DEPARTMENT: Regulatory Compliance Support	**POLICY DESCRIPTION:** LABORATORY - Reflex Tests
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APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE:

All HCA Healthcare affiliated hospitals performing and/or billing laboratory services. Specifically, the following departments:

Laboratory	Administration
Health Information Management	Information Systems
Medical Staff Services	Shared Service Centers
Credentialing Processing Centers	

PURPOSE: To establish guidelines regarding laboratory reflex testing.

POLICY:

Laboratory reflex testing must be medically necessary and must be approved by the Medical Executive Committee (MEC) on an annual basis as evidenced in the MEC minutes. Only those reflex tests documented as approved by the MEC may be utilized. Physicians must be informed of those tests for which an approved reflex test exists and the implications of ordering such tests. A notification listing the hospital's active reflex tests must be provided to the physician initially, then every two years during the recredentialing process. The hospital's laboratory requisition or electronic order entry must allow the physician to select the initial test without the reflex for Optional Reflex Tests.

Definitions:

Reflex Testing: Laboratory testing performed subsequent to initial test results and used to further identify significant diagnostic information for appropriate patient care. Testing performed as a step necessary to complete a physician's order is not considered reflex testing.

There are two types of reflex tests:

a. **Required Reflex Tests:** Laboratory tests which, if positive, require additional separate follow-up testing in order to have clinical value. The need for the follow-up testing is implicit in the physician order. Reflex tests required by state, regulatory, or accreditation standards are also considered to be of this type. Examples include, but are not limited to, a positive RBC antibody screen reflexing an RBC antibody identification, and a positive urine culture reflexing an organism identification and susceptibility. These additional tests are separately reportable because they are not performed to complete the ordered test.

b. **Optional Reflex Tests:** Laboratory tests where the initial test result may have clinical value without the additional reflex testing. In situations where the MEC has approved an optional reflex test, hospitals and laboratories are required to offer the initial test without the reflex, if the physician so orders. An example of this type of reflex test is a serum protein electrophoreses with a monoclonal protein band, with a reflex for band identification by serum immunofixation or immunoelectrophores. A laboratory should not routinely perform optional reflex tests unless ordered by the treating physician.

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PROCEDURE:

1. The Laboratory Director must consult with the Medical Director, Pathologist(s), or Clinical Consultant to:
   a. Identify all reflex tests.
   b. Determine specific criteria for reflex testing.
   c. Present all reflex testing to the MEC annually.
   d. Design the facility's laboratory requisition to clearly indicate which tests may be reflexed and identify which reflex tests are Required Reflex Tests and Optional Reflex Tests. For any Optional Reflex Test, the requisition must permit the ordering physician to select the initial test without the reflex.
   e. Ensure the specific reflex testing documentation and MEC approval are reflected in the MEC minutes.

2. The facility must implement a process to inform all credentialed and contracted physicians of the approved reflex testing via the following mechanisms:
   a. Provide a copy of Reflex Testing Notice initially and at least once every two years during the credentialing process. A form similar to Attachment A may be used to satisfy the notification requirement. The Reflex Testing Notice must be accompanied by a listing that defines the initial tests, reflex criteria, reflex tests and identification of whether each test is a Required Reflex Test or an Optional Reflex Test. It is also strongly recommended that this listing include the CPT code utilized for billing for the reflex test.
   b. Notify credentialed and contracted physicians of changes to the approved reflex tests that occur prior to the next credentialing cycle. Refer to Attachment B for a sample notification form. The Reflex Testing Change Notice must be accompanied by a listing of the reflex tests that defines the initial tests, reflex criteria, reflex tests and identification of whether each test is a Required Reflex Test or Optional Reflex Test. It is also strongly recommended that this listing include the CPT code utilized for billing the reflex test.
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3. The facility must establish an annual monitoring process that includes review of the medical necessity and criteria for reflex testing, MEC approval process, and adherence to the Reflex Testing notification processes.
   a. Review should be documented by the Laboratory Director and provided to the ECO.
   b. ECO will provide a report to the Facility Ethics and Compliance Committee (FECC).

4. Laboratory and/or hospital designated personnel must educate all staff responsible for ordering, testing, charging, or billing laboratory services on the contents of this policy.

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REFERENCES:

1. OIG Model Compliance Plan for Clinical Laboratories (March 1997)
2. Office of Inspector General's Compliance Program Guidance for Clinical Laboratories (August 1998)
3. Medicare National Correct Coding Initiative Policy Manual for Medicare Services, Introduction and Chapter 10
4. Attachment A: Sample Reflex Test Notice
5. Attachment B: Sample Reflex Testing Change Notice of Additions or Modifications