DEPARTMENT: Regulatory Compliance Support	**POLICY DESCRIPTION:** Maintenance of Company Standard Laboratory Chargemaster
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EFFECTIVE DATE: October 1, 2021	**REFERENCE NUMBER:** REGS.LAB.025
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: All Company-affiliated hospitals performing and/or billing for laboratory services. Specifically, the following departments:

Administration
Laboratory
Regulatory Compliance Support
Revenue Integrity
Shared Services Centers

PURPOSE: To define the procedures for updating and maintaining the Company Standard Laboratory Chargemaster and to describe the responsibilities of Regulatory Compliance Support, company-affiliated hospitals, and Shared Services Centers (SSC).

POLICY: The Company Standard Laboratory Chargemaster (LCDM) is maintained according to the procedures herein and is consistent with American Medical Association (AMA), Centers for Medicare and Medicaid Services (CMS), National Correct Coding Initiative (NCCI), and Clinical Laboratory Improvement Amendment (CLIA) rules, guidelines and standards. Company-affiliated hospital chargemasters must be maintained in accordance with the LCDM.

PROCEDURE:

1. Structure: The LCDM is a reference tool each hospital must use to match their laboratory chargemaster to the Company standard. The following fields are present in the LCDM. Hospital chargemaster entries must **exactly** match the LCDM for those fields indicated by **bold type**.
   - **CPT code**
   - **HCPCS code**
   - **Standard Description**
   - **Revenue code**
   - CPT/HCPCS code required for Revenue code (Y/N)
   - Ordering Mnemonic
   - Group
   - Category

2. Maintenance: Regulatory Compliance Support colleagues enters modifications, deletions and additions necessitated by regulatory agency requirements, AMA CPT changes, CMS HCPCS changes, emerging technologies and facility requests. Regulatory Compliance Support colleagues perform a detailed quality control process to verify all changes have been entered and updated correctly. A maintenance report is distributed quarterly.

   Company-affiliated hospitals and SSC colleagues are responsible for reviewing the quarterly maintenance and updating their chargemasters accordingly. In addition, facility

colleagues must review and verify applicable entries are present in the facility chargemaster in accordance with the LCDM and appropriately tied to the related Laboratory and Order Entry Masterfile/Dictionaries. Company-affiliated hospitals and SSC colleagues are also responsible for correcting any discrepancies noted on their monthly exception report. Regulatory Compliance Support colleagues will follow-up with the SSC and non-compliant hospitals.

Hospitals are responsible for identifying any necessary updates required for front-end systems and processes (e.g., HIS, order entry, requisitions, etc.)

3. Modification Requests: Hospitals may submit requests for an addition, deletion or modification of the LCDM to the Regs Helpline. The following information must be included in each request:

   - Name and title of requester
   - Telephone number of requester
   - Hospital name and COID
   - Test name and synonyms
   - Test methodology
   - Name of reference laboratory performing test (if applicable)
   - Reference lab test code, if available
   - Additional supporting information (package insert, reference lab technical bulletin, and information on clinical application of the test) should also be submitted, if available.

4. Annual External Review: Regulatory Compliance Support contracts for an annual, external review of the Company Standard Laboratory Chargemaster. This external review provides for an independent assessment of the accuracy of the LCDM.

SPECIAL CONSIDERATIONS:

1. **Calculated test results:** It is not appropriate to bill for a laboratory test result that is derived by calculation from an underlying laboratory test. Therefore, these tests are excluded from the LCDM. The only exception is the automated hematocrit. This test is derived by calculation from one measured, separately billable test (RBC), and one non-billable, calculated test (Mean Corpuscular Volume MCV). CMS and other entities have ruled that this test is separately billable.
2. **Unlisted laboratory procedure codes:** Unlisted laboratory procedure codes may only be used to report a laboratory service that is not described in any other code listed in the current CPT and/or HCPCS manuals. Requests for addition of tests to the LCDM using CPT codes described as unlisted procedures will be thoroughly researched by the Regulatory Compliance Support colleagues prior to addition to determine if an alternative

analyte or methodology code is available. Only test-specific entries will be made in the LCDM for these CPT codes.

3. **Investigational use only tests:** CMS does not cover tests that the FDA has approved for investigational use only. Other payers may have specific policies regarding coverage of tests that are considered investigational.
4. **Laboratory Developed Tests:** Test protocols developed by laboratories in-house are referred to as laboratory-developed tests (LDTs), also known as “home brew” tests. These tests may use reagents that are produced in-house or are purchased from other suppliers. Some purchased reagents fall into the category of analyte specific reagents and special labeling rules apply (see below). Medicare covers LDTs when the method validation studies required by CLIA have been performed, except where other coverage limitations apply. Since a test listed in the LCDM may be performed using a variety of assays or methodologies, the LCDM does not indicate LDTs and tests performed by “home brew” protocols.
5. **Analyte specific reagent tests:** Certain chemicals and antibodies purchased by laboratories as the active ingredients of tests developed in-house (LDTs) are termed analyte specific reagents (ASR) by the Food and Drug Administration (FDA). The majority of ASRs are exempt from FDA approval or clearance. Laboratories using ASRs in testing protocols are required to include a specific disclaimer on the test report. Medicare covers tests performed using ASRs when the method validation studies required by CLIA have been performed, except where other coverage limitations apply. Since a test listed in the LCDM may be performed using a variety of assays or methodologies, the LCDM does not indicate ASR tests.
6. **Excluded tests:** Certain CPT/HCPCS codes that describe lab tests with complex billing rules and/or significant risk for billing errors may be restricted from use by the Company. These restricted tests are excluded from the LCDM and company-affiliated hospitals must not bill for these test. The excluded lab test and/or CPT/HCPCS codes are included in the HCA Healthcare Laboratory Billing Compliance Plan.
7. **Emergency Use Authorization and Emergency Approval**: CMS may cover tests that have been given Emergency Use Authorization (EUA) clearance by the FDA. The settings in which an EUA authorized test may be used are included in the Letter of Authorization. The EUA remains in effect until the emergency declaration is terminated or the authorization is revoked by the FDA. Assays that have been issued an EUA remain subject to CLIA regulations. Tests that have been granted EUA approval are located on the FDA website.

REFERENCES:

1. Federal Register / Vol. 66, No. 226 / Friday, November 23, 2001 / Rules and Regulations
2. Title 21-Food and Drugs Chapter I-Food and Drug Administration Department of Health and Human Services Subchapter H-Medical Devices

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3. Federal Register: January 5, 2001 (Volume 66, Number 4)
4. OIG Compliance Program Guidance for Clinical Laboratories
5. NCCI Policy Manual for Medicare, Chapter 10: Pathology/Laboratory Services
6. Federal Register / Vol. 54, No. 18 / Monday, January 30, 1989, pg. 4307
7. Federal Register / Title 21, Vol. 8 / Revised April 1, 2020, Section 809.10
8. Federal Register / Title 21, Vol. 8 / Revised April 1, 2020, Section 809.30
9. U.S. Food & Drug Administration: Emergency Use Authorization