2019 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 Lilly Andress, HealthTrackRX, Inc. Vice President of Legal Affairs and CCO at Lilly.Andress@healthtrackrx.com or 940-383-2223 ext 4682, 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 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 General Services Administration (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 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 require health care entities to screen against this list. This is in addition to and 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 their

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 their 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. Signature stamps are NOT acceptable.

All requisitions both electronic and paper must be signed by the referring provider. The requisition will serve as acceptable documentation of a physician order for the testing. 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'.

A pre-printed test order requisition is a 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 or electronic Client Web Portal (CWP) order 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 providers to have them resubmit the test order on an AIT Laboratories test requisition form or otherwise clarify each specific test being ordered.

Physician Custom Profiles

AIT Laboratories does not accept "Standing Orders" or the default to a standing order if no order is on the Test Requisition Form. AIT Laboratories does not offer the ability to continue using Custom Profiles for test ordering. Requisitions must include test orders (both paper requisitions and electronic order entry through the Client Web Portal) that have been deemed as medically necessary by the authorized ordering provider.

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.

Infectious Disease Test Menu Updates

AIT Laboratories will notify Providers and distribute new requisitions as updates occur to our test menus. In addition, lists of pathogens in our pathogen profiles will also be updated in real time on our website. This is to ensure Providers always have access to the most recent information and help assist with requesting the medically necessary tests for enhanced patient care. When ordering pathogen profiles, providers are advised to visit our website, www.healthtrackrx.com/solutions/antibiotic-stewardship to view our current test menu.

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.

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

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

The LCD issued by Novitas Solutions entitled "Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)" 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.

The LCD issued by Novitas Solutions entitled "Molecular Diagnostics: Genitourinary Infectious Disease Testing (L35015)" provides guidance regarding appropriate testing and medical necessity for Infectious Disease testing. This policy is applicable to Laboratories in jurisdiction JH which includes Texas.

AIT Laboratories adopted a Compliance Program that reflects the OIG Clinical Laboratory Compliance Program Guidelines and encourage all Healthcare Partners to do the same.

Waiver of Charges to Managed Care Plans

Laboratories must have provisions preventing writing off managed care work and must require acknowledgement confirming there is no financial benefit from the managed care plan in the form of bonus payments for not exceeding utilization thresholds, protection from financial penalties for over utilization, or otherwise. AIT Laboratories does not pay sales commissions on HMO business that can not be collected due to an exclusive contact arrangement with other laboratories.

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 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 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 avoid false claim submission, please be sure to:

1. Order only those tests necessary for diagnosis or treatment. Each component of a test must be necessary for the test 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

AIT Laboratories has included statements from the CMS National Coverage Policy and is attached hereto in Exhibit 1

Medicare Rates

Medicaid reimbursement amounts will be equal to or less than the amount of the Medicare reimbursement. AIT Laboratories' test list with CPT and HCPS G-Codes and Medicare maximum reimbursement rates for each test is attached hereto as Exhibit 2.

Exhibit 1

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.

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 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 section 411.15 (k)(1) of this chapter).

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.

Exhibit 2

2. Medicare 2019 Clinical Laboratory Fee Schedule (CLFS)

HCPCS	Short Description	National Limit
80307	Drug test prsmv chem anlyzr	$ 64.65
G0480	Drug test def 1-7 classes	$ 114.43
G0481	Drug test def 8-14 classes	$ 156.59
G0482	Drug test def 15-21 classes	$ 198.74
G0483	Drug test def 22+ classes	$ 246.92
87481	Candida DNA Amp Probe	$ 38.99
87486	Chylmd Pneum DNA Amp Probe	$ 38.99
87491	Chylmd Trach DNA Amp Probe	$ 38.99
87493	C Diff Amp Probe	$ 38.99
87496	Cytomeg DNA Amp Probe	$ 38.99
87498	Enterovirus Probe & Revrs Trns	$ 38.99
87500	Vanomycin DNA Amp Probe	$ 38.99
87502	Influenza DNA Amp Probe	$ 95.80
87505	IADNA-DNA/RNA Probe TQ 3-5	$ 142.54
87506	IADNA-DNA/RNA Probe TQ 6-11	$ 262.99
87507	IADNA-DNA/RNA Probe TQ 12-25	$ 463.09
87511	Gardner Vag DNA Amp Probe	$ 38.99
87529	HSV DNA Amp Probe	$ 38.99
87541	Legion Pneumo DNA Amp Prob	$ 38.99
87581	M.Pneumon DNA Amp Probe	$ 38.99
87591	N.Gonorrhoeae DNA Amp Probe	$ 38.99
87624	HPV High-risk Types	$ 38.99
87631	Resp Virus 3-5 Targets	$ 142.63
87632	Resp Virus 6-11 Targets	$ 237.14
87633	Resp Virus 12-25 Targets	$ 463.09
87634	Resp Sync Virus Amp Probe	$ 86.66
87640	Staph A DNA Amp Probe	$ 38.99
87641	Mr-Staph DNA Amp Probe	$ 38.99
87651	Strep A DNA Amp Probe	$ 38.99
87653	Strep B DNA Amp Probe	$ 38.99
87661	Trichomonas Vagin Dir Probe	$ 38.99
87798	Detect Agent NOS DNA Amp	$ 38.99
87801	Detect Agent Mult DNA Amp Probe	$ 77.99

Reference Information and Websites

ICD-10 Resources

https://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=BAAAAAAAAAAA&

Local Coverage Determination

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35006&ver=76&name=314*1&UpdatePeriod=749&bc=AAAAEAAAAAAAAA%3d%3d&

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/Clinical-Laboratory-Fee-Schedule-Files.html

42 CFR 1001.1901
https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr1001_main_02.tpl

42 CFR 410.32
http://www.ecfr.gov/cgi-bin/text-idx?SID=45d58e853a7721326444d687746040f5&mc=true&node=pt42.2.410&rgn=div5#se42.2.410_132

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>

Exhibit 2 (Con't)

Oral Fluid, Blood and Urine
Drug Testing

CMS HCPCS Code	Code Description	2019 Medicare Allowable
80307	Presumptive drug test - any number of drug classes, any number of devices or procedures by instrumented chemistry analyzers, includes sample validation when performed, per date of service	$64.65
G0480	Definitive drug tests, 1-7 drug classes*	$114.43
G0481	Definitive drug tests, 8-14 drug classes*	$156.59
G0482	Definitive drug tests, 15-21 drug classes*	$198.74
G0483	Definitive drug tests, 22+ drug classes*	$246.92

***** Drug class includes any of the classes listed below. The list below matches the drugs included in those drug classes, for reference. Includes specimen validity testing, per day, including metabolites if tested.

List of Drug Classes that may be included in Definitive Drug Testing Codes listed above

Drug	Drug Class	CPT/HCPCS
Ethylglucuronide	Alcohol Biomarkers	80321
Ethylsulfate		
Cotinine	Alkaloids, NOS	80323
Kava Metabolite		
Kratom Metabolite		
LSD Metabolite		
Amphetamine	Amphetamines	80324
Ephedrine/Pseudoephedrine		
Lisdexamphetamine		
Methamphetamine		
Phentermine		
Bupropion Metabolite	Antidepressants, NOS	80338
Trazodone Metabolite		
Venlafaxine Metabolite		
Citalopram Metabolite	Antidepressants, serotonergic	80332
Duloxetine		
Fluoxetine Metabolite		
Fluvoxamine		
Mirtazapine Metabolite		
Paroxetine		

Sertraline Metabolite		
Amitriptyline	Antidepressants, tricyclic	80335
Clomipramine Metabolite		
Desipramine		
Doxepin		
Doxepin Metabolite		
Imipramine		
Nortriptyline		
Carbamazepine	Antiepileptics	80339
Lamotrigine		
Levetiracetam		
Phenytoin		
Primidone		
Topiramate		
Valproic Acid		
Aripiprazole Metabolite	Antipsychotics	80342
Clozapine Metabolite		
Haloperidol		
Olanzapine		
Quetiapine Metabolite		
Risperidone Metabolite		
Ziprasidone		
Amo-Pentobarbital	Barbiturates	80345
Butabarbital		
Butalbital		
Phenobarbital		
Secobarbital		
Alprazolam	Benzodiazepines	80346
Alprazolam Metabolite		
Chlordiazepoxide		
Clobazam		
Clonazepam		
Clonazepam Metabolite		
Diazepam		
Estazolam		
Flunitrazepam		
Flunitrazepam Metabolite		
Flurazepam		
Flurazepam Metabolite		
Lorazepam		
Midazolam		
Midazolam Metabolite		
Nordiazepam		
Oxazepam		
Temazepam		
Triazolam		
Triazolam Metabolite		

Buprenorphine	Buprenorphine	80348
Norbuprenorphine		
Cocaine Metabolite	Cocaine	80353
DMT	Drug or substance definitive, NOS	80375
MeO-Dmt		
PCP		
Acetyl Norfentanyl	Fentanyl	80354
Fentanyl		
Norfentanyl		
Gabapentin	Gabapentine	80355
Heroin Metabolite	Heroin	80356
Ketamine Metabolite	Ketamine and norketamine	80357
Methadone	Methadone	80358
Methadone Metabolite		
MDA	Methylenedioxyamphetamines	80359
MDEA		
MDMA		
Methylphenidate Metabolite	Methylphenidate	80360
Carboxy-THC	Natural Cannabinoids	80349
Acetaminophen	Non-Opioid Analgesics	80329
Aspirin Metabolite		
Ibuprofen		
Naproxen		
Codeine	Opiates	80361
Hydrocodone		
Hydromorphone		
Morphine		
Norcodeine		
Norhydrocodone		
Butorphanol	Opioids	80362
Dextromethorphan		
Dextrorphan		
Meperidine		
Naloxone		
Naltrexone		
Normeperidine		
Pentazocine		
Noroxycodone	Oxycodone	80365
Noroxymorphone		
Oxycodone		
Oxymorphone		
Pregabalin	Pregabalin	80366
Norpropoxyphene	Propoxyphene	80367
Zaleplon	Sedative hypnotics	80368
Zolpidem		
Zopiclone		
Baclofen	Skeletal muscle relaxants	80369

Carisoprodol		
Cyclobenzaprine		
Meprobamate		
Isomer testing	Stereoisomer	80374
MDPV Metabolite	Stimulants, synthetic	80371
Methylone		
Normephedrone		
PVP Metabolite		
JWH073 Metabolite	Synthetic Cannabinoids	80350
JWH122-MAM2201 Metabolite		
JWH18-AM2201 Metabolite		
JWH210 Metabolite		
PB22 Metabolite		
RCS4 Metabolite		
UR144-XLR11 Metabolite		
Tapentadol	Tapentadol	80372
Tramadol	Tramadol	80373
Tramadol Metabolite		