CDx ANNUAL PHYSICIAN CLIENT NOTICE - 2018

CDX Diagnostics is providing this annual notice in accordance with the recommendations made by the Office of Inspector General (OIG) as part of our CDx Compliance Program. The Office of Inspector General of the Department of Health and Human Services encourages clinical laboratories to publish an annual notice to promote adherence to federal and state laws and the requirements of federal, state, and private health plans. This annual notice aims to further the fundamental mission of providing quality services and care to patients while also promoting the prevention of fraud, waste and abuse. Specifically, this notice provides information on (i) Clinician or Ordering/Referring Provider (ORP) Requirements & Responsibilities; (ii) Medical Necessity; (iii) Test Orders; (iv) Patient Privacy (HIPAA); (v) Key Laws & Regulations; (vi) Clinical Consultation; and (vii) the Medicare Laboratory Fee Schedule. Please contact CDx Diagnostics at (845) 369-7096 with any questions regarding the information contained in this notice.

LICENSED PHYSICIANS AND NON-PHYSICIAN PRACTITIONERS (NPP)

A laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized to order laboratory tests. If your license has been revoked or suspended, please immediately notify CDx at (845) 369-7096. As of 2014, Medicare requires individuals ordering laboratory services to be registered in the Center for Medicare and Medicaid Services Provider Enrollment Chain and Ownership System (PECOS). Additional information on PECOS and how to enroll in the system may be viewed at: https://pecos.cms.hhs.gov/pecos/login.do#headingLv1.

MEDICAL NECESSITY

The Office of the Inspector General (OIG) has advised clinical laboratories to remind physicians (or other individuals authorized by law to order tests) to ensure that when ordering tests for which Medicare reimbursement will be sought, they should only order tests that are medically necessary for the diagnosis or treatment of a patient.

It is incumbent upon us to remind you that Medicare will only pay for those tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose a patient. The Social Security Act states that "no payment may be made under Part A or Part B [of Medicare] for any expense incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member." Accordingly, Medicare may deny payment for a test that you believe is appropriate, but which does not meet the Medicare coverage criteria (i.e. a test done for screening purposes or part of a routine physical examination does not meet the coverage criteria) or where documentation in the patient record (including the patient record you maintain) does not support a finding that the test was reasonable and necessary, for a given patient.

It is also incumbent upon us to advise you that Medicare will only pay for medically necessary tests. Please do not order any of the panels or profiles outlined in the attached list unless each and every test in the panel or profile is medically necessary. Any of the tests offered as part of a panel or profile may be ordered individually using the CDx requisition form.

We urge all ordering physicians to retain in the patient's medical record and history, notes documenting the patient's conditions and diagnoses, with relevant clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications. Documentation in the beneficiary's medical record must support the medical necessity of the test(s) provided. We ask that you provide us with all of the relevant

diagnostic information requested in the requisition form submitted with the specimen. This information should come from your medical records, for the dates of service that you request clinical lab testing from CDx Diagnostics (CDx). It is critical that the codes are as specific as possible. This means that the ICD sub-classifications should be used in your coding.

USE OF DIAGNOSTIC CODES (ICD)

Laboratories do not treat patients or make determinations regarding medical necessity. Diagnostic information, such as ICD-10 codes, is one way to document medical necessity. As a licensed laboratory, we are required by the OIG to "require physicians to document the need for each test by inserting a diagnosis code for each test." Further, many third-party carriers require us to provide this information before a claim is reviewed.

Please note, however, that these codes must be as accurate and specific as possible. Thus, to avoid potential liability, you should not code on what you assume the diagnosis to be, but rather should only code on the basis of what you actually know of the patient's condition. If you are ordering tests and cannot as yet determine a diagnosis, you should provide the appropriate codes that describe the patient's signs and symptoms. You should not code on the basis of any diagnosis you are seeking to "rule-out". A pattern of inaccurate or incomplete diagnosis codes may create the appearance of impropriety, which can be interpreted by regulators as fraud and/or abuse deserving of the aforementioned penalties. Naturally, the codes you provide must be based on the patient's actual condition as documented in the medical record.

CDx may "only submit diagnostic information that is obtained from the ordering physician." We are prohibited from using diagnostic information provided from earlier dates (except for certain standing orders described below), and from inserting diagnosis codes based on our own estimate of the patient's condition. Therefore, for your protection, as well as ours, we ask that you provide the most specific ICD-10 code for each test you order. Providing this information on the requisition submitted with the specimen will ensure our mutual compliance with government rules, and will also minimize the need for us to contact you afterwards.

TEST ORDER REQUISITION FORM

A standard CDx 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 CDx receives a non-CDx requisition form or an incomplete CDx requisition form, processing of your test order may be delayed. As necessary, CDx will contact physicians to have them resubmit the test order on a CDx test requisition form or otherwise clarify each specific test being ordered.

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. A signed laboratory requisition form and documentation of your intent to order each laboratory test must be included in the patient's medical record and available to CDx upon request. 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 CDx 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.

To avoid a potential false claims act violation, 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 for 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.

REFERRING PHYSICIAN NAME

Laboratories are required to supply the ordering/referring physician name and NPI on all claims to Medicare. Further, many third-party carriers require us to provide this information before a claim is reviewed.

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, CDx 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 CDx requisition form is returned to the laboratory.

ADVANCED BENEFICIARY NOTIFICATION

If reimbursement is denied due to lack of medical necessity documentation, Medicare rules prohibit the laboratory or health care provider from billing the patient unless an Advance Beneficiary Notice (ABN) has been signed and dated by the patient prior to the service. If applicable, an ABN must be completed each time services are ordered. A blanket ABN is not acceptable to the Medicare program.

The Centers for Medicare and Medicaid Services (CMS) has established a standardized ABN that ensures the patient understands that he/she may be responsible for payment if the test is considered to be medically unnecessary by Medicare. The ABN identifies the limited coverage laboratory test(s) and gives the reason(s) the test(s) is likely to be denied. In order for the patient to make an informed decision whether or not to receive the service, the ABN provides two options. Option 1 states that the patient chooses to have the service performed and understands that he/she is personally responsible for payment in the event Medicare denies payment. Option 2 states that the patient refuses to have the service performed and will notify his/her doctor of that decision. If a Medicare patient in a CDx's patient service center refuses to sign an ABN, the service generally will not be performed.

To comply with these new guidelines, physicians should (1) only order tests that are medically necessary in diagnosing or treating their patients; (2) be certain to enter the appropriate and correct ICD code in both their patient files and on the test request forms; and (3) always have their patients sign and date an Advance Beneficiary Notice if they believe that the service is likely to be denied.

RULES FOR HOSPITAL BILLING

CMS requires that when the facility notifies CDx that the specimen was taken from a Medicare beneficiary at a hospital facility or facility in which consolidated billing applies, that CDx bill the hospital or facility for the Technical Component (TC) of all CPT codes included in the Physician Fee Schedule (PFS). A CDx Laboratory Services Agreement (LSA) must be fully executed and available for review at all times in order to comply with this requirement. The LSA will stipulate the fees being charged and the terms of payment from the hospital to CDx.

CLINICAL CONSULTATIONS

CDx has clinical consultants and a pathologist available to answer questions and ensure proper test orders. Clinicians authorized to order testing may access these services by contacting CDx Client Relations at (845) 369-7096 or your local CDx representative.

PATIENT PRIVACY (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), CDx is a health care provider and a covered entity. It is our policy to fully comply with the HIPAA privacy and security standards. Our privacy policy is available at https://cdxdiagnostics.com/privacy.html.

CDx Diagnostics and ordering physicians represent that they are covered entities as that term is defined in the Health Insurance Portability and Accountability Act of 1996, as it may be amended from time to time ("HIPAA"), and as further modified by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), along with its accompanying regulations (collectively, the "HIPAA Laws"), including, but not limited to, the "HIPAA Privacy Rule," at 45 CFR, part 160 and part 164, subparts A and E. There is nothing preventing CDx Diagnostics and ordering physicians from using or disclosing protected health information (PHI) as defined in HIPAA in a manner that would otherwise be permitted under the HIPAA Laws. CDx Diagnostics and ordering physicians represent that they shall use or disclose any records, information or data obtained or created in connection with the use of information that may constitute or contain PHI only in a manner that is consistent with HIPAA, including but not limited to using PHI for the provision of treatment to patients, de-identification or aggregation of PHI, or using PHI to obtain payment for health care services.

INDUCEMENTS

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce or reward the referral of services 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 the CDx compliance hotline by calling (855) 607-8551.

PROHIBITED REFERRALS

It is the policy of CDx to comply with all aspects of the laws and regulations governing physician self-referral, most notably including the federal Stark law (also known as the physician self-referral 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 maybe 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.

MEDICARE RATES

CDx's test list with CPT and HCPCS G-Codes and Calendar Year 2018 Medicare reimbursement rates for each test is attached hereto as Exhibit 1. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

FINANCIAL ASSISTANCE PROGRAMS

CDx understands that providing quality patient care has a related cost, which in some situations may be burdensome for patients and result in some patients avoiding certain necessary services because they are concerned about the expense. CDx is committed to delivering the best patient care to all, and to meet this objective has established a financial assistance program. This financial assistance program helps ensure affordable access to CDx's services. Patients with special financial needs may be eligible for support to help defray some of CDx's testing costs. CDx encourages those patients who may not be able to pay fully for CDx's services to contact us for an assessment of eligibility for financial support in accordance with federal guidelines.

PATIENT BILLING POLICY

Medicare, Medicare Advantage and patients from insurers contracted with CDx as in-network providers are billed for deductibles, co-insurance and co-payments as required by their Insurance Provider. CDx reserves the right to use resources available to search for active insurance if information is not provided or if the order is marked "Uninsured" or "Patient Does Not Have Insurance Coverage."

Under HIPAA, patients may opt out of using their insurance benefits in order to prevent reporting this service to their insurance carrier. CDx must be informed at the time of ordering if the patient is choosing this option and the patient's insurance information **must** be provided. Non-Medicare patients may be billed at Medicare rates for the services performed in accordance with applicable laws.

If payment for such service is not received within 60 days, CDx will bill the patient's insurance in order to secure reimbursement. CDx offers a patient self-pay option for patients who wish to waive insurance benefits and pay a flat, out-of-pocket rate for testing services. Coverage of testing services will vary according to type of test ordered, insurance type and patient benefits. Certain tests may not be a covered benefit for some patients due to active Local Coverage Decisions or other insurer coverage policies that limit benefits to narrow clinical indications. Patients seeking testing services who do not wish to use their insurance coverage must sign a Patient Self Payment Agreement or Advanced Beneficiary Notice (Medicare patients only) at the time of ordering. CDx will invoice the patient and payment must be received timely. If the patient is found to have no insurance, CDx may offer an uninsured rate. Patients are encouraged to contact us if they believe there is a billing error, need to establish payment arrangements or have questions about their bill. To learn more, please call (845) 369-7096 or visit our website www.cdxdiagnostics.com.

SUPPLIES

CDx provides supplies and materials to ordering physicians only to the extent that such items are necessary and directly related to the collection, preservation, transport or storage of specimens for which tests are being ordered from our laboratory. In addition, such items are provided only if there are assurances that they are in fact being used for these limited purposes only. We track the amount of supplies that we provide to your office and compare that number to the number of specimens sent to us by you so that excessive and or improper ordering or use of supplies can be prevented. If you have any questions regarding your supply orders, please contact your laboratory representative.

PERTINENT PATIENT INFORMATION

Pertinent patient information includes the name of the patient, as well as the patent's date of birth, sex, and address. If such information is not supplied, we need to obtain it from your office, thus necessitating a telephone call to your staff. In order to avoid having to interrupt your staff during working hours, we would greatly appreciate it if you could assure that all laboratory requisition forms are completed fully before the specimens are sent in to CDx.

I have read and understand my responsibility to order medically necessary testing and to provide CDx with all information required to support the medical necessity of all test orders.

_____ _____

Print Name of Practice Representative | Date

_____ _____

Signature of Practice Representative | Name of Practice and Location