DEPARTMENT: Regulatory Compliance Support	**POLICY DESCRIPTION:** BILLING - Custom Profiles
PAGE: 1 of 2	**REPLACES POLICY DATED:** 4/6/98, 10/1/00, 10/1/01 (GOS.LAB.007); 3/6/06, 2/1/11; 10/1/15; 2/1/2017, 5/12/17
EFFECTIVE DATE: February 1, 2024	**REFERENCE NUMBER:** REGS.LAB.007
APPROVED BY: Ethics and Compliance Policy Committee	

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

Administration
Information Systems
Laboratory
Medical Staff Services
Revenue Integrity
Shared Service Centers

PURPOSE: To outline the requirements for the use of laboratory test panels and profiles so that Medicare will be billed only for those tests that it considers to be reasonable and necessary.

POLICY: Hospitals may recognize panels developed by the American Medical Association (AMA) and adopted for reimbursement by Centers for Medicare & Medicaid Services (CMS). Hospitals may choose to permit custom profiles provided they are valid, documented, medically necessary, and monitored for appropriateness.

PROCEDURE:

The following steps must be performed when establishing and utilizing custom profiles.

IMPLEMENTATION AND ANNUAL REVIEW

1. Laboratory Director and Shared Service Center (SSC) Chargemaster personnel must review and verify applicable revisions are made to the chargemaster and related Laboratory and Order Entry masterfiles/dictionaries to ensure all custom profiles are established and maintained in accordance with this policy.

2. A custom profile is established as defined by the requesting physician and may be used only by that physician. Laboratory Directors are responsible for validating custom profiles by obtaining a signed Physician Acknowledgement annually from each physician for each custom profile utilized in the treatment of his/her patients. Refer to Attachment A – Physician Acknowledgement for a Custom Profile. Results of the Physician Acknowledgement annual review (e.g. attestation) must be provided to the facility ECO.

3. Hospitals that allow the use of custom profiles must educate physicians regarding this policy as well as the Medicare – National and Local Coverage Determinations Policy (REGS.GEN.011).

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

5. The requirements and implementation of this policy must be reviewed on an annual basis. This review should be documented by the Laboratory Director and provided to the ECO.

6. The ECO will provide a report to the Facility Ethics and Compliance Committee (FECC) on both the annual review for policy compliance and completion of physician custom profile acknowledgement.

DAILY

Individuals responsible for registering and/or ordering laboratory services must review each component test of a custom profile for medical necessity according to the Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and National Coverage Determinations (NCDs). If the laboratory test order for a custom profile does not include a specific diagnosis, sign, symptom, and/or ICD-CM code, or does not meet the criteria as defined in the LCD and/or the NCD, an Advance Beneficiary Notice of Noncoverage (ABN) should be obtained from the patient for the non-covered component test(s). The process for obtaining an ABN is defined in the Advance Beneficiary Notice of Noncoverage – Outpatient Services Policy (REGS.GEN.003).

DEFINITIONS:

Custom Profiles: A custom profile is a physician specific group of commonly ordered laboratory tests or panels, which have not been defined by the AMA or CMS that are medically necessary in treating a patient's condition. Custom profiles are for use by the defining physician only and an acknowledgement must be signed by the physician on an annual basis. Refer to Attachment A – Physician Acknowledgement for a Custom Profile.

Organ or Disease-Oriented Panels: A group of medically necessary laboratory tests defined by the AMA and approved for reimbursement by CMS. (Reference the Hematology Procedures, Urinalysis Procedures, and Organ or Disease-Oriented Panels Policy, REGS.LAB.026.)

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. Hematology Procedures, Urinalysis Procedures, and Organ or Disease-Oriented Panels Policy, REGS.LAB.026