

2022 Annual Physician Notice of Laboratory Compliance

To our Valued Healthcare Partners:

HealthTrackRx, Inc. (“HealthTrackRx”), maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state, and local laws. As a participant in federally funded healthcare programs, HealthTrackRx delivers annual provider information and education regarding laboratory compliance, billing and coding guidelines, and information to our provider clients on the responsibilities we share.

This physician annual notice specifies current Medicare/Medicaid program requirements and HealthTrackRx policies. HealthTrackRx also offers an anonymous hotline for reporting any compliance concerns and can be accessed using the following methods:

Toll Free Number: 844-990-0002
Website: www.lighthouse-services.com/healthtrackrx
Email: reports@lighthouse-services.com
Fax: 215-689-3885

HealthTrackRx must rely on you, our provider clients, for the following key compliance elements:

Medical Necessity

Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. Criteria to establish medical necessity for testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient’s medical record. Tests used for routine screening of patients without regard to individual need are not usually covered by the Medicare Program, and therefore are not reimbursed. As a participating provider in the Medicare Program, HealthTrackRx has a responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. As the ordering physician, you are responsible for documenting medical necessity in the patient’s medical record (including physician signature) and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to HealthTrackRx. The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act. Refer to Exhibit 1B under “Documentation Requirements” for further details.

Recent policy changes and health plan actions, including increased use of post-payment audits, has encouraged HealthTrackRx to more aggressively enforce long-standing policies that patients’ medical records must include documentation of medical necessity for ordering tests. Though this is specified in each HealthTrackRx Practitioner Acknowledgement Form that is signed by the provider, we are also educating any laboratory that is currently using HealthTrackRx as the Reference Laboratory. Client Web Portal (“CWP”) Personalized Menu Selection may be used if patient specific medical necessity is recorded clearly in the patient’s medical records and reflected clearly on the Test Order Requisition.

Test Order Requisition

To ensure accurate processing and testing, efficient patient identification, timely reporting of laboratory results, valid laboratory orders must include the following:

- patient's full legal name
- date of birth
- reason for each test ordered
- date and time of collection
- specimen source (when applicable)
- diagnosis code
- the licensed ordering practitioner's name and address.

Handwritten orders must be signed and dated by the provider. Signature stamps are NOT acceptable.

Although the provider signature is not required on laboratory requisitions, if signed, the requisition will serve as acceptable documentation of a physician order for the testing and so is strongly encouraged. In the absence of a signed requisition, documentation of your intent to order each laboratory test must be included in the patient's medical record and available to HealthTrackRx upon request, as needed. Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered.'

Upon request by HealthTrackRx or its payers/auditors, ordering providers are required to provide any/all chart documentation (including physician signature) that reflect the actual lab order and supports the authenticity and medical necessity of the lab order(s) submitted.

Test Ordering

A standard HealthTrackRx test requisition form should be used when ordering tests. This requisition is designed to emphasize physician choice and encourage physicians to order only those tests which the physician believes are appropriate and medically necessary for the treatment and diagnosis of each patient. If HealthTrackRx receives a non-HealthTrackRx requisition form or an incomplete HealthTrackRx requisition form, processing of your test order may be delayed. As necessary, HealthTrackRx will contact physicians to have them resubmit the test order on a HealthTrackRx test requisition form or otherwise clarify each specific test being ordered.

Verbal Test Orders

Medicare regulations require that all orders for laboratory tests be in writing. If a physician or his/her authorized representative 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, HealthTrackRx will send a confirmation of the verbal order request to the ordering physician, requesting it to be signed and sent back to the laboratory for its records. Testing will not be performed until the signed confirmation or a properly completed HealthTrackRx requisition form is returned to the laboratory.

ABN

If a physician requests a test for a Medicare beneficiary and reports a 'non-covered' diagnosis, the patient must be notified prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient where claim denial is anticipated based on medical necessity, frequency limitations or other Medicare policy. Medicare does not cover most routine screening tests. The signed, original ABN must be attached to the original lab order prior to submission. Per Medicare rules, routine provision of the ABN on all Medicare beneficiaries is considered an unacceptable practice. The ABN Form CMS-R-131, and instructions for use

were approved by the Office of Management and Budget (OMB) for renewal in 2020. The mandatory start date for the use of this renewed ABN form was 1.1.2021. Please check the expiration date located in the lower left-hand corner of the ABN, to assure the most current form is being utilized and completed when an ABN is necessary for a Medicare beneficiary, (Exp. 6.30.2023).

Information about ABNs may be viewed at:

<http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), HealthTrackRx is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at <http://www.healthtrackrx.com>.

Prohibited Referrals & Inducements

It is the policy of HealthTrackRx to comply with all aspects of the federal and state laws and regulations governing physician self-referral, most prominently the 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.

Federal Law prohibits offering or paying remuneration-meaning anything of value-to induce the referral of tests that are covered by Medicaid, Medicare or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited and should be reported to the HealthTrackRx Compliance Hotline by calling 844-990-0002.

Clinical Consultants

Physicians and other clinicians authorized to order tests have access to the services of clinical consultants and toxicologists available to answer questions and provide guidance on proper test ordering. They may be reached at 940-435-0242.

To ensure compliance with applicable reimbursement laws, please be sure to:

1. Order only those tests necessary for diagnosis or treatment of a specific patient. Each component of a testing panel must be medically necessary in order for the panel to qualify for Medicare reimbursement.
2. Provide a diagnosis, sign or symptom for each test ordered
3. Document this information in the patient's medical record followed by the ordering physician's signature
4. Obtain an ABN from Medicare patients when tests do not meet the medical necessity or other coverage criteria.

Medicare National and Local Coverage Determinations

The Medicare Program publishes National Coverage Determinations (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions or other circumstances, including diagnosis codes, for which the included tests are or are not covered or reimbursed by Medicare. Further information can be found at the following website:

<https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Code of Federal Regulations (CFR) Title 42 § 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see 42 CFR § 411.15(k)(1)).

Except where authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

Medicare's Clinical Laboratory Fee Schedule (CLFS), including all CPT codes, can be found at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>

<https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf>

<https://www.cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing>

Applicable Medicare 2022 Clinical Laboratory Fee Schedule (CLFS)

Infectious Disease Testing	
Pathogen/ABx Gene	CPT Code
Acanthamoeba castellanii, polyphaga; Vermamoeba (Hartmannella) vermiformis	87798
Acinetobacter baumannii	87798
ACT, MIR, FOX, ACC Groups	87798
Actinomyces israelii	87798
Adenovirus HAdV-B, HAdV-F, HAdV-G	87798
Alternaria spp, Curvularia lunata, Penicillium spp	87798
Aspergillus flavus, fumigatus, niger, terreus	87798
Astrovirus, Sapovirus G1, G2	87798
Atopobium vaginae	87798
Bacillus cereus, thuringiensis	87798
Bacteroides fragilis, vulgatus	87798
Blastomyces dermatitidis	87798
Bordetella pertussis, parapertussis, bronchiseptica	87798
Burkholderia cepacia, pseudomallei	87798
BVAB 2,3 (bacterial vaginosis associated bacteria 2,3); Mobiluncus spp.	87798
Campylobacter jejuni, coli	87798
Candida albicans, auris, glabrata, parapsilosis, tropicalis	87481
Chlamydia pneumoniae	87486
Chlamydia trachomatis	87491
Citrobacter freundii	87798
Clostridioides difficile (toxins A, B)	87798
Clostridium perfringens, novyi, septicum	87798

Infectious Disease Testing	
Pathogen/ABx Gene	CPT Code
Coronavirus (229E, NL63, OC43, and HKU1)	87798
Corynebacterium jeikeium, striatum, tuberculostearicum	87798
COVID-19 Coronavirus (SARS-CoV-2)	U0003
Cryptosporidium hominis, parvum, felis	87798
CTX-M1 (15), M2 (2), M9 (9), M8/25 Groups	87798
Cutibacterium (Propionibacterium) acnes	87798
Cyclospora cayetanensis, Cystoisospora belli	87798
Cytomegalovirus	87798
Demodex folliculorum	87798
dfr (A1, A5), sul (1, 2)	87798
Dientamoeba fragilis, Entamoeba histolytica	87798
Enterogastric E. coli (EAEC)	87798
Enterobacter aerogenes, cloacae	87798
Enterococcus faecalis, faecium	87798
Enteroinvasive E. coli (EIEC) / Shigella spp.	87798
Enteropathogenic E. coli (EPEC)	87798
Enterotoxigenic E. coli (ETEC)	87798
Enterovirus A, B, C, D68, (pan)	87798
Epidermophyton floccosum	87798
Epstein-Barr virus	87798
ermB, C; mefA	87798
Escherichia coli	87798
Fingoldia magna	87798
Fusarium oxysporum, solani	87798
Fusobacterium nucleatum, necrophorum	87798
Gardnerella vaginalis	87511
Giardia intestinalis	87329
Haemophilus ducreyi	87798
Haemophilus influenzae	87798
Helicobacter pylori	87338
Herpes simplex virus 1, 2	87529
High Risk HPV types 16, 39, 26, 18, 51, 53, 31, 52, 66, 33, 58, 73, 35, 59, 82, 45, 56, 68, 67, 69, 70	87624
Human metapneumovirus	87798
IMP, NDM, VIM Groups	87798
Influenza virus A, B	87502
Klebsiella (Calymmatobacterium) granulomatis	87798
Klebsiella pneumoniae, oxytoca	87798
Legionella pneumophila	87541
Listeria monocytogenes	86609
Malassezia furfur, restricta, sympodialis, globosa	87798
mecA	87641
Megasphaera (types 1, 2)	87798
Microsporidia (Encephalitozoon hellum, cuniculi, Nosema (Vittaforma) ocularum)	87798
Microsporidium (Enterocytozoon bienersi, Encephalitozoon intestinalis)	87798
Microsporium audouinii, canis, gypseum	87798
Moraxella catarrhalis	87798

Infectious Disease Testing	
Pathogen/ABx Gene	CPT Code
Morganella morganii	87798
Mycobacterium abscessus, avium-intracellulare, chelonae, fortuitum, kansasii, marinum, ulcerans	87551
Mycobacterium spp	87798
Mycobacterium tuberculosis	87556
Mycoplasma genitalium, hominis	87563
Mycoplasma pneumoniae	87581
Neisseria gonorrhoeae	87591
Norovirus (Genogroup 1, 2)	87798
OXA-48, OXA-51	87798
Parainfluenza virus (types 1, 2, 3, 4)	87798
Peptostreptococcus anaerobius, asaccharolyticus, magnus, prevotii	87798
Proteus mirabilis, vulgaris	87798
Pseudomonas aeruginosa	87798
qnrA1, A2, B2	87798
Respiratory syncytial virus	87634
Rhinovirus A, C	87798
Rhizopus spp, Mucor spp	87798
Rotavirus A, B	87425
Salmonella enterica	87798
Serratia marcescens	87798
Shiga toxin-producing E. coli 0157 (STEC 0157)	87798
SHV, KPC Groups	87798
Sporothrix schenckii	87798
Staphylococcus aureus	87640
Staphylococcus epidermidis, haemolyticus, lugdunensis, saprophyticus	87798
Stenotrophomonas maltophilia	87798
Streptococcus agalactiae	87653
Streptococcus anginosus, constellatus, intermedius, mitis, mutans, pneumoniae, sanguis	87798
Streptococcus pyogenes	87651
tet B, tet M	87798
Toxoplasma gondii	87798
Treponema pallidum	87798
Trichomonas vaginalis	87661
Trichophyton mentagraphophytes/interdigitale, rubrum, soudanense, terrestre, tonsurans, verrucosum, violaceum	87798
Trichosporon mucoides, asahii	87798
Ureaplasma urealyticum, parvum	87798
VanA, VanB	87500
Varicella zoster virus	87798
Vibrio cholerae, parahaemolyticus, vulnificus	87798
Yersinia enterocolitica	87798

Toxicology Testing	
Short Description	CPT Code
Drug test presumptive chemistry analyzer, any number of drug classes	80307
Drug test definitive 1-7 classes	G0480
Drug test definitive 8-14 classes	G0481
Drug test definitive 15-21 classes	G0482
Drug test definitive 22+ classes	G0483