

2024 Annual Notice to Providers of Laboratory Compliance

Dear Valued Healthcare Partners,

Thyroid Specialty Laboratory, Inc., d/b/a TEN Healthcare, 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, TEN Healthcare delivers annual provider information and education regarding laboratory compliance, billing and coding guidelines, and information on the responsibilities we share.

TEN Healthcare is providing this notice in accordance with the TEN Healthcare compliance policies and guidance provided by the Office of Inspector General (OIG) of the United States Department of Health and Human Services. The OIG requires in its Compliance Program Guidance that clinical laboratories send notices to physicians and other providers who use their services to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services.

The following information is intended to promote awareness of federal regulations and to explain the requirement for physicians and other authorized providers to furnish appropriate documentation when ordering testing services. If you have questions about the contents in this notice, we encourage you to contact us for more information at toll-free number (844) 836-3890, customerservice@tenhealthcare.com, or compliance@tenhealthcare.com.

To ensure compliance with applicable reimbursement laws:

- Order only the 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.
- Provide a diagnosis for each test ordered.
- Document this information in the patient's medical record. Add supporting clinical information followed by the ordering physician's signature.
 - Medicare may deny payment for a test that a physician believes is appropriate, but which does not meet Medicare criteria, e.g. screening purposes or where the entire medical record does not support that the tests were reasonable and necessary for a given patient.
- Obtain an ABN from Medicare patients when tests do not meet the medical necessity or other coverage criteria.

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 needs are not usually covered by the Medicare Program, and therefore are not reimbursed. As a participating provider in the government healthcare programs, TEN Healthcare strives to ensure that any claims it submits for reimbursement to federally funded healthcare programs meet appropriate program requirements. To this end, TEN has a responsibility to advise physicians of the importance of ordering only those tests believed to be medically necessary for the diagnosis and treatment of the patient. As the physician, you are responsible for documenting medical necessity in the patient's permanent medical record and

for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity. TEN Healthcare requires that all orders conform to its policies including the use of TEN Healthcare Order Requisition forms and appropriate documentation of medical necessity. The Office of Inspector General takes the position that an individual who knowingly causes a false claim to be submitted, such as ordering medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act. Recent policy changes and health plan actions, including increased use of post-payment audits, has encouraged TEN Healthcare to more aggressively enforce long-standing policies that patients' medical records must include documentation of medical necessity for ordering tests. This is specified in each TEN Healthcare Order Requisition form that is signed by the provider.

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 for which the included tests are or are not covered or reimbursed by Medicare with reference to specific ICD-10 codes. For a complete list of NCD/LCD policies, with test name(s), CPT and ICD-10 code(s), please review:

NCD: <http://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx?bc=BAAAAAAAAAAAAA>

LCD: <https://med.wpsgha.com/>

Test Order Requisition

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

- patient name
- patient address
- date of birth
- date and time of collection
- specimen source (when applicable)
- diagnosis code
- payor information
- testing option (comprehensive panel or individual tests)
- the licensed ordering practitioner's name
- physician signature
- facility name and address

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

Upon request by TEN Healthcare 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 TEN Healthcare test requisition form must be used when ordering tests. TEN Healthcare Requisitions are designed to meet federal healthcare program requirements and include an attestation statement that the physician understands that he/she has the option to order tests individually or select a panel/combination of tests and that the physician has determined that the ordered tests are medically necessary for the diagnosis/treatment of the patient. 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 diagnosis or treatment of each patient. If TEN Healthcare receives a test order on a non-TEN Healthcare requisition form or an incomplete TEN Healthcare requisition form, processing of your test order may be delayed. As necessary, TEN Healthcare will contact physicians to have them resubmit the test order on a TEN Healthcare test requisition form or otherwise clarify each specific test being ordered. TEN Healthcare requires accurate and complete information in order to process specimens. The information you provide on the test requisition must accurately reflect the medical reasons for requesting the specified tests.

To avoid false claim submission, be sure to: (i) order only those tests necessary for diagnosis or treatment; (ii) provide a diagnosis, sign or symptom for the test(s) ordered; (iii) document this information in the patient's medical record; and (iv) obtain an Advanced Beneficiary Notice (ABN) from the Medicare patient when tests do not meet medical necessity criteria. A completed requisition form must include the information listed in the section "Test Order Requisition" above, and any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results. In the event of a Medicare or compliance audit or request for medical necessity documentation, TEN Healthcare may request a copy of your medical record documentation to support the medical necessity of the test that was ordered.

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 to all Medicare beneficiaries is considered an unacceptable practice. The ABN, Form CMS-R-131, and form instructions have been approved by the Office of Management and Budget (OMB) for renewal. The use of the renewed form with the expiration date of 01/31/2026 will be mandatory on 6/30/23. 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. 1/31/2026).

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), TEN Healthcare 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.

Inducements

TEN's compliance with Federal healthcare program requirements includes ensuring its business practices do not violate the Anti-Kickback Statute (AKS) or the Stark Law.

The Federal Anti-Kickback Statute (AKS) prohibits and criminalizes the knowing and wilful payment of remuneration to induce or reward referrals or the generation of business involving items or services payable by any Federal health care program unless an exception applies. (See 42 U.S.C. § 1320a-7b for additional information.)

The Physician Self-Referral Law (Stark Law) prohibits a physician from making a referral for certain designated health services (including Laboratory Services) to an entity in which the physician (or an immediate family member) has an ownership/investment interest or with which he or she has a compensation arrangement, unless an exception applies. Penalties for physicians who violate the Stark Law may include fines as well as exclusion from participation in all Federal healthcare programs. (See 42 U.S.C. § 1395nn for additional information).

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce the referral of tests that are covered by Medicare, Medicaid, or other federal healthcare 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 TEN Healthcare by calling toll-free number (844) 836-3890, or emailing customerservice@tenhealthcare.com, or compliance@tenhealthcare.com.

Eligible Provider Enrollment (PECOS)

Physicians and others who are eligible to order and refer items or services need to establish their Medicare enrollment record with a valid National Provider Identifier (NPI) and must be of a specialty that is eligible to order and refer.

<https://pecos.cms.hhs.gov/providers/index.html>

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>

Based upon the OIG's recommendation, we are providing you with a link to the Medicare laboratory fee schedule, which may be found on the CMS webpage at <http://www.cms.hhs.gov/ClinicalLabFeeSched>. Please note that the Medicaid reimbursement amount may be equal or less than the amount of Medicare reimbursement that TEN Healthcare will receive on the tests you order.

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 that 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>

Missouri Medicaid Urine Drug Tests

The MO HealthNet program only covers quantitative (definitive) or “confirmative” tests (i.e., procedure codes from the Therapeutic Drug Assay or Chemistry sections of the CPT book) if there is a positive screen for the drug class to be quantified and if the physician has documented the medical necessity in the patient medical record.

Physician offices may bill for initial drug screens performed at point of care (e.g., by use of CLIA waived test devices) or independent and/or hospital laboratories may bill for screenings they performed. Providers cannot bill for the same date of service for the same participant.

The ordering physician has certain responsibilities:

- The ordering physician must coordinate the billing of the drug screen tests with the performing laboratory.
- The ordering physician must document medical necessity in the patient medical record when ordering quantification of a drug class or a confirmatory drug test.
- The ordering physician must sign each order for drug screening tests by signing a paper order, or by electronic signature that conforms with the requirements of 13 CSR 65-3.050.
 - The requirements state that an electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual with the intent to be the legally binding equivalent of the individual’s handwritten signature.
 - The use of biometrics does not constitute an electronic signature; however, biometrics may be used as part of electronic signature verification.
 - A signature stamp does not constitute an electronic signature.

The performing laboratory has certain responsibilities:

- The performing laboratory must ensure the physician has provided documentation of medical necessity when requesting quantification of a drug class or a confirmatory drug test.
- The performing laboratory must not perform quantification of a drug class or a confirmatory drug test without documentation of medical necessity.

For more information on Missouri Medicaid please visit <https://mydss.mo.gov/media/pdf/physicians-provider-manual>

Applicable Medicare 2024 Clinical Laboratory Procedure Codes

Billing codes can be unique to each individual insurance provider. Required billing codes are subject to change from time to time based on tests ordered and individual payor policy.

Procedure Code	Test
36415	Specimen collection, venipuncture
80048	Basic Metabolic Panel
80051	Electrolyte Panel
80053	Comprehensive Metabolic Panel
80061	Lipid Panel
80069	Renal Function Panel
80074	Hepatitis Panel, Acute
80076	Hepatic Function Panel
80151	Amiodarone

80156	Carbamazepine
80158	Cyclosporine
80162	Digoxin
80164	Valproic acid, total
80171	Gabapentin, blood
80177	Keppra
80183	Oxycarbazepine
80184	Phenobarbital
80185	Phenytoin
80307	Presumptive drug class screening
80321	Ethyl glucuronide
80321	Ethyl sulfate
80323	Cotinine
80323	Nicotine
80324	Amphetamine
80324	Methamphetamine
80324	Phentermine
80325	Amphetamines, 3 or 4 drugs
80336	Amitriptyline
80336	Desipramine
80336	Imipramine
80336	Nortriptyline
80343	Aripiprazole
80343	Haloperidol
80343	Quetiapine
80343	Risperidone
80345	Butalbital
80345	Secobarbital
80346	7-Aminoclonazepam
80346	Alprazolam
80346	Clonazepam
80346	Diazepam
80346	Hydroxyalprazolam
80366	Pregabalin
80368	Zolpidem
80369	Carisoprodol
80369	Cyclobenzaprine
80369	Meprobamate
80370	Skeletal muscle relaxants, 3 or more
80371	Butylone
80371	Ethylone
80371	MDPV
80371	Mephedrone
80372	Tapentadol
80373	O-DM Tramadol
80373	Tramadol
81003	Urinalysis
82040	Albumin
82103	Alpha-1 antitrypsin
82150	Amylase

82172	APO-A1
82172	APOB
82232	Beta-2 microglobulin
82247	Bilirubin, total
82248	Bilirubin, direct
82306	Vitamin D
82310	Calcium
82374	Bicarbonate
82390	Ceruloplasmin
82435	Chloride
82465	Cholesterol, total
82533	Cortisol
82550	Creatinine Kinase
82565	Creatinine
82607	Vitamin B12
82610	Cystatin C
82627	DHEA-S
82670	Estradiol
82728	Ferritin
82746	Folate
82747	Folic acid
82784	IgA
82784	IgG
82784	IgM
82947	Glucose
82977	Gamma glutamyl transferase
82985	Fructosamine
83001	FSH
83002	Luteinizing hormone
83010	Haptoglobin
83036	HbA1C
83090	Homocysteine
83525	Insulin
83540	Iron
83550	Iron binding test
83615	Lactate dehydrogenase
83655	Lead
83690	Lipase
83695	Lipoprotein A
83718	HDL
83721	LDL
83735	Magnesium
83880	ProBNP
83992	Assay for phencyclidine
84075	Alkaline phosphatase
84100	Phosphate
84132	Potassium
84134	Prealbumin
84144	Progesterone
84146	Prolactin

84153	Total PSA
84154	Free PSA
84155	Total protein
84270	Human sex hormone binding globulin
84295	Sodium
84305	Insulin-like growth factor
84403	Testosterone
84436	T4
84439	FT4
84443	Thyroid stimulating hormone
84450	Aspartate aminotransferase
84460	Alanine aminotransferase
84466	Transferrin
84478	Triglycerides
84479	T-Uptake
84480	T3
84481	FT3
84520	Blood urea nitrogen
84550	Uric acid
84702	HCG-Beta
84999	Kappa free light chain
84999	Lamba free light chain
85014	Hematocrit
85018	Hemoglobin
85025	CBC w/ auto differential
85048	WBC
86038	Antinuclear antibodies, screen
86039	Antinuclear antibodies, titer
86060	Anti-Streptolysin O
86140	C-Reactive protein
86141	C-Reactive protein, high sensitivity
86160	C3
86160	C4
86301	CA-19
86430	Rheumatoid factor
86480	Tuberculosis
86618	Lyme disease antibody
86695	Herpes simplex 1
86696	Herpes simplex 2
86703	HIV Duo
86704	Anti-HBc II
86705	Anti-HBc IgM
86706	Anti-HBs
86708	Anti-HAV II
86709	Anti-HAV IgM
86780	Syphilis
86787	Varicella zoster
86803	Anti-HCV
87070	Wound culture
87340	Anti-HBsAg

87341	HBsAg confirmatory
87350	HBeAg
87481	Candida albicans
87481	Candida dubliniensis
87481	Candida glabrata
87481	Candida krusei
87481	Candida lusitaniae
87481	Candida parapsilosis
87481	Candida tropicalis
87486	Chlamydia pneumoniae
87491	Chlamydia trachomatis
87496	Cytomegalovirus
87498	Enterovirus A
87498	Enterovirus B
87498	Enterovirus C
87498	Enterovirus D
87498	Enterovirus D68
87500	Vancomycin resistance
87501	Influenza A virus H1-2009
87501	Influenza virus A H3
87501	Influenza virus B
87502	Influenza virus, multiple types or subtypes
87511	Gardnerella vaginalis
87529	Herpes simplex virus 1
87529	Herpes simplex virus 2
87532	Human herpesvirus 6
87541	Legionella pneumophila
87556	Mycobacterium tuberculosis
87563	Mycoplasma genitalium
87581	Mycoplasma pneumoniae
87591	Neisseria gonorrhoeae
87593	Monkeypox
87624	Human papillomavirus 16
87624	Human papillomavirus 18
87624	Human papillomavirus 45
87625	Human papillomaviruses 16, 18 & 45
87635	COVID-19
87640	Staphylococcus aureus
87641	Staphylococcus aureus, methicillin resistant
87651	Streptococcus pyogenes
87653	Streptococcus agalactiae
87661	Trichomonas vaginalis
87798	1546 Transposon
87798	ACC-4
87798	Acinetobacter baumannii
87798	Actinobaculum schaalii
87798	ACTM
87798	Adenovirus 1
87798	Adenovirus 2
87798	Aerococcus urinae

87798	Alloscardovia omnicolens
87798	ampC/CMY2
87798	AMPC1
87798	Anaerococcus vaginalis
87798	Atopobium vaginae
87798	Bacterial vaginosis associated bacterium 2
87798	Bacteroides fragilis
87798	BLASHV
87798	BLC
87798	Bocaparvovirus
87798	Bordetella holmesii
87798	Bordetella pertussis
87798	Cfr23S
87798	Citrobacter freundii
87798	Citrobacter koseri
87798	Clostridium perfringens
87798	Clostridium septicum
87798	CMYMOX
87798	Coronavirus 229E
87798	Coronavirus HKU1
87798	Coronavirus NL63
87798	Coronavirus OC43
87798	Corynebacterium jeikeium
87798	Corynebacterium striatum
87798	Corynebacterium urealyticum
87798	Coxiella burnetii
87798	CTX-M1
87798	CTX-M2
87798	CTX-M8
87798	CTX-M9
87798	DFRA1
87798	DFRA5
87798	Enterobacter aerogenes
87798	Enterobacter cloacae
87798	Enterobacter cloacae complex 1
87798	Enterobacter cloacae complex 2
87798	Enterococcus faecalis
87798	Enterococcus faecium
87798	Epstein-Barr virus
87798	ERMA
87798	ERMB
87798	ERMB1
87798	ERMC
87798	Escherichia coli
87798	Fingoldia magna/Peptostreptococcus magnus
87798	FOX (AmpC beta lactamase resistance)
87798	Fusobacterium necrophorum
87798	Fusobacterium nucleatum
87798	GES-1
87798	Haemophilus ducreyi

87798	Haemophilus influenzae
87798	Human metapneumovirus
87798	Human parechovirus
87798	Human respiratory syncytial virus A
87798	Human respiratory syncytial virus B
87798	Human rhinovirus 1
87798	Human rhinovirus 2
87798	IMP1
87798	IMP2
87798	Klebsiella oxytoca
87798	Klebsiella pneumoniae
87798	KPC2
87798	Lactobacillus crispatus
87798	Lactobacillus gasseri
87798	Lactobacillus iners
87798	Lactobacillus jensenii
87798	mcr-1
87798	Measles virus
87798	MECA
87798	MECC
87798	MEFA
87798	Megasphera 1
87798	Megasphera 2
87798	Middle East Respiratory Syndrome
87798	Mobiluncus curtisii
87798	Mobiluncus mulieris
87798	Moraxella catarrhalis
87798	Morganella morganii
87798	Mumps virus
87798	Mycoplasma hominis
87798	NDM-1
87798	OXA-48
87798	OXA-51
87798	Pantoea agglomerans
87798	Parainfluenza virus type 1
87798	Parainfluenza virus type 2
87798	Parainfluenza virus type 3
87798	Parainfluenza virus type 4
87798	Peptoniphilus harei
87798	Peptoniphilus ivorii
87798	Peptostreptococcus anaerobius
87798	Peptostreptococcus asaccharolyticus/ Peptoniphilus asaccharolyticus
87798	Peptostreptococcus prevotii
87798	PER-1
87798	Pneumocystis jirovecii
87798	Prevotella bivia
87798	Proteus mirabilis
87798	Proteus vulgaris
87798	Providencia stuartii
87798	Pseudomonas aeruginosa

87798	QNRA2
87798	QNRAB
87798	Rhinovirus A
87798	Rhinovirus B
87798	Rhinovirus C
87798	Serratia marcescens
87798	Severe acute respiratory syndrome coronavirus
87798	SHV2
87798	SHV2/SHV5
87798	Staphylococcus epidermis
87798	Staphylococcus lugdunensis
87798	Staphylococcus saprophyticus
87798	Streptococcus pneumoniae
87798	SUL1
87798	SUL2
87798	TetM
87798	TetS
87798	Treponema pallidum
87798	Ureaplasma urealyticum
87798	VANA1
87798	VANA2
87798	VanB
87798	Varicella zoster virus
87798	VEB-1
87798	VIM-1
G0471	Specimen collection, venous blood
G0480	Definitive drug testing, 1-7 drug classes
G0481	Definitive drug testing, 8-14 drug classes
G0482	Definitive drug testing, 15-21 drug classes
G0483	Definitive drug testing, 22 or more drug classes