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2020-2021 Annual Physician Notice of Laboratory Compliance

To our Valued Healthcare Partners:

AIT Laboratories, a HealthTrackRX company, 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, AIT Laboratories 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 AIT Laboratories policies. Please carefully review the information and contact David Anderson, AIT Laboratories Chief Compliance Officer, at (650) 392-5869 or david.anderson@healthtrackrx.com if you have any questions or concerns. AIT Laboratories 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

AIT Laboratories 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 HHS Office of Inspector General (OIG) rules, providers must not employ or contract with individuals or entities excluded from participation in any federal health care program or debarred by the General Services Administration ("GSA"). OIG has recommended that providers search the HHS OIG website monthly to capture exclusions and reinstatements. Professionals who are required to be licensed shall notify AIT Laboratories 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 an applicable state licensing board taken or pending; any adverse action which has resulted in the filing of a report with the applicable state 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 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 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, AIT Laboratories 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-10 codes to the highest level of specificity or a narrative to AIT Laboratories. 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 AIT Laboratories 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 AIT Laboratories Practitioner Acknowledgement Form that is signed by the provider and filed with AIT Laboratories we are also educating any laboratory that is currently using AIT Laboratories 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)
- diagnosis code
- the licensed ordering practitioner's name and address.

Handwritten orders must be signed and dated by the provider. Client Web Portal ("CWP) Personalized Menu Selection 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 AIT Laboratories 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 AIT Laboratories 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 AIT Laboratories 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 AIT Laboratories receives a non-AIT Laboratories requisition form or an incomplete AIT Laboratories requisitions form, processing of your test order may be delayed. As necessary, AIT Laboratories will contact physicians to have them resubmit the test order on a AIT Laboratories 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, AIT Laboratories 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 AIT Laboratories 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. Medicare does not cover routine test screens. 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. 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), AIT Laboratories 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 AIT Laboratories to comply with all aspects of the 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 AIT Laboratories 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 ensure compliance with applicable reimbursement laws, 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.

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. Further information can be found at the following websites:

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

Respiratory Viral Panels:
https://www.cms.gov/medicare-coverage-database/details/lcddetails
aspx?LCDId=37348&ver=12&Date=&DocID=L37348&bc=iAAAABABIAAA&

Controlled Substance Monitoring and Drugs of Abuse Testing:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=35006&ver=119&KeyWord=controlled%20substance&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA

Gastrointestinal panels:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38229&ver=8&NCDId=188&ncd-ver=1&NCAId=166&CALId=88&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNC-D%7CMEDCAC%7CTA%7CMCD&ArticleTy pe=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=-%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=kidney+transplant&KeyWordLookUp=Doc&KeyW-ordSearchType=And&kq=true&bc=IAAAABgAAAAA&

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). 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 (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." Thus, except where other uses have been 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

Applicable Medicare 2021 Clinical Laboratory Fee Schedule (CLFS)

Infectious Disease Testing		
CPT Codes	**Rates**	**Short Description**
87481	$35.09	Candida dna amp probe
87486	$35.09	Chylmd pneum dna amp probe
87491	$35.09	Chylmd trach dna amp probe
87493	$37.27	C diff amplified probe
87496	$35.09	Cytomeg dna amp probe
87498	$35.09	Enterovirus probe&revrs trns
87500	$35.09	Vanomycin dna amp probe
87502	$95.80	Influenza dna amp probe
87511	$35.09	Gardner vag dna amp probe
87529	$35.09	Hsv dna amp probe
87541	$35.09	Legion pneumo dna amp prob
87551	$48.24	Mycobacteria dna amp probe
87556	$41.68	M.tuberculo dna amp probe
87563	$35.09	M. genitalium amp probe
87581	$35.09	M.pneumon dna amp probe
87591	$35.09	N.gonorrhoeae dna amp prob
87624	$35.09	Hpv high-risk types
87634	$70.20	Rsv dna/rna amp probe
87637*	142.63	Sars-COV2-COVID 19
87640	$35.09	Staph a dna amp probe
87641	$35.09	Mr-staph dna amp probe

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Infectious Disease Testing		
CPT Codes	**Rates**	**Short Description**
87651	$35.09	Strep a dna amp probe
87653	$35.09	Strep b dna amp probe
87661	$35.09	Trichomonas vaginalis amplif
86769*	$42.13	Sars-cov-2 covid-19 antibody
87798	$35.09	Detect agent nos dna amp
87801	$70.20	Detect agnt mult dna ampli
U0003#	$75.00	Cov-19 amp prb hgh thruput
U0005#	$25.00	Infec agen detec ampli probe

Toxicology Testing		
CPT Codes	**Rates**	**Short Description**
80307	$ 62.14	Drug test prsmv chem anlyzr
G0480	$ 114.43	Drug test def 1-7 classes
G0481	$ 156.59	Drug test def 8-14 classes
G0482	$ 198.74	Drug test def 15-21 classes
G0483	$ 246.92	Drug test def 22+ classes

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

cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing