
CMS Manual System

Pub. 100-20 One-Time Notification

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

Transmittal 166

DATE: JULY 22, 2005

CHANGE REQUEST 3751

SUBJECT: Overnight Oximetry Testing

I. SUMMARY OF CHANGES: This instruction provides guidance on when a DME supplier may deliver test equipment on behalf of a Medicare-enrolled Independent Diagnostic Test Facility (IDTF).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: August 22, 2005

IMPLEMENTATION DATE: August 22, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|-------|----------------------------------|
| | N/A |
| | |
| | |

III. FUNDING: No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

| | |
|---|-------------------------------|
| | Business Requirements |
| | Manual Instruction |
| | Confidential Requirements |
| X | One-Time Notification |
| | Recurring Update Notification |

*Unless otherwise specified, the effective date is the date of service.

Attachment – One-Time Notification

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|-------------|------------------|---------------------|---------------------|
| Pub. 100-20 | Transmittal: 166 | Date: July 22, 2005 | Change Request 3751 |
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SUBJECT: Overnight Oximetry Testing

I. GENERAL INFORMATION

A. Background: CMS Pub100-3, Section 240.2.C requires all claims for home oxygen therapy to be supported by valid qualifying test results “performed by a qualified provider or supplier of laboratory services.”

Qualifying test results may be obtained by oximetry testing, and in certain circumstances overnight oximetry testing may be appropriate. Overnight oximetry testing (code 94762) can be performed in the beneficiary’s home or in another location.

B. Policy: Beneficiaries may self administer home based overnight oximetry tests under the direction of a Medicare enrolled Independent Diagnostic Testing Facility (IDTF). Further, a DME supplier or another shipping entity may deliver a pulse oximetry test unit and related technology used to collect and transmit test results to the IDTF to a beneficiary’s home under the following circumstances:

- 1) The beneficiary’s treating physician has ordered an overnight pulse oximetry test.
- 2) The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the beneficiary who self-administers this test, the IDTF must provide clear written instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns which may arise. Because CMS Pub100-3, Section 240.2.C prohibits DME suppliers from performing tests, the DME supplier may not create this instruction nor participate in the conduct of the test.
- 3) The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF who is responsible for transmitting a test report to the treating physician. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no cases may the DME supplier access or manipulate the test results in any form.

CMS does not intend to regulate the ownership of either the testing unit or the technology used to transmit test results.

Regulations regarding the operation of IDTFs are not changed by this instruction.

The carrier jurisdiction for the overnight pulse oximetry test is the location of the IDTF to which the test results are transmitted.

No shipping and/or handling charges may be made to or paid by a beneficiary because such charges are included in the indirect practice expenses for the Medicare physician fee schedule (MPFS) payment for the overnight pulse oximetry test.

Because the DME supplier cannot access the test results, and is acting merely as a courier of equipment, and is not involved in instructing the beneficiary how to perform the test, this does not violate the prohibition found in CMS Pub100-3, Section 240.2.C “A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines.”

Test results obtained under these circumstances will be accepted by DMERCs and will be used for purposes of qualifying the beneficiary for home oxygen therapy.

Contractors shall follow all applicable instructions regarding “purchased tests” as found in CMS IOM Pub.100-4.

According to the **Code of Federal Regulations** (42CFR§ 410.33) and CMS Manual System, Pub. 100-8, Medicare Program Integrity Manual Chapter 10 - Healthcare Provider/Supplier Enrollment, Section 5, there are specific requirements that must be met in order for an applicant to be enrolled in Medicare as an IDTF. All IDTFs, whether they provide multiple types of tests or only self-administered pulse oximetry testing must meet all the requirements for enrollment into the Medicare program.

Due to the previous uncertainty concerning reimbursement for home oximetry tests if you have enrolled IDTFs solely to do these tests you should reevaluate those enrollments to make sure they meet all IDTF qualifications. If there are any concerns you should communicate those with the IDTF to give them an opportunity to meet the standards. If the IDTF is unable to meet the requirements their enrollment should be revoked. The IDTF should be given 30 days to provide additional proof. After that time a revocation letter should be issued using reason 4 from the PIM Chapter 10 section 14.4.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | | |
|--------------------|---|---|-------|-------|---------|---------------------------|-------|-------|--|-------|
| | | F I | R H I | C H I | D E R C | Shared System Maintainers | | | | Other |
| | | | | | F I S S | M C S | V M S | C W F | | |
| 3751.1 | DMERCs shall accept the results of overnight pulse oximetry tests when determining qualification for home oxygen therapy in cases where the test equipment is delivered by a DME supplier but only when: the beneficiary’s treating physician has ordered an overnight pulse oximetry test; the test is performed under | | | X | X | | | | | |

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | | |
|--------------------|---|---|-------------|---------------------------------|-----------------------|---------------------------|-------------|--|--|-------|
| | | F I | R H I | C a r r i e r | D M E R C | Shared System Maintainers | | | | Other |
| F I S S | M C S | | | | | V M S | C W F | | | |
| | direction or instruction of a Medicare-approved Independent Diagnostic Testing Facility (IDTF); and the test unit is sealed and tamper-proof. | | | | | | | | | |
| 3751.2 | Contractors shall follow all applicable instructions regarding “purchased tests” as found in CMS IOM Pub.100-4. | | | X | X | | | | | |

III. PROVIDER EDUCATION

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | | |
|--------------------|--------------|---|-------------|---------------------------------|-----------------------|---------------------------|-------------|--|--|-------|
| | | F I | R H I | C a r r i e r | D M E R C | Shared System Maintainers | | | | Other |
| F I S S | M C S | | | | | V M S | C W F | | | |
| | None. | | | | | | | | | |

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

| X-Ref Requirement # | Instructions |
|---------------------|--------------|
| | |

B. Design Considerations: N/A

| X-Ref Requirement # | Recommendation for Medicare System Requirements |
|----------------------------|--|
| | |

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

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| <p>Effective Date*: August 22, 2005</p> <p>Implementation Date: August 22, 2005</p> <p>Pre-Implementation Contact(s): Misty Whitaker (410) 786-3087</p> <p>Post-Implementation Contact(s): Misty Whitaker (410) 786-3087</p> | <p>No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.</p> |
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