FAX TRANSMISSION

HEALTH CARE FINANCING ADMINISTRATION
OFFICE OF CLINICAL STANDARDS & QUALITY
7500 SECURITY BOULEVARD, S-3-02-01
BALTIMORE, MARYLAND 21244-1850
FAX NUMBER: (410) 786-6857
Office Phone (410) 786-6841

ADDRESSEE:	FROM:
Greg White 3910 FAX 202-395-~~5391~~ ph 202-395-7791	Jeff Kang

TOTAL PAGES: (Including Cover)	DATE:	SENDERS VOICE PHONE:
6	5/3/00	410-786-6841

REMARKS:

(1) Coverage issues manual related to cardiac cath

(2) new briefing memo - currently undergoing revisions

Jeff

Date: 5/4/00

FAX

Health Division

Office of Management and Budget
Executive Office of the President
Washington, DC 20503

To: Deuoeah
Fax:

From: Jeff F.

Number of Pages (excluding cover): 6

Subject: As discussed.

Voice Numbers:

Health Division (Front Office)	202/395-4922
Health & Human Services Branch	202/395-4925
Health Programs & Services Branch	202/395-4926
Health Financing Branch	202/395-4930

Fax Numbers:

Health Division (Front Office)	202/395-3910
Health Division (Room 7001)	202/395-7840
Health Division (Room 7002)	202/395-5648

General Exclusions From Coverage

2300. GENERAL EXCLUSIONS.

No payment can be made under either the hospital insurance or supplementary medical insurance programs for certain items and services.

A. Not reasonable and necessary (§ 2303);

B. No legal obligation to pay for or provide services (§ 2306);

C. Furnished or paid for by government instrumentalities (§ 2308);

D. Not provided within United States (§ 2312);

E. Resulting from war (§ 2315);

F. Personal comfort (§ 2318);

G. Routine services and appliances (§ 2320);

H. Supportive devices for feet (§ 2323);

I. Custodial care (§ 2326);

J. Cosmetic surgery (§ 2329);

K. Charges by immediate relatives or members of household (§ 2332);

L. Dental services (§ 2336);

M. Paid or expected to be paid under worker's compensation (§ 2370).

N. Nonphysician services provided to a hospital inpatient which were not provided directly or arranged for by the hospital (§ 2380).

2300.1 Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare.--

A. Medical and hospital services are sometimes required to treat a condition that arises as a result of services which are not covered because they are determined to be not reasonable and necessary or because they are excluded from coverage for other reasons. Services "related to" noncovered services (e.g., cosmetic surgery, noncovered organ transplants, noncovered artificial organ implants, etc.), including services related to followup care and complications of noncovered services which require treatment during a hospital stay in which the noncovered service was performed, are not covered services under Medicare. Services "not related to" noncovered services are covered under Medicare.

B. Identify which services are related to noncovered services and which are not. Following are some examples of services "related to" and "not related to" noncovered services while the beneficiary is an inpatient:

1. A beneficiary was hospitalized for a noncovered service and broke a leg while in the hospital. Services related to care of the broken leg during this stay is a clear cut example of "not related to" services and are covered under Medicare.

2. A beneficiary was admitted to the hospital for covered services, but during the course of hospitalization became a candidate for a noncovered transplant or implant and actually received the transplant or implant during that hospital stay. When the original admission was entirely unrelated to the diagnosis that led to a recommendation for a noncovered transplant or implant, the services related to the admitting condition would be covered.

3. A beneficiary was admitted to the hospital for covered services related to a condition which ultimately led to identification of a need for transplant and receipt of a transplant during the same hospital stay. If, on the basis of the nature of the services and a comparison of the date they are received with the date on which the beneficiary is identified as a transplant candidate, the services could reasonably be attributed to preparation for the noncovered transplant, the services would be "related to" noncovered services and would also be noncovered.

C. After a beneficiary has been discharged from the hospital stay in which he received noncovered services, medical and hospital services required to treat a condition or complication that arises as a result of the prior noncovered services may be covered when they are reasonable and necessary in all other respects. Thus, coverage could be provided for subsequent inpatient stays or outpatient treatment ordinarily covered by Medicare, even if the need for treatment arose because of a previous noncovered procedure. Some examples of services that may be found to be covered under this policy are the reversal of intestinal bypass surgery for obesity, repair of complications from transsexual surgery or from cosmetic surgery, removal of a noncovered bladder stimulator, or treatment of any infection at the surgical site of a noncovered transplant that occurred following discharge from the hospital.

However, any subsequent services that could be expected to have been incorporated into a global fee should be denied. Thus, where a patient undergoes cosmetic surgery and the treatment regimen calls for a series of postoperative visits to the surgeon for evaluating the patient's progress, these visits should be denied.

(See Intermediary Manual, § 3637.15 and Hospital Manual, § 415.15 for billing procedures.)

2303. SERVICES NOT REASONABLE AND NECESSARY.

Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member; e.g., payment cannot be made for the rental of a special hospital bed to be used by the patient in his home unless it was a reasonable and necessary part of the patient's treatment. See also § 2313.

ISSUES CONCERNING MEDICARE COVERAGE OF CANCER CLINICAL TRIALS

I. Current policy - As described in the Coverage Issues Manual, services related to the provision of a service that is not reasonable and necessary are not covered. An exception is the treatment of complications from a non covered service when that treatment is not provided during the same hospital stay. This policy has been extended to preclude coverage of services in clinical trials, although that policy is not formalized in any official document.

II. Services in clinical trials can be categorized as:

1) the drug, device or procedure under study;

2) services required for the administration, monitoring or follow-up of the service under study;

3) services required by the protocol for purposes of data collection and evaluation;

4) routine patient care services that the patient would receive in absence of the protocol.

III. The CIM policy would clearly exclude 1) - 3), but the reimbursement of 4) is problematic for Medicare, particularly in light of the IOM recommendation. The IOM report recommends that HCFA reimburse 4) in all clinical trials. By singling out these routine services, the report creates several potential difficulties for HCFA. It will be difficult to explain why we wouldn't reimburse services otherwise reasonable and necessary for patient care. On the other hand, the operational and program integrity aspects of changing our policy will be significant. In particular, distinguishing 1) - 3) from 4) is difficult, and deciding on how to reimburse the same services provided to the patient outside of the trial during the same time period would be very challenging.

IV. While we need to put forward our best options and recommendations, OA should be aware that the IOM report may have shifted the nature of the debate on this issue. That is, they are not blind sided by the question, "Are you saying you don't cover medically necessary services just because the patient is participating in a trial?"

OPTION 1 (NCI Preferred)

Allow billing of routine patient care costs in all NCI trials for a limited time period. NCI would work with their Cooperative Groups to distinguish routine costs from others, and to bill cautiously.

Pros

Would look good for Medicare

Provide good data for a possible Option 3

Cons

More difficult to administer

May be difficult to take back

OPTION 2

Do OPTION 1 for a limited set of NCI trials

Pros

Easier to administer and analyze

Limited enough not to commit Medicare to a policy

Cons

May be viewed as too little

Would not provide sufficient data for OPTION 3

OPTION 3

Organize a demonstration that would provide a capitated amount for each beneficiary in a clinical trial. The amount would reflect the routine patient care costs for a similar patient not treated in a clinical trial.

Pros

Avoids some but not all of the billing issues

Cons

Needs to be a formal pricing demonstration and would require substantial resources and at least 2 years to develop

OPTION 4

Wait for legislation such as the Demonstration project proposed in the President's budget.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administr

Washington D.C. 20201 ~ 0001

FAX COVER SHEET

HCFA'S OFFICE OF LEGISLATION

200 independence Avenue S.W. 341-H

TO: B Jeanne Deborah Greg Mike / Yvette Shenanda ***FAX NO:*** _____

NO. of PAGES: 4 ***DATE:*** 7/25

FROM: Bonnie ***Phone:*** _____

Remarks:

Fax Number 202-690-8168

Problems with transmission please call 202-690-5444

CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

Bonnie

July 24, 2000

Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Department Health & Human Services
200 Independence Ave., S.W.
Room 314-G – HHH Bldg.
Washington, D.C. 20201

Dear Ms. DeParle:

We write to you as representative leadership of the cancer treatment, research, support, and advocacy community to ask that you once again become personally involved in the implementation of the President's Executive Memorandum announced on June 7, 2000. The Executive Memorandum was intended to resolve an issue that had been of longstanding concern to us – i.e., the question of Medicare reimbursement for routine patient care costs for beneficiaries enrolled in clinical trials. The announcement was made after the White House expressly promised representatives of the community that the Administration's initiative would cover all phases of clinical trials and would include not just government-sponsored trials but also those sponsored by the private sector. The White House also represented that this agreement was reached only after consultation with both the Health Care Financing Administration (HCFA) and the National Institutes of Health (NIH).

The community has now met three times with HCFA staff and seen some progress, but no firm resolution of implementation efforts. Recently, additional scheduled meetings have been postponed and not rescheduled. In the absence of these meetings, we are hearing from a variety of concerned parties that efforts to dilute and diminish the scope of coverage promised in the President's announcement are underway. These reports raise questions about the resolve of the Administration, and specifically HCFA, to honor the promises made to the cancer community. It was on the basis of those promises that we stood with a bipartisan group of Senators and Representatives to issue press releases and praise publicly the Administration for its action. And it was those promises that led to favorable coverage for President Clinton and Vice President Gore in national television and print media. If those promises are not fulfilled, some will believe that the public record should be corrected.

Contact: 1900 K Street N.W. • Suite 750 • Washington, D.C. 20006
Phone: 202-833-4500 • Fax: 202-833-2859 • Email: clc@btclaw.com • www.cancerleadership.org

To clarify our position, we will not be satisfied with coverage of clinical trials that does not cover, as represented, all phases of clinical trials and privately-sponsored trials as well as those that are government-sponsored. These issues have been reviewed time and again over the years, have resulted in state-by-state coverage of all phases of cancer clinical trials, and, in our view, were thankfully resolved for Medicare by Executive decision of the President. The cancer community wants to know, does HCFA now stand in opposition to that decision?

At the last meeting with HCFA staff, the community was promised a final decision consistent with our understanding of the Executive Memorandum no later than mid-September. We expect HCFA to honor that commitment, but, based on recent events, the cancer community questions the agency's willingness to meet that deadline or to abide by the President's promises.

The Cancer Leadership Council (CLC) is next meeting September 7. We are inviting you and your staff, as well as key officials of NIH and the Food and Drug Administration (FDA), to explain the position of the Administration on this issue of utmost importance to people with cancer.

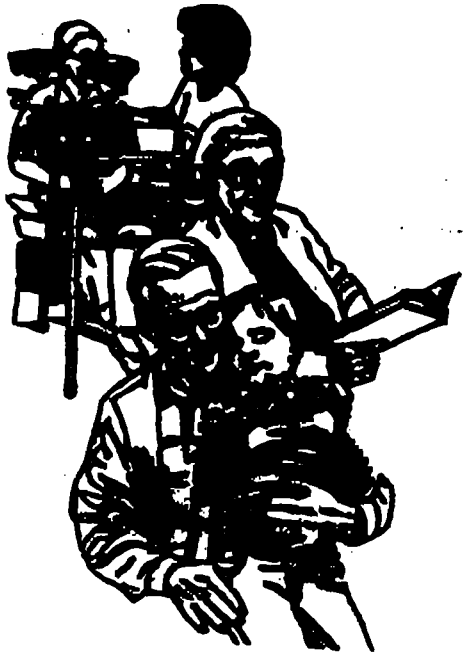
With respect and in appreciation for your leadership on these matters, we thank you in advance for your personal intervention so that bureaucratic resistance to implementing the good intentions of the Administration does not thwart the reasonable expectation of hundreds of thousands of Medicare beneficiaries living under a diagnosis of cancer.

Cancer Leadership Council

Alliance for Lung Cancer Advocacy, Support, and Education
American Cancer Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology, Inc.
Association of American Cancer Institutes
Cancer Care, Inc.
Cancer Research Foundation of America
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
Cure For Lymphoma Foundation
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
Multiple Myeloma Research Foundation
National Alliance of Breast Cancer Organizations
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Oncology Nursing Society
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
The Susan G. Komen Breast Cancer Foundation
US-TOO International, Inc.
Y-ME National Breast Cancer Organization

cc: The Honorable William Jefferson Clinton, President of the U.S.
The Honorable Albert Gore, Vice President of the U.S.
The Honorable Donna Shalala, Secretary, HHS
Ruth Kirschstein, M.D., Acting Director, NIH
Jane E. Henney, M.D., Commissioner, FDA
The Honorable Connie Mack
The Honorable John D. Rockefeller
The Honorable Nancy L. Johnson
The Honorable Benjamin L. Cardin
The Honorable Ken Bentsen
The Honorable Henry A. Waxman

HEALTH CARE FINANCING ADMINISTRATION



ADDRESSEE: Devorah	FROM: Patti
PHONE: _____	OFFICE OF THE ADMINISTRATOR 200 INDEPENDENCE AVE., S.W. ROOM 314G WASHINGTON, DC 20201 PHONE: 202-690-6726 FAX : 202-690-6262

TOTAL PAGES: 3	ADDRESSEE'S FAX MACHINE NUMBER:	DATE: 8/4

REMARKS:

Fact Sheet

HCFA FACT SHEET

August 4, 2000

Contact: HCFA Press Office
(202) 690-6145

MEDICARE COVERAGE OF BENEFICIARIES IN CLINICAL TRIALS

Overview: The Health Care Financing Administration has issued a proposed national coverage decision to implement President Clinton's order for Medicare to cover the routine health care costs of beneficiaries in clinical trials. The proposed decision not only implements the President's order to cover the "routine costs" of Medicare beneficiaries in clinical trials, but would also expand the definition of such costs to include payment of most other beneficiary costs. HCFA expects to issue a final decision, effective in mid-September, after receiving and studying public comments.

Reassuring Beneficiaries, Encouraging Research. In announcing the decision to assure Medicare coverage to those in clinical trials, President Clinton noted that many seniors and people with disabilities were reluctant to participate in trials for fear they would lose their Medicare coverage. Assuring Medicare beneficiaries that their costs will be covered is expected to encourage them to participate in clinical trials. Medical researchers believe that higher participation by older Americans and those with disabilities in clinical trials could lead to faster development of therapies. The knowledge gained from clinical trials will lead to better health care for Medicare's more than 39 million beneficiaries.

Covered Costs. Medicare will pay most of the costs of beneficiaries in clinical trials. This includes costs associated with providing items and services that would otherwise be covered by Medicare if they were not provided in the context of a clinical trial. Also covered are items and services required "solely for the provision of the investigational item or service." For example, Medicare will pay for the administration of a chemotherapy drug that is being tested in a trial, including the provision of anti-nausea drugs to prevent complications from the chemotherapy drug. Medicare also will pay for monitoring and evaluation, device implantation, and other costs, such as room and board as part of a hospital stay required as part of a clinical trial, for trials of importance to Medicare beneficiaries.

All Beneficiaries Would Be Covered. All Medicare beneficiaries will be eligible for the coverage while in approved clinical trials. The new policy is binding on all the private contractors that process and pay Medicare claims as well as Medicare+Choice managed care plans. The Balanced Budget Act permits Medicare to pay additional funds to Mediare+Choice plans to compensate them for significant costs associated with national coverage decisions. Coverage becomes effective when a final decision is announced, expected to be by mid-September. Coverage decisions are not retroactive.

- more -

Things Not Covered. Medicare will not pay for the medical device or drug being tested in a trial. And it will not pay for items and services provided solely to satisfy the data collection needs of the trial. It also will not pay for anything being provided free by the sponsor of the trial.

Registry of Trials. HCFA is developing a registry of ongoing clinical trials in which beneficiary costs are being reimbursed by Medicare. This registry will track Medicare expenditures in clinical trials. HCFA also is working to use the information contained in the current National Institutes of Health and Food and Drug Administration clinical trial registries to develop a national registry of all clinical trials receiving Medicare reimbursement.

Eligible Trials. To ensure the safety of Medicare beneficiaries, the proposal establishes a process to determine which clinical trials are eligible for its participants to receive payments for routine medical costs. The HCFA decision proposes that clinical trials must meet specified requirements in order to be approved for Medicare coverage, including scientific support, credible and capable sponsorship and protection of participating patients.

Some clinical trials are "deemed" to be qualified and do not have to go through this process. These include trials that are federally funded by the National Institutes of Health (including those conducted at National Cancer Institute cancer centers), the Centers for Disease Control and Prevention, HCFA, the Agency for Healthcare Research and Quality, the Department of Defense, the Department of Veterans Affairs, and trials conducted under an Investigational New Drug application approved by the Food and Drug Administration, or those that are exempt from having an Investigational New Drug application.

The proposal is posted on HCFA's web site at http://www.hcfa.gov/quality/8b.htm.

###

HEALTH CARE FINANCING ADMINISTRATION

ADDRESSEE: D. Adler

PHONE: _____

FROM: Debbi

OFFICE OF THE ADMINISTRATOR
200 INDEPENDENCE AVE., S.W.
ROOM 314G
WASHINGTON, DC 20201

PHONE: 202-690-6726
FAX : 202-690-6262

TOTAL PAGES:	ADDRESSEE'S FAX MACHINE NUMBER:	DATE:
7		8/4

REMARKS:

Dovorah,

In case you didn't get my voicemail message. The clinical trials coverage decision is on the web. You may be hearing about it. Additional Q's & A attached.

Medicare National Coverage Decision to Cover Routine Costs in Approved Clinical Trials
Questions and Answers
For Internal Use Only
08/04/00

Q. The President announced this on June 7. Why has it taken you so long to carry out his order?

A. The President's announcement required significant effort for implementation. We had to draft language that would carry out the intent of the President's directive without jeopardizing its true intent of providing coverage for all Medicare beneficiaries in clinical trials. This meant we had to produce a detailed policy that would cover all beneficiaries -- including both those in fee-for-service Medicare and those in Medicare+Choice managed care plans.

The President also directed the Secretary to report back to him within 90 days on the feasibility and advisability of additional actions to promote clinical research on issues of importance to the Medicare population. The coverage decision's expanded definition of "routine costs" actually implements these additional actions by covering things that "are required solely for the provision of the item or service involved in the trial." An example of things required solely for the provision of the item or service is the administration of a chemotherapy drug that is being tested in the clinical trial, including the provision of an anti-nausea drug to prevent complications from the chemo-therapy drug.

Q. Will the new policy be retroactive to June 7 when the President made his announcement?

A. No. This is a coverage decision, and coverage decisions are not retroactive. The President's announcement required significant effort for implementation. It was not possible to make this immediately effective for all Medicare beneficiaries (fee-for-service and managed care enrollees) without jeopardizing the true intent of the President's policy. We also wanted to allow the public an opportunity to comment on our implementation plans. But some of the additional actions the President asked for to support clinical trials among the Medicare population are included in this coverage decision.

Q. Why did you have to go to all this trouble just to cover routine medical expenses?

A. Most experimental services are not covered by Medicare because they are not considered to be "reasonable and necessary," the standard set by law for Medicare coverage. In the past, services furnished as part of any noncovered service such as a clinical trial also have been considered non-covered. The proposed national coverage decision will change this policy to allow Medicare coverage of the routine patient care costs incurred in an approved clinical trial. The old policy on routine medical costs caused confusion and may have influenced some Medicare beneficiaries not to join clinical trials. This new policy will clear up that confusion and assure older Americans that they can take part in clinical trials without losing their Medicare. Treatment of complications arising from a noncovered item or service continues to be covered for all noncovered items and services.

Q. Weren't some clinical trial expenses already covered?

A. Yes. Diagnosis and treatment of complications arising from clinical trials have always been covered. This will not change.

Q. Will every clinical trial be covered?

A. Most clinical trials will be covered. All trials that are funded by NIH, (including those conducted at the National Cancer Institutes cancer centers) AHRQ, HCFA, CDC, VA, DOD, and FDA are automatically deemed to meet certain quality requirements. These quality standards are important for the welfare of the beneficiary and the Medicare program. The national coverage decision spells out seven quality requirements that trials must meet to receive Medicare coverage. The requirements include scientific support for the trial, credible and capable sponsorship, and protection of participating patients.

Trials that are not funded by federal agencies can also be eligible for Medicare coverage. The principal investigators of a clinical trial must self-certify that their trial meets the seven quality requirements. This self-certification will be achieved by the principal investigator who will complete a certification form. The form will be developed by a panel of federal agencies (AHRQ, NIH, CDC, VA, DOD).

Finally, to receive Medicare payment, all trials must be evaluating an item or service that falls within a Medicare benefit category (physician service, durable medical equipment) and are not statutorily excluded from coverage (cosmetic surgery, hearing aids). In addition, all trials must only enroll patients with diagnosed disease, rather than healthy volunteers.

Q. Does this mean you are paying for the trials?

A. For trials that are deemed or certified to meet the criteria, Medicare will pay for the beneficiary's costs. These are costs associated with the provision of items and services that would otherwise be covered by Medicare if they were not provided in the context of a clinical trial. They do not include the actual investigational drugs or devices or any services or charges supplied without charge by the sponsor of the trial. In addition, they do not include protocol-induced costs or items or services provided solely for the trial's data collection needs.

Q: When the President made his original announcement, you said that the costs were minimal. Has that changed? This seems like a broad expansion of coverage.

A:

The proposed national coverage decision authorizes payment for routine patient care costs, and takes additional steps that the President asked the Secretary to review. In refining our initial policy and discussing the additional, broader coverage issues as the President directed, two things became clear. First, our initial policy proposal would have been difficult to implement as an administrative and coverage matter. Second it was fully possible and appropriate to broaden our coverage policy which would subsume the initial policy. Therefore, we're announcing a policy to cover a broad range of costs for those clinical trials approved for Medicare coverage. This change, when implemented later this year, would likely increase Medicare spending. Like all changes that result from coverage decisions, this change will be reflected in the next re-estimate of the Medicare baseline.

Q. Since the goal of this coverage decision is to increase participation in clinical trials, what is HCFA doing to let beneficiaries know that these things are now covered?

A. HCFA is developing an informational brochure on Medicare coverage of the routine and other associated health care costs of beneficiaries who participate in qualified clinical trials. In addition, information on Medicare coverage of clinical trials will be added to next year's beneficiary handbook. Finally, individuals who answer Medicare's information hotlines will also be prepared to respond to questions about clinical trials coverage.

Q. How is this national coverage decision different from the Rockefeller-Mack bill (S.784, Medicare Cancer Clinical Trial Coverage Act of 1999)?

A. The NCD is broader than the Rockefeller-Mack bill. This NCD applies to all clinical trials, not only cancer clinical trials. Also the definition of approved clinical trials is different. The Rockefeller-Mack bill defines an approved clinical trial program as a clinical trial program that has been approved by

- The National Institutes of Health (NIH);
- A NIH cooperative group or a NIH center;
- The Food and Drug Administration (in the form of an investigational new drug or device exemption);
- The Department of Veterans Affairs;
- The Department of Defense; or
- A qualified nongovernmental research entity identified in the guidelines issued by the NIH for center support grants.

The Medicare NCD gives deemed approval status to trials funded by NIH, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, HCFA, the Department of Defense, and the Department of Veterans Affairs, trials conducted at National Cancer Institute cancer centers, and all trials of patients that are either conducted under an investigational new drug application (IND) or are exempt from having an IND under 21 CFR 312.2(b)(1). Trials that are not deemed have a mechanism to self-certify that they meet required qualifying criteria.

The definition of routine costs in this NCD is similar to the definition included in the Rockefeller-Mack bill.

Q. How does this NCD differ from the recommendations put forward by the Institute of Medicine (IOM) in its recent report?

A. The IOM's first recommendation was that Medicare should reimburse routine care for patients in clinical trials but not the costs of the experimental interventions or of protocol induced costs. The NCD's definition of routine costs is consistent with this recommendation. The IOM also recommended that the same policy be extended to Medicare beneficiaries in managed care. This NCD is binding on all Medicare contractors, including Medicare+Choice plans.

The NCD also addresses other recommendations made by the IOM. Claims for routine costs rendered in approved clinical trials will be submitted like any other claim. There will also be a Medicare clinical trials registry established.

Q. Do all Medicare beneficiaries get this coverage? What about those in HMOs?

A. All beneficiaries are eligible. This policy is binding on all Medicare Carriers -- the private insurance companies that process and pay Medicare claims. It also is binding on Medicare+Choice managed care plans and Peer Review Organizations.

Q. Do all clinical trials have to go through the approval process?

A. No. We are proposing that trials that are federally funded by the National Institutes of Health (including clinical trials at the National Cancer Institutes cancer centers), the Centers for Disease Control and Prevention, the Agency for Healthcare Research and quality, the Department of Defense, the Department of Veterans Affairs, the Investigational New Drug trials approved by the Food and Drug Administration (and those exempted from Investigational New Drug applications) have deemed status. That is, these trials are automatically approved as meeting the desirable characteristics. These requirements include scientific support for the trial, credible and capable sponsorship, and protection of participating patients.

###

Q. Is a Medicare + Choice Organization required to provide coverage for services related to clinical trials, even if those services are provided outside of the organization's network of providers?

A.

Ordinarily, Medicare + Choice Organizations must furnish, or pay for, services covered under original Medicare only within the limits of the plan rules governing its network of providers and out-of-network referrals. For example, Medicare +Choice Organizations are not required to pay for services covered under original Medicare if an enrollee obtains covered services outside of network without obtaining a required pre-approval or referral. However, we expect, in most cases, that physicians and other health care personnel providing services related to clinical trials will be outside a specific plan's network.

We recognize the essential role that plan networks play in the appropriate management and coordination of beneficiary health care. However, services that meet the definition of routine costs in clinical trials that have been approved under the process established in this NCD may not be denied on the grounds that they will be provided outside the plan's network or that they will be rendered pursuant to a clinical trial.

Services related to clinical trials are inextricably linked to those trials, and those services cannot be provided, without serious patient disruption, except by the physicians and others conducting the trials. Thus, if the providers participating in the eligible clinical trial are not part of the Medicare + Choice Organization's network, the plan cannot provide this required coverage within its network, and must authorize out of network servicess in order to fulfill its obligation.

Q. What is the Medicare + Choice enrollee's liability for services related to clinical trials?

A.

Medicare + Choice enrollees will be liable for any applicable coinsurance amounts under the payment rules of original Medicare, but not for the Part A deductible.

Q. How will HCFA pay for Medicare + Choice enrollees in clinical trials? (NOTE: The following answer should be used for all operational questions related to Medicare + Choice.)

We recognize that there are complex operational issues that must be addressed before this NCD can be fully implemented. We expect that Medicare + Choice Organizations and others will raise many issues and suggest recommendations for solving these problems during the comment period. In the meantime, we will be working to ensure that Medicare beneficiaries in managed care plans will receive the services they are entitled and that Medicare + Choice Organizations are not unfairly burdened in providing these services.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 6 2000

MEMORANDUM FOR THE PRESIDENT

Promoting biomedical research and ensuring that Medicare beneficiaries receive the highest quality care are longstanding priorities of the Department of Health and Human Services. We recognize that Medicare beneficiaries should not face barriers in accessing cutting-edge treatments that clinical trials can provide.

However, elderly individuals and their physicians may be deterred from participating in potentially life-saving clinical trials because of the uncertainty of Medicare reimbursement for their patient care costs for the many diseases from which they suffer. Up to now, some clinical trial investigators may have been uncertain about whether Medicare would pay for routine patient care if a beneficiary participated in their clinical trials. Some patients considering whether to enter these trials may have assumed that they could be responsible for routine costs.

Out of these concerns, the Balanced Budget Act of 1997 authorized the Health Care Financing Administration (HCFA) to sponsor a study conducted by the Institute of Medicine (IOM). The purpose of the study was to determine whether there were barriers to Medicare beneficiary participation in clinical trials. Last December, IOM issued a report entitled "Extending Medicare Reimbursement in Clinical Trials" which recommended that Medicare cover the routine patient care costs associated with clinical trials. This new information prompted a review by the Department. Following this review, the Department concluded that it could exercise its administrative authority to provide Medicare reimbursement for the routine patient care costs associated with clinical trials in which Medicare beneficiaries participate.

I recommend that we take the following actions. First, HCFA should immediately prepare a revision to the Medicare manual to authorize Medicare's claims processing contractors to reimburse for the routine patient care costs that are reasonable and necessary during a beneficiary's participation in a clinical trial. Second, HCFA should authorize its contractors to reimburse providers for costs incurred to treat medical complications that may occur after a patient receives experimental services in a clinical trial. This action is consistent with the IOM's primary recommendation and would not include Medicare reimbursement of costs specifically related to non-covered services.

In addition, HCFA, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) will undertake a series of activities to promote the goal of improving older Americans' access to cutting-edge treatments. The Department will launch educational activities to increase beneficiary awareness of the new coverage option; will ensure collaboration between HCFA and NIH so that information gained

from clinical trials is used to inform Medicare coverage decisions; and will establish a system that tracks Medicare payments for costs associated with beneficiaries participating in clinical trials. In addition, HCFA, NIH, and FDA will review the feasibility and advisability of expanding further Medicare's coverage of other costs associated with certain clinical trials.

I am pleased to be able to inform you about these new developments. I know you and the Vice President share my commitment to ensuring that Medicare beneficiaries have access to clinical trials which also serve to promote critical biomedical research. I look forward to keeping you apprised of our progress in this important area.

Donna E. Shalala

Copy

MEMORANDUM FOR THE VICE PRESIDENT OF THE UNITED STATES

FROM: Janice R. Lachance
Director

SUBJECT: Leave for Cancer and Other Preventive Screenings

The many benefits of health education and preventive health screenings are well-known to the American people and the medical care profession. As the single largest employer in the Nation, we are proposing a work-site initiative for Federal employees that would provide for a wider variety of preventive health measures and one that would provide increased excused absence for those employees who, we believe, would benefit most.

The genesis for this new initiative was your August 10, 1999, directive to the Office of Personnel Management (OPM) to look into the advisability and feasibility of giving Federal employees time off from work each year for cancer and other preventive screenings.

We are convinced that any effort to increase the level of employee participation in health screening activities must be part of a comprehensive preventive health services program that includes not only screenings, but health education, counseling, and intervention. A growing body of literature links some of the leading causes of death in America to a handful of personal health behaviors such as smoking, failing to use seat belts, driving while intoxicated, physical inactivity, dietary factors, and high risk sexual practices. Changing personal health behaviors before disease develops also plays a vital role in maintaining good health. By providing comprehensive preventive health services at the work-site, without charge to leave, agencies can help employees identify their risk for disease, evaluate their health care needs, and make healthy lifestyle choices.

According to the Bureau of Labor statistics 1997 figures, 34 percent of employees in large establishments in the non-Federal sector are offered some type of health promotion program. However, most Federal agencies provide pertinent health care information to their employees through activities such as smoking cessation clinics, exercise/physical fitness programs, weight control programs, nutrition education, hypertension tests, and stress management courses. Many agencies offer health fairs which allow employees to conveniently explore, under one roof, resources related to the health issues that are of particular concern to them.

We believe the Federal Government's leave system is sufficient to accommodate most Federal employees' needs for participation in screenings and other preventive health activities. (Attachment 1 provides more detail about time off for cancer and other preventive screenings in the Federal and non-Federal sectors.) Nevertheless, we are concerned about those Federal

employees who have not worked long enough to accrue a substantial balance of paid sick leave or who have been forced to use most or all of their paid sick leave as a result of previous illnesses or periods of incapacitation. In these cases, we believe it would be appropriate for agency heads to provide up to 4 hours of excused absence with pay each year to participate in preventive health screenings not directly sponsored by the agency.

We have prepared a memorandum from the President (Attachment 2) that directs agencies to review their leave and work schedule policies and to inform employees of the various flexibilities available to them for arranging to participate in screening activities. In the case of employees with less than 3 years of service or fewer than 80 hours (2 weeks) of accrued sick leave, the memorandum asks agencies to provide up to 4 hours of excused absence each year, without loss of pay or charge to leave, for participation in preventive health screenings not directly sponsored by the agency. The memorandum also asks agencies to expand or develop programs offered at the work-site that help employees understand their risks for disease, obtain preventive health services, and make healthy lifestyle choices. We will provide departments and agencies with appropriate guidance on developing preventive health initiatives. In addition, it requests agencies to share their best practices and preventive health initiatives with OPM within 120 days. OPM will use this information to identify and share agency best work-site practices.

Your request was based upon a program implemented in Boston that gives city employees 4 hours off annually for cancer screenings. We have researched the issue and consulted with colleagues from the Department of Health and Human Services (HHS). This effort has resulted in our proposed initiatives that are designed to help our employees remain both healthy and productive.

It is important to note that, under the Federal Employees Health Benefits (FEHB) Program, insurance carriers are required to cover mammography, prostate-specific antigen, and colorectal screening. Many carriers cover other screenings as well. OPM will continue to monitor the screening recommendations adopted by authoritative bodies such as the National Cancer Institute and we will assure that the FEHB Program provides appropriate benefits.

The issue of employee health is one of deep concern to me and to OPM. We appreciate your support in calling the Nation's attention to this important issue.

Attachments

Attachment 1

Time Off for Cancer and Other Preventive Screenings in the Federal Government

The Federal personnel system provides employees with considerable flexibility in scheduling their hours of work and taking time off for medical needs, including routine examinations and preventive screenings. Examples of the work and leave flexibilities available to employees for screenings include the following:

- **Alternative Work Schedules**. Federal agencies may establish flexible or compressed work schedules, collectively referred to as "alternative work schedules." Alternative work schedules allow for a variety of working arrangements tailored to fit the needs of individual employees.

- **Annual leave.** Most employees accrue 13, 20, or 26 days of annual leave each year, depending on years of service (which accumulates to a maximum of 240 hours each year).

- **Excused Absence.** Agencies may grant excused absence to employees to participate in agency sponsored preventive health activities, such as health fairs, mobile health van screenings, and smoking cessation and stress reduction classes. Agencies should also establish a policy that provides employees with less than 3 years of service or fewer than 80 hours (2 weeks) of accrued sick leave with up to 4 hours of excused absence each year, without loss of pay or charge to leave for participation in preventive health screenings not directly sponsored by the agency.

- **Sick leave.** Most employees accrue 13 days of sick leave each year without regard to length of service (which accumulates without limit in succeeding years).
- **Advance leave.** Supervisors may advance annual and sick leave to employees who do not have available paid leave and have already used 4 hours of excused absence for preventive health screenings not directly sponsored by the agency. In addition, supervisors may advance annual and sick leave to employees for additional examinations and follow-up treatments.

When an employee needs additional medical attention, e.g., a serious health condition is identified by a screening process, the following additional leave programs are available:

- **The Family and Medical Leave Act of 1993 (FMLA).** Under the FMLA, an employee is entitled to a total of 12 workweeks of unpaid leave during any 12-month period for certain needs, including an employee's serious health condition and screenings for such conditions. An employee may substitute annual leave or sick leave, as appropriate, for unpaid leave under the FMLA.

Attachment 1 continued

- **Leave Sharing.** Employees who experience a personal or family medical emergency and who exhaust their available paid leave may receive donated annual leave from other Federal employees through the voluntary leave transfer or leave bank programs.

Information on these programs is available on OPM's web site at www.opm.gov/oca.

Time Off for Cancer and Other Preventive Screenings in the Non-Federal Sector

The Bureau of Labor Statistics (BLS) reported that in 1997 only 56 percent of full-time employees in establishments with 100 or more employees receive paid sick leave. The average number of sick leave days available after 1 year of service was 11 days, with 21 days available after 25 years. In the large establishments surveyed, 39 percent of employees could not accumulate sick leave in succeeding years, 19 percent were allowed unlimited accumulation, and the remainder were limited to a maximum accumulation of sick leave, most often in the 30-39 day range.

In comparison, Federal employees accrue 13 days of sick leave each year without regard to length of service and may accumulate sick leave in succeeding years without limitation. The average use of sick leave by Federal employees in 1998 was 9.47 days. Assuming a Federal employee uses the average amount of sick leave each year, he or she can accumulate 18 days of sick leave after 5 years of service, 35 days after 10 years, and 88 days after 25 years.

Attachment 2 **Last updated 6/1/00**

THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Preventive Health Services at the Federal Workplace

I have been heartened by progress in preventive research into cancer and other serious diseases. Vice President Gore announced on the second anniversary of the Cancer Genome Anatomy Project, that over 30,000 human genes predisposing individuals to cancer have been identified, more than double the original goals, and that 8.4 million Americans have survived cancer. This is good news indeed.

I am still concerned about another front in the war against disease. We know a great deal about screening procedures that can detect diseases early, and about behaviors, such as smoking cessation and sun avoidance, that can greatly reduce a person's risk of disease. The challenge that remains is to ensure that all Americans not only take advantage of the screening programs and other effective preventive measures that are available and appropriate, but that they make positive changes in their lifestyle before disease develops. For example, *Healthy People 2010*, a report on our Nation's health objectives, released in January by the Department of Health and Human Services estimates that as much as 50 percent or more of cancer incidence can be prevented through smoking cessation and improved dietary habits such as reducing fat consumption and increasing intake of fruits and vegetables.

The workplace is a logical place to provide employees with health information and services to help employees learn about preventive health. The Federal Government, the Nation's largest employer, has already developed many effective measures for encouraging preventive health care for its employees. These measures, available to all Federal employees, cover a broad range of preventive health services, including screening for prostate, cervical, colorectal, and breast cancer and screening for sickle cell, blood lead level, and blood cholesterol level, as well as all recommended childhood immunizations, well child care, and adult preventive care visits. In addition, the Federal personnel system provides employees with considerable flexibility in scheduling their hours of work and taking time off for medical needs, including routine examinations and preventive screenings. Many agencies offer creative, effective employee health programs that provide opportunities for employees to take advantage of preventive health screenings at the worksite.

There is still room for progress. Therefore, I am today asking Federal departments and agencies to review their policies and make maximum use of existing work schedule and leave flexibilities to allow Federal employees to take advantage of screening programs and other effective preventive health measures. Each department and agency should also inform its employees of the various work schedule and leave flexibilities available to them to participate in these preventive screenings and examinations. Such flexibilities include promoting alternative work schedules (flexible and compressed work schedules), which allow for a variety of working arrangements tailored to fit the needs of individual employees, granting leave under the Federal Government's sick and annual leave programs, and granting excused absence to employees to participate in agency sponsored preventive health activities. In the case of employees with less than 3 years of service or fewer than 80 hours (two weeks) of accrued sick leave, I am asking each department and agency to establish a policy that provides up to four hours of excused absence each year, without loss of pay or charge to leave, for participation in preventive health screenings not directly sponsored by the agency.

I am also asking agencies to develop or expand programs offered at the worksite to help employees understand their risks for disease, obtain preventive health services, and make healthy lifestyle choices and to share these initiatives with the Office of Personnel Management (OPM) within 120 days. OPM will use this information to identify and share agency best worksite practices. Finally, I direct the OPM to prepare guidance to assist agencies in carrying out this directive.

I want the Federal Government to serve as a model for the rest of the country. While Federal agencies have led the way in many instances, I want to go even further in demonstrating that preventive health care for all employees is not only desirable, but also very practical and sensible.

WILLIAM J. CLINTON

AMERICAN CANCER SOCIETY® Hope. Progress. Answers.

National Government Relations Office

June 14, 2000

Chris Jennings
Deputy Assistant to the President, Health Policy Development
216 Old Executive Office Building
Washington, DC 20500

Dear Chris:

On behalf of the 2 million volunteers and more than 16 million supporters of the American Cancer Society, I would like to applaud the Clinton/Gore Administration for its announcement last week that it will remove one of the key barriers Medicare beneficiaries face when deciding whether or not to enroll in a clinical trial. This year, more than 1.2 million Americans will be newly diagnosed with cancer – of these more than 60 percent will be over the age of 65. For many of these cancer patients, new treatments available through high-quality, peer reviewed clinical trials offer their best hope for survival. An Executive Memorandum directing the Medicare program to begin reimbursing providers for the cost of routine patient care associated with participation in clinical trials will go a long way toward improving Medicare patients' access to these often life-saving therapies.

As the nation's largest voluntary health organization, the Society has a longstanding interest in this issue and has identified increasing access to clinical trials for Medicare and managed care patients as one of its top priorities for many years. As part of this advocacy effort, we were actively working for passage of "The Medicare Cancer Clinical Trials Coverage Act" (S.784/H.R.1388) and to garner broad, bipartisan support for the legislation. This push led to co-sponsorship by 169 Members of the House and 47 Senators. You may also recall that Ilisa Halpern and I met with you last spring to discuss the Institute of Medicine's report on Medicare coverage policy for clinical trials. The Society is also working with Members of Congress for inclusion of a strong clinical trials provision in the "Patients' Bill of Rights."

Throughout all of our advocacy efforts, the Society has not only focused on the need for improved patient access to clinical trials but also on the need to ensure that these trials are high quality, scientifically based, and peer-reviewed. We recognize that the Administration has also articulated this position, as evidenced by your recent proposals on safety of gene therapy trials.

701 PENNSYLVANIA AVE., N.W., SUITE 650, WASHINGTON, DC 20004-2608 • PHONE (202) 661-5700 • FAX (202) 661-5750

We have noted that "quality" trials were not defined in the President's announcement. Over the last week, our National Government Relations staff has had several conversations with the Administration about this critical patient safety issue. We understand and appreciate the statutory challenges you face in taking this initiative, but we are hopeful that we can work together to make sure that the revised Medicare policy leads patients to enroll in high quality trials. In particular, the Society advocates that patients make the decision to enter a clinical trial in consultation with their physician and that enrollment should occur only if appropriate guidelines and rules are in place to ensure the safety of the patients participating in the trial. This position was also included in our March 1999 letter to the IOM committee examining Medicare coverage for clinical trials. I have enclosed this letter for your review.

Again, we wholeheartedly appreciate and support the Administration's recent decision to require that Medicare provide coverage for routine costs if beneficiaries enroll in a clinical trial. We look forward to working with you to make sure that Medicare beneficiaries reap the full rewards of the access to clinical trials benefit and secure the quality of care they so desperately need. Should you or your staff have any questions, please feel free to contact myself at 202-661-5701, Megan Gordon, Manager of Federal Government Relations at 202-661-5716, or Shalini Vallabhan, Director of Policy Research at 202-661-5728.

Sincerely,

Daniel E. Smith

National Vice President, Federal and State Government Relations

cc: David Beier - Chief Domestic Policy Advisor to the Vice President
Bonnie Washington – Director, HCFA Office of Legislation

Enclosure: ACS letter to Dr. Henry Aaron, Chair of the Institute of Medicine's Committee on Reimbursement of Routine Patient Care Costs for Medicare Patients Enrolled in Clinical Trials

AMERICAN CANCER SOCIETY® NATIONAL GOVERNMENT RELATIONS OFFICE

Henry J. Aaron, Ph.D.
Chairman
Committee on Reimbursement of Routine Patient Care Costs
for Medicare Patients Enrolled in Clinical Trials
Institute of Medicine
National Academy of Sciences
2 101 Constitution Avenue, NW
Washington, DC 20418

March 19, 999

Dear Dr. Aaron:

On behalf of the American Cancer Society and its 2 million volunteers, I am writing to voice to you and the IOM Committee our strong support for enhancing the Medicare program by allowing it to cover the routine patient care costs for Medicare beneficiaries who choose to enroll in clinical trials. We appreciate your commitment to studying this issue critical to improving and protecting the well-being of a population disproportionately affected by cancer.

As you know, the risk of chronic disease, such as cancer, increases with age and Medicare beneficiaries account for more than 50% of all cancer diagnoses and 60% of cancer deaths. A significant portion of those in the Medicare program suffer from co-morbidities and those additional health problems can make some cancer therapies that are effective in younger people inappropriate for older patients. Therefore, it is critical to evaluate new therapeutic approaches in the Medicare population.

Currently, when a Medicare beneficiary is being treated for cancer, her routine patient care costs (e.g. blood work, physician visits, hospital stays) provided along with the treatment are covered by the Medicare program – even if that treatment proves ineffective. When Medicare beneficiaries who want to enroll in clinical trials have coverage of routine patient care costs refused, these patients then often are denied participation in the clinical trial and possibly denied a chance at improved survival or better quality of life. Furthermore, we as a nation lose an opportunity to collect data about the safety and efficacy of a new therapy or technology that could potentially benefit future generations of patients. We therefore believe that routine patient care items and services covered when standard therapy is provided should also be covered if a Medicare beneficiary chooses to receive treatment in the context of a clinical study.

The American Cancer Society recognizes that to ensure continued success of our nation's clinical research program we must sustain and augment the existing partnership between researchers, patients, advocates, investors and payers from the public, private, and non-governmental sectors. We believe that there are three categories of costs associated with clinical trials which should be borne as follows:

- The investigational drug or other agent provided free of charge by the pharmaceutical sponsor.

- The costs associated with collecting and analyzing the data from the trial covered by the trial sponsor through a federal research grant or other funding source (i.e. NIH, FDA, American Cancer Society, pharmaceutical company, etc.).
- The routine patient care costs – such as physician charges, hospital fees and routine diagnostic tests – for enrolled patients paid for by third party payers. Specifically, Medicare routine patient care costs are those that the program would otherwise cover if the patient care items and services were not provided in connection with a clinical trial.

In recent years, a number of federal legislative proposals have been introduced to provide patients with assured access to clinical trials. We believe that the broad-based approach taken in such bills with regards to the types of trials that should be eligible for Medicare coverage is appropriate and effective policy. We appreciate that some have concerns regarding how to assure that the types of trials in which Medicare beneficiaries can enroll and have their routine patient care costs covered are of the highest-quality and peer-reviewed. Therefore, the American Cancer Society advocates that eligible clinical trials should include those approved or sponsored by any of the following:

- The National Institutes of Health (NIH)
- A NIH cooperative group or NIH center
- The Food and Drug Administration
- The Department of Veterans Affairs
- The Department of Defense
- A qualified non-governmental research entity meeting NIH guidelines
- A peer-reviewed and approved research program as defined by the Secretary of the US Department of Health and Human Services.

Clinical trials that meet the stringent criteria of the above entities are considered to be high-quality by the scientific and patient advocacy community. The NIH estimates that cancer clinical trials comprise 30-40% of all the clinical trials conducted in the United States. Despite the disproportionate burden of cancer among those aged 65 and older, only 1.5% of people with cancer over 65 enroll in clinical trials as compared to 3% of all cancer patients. It is clear that we must adopt measures to ensure that more Medicare beneficiaries enroll in such high-quality, peer-reviewed clinical trials so they can benefit from state-of-the-art care while also making an important contribution to the advancement of medical research. Medicare coverage of routine patient care costs for beneficiaries who want to participate in such trials is critical to assuring that patients have access to critical new therapies and researchers accrue enough participants for valid and reliable study results.

Please know that we stand committed to working with you and your Committee members on this important issue. Please contact Kerrie Wilson (kwilson@cancer.org) Acting Strategic Business Manager for Advocacy or Ilisa Halpern (ihalpern@cancer.org) Acting Director Federal Government Relations in the ACS National Government Relations Department (202-661-5700 phone and 202-661-5750 fax) for any information you need. We appreciate your attention to this critical health and research matter. We are confident that what is learned from clinical trials will benefit future patients, may reduce health care costs through the development of more effective therapies, and could help to reduce suffering from cancer for patients.

Sincerely,

Charles J. McDonald, MD
President

[redacted] Cancer Clinical Trial

DRAFT 06/12/00 12:24 PM --

Program Memorandum

This program memorandum is intended to guide contractors as they process Medicare claims for services associated with non-covered services, including non-covered services delivered to Medicare beneficiaries in clinical trials.

Our policy to date regarding services provided related to non-covered service is articulated in MCM §2300 and MIM §3101. We are hereby revising this policy to further clarify eligibility for Medicare coverage. By this revision, Medicare excludes from coverage eligibility only those services that are clearly "specific to" the non-covered services.[1] The non-covered services, continue to be excluded from coverage. These include those services and items that are statutorily excluded, have a national noncoverage policy, or those not considered reasonable and necessary at the local level. All services must be medically necessary for the individual patient in order to be covered by Medicare.

Only services that are "specific to" a non-covered service are to be excluded from coverage. In other words, you may exclude from coverage only those services that are performed only because the noncovered service was rendered. Items or services that are "specific to" a non-covered service (and thus are not covered) include:

1. The non-covered item or service itself (e.g. cosmetic surgery, weight loss treatments);

2. Any item or service necessary, given the patient's clinical circumstances, to prepare for the delivery of the non-covered item or service (e.g., pre-operative testing);

3. Any item or service necessary, given the patient's clinical circumstances, to deliver the non-covered item or service, in particular:

    a) If the reason for admission under Medicare's prospective payment systems is solely for the purpose of providing the non-covered service, then the entire episode is non-covered;

    b) All items and services specifically related to the delivery of the non-covered service;

---

[1] We note that the original articulation of policy to exclude from coverage, services that were "related to" non-covered services pre-dated the hospital inpatient prospective payment system. Therefore, with respect to services that are not "specific to" a non-covered service but are provided during the same inpatient stay as that during which the non-covered service is provided, the admission is not to be covered unless the principal reason for the admission is a separate, covered purpose.

In addition, we note that our policy concerning services associated with investigational devices is separately codified at 42 C.F.R 405.201 - 405.215. This program memorandum does not alter that policy.

DRAFT 06/12/00 12:24 PM --

c) Items or services needed to manage the complications during the delivery of the non-covered service. During the delivery is defined as temporarily related to the "payment episode" of the delivery of the non-covered service. However, the services necessary to manage the complications after the "payment episode" of a non-covered service may be covered, to the extent they are not statutorily excluded and found to be reasonable and necessary; and

4. Any post-delivery item or service necessary to monitor the effects of the non-covered service but only where there are no clinical signs or symptoms necessitating the monitoring. In making the distinction between services necessary to monitor the effects of the non-covered service post-delivery and services necessary given the patient's signs or symptoms, contractors should consider conventional medical practice and the patient's known risks (apart from those inherent to the non-covered service) and signs or symptoms.

Services that are not "specific to" a non-covered service (and thus are eligible for coverage) include:

1. items or services that are not associated with the non-covered service, and

2. items or services that are necessitated by complications, clinical signs or symptoms arising after the delivery of the non-covered service, whether or not they are caused by the non-covered service.

Of course, services that are not "specific to" a non-covered service may be covered only to the extent that they would otherwise be covered (e.g., to the extent that they are reasonable and necessary).

While our policy applies equally with respect to all types of non-covered services (e.g., non-covered organ transplants, cosmetic surgery), we are particularly interested in its application to non-covered services provided in clinical trials. Medicare coverage policy should not unduly or inappropriately disadvantage Medicare beneficiaries who choose to participate in clinical trials. In other words, a Medicare beneficiary must not "lose" his or her Medicare benefits upon enrollment in a clinical trial. Therefore, we have provided the following illustrations that are largely "specific to" the context of and clinical trials:

1. A non-covered screening test to detect breast cancer in asymptomatic women is performed. The non-covered screening test and the fee to administer the test is not covered. However, the person performing the test is interested in comparing the non-covered result with a conventional mammogram. The conventional mammogram would be covered as long as it is consistent with the Medicare statutory benefit. However, if the person also wanted to get a CT scan to compare with the non-covered

Need to clarify how PPS-Exempt Cancer hospitals are treated.

screening test, the CT scan would be non-covered unless there were other signs or symptoms necessitating the CT scan.

2. A patient is in an outpatient clinical trial for a non-covered drug for congestive heart failure administered weekly for six weeks. The drug and its administration and the associated professional fees are not covered. Items or services temporally outside of the payment episode of the drug delivery that are reasonable and necessary to treat the patient, irrespective of whether they are due to congestive heart failure, the administered drug, or any other clinical condition, are all covered (excepting services used to monitor the drug in the absence of any signs or symptoms necessitating such services).

3. A non-covered cancer chemotherapeutic drug is administered. The anti-emetic drugs and services needed in preparation to delivery and needed during the delivery of the non-covered ~~the non-covered~~ chemotherapeutic drug are all non-covered. However, after the delivery (i.e., after the "payment episode" of the non-covered chemotherapeutic drug) if the patient's signs or symptoms require further anti-emetic treatment this would be covered.

4. A non-covered procedure for cosmetic surgery is being performed. The procedure and its costs of administration are non-covered. If, during the procedure, the patient experiences uncontrolled bleeding, the services necessary to treat the bleeding during the payment episode of the procedure are non-covered. If the patient requires further attention for the bleeding episode after the payment episode of the procedure, for example the patient is discharged and later admitted to an emergency room- the ER visit is covered as long as it was otherwise reasonable and necessary.

5. Same as above but the patient does not develop bleeding during the non-covered cosmetic surgery. If the physician orders a hematocrit (red blood cell count) after the surgery without accompanying signs and symptoms then the hematocrit would be non-covered.

6. A non-covered surgery is performed on a patient in an ambulatory surgical center. The ambulatory surgical center visit, the physician's service, and the pre-operative work-up labs and the post-operative follow-up (in the absence of signs or symptoms) would not be covered. However, if following the non-covered surgery, the patient developed complications, or signs or symptoms, requiring medical attention, then the services reasonable and necessary for the diagnosis and treatment of that patient are covered.

7. Cosmetic surgery (a non-covered service) is performed in a doctor's office. The beneficiary has a heart condition requiring special cardiac monitoring, the cardiac monitoring would not be covered during the non-covered service. Following the service, cardiac monitoring would be covered if the patient's signs and symptoms indicate that it is reasonable and necessary.

DRAFT 06/12/00 12:24 PM –

8. A covered chemotherapeutic drug is administered. The anti-emetic drugs needed in preparation of, during and after the covered chemotherapeutic drug are all covered. However, all Medicare coverage and payment rules must be met.