 individual solely because the individual is receiving or (or  
19 has received) an investigational treatment that is not a  
20 qualifying investigational treatment.

21 (f) DEFINITIONS.—For purposes of this subtitle:

22 (1) APPROVED RESEARCH TRIAL.—The term  
23 “approved research trial” means—

24 (A) a research trial approved by the Sec-  
25 retary of Health and Human Services, the Di-

delete  
^

(through an investigational  
new drug exemption)

3

5  
1 rector of the National Institutes of Health, the  
2 Commissioner of the Food and Drug Adminis-  
3 tration, the Secretary of Veterans Affairs, the  
4 Secretary of Defense, or a qualified non-  
5 governmental research entity as defined in  
6 guidelines of the National Institutes of Health;  
7 or

8 (B) a peer-reviewed and approved research  
9 program, as defined by the Secretary of Health  
10 and Human Services, conducted for the primary  
11 purpose of determining whether or not a treat-  
12 ment is safe, efficacious, or having any other  
13 characteristic of a treatment which must be  
14 demonstrated in order for the treatment to be  
15 medically necessary or appropriate.

16 (2) INVESTIGATIONAL TREATMENT.—The term  
17 "investigational treatment" means an agent, device,  
18 treatment, or procedure the effectiveness of which  
19 has not been determined.

→ What about  
treatment  
investigational  
new drugs?

20 (3) QUALIFYING INVESTIGATIONAL TREAT-  
21 MENT.—The term "qualifying investigational treat-  
22 ment" means an investigational treatment that is  
23 under clinical investigation as part of an approved  
24 research trial.

1           (4) ROUTINE MEDICAL COSTS.—The term “rou-  
2       tine medical costs”, when used with respect to a  
3       qualifying investigational treatment, means the cost  
4       of health services required to provide the investiga-  
5       tional treatment according to the design of the ap-  
6       proved research trial of which the treatment is a  
7       part. Such term does not include costs—

8                   (A) normally paid for by other funding  
9       sources (as defined by the Board);

10                  (B) of any nonhealth services that might  
11       be required to provide the investigational treat-  
12       ment; or

13                  (C) of managing the approved research  
14       trial.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
ASSISTANT SECRETARY FOR PLANNING AND EVALUATION  
OFFICE OF HEALTH POLICY



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Number of Pages (Including Cover): 3

Comments:

Here is how Cooper handles Treatment INDs per our discussion yesterday. It seems like a clean way to do it.

113

1 (A) APPROVED DRUGS, BIOLOGICALS, AND  
2 MEDICAL DEVICES.—

3 (i) DRUGS.—A drug that has been  
4 found to be safe and effective under sec-  
5 tion 505 of the Federal Food, Drug, and  
6 Cosmetic Act is deemed to meet the re-  
7 quirements of paragraphs (1)(B) and  
8 (1)(C) (relating to not investigational and  
9 safety and effectiveness).

10 (ii) BIOLOGICALS.—A biological that  
11 has been found to be safe and effective  
12 under section 351 of the Public Health  
13 Service Act is deemed to meet the require-  
14 ments of paragraphs (1)(B) and (1)(C)  
15 (relating to not investigational and safety  
16 and effectiveness).

17 (iii) MEDICAL DEVICES.—A medical  
18 device that is marketed after the provision  
19 of a notice under section 510(k) of the  
20 Federal Food, Drug, and Cosmetic Act or  
21 that has an application for premarket ap-  
22 proval approved under section 515 of such  
23 Act is deemed to meet the requirements of  
24 paragraphs (1)(B) and (1)(C) (relating to

114

1 not investigational and safety and effec-  
2 tiveness).

3 (B) OTHER DRUGS, BIOLOGICALS, AND DE-  
4 VICES.—A drug, biological, or medical device  
5 not described in subparagraph (A) shall be con-  
6 sidered to be investigational. Nothing shall pro-  
7 hibit a AHP from covering such drugs,  
8 biologicals, and medical devices, including treat-  
9 ment investigational new drugs (IND).

10 (C) OFF-LABEL USE.—An off-label use for  
11 a drug described in subparagraph (A)(i) is pre-  
12 sumed to meet the requirements of paragraph  
13 (1)(C) if the medical indication for which it is  
14 used is listed in one of the following 3 compen-  
15 dia: the American Hospital Formulary Service-  
16 Drug Information, the American Medical Asso-  
17 ciation Drug Evaluations, and the United  
18 States Pharmacopeia-Drug Information.

19 (4) COVERAGE OF INVESTIGATIONAL TREAT-  
20 MENTS IN APPROVED RESEARCH TRIALS.—

21 (A) IN GENERAL.—Coverage of the routine  
22 medical costs (as defined in subparagraph (C))  
23 associated with the delivery of investigational  
24 treatments (as defined in subparagraph (B))  
25 shall be considered to be medically appropriate

Prepared: 3/30/94

PROPOSED STATUTORY LANGUAGE

Proposed additions to the Act are indicated by underscoring, and suggested deletions are set off by brackets. All section and page references are to S. 1775, the version of the Health Security Act introduced by Sen. Moynihan on November 22, 1993.

1. Definition of Academic Health Center

Title III -- Public Health Initiatives

Subtitle B -- Academic Health Centers

Sec. 3101(a); pp. 548-49

(1) ACADEMIC HEALTH CENTER. -- For purposes of this subtitle, the term "academic health center" means an entity that either

-- (A) (i) operates a school of medicine or osteopathic medicine, as defined in section 799 of the Public Health Service Act;

[(B)] (ii) operates, or is affiliated with, one or more other types of schools or programs described in such section, or with one or more schools of nursing (as defined in section 853 of such Act); and

[(C)] (iii) operates, or is affiliated with, one or more teaching hospitals[.] or

(B) is a National Cancer Institute-designated freestanding cancer center or a children's medical center as presently excluded from the Medicare Prospective Payment System, as defined in sections 1886(d)(1)(B)(v) and (iii), respectively.

of the Social Security Act, or other provider of specialized care as designated by the Secretary of Health and Human Services..

(2) TEACHING HOSPITAL. -- For purposes of this subtitle, the term "teaching hospital" means a hospital that operates an approved physician training program (as defined in section 3011(b)).

(3) QUALIFIED CENTER OR HOSPITAL. -- For purposes of this subtitle:

(A) The term "qualified academic health center" means an academic health center that operates a teaching hospital, or an entity that is an academic health center pursuant to subsection (c)(1)(B).

(B) The term "qualified teaching hospital" means any teaching hospital other than a teaching hospital that is operated by an academic health center.

(4) ELIGIBLE INSTITUTION. -- For purposes of this subtitle, the term "eligible institution," with respect to a calendar year, means a qualified academic health center, or a qualified teaching hospital, that submits to the Secretary a written request in accordance with section 3102.

## 2. Access

### Title I -- Health Care Security

#### Subtitle E -- Health Plans

Sec. 1402; p. 228

(d) REQUIREMENTS FOR PLANS OFFERING LOWER COST SHARING. --

Each health plan that offers enrollees the lower cost sharing schedule referred to in section 1131 --

(1) shall apply such schedule to all items and services in the comprehensive benefit package;

(2) shall offer enrollees the opportunity to obtain coverage for out-of-network items and services (as described in subsection (f)(2), including the opportunity to obtain coverage for treatment at a cancer center designated by the National Cancer Institute pursuant to sections 411-14 of the Public Health Service Act; and

(3) notwithstanding section 1403, in the case of an enrollee who obtains coverage for such items and services, may charge an alternative premium to take into account such coverage[.], provided, however, that a health plan shall not charge such an alternative premium with respect to coverage for treatment provided at a National Cancer Institute-designated cancer center.

**Subtitle B -- Benefits****Sec. 1132; pp. 79-80**

(a) IN GENERAL. -- The lower cost sharing schedule referred to in section 1131 that is offered by a health plan -- . . .

(4) shall require payment of coinsurance for an out-of-network item or service (as defined in section 1402(f)) in an amount that is a percentage (determined under subsection (b)) of the applicable payment rate for the item or service established under section 1322(c), but only if the item or service is subject to coinsurance under the higher cost sharing schedule described in section 1133; provided, however, that the lower cost sharing schedule shall not require payment of coinsurance for treatment at a cancer center designated by the National Cancer Institute pursuant to sections 411-14 of the Public Health Service Act.

**Sec. 1134; p. 85**

(c) OUT-OF-NETWORK ITEMS AND SERVICES. -- With respect to an out-of-network item or service (as defined in section 1402(f)(2)), the combination cost sharing schedule that is offered by a health plan --

(1) shall require an individual and a family to incur expenses before the plan provides benefits for the item or service in accordance with the deductibles under the higher cost sharing schedule described in section 1133;

(2) shall prohibit payment of any copayment; and

(3) shall require payment of coinsurance in accordance with such schedule.

(4) Notwithstanding the foregoing, with respect to an out-of-network item or service provided at a cancer center designated by the National Cancer Institute pursuant to sections 411-14 of the Public Health Service Act, the cost sharing schedule applicable to in-network items and services under subsection (b) shall apply.

**Title III -- Public Health Initiatives**

**Subtitle B -- Academic Health Centers**

**Sec. 3131; pp. 557-58**

(a) CONTRACTS WITH HEALTH PLANS. -- Regional and corporate health alliances under this Act shall ensure that, in accordance with subsection (b), the health plans of the alliances enter into sufficient contracts with [eligible] academic health centers (as defined in section 3101(c)(1)), including centers in other states, to ensure that enrollees in regional or corporate alliance health plans, as appropriate, receive the specialized treatment expertise of such centers, subject to such exceptions as the Secretary may provide. With respect to the treatment of cancer, such contracts shall include arrangements with cancer centers designated by the National Cancer Institute pursuant to sections 411-14 of the Public Health Service Act. Such arrangements shall ensure that enrollees of a health plan may

elect treatment at the National Cancer Institute-designated cancer center(s) under contract with the plan.

(b) UTILIZATION OF SPECIALIZED TREATMENT EXPERTISE OF CENTERS. -- Contracts under subsection (a) between [eligible] academic health centers and health plans are in accordance with this subsection if the contracts provide that, with respect to health conditions within the specialized treatment expertise of the centers, health plans will refer medical cases involving such conditions to the centers.

**Title I -- Health Care Security**

**Subtitle C -- State Responsibilities**

**Sec. 1203(a); pp. 102-103**

(2) ACCESS TO PLANS USING CENTERS OF EXCELLENCE. -- Each participating State [may] shall require, as a condition of entering into a contract with a regional alliance under section 1321, that one or more certified health plans provide access (through reimbursement, contracts, or otherwise) of enrolled individuals to services of centers of excellence (as designated by the State in accordance with rules promulgated by the Secretary)[.], which shall include cancer centers designated by the National Cancer Institute pursuant to sections 411-14 of the Public Health Service Act.

**Subtitle D -- Health Alliances****Sec. 1382; pp. 199-200**

(b) OFFERING OF PLANS BY ALLIANCES. -- A corporate alliance shall include among its health plan offerings for any eligible enrollee at least 3 health plans to enrollees, of which the alliance must offer --

(1) at least one fee-for-service plan (as defined in section 1322(b)(2)); and

(2) at least two health plans that are not fee-for-service plans, including a plan that meets the requirements of section 1203(e)(2).

### 3. Clinical Trials

#### Title I -- Health Care Security

#### Subtitle B -- Benefits

Sec. 1128; pp. 73-75

(a) COVERAGE. -- [Subject to subsection (b), the] ~~The~~ items and services described in this subsection are qualifying investigational treatments that are administered for a life-threatening disease, disorder, or other health condition (as defined by the National Health Board). A health plan shall cover an investigational treatment as described in subsection (b).

[(b) DISCRETION OF PLAN. -- A health plan may cover an investigational treatment described in subsection (a) at its discretion.]

[(c)] ~~(b)~~ [ROUTINE] PATIENT CARE DURING INVESTIGATIONAL TREATMENTS. -- The comprehensive benefit package includes an item or service described in any other section of this part, subject to the limitations and cost sharing requirements applicable to the item or service, when the item or service is provided to an individual in the course of an investigational treatment, if --

(1) the treatment is a qualifying investigational treatment; and

(2) the item or service [would have been provided to the individual even if the individual were not receiving the investigational treatment.] is required to provide patient care pursuant to the design of the treatment.

[(d)] (c) DEFINITIONS. -- For purposes of this subtitle:

(1) QUALIFYING INVESTIGATIONAL TREATMENT. -- the term

"qualifying investigational treatment" means a treatment --

(A) the effectiveness of which has not been determined; and

(B) that is under clinical investigation as part of an approved research trial.

(2) APPROVED RESEARCH TRIAL. -- The term "approved research trial" means --

(A) a research trial approved by the Secretary of Health, and Human Services, the [Director] Directors 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 a qualified nongovernmental research entity as defined in guidelines of the National Institutes of Health, including guidelines for National Cancer Institute-designated cancer center support grants pursuant to section 414 of the Public Health Service Act; or

(B) a peer-reviewed and approved research program, as defined by the Secretary of

Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.

#### 4. Reimbursement/Payment

##### Title I -- Health Care Security

##### Subtitle D -- Health Alliances

Sec. 1322; pp. 133-34

#### (c) ESTABLISHMENT OF FEE-FOR-SERVICE SCHEDULE. --

(1) IN GENERAL. -- Except in the case of regional alliances of a State that has established a Statewide fee schedule under paragraph (3), each regional alliance shall establish a fee schedule setting forth the payment rates applicable to services furnished during a year to individuals enrolled in fee-for-service plans (or to services furnished under the fee-for-service component of any regional alliance health plan) for use by regional alliance health plans under section 1406(c) and corporate alliance health plans providing services subject to the schedule in the regional alliance area[.]; provided, however, that, with respect to services furnished by freestanding cancer centers (as defined in section 1886(d)(1)(B)(v) of the Social Security Act), the Secretary of Health and Human Services shall determine a rate-setting methodology for such hospitals as described in section 1886(b) of the Social Security Act. . . .

(3) USE OF STATEWIDE SCHEDULE.-- At the option of a State, the State may establish its own statewide fee schedule which shall apply to all fee-for-service plans offered by regional alliances and corporate alliances in the State instead of alliance-specific schedules established under paragraph (1);

provided, however, that, with respect to services furnished by freestanding cancer centers, the Secretary shall determine an appropriate rate-setting methodology as described in paragraph (1). . . .

(d) PROSPECTIVE BUDGETING OF FEE-FOR-SERVICE.-- . . . .

(3) USE OF PROSPECTIVE BUDGETING EXCLUSIVE.-- If a regional alliance or State establishes the fee schedule for fee-for-service plans on the basis of prospective budgeting under this subsection, payment for all services provided by fee-for-service plans in the alliance or State shall be determined on such basis; provided, however, that payments to freestanding cancer centers shall be made as described in subsection (c)(1).

5. Medicare Limits on High-Cost Hospital Medical Staffs

Title IV -- Medicare and Medicaid

Subtitle B -- Savings in Medicare Program

Sec. 4114; pp. 769-70

"SEC. 1849. (a) SERVICES SUBJECT TO REDUCTION.--

"(4) For physicians' services furnished by medical staffs at National Cancer Institute-designated freestanding cancer centers and children's medical centers excluded from the Prospective Payment System, as defined in sections 1886(d)(1)(B)(v) and (iii), respectively, the Secretary shall develop an alternative payment methodology in lieu of the methodology set out in this section."

225-4952

① Investigational ⇒

→ Want to pay for  
routine care associated  
w/ clinical trials

② - Cancer hospitals want  
patients to self-refer  
/ NIH designated

③ Cancer hospitals want  
to be AMCs.

1. eligible for payments
2. eligible for King

5-5349

J. Klepner's office

## Investigational Treatment Issues

### 1. Rather than our language on "routine care" --

( ) Patient Care During Investigational Treatments. --  
The items and services described in this section are the items and services described in any other section of this part, subject to the limitations and cost sharing requirements applicable to the item of service, when the item of service is provided to an individual in the course of an investigational treatment, if --

(1) the treatment is a qualifying investigational treatment; and

(2) the item or service is required according to the design of the trial, except those items or services normally paid for by other funding sources (as defined by the National Health Board) such as the cost of the investigational agent or device itself; the costs of any non-health services that might be required for a person to receive the treatment; and the costs of managing the research.

- We are in the process of costing out this language. I do not think it will add estimable cost. I will get back to you as soon as it is done.
- As I mentioned on the phone, I don't think there is a need to limit health plan discretion to cover only investigational treatments for life-threatening diseases. In addition, you might want to consider giving plans discretion to cover investigational treatments that are not part of an approved research trial.

### 2. Also, the groups like the following language from Section 1302 of Cooper:

A drug, biological, or medical device not described in [ ] shall be considered to be investigational. Nothing shall prohibit a health plan from covering such drugs, biologicals, and medical devices, including treatment investigational new drugs (IND).

FROM

(FRI) 03. 04' 94 14:41/ST. 14:40/NO. 3560500519 P 1

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MESSAGE:

**RATIONALE FOR AMENDMENTS TO § 1128 OF THE HEALTH SECURITY ACT  
(Investigational Treatments)**

1. Discretion of Plan

Section 1128(b) of the Administration's proposal states that a health plan may cover investigational treatments "at its discretion." Although this language was intended to give plans discretion only with respect to the actual investigational agent or device, it was interpreted by many as applying to patient care costs as well. The amendment retains the original language but adds language indicating that there is no discretion with regard to coverage of patient care costs for qualifying clinical trials.

2. Coverage According to Trial Design

The current § 1128(c)(2) states that patient care costs will be covered for items or services that "would have been provided to the individual even if the individual were not receiving the investigational treatment." While not intended to restrict reimbursement, this language could be read to deny payment for some items or services based on retrospective review when compared to care given in a noninvestigational setting. Moreover, in many cases it would be difficult or impossible to determine precisely what services would have been rendered in a hypothetical non-trial situation. This uncertainty could lead to numerous denied claims and endless disputes between cancer patients and their insurers. The amendment clarifies that coverage extends to all patient care items and services "required according to the design of the trial."

3. Deletion of Reference to "Routine" Care

Consistent with the previous amendment, the confusing reference to "routine" care should be deleted. For example, as drafted, § 1128 could be interpreted to give plans discretion as to coverage of investigational procedures, since procedures such as surgery might not be viewed as "routine." The intent of the legislation is to cover those categories of patient care costs likely to be incurred by individuals enrolled in clinical trials. Thus, in order to ensure reimbursement for investigational procedures which are under study in a qualifying clinical trial and to otherwise eliminate ambiguities, the reference to "routine" care is deleted and replaced by "patient" care.

**SEC. 1128. INVESTIGATIONAL TREATMENTS**

(a) **COVERAGE.**--Subject to subsection (b), the items and services described in this subsection are qualifying investigational treatments that are administered for a life-threatening disease, disorder, or other health condition (as defined by the National Health Board).

(b) **DISCRETION OF PLAN.**--A health plan may cover an investigational treatment described in subsection (a) at its discretion *and shall cover the patient care provided pursuant to investigational treatment as described in subsection (c).*

(c) **~~ROUTINE~~ PATIENT CARE DURING INVESTIGATIONAL TREATMENTS.**  
--The comprehensive benefit package includes an item or service described in any other section of this part, subject to the limitations and cost sharing requirements applicable to the item or service, when the item or service is provided to an individual in the course of an investigational treatment, if--

(1) the treatment is a qualifying investigational treatment;  
and

(2) ~~the item or service would have been provided to the individual even if the individual were not receiving the investigational treatment~~ *is required according to the design of the trial, except those items or services normally paid for by other funding sources (as defined by the National Health Board) such as the cost of the investigational agent or device itself; the costs of any nonhealth services that might be required for a*

*person to receive the treatment; and the costs of managing the research. These items or services may be covered in addition to patient care at the discretion of the plan.*

(d) DEFINITIONS.--For purposes of this subtitle:

(1) QUALIFYING INVESTIGATIONAL TREATMENT.--The term "qualifying investigational treatment" means a treatment--

(A) the effectiveness of which has not been determined; and

(B) that is under clinical investigation as part of an approved research trial.

(2) APPROVED RESEARCH TRIAL.--The term "approved research trial" means--

(A) a research trial approved by the Secretary of Health and Human Services, the Director 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 non-governmental research entity as defined in guidelines of the National Institutes of Health;  
or

(B) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.

**FOX, BENNETT & TURNER**

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MEMORANDUM

Via Telecopy

DATE: February 8, 1994  
TO: Cheryl Austein  
FROM: Sam Turner *SW*  
RE: Kerrey Hearing on Clinical Cancer Research

I am attaching a "Pink Sheet" article on the hearing on clinical cancer research held by Senator Kerrey last week. The hearing was another vivid example of the confusion in the oncology community over whether the Administration's plan covers patient care costs in clinical trials. You will note that even the President-Elect of the American Society of Clinical Oncology (ASCO), Karen Antman, seems to have gotten it wrong in her response to a question (although her written remarks were on target).

I understand that Phil Lee indicated at the hearing the willingness of the Administration to amend its language to address coverage concerns, but unfortunately those comments were not recorded by the Pink Sheet. Instead, the Pink Sheet states that Dr. Lee would refer these issues to the Administration's proposed National Health Board -- a result which we would not favor.

Thanks for your attention to this issue, and remember my offer to provide specific legislative language if you think it would be helpful.

SDT/dbc  
Attachment

cc: Jennifer Klein ✓



# NIH CLINICAL CANCER RESEARCH STUDY SECTION

dedicated specifically to reviewing grant requests for "clinical" — as opposed to "basic" — cancer research would address the "crisis in clinical research," Senators Inouye (D-Hawaii) and Mack (R-Fla.) write in a Jan. 18 "Dear Colleague" letter to fellow senators. The letter maintains that the system for reviewing grant applications "unfortunately has developed in a manner which appears to favor basic over clinical research proposals." The senators assert that research grants are often "reviewed by basic or preclinical researchers who may not appreciate the importance of clinical research proposals."

- ¶ Inouye and Mack plan to forward their recommendation to National Institutes of Health Director Harold Varmus. A draft of the letter notes Varmus' previously expressed commitment to re-examine the NIH peer review system and urges the director to "complete your evaluation as soon as possible."

The need for the specific study section was mentioned by American Society of Clinical Oncology President-elect Karen Antman, MD, at a Jan. 31 "Forum on Clinical Research" sponsored by Sen. Kerrey (D-Neb.). The hearing was held to examine the effects the Clinton Administration health reform proposal would have on clinical research.

- ¶ Antman argued that the Clinton bill could jeopardize the development of new treatments "if the bill report language is finally that third party insurers 'may' cover the patient care costs of evaluating new therapies." Antman asserted that "insurance should cover the patient care costs of FDA or NIH approved research studies." The Clinton bill language allows individual health plans to cover investigational treatments at their discretion ("The Pink Sheet" Nov. 8, 1993, p. 7).

- ¶ University of California-Los Angeles Breast Center Director Susan Love, MD, agreed with Antman, saying that payors would actually save money by covering such costs because clinical trials of unproven treatments would eliminate therapies that were ineffective or unsafe.

- ¶ Antman warned against assuming that pharmaceutical companies would pick up the tab for all investigational treatment costs. Bristol-Myers Squibb Senior VP-Clinical R&D Steven Carter, MD, concurred, asking policy makers not to create "disincentives" for patients to enroll in trials.

► New health care legislation should encourage research not only in the clinical stage, but "at each stage of the process," Carter said. He mentioned BMS' BR96-DOX as an illustration of the difficulty of bringing a cancer drug into the clinic. Development of the doxorubicin immunoconjugate began in 1984, Carter said, and the company invested "tens of millions of dollars" to construct a manufacturing plant for the production of clinical supplies. Phase I trials with approximately 30 subjects began in January at the University of Alabama-Birmingham and MD Anderson Cancer Center in Houston.

- ¶ Sen. Kerrey emphasized the need for a consistent mechanism to determine who would pay for ancillary patient care during investigational treatment. The private sector, the government and the individual should each understand how much they have to pay, he said. The mechanism would give "an opportunity for the citizen to enter into an accountable environment" when making decisions about enrolling in clinical trials. HHS Assistant Secretary Philip Lee, MD, suggested that the National Health Board established under the Clinton bill could be a vehicle to address the issue.

# INVESTIGATIONAL

| HSA                                                                                                                                          | COOPER                                                                                                                                                                                                                   | COMMENT                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| Health plan may cover an investigational treatment - effectiveness not determined and part of an approved trial                              | Nothing shall preclude a plan from covering investigational drugs, biologicals, and medical devices, including treatment INDs                                                                                            | Cooper more specific by including Treatment INDs<br><br>What happens to a drug like a treatment IND that is received outside of an approved trial? |
| Routine care covered if the item or service would have been provided even if the individual were not receiving the investigational treatment | Routine medical 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 Commission) | Cooper broader by letting the trial define routine costs, rather than the plan. Probably more user friendly to providers and patients.             |
| Medicare investigational treatments                                                                                                          |                                                                                                                                                                                                                          | Silent - potential inconsistency                                                                                                                   |
|                                                                                                                                              |                                                                                                                                                                                                                          |                                                                                                                                                    |

Ask Cheryl --  
what is the issue?

**Question:**

A recent article has highlighted that health plans make "arbitrary and capricious" decisions when it comes to the coverage of experimental treatments. How will the President's plan address this?

**Answer:**

The Health Security Act will improve this situation in a number of ways:

- First, the Act specifies that routine medical costs for patients enrolled in approved research trials are covered. Routine medical costs are defined as those that would normally have been provided even if the patient were not receiving the investigational treatment.
- Second, the Act allows health plans to cover the experimental treatment itself for certain life threatening conditions.
- Third, the Act significantly improves the information available to individuals and plans in order to both enroll in clinical trials and to better judge whether an experimental treatment may be warranted.

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**Fox, Bennett & Turner  
750 17th Street, N.W.  
Suite 1100  
Washington, DC 20006**

PLEASE DELIVER TO:

NAME: Jennifer Klein  
FIRM: The White House  
CITY/STATE: Washington, DC  
RECEIVING TELECOPIER: 456-2078  
FROM: Sam Turner  
DATE OF TRANSMITTAL: January 26, 1994  
TIME OF TRANSMITTAL: 1:39pm  
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(including cover sheet): 19  
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FOX, BENNETT & TURNER  
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SUITE 1100  
WASHINGTON, D. C. 20006

SAMUEL D. TURNER

TELEPHONE: 202-776-2300  
TELECOPIER: 202-776-2330MEMORANDUMVia Telecopy

DATE: January 26, 1994  
TO: Jennifer Klein  
FROM: Sam Turner *ST*  
RE: Materials for Tomorrow's Meeting

In connection with our meeting tomorrow at 11:00 a.m.  
at HHS, I am forwarding the following information:

- A memorandum to Jeff Levi and Derek Hodel at AIDS Action regarding perceived problems with the Administration's language on clinical trials;
- A briefing paper on "Clinical Research and Health Care Reform";
- An article by Lee Mortenson, a consultant to cancer interests, criticizing the Administration's plan; and

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- 2 -

- A legal opinion by a Washington lawyer representing various health interests concluding (erroneously, in my view) that the Administration's plan will not require coverage of participation in clinical trials.

As Cheryl has probably told you, the people I represent, including the American Society of Clinical Oncology (ASCO), appreciate that the Administration intended to fully cover patient care costs in clinical trials. We would like to work with the Administration to clarify any perceived problems with the legislative language.

SDT/dbc  
Attachments

cc: Cheryl Austein  
Stacey Beckhardt, ASCO Government Relations Director

## FOX, BENNETT &amp; TURNER

760 17TH STREET, N. W.

SUITE 1100

WASHINGTON, D. C. 20006

SAMUEL D. TURNER

TELEPHONE 202-778-4300  
TELECOPIER 202-778-2310MEMORANDUMVia Telecopy and Hand-Delivered

DATE: January 24, 1994  
TO: Jeff Levi  
Derek Hodel  
FROM: Sam Turner *ST*  
RE: Coverage of Clinical Trials in Health Care Reform

We were in contact with you last year concerning use of standards developed by the American Society of Clinical Oncology (ASCO) to require coverage of patient care costs in clinical trials. After consulting with you as well as NIAID officials, we were able to persuade several health care reform plans, including the Administration's, to incorporate the ASCO standards.

The Administration's legislative language, however, is open to criticism when compared to that in the Cooper and Chafee plans. There are two perceived problems with the Administration's language.

First, some confusion has been engendered by the Administration's statement that "[a] health plan may cover an investigational treatment ... at its discretion." This appears intended to tell plans

## FOX, BENNETT &amp; TURNER

- 2 -

that they can choose to pay for treatment IND drugs, but need not do so. Some have read it to give plans discretion whether to cover patient care costs in connection with qualified investigational treatments despite the fact that these costs are specifically referenced as part of the "comprehensive benefit package." The Cooper-Chafee language is clearer, stating that "[n]othing shall prohibit" plans from covering unapproved products like treatment IND drugs.

Second, the Administration plan covers patient care costs in approved clinical trials only if "the item or service would have been provided to the individual even if the individual were not receiving the investigational treatment." Researchers have expressed concern that this language might invite third-party payors to restrict payment for patient care costs in a variety of ways, including declining to pay for additional diagnostic tests required by the trial. In contrast, the Cooper-Chafee approach is to define covered costs as those "required to provide treatment according to the design of the trial."

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- 3 -

I understand that you have been invited to participate in a forum sponsored February 4-5 by the Association of Community Cancer Centers (ACCC). Since Lee Mortenson is one of the vocal critics of the Administration's plan (see enclosed article), I wanted to share our view of the provisions relating to clinical trials. The position of ASCO and other clients we work with in the cancer patient community is that the Administration's treatment of the issue is well-intentioned, if imperfect. We are working with Administration officials to alert them to the perceived problems and to persuade them to accept reasonable modifications. We would like your support in that effort.

To sort out the various concerns, we have prepared and enclosed a short briefing paper on "Clinical Research in Health Care Reform." Also enclosed are copies of the Administration's and Cooper's language relating to this issue.

If you have time to discuss this, preferably before your ACCC presentation, we would appreciate it. Give me a call at your convenience.

SDT/dbc  
Attachments

## CLINICAL RESEARCH AND HEALTH CARE REFORM

For people with cancer, AIDS and certain other life-threatening diseases, treatment in the context of clinical trials often provides the best available patient care. Cancer and AIDS advocacy groups have insisted on coverage of patient care costs in clinical trials as an essential goal of health care reform.

### Cost of Clinical Trials

In order to obtain approval from the Food and Drug Administration (FDA) for new drugs or biologicals, sponsors must offer evidence of safety and effectiveness derived from clinical trials. The cost of these trials can be divided into three main components:

- The investigational agent -- In most instances, the cost of the investigational agent will be borne by the sponsor. FDA regulations preclude charging for products which have not yet received FDA approval. One exception to this rule is investigational new drug (IND) products, for which the sponsor may seek cost recovery.
- Data collection and analysis -- The cost of collecting and analyzing data relating to safety and effectiveness is covered by a research grant, which usually comes from a pharmaceutical sponsor or from an agency of the federal government, such as one of the National Institutes of Health (NIH).

- 2 -

- Patient care -- Most research grants do not cover the cost of patient care provided to those enrolled in trials. Third-party payors frequently deny coverage for these costs, which in the case of hospital and physician charges can be substantial, on the ground that they are "experimental" or "investigational." It is these denials of payment for patient care costs that have inhibited patient accrual to clinical trials and prompted a demand for reform.

#### Health Care Reform Proposals

Virtually every major health care reform proposal (with a notable exception of the McDermott single payer plan) has addressed the problem of reimbursement for patient care costs in clinical trials. The primary criterion for coverage is that a trial be approved by one of a number of specified government agencies, including NIH and FDA.

- Administration plan -- The Health Security Act, Section 1128, provides that, in the case of an approved research trial, "[t]he comprehensive benefit package includes an item or service ... when the item or service is provided to an individual in the course of an investigational treatment, if ... the item or service would have

- 3 -

been provided to the individual even if the individual were not receiving the investigational treatment." Thus, the Administration plan extends coverage to routine patient care costs incurred in the course of an approved clinical trial. A question remains as to whether this language would permit insurers to deny coverage for certain items or services on the theory that they exceed those which would have been received outside the investigational context, the most notable example of which might be extra diagnostic tests required by the trial design. The investigational agent itself may be covered at the discretion of the health plan.

- Cooper & Chafee plans -- Both the Conservative Democratic Forum plan, also known as Cooper-Grandy, and the Senate Republican plan authored by Senator Chafee feature the same language on coverage of clinical trials. Like the Administration's bill, the Cooper and Chafee plans permit coverage of the investigational agent at the discretion of the health plan. With respect to patient care costs, Cooper and Chafee deem medically appropriate, and thus covered, all "routine medical costs," which are defined to mean

- 4 -

"the cost of health services required to provide treatment according to the design of the trial." The Cooper and Chafee plans therefore make clear that any items or services, including diagnostic tests, which are required by the clinical trial protocol will be considered reimbursable.

#### Differences Among Plans

When a research trial has been approved by a qualified government agency or other entity with adequate peer-review processes, patient care costs should be fully reimbursable, even if the protocol requires more tests or other procedures than usual. In this manner, patients will be protected and medical knowledge advanced. The Cooper and Chafee plans clearly accomplish this result. The Clinton plan could be interpreted to achieve the same, but clarifying report language would be required. All three plans commendably reverse current practice by making patient care costs coverable in an approved clinical research trial.

#### Coverage of Investigational Agents

No plan mandates coverage of investigational agents . . . i.e., drugs, biologicals or other agents without initial FDA approval. Recent years, however, have witnessed the more widespread use of such products prior to their approval and

- 5 -

outside the context of an approved clinical trial. The most notable example of pre-approved distribution and usage is the treatment IND, widely used in AIDS therapies. Because the sponsor of a treatment IND is permitted to charge an amount reflecting cost recovery, patients receiving treatment IND products may have out-of-pocket expenses. Many experts, including the so-called Lasagna Committee, have recommended coverage of treatment IND products.<sup>1/</sup> Health care reform proposals should consider making coverage of treatment INDs and similarly situated products mandatory rather than discretionary because they may represent the best available treatment option for people with serious or life-threatening disease.

---

<sup>1/</sup> Final Report of the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS, August 15, 1990.

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The Journal of the Association of Community Cancer Centers

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*Oncology Issues* Fall 1993

## FROM THE EDITOR

## Clinical Research

by Lee E. Mortenson, D.P.A.

**N**ow you see it...zap, zoom, ugh...Now you don't. After a cursory look at the President's 240-page health care reform plan, you tend to breathe a sigh of relief! It says that the costs of care for patients on clinical trials are covered. It says there is even going to be a \$6 billion trust fund established for clinical research!

But, I've been living in Washington, D.C., for too long not to be suspicious. So, I sat down to grind through every page and paragraph. Guess what? Clinical trials in community cancer programs are dead meat under this proposal, and all the AmFAR AIDS research sites are history, too. Even university-based clinical trials may have a little difficulty, since the dean is now going to control the funding.

"What?" you ask, "But it says right here that routine costs of patients on clinical trials are covered!"

Yes, it does say that. But, if you read all the cross references, you find out that the routine costs are limited to no more than conventional management of the disease without a clinical trial. Right. So, let me make this clear: It costs you \$20,000 to treat a patient using conventional management, and the trial also requires \$10,000 in extra testing, plus data collection and drugs.

Well, we know the data collection and drugs are taken care of by the sponsor. But, the extra \$10,000 in tests? Are they covered by this comprehensive package? Nope!

Okay, so what happens now? Well, the \$6 billion kicks in. Whew! That was close! Right. Yeah, but if you read the cross references, it turns out that the Clinton plan zaps the academic health centers, and the \$6 billion all goes to the deans for their use to make up some of the money they are taking away from other stuff.

Careful now. Don't nod off. This is important. The Clinton plan asks: Why supplement the academic centers anymore? All those indigent patients are now going to be paying customers. So, zap, there goes their medical education supplement. Instead, the academic medical centers are going to get some share of this \$6 billion pie to make up for the costs of clinical trials not covered by the basic benefits.

So, zoom, we're back in the 1960s...with clinical research done only at university medical centers. Good-bye, community-based cancer and AIDS research programs. Hello again, two-hour drive to get on a clinical trial!

Ugh! So what happened here? Well, if you don't know much about research at NIH these days...if you are an old public health staffer...you probably missed the eighties and nineties in clinical research. You probably still think all research goes on in medical schools and don't know that north of 60 percent of all patients on NCI trials are entered by community investigators.

And all those cancer prevention trials...guess who is doing those? Opps. You don't know that cancer prevention trials on breast and prostate are being done at the community level where community institutions have access to these asymptomatic individuals and patients? My guess is that the members of the Health Care Task Force who wrote this section just didn't know better.

So, we need to discuss with Congress and the White House the way the money flows.

Here's my suggestion: Use the \$6 billion to supplement any unpaid treatments of patients on clinical trials...make it a voucher system or something...but how about we start a new tradition and have the funding be where the work is! ☐

1 (b) DISCRETION OF PLAN.—A health plan may offer  
2 education and training classes at its discretion.

3 (c) CONSTRUCTION.—This section shall not be con-  
4 strued to include or limit education or training that is pro-  
5 vided in the course of the delivery of health professional  
6 services (as defined in section 1112(c)).

CLINTON  
PLAN

7 SEC. 1128. INVESTIGATIONAL TREATMENTS.

8 (a) COVERAGE.—Subject to subsection (b), the items  
9 and services described in this subsection are qualifying in-  
10 vestigational treatments that are administered for a life-  
11 threatening disease, disorder, or other health condition (as  
12 defined by the National Health Board).

13 (b) DISCRETION OF PLAN.—A health plan may cover  
14 an investigational treatment described in subsection (a) at  
15 its discretion.

16 (c) ROUTINE CARE DURING INVESTIGATIONAL  
17 TREATMENTS.—The comprehensive benefit package in-  
18 cludes an item or service described in any other section  
19 of this part, subject to the limitations and cost sharing  
20 requirements applicable to the item or service, when the  
21 item or service is provided to an individual in the course  
22 of an investigational treatment, if—

23 (1) the treatment is a qualifying investigational  
24 treatment; and

1 (2) the item or service would have been pro-  
2 vided to the individual even if the individual were  
3 not receiving the investigational treatment.

4 (d) DEFINITIONS.—For purposes of this subtitle:

5 (1) QUALIFYING INVESTIGATIONAL TREAT-  
6 MENT.—The term “qualifying investigational treat-  
7 ment” means a treatment—

8 (A) the effectiveness of which has not been  
9 determined; and

10 (B) that is under clinical investigation as  
11 part of an approved research trial.

12 (2) APPROVED RESEARCH TRIAL.—The term  
13 “approved research trial” means—

14 (A) a research trial approved by the Sec-  
15 retary of Health and Human Services, the Di-  
16 rector of the National Institutes of Health, the  
17 Commissioner of the Food and Drug Adminis-  
18 tration, the Secretary of Veterans Affairs, the  
19 Secretary of Defense, or a qualified non-  
20 governmental research entity as defined in  
21 guidelines of the National Institutes of Health;  
22 or

23 (B) a peer-reviewed and approved research  
24 program, as defined by the Secretary of Health  
25 and Human Services, conducted for the primary

1 purpose of determining whether or not a treat-  
2 ment is safe, efficacious, or having any other  
3 characteristic of a treatment which must be  
4 demonstrated in order for the treatment to be  
5 medically necessary or appropriate.

### 6 PART 3—COST SHARING

#### 7 SEC. 1131. COST SHARING.

8 (a) IN GENERAL.—Each health plan shall offer to in-  
9 dividuals enrolled under the plan one of the following cost  
10 sharing schedules, which schedule shall be offered to all  
11 such enrollees:

12 (1) lower cost sharing (described in section  
13 1132);

14 (2) higher cost sharing (described in section  
15 1133); or

16 (3) combination cost sharing (described in sec-  
17 tion 1134).

#### 18 (b) COST SHARING FOR LOW-INCOME FAMILIES.—

19 For provisions relating to reducing cost sharing for certain  
20 low-income families, see section 1371.

#### 21 (c) DEDUCTIBLES, COST SHARING, AND OUT-OF- 22 POCKET LIMITS ON COST SHARING.—

23 (1) APPLICATION ON AN ANNUAL BASIS.—The  
24 deductibles and out-of-pocket limits on cost sharing  
25 for a year under the schedules referred to in sub-

COOPER  
PLAN

1 not investigational and safety and effec-  
2 tiveness).

3 (B) OTHER DRUGS, BIOLOGICALS, AND DE-  
4 VICES.—A drug, biological, or medical device  
5 not described in subparagraph (A) shall be con-  
6 sidered to be investigational. Nothing shall pro-  
7 hibit a AHP from covering such drugs,  
8 biologicals, and medical devices, including treat-  
9 ment investigational new drugs (IND).

10 (C) OFF-LABEL USE.—An off-label use for  
11 a drug described in subparagraph (A)(i) is pre-  
12 sumed to meet the requirements of paragraph  
13 (1)(C) if the medical indication for which it is  
14 used is listed in one of the following 3 compen-  
15 dia: the American Hospital Formulary Service-  
16 Drug Information, the American Medical Asso-  
17 ciation Drug Evaluations, and the United  
18 States Pharmacopeia-Drug Information.

19 (4) COVERAGE OF INVESTIGATIONAL TREAT-  
20 MENTS IN APPROVED RESEARCH TRIALS.—

21 (A) IN GENERAL.—Coverage of the routine  
22 medical costs (as defined in subparagraph (C))  
23 associated with the delivery of investigational  
24 treatments (as defined in subparagraph (B))  
25 shall be considered to be medically appropriate

1 only if the treatment is part of an approved  
2 search trial (as defined in subparagraph (D)).

3 (B) INVESTIGATIONAL TREATMENT DE-  
4 FINED.—In subparagraph (A), the term “inves-  
5 tigational treatment” means a treatment for  
6 which there is not sufficient evidence to deter-  
7 mine the health outcome of the treatment com-  
8 pared with the best available alternative treat-  
9 ment (or with no treatment if there is no alter-  
10 native treatment).

11 (C) ROUTINE MEDICAL COSTS DEFINED.—  
12 In subparagraph (A), the term “routine medical  
13 costs” means the cost of health services re-  
14 quired to provide treatment according to the de-  
15 sign of the trial, except those costs normally  
16 paid for by other funding sources (as defined by  
17 the Commission). Such costs do not include the  
18 cost of the investigational agent, devices or pro-  
19 cedures themselves, the costs of any nonhealth  
20 services that might be required for a person to  
21 receive the treatment, or the costs of managing  
22 the research.

23 (D) APPROVED RESEARCH TRIAL DE-  
24 FINED.—In subparagraph (A), the term “ap-  
25 proved research trial” means a trial—

1 (i) conducted for the primary purpose  
2 of determining the safety, effectiveness, ef-  
3 ficacy, or health outcomes of a treatment,  
4 compared with the best available alter-  
5 native treatment, and

6 (ii) approved by the Secretary of  
7 Health and Human Services.

8 A trial is deemed to be approved under clause  
9 (ii) if it is approved by the National Institutes  
10 of Health, the Food and Drug Administration  
11 (through an investigational new drug exemp-  
12 tion), the Department of Veterans Affairs, or  
13 by a qualified nongovernmental research entity  
14 (as identified in guidelines issued by one or  
15 more of the National Institutes of Health).

16 (5) DOCUMENTATION.—

17 (A) IN GENERAL.—Each AHP is respon-  
18 sible for maintaining documentary evidence sup-  
19 porting the plan's decisions to cover or to deny  
20 coverage based on the criteria specified in this  
21 subsection.

22 (B) REFERENCES.—The evidence that may  
23 be used in making such coverage decisions  
24 includes—

25 (i) published peer-reviewed literature,

- 1 (ii) opinions of medical specialty  
2 groups and other medical experts,  
3 (iii) evidence of general acceptance by  
4 the medical community, and  
5 (iv) recommendations of the Commis-  
6 sion.

7 (C) DISCLOSURE.—Each AHP shall dis-  
8 close to its members, in a manner specified by  
9 the Commission, its coverage decisions and  
10 must submit information on such decisions to  
11 the Benefits, Evaluations, and Data Standards  
12 Board.

13 (6) TREATMENT AND HEALTH OUTCOME DE-  
14 FINED.—In this subsection (and subsection (a)(2)):

15 (A) IN GENERAL.—The term “treatment”  
16 means any health care intervention undertaken,  
17 with respect to a specific indication, to improve,  
18 maintain, or stabilize a health outcome or to  
19 prevent or mitigate an adverse change in a  
20 health outcome.

21 (B) HEALTH OUTCOME DEFINED.—The  
22 term “health outcome” means an outcome that  
23 affects the length or quality of an enrollee’s life.

FROM

(THU) 01. 27' 94 11:05/ST. 11:04/NO. 3560500228 P 1

# FOX, BENNETT & TURNER

750 17TH STREET N.W. SUITE 1100 WASHINGTON, D.C. 20006

T R A N S M I T T A I

**NAME:** Jennifer Klein

**FIRM:** White House

**RECEIVING TELECOPIER:** 456-2878

**FROM:** Sam Turner

**DATE:** January 27, 1994

**TIME:** 9:56am

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**IF TRANSMISSION PROBLEMS OCCUR, CALL:**

**REGARDING:** This was left out of the package I faxed to you yesterday in regards to the meeting with Cheryl at 11:00 a.m. today.

**TELEPHONE 202.778.2300**

**FAX 202.778.2330**

HOGAN &amp; HARTSON

**MEMORANDUM**

TO: Dr. Robert W. Day, President  
National Coalition for Cancer Research

FROM: Stephan E. Lawton  
Anne M. Dellinger

DATE: December 8, 1993

RE: Coverage Under the Health Security Act for Participation  
in Investigational New Drug (IND) Trials

-----

You have requested our opinion as to whether the Clinton Administration's Health Security Act (H.R. 3600) would require health plans to cover the cost of an enrollee's participation in research on investigational new drugs. We conclude that it would not.

Since the Act requires that all plans offer every enrollee the comprehensive benefit package 1/, the question is whether participation in IND trials is one of the benefits guaranteed by the package. Title I, Subtitle B, Part 1 of the Act provides that "[t]he comprehensive benefits package shall consist of the following items and services." 2/ Part 2 lists the benefits and defines them. The

---

1/ See Title I, Subtitle E, Part 1, Sec. 1402(b), providing that no plan may terminate, restrict or limit coverage for the comprehensive benefit package for any reason, and Title I, Subtitle F, Part 1, Sec. 1503(a)(1), requiring the National Health Board to "take such steps as may be necessary to assure that the comprehensive benefit package is available on a uniform national basis to all eligible individuals".

2/ Title I, Subtitle B, Part 1, Sec. 1101(a)

## HOGAN &amp; HARTSON

last item in the list of benefits 3/ is "investigational treatments", which are described in section 1128. Section 1128 states that a plan may "at its discretion" cover investigational treatments. Thus, coverage is not guaranteed. Each patient's coverage for the investigational portion of treatment will depend on the decision of her or his plan's administrator. If a plan decides to cover the treatment, it also sets the cost-sharing requirement for the patient. 4/

In order for a plan to be able to cover investigational treatment, should it wish to do so, the treatment must meet two conditions. First, it must be for "a life-threatening disease, disorder, or other health condition (as defined by the National Health Board)." 5/ Second, the treatment must be a "qualifying investigational treatment", which means it must be one whose effectiveness is not yet determined, but is under clinical investigation as part of an approved research trial (defined in the Act). 6/

The Act contains only one guarantee for patients participating in investigational treatments. It requires plans to pay for any "item or service" provided during the investigational treatment that "would have been provided to the individual even if the individual were not receiving the investigational treatment." 7/

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3/ Title I, Subtitle B, Part 1, Sec. 1101(a)(18).

4/ Title I, Subtitle B, Part 3, Sec. 1135(a).

5/ Title I, Subtitle B, Part 2, Sec. 1128(a).

6/ Title I, Subtitle B, Part 2, Sec. 1128(d).

7/ Title I, Subtitle B, Part 2, Sec. 1128(c)(2).

## FOX, BENNETT &amp; TURNER

750 17TH STREET, N. W.

SUITE 1100

WASHINGTON, D. C. 20006

TELEPHONE: 202-776-2300  
TELECOMPER: 202-776-2330

SAMUEL D. TURNER

MEMORANDUMVia Telecopy

DATE: January 28, 1994  
TO: Jennifer Klein  
FROM: Sam Turner *SWI*  
RE: Possible Revisions to Administration's Legislative Language

As promised, I am confirming in writing the issues we raised yesterday with respect to matters requiring clarification in Section 1128 ("Investigational Treatments") of the Health Security Act:

1. In general, the language in subsection (a) is confusing and seems to serve no purpose other than to indicate that the section applies only to treatments for life-threatening diseases or other conditions approved by the Board.
2. Because "investigational treatment" is not defined, the statement in subsection (b) to the effect that a plan may cover such treatments "at its discretion" has led many people to believe that plans have discretion whether to permit their

## FOX, BENNETT &amp; TURNER

- 2 -

- enrollees to participate in clinical trials. There needs to be some clarification that this phrase refers to unapproved drugs, biologicals, devices or other items and not to associated patient care costs.
3. Again with respect to "investigational treatment," because their coverage is left to the discretion of plans, there is no automatic coverage for products like treatment IND drugs which, though unapproved by FDA, may nevertheless result in charges to patients, and thus out-of-pocket expenses potentially reimbursable by insurance. In addition, since these quasi-approved products are likely to be received outside the context of an approved clinical trial, patients may not be eligible for reimbursement for associated patient care costs.
4. One problem with both the Administration plan and the Cooper and Chafee approach is that investigational procedures are considered not covered. As we discussed, noncoverage of investigational treatments is not a problem with respect to drugs, biologicals or devices to the extent that FDA regulations foreclose payment for them by patients. However, failure to reimburse surgeons and other physicians for investigational

FROM

(FRI) 01.28'94 18:14/ST. 18:14/NO. 3560500253 P 1

# FOX, BENNETT & TURNER

750 17TH STREET N.W. SUITE 1100 WASHINGTON, D.C. 20006

T R A N S M I T T A L

**NAME:** Jennifer Klein

**FIRM:** The White House

**RECEIVING TELECOPIER:** 456-2878

**FROM:** Sam Turner

**DATE:** January 28, 1994

**TIME:** 5:01pm

**TOTAL NUMBER OF PAGES:** 5  
(INCLUDING COVER SHEET)

**IF TRANSMISSION PROBLEMS OCCUR, CALL:**

---

**REGARDING:**

TELEPHONE 202.778.2300

FAX 202.778.2330

## FOX, BENNETT &amp; TURNER

- 3 -

procedures could prove a significant deterrent. In addition, because many investigational procedures are pursued because of their promise of cost-effectiveness, denial of coverage may cost the system more in both the short and the long run. (Although Cooper and Chafee are explicit in making coverage of investigational procedures discretionary with the plans, the same discretion is implied in the Administration's language.)

5. Our primary concern is that the Administration's language, by limiting patient care costs to items or services that would have been provided "even if the individual were not receiving the investigational treatment," may give third-party payors an excuse to restrict payment for such costs. Much preferable is the language found in the Cooper and Chafee plans to the effect that routine medical costs are defined to include "the cost of health services required to provide treatment according to the design of the trial." This will ensure not only that the trial is uninhibited by reimbursement restrictions but also that patients incur no additional out-of-pocket expense.

Intention?

## FOX, BENNETT &amp; TURNER

- 4 -

6. Our final concern does not relate to the language of the Administration's plan but is rather a product of the decision not to wrap Medicare into the overall system. It is not appropriate that Medicare beneficiaries be excluded from participation in approved clinical trials, which is current Medicare policy. About half of the cancers diagnosed each year are in Medicare beneficiaries, and the systematic exclusion of them from clinical trials because of reimbursement restrictions raises issues both of discrimination and of unreliable data. Just as women and minorities must have full access to clinical trials, the safety and effectiveness of products - particularly products with the toxic potential of anticancer drugs -- should be supported with age-specific data.

Move invest.  
treatment  
lang. outside  
of COP.

Thanks very much for your time. I appreciate the fact that you are not interested in receiving draft legislative language, but if possible, it might be a good idea for you to share any new drafts with us. We look forward to working with you.

SDT/dbc

cc: Cheryl Austein  
Lisa Simpson

TO: Cheryl Austein  
FROM: Jennifer Klein  
RE: Miscellaneous Benefits Issues  
DATE: 12/26/93

1. Investigational treatment issues

I reviewed our investigational treatment provision against the language in the Cooper bill. Our bill language accurately reflects our policy, and it is definitely more restrictive than Cooper.

Nothing in our bill prevents NIH from paying cost sharing for routine care provided during investigational treatments.

2. Nothing in our bill prevents a provider from refusing to provide a service if an individual refuses to pay a copayment.

3. Nothing in our bill prevents a state from buying down cost sharing for its citizens, as long as the state does not use funds provided under the Act. (See section 1205.)

4. I am still looking into the "alternative medicine" issue that we discussed. However, my initial view is that a fee-for-service plan may not refuse to reimburse a particular type of provider, as long as that provider is: (1) legally authorized by the state to perform that service in the state; and (2) the service is a service in the comprehensive benefit package.

5. Nothing in the bill prevents cost sharing incurred when using an HMO point-of-service option from applying to the annual out-of-pocket maximum.

## FOX, BENNETT &amp; TURNER

750 17TH STREET, N. W.  
SUITE 1100  
WASHINGTON, D. C. 20006

SAMUEL D. TURNER

TELEPHONE: 202-778-2300  
TELECOPIER: 202-778-2330

MEMORANDUMVia Telecopy

DATE: December 15, 1993  
TO: Cheryl Austein  
FROM: Sam Turner *ST*  
RE: Administration Language on Clinical Trials

As promised, I am faxing you some information on the relative merits of different approaches to coverage of clinical trials:

- First, in the Clinton plan, note in Section 1128(c)(2), coverage is available only if "the item or service would have been provided to the individual even if the individual were not receiving the investigational treatment."
- Second, in both the Cooper and Chafee plans, in contrast to the Clinton plan, coverage is provided "according to the design of the trial."
- Third, Lee Mortenson in a recent Oncology Issues, attacked the Clinton plan for this shortcoming.

FOX, BENNETT &amp; TURNER

- 2 -

- Fourth, on background, is an unpublished response to the Mortenson article, which we hope to have published in Oncology Issues.

As I told you, both clinical researchers and patients are very concerned about the language employed in the Administration bill. I hope we can work to resolve this discrepancy in a manner satisfactory to everyone. Call me when you want to discuss.

SDT/dbc  
Attachments

11

1 (b) DISCRETION OF PLAN.—A health plan may offer  
2 education and training classes at its discretion.

3 (c) CONSTRUCTION.—This section shall not be con-  
4 strued to include or limit education or training that is pro-  
5 vided in the course of the delivery of health professional  
6 services (as defined in section 1112(c)).

CLINTON  
PLAN

7 SEC. 1128. INVESTIGATIONAL TREATMENTS.

8 (a) COVERAGE.—Subject to subsection (b), the items  
9 and services described in this subsection are qualifying in-  
10 vestigational treatments that are administered for a life-  
11 threatening disease, disorder, or other health condition (as  
12 defined by the National Health Board).

13 (b) DISCRETION OF PLAN.—A health plan may cover  
14 an investigational treatment described in subsection (a) at  
15 its discretion.

16 (c) ROUTINE CARE DURING INVESTIGATIONAL  
17 TREATMENTS.—The comprehensive benefit package in-  
18 cludes an item or service described in any other section  
19 of this part, subject to the limitations and cost sharing  
20 requirements applicable to the item or service, when the  
21 item or service is provided to an individual in the course  
22 of an investigational treatment, if—

23 (1) the treatment is a qualifying investigational  
24 treatment; and

1 (2) the item or service would have been pro-  
2 vided to the individual even if the individual were  
3 not receiving the investigational treatment.

4 (d) DEFINITIONS.—For purposes of this subtitle:

5 (1) QUALIFYING INVESTIGATIONAL TREAT-  
6 MENT.—The term “qualifying investigational treat-  
7 ment” means a treatment—

8 (A) the effectiveness of which has not been  
9 determined; and

10 (B) that is under clinical investigation as  
11 part of an approved research trial.

12 (2) APPROVED RESEARCH TRIAL.—The term  
13 “approved research trial” means—

14 (A) a research trial approved by the Sec-  
15 retary of Health and Human Services, the Di-  
16 rector of the National Institutes of Health, the  
17 Commissioner of the Food and Drug Adminis-  
18 tration, the Secretary of Veterans Affairs, the  
19 Secretary of Defense, or a qualified non-  
20 governmental research entity as defined in  
21 guidelines of the National Institutes of Health;  
22 or

23 (B) a peer-reviewed and approved research  
24 program, as defined by the Secretary of Health  
25 and Human Services, conducted for the primary

purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.

### PART 3—COST SHARING

#### SEC. 1131. COST SHARING.

(a) IN GENERAL.—Each health plan shall offer to individuals enrolled under the plan one of the following cost sharing schedules, which schedule shall be offered to all such enrollees:

(1) lower cost sharing (described in section 1132);

(2) higher cost sharing (described in section 1133); or

(3) combination cost sharing (described in section 1134).

#### (b) COST SHARING FOR LOW-INCOME FAMILIES.—

For provisions relating to reducing cost sharing for certain low-income families, see section 1371.

#### (c) DEDUCTIBLES, COST SHARING, AND OUT-OF-POCKET LIMITS ON COST SHARING.—

(1) APPLICATION ON AN ANNUAL BASIS.—The deductibles and out-of-pocket limits on cost sharing for a year under the schedules referred to in sub-

1 not investigational and safety and effec-  
2 tiveness).

3 (B) OTHER DRUGS, BIOLOGICALS, AND DE-  
4 VICES.—A drug, biological, or medical device  
5 not described in subparagraph (A) shall be con-  
6 sidered to be investigational. Nothing shall pro-  
7 hibit a AHP from covering such drugs,  
8 biologicals, and medical devices, including treat-  
9 ment investigational new drugs (IND).

10 (C) OFF-LABEL USE.—An off-label use for  
11 a drug described in subparagraph (A)(i) is pre-  
12 sumed to meet the requirements of paragraph  
13 (1)(C) if the medical indication for which it is  
14 used is listed in one of the following 3 compen-  
15 dia: the American Hospital Formulary Service-  
16 Drug Information, the American Medical Asso-  
17 ciation Drug Evaluations, and the United  
18 States Pharmacopeia-Drug Information.

19 (4) COVERAGE OF INVESTIGATIONAL TREAT-  
20 MENTS IN APPROVED RESEARCH TRIALS.—

21 (A) IN GENERAL.—Coverage of the routine  
22 medical costs (as defined in subparagraph (C))  
23 associated with the delivery of investigational  
24 treatments (as defined in subparagraph (B))  
25 shall be considered to be medically appropriate

COOPER  
PLAN

1 only if the treatment is part of an approved re-  
2 search trial (as defined in subparagraph (D)).

3 (B) INVESTIGATIONAL TREATMENT DE-  
4 FINED.—In subparagraph (A), the term “inves-  
5 tigational treatment” means a treatment for  
6 which there is not sufficient evidence to deter-  
7 mine the health outcome of the treatment com-  
8 pared with the best available alternative treat-  
9 ment (or with no treatment if there is no alter-  
10 native treatment).

11 (C) ROUTINE MEDICAL COSTS DEFINED.—  
12 In subparagraph (A), the term “routine medical  
13 costs” means the cost of health services re-  
14 quired to provide treatment according to the de-  
15 sign of the trial, except those costs normally  
16 paid for by other funding sources (as defined by  
17 the Commission). Such costs do not include the  
18 cost of the investigational agent, devices [or pro-  
19 cedures themselves], the costs of any nonhealth  
20 services that might be required for a person to  
21 receive the treatment, or the costs of managing  
22 the research.

23 (D) APPROVED RESEARCH TRIAL DE-  
24 FINED.—In subparagraph (A), the term “ap-  
25 proved research trial” means a trial—

1 (i) conducted for the primary purpose  
2 of determining the safety, effectiveness, ef-  
3 ficacy, or health outcomes of a treatment,  
4 [compared with the best available alter-  
5 native treatment, and]

6 (ii) approved by the Secretary of  
7 Health and Human Services.

8 A trial is deemed to be approved under clause  
9 (ii) if it is approved by the National Institutes  
10 of Health, the Food and Drug Administration  
11 (through an investigational new drug exemp-  
12 tion), the Department of Veterans Affairs, or  
13 by a qualified nongovernmental research entity  
14 (as identified in guidelines issued by one or  
15 more of the National Institutes of Health).

16 (5) DOCUMENTATION.—

17 (A) IN GENERAL.—Each AHP is respon-  
18 sible for maintaining documentary evidence sup-  
19 porting the plan's decisions to cover or to deny  
20 coverage based on the criteria specified in this  
21 subsection.

22 (B) REFERENCES.—The evidence that may  
23 be used in making such coverage decisions  
24 includes—

25 (i) published peer-reviewed literature,

(ii) opinions of medical specialty groups and other medical experts,  
(iii) evidence of general acceptance by the medical community, and  
(iv) recommendations of the Commission.

(C) DISCLOSURE.—Each AHP shall disclose to its members, in a manner specified by the Commission, its coverage decisions and must submit information on such decisions to the Benefits, Evaluations, and Data Standards Board.

(6) TREATMENT AND HEALTH OUTCOME DEFINED.—In this subsection (and subsection (a)(2)):

(A) IN GENERAL.—The term “treatment” means any health care intervention undertaken, with respect to a specific indication, to improve, maintain, or stabilize a health outcome or to prevent or mitigate an adverse change in a health outcome.

(B) HEALTH OUTCOME DEFINED.—The term “health outcome” means an outcome that affects the length or quality of an enrollee’s life.

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## FROM THE EDITOR



## Clinical Research

by Lee E. Mortenson, D.P.A.

**N**ow you see it...zap, zoom, ugh...Now you don't. After a cursory look at the President's 240-page health care reform plan, you tend to breathe a sigh of relief! It says that the costs of care for patients on clinical trials are covered. It says there is even going to be a \$6 billion trust fund established for clinical research!

But, I've been living in Washington, D.C., for too long not to be suspicious. So, I sat down to grind through every page and paragraph. Guess what? Clinical trials in community cancer programs are dead meat under this proposal, and all the AmFAR AIDS research sites are history, too. Even university-based clinical trials may have a little difficulty, since the dean is now going to control the funding.

"What?" you ask, "But it says right here that routine costs of patients on clinical trials are covered!"

Yes, it does say that. But, if you read all the cross references, you find out that the routine costs are limited to *no more* than conventional management of the disease *without* a clinical trial. Right. So, let me make this clear: It costs you \$20,000 to treat a patient using conventional management, and the trial also requires \$10,000 in extra testing, plus data collection and drugs.

Well, we know the data collection and drugs are taken care of by the sponsor. But, the extra \$10,000 in tests? Are they covered by this comprehensive package? Nope!

Okay, so what happens now? Well, the \$6 billion kicks in. Whew! That was close! Right. Yeah, but if you read the cross references, it turns out that the Clinton plan zaps the academic health centers, and the \$6 billion all goes to the deans for their use to make up some of the money they are taking away from other stuff.

Careful now. Don't nod off. This is important. The Clinton plan asks: Why supplement the academic centers anymore? All those indigent patients are now going to be paying customers. So, zap, there goes their medical education supplement. Instead, the academic medical centers are going to get some share of this \$6 billion pie to make up for the costs of clinical trials not covered by the basic benefits.

So, zoom, we're back in the 1960s...with clinical research done only at university medical centers. Good-bye, community-based cancer and AIDS research programs. Hello again, two-hour drive to get on a clinical trial!

Ugh! So what happened here? Well, if you don't know much about research at NIH these days...if you are an old public health staffer...you probably missed the eighties and nineties in clinical research. You probably still think all research goes on in medical schools and don't know that north of 60 percent of all patients on NCI trials are entered by *community* investigators.

And all those cancer prevention trials...guess who is doing those? Opps. You don't know that cancer prevention trials on breast and prostate are being done at the community level where community institutions have access to these asymptomatic individuals and patients? My guess is that the members of the Health Care Task Force who wrote this section just didn't know better.

So, we need to discuss with Congress and the White House the way the money flows.

Here's my suggestion: Use the \$6 billion to supplement any unpaid treatments of patients on clinical trials...make it a voucher system or something...but how about we start a new tradition and have the *fund-ing be where the work is!* ☐

PRAISE REFORM? OR PASS THE AMMUNITION?

The fall 1993 installment of Oncology Issues offered an apparent contrast in possible responses to health care reform. On one page were the views of ACCC President Al Einstein, recognizing the need for reform, accepting its inevitability and outlining constructive steps which could be taken by the oncology community to take advantage of opportunities posed by the process. Literally on the reverse side of the page were the comments of Lee Mortenson as Editor and ACCC Executive Director. Dr. Mortenson's contribution was, to say the least, alarmist about the impact of health care reform.

I prefer the approach taken by Dr. Einstein. Initially, I cannot agree with Dr. Mortenson's interpretation of the President's plan. Rather than imposing cost limits on clinical trials, the plan makes clear that routine patient care costs in the context of approved trials are covered as part of the "comprehensive benefit package" if they would have been covered "even if the individual were not receiving the investigational treatment."

Admittedly, the coverage language is not as clear as one might like, nor is it as generous as the parallel provision found in the legislation introduced by Congressman Cooper and the Conservative Democratic Forum. The Cooper plan defines "routine medical costs" as "the cost of health services required to

- 2 -

provide treatment according to the design of the trial," ensuring that clinical trials will be supported to an extent rarely seen today even in the best of insurance plans.

Regardless of potential quibbles with the President's plan, the fact remains that it does make an obvious effort to provide coverage for the patient care costs. Health care reform has become not just one proposal, but a process involving the synthesis of four or more major bills. Undoubtedly, the final outcome will incorporate portions from each of them, and the task of those involved in oncology policy is to advocate the best possible version on key issues like clinical trial coverage.

Aside from areas still requiring improvement, the various health care reform proposals are notable for what they all accomplish. First, virtually all the plans adopt the liberal coverage provisions of the Rockefeller-Levin Medicare Cancer Coverage Improvement Act for unlabeled indications. Second, problems of insurance discrimination that have plagued our patients for years will almost certainly be eliminated, regardless of the final contours of the legislation. Thus, people with cancer will no longer be subjected to unfair preexisting condition limits or foreclosed from changing jobs or other life circumstances because of fear of losing their insurance.

- 3 -

Not only does Dr. Mortenson's discussion fail to credit the President's plan for these clear advances, but it also evokes an image of divisiveness and competition between academic and community treatment centers. If the truth be told, academic health centers are among those most at risk under the Clinton plan.<sup>1/</sup> Certainly most analysts believe that community hospitals are better positioned than their academic counterparts to survive in an intensely competitive new environment. Moreover, coverage for clinical trials should arguably improve the situation of community cancer centers without the crippling reductions in Medicare direct and indirect medical payments envisioned for teaching hospitals by the Administration.

Many questions remain about how patients will be able to choose their physicians, how physicians will be trained and reimbursed for their services and how academic medicine will survive. These are issues which should be of interest to anyone involved in oncology, whether they are in an academic or a community setting, whether they are solo practitioners or part of large practice groups and whether they reside in urban or rural geographical locations.

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<sup>1/</sup> Blumenthal D, Meyer GS. The future of the academic medical center under health care reform. N Engl J Med 1993;329:1812-14.

- 4 -

If we are to be successful in addressing these issues, we must be open to new approaches while seeking to conserve the best aspects of our current system. To be heard in the health care reform debate, our voices must be informed, reasonable and credible.

MEMORANDUM

TO: Dr. Robert W. Day, President  
National Coalition for Cancer Research

FROM: Stephan E. Lawton  
Anne M. Dellinger

DATE: December 8, 1993

RE: Coverage Under the Health Security Act for Participation  
in Investigational New Drug (IND) Trials

-----

You have requested our opinion as to whether the Clinton Administration's Health Security Act (H.R. 3600) would require health plans to cover the cost of an enrollee's participation in research on investigational new drugs. We conclude that it would not.

Since the Act requires that all plans offer every enrollee the comprehensive benefit package 1/, the question is whether participation in IND trials is one of the benefits guaranteed by the package. Title I, Subtitle B, Part 1 of the Act provides that "[t]he comprehensive benefits package shall consist of the following items and services." 2/ Part 2 lists the benefits and defines them. The

---

1/ See Title I, Subtitle E, Part 1, Sec. 1402(b), providing that no plan may terminate, restrict or limit coverage for the comprehensive benefit package for any reason, and Title I, Subtitle F, Part 1, Sec. 1503(a)(1), requiring the National Health Board to "take such steps as may be necessary to assure that the comprehensive benefit package is available on a uniform national basis to all eligible individuals".

2/ Title I, Subtitle B, Part 1, Sec. 1101(a)

last item in the list of benefits 3/ is "investigational treatments", which are described in section 1128. Section 1128 states that a plan may "at its discretion" cover investigational treatments. Thus, coverage is not guaranteed. Each patient's coverage for the investigational portion of treatment will depend on the decision of her or his plan's administrator. If a plan decides to cover the treatment, it also sets the cost-sharing requirement for the patient. 4/

In order for a plan to be able to cover investigational treatment, should it wish to do so, the treatment must meet two conditions. First, it must be for "a life-threatening disease, disorder, or other health condition (as defined by the National Health Board)." 5/ Second, the treatment must be a "qualifying investigational treatment", which means it must be one whose effectiveness is not yet determined, but is under clinical investigation as part of an approved research trial (defined in the Act). 6/

The Act contains only one guarantee for patients participating in investigational treatments. It requires plans to pay for any "item or service" provided during the investigational treatment that "would have been provided to the individual even if the individual were not receiving the investigational treatment." 7/

---

3/ Title I, Subtitle B, Part 1, Sec. 1101(a)(18).

4/ Title I, Subtitle B, Part 3, Sec. 1135(a).

5/ Title I, Subtitle B, Part 2, Sec. 1128(a).

6/ Title I, Subtitle B, Part 2, Sec. 1128(d).

7/ Title I, Subtitle B, Part 2, Sec. 1128(c)(2).

1 that may be incurred by a family within a class of  
2 family enrollment in a year.

3 (d) CRITERIA FOR DETERMINATION OF MEDICAL  
4 NECESSITY AND APPROPRIATENESS.—

5 (1) IN GENERAL.—A qualified health plan shall  
6 provide for coverage of the items and services de-  
7 scribed in subsection (b) only for treatments and di-  
8 agnostic procedures that are medically necessary or  
9 appropriate. In the case of dispute concerning a de-  
10 termination of medical necessity or appropriateness  
11 and subject to the succeeding provisions of this sub-  
12 section, for purposes of this title, a treatment (as de-  
13 fined in subparagraph (6)(A)) or diagnostic proce-  
14 dure shall be considered to be “medically necessary  
15 or appropriate” if the following criteria are met:

16 (A) TREATMENT OR DIAGNOSIS OF MEDI-  
17 CAL CONDITION.—

18 (i) IN GENERAL.—The treatment or  
19 diagnostic procedure is for a medical con-  
20 dition.

21 (ii) MEDICAL CONDITION DEFINED.—  
22 The term “medial condition” means a dis-  
23 ease, illness, injury, or biological or psycho-  
24 logical condition or status for which treat-  
25 ment is indicated to improve, maintain, or

1 stabilize a health outcome (as defined in  
2 paragraph (6)(B)) or which, in the absence  
3 of treatment, could lead to an adverse  
4 change in a health outcome.

5 (iii) ADVERSE CHANGE IN HEALTH  
6 OUTCOME DEFINED.—In clause (ii), an ad-  
7 verse change in a health outcome occurs if  
8 there is a biological or psychological  
9 decremental change in a health status.

10 (B) NOT INVESTIGATIONAL.—There must  
11 be sufficient evidence on which to base conclu-  
12 sions about the existence and magnitude of the  
13 change in health outcome resulting from the  
14 treatment or diagnostic procedure compared  
15 with the best available alternative (or with no  
16 treatment or diagnostic procedure if no alter-  
17 native treatment or procedure is available).

18 (C) EFFECTIVE AND SAFE.—The evidence  
19 must demonstrate that the treatment or diag-  
20 nostic procedure can reasonably be expected to  
21 produce the intended health result or provide  
22 intended information and is safe and the treat-  
23 ment or diagnostic procedure provides a clini-  
24 cally meaningful benefit with respect to safety  
25 and effectiveness in comparison to other avail-

1 (2) SPECIFICATION OF ALL MEDICALLY APPRO-  
2 PRIATE TREATMENTS.—

3 (A) MEDICALLY APPROPRIATE TREAT-  
4 MENTS.—The uniform set of effective benefits  
5 submitted under paragraph (1) shall include  
6 such categories of health care services that the  
7 Commission determines will provide for the de-  
8 livery of medically appropriate treatment by  
9 AHPs.

10 (B) COVERAGE OF CLINICAL PREVENTIVE  
11 SERVICES.—Such benefits shall include the full  
12 range of effective clinical preventive services  
13 (including appropriate screening, counseling,  
14 and immunization and chemoprophylaxis), spec-  
15 ified by the Commission, appropriate to age and  
16 other risk factors.

17 (C) COVERAGE OF DIAGNOSTIC SERV-  
18 ICES.—Such benefits shall include a full range  
19 of diagnostic services not covered under sub-  
20 paragraph (B).

21 (D) GUIDELINES.—Nothing in this para-  
22 graph shall prohibit the Commission from devel-  
23 oping guidelines that would specify the appro-  
24 priate uses of treatment in greater detail.

1 (D) ADDITIONAL COVERAGE.—Nothing in  
2 this paragraph shall be construed as preventing  
3 a plan from providing coverage of treatment  
4 that has not been determined (under subsection  
5 (b)) by the Commission to be medically appro-  
6 priate for purposes of this paragraph.

7 (3) COST-SHARING.—

8 (A) IN GENERAL.—Subject to subpara-  
9 graph (B), such set shall include uniform cost-  
10 sharing associated with such benefits consistent  
11 with subsection (c).

12 (B) TREATMENT OF NETWORK PLANS.—In  
13 the case of a network plan (as defined in sec-  
14 tion 1222(b)), the plan may provide for charg-  
15 ing cost-sharing in excess of the uniform cost-  
16 sharing under subparagraph (A) in the case of  
17 services provided by providers that are not par-  
18 ticipating providers (as defined in such section).

19 (b) CRITERIA FOR DETERMINATION OF MEDICALLY  
20 APPROPRIATENESS FOR BENEFIT COVERAGE.—

21 (1) IN GENERAL.—An AHP is required to pro-  
22 vide for coverage of the uniform set of effective ben-  
23 efits only for treatments and diagnostic procedures  
24 that are medically appropriate. Subject to the suc-  
25 ceeding provision of this subsection, for purposes of

1 this section, a treatment (as defined in paragraph  
 2 (6)(A)) or diagnostic procedure is considered to be  
 3 “medically appropriate” if the following criteria are  
 4 met (as interpreted by the Commission):

5 (A) TREATMENT OR DIAGNOSIS OF MEDI-  
 6 CAL CONDITION.—

7 (i) IN GENERAL.—The treatment or  
 8 diagnostic procedure is for a medical con-  
 9 dition.

10 (ii) MEDICAL CONDITION DEFINED.—  
 11 The term “medical condition” means a dis-  
 12 ease, illness, injury, or biological or psycho-  
 13 logical condition or status for which treat-  
 14 ment is indicated to improve, maintain, or  
 15 stabilize a health outcome (as defined in  
 16 paragraph (6)(B)) or which, in the absence  
 17 of treatment, could lead to an adverse  
 18 change in a health outcome.

19 (iii) ADVERSE CHANGE IN HEALTH  
 20 OUTCOME DEFINED.—In clause (ii), an ad-  
 21 verse change in a health outcome occurs if  
 22 there is a biological or psychological  
 23 decremental change in a health status or if  
 24 the original endowment for a feature lies  
 25 outside the normal range.