Program Memorandum Carriers/Intermediaries

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Transmittal AB-02-129 **Date: SEPTEMBER 27, 2002**

CHANGE REQUEST 2169

SUBJECT: Claims Processing Requirements for Clinical Diagnostic Laboratory Services Based on the Negotiated Rulemaking

Scope:

This Program Memorandum (PM) provides instructions to implement certain administrative policies for clinical diagnostic laboratory services under Medicare Part B. The administrative policies for the Negotiated Rulemaking for Clinical Diagnostic Laboratory Services are in the final regulation published in the Federal Register on November 23, 2001, 66 FR 58788.

Transmittal AB-02-110, dated July 31, 2002, and the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the Federal Register on November 23, 2001 stated an effective date for these provisions of November 25, 2002. For claims processing purposes it is necessary to provide additional detail regarding how this effective date would be applied (e.g., claims received on that date, claims processed on that date, services furnished on that date, etc.) The effective date of this PM and AB-02-110 is for services furnished on or after November 25, 2002.

Background:

Section 4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33 mandated the use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Part B of Medicare. The BBA required that these national policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Part B.

In March 2002, we issued PM (AB-02-030) that implemented certain administrative policies from the final rule effective, February 23, 2002. PM AB-02-087, released on June 26, 2002, announced the delay in the implementation of the editing for the NCDs to January 1, 2003 for dates of service on or after November 25, 2002. The National Coverage Decisions for Clinical Diagnostic Laboratory Service was released through PM AB-02-110 on July 31, 2002. The purpose of this PM is to implement the remaining administrative policies specified in the final regulation.

Policy:

The changes in this PM apply to every diagnostic clinical laboratory service that is payable under Medicare Part B. Neither the place where the service was performed, nor the type of contractor that will process the request for payment, has any effect on the applicability of these policies. A clinical laboratory service done in a hospital laboratory, independent laboratory, physician/practitioner office laboratory or other type of CLIA approved laboratory service is subject to these administrative policies.

The final rule did not supercede the requirement that all physician claims must have a diagnosis. If a physician submits a claim for a service performed in a physician office laboratory, that claim is considered a physician claim and must meet the requirements for physician claims.

Implementation:

A. Date of Service

- Date of service should be reported as the date of specimen collection.
- The person obtaining the specimen must furnish the date of collection for the specimen to the entity billing Medicare.
- For specimen collections that span more than a 24-hour period, the date of service should be reported as the date the collection began.
- For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives.
- If a situation occurs that does not correspond to the two situations described, the contractor should submit to the regional office the question with the appropriate documentation. The regional office will contact the Division of Supplier Claims Processing in CMS, who will serve as the point of contact. The information will be addressed in a PM if necessary.

B. Grace Period

- Upon request, we will consider granting a grace period of up to 12 months from November 25, 2002 for claims with dates of service on or after November 25, 2002, to accommodate any provider system changes required by the policy changes or clarifications resulting from the provisions of this rule.
- Entities that want to request a grace period to permit additional time to implement computerized system changes must contact you in writing on or before November 25, 2002.
- The request for a grace period must include:
    1. A description of the nature of the system changes not able to be implemented timely,
    2. A description of the actions the entity has taken to implement timely,
    3. A work plan with a timeline providing a detailed description of the tasks which the entity shall undertake to accomplish full implementation, and
    4. The dates when tasks shall be performed,
    5. The date that the entity will be able to implement fully.
- Establish an address and contact for receipt of applications for the grace period.
- Identify a contact person to evaluate and track the requests.
- Review the information submitted and respond to the requester advising them whether the request has been granted. If you grant the request, advise the requestor of the revised implementation date. Revised implementation dates must be on or before November 25, 2003. You should approve any request that is reasonable and includes all of the required information. Any request that will result in further unapproved administrative costs should be referred to the regional office for their approval or disapproval.
- If an entity does not meet the deadline for submitting a request for the grace period, the contractor may use discretion to allow limited additional time for the submittal.

- If an entity requested and was granted a grace period and then does not meet the requirements of these instructions by the revised implementation date, you may return as unprocessable claims from that entity.

C. Matching of Diagnosis to Procedure

- If there is a LMRP or NCD for one or more of the services included on the claim, review all of the diagnosis codes in making a determination regarding medical necessity of the service.

- Even though a claim matches diagnosis to procedure in accordance with an NCD, other rules of adjudication may apply, which could result in denial.

Diagnoses are not required on claims for laboratory services from hospitals or independent laboratories unless there is a national coverage determination (NCD) for the service, you have a local medical review policy (LMRP) for the service, or you have notified the provider of the need for diagnoses on their claims due to medical review.

Physicians who submit claims for tests done in a physician office laboratory are still subject to the requirement for an ICD-9 diagnosis on a claim.

D. Clarification of the Use of the Term "Screening" or "Screen"

The final rule clarifies that effective, February 21, 2002, the use of the term "screening" or "screen" in CPT code descriptor does not necessarily describe a test performed in the absence of signs and symptoms of illness, disease or condition. Contractors should not deny a service based solely on the presence of the term "screening" or "screen" in the descriptor.

Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers a tests for screening as described.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. You have discretionary authority to make reasonable and necessary scope of benefit determinations.

E. Provider Education

Update your website with this information.

It is especially important that this information be available to the laboratory community as soon as possible since they will have to make changes to their systems.

Contact Joan Proctor-Young at (410) 786-0949 or e-mail jproctoryoung1@cms.hhs.gov for issues related to claims processing issues. Contact Dan Schwartz at (410) 786-4197 or e-mail dschwartz@cms.hhs.gov for questions related to medical review issues.

The *effective date* for sections A, B, C and E is November 25, 2002. The *effective date* for section D is February 21, 2002. These instructions should be implemented within your current operating budget.

The *implementation date* for section D is September 27, 2002.

The *implementation date* for sections A, B, and E is November 25, 2002.

The *implementation date* for section C is January 1, 2003.

This PM may be discarded after January 1, 2004.