COMPREHENSIVE BENEFIT PACKAGE

Page	Issue	Type of fix
35	**Hospital Services**: specifically exclude rehab. hospitals from definition of hospitals.	technical
36	**Health Professional Services**: on hold til further discussions / review of state issues (Lisa Rovin)	policy
38	**Ambulatory Medical and Surgical Services**: this language does not appear to cover what it was intended to - modifications required.	technical
94	**Clinical Preventive Services**:	
	• insert language to clarify that the NHB will determine a cost sharing schedule to apply to POS clinical preventive services and that cost sharing incurred from POS services does not contribute to the OOP maximum. The former will require specific language giving the NHB authority to change cost sharing for POS services.	policy
	• edit on page 94 - modify (b) to "consult with experts in clinical preventive services for children and adults".	technical
	• change provisions related to sexually transmitted diseases to allow for screening of males: i.e. add "annual screening for persons at risk of sexually transmitted diseases"	
63	• add to page 40 for children under 3: "newborn screening for genetic and metabolic disorders" - cost estimate	policy/cost
	• family planning inclusion - cost estimate	policy/cost
	Mental Illness and Substance Abuse:	cost
	• correct language on page 338 to include "or a determination of not guilty by reason of insanity"	technical
	• NHB language to be modified to allow authority to define visit differently	technical

Simpson/OASH
2/10/94
TECHNIC.FIX

Page	Issue	Type of Fix
64	**Drugs:** • formularies - language adequate, will incorporate specific intent to allow plans to use formularies in report language; • medical foods - intend to cover very specific ones like PKU foods, but not Ensure (Lisa Simpson checking on scope and cost) - see attached proposed language; • Medical devices - bill silent - do we want to be explicit?	technical policy/cost policy/cost
69	**Outpatient Rehabilitation Services**: see attached draft language	policy
70	**Durable Medical Equipment**: include Bobbie Silverstein language (attached); also ensure that report language/legislative history speaks to the fact that DME is intended to be used in either the home or office.	
71	**Dental**: change genetic to congenital	policy/ ?cost
74	**Investigational treatments**: see attached	policy/cost
80	**Exclusions**: hearing aids for kids - awaiting cost estimate from ARC, using BC/BS language	

	ISSUE	
OTHER	Plan discretion re: individual benefit management and supplemental insurance exclusions; Uncovered/unattached children (foster, diversion, children of undocumented parents); Prior authorization issues for children (e.g. referral from an IEP, IFSP, child find program for evaluation).	

Amendment

Amend Section 2001 (b)(5)(B), to read as follows (added language is underlined):

"(B) Not later than January 1, 1996, (and periodically thereafter), the Secretary shall publish a list of the drugs and indications for such drugs, that are covered home infusion drugs, with respect to which home infusion drug therapy may be provided under this title. The Secretary shall also establish by regulation not later than January 1, 1996 the circumstances and conditions where the provisions of oral medical foods (as defined in 21 U.S.C. 360 ee(b)(3)) is medically appropriate and cost effective."

SEC. 1124. DURABLE MEDICAL EQUIPMENT, PROSTHETIC DEVICES, ORTHOTICS, AND PROSTHETICS.

(a) COVERAGE.- The items and services described in this section are-

(1) durable medical equipment;

(2) prosthetic devices (other than dental devices) which replace all or part of the function of an internal body organ (including devices that are surgically inserted, devices that are physically attached to the body, such as colostomy bags and supplies directly related to colostomy care, and external devices;

(3) orthotics (leg, arm, back and neck braces) and prosthetics (artificial legs, arms and eyes); and

(4) (A) accessories and supplies which are used directly with equipment or devices described in paragraphs (1)-(3) to achieve the therapeutic benefits of such equipment or devices or to assure the proper functioning of such equipment or devices,

(B) replacements of such equipment or devices when required in cases of loss, irreparable damage, wear, or because of a change in the patient's condition, and

(C) repair and maintenance of such equipment and devices;

(5) fitting (including adjustments) and training for use of the items described in paragraphs (1) through (4).

(b) LIMITATION.-An item or service described in this section is covered only if it improves functional ability or prevents or minimizes deterioration in function.

(c) DURABLE MEDICAL EQUIPMENT.- For purposes of this subtitle, the term "durable medical equipment" has the meaning given such term in section 1861(n) of the Social Security Act.

EXPLANATION OF THE PROPOSED CHANGES

1. DURABLE MEDICAL EQUIPMENT

The bill includes "accessories and supplies necessary for repair, function, and maintenance" of DME; it is silent on "replacement." Replacement of DME is clearly covered under current Medicare policy. Under the proposed amendment, coverage for all of these services is moved to separate paragraphs (see below).

2. PROSTHETIC DEVICES

The bill specifies that prosthetic devices (other than dental devices) are covered if they "replace all or part of the function of an internal body organ." This is a "functional" test i.e., does the device replace all or part of the function of an internal body organ. The bill is not limited to replacing all or part of the body organ. No change to this language is proposed. However, clarifications to other aspects of this section of the bill are proposed.

First, the proposal simply clarifies the meaning of the phrase "prosthetic devices (other than dental devices) which replace all or part of the function of an internal body organ." One generally accepted category of "prosthetic devices" includes devices that are "physically attached to the body". The bill does not reference this general category; instead, it includes one specific application of this general category ("including colostomy bags and supplies directly related to colostomy care"). This is confusing because a specific application of a general category is set out in the statute in lieu of the general category and other generally accepted categories are not referenced, i.e., devices that are surgically inserted and external devices.

The proposed amendment explicitly recognizes all three categories. The proposal recognizes that prosthetic devices include devices that are surgically inserted. An example of such a device would be a pacemaker. The proposal also recognizes that prosthetic devices include devices that are physically attached to the body, such as colostomy bags and supplies directly related to colostomy care.

In addition, the proposal recognizes that prosthetic devices include external devices such as augmentative communication devices. Augmentative communication devices replace a mal- or nonfunctioning element of the body's oral motor mechanisms consisting of the speech center of the brain as well as the nerves, muscles, and organs that together control the production of speech and improve the functions of speaking for individuals whose oral motor mechanisms do not work. Obviously, "improving functional ability" includes improving the ability to speak; otherwise, Medicare and private insurance policies would not pay

for an artificial larynx.

Clearly, such external devices are subject to the general policy that all devices provided under the comprehensive benefits package must be prescribed by a qualified health care professional within the scope of the professional's practice and must be medically necessary or appropriate under the comprehensive benefit package.

As explained above, the first change to the bill clarifies the scope of the term "prosthetic device." Second, the bill is silent with respect to "repair, function, and maintenance." It does not appear that the bill intended to preclude payment for repair, function, and maintenance. (See current policy under Medicare, for example, under which rules governing prosthetic devices incorporate by reference policies regarding repair, function, and maintenance under DME. The proposal covers these functions (see below).

Third, the bill covers accessories and supplies which are used directly with a prosthetic device. The proposal moves this provision to a separate paragraph, which is then made applicable to all categories of devices.

3. ORTHOTICS AND PROSTHETICS

The bill includes two lists of covered equipment. The proposal simply includes a term to describe each of these lists--"orthotics" to describe leg, arm, back and neck braces; and "prosthetics" to describe artificial legs, arms, and eyes. Thus, no intent to change policy in bill.

The bill includes "replacement if required because of a change in the patient's physical condition" with respect to artificial legs, arms, and eyes; but is silent with respect to leg, arm, back and neck braces. This provision is modeled on Medicare policy, which not only covers replacement for both categories of equipment but also provides coverage for repair, function, and maintenance.

The proposal makes "replacement..." applicable to both orthotics and prosthetics" and includes "repair, function, and maintenance" under a new separate paragraph (see below).

4. ACCESSORIES AND SUPPLIES.

The bill covers accessories and supplies necessary for repair, function, and maintenance of DME. The bill also covers accessories and supplies which are used directly with a prosthetic device to achieve the therapeutic benefits of the prosthesis or to assure the proper functioning of the device.

It is unclear why such "accessories and supplies" only apply to prosthetic devices and durable medical equipment and not to

orthotics, and prosthetics as well. The proposed amendment makes this section applicable to all equipment and devices covered by this section.

This proposed change is consistent with current policy and therefore should not add any additional costs.

5. REPLACEMENT, REPAIR, FUNCTION AND MAINTENANCE.

Current policy under Medicare developed by HCFA covers payment for replacement, repair, and maintenance for all of the equipment and devices included in the bill. The bill unintentionally treats these functions in a disparate fashion.

The proposal codifies current policy under Medicare with respect to replacement, repair, and maintenance of the categories of devices and equipment covered under the bill. In other words, this new paragraph does not change current policy.

6. FITTING

The bill covers "fitting." The proposed amendment clarifies that "fitting" includes "adjustments." Adjustments are covered under current Medicare rules. Thus, by codifying current policy, this proposal does not add any costs.

7. LIMITATIONS.

The bill specifies that an item or service is covered only if it "improves functional ability or prevents further deterioration in function." The proposal inserts "or minimizes". after "prevents." This change is consistent with overall purposes of the devices and equipment made available and conforms the provision to the language in the section of the bill pertaining to outpatient rehabilitation therapies.

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 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

Attachment B

STAFF DISCUSSION DRAFT
AMENDMENT TO OUTPATIENT REHABILITATION SERVICES PROVISION OF THE HEALTH SECURITY ACT

SEC. 1123. OUTPATIENT REHABILITATION SERVICES

(a) COVERAGE-The outpatient rehabilitation services described in this section are:

(1) outpatient occupational therapy;

(2) outpatient physical therapy;

(3) outpatient respiratory therapy; and

(4) outpatient speech-language pathology services and audiology services.

(b) LIMITATIONS.-Coverage for outpatient rehabilitation services is subject to the following limitations:

(1) RESTORATION OF CAPACITY OR MINIMIZATION OF LIMITATIONS.- Such services include only items or services used to restore functional capacity or minimize limitations on physical and cognitive functions as a result of an illness, injury, disorder, or other health condition.

(2) MAINTENANCE OR PREVENTION PROGRAM. Services described in paragraph (1) include the following outpatient rehabilitation services designed to maintain functioning or prevent or minimize deterioration:

(A) the initial evaluation and periodic oversight of the patient's needs by a qualified rehabilitation health professional,

(B) the designing by the qualified rehabilitation health professional of a maintenance or prevention program which is appropriate to the capacity and tolerance of the patient and the treatment objectives,

(C) the instruction of the patient, family members, or support personnel in carrying out the program, and

(D) reevaluations.

(3) REEVALUATION.- (A) At the end of each 60 day period of outpatient rehabilitation services (other than services described in paragraph (2)), the need for continued services shall be reevaluated by the person who is primarily responsible for providing the services. Additional periods of services are covered only if such person determines that the requirement in paragraph (1) is satisfied.

(B) Periodically, outpatient rehabilitation services described in paragraph (2) shall be reevaluated by a qualified rehabilitation health professional.

Benefits Issues
Draft 2/10/94

Health professional services

- What is included?
- Do we create any right of expectation that a health plan must contract with any class of professionals? What reasons may a health plan give for choosing not to contract with particular providers or classes of providers?
- How does this provision interact with provision on override of restrictive practice laws? What does that provision do?

Preventive services

- Costs of adding: additional mammography screening, cholorectal screening, prostate cancer screening, genetic screening (is this included now?) and HIV testing? Cost
- ~~Do we use the right age categories for kids?~~
- Why do we include only screening of women for sexually transmitted diseases?
- Do we want to include major prenatal procedures (amnio, sonograms)? Drafting could be interpreted to cover only the clinician visists and incidental services (e.g., minor lab tests).
- How do our provisions on immunization (no bulk purchasing specified) interact with immunization legislation?

Family planning and services for pregnant women?

- In vitro fertilization
  - What about other "assistive reproductive technologies"?
  - Why do we exclude this without a provision that if it is a more effective or lower cost alternative to surgical procedures it may be covered at the discretion of the health plan?
- Have we unintentionally excluded certain services by using "services for pregnant women" rather than "pregnancy related services"?
- Costs of removing cost sharing for contraception?

Home health care

- Omission of respiratory therapy.
- Illness or injury issue. See alternative language.
- Alternative language for reevaluation criteria?

Extended care services

- Illness or injury issue. See alternative language.
- What is the difference between requirement that a patient have a previous hospitalization and a requirement that the extended care services be an alternative to hospital care?

Prescription drugs

- Did we intend to exclude syringes?
- Issue of "medically necessary or appropriate" drugs?

Outpatient rehabilitation

- See alternative language.

Durable Medical Equipment

- See alternative language. Cost implications of suggested changes on prosthetic devices and "minimizing" limitations?
- Any problems for kids of using Medicare definition for DME?
- Are cochlear implants included?
- Coverage of motorized wheelchairs that are needed outside the home?

Investigational treatments

- What "routine costs" do we cover?
- Does this differ from Cooper or Chafee?

AMENDMENTS ON "ILLNESS OR INJURY"

CURRENT PROVISION	PROPOSED REVISION
Section 1118. Home Health Care "(b) LIMITATIONS. Coverage for home health care is subject to the following limitations: (1) INPATIENT TREATMENT ALTERNATIVE - Such care is covered only as an alternative to inpatient treatment in a hospital, skilled nursing facility, or rehabilitation facility after an illness or injury.	Amend (b)(1) to read as follows: "Such care is covered only to treat an illness, injury, disorder or other health condition [following a period of **OR** as an alternative to] hospitalization or treatment in a more restrictive or costly setting for that illness, injury, disorder or condition." [NOTE: This would allow patients receiving costly OPD or day clinic care to be treated in the home -- a less costly alternative.]

Section 1119. Extended Care Services	
"(b) LIMITATIONS. -- Coverage for extended care services is subject to the following limitations: (1) HOSPITAL ALTERNATIVE -- Such services are covered only ... after an illness or injury."	"(b) LIMITATIONS. -- Coverage for extended care services is subject to the following limitations: (1) HOSPITAL ALTERNATIVE -- Such services are covered only ... after an <u>illness, injury, disorder or other health condition.</u>"
"(c) DEFINITIONS -- (1) REHABILITATION FACILITY -- The term "rehabilitation facility" means an institution ... for rehabilitation from illness or injury." (2) SKILLED NURSING FACILITY -- The term "skilled nursing facility" means an institution ... (B) for rehabilitation from illness or injury.	"(c) DEFINITIONS -- (1) REHABILITATION FACILITY -- The term "rehabilitation facility" means an institution ... and rehabilitation services." (2) SKILLED NURSING FACILITY -- The term "skilled nursing facility" means an institution ... (B) rehabilitation services. [NOTE: There is no reason to define the institutions as providing services only for illness, injury, etc. The limitation is already included in the definition of the service.]

Section 1123. Outpatient Rehabilitation Services "(a) COVERAGE. -- The outpatient rehabilitation services described in this section are -- (3) outpatient speech pathology services .... for the purpose of attaining or restoring speech. "(b) LIMITATIONS. -- Coverage for outpatient rehabilitation services is subject to the following limitations: (1) RESTORATION OF CAPACITY OR MINIMIZATION OF LIMITATIONS. -- Such services include only items or services used to restore functional capacity or minimize limitations on physical and cognitive functions as a result of illness or injury."	"(a) COVERAGE. -- The outpatient rehabilitation services described in this section are -- . . . (3) outpatient respiratory therapy; (4) outpatient speech-language pathology services and audiology services. "(b) LIMITATIONS. -- Coverage for outpatient rehabilitation services is subject to the following limitations: (1) TREATMENT PURPOSES. -- Such services include only items or services used to achieve developmentally appropriate activities of daily living, restore functional capacity, minimize limitations on, or prevent further deterioration of physical and cognitive functions as a result of illness, injury, disorder or other condition."
	Rehabilitation provisions (Cont.) (2) REEVALUATION. -- At the end of each 60-day period (or such other period specified by a health professional primarily responsible for providing the rehabilitation services, which may exceed 60 days, the need for continued services shall be reevaluated....Additional periods of care are covered only if such professional determines that the requirements of paragraph (1) are satisfied."