
Program Memorandum Intermediaries/Carriers

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

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Date: JUNE 26, 2002

CHANGE REQUEST 2203

SUBJECT: Delay in Enforcement of National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services

On November 23, 2001, CMS issued a final rule on coverage and administrative policies for clinical diagnostic laboratory services in the *Federal Register* (66 FR 58788). In an addendum to that rule, we announced 23 NCDs for clinical diagnostic laboratory services that would become effective November 25, 2002. The NCDs apply to all clinical diagnostic laboratory services payable under Part B of Medicare, regardless of whether they are processed by fiscal intermediaries (FIs) or carriers.

One of the major purposes of the laboratory negotiated rulemaking provision, as stated in §4554 of the Balanced Budget Act (BBA) of 1997, is to promote national uniformity in the processing of clinical diagnostic laboratory services. In order to achieve this goal, the NCDs are specific to an ICD-9-CM level. To avoid having all Medicare FIs and carriers individually establish separate programs with thousands of edits necessary for enforcement of these laboratory policies, we are contracting for the development of a downloadable system module to enforce the new NCDs.

Unfortunately, the new system module will not be implemented on November 25, 2002. In issuing the rule, we contemplated the possibility of delay in implementation or enforcement of selected provisions where system changes are needed but cannot be made by the effective date. In light of the time required to develop the system changes described above, we are applying this policy to delay the enforcement of the NCDs as announced in the November 23, 2001 final rule.

Current local medical review policies (LMRPs) need to be eliminated or made consistent with the new NCDs by the November 25, 2002 effective date. Contractors may review claims for adherence to the new NCDs beginning with claims submitted on the effective date. If you are unable to review NCDs without the downloadable system module, you may go back and review claims submitted after the effective date for adherence to the new NCDs once the module is in place on January 1, 2003. The NCDs are available in the November 23, 2001 Federal Register which is posted on the Internet at www.cms.hhs.gov/coverage. In keeping with the contract provisions to include all program requirements in the CMS issuance system, we will issue a Program Memorandum formally implementing the NCDs in the near future as progress on the system changes evolves.

The *effective date* for this Program Memorandum (PM) is June 26, 2002.

The *effective date* for the final rule is November 25, 2002.

The *implementation date* for the provisions of the rule that rely on the new systems module is January 1, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after August 31, 2003.

If you have any questions, contact Jackie Sheridan-Moore at 410-786-4635.

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