

#### 2024 Laboratory Compliance Program NOTICE TO PHYSICIANS AND AUTHORIZED PROVIDERS

UCLA Health Clinical Laboratories is providing this notice in accordance with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS).

The laboratory advises UCLA Health physicians and clients on updates related to federallyfunded healthcare programs that affect both the physician, laboratory and <u>UCLA Health's</u> <u>Code of Conduct</u> including laboratory policies for test ordering, billing, and other information regarding the laws, rules, and regulations governing laboratory services.

Providers ordering tests through UCLA Health Clinical Laboratories are responsible for adhering to all applicable federal and state regulations concerning provision of health care services. Medicare works with medical review contractors such as the OIG to review the Statutes and Laws under the Compliance Program.

 <u>LICENSED PHYSICIANS and NON-PHYSICIANS PRACTITIONERS (NPP)</u> UCLA Health laboratory services ordered by the treating physicians and qualified nonphysician practitioner (NPP) must meet all CLIA and State of California regulations.

### <u>MEDICAL NECESSITY</u>

Licensed physicians and NPP can order any tests that they believe are appropriate however Medicare will only pay for those tests which are covered, reasonable and necessary. Routine screening of patients without regard to their individual need are not usually covered by the Medicare Program. Medicare does not pay for screening tests, except for certain specifically approved procedures, and may not pay for non-FDAapproved tests or tests considered experimental.

Test panels must only be ordered when every test in that panel is medically necessary. If all components of the panel are not medically necessary, individual tests or a panel that contains only the medically necessary tests should be ordered.

## AMA APPROVED ORGAN or DISEASE ORIENTED PANELS

American Medical Association (AMA) has grouped certain tests into panels for coding purposes (List of AMA Organ/Disease Oriented Panels). If a provider orders tests in addition to those specifically indicated for a particular panel, those tests are billed separately in addition to the panel code. A valid diagnosis code must be provided for each AMA-approved panel ordered.

It is the responsibility of the provider to accurately describe the patient's condition (ICD-10 code or through narrative diagnostic information) on the date of service in the patient's medical record for each test ordered, including all tests listed as part of organ or disease-



oriented panels. Providers will be contacted for requisitions that do not include this required information.

#### INFORMED CONSENT/PRE-AUTHORIZATION

Payers may have pre/prior authorization requirements in place for certain laboratory testing including, but not limited to, genetic carrier biomarkers and infectious disease panels. In addition, certain tests may require consent from the patient (or legally authorized representative) prior to testing. It is the treating provider's responsibility to obtain the consent and/or pre-authorization number. If this information is not received, there may be a delay in patient testing.

 <u>CMS CLINICAL LABORATORY FEE SCHEDULE</u> The 2024 Clinical Laboratory Fee Schedule is available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched

## LABORATORY TEST DIRECTORY

The <u>UCLA Health Laboratory Test Directory</u> provides guidelines for test ordering and specimen collection for laboratory services, policies and procedures, and shipping to ensure the specimen is viable when it arrives at the performing laboratory. Additionally, the Laboratory Test Directory provides information on established Turnaround Time (TAT), including laboratory-defined STAT tests.

**NOTE**: The current Laboratory Information System (LIS) setting allows the provider to order STAT on all available tests. However, a STAT request will ONLY apply to the laboratory-defined STAT tests. Routine turn-around-times will apply for STAT orders for tests that are not defined as STAT under the TAT section.

<u>TEST ORDERING</u>

Laboratory test orders must be in written (UCLA Health test requisition) or electronic format via CareConnect. Documentation in the medical record must show intent to order and medical necessity for testing. A non-UCLA Health requisition form or an incomplete requisition form may result in delayed processing or cancellation of the test. As necessary, UCLA Health laboratories may contact ordering providers to resubmit a test order that is incomplete or request clarification for a specific order. Only orders that are complete, signed, and dated and associated with a suitable specimen will be performed.

**NOTE**: Medicare regulations require that all orders for laboratory tests be in writing. For verbal orders, refer to UCLA Health policy HS 1304, *Verbal and Telephone Orders*, (<u>https://ucla-ronaldreagan.policystat.com/policy/10993909/latest</u>).

## <u>REFLEX TESTING</u>

UCLA Health laboratories offer reflex testing, in which additional testing will be performed on specimens depending on the results of the initial test. Reflex testing may be medically indicated when initial test results fall within certain parameters. UCLA Health's <u>Reflex</u> <u>Test List</u> provides information on tests and test results that may generate additional



testing and the conditions under which they are performed. Some reflex testing may result in additional charges. For reference laboratory testing, reflex testing policies are defined by each reference laboratory.

#### • REFERENCE RANGE, ABNORMAL FLAGS AND CRITICAL VALUES FOR SOGI

UCLA Health provides the opportunity for patients to share information about their sexual orientation or gender identity (SOGI). Providers who are informed of their patients' SOGI are better able to provide relevant, specific and compassionate care in a patient-centered environment. In CareConnect, non-binary genders are defined as "Unknown" or "Unspecified". In patients where SOGI is non-binary, the following parameters are utilized for laboratory tests that have sex-based reference ranges:

- Both Male & Female reference ranges are added to the laboratory test result as a result comment.
- Abnormal flag and critical value limits are based on the highest value of the lower limit and the lowest value of the higher limit of the male and female defined reference ranges (the most conservative algorithm).
- PATIENT PRIVACY (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA) UCLA Health is a healthcare provider and a covered entity. It is the policy of ULCA Health laboratories to fully comply with the <u>HIPAA privacy standards</u>.

• FALSE CLAIM ACT

The False Claims Act, or "FCA," provides a way for the government to recover money when someone submits or causes to be submitted false or fraudulent claims for payment to the government, including the Medicare and Medicaid programs. The OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law. Healthcare providers should take proactive measures to ensure compliance with program rules, including review of current billing and coding practices.

- <u>FEDERAL ANTI-KICKBACK STATUTE</u> [Section 1128B (b) of the Social Security Act] It is a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward referrals of items or services reimbursable by a Federal health care program and should be reported to the UCLA Health Office of Compliance Services.
- PHYSICIAN SELF-REFERRAL LAW [Section 1877 of the Social Security Act]

It is the policy of UCLA Health to comply with all aspects of the laws and regulations governing physician self-referral (federal Stark law). The Stark Law prohibits a physician from referring for certain designated health services payable by Medicare to an entity where the physician (or an immediate family member) has an ownership/investment interest or a compensation arrangement, unless an exception applies.



# <u>CONTACTS</u>

Laboratory Directors, Clinical Consultants, and other Scientific Directors are available to discuss appropriate testing and proper test ordering. For assistance, contact the CLIA Laboratory Director accordingly.

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