

2021

Laboratory Compliance Notice to Physicians and Authorized Providers

UCLA Health Clinical Laboratories compliance program is providing this notice in accordance with the Office of Inspector General (OIG) of the Department of Health and Human Services. The laboratory advises the physicians and clients on updates related to federally funded healthcare programs that affect both the physician, laboratory and UCLA Health's Code of Conduct.

This notice is intended to assist in ordering laboratory tests, processing and billing to Medicare and Medicaid for reimbursement. 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.

- **LICENSED PHYSICIANS and NON-PHYSICIANS PRACTITIONERS (NPP)**

Laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests ("Providers"). If your license has been revoked or suspended, immediately notify the laboratory.

Medicare requires that individuals referring orders for laboratory services to be registered in the Centers for Medicare & Medicaid Services' (CMS') Provider Enrollment, Chain and Ownership System ([PECOS](#)).

- **MEDICAL NECESSITY**

Tests that are medically necessary for the diagnosis or treatment of a Medicare patient are covered and may be reimbursed by Medicare. Routine screening of patients without regard to their individual need are not usually covered by the Medicare Program. 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.

Section 4317 of the Balanced Budget Act of 1997 (42 USC §1395u(p)) requires the physician or authorized ordering party to submit a diagnosis to the laboratory for submission of a Medicare claim. It is the responsibility of the Provider to accurately describe the patient's condition (ICD-10 code or a narrative diagnostic information) on the date of service in the patient's medical record: ICD-10 code (or a narrative diagnostic information) supported by 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 by for requisitions that do not include this required information.

The CMS has developed a billing and coding guidance that identify tests that CMS determined will be covered under the Medicare program, [Medicare Coverage](#).

- **INFORMED CONSENT/PRE-AUTHORIZATION**

Payers may have pre/prior authorization requirements in place for certain laboratory testing including certain genetic carrier biomarkers and infectious disease panels. In addition, when required by law requiring consent from the patient (or legally authorized representative) for certain tests, it is the treating provider's responsibility to provide the consent or pre-authorization number. If not received at the time of test ordering, it risks delay to the patient's testing.

- **2021 MEDICARE CLINICAL DIAGNOSTIC LABORATORY TEST PAYMENT SYSTEM**

Effective January 1, 2018, the Clinical Laboratory Fee Schedule (CLFS) reimbursement rates were revised to be based on the weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) 2014. Co-payments and deductibles do not apply to services paid under CLFS. Also Medicaid reimbursement will be equal to, or lesser than Medicare reimbursement. The 2021 Medicare Clinical Laboratory Fee schedule may be viewed and downloaded at: <https://www.cms.gov/license/ama?file=/files/zip/21clabq1.zip> for the fee schedule listing.

- TEST ORDERING

Laboratory tests orders must be in writing or electronically through CareConnect. Standard UCLA Health test requisition (CareConnect or paper form) should be used when ordering tests. Documentation in the medical record must show intent to order and medical necessity for the testing. If UCLA Health laboratories receives a non-UCLA Health requisition form or an incomplete requisition form, processing of the test order may be delayed or cancelled. As necessary, UCLA Health laboratories may contact physicians to resubmit the test order on a UCLA requisition form or otherwise clarify each specific test being ordered. Only orders that are complete and signed will be performed.

Routine orders are for services and treatments that apply to patients with the same or similar medical condition(s). These frequently called “routine, protocol or standing orders” are based on an assessment of a given condition in patients with medical illness or injury.

- Medicare defines any order(s) that does not specifically address an individual patient’s unique illness, injury or medical status, as not reasonable and necessary.
- As required by law, Medicare does not accept such “standing orders” as supporting medical necessity for the individual patient.

- AMA APPROVED ORGAN or DISEASE ORIENTED PANELS

American Medical Association (AMA) has grouped certain tests into panels for coding purposes. If one 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.

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.

- VERBAL TEST ORDERS

Medicare regulations require that all orders for laboratory tests be in writing. If a provider orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. In these cases, UCLA Health Clinical Laboratory will require the ordering clinician to send a written confirmation of the verbal order request for its records

- LAB and FORMULARY MANUAL

The [Lab and Formulary Manual](#) provides guidelines to specimen collection for laboratory services, policies and procedures, and shipping to ensure the specimen is viable when it arrives at our laboratory.

- REFLEX TESTING

Reflex testing and confirmatory testing may be medically indicated when initial test results fall within certain parameters. UCLA Health Laboratories use Medical Executive Committee-approved testing algorithms to avoid delays in patient care. List of UCLA Health [Reflex testing](#) that may generate additional testing and the conditions under which they are performed available in each laboratory’s test catalog. Some reflex testing may result in additional charges. If you DO NOT want reflex testing, please clearly communicate this request on the laboratory test requisition form (in CareConnect or paper).

- PATIENT PRIVACY (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), UCLA Health is a healthcare provider and a covered entity. It is our policy to fully comply with the HIPAA privacy and security standards

- INDUCEMENTS/ANTI-KICKBACK STATUTE

Federal law prohibits offering or paying any remuneration to induce the referral of tests that are eligible for payment by Medicare, Medicaid or other federal health care programs. Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. The statute covers the payers of kickbacks, those who solicit or receive remuneration. Any form of payment or kickback that is intended to secure business for federal health care testing referrals is strictly prohibited and should be reported to the UCLA Health Office of Compliance Services.

- PROHIBITED REFERRALS

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's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers), and the relationship does not fit into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory, and (b) the laboratory may not bill Medicare for services referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include the lease or rental of space or equipment and the purchase of medical or other services by a laboratory from a referring physician.

- DE-IDENTIFIED TEST DATA

From time to time, de-identified test result data may be made available to pharmaceutical companies and other entities engaged in healthcare research. In accordance with applicable regulations under HIPAA, we are permitted to de-identify protected health information (PHI) and provide such de-identified information to third parties. None of the data provided to third parties shall contain any PHI protected under HIPAA. [Summary of HIPAA privacy rule](#)

- CONTACTS

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

Clinical Laboratory	Laboratory Director	Telephone	Email
Ronald Reagan UCLA Medical Center	Alyssa Ziman, MD	310-267-8090	AZiman@mednet.ucla.edu
Santa Monica-UCLA Medical Center and Orthopaedic Hospital	Steven Hart, MD	424-259-8123	SHart@mednet.ucla.edu
BURL – Panorama City	Thomas Drake, MD	310- 825-6975	TDrake@mednet.ucla.edu

AMA ORGAN / DISEASE ORIENTED PANELS

American Medical Association (AMA) defined ORGAN OR DISEASE PANELS	Panel CPT CODE
BASIC METABOLIC PANEL Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) Urea Nitrogen (BUN) (84520)	80048
COMPREHENSIVE METABOLIC PANEL Albumin (82040) Bilirubin, total (82247) Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Phosphatase, alkaline (84075) Potassium (84132) Protein, total (84155) Sodium (84295) Transferase, alanine amino (ALT) (SGPT) (84460) Transferase, aspartate amino (AST) (SGOT) (84450) Urea Nitrogen (BUN) (84520)	80053
ELECTROLYTE PANEL Carbon dioxide (bicarbonate) (82374) Chloride (82435) Potassium (84132) Sodium (84295)	80051
LIPID PANEL Cholesterol, serum, total (82465) Lipoprotein, direct measurement, HDL cholesterol (83718) Triglycerides (84478)	80061

HEPATIC FUNCTION PANEL Albumin (82040) Bilirubin, total (82247) Bilirubin, direct (82248) Phosphatase, alkaline (84075) Protein, total (84155) Transferase, alanine amino (ALT) (SGPT) (84460) Transferase, aspartate amino (AST) (SGOT) (84450)	80076
ACUTE HEPATITIS PANEL Hepatitis A antibody (HAAb), IgM antibody (86709) Hepatitis B core antibody (HBcAb), IgM antibody (86705) Hepatitis B surface antigen (HBsAg) (87340) Hepatitis C antibody (86803)	80074
RENAL FUNCTION PANEL Albumin (82040) Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Phosphorus inorganic (phosphate) (84100) Potassium (84132) Sodium (84295) Urea Nitrogen (BUN) (84520)	80069