averhealth

2021 Annual Compliance Notice

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 Averhealth with any questions regarding the information contained in this notice.

Clinician or ORP Requirements & Responsibilities:

1. To qualify as an ORP, you are required to:
    a. Have or obtain a Type I (individual) National Provider Identifier (NPI);
    b. Enroll as a Medicare Provider or Referring Provider (if client is covered by Medicare);
    c. Enroll as a Medicaid Provider or Referring Provider (if client is covered by Medicaid); and
    d. Be of a specialty type (e.g., physician, clinical psychologist, clinical social worker, clinical nurse specialist, nurse practitioner, physician assistant, etc.) eligible to order or refer.
2. Clinicians are responsible 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 and or a narrative supporting the patient's diagnosis.

Medical Necessity:

1. General Requirement – Medicare, Medicaid, and private health plans will only pay for services that meet the relevant coverage criteria and are reasonable and necessary to treat or diagnose an individual patient. Criteria to establish medical necessity 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 Medicare, Medicaid and private insurance plans.

2. Substance Use Disorder (SUD) Treatment

    a. Drug Screen/Qualitative – Qualitative drug tests are considered medically reasonable and necessary for (i) monitoring patient compliance during active treatment for substance abuse or dependence and/or (ii) for patients on chronic opioid therapy in whom illicit drug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or in those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse[1].

    b. Confirmation/Definitive – Definitive drug testing is indicated when (i) the results of the screen are presumptively positive (and the patient adamantly denies use); (ii) results of the screen are negative and this negative finding is inconsistent with the patient's medical history; or (iii) there is no drug screen available, locally and/or commercially, as may be the case for certain synthetic or semi-synthetic substances[2].

    c. Drug testing is a medically necessary and useful component for monitoring patient compliance during active treatment for substance abuse or dependence. Drug test results influence treatment and level of care decisions. Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis. For patients with a diagnosed SUD, the clinician should perform regular drug tests at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

        - Patient history, physical examination, and previous laboratory findings
        - Stage of treatment or recovery;
        - Suspected abused substance;
        - Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

The patient's medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care[3].

Test Orders: aversys, a proprietary web-based application, is required for most test requisitions. Clinicians are required to treat aversys credentials, comprised of a unique user identification and

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1 Local Coverage Determination, Qualitative Drug Testing (L34645), Wisconsin Physicians Service Insurance Corporation, 08/01/2016, http://www.cms.gov/medicare-coverage-database.

2 Local Coverage Determination, Qualitative Drug Testing (L34645), Wisconsin Physicians Service Insurance Corporation, 08/01/2016, http://www.cms.gov/medicare-coverage-database.

3 Local Coverage Determination, Controlled Substance Monitoring and Drugs of Abuse Testing (L34707), Noridian Healthcare Solutions, LLC, 06/28/2016, http://www.cms.gov/medicare-coverage-database.

password, as confidential information and to use appropriate safeguards to prevent the unauthorized use, disclosure, or access to aversys credentials. aversys empowers clinicians to tailor the test parameters to the individual needs of each patient and to alter standing test orders when needed. Test parameters include assays or drug classes, test frequency for a given period, confirmation or reflex specifications, and specimen type, among other parameters. Clinicians should not submit 'blanket' or non-patient specific test orders. Clinicians must submit diagnosis information for all tests ordered as documentation of the medical necessity of the service.

Patient Privacy (HIPAA): Under the Health Insurance Portability and Accountability Act (HIPAA), Averhealth is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at https://averhealth.com/wp-content/uploads/Notice-of-Privacy-Practices.pdf.

Key Laws & Regulations:

1. Anti-Kickback Statute – Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals of tests 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.
2. Stark Law – Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies.
3. False Claims Act – a Federal law that imposes liability on persons and companies who defraud governmental programs. Clinicians who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.

Should you observe or suspect any violation of the above laws please notify the Averhealth compliance hotline by calling 866.386.0806 or online: www.lighthouse-services.com/Averhealth

Clinical Consultations: Averhealth has clinical consultants and a toxicologist available to answer questions and ensure proper test orders. Clinicians authorized to order testing may access these services by contacting your local Averhealth representative.

Medicare Laboratory Fee Schedule: Averhealth test codes and the corresponding Medicare maximum reimbursement rates may be found at the Centers for Medicare & Medicaid (CMS) website, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html.
The Medicaid reimbursement amount will be equal to or less than the amount of Medicare reimbursement.