



CDx ANNUAL PHYSICIAN CLIENT NOTICE - 2019

CDx Diagnostics (CDx) is providing this annual notice in accordance with the recommendations made by the Department of Health & Human Services' Office of Inspector General (OIG) as part of our CDx Compliance Program. The OIG 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 If your license has been revoked or suspended, please immediately notify CDx at (845) 369-7096.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 Centers 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>.

TESTING INFORMATION

The WATS^{3D} sampling device is designed to collect a full thickness epithelial sample. The risks associated with upper endoscopy and WATS^{3D} are similar to those associated with upper endoscopy and a standard forceps biopsy. Specifically, these risks are those related to sedation for the procedure (allergic reaction, respiratory depression), and endoscopy with biopsy (small amounts of bleeding or infection). Rare side effects include significant bleeding and perforation of the esophagus. Patients with persistent clinical signs or symptoms of esophageal disease should be re-evaluated.

MEDICAL NECESSITY

The 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.

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.

Moreover, Medicare will only pay for medically necessary tests. 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. It is critical that the codes are as specific as possible. This means that the ICD sub-classifications should be used in your coding.

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), the licensed ordering practitioner's name and address, and physician signature. Handwritten orders must be signed and dated by the provider. A laboratory requisition form and/or other 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'. Upon request by CDx or its payers/auditors, ordering providers are required to provide any/all chart documentation, including physician signature, that reflect the provider's intent to order the laboratory test(s) and that supports the authenticity and medical necessity of the laboratory order(s) submitted.

The pre-printed test requisition form is the tool used to communicate the physician order to the laboratory, which may serve to show that you deem the test to be medically necessary for your patient's care. Also, this form provides us with information that helps us properly bill for the services that you have ordered and that we provide in response. Thus, for example, the form asks you to indicate if the patient for whom you are ordering testing was registered as a hospital inpatient or outpatient at the time of the biopsy. If you do not indicate that a patient was a registered hospital inpatient or outpatient at the time of the biopsy, CDx will conclude that the patient was neither a hospital inpatient nor a hospital outpatient and will bill government and commercial payers accordingly.

To avoid a potential False Claims Act violation, please be sure to:

1. Order only those tests necessary for diagnosis or treatment.
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 the provider's National Provider Identifier (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.

PERTINENT PATIENT INFORMATION

Pertinent patient information includes the name of the patient, as well as the patient'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. In addition, all specimens must be labeled with two forms of unique patient identifiers. Cases may be held and/or rejected if they are not submitted with the patient identifiers necessary for CDx to properly associate patients with samples as required to comply with state law and national accreditation standards. In the event that CDx return a patient sample in order to supplement or correct patient identifiers, you release CDx from all liability.

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.

ADVANCED BENEFICIARY NOTIFICATION

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 10 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 despite compliance with (1) and (2). 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. A blanket ABN is not acceptable to the Medicare program; therefore, if applicable, an ABN must be completed each time services are ordered.

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.

CLINICAL CONSULTATIONS

CDx has clinical consultants and a pathologist available to answer questions from ordering physicians to 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 of 1996 (HIPAA), CDx is a health care provider and a covered entity. It is our policy to fully comply with the HIPAA's 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 HIPAA, 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.

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 an in-network provider 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 non-Medicare 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. 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.

I have read this Annual Physician Client Notice - 2019 and understand the physician responsibilities, as set forth herein. These responsibilities include the ordering of medically necessary testing and the provision to CDx of all the information it needs to support the medical necessity of, and properly bill for, all ordered tests. If I am signing this in my capacity as a practice representative, I confirm that this disclosure has been shared with, read by and will be maintained by all of the physicians in the group.

Print Name of Physician/Practice Representative

Date

Signature of Physician/Practice Representative

Name of Practice and Location

If signing as a representative of the practice on behalf of the physicians, please write the names of those physicians on the lines below: (Please use additional pages as necessary.)

_____	_____
_____	_____
_____	_____
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_____	_____
_____	_____