2024 Annual Provider Notice

Dear Valued Client,

Precision Diagnostics continually strives to provide the best toxicology service for you and your patients and clients. As part of that mission, we would like to provide you with the following specimen stability information annually:

Most urine specimen(s) are stable up to 14 days at room temperature, and most oral fluid specimen(s) are stable up to 13 days at room temperature; stability of some analytes tested beyond the aforementioned windows at room temperature may be affected. For example, 7-aminoclonazepam and 9-hydroxyrisperidone are stable up to 7 days room temperature in urine; Fentanyl, Amitriptyline, and Nortriptyline are stable up to 5 days room temperature in oral fluid. Testing beyond these dates may yield lower concentrations than at collection.

Most urine specimen(s) are stable up to 50 days at refrigerated temperatures, and most oral fluid specimen(s) are stable up to 22 days at room temperature; stability of some analytes tested beyond the aforementioned windows at refrigerated temperatures may be affected. Testing beyond these dates may yield lower concentrations than at collection.

***To align with the above mentioned stability recommendations, specimens collected outside of the 50 day stability window will require signed authorization to proceed with testing**.*

If you have further questions, please call our Clinical Support team at 800-635-6901, option 2 or reach out to your Precision Diagnostics Sales Representative.

NOTICE:

Precision Diagnostics is dedicated to ethical business practices and being compliant with all regulations and laws governing our industry. As part of our ongoing commitment to compliance, it is our policy to ensure our customers understand the need to order only laboratory tests that are medically necessary.

The Office of Inspector General (OIG) recommends clinical laboratories provide notices to providers who use their services, at least once a year, to inform them 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 providers 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.

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. The medical need for drug 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, Precision Diagnostics ("Precision") has a responsibility to educate providers and to implement test ordering procedures to help ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. As the provider, you are responsible for ordering tests only when they are medically necessary, for documenting medical necessity in the patient's permanent medical record, and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to Precision. The OIG takes the position that a provider who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.

Precision has developed Analytics Dashboards to provide visibility into utilization within your patient population. The Analytics Dashboard can be provided to Clients upon request.

PRIOR AUTHORIZATION:

Certain payers may require pre-authorization for Precision's services. Any required pre-authorization paperwork should be completed by the ordering provider's office before the lab test order is submitted. Please include the pre-authorization paperwork with the test order.

PAYER POLICY:

Most Commercial, Medicare Advantage, and Managed Medicaid plans issue policies that outline medical necessity requirements for both presumptive and definitive drug testing. In some instances, payer policies will include annual or monthly frequency limits per patient that may include prior authorization requirements to order beyond the limitation.

To avoid improperly billing payers, laboratories are required to coordinate with providers and organizations to identify if circumstances exist that affect the billing and reimbursement of services rendered by the laboratory. Per payer policies, laboratories cannot bill payers for laboratory services under some value-based payment models - such as capitated and bundled payment structures (e.g., all-inclusive rates and episode- based payments) - or for workplace and court-related drug testing. Precision relies on providers and organizations to inform Precision if either (1) tests are ordered for any patients being treated under a value-based payment model, or (2) tests are ordered for workplace or court-related drug testing, as both affect the billing and reimbursement of services rendered by Precision.

MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS:

The Medicare Program publishes National Coverage Determinations (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, typically by reference to specific ICD-10 codes that are deemed to support coverage.

Urine Drug Testing:

On June 28, 2016, and updated on October 8, 2023, our Medicare Administrative Contractor Noridian Healthcare Solutions, LLC (Noridian), implemented an LCD entitled "**Urine Drug Testing (L36668)".** This policy, among other things, provides guidance regarding covered indications, ICD-10 codes that support medical necessity and expected frequency for Urine Drug Testing (UDT).

This policy can be accessed on the Medicare website via the link https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36668&DocID=L36668.

TEST ORDERING:

All tests are available for order by paper test requisition forms, CareEvolve web based platform, and bi-directional EMR/EHR interfaces. All test orders must be communicated in writing from an authorized person or via an electronic transmission compatible with Precision Diagnostics' laboratory information system. All test orders must clearly identify the ordering professional, the test(s) to be performed, the source of the specimen (when appropriate), the patient's unique name and unique identifiers (gender, DOB, SSN, address), insurance details, diagnosis code(s) and ordering provider signature. CMS requires that each order for testing billed under the Clinical Laboratory Fee Schedule must be signed by the authorized person or available in the medical record. Rubber stamps, pre-printed signatures or letterheads are not acceptable in lieu of a signature, unless it falls within exception 4 within CMS guidelines, Transmittal 465, CR 8219.

If Precision receives a test order on a non-Precision requisition form or incomplete Precision requisition form, processing of your test order may be delayed. As necessary, Precision will contact providers to have them resubmit the test order or otherwise clarify each specific test being ordered. Only tests that are ordered will be reported.

CUSTOM PROFILES / TEST GROUPS:

Policy changes and guidance from Medicare Administrative Contractors, other government regulatory authorities and commercial insurers now discourage providers' use of non-patient-specific panels, including custom profiles or test groups when ordering laboratory drug testing. Precision supports these efforts and encourages the ordering of only medically necessary tests for each patient.

If a provider wishes to establish a custom profile or test group, Precision is committed to ensuring each ordering provider understands the following:

- A provider should order only those tests which the provider believes are medically necessary for each patient. Medically necessary testing should be based on individual patient specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record.
- Using a custom profile may result in the ordering of tests for which Government or private third-party payers will deny payment of tests not covered, reasonable or necessary.
- The provider should order only individual tests or a less inclusive profile when not all the tests in the custom profile are medically necessary for each individual patient; and
- The United States Department of Health and Human Service, Office of Inspector General, takes the position that a provider who orders medically unnecessary tests may be subject to civil and criminal penalties.

VERBAL TEST ORDERS:

Medicare regulations require that all orders for laboratory tests be in writing. If a provider 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, Precision will send confirmation of the verbal order request to the ordering provider, 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 Precision requisition form is returned to the laboratory.

PATIENT PRIVACY (HIPAA):

Under the Health Insurance Portability and Accountability Act (HIPAA), Precision 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://www.precisiondxlab.com/privacy-notices/.

CLINICAL CONSULTANTS:

Providers and other clinicians authorized to order tests have the services of Clinical Consultants and Toxicologists available to review results and answer questions. They may be reached at (800) 635-6901 option 2.

INDUCEMENTS:

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce or reward the referral of tests 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 Precision Compliance Hotline by calling (888-294-4527).

PROHIBITED REFERRALS:

It is the policy of Precision Diagnostics 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 provider (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 provider may not refer Medicare patients to the laboratory, and (b) the laboratory may not bill Medicare for services referred by the provider.

MEDICARE RATES:

Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement. The Medicare Clinical Laboratory Fee Schedule can be found on the CMS website: Clinical Laboratory Fee Schedule | CMS https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs.

FINANCIAL ASSISTANCE PROGRAMS:

Precision Diagnostics performs lab testing ("Precision Testing Services") for patients across the country at the request of their treating providers. Precision Diagnostics is sensitive to patient and provider concerns regarding insurance coverage and affordability for patients of medically necessary Precision Testing Services. In addition, in the interest of patient care and safety, Precision has an obligation to perform Precision Testing Services on specimens submitted by healthcare providers for their patients, regardless of the extent or type of the patients' insurance or ability to pay.

Precision Diagnostics complies with the "coordination of benefit" rules if multiple payers are involved (e.g., primary payor and secondary payor). This Patient Billing Policy section below is intended to provide treating providers with clear and consistent information about patients' financial responsibility for Precision Testing Services.

Precision encourages those patients who may not be able to pay fully for Precision's services to contact us for an assessment of eligibility for financial support in accordance with federal guidelines.

PATIENT BILLING POLICY:

Medicare and Medicaid Patients.

- Precision Diagnostics is enrolled in Medicare and in many state Medicaid programs, and accepts payment from Medicare or Medicaid for "covered services". Medicare and Medicaid patients may have co-insurance responsibility, and Precision will follow the directive of the EOB.

Patients with commercial insurance for which Precision is in-network.

- As an in-network provider, Precision Diagnostics bills the insurance company directly and accepts payment from the contracted commercial insurer as payment in full unless the carrier requires patient co-insurance payments. Most commercial insurers require their beneficiaries to pay some kind of co-payment and deductible. By contract, Precision Diagnostics is required to bill these patients for co-pays, co-insurance and deductibles, in accordance with insurer instructions and with the directions of the explanation of benefits ("EOB").

Patients with commercial insurance for which Precision is out-of-network.

- Precision Diagnostics accepts payment for its services from all commercial health plans, although Precision Diagnostics has not been given the opportunity to contract with all commercial health plans. Precision Diagnostics bills non-contracted insurers at Precision's standard third-party insurance prices and accepts the amounts paid by the insurers as payment in full. To the extent that the plan requires a patient co-insurance, Precision Diagnostics will use reasonable efforts to collect the required patient coinsurance. Precision will apply in-network rates for patients living in a state that regulates laboratory services.

Non-covered services.

- Some types of testing may not be covered by a patient's insurer (commercial or governmental) in any case. Precision Diagnostics' test request form is designed to provide patients with advance written notice, at the time of specimen collection, that if their insurer does not cover the testing, the patient will be expected to pay for the testing. Similarly, for Precision Diagnostics Testing Services that are not expected to be covered by Medicare, Precision Diagnostics may request a signed Advance Beneficiary Notice ("ABN").

Workers' Compensation.

- Laws regarding workers' compensation vary state to state. Consult Precision Diagnostics' Billing Management and/or legal counsel to determine the process for billing in that particular state.

Self-Pay Patients.

- Precision Diagnostics generally bills Self-Pay Patients who do not have medical insurance at Precision Diagnostics' patient list price. However, Self-Pay Patients may apply for the Precision Diagnostics Prompt Pay Discount and/or the Precision Diagnostics Patient Assistance Program

    - *Patient Prompt-Pay Discount*. To encourage and reward the prompt payment of any patient charges for Precision Testing Services, Precision Diagnostics offers to Self- Pay Patients a discount of forty percent (40%) off of Precision Diagnostics' patient list price (the "Patient Prompt-Pay Discount"). The Patient Prompt Pay Discount requires the patient to make payment within the industry standard reimbursement cycle time-frame after the date of Precision Diagnostics' first billing statement to the patient.

- *Patient Assistance Program.* As part of Precision Diagnostics' commitment to patient care, Precision Diagnostics works with providers and their patients to address patient financial responsibility in a manner that is fair and sensitive to individual patient and household circumstances. Precision Diagnostics has instituted the Precision Diagnostics Patient Assistance Program, allowing for patients whose documented household financial resources and/or income fall at or below 300 percent of the Federal Poverty Level, may be eligible for discounts at Management's discretion.

Under HIPAA, patients may opt out of using their insurance benefits in order to prevent reporting this service to their insurance carrier. Precision must be informed at the time of ordering if the patient is choosing this option and the patient's insurance information must be provided. The patient will be billed at Medicare rates for the services performed. 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 (800) 635-6901 or visit our website https://www.precisiondxlab.com/lab-services/#billing.

ACCESS:

The availability of Client's medical records must at all times be subject to the criteria and procedures for seeking or obtaining access as may be promulgated by the Secretary of HHS in regulations and other applicable laws. Client's disclosure under this provision is not as a waiver of any legal rights to which Precision or Client may be entitled under statute or regulation. Client shall make available to Precision all laboratory orders, medical records, or other information related to any testing ordered by Client to Precision that is determined to be required for any audits or reviews. Client shall provide such documents to Precision as promptly as possible, but not later than five (5) business days after a request by Precision. The laboratory shall only access the minimum necessary information needed to substantiate Precision's billing.

The parties shall comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. § 1320d ("HIPAA") and any current and future regulations promulgated thereunder including without limitation the federal privacy regulations contained in 45 C.F.R. Parts 160 to 164 ("The Federal Privacy Regulations"), the federal security standards for electronic transactions contained in 45 C.F.R. Part 142 (the "Federal Security Regulations"), the federal standards for electronic transactions contained in 45C.F.R. Parts 160 and 162, all collectively referred to herein as "HIPAA Requirements," and the federal Health Information Technology for Economic and Clinical Health Act (the "HITECH Act").

COMMUNICATION:

The Client agrees that all laboratory tests must be ordered by the provider who is treating the beneficiary. The Client may assign an authorized designee to deliver the clinical laboratory order; however, the Client attests that any designee shall only have the authority to deliver the order as directed by the treating provider. CMS defines an order as a communication from the treating provider requesting that a diagnostic test be performed for a beneficiary. Although CMS does not require the order to be signed by the provider, the treating (ordering) provider must clearly document in the beneficiary's record the intent to order the diagnostic test and document the medical necessity supporting the ordered service.