2024 Annual Compliance Notice

The Office of Inspector General (OIG) 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 (1) Clinician or Ordering/Referring Provider (ORP) Requirements & Responsibilities; (2) Medical Necessity; (3) Test Orders; (4) Patient Privacy (HIPAA); (5) Proficiency Testing; (6) the Medicare Laboratory Fee Schedule; and (7) Key Laws & Regulations the Medicare Laboratory Fee Schedule. Please contact the Laboratory with any questions regarding the information contained in this notice.

Clinician or ORP Requirements & Responsibilities:

To qualify as an ORP, you are required to:

1. Have or obtain a Type I (individual) National Provider Identifier (NPI);
2. Enroll as a Medicare Provider or Referring Provider (if client is covered by Medicare);
    a. Effective April 7, 2014, the Center for Medicare and Medicaid Services requires referring physicians ordering laboratory tests on Medicare beneficiaries to be enrolled in the Provider Enrollment, Chain and Ownership System (PECOS). Please be aware of your status and complete required paperwork in a timely manner to avoid being ineligible to order services for Medicare beneficiaries
    b. Additional information on PECOS and how to enroll in the system may be viewed at: http://go.pardot.com/e/107622/r-enrollment-and-certification/6rdtyv/986364463?h=bNC-yyiKO8TK8P3jt-1sxDf_r49bnpXN8gkjKGapoXI
3. Enroll as a Medicaid Provider or Referring Provider (if client is covered by Medicaid); and
4. 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.
5. Clinicians are responsible for documenting the medical necessity for testing in the patient's permanent medical record and for providing appropriate diagnostic information.
6. 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:

Per applicable CMS regulations, we require all testing requisitions/orders to contain a diagnosis and/or ICD-10 code(s) supporting the tests ordered by our clients.

1. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs)
   CMS has developed National Coverage Determination (NCD) Policies that restrict Medicare coverage for certain lab tests/CPT codes. In addition, Wisconsin Physicians Service Insurance Corporation (05101, MAC-Part A; 05102, MAC-Part B) has also developed Local Coverage Determination (LCD) and Local Coverage Articles (LCA) Policies that restrict Medicare coverage for additional testing. Any lab test contained in one of these NCD/LCD/LCA policies must be screened for medical necessity based on the applicable policy and the primary diagnosis code assigned. If a 'non-covered' diagnosis is used, the patient must be notified of their financial liability prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN).
   a. National Coverage Determinations (NCD)
      For a complete list of NCD policies, with test name(s), CPT's and covered ICD-10 code(s), please review: National Coverage Determinations (NCD) Database
   b. Local Coverage Determinations (LCD)
      For a complete list of LCD policies, with test name(s), CPT's and covered ICD-10 code(s), please review: Local Coverage Determinations (LCD) Database by State

c. Local Coverage Articles (LCA)
For a complete list of LCA policies, with test name(s), CPT's and covered ICD-10 code(s), please review: Local Coverage Articles (LCA) Database by State

2. Advanced Beneficiary Notice
Medicare requires Advanced Beneficiary Notice be given to the patient prior to the collection of a testing sample. The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. The signed, original ABN must be attached to the original lab order prior to specimen submission. Per Medicare rules, requesting the ABN on all Medicare beneficiaries is considered an unacceptable practice.

3. Prior Authorization
Many payers are now requiring prior authorization (PA) before testing will be reimbursed. Insurance payors continue to increase oversight and restrict access by requiring pre-authorization for certain lab tests, including but certainly not limited to any Genetic markers, Cytogenetics testing, Drug testing, Allergy & Celiac testing, etc. Please work with your patient to review their payor-specific preauthorization requirements. Any preauthorization paperwork must be completed by the ordering provider's office prior to submission of any lab orders and/or specimens. Please include the 'preauth' number on the lab order, along with any related documentation. If preauthorization is required by the payor but is not done by the ordering provider prior to submission, the laboratory may delay or suspend processing until the required authorization can be completed. If not authorized, the laboratory is unable to bill charges to the patient.

4. Diagnostic, Screening, Preventive, or Routine:
Statutorily, Medicare *does NOT* cover any lab testing for routine and/or screening purposes. However, Medicare *does* cover some Preventive lab tests (PSA, Glucose, Lipids, etc.) if ordered as required by Medicare. For Preventive benefit information including test names, CPT codes, required ICD-10 codes and frequency limitations, please reference: Medicare Prevention Services
When laboratory testing is ordered for screening purposes (asymptomatic), the patient should be advised that payment may be denied by Medicare or other insurance plans. Each lab test ordered for screening purposes must have the appropriate 'Z' code appended. Any test coded as 'diagnostic' rather than 'screening' (based on the ICD-10 code submitted) will not be payable at 100% per their Preventive benefit.

Test Ordering

1. Requisition Requirements
   a. In addition to having an accurate patient diagnosis (narrative and/or ICD-10) indicating the medical necessity for testing, each requisition form must also include complete patient demographic information including the patient's full legal name, date of birth (DOB), gender, and current insurance information.
   b. For gynecological testing, the requisition must also include all testing being requested for each patient including Pap test, HPV, gonorrhea and/or chlamydia testing. When a Pap test or HPV test is ordered, the requisition must also include the source (cervical v. vaginal), Last Menstrual Period (LMP) date and any other clinically significant information.
   c. Please note that if any required information is missing on a Requisition, it may impact turnaround time while we contact the client for the missing information.

2. Specimen Labeling
   a. Regulations require that each primary specimen be clearly labeled with at least two (2) patient identifiers. A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. Additionally, specimen collected for ABO/Rh or blood transfusions

compatibility testing require five (5) patient identifiers to include patient full legal name, date of birth, date of collection, time of collection, and collector initials or other identification number.

b. This may be in the form of a specimen collection tube, syringe, swab, slide or other form of specimen storage. For prepared slides submitted to a laboratory, if the slides only contain one identifier, they must be securely submitted in a container labeled with two identifiers. If specimen containers are not appropriately marked, turnaround time could be impacted while we contact the client to confirm specimen labeling information.

3. Ordering Organ/Disease Panels/Lab-Customized Panels:
   a. Before ordering, carefully review the components of any laboratory test panel, whether AMA-assigned, laboratory-developed, or client-developed. Only order the panel when ALL the individual components of the panel are medically necessary as determined by specific ICD-10 code(s) and documented in the patient's medical record/chart. If any panel component is not medically necessary, do not order the panel; order only those individual tests that are medically necessary. The following custom panels have been approved by the Laboratory Medical Director:
      i. Allergy Profile, Childhood [LAB2923/Sunquest CAPP/CPT 86003 x15, 82785]
      ii. Allergy Profile, Food [LAB2459/Sunquest FAPPP/CPT 86003 x12]
      iii. Allergy Profile, Respiratory [LAB2922/Sunquest RAPP/CPT 86003 x23, 82785]
      iv. Drug Screen, Monitoring, Urine [LAB3235/Sunquest UDMONI/CPT 80307]
      v. Torch Profile IgG [LAB2741/Sunquest TRCH12/CPT 86644, 86695, 86696, 86762, 86777]
      vi. Vitamin B12 & Folate [LAB2768 /Sunquest B12FOL/CPT 82607, 82746]

4. Reflex Testing and Interpretations by Pathologist:
   a. Some lab tests may trigger additional testing and additional charges based on laboratory policies that reflect standard of care, or by request from the ordering physician. All procedures that contain a reflexive pathway are identified in our test directory, including criteria that will lead to additional charges and the specific CPT code(s) used. Most test names should include 'w/reflex' to clearly identify them.
   b. Current list of Reflex Testing and Interpretations by Pathologists can be found at http://www.pathologylab.org/documents.aspx

Medicare Laboratory Fee Schedule:

Medicare's Clinical Laboratory Fee Schedule (CLFS), including all CPT codes, can be found at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html

Medicaid reimbursement will be equal to or less than Medicare reimbursement.

Patient Privacy (HIPAA):

Under the Health Insurance Portability and Accountability Act (HIPAA), UnityPoint Health – Des Moines 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 http://www.unitypoint.org/desmoines/privacy-policy.aspx

Proficiency Testing

Per Clinical Laboratory Improvement Amendments (CLIA) regulations, proficiency testing (PT) samples may NOT be referred to another laboratory for testing. As a result, UnityPoint Health – Des Moines will not accept PT testing. More information on Proficiency Testing can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf

2024 Annual Compliance Notice

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 order medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.
4. Should you observe or suspect any violation of the above laws, please notify UnityPoint Health – Des Moines compliance.

   Executive Director, Corporate Compliance
   UnityPoint Health - Des Moines
   1200 Pleasant Street
   Des Moines, IA 50309
   Phone (515) 241-6039

Other valuable information about the UnityPoint Health – Des Moines Laboratories Compliance Program includes:

1. Because we are a CMS-contracted provider, we are prohibited from billing any federal program for testing requested by any provider excluded from participation. If your license has been revoked or suspended, please notify the laboratory immediately. Lab testing ordered by any sanctioned provider should not be submitted to UnityPoint Health – Des Moines Laboratories/Pathology Laboratories and will not be accepted.
2. The OIG/Department of Justice takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal, and administrative law. The laboratory will not knowingly bill Medicare for testing that is non-covered, unreasonable and/or unnecessary.
3. If the laboratory receives an order without any diagnosis information or is unable to bill for testing performed because the coding supplied doesn't meet medical-necessity requirements, we will attempt to contact the ordering provider to gather additional coding information that may have been documented in the patient's chart but wasn't noted on the original lab requisition. It is illegal to code solely for reimbursement purposes. The laboratory may not assign diagnosis information.

As you can see, the Laboratories of UnityPoint Health – Des Moines have an active Compliance Program that reflects our commitment to conduct business in compliance with all federal, state, and local laws, and to adhere to all program requirements for federal, state, and private health plans.

Your partnership with our Laboratories is fundamental to the success of our compliance program, and we thank you for your cooperation and continued participation.

If you have any questions or comments about this annual notice, any information contained, or any other issue/concern related to laboratory financial compliance, or lab coding, please contact:

Carrie Beck, MBA/HCM, MLS
Executive Director of Laboratory Services Phone (515) 963-1556 www.pathologylab.org

UnityPoint Health
Des Moines

Pathology Laboratory
UnityPoint Health