August 2017

Dear Valued Health Care Provider,

The Office of Inspector General (OIG) recommends clinical laboratories send notices to physicians and other providers who use their services, at least once a year, to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services. This Annual Notice is provided pursuant to that recommendation.

The following information is intended to promote awareness of federal regulations and to explain the requirement for physicians to furnish appropriate documentation when ordering testing services. If you have questions about the contents in this notice, we encourage you to contact us for more information.

Specimen Integrity: In order to assure patient safety and provide accurate results on the correct patient, our laboratory requires that all samples be labeled with two patient identifiers. Please make sure that all samples collected in your office are labeled at the time of collection, in the presence of the patient. Use the patient's first and last name as the primary identifier, and then you may use the patient's date of birth, chart number, or requisition number as the second identifier. In addition, please include the actual date and time of specimen collection. This information helps you better interpret the results and it helps us monitor specimen quality.

Supplies: Providence Laboratory Services will provide supplies required for the collection of specimens that are to be sent to our laboratory. Anti-Kickback statutes govern these practices, and our laboratory monitors the volume of supplies provided to your offices. Supply volumes must reasonably match volumes of testing received.

Reflex Testing: Reflex testing occurs when the initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. In order to avoid performing unnecessary reflex tests, Providence will carefully evaluate reflex testing using the following criteria: All tests that have a reflex test available shall be clearly identified on the requisition, in the test directory, or other means by which a provider can choose a test to order. If a test is listed on a requisition form, the non-reflex option must be on the same requisition form when appropriate. The criteria under which the reflex test will be performed shall be clearly indicated on the requisition form or in the Test Directory.

Revenue Cycle/ Billing: **Claims** for reimbursement shall only be submitted for tests that are appropriately ordered and performed. If the test was either not appropriately ordered by an authorized individual/entity or was not actually performed, Providence shall not submit the claim for reimbursement.

Standing Orders: CMS requires that recurring test orders be monitored to ensure their continuing validity. If the recurring orders expire after a certain period of time, the provider shall resubmit them at

that time. To help ensure the validity of recurring orders, Providence laboratories will take the following steps: (1) Ensure the recurring order expires at the designated time frame (not to exceed 12 months). (2) If the frequency, test or diagnosis (medical necessity/ICD-10 code) are changed, a new recurring order must be written. (3) If the test(s) covered by the recurring orders may not be covered by Medicare, an Advance Beneficiary Notice of Noncoverage (ABN) may be executed to inform the patient that they may be responsible for payment. Notification that an ABN was obtained should be documented for each encounter under the recurring orders. The ABN expires when the recurring order expires. New and written confirmations of renewed recurring orders are retained for the period specified by the PROV-ICP-715 Records Retention and Disposal policy

Test Authorization / Test Ordering: The clinical laboratory shall examine specimens only at the written or electronic request of a physician, dentist, or other person legally authorized (hereto collectively referred to as clinician) to use the findings of the laboratory examinations.

Test Orders: An "order" is defined as a communication from the treating provider authorized in that state to order laboratory testing (physician/provider) requesting that a diagnostic test be performed for a patient. The medical record and/or the request itself must clearly document the provider's intent for the diagnostic test to be performed. A provider's signature is not required on a requisition form in order to perform and be paid for a clinical diagnostic test, however, some form of documentation as noted above must be available.

Custom Panels: The OIG discourages the use of custom panels as part of the OIG's Compliance Program Guidance for Clinical Laboratories. Concerns of excessive use of custom panels which results in the performance and billing of medically unnecessary testing. In order to minimize risk Providence Laboratory- Oregon Region discourages the use of custom panels.

Verbal Test Authorization: The Oregon Regional Laboratory does not accept verbal test authorization, due to state laws. Written or electronic authorization of verbal orders will be obtained.

Test Utilization: To ensure appropriate billing and medical necessity of outpatient and non-patient tests, Providence laboratories shall review their test utilization. This does not apply to inpatient testing.

Assignment of Diagnosis Codes (Medical Necessity): CMS requires that orders for tests be accompanied by diagnostic information to establish medical necessity. Failure to document medical necessity will cause the test to be denied coverage. Claims submitted by Providence shall use only diagnostic information submitted by the ordering provider.

Assignment of CPT and HCPCS Codes: CPT and/or HCPCS codes must accurately describe the clinical laboratory services that were ordered and performed. Providence selects the CPT/HCPCS code that most accurately reflects the service performed according to the most current guidelines from the American Medical Association (AMA) and regulatory agencies including Medicare A/B Administrative Contractors (MAC).

Advance Beneficiary Notification (ABN): Providence laboratories shall request a signed ABN from Medicare beneficiaries when appropriate. An ABN is presented to a Medicare beneficiary only when it is anticipated that Medicare may not reimburse for the ordered test(s). "Blanket" ABNs (in which all Medicare beneficiaries are asked to sign an ABN any time they present at a laboratory for services) are not allowed.

NCD/LCD: National Coverage Decisions (NCDs) and Medical Necessity: The Center for Medicare and Medicaid Services (CMS) developed to assure appropriate laboratory utilization.

MSP: For outpatient and any face-to-face encounter with a non-patient, CMS requires that laboratories determine if the beneficiary has any other insurance coverage and if Medicare is the primary or secondary insurance for each instance of service. Does not require hospitals, critical access hospitals (CAH) and independent reference laboratories to collect Medicare secondary payer information where there is no face-to-face encounter with a beneficiary.

Effective Date: This notice represents coverage decisions and policies currently in effect.

Notices will be sent as necessary throughout the year to update physicians when our policies or services change. Please read these notices carefully as they contain important information regarding the services you order for your patients.

If you have any questions concerning our Annual Notice or appropriate test use and ordering, please contact Providence Oregon Regional Laboratory at 503-216-6667.

We hope you find the information provided in this Annual Notice helpful.

Respectfully,

Mona Crow
Regional Director Laboratory Quality & Compliance
Providence Regional Laboratory – Oregon