

**To:** Orlando Health Physicians  
**From:** Orlando Health Laboratories  
**Date:** June 11, 2024  
**Subject:** Annual Physician Notice Regarding Orlando Health Laboratories

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Orlando Health Laboratories is providing this annual notice in accordance with the recommendations of the Office of Inspector General (OIG) to advise physicians of the elements of the laboratory's compliance program. This annual notice serves to provide helpful information regarding the ordering, performing, and billing of clinical laboratory tests. Please note these notices are intended to help both the physicians and laboratory comply with these regulations and promote the prevention of fraud, waste, and abuse.

**Advance Beneficiary Notice (ABN)** The Laboratory may bill Medicare Patients for services that are not covered. The ABN statement is used to document the patient is aware Medicare may not pay for services and has agreed to pay the laboratory in the event payment is denied. If you believe that Medicare will not pay for a test you have ordered, the patient should be made aware of the diagnostic value and make an informed choice about whether to receive laboratory services.

**Coordination of Benefits Questionnaire (COB)** Completion of COB is necessary for patients that have more than one health insurance policy. COB is necessary to reduce out of pocket expenses, ensure appropriate insurance coverage, and avoid duplication of payments.

**CPT/PLA (Proprietary Laboratory Analyses) Codes** Orlando Health Laboratories reviews CPT/HCPCS codes and PLA codes for additions, changes, revisions, and deletions on an annual basis. These additions, changes, revisions, and deletions could affect procedure coding and payment of laboratory tests. PLA codes are in addition to the CPT code set approved by the AMA CPT Editorial Panel. They are alphanumeric codes with a corresponding descriptor for labs or manufacturers that want to identify their test more specifically. If indicated, specific CPT/HCPCS/PLA codes will be updated on the laboratory requisition form and the Laboratory test catalog. The services for outpatient clinical laboratory are paid based on a fee schedule in accordance with Section 1833(h) of the Social Security Act. Medicaid reimbursement will be equal to, or less than Medicare reimbursement.

**Dex Codes** DEX is a web-based application designed to identify tests and help establish transparency between providers and payers. This tool enables labs to confidentially share test information with participating payers online. Labs register as an entity on the platform and may submit their tests for review. DEX codes are associated with CPT codes and submitted on billing claims when it is required by payers participating in the DEX program. Orlando Health participates in the submission of test information and has been assigned a unique DEX code for at least one type of laboratory test procedure. DEX code and Laboratory Developed Test information is available upon request.

**Diagnosis Information/Authorized Test Ordering:** Diagnosis codes are essential for correct billing. It is the provider's responsibility to ensure that correct diagnosis codes are included on the requisition. The diagnosis information should be relevant to testing requested that most accurately describes the patient's current condition. This information must be supplied with ICD-10 format. Generally, a laboratory can only bill third-party payors, including Medicare and Medicaid, for testing ordered by a licensed physician or other non-physician practitioner ("NPP") authorized by state law to order laboratory tests. Additionally, Medicare requires that ordering providers for Medicare beneficiaries must be registered in the Centers for Medicare and Medicaid Services ("CMS") Provider Enrollment, Chain and Ownership System ("PECOS"). Additional information can be found at: [Welcome to the Medicare Provider Enrollment, Chain, and Ownership System \(PECOS\) \(hhs.gov\)](https://www.hhs.gov/medicare/provider-enrollment-chain-and-ownership-system-pecos/)

**Electronic Orders** To facilitate compliance, the laboratory has electronic requisitions available for specimens sent to our laboratories, based on client needs and preferences. The electronic order system has flags and edits built in to notify the person using the system when medical necessity or billing requirements have been met.

**Laboratory Developed Tests (LDTs)** LDTs are diagnostic tests developed, validated, and performed in-house by individual laboratories, including hospital laboratories. LDTs need to meet safety and effectiveness standards. The FDA has proposed increased oversight for LDTs due to their complexity and associated risks. Orlando Health laboratories include LDTs in their testing menu. Additional information regarding LDTs can be obtained by contacting the laboratory and requesting more information.

**Medicare National Coverage Determinations and Local Medical Review Policies** Local Medicare Contractors have been given the authority by CMS to adopt and implement Local Coverage Determinations (LCDs) for laboratory tests provided, the policy does not conflict with the National Coverage Determinations (NCDs). This information is available at <http://medicare.fcso.com>. This information is updated quarterly.

**Medical Necessity** It is the OIG's position to recommend that the ordering of tests grouped into panels or profiles may result in medically unnecessary testing. Therefore, when Panels or Profiles are ordered, all the individual component tests should be medically necessary. In cases where only some of the component tests of a panel or profile are medically necessary, the individual tests desired should be ordered separately.

**Reflex Testing** Some lab tests may trigger reflex testing and additional charges based on laboratory policy that reflects standard of care or by request of the ordering provider. Procedures that contain a reflexive pathway can be found in Orlando Health's test directory. See our website <https://orlandohealthlaboratories.testcatalog.org/> for disclosure of reflexive criteria and the specific CPT code(s) used.

**Release of Results** The 21<sup>st</sup> Century Cures Act requires immediate release of information to the patient portal unless an approved exemption defined in the regulation applies. Time for physicians to review results is not an approved exemption, thus pathology results do not have a delayed release and will be available immediately in the patient portal. Clinicians can prevent immediate release of results only in cases of pre-defined "sensitive" results including:

- HIV/STI testing, pregnancy testing, and Hep A/B/C testing
- Patient's explicitly stated preference
- Reasonable expectation of the clinician that there will be a substantial harm to the patient on an individual basis.

Refer to the Clinical Education Brief titled *Pathology Results Release Changes to Comply with Federal Information Blocking Regulations* dated 9/11/23 for more information.

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The Medical Director is responsible for the oversight of all the aspects of laboratory operations. Therefore, the fees associated with regulatory oversight may be indicated and assessed to the patient and/or the patient's insurance by Pathology Specialists, P.A.

Questions regarding information contained in this notice can be directed to the Orlando Health Clinical Consultant at (321) 841-5215 or Laboratory Billing at (321) 841-8194 or (321) 843-2636.