
Annual Compliance Notification for 2022

Dear Outreach Clients, Ordering Providers, Administration and Staff:

Avera Laboratory Network-Sioux Falls (ALN-SF) has adopted and continues to enforce a comprehensive Compliance Program that assures adherence to applicable federal and state laws, and program requirements for federal, state, and private health plans when we are requested to bill services to Medicare, Medicaid or other payers. Through this formal compliance program, we are showing our commitment to the compliance process. We also remind all providers requesting services from our reference laboratory that they as the ordering provider are responsible by law to enforce and abide by rules and regulations relating to compliance.

Medicare Program Compliance Reminders

Medical Necessity & Diagnostic Information Requirements:

- Medicare does not pay for screening tests except for those tests covered under the Medicare Preventive Services programs.
- Medicare does not pay for tests classified by the performing laboratory as 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. An Advance Beneficiary Notice (ABN) form should be used for this patient notification requirement.
- It is the responsibility of the ordering provider 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 documented by the ordering provider at the time the service is requested.
- The ordering provider and/or facility must maintain, in the facility's patient record, all required documentation to support the medical necessity of the service ordered. In the event of a Medicare or compliance audit or request for medical necessity documentation, a copy of the facility's medical record documentation may be requested.
- The ordering provider must document, at the time of the test request, specific diagnostic information (reason test was ordered) documenting the medical necessity of the service requested. The provision of diagnostic information for clinical laboratory services should not be "held" to determine specific diagnosis after testing results are reviewed.
 - ICD-10 coding is highly recommended
 - If narrative coding is used, it must be in such format as to allow for direct conversion to an approved ICD-10 – if narrative cannot be directly converted, the ordering provider will be contacted for definitive coding information
 - Only abbreviations approved by Avera McKennan are acceptable; truncated terminology is not acceptable
 - If diagnostic information is not provided at the time the service is ordered, testing may 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 unapproved terminology will not be completed until the ordering provider or facility can be contacted to verify the specific test being requested.

Provider Reminder:

- Providers 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-10 screening codes must be used to indicate that services were ordered for screening purposes.

Non-Covered Services:

- Non-covered services as defined by 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]:

- An ABN must 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 or the specimen and requisition is sent to the laboratory for testing.
- Ordering providers or facilities that do not provide complete medical necessity documentation or do not submit ABN’s appropriately will have appropriate follow up completed. In accordance with compliance policy, incomplete or incorrect documentation by the ordering provider or assigned facility staff that result in payer denial may result in billing the ordering facility for the denied services. Charges assessed will be the responsibility of the client.
- 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 provided service
 - ◆ 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 use of the ABN is unacceptable
 - ◆ Must cite the ordering provider’s specific reason(s) for believing Medicare payment will be denied
 - ◆ Must provide cost estimate for the beneficiary

Compliance Program Resources & References

Avera Laboratory Network has many compliance references and resources available to providers and facilities utilizing our services.

If you have questions on compliance, test ordering/utilization or would like to visit with one of our pathologists (clinical consultants) or laboratory management staff, please contact:

Client Service Department 605.322.7187 -or- 800.560.4846

Listed on the next page are ALN-SF's easily accessible compliance references and resources.

Avera Laboratory Network-Sioux Falls Online Compliance References & Resources

Reference/Resource/Type of Information	Quick Access Link
<p>ALN-SF Online Test Directory</p> <ul style="list-style-type: none"> -Compliance/Service Center Information -Panel testing components -CPT Code(s) -Medical Necessity Notifications -Medicare Coverage & ABN reminders -Reflex test information and CPT Coding 	<p>www.testmenu.com/averamckennan</p>
<p>Avera McKennan Pathologists and Managers/Supervisors</p> <ul style="list-style-type: none"> -References and resources on test utilization and/or selection 	<p>All can be contacted by calling Client Service 605.322.7187 -or- 800.560.4846</p>
<p>ALN Outreach Services Resources</p> <ul style="list-style-type: none"> -Available on our laboratory webpage -Includes: <ul style="list-style-type: none"> • Medicare NCD/LCD Reference Manual - identifies all laboratory testing covered under Medicare Coverage policies • Advance Beneficiary Notice • Medicare Preventive Services Guide • Licensure and Accreditation information • Forms and other resources 	<p>www.avera.org/health-care-professionals/laboratory-network/sioux-falls-service-center/</p>
<p>Third Party Payer (Insurance) - Coverage Reminders</p>	<p>Many third party payers now utilize medical policies that determine whether laboratory testing is covered and whether pre-authorizations are required. Ordering providers are required to assist patients with coverage questions and provide insurer documentation if required.</p> <p>If pre-authorization for testing is required, it must be obtained <u>prior</u> to requesting the laboratory service and documentation must be submitted with the testing request.</p> <p>It is common for Molecular Genetic testing to be not covered or to require pre-authorization.</p> <p>It is the responsibility of the ordering provider and facility to assure that Waiver of Non-Coverage forms are completed <u>prior</u> to requesting the non-covered laboratory service. Waivers should be submitted with the testing request.</p> <p>In accordance with policy, incomplete or incorrect documentation by the ordering provider or assigned facility staff that result in payer denial may result in billing the ordering facility for the denied services. Charges assessed will be the responsibility of the client.</p>

**Please disseminate to all appropriate professionals and providers.
Thank you for allowing us to serve you and your patients' clinical laboratory testing needs.**