

Annual Compliance Notification for 2008

Dear Outreach Physicians, Facility Administration and Staff:

Avera McKenna Regional Laboratory has adopted and continues to enforce a comprehensive Compliance Program that follows protocol that promotes adherence to applicable federal and state laws, and program requirements for federal, state, and private health plans. Through this formal program, we are showing our commitment to the compliance process. We also remind all providers requesting services from our reference laboratory that they too are responsible by law to enforce and abide by rules and regulations relating to compliance.

Compliance Program Reminders.....

Medical Necessity & Diagnostic Information Requirements:

- Medicare does not pay for screening tests except for specifically approved procedures.
- Medicare does not pay for non-FDA approved tests or those tests considered experimental [research use or investigational use only].
- Organ and disease related panels should only be ordered when all panel components are medically necessary. Individual test ordering is highly encouraged.
- If there is reason to believe that Medicare will not pay for a service, the patient should be informed. The patient must then be presented with the appropriate Advanced Beneficiary Notice which must be filled out completely.
- It is the responsibility of the ordering physician and/or facility to ensure that claims being submitted for payment to federally funded programs only occur when services are covered, reasonable and necessary. Non-covered services must be clearly identified on the test request.
- The ordering physician and/or facility must maintain, in the patient record, all required documentation to support the medical necessity of the service ordered.
- The ordering physician must provide, at the time of the test request, specific diagnostic information (reason test was ordered) documenting the medical necessity of the service requested. Diagnostic information should not be "held" to determine specific diagnosis after testing results are reviewed.
 - ICD-9 coding is highly recommended
 - If narrative coding must be used, it must be in such format as to allow for direct conversion to an approved ICD-9 – if narrative can not be directly converted, the physician will be contacted for clarification
 - Only abbreviations approved by Avera McKenna are acceptable; truncated terminology is not acceptable
 - If diagnostic information is not provided at the time the service is ordered, testing will not be completed until the required information is obtained
- Testing will only be performed with receipt of an appropriate written or electronic order. Verbal orders require written confirmation.
- Any test order that is non-specific or utilizes unacceptable terminology will not be completed until the ordering physician or facility can be contacted to verify the order.

Physician Reminder:

- Physicians and authorized individuals are reminded that the Office of the Inspector General [OIG] takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies under federal law.

Screening vs. Diagnostic Test:

- Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease.
- Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to disease.
- The testing of a person to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not screening. In these cases, the sign or symptom should be used to document the reason [medical necessity] for the test.
- For screening tests, the appropriate ICD-9 screening codes must be used to indicate that services were for screening purposes.

Non-Covered Services:

- Non-covered services under Medicare will be billed directly to the patient. As a courtesy to your patient, please inform them that the service being ordered is not covered under the Medicare program and that they will be responsible for payment of services.
- The Advanced Beneficiary Notice may be used to inform the patient that they will be responsible for the non-covered services but are not required.

Advanced Beneficiary Notice [ABN] or Waiver of Liability:

- An ABN should only be obtained for services that Medicare may define as “not reasonable or necessary”. This includes testing for which either a National or Local Coverage Determination exists that defines when the testing is determined to be medically necessary or if the testing is determined to be for “research use or investigational use” only
- Obtaining an ABN in correct format is the responsibility of the ordering provider/facility. The ABN must be submitted at the same time the test is requested and the specimen is sent for testing.
- Ordering physicians or facilities that do not complete and submit ABN’s appropriately will be contacted and appropriate actions will be taken. Initial action will be educational. Recurring or unresolved problems may result in additional actions that may include, but may not be limited to, verbal or written notification and assignment of financial responsibility for services denied.
 - Criteria for an appropriately obtained and documented ABN includes:
 - ◆ Must be in writing, using approved notice language
 - ◆ Must be retained by the laboratory billing for the service provided
 - ◆ Must be signed and dated by the beneficiary [or person acting in their behalf] prior to the specimen being collected
 - ◆ Must cite the specific service [test] for which payment is likely to be denied; Blanket waivers are unacceptable
 - ◆ Must cite the ordering physician’s specific reason(s) for believing Medicare payment will be denied.

Please contact us with any questions/concerns or needs for continuing education that you may have.

Thank you for allowing us to serve you and your patient clinical laboratory testing needs..