innovative
DIAGNOSTIC LABORATORY

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Date: March 14, 2018

To: All Clients

From: Compliance Department

Re: Annual Notice to Physicians

VIA: Electronic Mail

Innovative Diagnostic Laboratory (IDL) is committed to creating an environment which is compliant with all federal, state, and local laws while following the Office of Inspector General (OIG) and Department of Justice's (DOJ) requirements for federal, state and private health plans. As a participant in federally-funded healthcare programs, IDL is required by the OIG and DOJ to provide an annual physician's notice to providers who have requested tests from IDL within the previous calendar year. Periodically, IDL advises its physicians and clients about program changes and information related to federally-funded healthcare programs that affect both the physician and the laboratory. This notice explains IDL's laboratory compliance, billing, and coding guidelines, and informs you, as a provider, of those responsibilities.

Medicare Necessity Policy

While physicians are able to order any test they deem appropriate for a patient's treatment, Medicare will only pay for tests that are reasonable and medically necessary for the diagnosis or treatment of an illness or disease of a Medicare beneficiary. An approved panel should be ordered only when every test in that panel is medically necessary. If all components of the panel are not medically necessary, you should order individual tests or a panel that contains only the medically necessary tests. Tests ordered to diagnose or treat patient signs, symptoms or complaints are subject to Medicare guidelines for medical necessity. Tests ordered in the absence of signs, symptoms or complaints are considered screening and are subject to Medicare's Preventive Services benefits. Tests used for routine screening without preventive service coverage are the financial responsibility of the beneficiary.

IDL has the responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all applicable federal and state laws and regulations. It is your responsibility as a physician to document medical necessity in the patient's medical record and provide the appropriate diagnostic ICD 10-codes or narrative that supports the ordered tests. The OIG takes the position that physicians or other individuals authorized by law to order laboratory tests, who order tests that are not medically necessary, and who knowingly cause a false claim to be submitted to a federally funded program including Medicare and Medicaid may be subject to sanctions or remedies available under civil, criminal and administrative laws, such as the False Claims Act.

Licensed Physicians and Non-Physician Practitioners
A clinical laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individual authorized by law to order laboratory tests. If your license has been revoked or suspended, or if you have been notified that you have been placed on the OIG's List of Excluded Individuals/Entities (LEIE) and are currently excluded from participating in Medicare, Medicaid and all other Federal health care programs, please immediately notify IDL.

Medicare requires that individuals referring orders for laboratory services must also be registered in the Centers for Medicare and Medicaid Services Provider Enrollment, Chain, and Ownership System (PECOS).

Diagnosis Information
Section 4317 of the Balanced Budget Act of 1997 requires the physician or authorized ordering party to submit diagnosis information on the laboratory order for submission of a Medicare claim. The diagnosis information supplied should accurately describe the patient's condition on the date of service as documented in the patient's medical record. Physicians and non-physician practitioners will be contacted by IDL for all requisitions that do not include this required information.

Medicare Laboratory Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs)
These policies define the medical conditions through the inclusion of a list of ICD-10 diagnosis codes for which tests are covered or reimbursed by Medicare. HIPAA regulations require ICD-10 code(s) to be present on each claim filed. These codes must also be documented in the patient's medical record.

National coverage determinations may be viewed at https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx or by clicking here.

Section 522 of the Benefits Improvement and Protection Act (BIPA) defines a local coverage determination as a decision by a fiscal intermediary (FI) or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (e.g., a determination as to whether the service or item is reasonable and necessary). FIs, Carriers, and Medicare Administrative Contractors (MACs) are Medicare contractors that develop and/or adopt LCDs. Medicare contractors develop LCDs when there is no National Coverage Determination (NCD) or when there is a need to further define an NCD. Local coverage determinations may be viewed here.

Advance Beneficiary Notice of Non-coverage (ABN)
Not all laboratory services are covered by Medicare. For statutorily excluded services, IDL may bill Medicare beneficiaries directly. For certain other laboratory tests, an Advance Beneficiary Notice of Non-coverage (ABN) is used to document that the patient has been made aware that Medicare may not pay for services and that the patient has agreed to pay the laboratory in the event payment is denied. A separate ABN must be used for each encounter. IDL will provide ABN forms to clients at their request. Client-collected ABN's must be attached to the requisition when samples are submitted to the laboratory.

Components of Profiles Offered

BreastSentry™ Assay for Breast Cancer Risk - Neurotensin (pro-NT) - Enkephalin (pro-ENK)
ColonSentry® Gene Expression for Colorectal Cancer Risk - ANXA3 Gene - CLEC4D Gene - TNFAIP6 Gene - LMNB1 Gene - PRRG4 Gene - VNN1 Gene - IL2RB Gene
Early CDT® Lung Antigen Assay for Early Lung Cancer Risk - CAGE - GBU4-5 - HuD - MAGE A4 - NY-ESO-1 - P53 - SOX-2
Prostate Health Index - Total PSA - Free PSA (when Total PSA ≥ 2 and ≤10 ng/ml) - pro2PSA (when Total PSA ≥ 2 and ≤10 ng/ml) - % Free PSA (when Total PSA ≥ 2 and ≤10 ng/ml) - Prostate Health Index (PHI) Score (when Total PSA ≥ 2 and ≤10 ng/ml)
PHI-OIR (Prostate Health Index – Outside of Interpretive Range) - Total PSA - Free PSA (regardless of Total PSA level) - pro2PSA (regardless of Total PSA level) - % Free PSA (regardless of Total PSA level) - Prostate Health Index (PHI) Score (regardless of Total PSA level)

Medicare Clinical Laboratory Fee Schedule

For Medicare beneficiaries, outpatient clinical laboratory services are paid based on a fee schedule in accordance with Section 1833(h) of the Social Security Act. Payment is the lesser of the amount billed, the local fee for a geographic area, or a national limit. Co-payments and deductibles do not apply to

services paid under the Medicare clinical laboratory fee schedule. In many states, the Medicaid reimbursement amount will be equal to or less than the amount of Medicare reimbursement.

Analyte	Analyte - Full Name	CPT Code	2018 Medicare Fee Schedule
Biomarker	Biomarkers (pro-NT) and (pro-ENK), yields derived risk for BCA	81479	NA Unlisted Code
Breast Cancer Index	Breast Cancer Risk-Calculated	By Report	-
Gene	Seven Genes, yields derived risk for CRC	81479	NA Unlisted Code
CRC Index	CRC Risk-Calculated	By Report	-
Antigen	Seven Antigens yields derived risk for early lung cancer	83520 X7	$ 120.89
Lung Cancer Index	Early Lung Cancer Risk-Calculated	By Report	-
PSA, Total	Prostate Specific Antigen, total	84153	$ 22.71
PSA, Free	Prostate Specific Antigen, free	84154	$ 22.71
p2PSA	Immunoassay for Tumor Antigen, Other Antigen, Quantitative, Each	86316	$ 25.70
PHI Index	PHI Index-Calculated	By Report	-

Billing Information

According to Medicare's "medical necessity" rule, profiles/panel tests must be reasonable and necessary for Medicare reimbursement. IDL requires a completed requisition form signed by both the patient and the authorizing physician which is designed to help promote accurate billing and to capture required information by federal healthcare programs. Each submitted requisition form must include the following information:

- The patient's:
  - Full Name;
  - Date of Birth; and
  - Gender
- The Referring Physician's:
  - Name; and
  - NPI number
- Insurance Information, including ID and group number, with a copy of both the front and back of the card;
- Valid ICD-10 Diagnosis Code(s) for each test;
- Valid Medicare Advance Beneficiary Notice (ABN), when mandated by Medicare NCD/LCD policy; and
- Valid ABN, when ordering a ColonSentry® test.

Clinical Consultant

IDL's clinical consultant, Dr. Sarwat Siddiqui, is available to discuss appropriate testing and test ordering. Please call 804-261-3341 for further assistance.

Conclusion

Please take a few minutes to review this communication with your appropriate staff. To learn more about IDL's tests, please click on ColonSentry, Early CDT Lung, and/or Prostate Health Index or visit www.myinnovativelab.com and click on the "Products & Programs" tab at the top of the page for

additional information on the use and benefits of each test. We value your business and appreciate the opportunity to serve your patient's laboratory needs in conjunction with these initiatives. If there are further questions regarding this information, please contact Joanna M. Halsey, Esq., Chief Compliance Officer, at 804-261-3341.

Thank you.