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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 3485 | Date: March 25, 2016 |
| | Change Request 9584 |

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2016

I. SUMMARY OF CHANGES: This transmittal announces the changes that will be included in the July 2016 quarterly release of the edit module for clinical diagnostic laboratory services. The national coverage determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the Medicare shared systems so that laboratory claims subject to one of the 23 NCDs (Publication 100-03, Sections 190.12-190.34) were processed uniformly throughout the nation effective April 1, 2003.

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. 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 is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

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

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

| Number | Requirement | Responsibility | | | | | | | | | |
|--------|---|----------------|---|-------------|----------------------------------|-------------|------------------|-------------|-------|-------------|-------------|
| | | A/B MAC | | D M E | Shared- System Maintainers | | | | Other | | |
| | | A | B | | H H H | M A C | F I S S | M C S | | V M S | C W F |
| 9584.3 | The SSMs shall install the edit module after testing and distribute it to the contractors as part of their routine release. | | | | | | X | X | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | | | |
|--------|---|----------------|---|-------------|-------------|------------------|-------------|--|
| | | A/B MAC | | | D M E | C E D I | | |
| | | A | B | H H H | | | M A C | |
| 9584.4 | MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | X | | | | | |

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| | |

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, patricia.brocato-simons@cms.hhs.gov , Wanda Belle, wanda.belle@cms.hhs.gov , Kimberly Long, kimberly.long@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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ATTACHMENTS: 0