



2016-2017 Annual Physician Notice of Laboratory Compliance

To our Valued Healthcare Partners:

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 to inform our provider clients on the responsibilities we share.

This annual notice specifies current Medicare/Medicaid program requirements and HealthTrackRx policies. Please carefully review the information and contact Melissa Stokes, HealthTrackRx Compliance Manager, at 940-383-2223 or melissa@healthtrackrx.com if you have any questions or concerns.

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

Disclosure of Exclusions from Federal Healthcare Programs

Under federal law, no payment will be made by any federal healthcare program for any items or services furnished, ordered, or prescribed by an excluded individual or entity. Under the Centers for Medicare & Medicaid Services' (CMS) rules, providers must not employ or contract with individuals or entities excluded from participation in any health care program or debarred by the GSA. CMS does not permit payments furnished under the plan by an individual or entity while being excluded from participation. CMS has further advised states that they should require providers to search the HHS OIG website monthly to capture exclusions and reinstatements. Professionals who are required to be licensed shall notify HealthTrackRx in writing within (5) days of receiving any written or oral notice of any adverse action, including, without limitation, exclusion from participation in any federal or state health care or procurement programs, any filed and served malpractice suit or arbitration action; any adverse action by a Texas Licensing Board taken or pending; any adverse action which has resulted in the filing of a report with the Texas Licensing Board; any revocation of DEA license; or a conviction of any felony or a misdemeanor of moral turpitude; any action against any certification under the Medicare or Medicaid programs.

List of Excluded Individuals/Entities (LEIE): The OIG established a program to exclude individuals and entities who have been found to have violated federal law and/or regulations. The effect of an OIG exclusion from Federal healthcare programs is that no Federal healthcare program payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician (42 CFR 1001.1901). This payment ban applies to all methods of Federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules or a prospective payment system (PPS). Any items and services furnished by an excluded individual or entity are not reimbursable under Federal health care programs. In addition, any items and services furnished at the medical direction or prescription of an excluded physician are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to another provider, practitioner or supplier that is not excluded.

System for Award Management (SAM) is the Official U.S. Government system that consolidated the capabilities of CCR/FedReg, ORCA, and the List of Parties Excluded from Federal Procurement and Non-procurement Programs (EPLS). The GSA maintains the a single comprehensive list of individuals and firms excluded by Federal government agencies from receiving federal contracts or federally approved subcontracts and from certain types of federal financial and nonfinancial assistance and benefits. The EPLS was originally created for information of and use by Federal agencies.

Medicaid State Sanction Data: Many states maintain their own database of individuals and entities they sanction. Several call for or require health care entities to screen against this list. This is in addition to not in lieu of screening against the Federal sanction information.

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 drug 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 their 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 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-9/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 and filed with HealthTrackRx we are also educating any laboratory that is currently using HealthTrackRx as the Reference Laboratory.

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, source (when applicable), and the licensed ordering practitioner's name and address. Handwritten orders must be signed and dated by the provider. Custom Profiles may be used if patient specific medical necessity is recorded in the patient's medical records and clearly marked on the Test Order Requisition. 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. 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'.

The pre-printed test order requisition is the tool used to communicate the physician order to the laboratory, but is NOT considered the valid 'order' as defined by Medicare. 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 requisitions 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.

Physician Custom Profiles

Recent policy changes from Medicare Administrative Contractors support a growing movement away from physician's use of non-patient specific custom profiles when ordering laboratory drug testing. We support these efforts to help better ensure that only medically necessary tests are ordered for each patient and we have taken steps to ensure compliance.

HealthTrackRx does not accept "Standing Orders" or the default to a standing order if no order is on the Test Requisition Form. HealthTrackRx has provided all existing and new clients with a Custom Order Form that promotes physician choice for each test offered by HealthTrackRx. Along with the custom order form replacing standing orders, HealthTrackRx has enforced requirements on the Test Order Requisition that is submitted with each specimen for testing. The physician has the choice to order individual tests based on patient-specific medical necessity and if the custom profile is desired, the physician must indicate the order to use the "custom profile" for the specific patient. Test requisitions without a clearly marked test order will result in delay of test results.



Custom Profiles must contain the physician signature and date in addition to the ordering provider's printed name and NPI Number. Custom Profiles should only be used in connection with extended treatment by the same ordering physician, and with the same diagnosis code(s). The ordering provider should record the frequency and duration for the order, not to exceed 365 days from the original order date, in the patient's medical record and treatment plan.

Custom Profiles are to be reviewed on an annual basis and HealthTrackRx require you to submit a new custom [profile, noting your changes or renewing the custom profile in its current state. Also, you may amend your custom profile at any time. We suggest that the physician keep a copy of their custom profile readily available and in the patient's medical record when ordering laboratory test services as a reference to help ensure that only medically necessary tests are 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 'non-covered' diagnosis is used, 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 suspected based on medical necessity or frequency limitations. The signed, original ABN must be attached to the original lab order prior to submission. Per Medicare rules, requesting the ABN on all Medicare beneficiaries is considered an unacceptable practice.

Medicare National and Local Coverage Determinations

The Medicare Program publishes National Coverage Determination (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare with reference to specific diagnostic information. LCDs that apply to qualitative drug screens (presumptive tests), and confirmatory or quantitative drug tests (definitive testing) can be found through the Medicare website at <https://www.cms.gov/medicare/coverage/determinationprocess/LCDs.html>

HealthTrackRx will also make these LCDs available to any interested physician upon request.

The LCD issued by Novitas Solutions entitled "Qualitative Drug Testing (L34352) provides guidance regarding appropriate indications and expected frequency for Urine Drug Testing (UDT). This policy is applicable to laboratories located in Novitas Jurisdiction, which encompasses Texas, and we believe (and have already seen) many of the same requirements will be adopted by the individual CMS contractors nationwide, and are thus preparing to ensure both our and your compliance with Novitas standards. HealthTrackRx adopted a Compliance Program that reflects the OIG Clinical Laboratory Compliance Program Guidelines and encourage all Healthcare Partners to do the same.

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 laws and regulations governing physician self-referral, most noticeably the 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 the services of clinical consultants and toxicologists available to ensure proper test ordering and answer questions. They may be reached at 940-435-0242.

To avoid false claim submission, please be sure to:

1. Order only those tests necessary for diagnosis or treatment. Each component of a panel must be necessary for the panel to qualify 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 the Medicare patient when the tests do not meet the medical necessity criteria.

CMS National Coverage Policy

HealthTrackRx has included statements from the CMS National Coverage Policy and is attached hereto in Exhibit 1A.

Local Coverage Determination

HealthTrackRx has included statements from the Novitas Solutions, Inc. *Qualitative Drug Testing* (L34352) and is attached hereto as Exhibit 1B.

Medicare Rates

HealthTrackRx's test list with CPT and HCPS G-Codes and Calendar Year 2015-2016 Medicare maximum reimbursement rates for each test is attached hereto as Exhibit 2.

1A. 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.

Title XVIII of the Social Security Act, Section 1833€ states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Code of Federal Regulations (CFR) Title 42, Part 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his/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.

Medicare regulations at 42 CFR 410.32(a) state in part, that "...diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician 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." This, except where other uses have been authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

1B. Local Coverage Determination (LCD): Qualitative Drug Testing (L34352)

LCD ID: L34352 Jurisdiction: Texas Contractor: Novitas Solutions, Inc. Contract #: 04412

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

"A qualitative drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for broad qualitative screening..."

“Drugs or classes of drugs are commonly assayed by qualitative testing. A qualitative test may be followed by confirmation with a second method, when there is a positive inconsistent finding from the qualitative test in the setting of a symptomatic patient”.

“Examples of drug or classes that are commonly assayed by qualitative tests, followed by confirmation with a second method, are: alcohols, amphetamines, barbiturates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines, stimulants, opioid analgesics, salicylates, cardiovascular drugs, antipsychotics, cyclic antidepressants, and others. Focused drug screens, most commonly for illicit drug use, may be more useful clinically.”

“Although there is not a specific companion LCD on quantitative drug testing, there should be typically a direct correlation between those positive findings generated from initial qualitative testing and those requested quantitative tests to specifically confirm such qualitative finding.”

“Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physician in evaluating the patient if the diagnosis remains unclear.”

“Qualitative screening panels should be used when the results will alter patient management or disposition.”

List of Indications

A qualitative drug test may be indicated for a symptomatic patient when the history is unreliable, when there has been a suspected multiple-drug ingestion, to determine the cause of a patient in delirium or coma, for the identification of specific drugs that may indicate when antagonists may be used.

Medicare will consider performance of a qualitative drug test reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:

Unexplained coma;

Unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome;

Severe or unexplained cardiovascular instability (cardiotoxicity);

Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;

Seizures with an undetermined history.

A qualitative drug test may be reasonable and necessary for patients with known substance abuse or dependence, when the results of such testing may impact their ongoing treatment.

A qualitative drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication.

A qualitative drug test may be reasonable and necessary for chronic pain patients:

In whom other illicit drug use is suspected, when there has been an acute change in physical or mental status that meets the indications above.

To demonstrate abnormal findings, including the presence or absence of prescribed drugs, presence of nonprescribed substances, detection of illicit substances and adulterated urine samples.

Drugs or drug classes for which testing is performed should reflect only those likely to be present, based on the patient's medical history or current clinical presentation. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.

Documentation Requirements

All documentation must be maintained in the patient's medical record and available to the contractor upon request.



Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The record must include the identity of the physician or non-physician practitioner responsible for and providing the care of the patient.

The submitted medical record should support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.

Medical record documentation (e.g., history and physical, progress notes) maintained by the ordering physician/treating physician must indicate the medical necessity for performing a qualitative drug test. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in the order.

When a confirmatory test or a quantitative test is performed, the record must show that an inconsistent positive finding was noted on the qualitative testing or that there was no available, commercially or otherwise, qualitative test to evaluate the presence of a semi-synthetic or synthetic opioid in a patient who met the coverage criteria of this policy.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the lab results, along with copies of the ordering/referring physician's order for the qualitative drug test. The physician must include the clinical indication/medical necessity in the order for the for the qualitative drug test.

2. Medicare 2016 Clinical Laboratory Fee Schedule (CLFS)

HCPCS	SHORTDESC	National Limit
G0477	Drug test presumpt optical	14.86
G0478	Drug test presumpt opt inst	19.81
G0479	Drug test presumpt not opt	79.25
G0480	Drug test def 1-7 classes	79.94
G0481	Drug test def 8-14 classes	122.99
G0482	Drug test def 15-21 classes	166.03
G0483	Drug test def 22+ classes	215.23

Reference Information and Websites

ICD-10 Resources

<http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10>

Signature Requirements: MLN Complying with Medicare Signature Requirements within the Internet-Only Manuals and Medicare Program Integrity Manual (Ch. 3: Verifying Potential Errors and Taking Corrective Action).

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/>

Medical Necessity Policies for Laboratory Tests

National Coverage Determinations: <https://www.cms.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx?bc=BAAAAAAAAAAAA&>

Local Coverage Determination by Novitas Solutions: <https://www.cms.gov/medicare-coverage-database/license/cpt-license.aspx?from=/~/overview-and-quick-search.aspx&npage=/medicare-coverage-database/details/lcd-details.aspx&LCDId=34352&ver=12&ContrlId=338&ContrVer=1>

Advance Beneficiary Notices (ABN): ABN Form CMS-R-131

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



Medicare's Clinical Laboratory Fee Schedule (CLFS)

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

42 U.S.C. §§1320a-7b (2006).

<http://frwebgate2.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=cEcmOi/0/1/0&WAIAction=retrieve>

Department of Health and Human Services Office of Inspector General. OIG Supplemental Compliance Guidance for Hospitals. 70 Fed. Reg. 4858, 4865 (Jan. 31, 2005).

<http://oig.hhs.gov/fraud/docs/complianceguidance/012705hospsupplementalguidance.pdf>

Department of Health and Human Services Office of Inspector General. Compliance Program Guidance for Clinical Laboratories (63 Fed. Reg. 45076; August 24, 1998)

<http://oig.hhs.gov/authorities/docs/cpglab.pdf>

Centers for Medicare & Medicaid Services. State Medicaid Director Letter (SMDL #09-001). (Jan. 16, 2009).

<http://www.cms.gov/SMDL/downloads/SMD011609.pdf>

Department of Health and Human Services Office of Inspector General. "The Effect of Exclusion From Participation in Federal Health Care Programs." Special Advisory Bulletin. (Sept. 1999).

http://oig.hhs.gov/exclusions/effects_of_exclusion.asp

"National Practitioner Data Bank (NPDB)." July 2011. United States Department of Health and Human Services. 14 Jul. 2011

<<http://www.npdb-hipdb.hrsa.gov>>