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# 2023 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 recommendations made by the Office of Inspector General (OIG) of the Department of Health and Human Services. The OIG recommends 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 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 or customerservice@tenhealthcare.com.

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

- 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, sign or symptom for each test ordered.
- Document this information in the patient's medical record followed by the ordering physician's signature.
- 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 need are not usually covered by the Medicare Program, and therefore are not reimbursed. As a participating provider in the Medicare Program, TEN Healthcare 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 permanent medical record and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to TEN Healthcare (note: 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 The False Claims Act ("FCA") at the end of the document for further details.

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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=BAAAAAAAAAAA
LCD: http://wpsmedicare.com/j5macpartb/policy/active/local/

## 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's full legal name
- date of birth
- date and time of collection
- specimen source (when applicable)
- diagnosis code
- the licensed ordering practitioner's name
- 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 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 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. The information you provide on the test requisition should 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 should include the following information: collection date, patient name, patient's date of birth, test(s) to be performed, indications as to why the test is being ordered (such as a diagnosis code), 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.

## 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, TEN Healthcare 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 TEN Healthcare 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), 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

It is the policy of TEN Healthcare 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 any remuneration – meaning anything of value – to induce the referral of tests that are covered by Medicare, Medicaid 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 TEN Healthcare by calling (844) 836-3890.

## 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 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

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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 2023 Clinical Laboratory Procedure Codes

| 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 |

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|---|---|
| 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 |
| 82140 | Ammonia |
| 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 |

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|---|---|
| 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 |
| 84207 | Vitamin B6 |
| 84270 | Human sex hormone binding globulin |
| 84295 | Sodium |
| 84305 | Insulin-like growth factor |
| 84403 | Testosterone |
| 84425 | Vitamin B1 |
| 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 |
| 85610 | PT/INR |
| 86038 | Antinuclear antibodies, screen |

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|---|---|
| 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 |
| 87081 | Culture, streptococcus |
| 87086 | Urine 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 |
| 87493 | Clostridium difficile |
| 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 |

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|---|---|
| 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 | Adenovirus F40/41 |
| 87798 | Aerococcus urinae |
| 87798 | Alloscardovia omnicolens |
| 87798 | ampC/CMY2 |
| 87798 | AMPC1 |
| 87798 | Anaerococcus vaginalis |
| 87798 | Astrovirus |
| 87798 | Atopobium vaginae |
| 87798 | Bacterial vaginosis associated bacterium 2 |
| 87798 | Bacteroides fragilis |
| 87798 | Bacilus cereus |
| 87798 | BLASHV |
| 87798 | BLC |
| 87798 | Bocaparvovirus |
| 87798 | Bordetella holmesii |
| 87798 | Bordetella pertussis |
| 87798 | Campylobacter coli |
| 87798 | Campylobacter jejuni |
| 87798 | Cfr23S |
| 87798 | Citrobacter freundii |
| 87798 | Citrobacter koseri |
| 87798 | Clostridium perfringens |
| 87798 | Clostridium septicum |
| 87798 | CMYMOX |

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|---|---|
| 87798 | Coronavirus 229E |
| 87798 | Coronavirus HKU1 |
| 87798 | Coronavirus NL63 |
| 87798 | Coronavirus OC43 |
| 87798 | Corynebacterium riegelii |
| 87798 | Corynebacterium striatum |
| 87798 | Corynebacterium urealyticum |
| 87798 | Coxiella burnetiid |
| 87798 | Cryptosporidium |
| 87798 | CTX-M1 |
| 87798 | CTX-M2 |
| 87798 | CTX-M8 |
| 87798 | CTX-M9 |
| 87798 | Cyclospora cayatanensis |
| 87798 | DFRA1 |
| 87798 | DFRA5 |
| 87798 | Entamoeba histolytica |
| 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 | Escherichia coli enteroaggregative |
| 87798 | Escherichia coli enteropathogenic |
| 87798 | Escherichia coli enterotoxigenic |
| 87798 | Escherichia coli O157 |
| 87798 | Escherichia coli Shiga-like toxin 1 and 2 |
| 87798 | Finegoldia magna/Peptostreptococcus magnus |
| 87798 | FOX (AmpC beta lactamase resistance) |
| 87798 | Fusobacterium necrophorum |
| 87798 | Fusobacterium nucleatum |
| 87798 | GES-1 |
| 87798 | Giardia lamblia |
| 87798 | Haemophilus ducreyi |
| 87798 | Haemophilus influenzae |
| 87798 | Helicobacter pylori |
| 87798 | Hepatitis A |
| 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 |

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|---|---|
| 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 | Listeria monocytogenes |
| 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 | Norovirus group 1 |
| 87798 | Norovirus group 2 |
| 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 |

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|---|---|
| 87798 | Rhinovirus C |
| 87798 | Rotavirus A |
| 87798 | Rotavirus B |
| 87798 | Rotavirus C |
| 87798 | Salmonella |
| 87798 | Sapovirus 1 |
| 87798 | Sapovirus 2 |
| 87798 | Serratia marcescens |
| 87798 | Severe acute respiratory syndrome coronavirus |
| 87798 | Shigella sonnei |
| 87798 | SHV2 |
| 87798 | SHV2/SHV5 |
| 87798 | Staphylococcal enterotoxins A,B |
| 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 | Vibrio cholerae |
| 87798 | Vibrio parahemolyticus |
| 87798 | Vibrio vulnificus |
| 87798 | VIM-1 |
| 87798 | Yersinia enterocolitica |
| 87804 | Influenza swab |
| 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 |
| P9603 | Per Mile Travel |
| P9604 | Flat Rate Travel |
| U0004 | COVID-19 |
| U0005 | COVID-19 |

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## The False Claims Act ("FCA")

The following is cited from CMS website https://downloads.cms.gov/cmsgov/archived-downloads/smdl/downloads/smd032207att2.pdf
The False Claims Act ("FCA") provides, in pertinent part, that:

a. Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;. . . or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person

b. For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729. While the False Claims Act imposes liability only when the claimant acts "knowingly," it does not require that the person submitting the claim have actual knowledge that the claim is false. A person who acts in reckless disregard or in deliberate ignorance of the truth or falsity of the information, also can be found liable under the Act. 31 U.S.C. 3729(b).

In sum, the False Claims Act imposes liability on any person who submits a claim to the federal government that he or she knows (or should know) is false. An example may be a physician who submits a bill to Medicare for medical services she knows she has not provided. The False Claims Act also imposes liability on an individual who may knowingly submit a false record in order to obtain payment from the government. An example of this may include a government contractor who submits records that he knows (or should know) is false and that indicate compliance with certain contractual or regulatory requirements. The third area of liability includes those instances in which someone may obtain money from the federal government to which he may not be entitled, and then uses false statements or records in order to retain the money. An example of this so-called "reverse false claim" may include a hospital who obtains interim payments from Medicare throughout the year, and then knowingly files a false cost report at the end of the year in order to avoid making a refund to the Medicare program.

In addition to its substantive provisions, the FCA provides that private parties may bring an action on behalf of the United States. 31 U.S.C. 3730 (b). These private parties, known as "qui tam relators," may share in a percentage of the proceeds from an FCA action or settlement.

Section 3730(d)(1) of the FCA provides, with some exceptions, that a qui tam relator, when the Government has intervened in the lawsuit, shall receive at least 15 percent but not more than 25 percent of the proceeds of the FCA action depending upon the extent to which the relator substantially contributed to the prosecution of the action. When the Government

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does not intervene, section 3730(d)(2) provides that the relator shall receive an amount that the court decides is reasonable and shall be not less than 25 percent and not more than 30 percent.

The FCA provides protection to qui tam relators who are discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of their employment as a result of their furtherance of an action under the FCA. 31 U.S.C. 3730(h). Remedies include reinstatement with comparable seniority as the qui tam relator would have had but for the discrimination, two times the amount of any back pay, interest on any back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.

If you have any questions concerning this notice or appropriate test use and ordering, please contact us at customerservice@tenhealthcare.com or (844) 836-3890.