Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-01-103 **Date: July 27, 2001**

CHANGE REQUEST 1637

This PM supersedes AB-01-130 as of 12/31/01. Discard AB-01-130 on 12/31/01.

SUBJECT: Revised Guidelines for Processing Claims for Clinical Trial Routine Care Services

The purpose of this program memorandum (PM) is to provide revised diagnosis coding requirements and claims processing instructions for Medicare qualifying clinical trial services processed by carriers, DMERCS, fiscal intermediaries, Regional Home Health Intermediaries (RHHIs) and Program Safeguard Contractors. In addition, this PM clarifies Medicare contractor responsibility with respect to local medical review policy edits and requests for medical documentation for clinical trial services

Revised Diagnosis Reporting Requirements for Routine Care Clinical Trial Services Billed on the HCFA-1500 or Electronic Claim Equivalent (Carriers and DMERCs)

Effective for services furnished on or after January 1, 2002, HCFA-1500 or electronic equivalent billers will use procedure code modifier "QV" to identify and report routine care for Medicare qualifying clinical trial services. The reporting of diagnosis code V70.5 as a secondary diagnosis on HCFA-1500 or the electronic claim equivalent will no longer be required for dates of service on or after January 1, 2002. For dates of service on or after January 1, 2002, the QV modifier constitutes the billers attestation that a service, supply or equipment meets the Medicare qualifying coverage criteria for clinical trial services processed by carriers and DMERCS.

EXCEPTION: Routine care clinical trial services furnished on or after January 1, 2002 to healthy, control group volunteers participating in Medicare qualifying diagnostic clinical trials are to be coded and billed in the following manner:

- The "QV" procedure code modifier is reported at the line item level.

- Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the primary diagnosis for applicable line items on the HCFA-1500 or electronic claim equivalent.

If diagnosis code V70.7 is reported as a secondary rather than the primary diagnosis do not consider the service as having been furnished to a healthy, control group, diagnostic trial volunteer.

Diagnosis Coding Requirements for UB-92 Billers (Intermediaries and RHHIs)

Until December 31, 2001, follow the diagnosis coding requirements for UB-92 billers as specified in transmittal AB-00-89.

For inpatient discharges and all other intermediary and RHHI processed services occurring on or after January 1, 2002, routine care for Medicare qualifying clinical trial services must be identified with diagnosis code V70.7 (Examination of participant in clinical trial). V70.7 is reported as the second or subsequent diagnosis code (generally the third or subsequent diagnosis for HHAs) on the HCFA-1450 or electronic claim equivalent.

Local and Regional Medical Review Edits

Contractors must adjust local and regional medical review edits to ensure that claims with charges for properly coded/reported routine care clinical trial services are paid correctly. Moreover, if the volume of clinical trial services you are receiving is not sufficient to warrant costly systems modifications to medical review edits, you may alternatively suspend, examine and approve Medicare qualifying clinical trial services.

National coverage policies continue to apply.

Medical Records Documentation Requirements

The following paragraph revises the medical records documentation requirements contained in transmittal AB-00-89.

"When submitting claims for routine items and services furnished in qualifying clinical trials, the billing provider should include information in the beneficiary's medical record about the clinical trial such as: the trial name, sponsor and sponsor assigned protocol number. This information should not be submitted with the claim but should be provided if requested for medical review. A copy of routine items and services should also be made available if requested for medical review activities."

Provider Education

Carriers, DMERCs, Intermediaries and RHHIs must disseminate information to providers, physicians and suppliers regarding the revised diagnosis coding and billing requirements contained in this PM in their next regularly scheduled bulletin, on their website, and in conjunction with other ongoing provider education activities.

The effective date is January 1, 2002.

The implementation date is January 1, 2002.

These instructions should be implemented within your current operating budget.

This PM may be discarded after January 1, 2003.

If you have any questions, please contact William Stojak at 410-786-6984.