ANNUAL NOTICE TO ORDERING PRACTITIONERS

Dear Practitioner:

Capstone Healthcare (Capstone) follows the US Department of Health and Human Services, Office of the Inspector General's (OIG), Model Compliance Program for Clinical Laboratories. The OIG asks independent clinical laboratories to publish an annual notice to its referral sources regarding laboratory test orders and fee schedules. While the Annual Notice is primarily geared toward federal healthcare benefit programs, Capstone's compliance policies acknowledge that many of the same billing and medical necessity requirements exist or are strongly encouraged when accepting referrals for laboratory testing of patients who have commercial insurance. More information is available at https://capstonehealthcare.com/contact. Please review this material carefully and contact your Capstone Account Representative or Capstone's Compliance Officer, with any questions you may have.

MEDICAL NECESSITY

One of the most important topics in healthcare coverage and reimbursement is medical necessity. Commercial and government healthcare Payers will only pay for laboratory testing that meets the program's definition of medical necessity. The definition of medically necessary laboratory testing is typically found in payer coverage and reimbursement articles and policies.

Medicare publishes National and Local Coverage Determinations (NCDs and LCDs) setting forth coverage and reimbursement criteria for clinical laboratory testing. Many commercial Payers have similar medical necessity policies, setting forth criteria for coverage and reimbursement of various laboratory testing services, including genetic/molecular and toxicology testing. This notification is written to cover laboratory testing ordered for beneficiaries covered by commercial or government health plans.

Practitioners should understand that ordering medically unnecessary tests may expose them and others to sanctions or remedies under civil, criminal, or administrative law. If items or services are deemed to be unreasonable or unnecessary, repayment may be requested by payers. As part of our effort to help you fully comply with medical necessity guidelines and documentation requirements relating to test orders and testing frequency, we encourage you to pay special attention to the medical necessity policies published by various payers. **Upon request, Capstone will provide you with major payer policies relative to the type of clinical laboratory testing it performs.**

Federal programs and private payers will only pay for tests that are deemed medically necessary for the diagnosis and treatment of the individual patient. As a participating provider in the Medicare program, Capstone has a responsibility to educate its clients (ordering physicians) to help ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. **Capstone operates under Palmetto GBA.**

The OIG requires a clinical laboratory to include mechanisms for it to determine that tests ordered by practitioners are, in fact, medically necessary and appropriate. Practitioners should only order those tests that they believe are medically necessary for the diagnosis and treatment of their patients. All test orders must be accompanied by diagnostic information (diagnosis codes and related items) demonstrating the medical necessity for the laboratory test. Additional reminders include:

- The laboratory will only submit diagnostic information obtained from the ordering practitioner;
- The laboratory cannot supply these diagnostic codes for you;
- The laboratory will not copy diagnostic codes from earlier tests;
- The practitioner should not submit standard diagnostic codes along with customized test panels and standing orders;
- All diagnostic codes should be selected based on the individual circumstances of each patient's case.

The laboratory does not use any form of a cheat sheet or make up diagnostic information for claims submission purposes. The laboratory will contact the ordering practitioner in the event that he/she has failed to provide diagnostic information along with the test requisition. Capstone notes that the OIG has said: "Standing orders [for laboratory tests] generally should be limited to cases of an extended course of treatment."

STANDING ORDER AND RELATE LIMITATIONS FOR TOXICOLOGY

Toxicology testing of Medicare Beneficiaries is subject to specific restrictions regarding the use of standing orders. Palmetto GBA defines a "standing order" and limits its use in toxicology testing as follows:

> **[A] test[]** request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits; individualized orders for certain patients for pre-determined tests based on historical use, risk and community trend patient profiles; clinician can alter the standing order.
>
> **Note:** A "profile" differs from a "panel" in that a profile responds to the clinical risks of a particular patient, whereas a panel may encourage unnecessary or excessive testing when no clinical cause exists for many of the tests. *See LCD L35724, accessed 10/30/19, and effective for dates of service on or after 08/29/19.*

Palmetto GBA also non-covers "blanket test orders" for drugs of abuse testing, and defines them as:

> **[a]** test request that is not for a specific patient; rather, it is an identical order for all patients in a clinician's practice without individualized decision making at every visit. *See LCD L35724, accessed 10/30/19, and effective for dates of service on or after 08/29/19.*

Palmetto discourages the use of panels and profiles that do not reflect individualization of testing orders to match the individual patient's medical history and treatment needs. This is especially the case in drugs of abuse testing, but it also applies to many other areas of laboratory. Specifically, Palmetto makes clear:

- Presumptive UDT testing typically involves testing for multiple analytes based on the beneficiary's clinical history and risk assessment and must be documented in the medical record.

- **Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice.** Definitive UDT orders should be individualized based on clinical history and risk assessment and must be documented in the medical record. *See LCD L35724, accessed 10/30/19, and effective for dates of service on or after 08/29/19.*

Palmetto also provides specific guidance to clinical laboratories and ordering providers regarding reference (independent – 81) laboratory "reflex-testing", and makes its medical necessity boundaries clear:

- [S]ince reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:
    - To verify a presumptive positive UDT using definitive methods that include, but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
    - To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician

- Direct to definitive UDT without a presumptive UDT is reasonable and necessary, when individualized for a particular patient.

- Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:

- The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
- Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
- To rule out an error as the cause of a negative presumptive UDT result.

- Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

Palmetto GBA always provides a list of "non-covered services" when it publishes its LCDs, and makes clear the following are considered unreasonable and medically unnecessary and are therefore non-covered services for drugs of abuse testing of Medicare Beneficiaries:

- Blanket Orders
- Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).
- Routine standing orders for all patients in a physician's practice are not reasonable and necessary.
- It is not reasonable and necessary for a physician to perform presumptive POCT and order presumptive IA testing from a reference laboratory. In other words, Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
- It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA testing from a reference laboratory with or without reflex testing. Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
- It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.
- IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods. Definitive UDT provides specific identification and/or quantification typically by GC-MS or LC-MS/MS.
- Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
- UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.
- Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

Referring providers should consult toxicology LCDs, and NCDs and LCDs for other types of laboratory testing to ensure proper use of standing orders, test panels, and physician-directed test profiles.

CUSTOM TEST PROFILES

Capstone's compliance plan involves monitoring of Physician Directed, Custom Test Profiles (PD-CTPs) and standing orders to ensure their continuing validity and expects its practitioners to work with our representatives on periodic reassessment of CTPs.

Capstone regularly requests written confirmation of the validity of all current PD-CTPs by requiring providers to mark the requisition form indicating which profile is appropriate for that specific patient. You have the option to establish multiple PD-CTPs for testing types that lend to tailoring profiles to individual patients based on treatment needs and status. You also have the option to order individual tests for any of our laboratory service areas; Our laboratory requisition forms, and electronic ordering process is designed to allow such individualization. If you choose to establish PD-CTPs, we will require you to complete a written acknowledgment that certifies that the practitioner:

- Has requested the PD-CTP and has spelled out each of its components, understanding that each component must be medically necessary for the individual patient for which the PD-CTP is used;
- Has the responsibility to notify the laboratory of any change to the custom profile and any changes with each individual specimen sent in requesting testing under the custom profile;
- Has been informed of the Medicare-reimbursable amount for each test included in the profile;
- Is aware that only medically necessary and reasonable tests should be ordered;
- Knows that the use of a PD-CTP could result in ordering tests for which Medicare will deny payment;
- Will not order the complete profile in cases in which some of the tests included in the profile may not be medically necessary;
- Has been informed that a practitioner who orders unnecessary tests could be subject to OIG penalties as they relate to billing federal plans and possible Attorney General penalties (state Medicaid matters and insurance commission matters), and contract issues as they relate to nonfederal plans:
    - The practitioner acknowledges that they will document the medical necessity of each individual test ordered in the patient's medical record;
    - The practitioner acknowledges that payers, including CMS, may at any time request additional documentation supporting the ordering of testing and that the practitioner will comply with this request.

In short, customized test profiles should be used only when every component of the same is medically necessary for the treatment of each individual patient.

FEE SCHEDULE AND OTHER ITEMS

Copies of Capstone's Annual Test and Fee Schedule for each line of testing services it performs are attached to this notification. Outpatient clinical laboratory services are paid based on the CLFS, which sets the maximum amount payable under Medicare for each specific laboratory code. The current Medicare clinical laboratory fee schedule can be viewed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html

Our goal is to partner with you to provide the results you need to make the best treatment decisions you can for your patients, while abiding by applicable guidelines and regulations. If you have questions about the any of the matters in this notice, please do not hesitate to contact us.

BASIC HIPAA AND PATIENT FINANCIAL POLICIES AND PROGRAMS

Capstone is a healthcare provider under the Health Insurance Portability and Accountability Act (HIPAA). Capstone is committed to fully complying with HIPAA privacy and security standards. Capstone's privacy and security policies are available online. Capstone has various patient financial policies and programs for assisting patients with the cost of laboratory testing. Patients may be eligible for support and are subject to an assessment of eligibility per federal and state laws and regulations.

Capstone bills patients for the "patient responsibility" portion of healthcare insurance, which includes co-insurance, co-payments, and deductibles. More information is available online.

MISCELLANEOUS

Capstone is committed to following federal and state laws and regulations governing its interaction with referral sources. Federal and state law prohibit the offering or paying of any remuneration (anything of value) to induce or reward the referral of tests that are covered by Medicare, Medicaid, or other federal healthcare programs.

A newer federal law, the Elimination of Kickbacks in Recovery Act (EKRA), appears to apply these prohibitions to commercial health programs. Unless there is clear cut evidence that the relationship between Capstone and a referral source meets a "safe harbor" under anti-kickback laws or inducement-related laws, including fee-splitting and patient brokering laws," Capstone will not knowingly engage in prohibited business activities. If you or a member of your staff has a concern about the conduct of any Capstone employee, manager, or sales representative, please email compliance@capstonehealthcare.com.

Capstone is also committed to following federal laws that prohibit physician self-referral. The federal law known as the "Stark Law" prohibits physician self-referral in the absence of a fact pattern that meets each element of a "safe harbor."

COMMITMENT TO EXCELLENCE

Capstone is committed to providing excellence in laboratory testing services and promoting appropriate business relationships with referral sources. Thank you for allowing us to serve you.

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The Capstone Healthcare Team

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