DEPARTMENT: Regulatory Compliance Support	**POLICY DESCRIPTION:** Laboratory – Client Billing Practices
PAGE: 1 of 6	**REPLACES POLICY DATED:** 1/21/98, 4/16/99, 1/1/00, 1/1/02, 12/15/02, 8/1/03, 11/30/04 (GOS.LAB.023), 3/6/06, 11/15/06, 6/1/07, 5/1/08, 7/1/09, 02/01/11, 10/1/15, 5/1/17, 9/1/19
EFFECTIVE DATE: February 1, 2025	**REFERENCE NUMBER:** REGS.LAB.023
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: All Affiliates of the Company performing and/or billing laboratory services.

PURPOSE: To establish guidelines for the billing of clinical laboratory services to Client(s) (as appropriate) in a compliant manner.

POLICY: Before any clinical laboratory that is owned or operated by any Affiliate of the Company provides clinical laboratory services to a Client and bills such Client for such services (rather than billing the applicable patient or their third party payor), such clinical laboratory must: (1) enter into and fully execute a written agreement with the Client on terms that are consistent with Fair Market Value and that are not determined in any manner based on the volume or value of referrals or business from the Client to the clinical laboratory or any Affiliate of the Company and (2) comply with all applicable federal or state laws, regulations or rules that might prohibit, restrict or limit the clinical laboratory from billing any Person other than the patient or their third party payor, such as direct billing laws, regulations or rules.

The clinical laboratory should verify that Clients fully understand the services offered, the services that will be provided when tests are ordered and the financial consequences for the tests ordered. Additionally, the clinical laboratory should verify that the Clients fully understand and will comply on their own with any applicable federal or state laws that might apply to, restrict or limit the Client, including any anti-mark-up laws, regulations or rules and/or any payor or patient disclosure laws, regulations or rules.

PROCEDURE: Clinical laboratory personnel must educate all Clients and their associates responsible for ordering and utilizing laboratory services on the contents of this policy.

IMPLEMENTATION AND ANNUAL REVIEW

1. **Test Orders & Requisitions:**
    - Requisition forms may be provided to all Clients at no charge.
    - Requisitions will allow ordering of CMS-approved panels only as well as single tests.
    - All test orders must include all of the elements defined in the Orders for Outpatient Tests and Services Policy, REGS.GEN.004.
    - Verbal orders must be authenticated as specified in accordance with the facility's medical staff bylaws and/or state rules and regulations. Reflex testing must be specifically requested by the ordering physician or performed as a result of approved reflex criteria when abnormal results exist. The REGS.LAB.010 (Laboratory – Reflex Orders) policy must be followed.

- Requisition forms will be reviewed for billing compliance and updated as needed. As this occurs, new or revised forms will be sent to all Clients with instructions to discard the outdated forms.

2. **Test/Pricing Information; Fair Market Value; and Direct Billing, Anti-Markup and Disclosure Requirements:**
   All Clients will be provided with a complete listing of laboratory services which includes: laboratory name and address, Medical Director name and phone number, laboratory phone and fax numbers, test name, CPT/HCPCS code, pricing structure, and other information (such as specimen requirements).

   All clinical laboratory services must be provided at Fair Market Value. Clinical laboratory services must never be provided to any Client free of charge or for less than Fair Market Value.

   Direct Billing Laws, Regulations or Rules – Federal or state law, regulations or rules might not permit a Client to directly bill the payor or patient for a purchased clinical laboratory service. Rather, such federal or state law may require that the clinical laboratory that provided the service directly bill the payor or patient. For instance:

   - Federal programs such as Medicare generally require direct billing of clinical laboratory services by the clinical laboratory performing the tests with the exception of the following:
     - The Skilled Nursing Facility Prospective Payment System (SNF PPS) and Consolidated Billing rules require that the SNF bill for virtually all services provided to its SNF patients who are covered by a Medicare Part A stay.
     - The End Stage Renal Disease Prospective Payment System (ESRD PPS) rules require that the ESRD facility bill for virtually all renal dialysis services provided to its patients.
     - The Inpatient Prospective Payment System (IPPS), Outpatient Prospective Payment System (OPPS), Inpatient Rehabilitation Prospective Payment System (IRF-PPS), Inpatient Psychiatric Prospective Payment System (IPF-PPS) and Long Term Care Hospital Prospective Payment System (LTCH) rules require a hospital to bill Medicare for clinical laboratory testing performed on specimens collected from its inpatients or outpatients unless specific exceptions apply.

- State laws might also require a clinical laboratory to directly bill the payor or patient. For example, the following states require direct billing to payors by clinical laboratories for anatomic pathology services: California, Colorado, Indiana, Kansas, Louisiana, Nevada, South Carolina and Tennessee. ***Please consult and work with applicable Operations Counsel to ensure proper identification and compliance such laws***.

Anti-Markup Prohibitions & Payor or Patient Disclosure Laws, Regulations or Rules – Federal or state laws, regulations or rules might also prohibit, limit or restrict the Client's ability to add to or otherwise mark-up the price of a clinical laboratory service referred to, and performed by, a clinical laboratory owned and operated by an Affiliate of the Company and/or may require the Client to disclose to the patient and/or payor the identity of the clinical laboratory that performed the service and the amount the Client paid for the clinical laboratory service. These applicable state law prohibitions, limitations and restrictions should be identified and explained to the Client. In addition, as set forth below, the clinical laboratory should require the Client to comply with such state laws, regulations and rules, including by requiring the Client to represent and covenant in the written agreement between the clinical laboratory and the Client that the Client will comply with all such applicable federal and state laws, regulations or rules, as well as any applicable payor requirements. ***Please consult and work with applicable Operations Counsel to ensure proper identification and compliance such laws***.

3. **Courier Service**:
   - Courier service may be provided at no charge to all laboratory Clients provided that specimens are to be delivered to the facility laboratory.
   - Transported specimens must be packaged and handled according to OSHA guidelines.

4. **Equipment & Supplies:**
   - Clinical laboratories may only provide equipment to a Client at no charge or below Fair Market Value if the equipment will be used exclusively in conjunction with ordering and testing of specimens by the clinical laboratory.
   - Clinical laboratories may only provide reusable items to a Client at no charge or below Fair Market Value if the reusable item could be of no independent value to the Client or the Client's operations separate and apart from the clinical laboratory work to be provided by the clinical laboratory.
     - Examples of permissible items (i.e., items that can be provided at no charge or below Fair Market Value if used exclusively to collect specimens for the clinical laboratory) are: specimen tubes, urine cups, venipuncture needles, and specimen pick-up boxes.
     - Examples of prohibited items (i.e., items that cannot be provided at no charge or below fair market value) that cannot be provided at no charge or below Fair Market Value are:

general office supplies, gloves, tourniquets, injection needles, snares, biopsy needles, syringes, phlebotomy chairs, and refrigerators.

- Provision of equipment and supplies must be in accordance with federal and state laws and regulations. If you have any questions concerning what equipment and supplies may and may not be provided at no charge or below Fair Market Value to Clients, consult and work with applicable Operations Counsel.

5. **Contracts & Agreements:**
   - The clinical laboratory must work with applicable Operations Counsel with regard to entering into a Fair Market Value written agreement with a Client consistent with HCA Healthcare Policy LL.001.
   - The written agreement between the clinical laboratory and the Client should contractually require the Client to represent, warrant and covenant that the Client will comply at all times with all applicable federal and state laws, regulations and rules, as well as any applicable payor requirements, including any direct billing, anti-markup and/or disclosure laws, regulations, rules or requirements.
   - The written agreement between the clinical laboratory and the Client should require the Client to submit the appropriate reference laboratory requisition when clinical laboratory testing requested by the Client for patients whose insurance requires testing to be performed by a contracted reference laboratory (other than the clinical laboratory owned and operated by an Affiliate of the Company).
   - Prior to contracting with any Client, a review must be conducted of (i) the OIG Program Exclusions list and (ii) applicable state law pertaining to any direct billing, anti-markup and disclosure laws, regulations or rules. Contracts shall not to be entered into with Clients that have been excluded from Medicare participation and listed on the OIG's Program Exclusion list.

6. **Education & Communication:**
   - Annual written notification of and/or training on the following policies and guidelines will be made available to Clients and medical staff:
     - Orders for Outpatient Tests and Services (REGS.GEN.004)
     - Advance Beneficiary Notice of Noncoverage – Outpatient Services Policy (REGS.GEN.003)
     - Medicare – Hospital Issued Notice of Non-Coverage Policy (REGS.GEN.010)
     - Medicare – National and Local Coverage Determinations Policy (REGS.GEN.011)
     - Billing – Hematology Procedures, Urinalysis Procedures, and Organ or Disease-Oriented Panels (REGS.LAB.026)
     - Billing - Custom Profiles Policy (REGS.LAB.007)
     - Laboratory - Reflex Orders Policy (REGS.LAB.010)

- Outpatient Services and Medicare Three Day Window Policy (REGS.GEN.009)
- Laboratory – Client Billing Practices Policy (REGS.LAB.023)

- Ordering physicians and their office staff must be contacted when ordering information is incomplete.
- The Medical Director or Clinical Consultant is available for consultation regarding laboratory orders and results.
- Updated Local Coverage Determinations and National Coverage Determinations will be sent to Clients/medical staff as applicable.

DEFINITIONS:

Affiliate means any person or entity Controlling, Controlled by or under common Control with the Company.

Client includes a Physician, Physician practice, skilled nursing facility, other healthcare provider or practitioner, or other clinical laboratory to which clinical laboratory services are provided as requested and billed on a periodic basis.

Company means HCA Healthcare, Inc.

Control means the direct or indirect power to govern the management and policies of an entity; or the power or authority through a management agreement or otherwise to approve an entity's transactions (includes **Controlled, Controlling**).

Fair Market Value means the value in arm's-length transactions consistent with the price that an item or service would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the service agreement. Usually, the fair market value price is the price at which *bona fide* sales have been consummated for items of like type, quality and quantity in a particular market or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

Person means any one or more natural persons, corporations, partnerships, limited liability companies, firms, trusts, trustees, governments, governmental authorities, facilities or other entities.

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Physician includes a doctor of medicine, osteopathy, dental surgeon, dental medicine, podiatric medicine, or optometry, as well as a chiropractor.

REFERENCES:

1. OIG Model Compliance Plan for Clinical Laboratories, March 1997, Federal Register Vol. 62, No. 41
2. The Office of Inspector General's Compliance Program Guidance For Clinical Laboratories (August 1998) Med-Manual, Med-Guide 10,285.03, Independent Laboratory Services
3. Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (October 1994), reprinted at 59 Fed. Reg 65,372,65,377 (December 19, 1994)
4. General Statements on Agreements with Referral Sources; Approval Process (LL.001)