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**2025 ANNUAL PHYSICIAN NOTICE OF LABORATORY COMPLIANCE**

To our Valued Healthcare Partners:

Advanta Genetics, LLC is committed to maintaining a comprehensive and proactive compliance program that ensures full adherence to all applicable federal, state, and local laws. As a trusted participant in federally funded healthcare programs, we recognize the importance of transparency, accountability, and ongoing education for our provider partners.

This annual notice serves to inform you of the latest Medicare and Medicaid regulatory requirements, reinforce our internal compliance standards, and clarify the shared responsibilities we hold in the delivery of laboratory testing services. It includes important updates related to billing, coding, documentation, and ordering practices aligned with 2025 policy expectations.

We encourage you to review the information carefully. Should you have any questions or require further clarification, please contact our Compliance Officer, Robia Soliz, at **903-805-9955** or **compliance@aalabs.com**.

Our continued compliance depends on your active participation in the following key areas:

**Disclosure of Exclusions from Federal Healthcare Programs**

In accordance with federal law, no payments will be made by any federal healthcare program for items or services that are furnished, ordered, or prescribed by an individual or entity that is excluded or debarred from participation in such programs.

The Centers for Medicare & Medicaid Services (CMS) prohibits providers from employing or contracting with individuals or entities excluded from participation in Medicare, Medicaid, or any other federally funded healthcare program. Similarly, the U.S. General Services Administration (GSA) maintains a government-wide exclusion list barring these individuals/entities from receiving federal contracts or benefits.

To remain compliant, providers must screen all employees, contractors, referring clinicians, and entities monthly against the following exclusion databases:

- OIG List of Excluded Individuals and Entities (LEIE): https://exclusions.oig.hhs.gov
- System for Award Management (SAM): https://sam.gov
- Applicable State Medicaid Exclusion Lists, as required by individual state regulations

**Reminder:** CMS strongly recommends maintaining documentation of monthly screening activity and retaining exclusion status reports in your compliance records.

**Mandatory Provider Disclosures to Advanta**

All licensed professionals affiliated with or referring to Advanta must notify us in writing within five (5) business days of any of the following adverse actions:

- Notice of exclusion or proposed exclusion from any federal or state healthcare or procurement program
- Receipt or service of a malpractice suit or arbitration notice
- Any action (final or pending) by a professional licensing board
- Revocation, suspension, or restriction of a DEA registration
- Conviction of any felony or a misdemeanor involving fraud, abuse, or moral turpitude
- Any sanctions impacting participation in Medicare, Medicaid, or other federal health programs

**Effect of Exclusion (42 CFR \u00a71001.1901)**

If an individual or entity is excluded, no federal healthcare payment will be made for:

- Services furnished directly by the excluded party
- Services ordered or prescribed by the excluded party, even if rendered by another provider
- Any claims submitted via fee-for-service, cost reports, prospective payment systems, or otherwise

This payment prohibition applies even if the excluded party is not the billing entity.

**Medical Necessity**

Medicare and other federally funded healthcare programs will only reimburse for diagnostic laboratory tests that are medically necessary for the diagnosis or treatment of an individual patient's specific condition. Laboratory services that are ordered for routine screening, protocol-based testing without clinical justification, or patient convenience are not covered and are subject to denial and recoupment.

**Clinical Documentation Requirements**

Medical necessity must be clearly supported by patient-specific clinical findings, which include:

- Documentation in the patient's medical record identifying the clinical rationale for each test ordered
- The treating provider's signature affirming the medical necessity
- ICD-10-CM diagnosis codes that are accurate, specific, and support the reason for testing

Note: Use of generalized or nonspecific codes (e.g., "R99 – Ill-defined conditions") without accompanying clinical justification may result in audit flags or denial of claims.

**Application to Drug Testing**

For toxicology and controlled substance monitoring, medical necessity must be based on:

- Documented risk factors (e.g., polypharmacy, history of substance use, aberrant behavior)
- Clear clinical reasoning for the frequency and scope of testing (e.g., targeted vs. broad panels)
- Relevant treatment decisions influenced by the results of the test

Routine or repeated drug testing without documented clinical justification for each instance is not reimbursable.

**Compliance Enforcement**

As a participating Medicare provider, Advanta Genetics is obligated to ensure that all tests ordered through our laboratory meet federal and state regulations. Providers referring specimens to Advanta must:

- Ensure all requisitions are backed by appropriate documentation in the medical record
- Submit ICD-10 codes or narrative justification that reflect the purpose of each test
- Respond to any post-payment audit requests from payers or compliance authorities

Providers should be aware that under the False Claims Act, the ordering of medically unnecessary services may expose referring physicians to civil and monetary penalties, including for inadvertent violations.

**Policy Update & Enforcement**

Due to increased scrutiny from CMS, Medicare Administrative Contractors (MACs), and commercial payers through post-payment audits and data mining, Advanta has enhanced enforcement of its documentation standards. All providers—including those using Advanta as a Reference Laboratory—are subject to:

- Validation of medical necessity on a per-order basis
- Rejection of incomplete or unsupported test requisitions
- Potential back-end review and denial escalation if insufficient documentation is identified

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**Test Order Requisition Requirements**

To ensure accurate test processing, precise patient identification, and compliant billing practices, all laboratory test orders must meet CMS and CLIA documentation requirements.

A valid laboratory order must include the following elements:

- Patient's full legal name and date of birth
- Date and time of specimen collection
- Source of specimen, if applicable (e.g., urine, nasopharyngeal swab)
- Specific test(s) being ordered
- ICD-10-CM diagnosis code(s) or descriptive clinical rationale
- Ordering provider's full name, address, and NPI number
- Handwritten or authenticated electronic signature and date
  (*Note: Signature stamps are not accepted under Medicare guidelines*)

**Clarifications Regarding Requisition Forms**

- The test requisition form functions as a communication tool but does not, by itself, constitute a valid physician order under Medicare definitions unless it is signed and dated by the treating provider.
- In the absence of a signed requisition, the provider must maintain documentation in the patient's medical record that clearly identifies:
  - The specific test(s) ordered
  - The reason for the order (medical necessity)
  - The ordering provider's intent and clinical rationale

Statements such as "labs ordered" or "routine labs" are not acceptable and will be rejected during compliance or audit review.

**Custom Profile Usage**

Providers may utilize custom testing profiles under the following conditions:

- The profile is patient-specific and tied to a current diagnosis and treatment plan
- The use of the profile is clearly marked on the test requisition form
- The profile is documented in the patient's medical record, including frequency and duration
- The order is renewed and signed annually

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**Audit and Documentation Enforcement**

All ordering providers are expected to retain and furnish supporting documentation upon request from Advanta or its auditing partners (e.g., CMS, MACs, commercial payers). This includes:

- The original lab order (or signed requisition, if applicable)
- Related clinical notes demonstrating medical necessity
- Provider authentication and order date

Failure to produce such documentation may result in:

- Claim denials or recoupment
- Reporting to payers for noncompliance
- Suspension of account access to Advanta services

**Test Ordering Protocol**

All laboratory testing submitted to Advanta Genetics must be ordered using the standard Advanta test requisition form. This form is specifically designed to:

- Ensure physician-directed test selection
- Reinforce the ordering of only those tests deemed medically necessary for the diagnosis, treatment, or management of the individual patient
- Promote compliance with CMS and commercial payer documentation standards

**Use of Non-Advanta Requisition Forms**

If Advanta receives:

- A non-Advanta requisition, or
- An incomplete or ambiguous test order,
  the laboratory will pause processing of the test request until proper clarification is obtained. In such cases, Advanta may:
- Request the ordering provider to resubmit the test request using the official Advanta requisition form
- Seek written or verbal clarification to identify each individual test ordered
- Delay or reject processing if the order remains unsupported or noncompliant

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**Provider Responsibility**

It is the responsibility of the ordering provider to ensure:

- All test orders are submitted on the most current version of the Advanta requisition
- The requisition is accurate, complete, and legible
- Only tests relevant to the patient's documented clinical condition are selected

**Reminder:** Routine or default selection of full test panels without individualized clinical justification may violate payer policies and trigger audit risk under both Medicare and commercial insurance plans.

**Physician Custom Profiles**

In alignment with recent directives from Medicare Administrative Contractors (MACs), Advanta Genetics has updated its policies to prohibit the use of generic or non-patient-specific standing orders for laboratory testing. These changes are designed to ensure that all tests are ordered based on individualized clinical need and consistent with evolving payer requirements for medical necessity.

**Prohibition of Standing Orders**

Advanta does not accept standing orders or implied default orders when no specific test is selected on the requisition form. To support compliance:

- A Custom Profile Order Form is available for providers who wish to order a predefined set of tests on a recurring basis for the same patient, based on a documented treatment plan.
- Each Custom Profile must reflect patient-specific medical necessity and cannot be used as a blanket default for multiple patients.

**Requirements for Custom Profile Use**

To be accepted by Advanta, all Custom Profiles must meet the following criteria:

- Clearly marked selection of the “Custom Profile” box on the Test Requisition Form for the individual patient
- Physician signature and date
- Printed provider name and NPI number
- Documented ICD-10 diagnosis code(s) supporting medical necessity
- Stated frequency and duration of the profile use, not to exceed 365 days from the original order date
- Profile usage must be tied to ongoing care by the same ordering physician

Incomplete or unmarked requisitions will result in delays in testing and reporting until clarification is obtained.

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**Annual Review & Amendment Requirements**

- All Custom Profiles must be reviewed and reauthorized at least annually
- Providers must submit an updated profile noting any changes or explicitly renewing the existing profile
- Physicians may amend a Custom Profile at any time to reflect changes in diagnosis, treatment, or medical necessity

**Recommendation:** Keep a copy of the active Custom Profile in the patient's chart to ensure continuity of care and to provide documentation in the event of an audit.

**Verbal Test Orders**

In accordance with Medicare regulations (42 CFR \u00a7410.32), all diagnostic laboratory tests must be ordered in writing by the treating provider. Verbal orders—whether issued by phone or in person—are only permitted in limited circumstances and must be immediately followed by written confirmation.

**Verbal Order Protocol**

If a test is ordered verbally (e.g., by telephone or in response to an urgent clinical need), the following steps are required to ensure compliance:

1. Advanta will generate a Verbal Order Confirmation Form and send it to the ordering provider for review and signature.
2. The provider must sign, date, and return the confirmation to Advanta promptly (preferably within 24 hours).
3. Testing will not proceed until:
    - The signed confirmation is received, or
    - A properly completed and signed Advanta Test Requisition Form is submitted

**Key Compliance Points**

- Verbal orders must originate from the treating provider or an authorized representative (e.g., PA, NP, RN acting under appropriate delegation)
- The intent to order and the clinical rationale must be documented in the patient's chart at the time the verbal order is given
- Verbal orders may be audited and must meet the same documentation standards as written orders

**Reminder:** CMS considers incomplete or undocumented verbal orders to be non-compliant and subject to claim denial or repayment requests during audit review.

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**Advance Beneficiary Notice (ABN) Requirements**

An Advance Beneficiary Notice of Noncoverage (ABN) must be provided to Medicare beneficiaries prior to specimen collection when a laboratory test is likely to be denied by Medicare due to one or more of the following reasons:

- Lack of medical necessity
- Frequency limitations exceeded based on Local Coverage Determinations (LCDs)
- Non-coverage for screening or preventive testing not otherwise authorized

In these instances, the ABN allows the patient to make an informed decision regarding whether or not to proceed with testing and accept potential financial responsibility.

**When an ABN Is Required**

You must complete and issue an ABN (Form CMS-R-131) before collecting a specimen when:

- You are ordering a test with a diagnosis code that is not covered under applicable NCDs or LCDs
- The same test has already been performed within the Medicare frequency limitation window
- There is a reasonable expectation that Medicare may deny payment

**Key Compliance Guidelines**

- The ABN must be signed and dated by the patient prior to specimen collection
- The original signed ABN must be submitted with the corresponding laboratory requisition
- The ABN must clearly specify:
    - The test(s) being performed
    - The reason Medicare may deny payment
    - The patient's acceptance or refusal of financial responsibility

Do not issue ABNs to all Medicare patients as a routine practice. Blanket or repetitive ABN use violates CMS policy and may result in penalties or payment denials.

**Resources**

- Official ABN Form (CMS-R-131): https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN
- ABN instructions and examples: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/ABN-Form-Instructions.pdf

Proper ABN management protects patient rights and ensures provider compliance with Medicare documentation standards.

**Medicare National and Local Coverage Determinations (NCDs & LCDs)**

The Centers for Medicare & Medicaid Services (CMS) issues National Coverage Determinations (NCDs) and delegates authority to Medicare Administrative Contractors (MACs) to publish Local Coverage Determinations (LCDs). These policies define:

- Whether a test or service is covered or non-covered by Medicare
- The clinical indications, frequency limits, and diagnosis codes that support medical necessity

These policies are binding and must be followed for test selection, coding, and documentation to ensure Medicare reimbursement.

**Coverage Resources**

The most current NCDs and LCDs may be accessed through CMS's official database:
The official link to the CMS Medicare Coverage Database, where you can access both National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs):

**CMS Medicare Coverage Database**
URL: https://www.cms.gov/medicare-coverage-database

From this portal, you can:

- Search for NCDs and LCDs by keyword, CPT/HCPCS code, or contractor
- Filter by jurisdiction (e.g., Novitas for Texas)
- View archived and active policies
- Access associated billing articles (ABs)

**Jurisdiction-Specific LCD: Novitas Solutions**

Advanta Genetics operates within the jurisdiction of Novitas Solutions, whose LCDs apply to Texas and other covered states.

**Drug Testing – LCD L38345**

**Title:** *Urine Drug Testing*
**LCD ID:** L38345
**Jurisdiction:** Novitas (TX and other regions)
**Effective Date:** February 28, 2021 (currently active)

**Direct Link:**
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38345

This LCD outlines:

- Covered clinical scenarios for presumptive and definitive drug testing
- Frequency limitations and medical necessity criteria
- Required documentation in the patient record

**Molecular Pathology and Genetic Testing – LCD L39063**

**Title:** *Molecular Pathology Procedures*
**LCD ID:** L39063
**Jurisdiction:** Novitas
**Effective Date:** October 1, 2021 (currently active)

**Direct Link:**
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39063

This LCD covers:

- Coverage guidelines for molecular diagnostic tests, including PGx and infectious disease panels
- CPT codes and clinical indications
- Testing limitations and expected use scenarios

**Billing Article (A59074) – Must be referenced alongside L39063**
https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59074

**Important:** Orders outside of defined parameters may be denied unless medical necessity is clearly documented in the medical record and supported by appropriate ICD-10 coding.

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**Compliance Program Alignment**

Advanta maintains a compliance program aligned with the OIG's Clinical Laboratory Compliance Program Guidelines and encourages all provider partners to do the same. These guidelines promote ethical ordering behavior, accurate documentation, and defensible billing practices in accordance with Medicare rules.

Reference:
OIG Compliance Guidance for Labs (63 Fed. Reg. 45076)

**Patient Privacy and Data Access (HIPAA & Cures Act Compliance)**

As a healthcare provider and covered entity under the Health Insurance Portability and Accountability Act (HIPAA), Advanta Genetics maintains strict policies and procedures to protect the confidentiality, integrity, and availability of all protected health information (PHI).

We are committed to full compliance with:

- The HIPAA Privacy Rule (45 CFR Part 164 Subpart E)
- The HIPAA Security Rule (45 CFR Part 164 Subpart C)
- The 21st Century Cures Act Information Blocking Rule (45 CFR Part 171), which governs patient access to lab data

**Patient Rights Under HIPAA and Cures Act**

Patients have the right to:

- Receive timely access to their laboratory test results
- Request and obtain electronic copies of their PHI
- Authorize or restrict the disclosure of their information to third parties

Advanta ensures that patients can access their results securely and efficiently through:

- Secure patient portals
- Fax, mail, or encrypted email (upon verified request)
- Authorized third-party integrations (when permitted)

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**Information Blocking Prohibition**

As of April 5, 2021, under the Cures Act Final Rule, it is a violation to delay, restrict, or interfere with a patient's right to access their electronic health information (EHI), including lab results, unless a defined exception applies.

Providers must not delay ordering or releasing results to avoid disclosure. Intentional obstruction may result in OIG enforcement actions and financial penalties.

**Our Commitment**

Advanta maintains:

- Comprehensive HIPAA training for all personnel
- Strong technical safeguards (e.g., encryption, role-based access)
- Regular risk assessments and compliance reviews

A published privacy policy accessible at:
http://www.aalabs.com/privacy

**Prohibited Referrals and Inducements**
*(Stark Law, Anti-Kickback Statute, and EKRA Compliance)*

Advanta Genetics maintains a strict zero-tolerance policy against any form of illegal referral arrangement or inducement related to laboratory testing services. We are fully committed to compliance with all federal and state laws governing physician self-referrals, financial relationships, and patient steering—including the Stark Law, the Anti-Kickback Statute (AKS), and the Eliminating Kickbacks in Recovery Act (EKRA).

**Stark Law (Physician Self-Referral Law)**
**42 U.S.C. § 1395nn**

The Stark Law prohibits physicians from referring Medicare patients for designated health services (including clinical laboratory testing) to an entity with which the physician or their immediate family member has a financial relationship, unless a statutory or regulatory exception applies.

- If no exception applies:
    - The physician is prohibited from referring Medicare patients to the lab
    - The laboratory is prohibited from billing Medicare for the referred services

**Examples of affected arrangements include**:

- Lease or rental agreements between labs and physician practices
- Personal services contracts for medical directorships or consulting
- Percentage-based compensation tied to test volume

Violations of the Stark Law are strict liability offenses (intent is not required) and may result in:

- Civil monetary penalties
- Denied or refunded claims
- Exclusion from federal healthcare programs

**Anti-Kickback Statute (AKS)**

**42 U.S.C. § 1320a-7b(b)**

The Anti-Kickback Statute makes it a criminal offense to knowingly offer, pay, solicit, or receive anything of value to induce or reward referrals for items or services reimbursable under any federal healthcare program, including Medicare, Medicaid, TRICARE, and others.

**Prohibited examples include**:

- Cash or in-kind gifts to providers or their staff
- "Free" phlebotomy services that exceed fair market value
- Waived patient financial responsibility offered selectively
- Commission-based marketing arrangements

Violations of the AKS are felony offenses and may result in:

- Criminal prosecution and imprisonment
- Civil monetary penalties and treble damages under the False Claims Act
- Program exclusion

**Note:** Arrangements that comply with a regulatory safe harbor (e.g., for personal services or space rental) may avoid AKS violations—but strict criteria must be met.

**Eliminating Kickbacks in Recovery Act (EKRA)**

**18 U.S.C. § 220**

Enacted in 2018, EKRA extends anti-kickback restrictions to all payors—not just federal programs. EKRA prohibits offering, paying, soliciting, or receiving remuneration to induce referrals to recovery homes, clinical laboratories, or clinical treatment facilities.

**Key facts:**

- Applies to commercial insurance claims and cash-pay patients, not just Medicare/Medicaid
- Outlaws volume-based compensation to marketers or sales reps for test referrals
- Penalties include up to $200,000 in fines and 10 years imprisonment per violation

EKRA is especially relevant to toxicology and molecular testing labs that engage third-party marketers, physicians, or telehealth providers.

**Reporting Concerns and Compliance Support**

All Advanta Genetics employees, clients, and healthcare partners are required to report any suspected violation of these laws. Reports may be made confidentially and without fear of retaliation.

Compliance Hotline:
903-805-9955
compliance@aalabs.com

**Reminder:** Even perceived violations—such as "free services," waived co-pays, or bonus-based referral patterns—can trigger audits, whistleblower claims, or criminal investigations. When in doubt, consult our compliance team.

**Clinical Consultation Services**

At Advanta Genetics, we believe clinical collaboration enhances diagnostic accuracy and improves patient outcomes. To support providers in ordering and interpreting complex laboratory tests, Advanta offers access to qualified doctoral-level clinical consultants, including board-certified PhD toxicologists and molecular scientists.

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**Available Consultation Services**

Providers may contact our laboratory consultants for expert guidance on:

- Appropriate test selection based on patient diagnosis and clinical scenario
- Interpretation of complex test results, including toxicology panels, pharmacogenomic profiles, or multiplex PCR findings
- Documentation requirements for medical necessity, ICD-10 alignment, and payer-specific policies
- Clarification of LCD/NCD-related test utilization
- Pre-audit preparation support, including order-to-result trail validation

These services are available to all providers who refer specimens to Advanta Genetics.

**How to Access Clinical Consultation**

You can contact a member of our clinical consulting team during normal business hours:

Compliance Hotline:
903-805-9955
compliance@aalabs.com

For urgent test interpretation questions, please indicate “CLINICAL CONSULTATION REQUEST” in the subject line or phone call.

**Documentation Reminder**

While Advanta consultants can assist with compliance alignment and result interpretation, all final decisions regarding test ordering, diagnosis, and clinical management remain the responsibility of the treating provider. Consultation does not substitute for documentation of medical necessity in the patient record.

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**Preventing False Claims: Key Compliance Practices**

To comply with federal guidelines and avoid exposure under the False Claims Act (FCA) and related enforcement statutes, all ordering providers should adhere to the following critical practices:

1. **Order only those tests that are medically necessary**
   Each individual test or component of a test panel must be justified by the patient's clinical condition. Panels should only be ordered if every component is medically necessary for diagnosis, monitoring, or treatment.

2. **Include a specific diagnosis, sign, or symptom for each test ordered**
   Use accurate ICD-10-CM codes that support the clinical rationale for testing. Avoid vague terms like “routine labs” or “annual screening” unless covered under preventive services guidelines.

3. **Ensure medical necessity is clearly documented**
   The patient’s medical record must contain:
   - A note or order specifying the test
   - Supporting clinical indications
   - The ordering provider’s authenticated signature and date

4. **Issue an ABN when coverage is uncertain or unlikely**
   For Medicare beneficiaries, complete and present an Advance Beneficiary Notice (ABN) when tests are likely to be denied based on:
   - Lack of coverage under an LCD or NCD
   - Exceeding frequency limitations
   - Lack of medical necessity

Failure to follow these practices may result in:

- Claim denials or recoupment
- Civil monetary penalties
- Potential exposure under the FCA

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**CMS National Coverage Policy Reference**

Advanta Genetics adheres to all applicable policies outlined in the Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs). These policies define which clinical laboratory services are reimbursable under Medicare based on nationally recognized criteria for reasonableness and medical necessity.

The following key federal statutes and regulations govern Medicare coverage for diagnostic testing:

- **Social Security Act § 1862(a)(1)(A)**
  No payment may be made under Medicare for any items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

- **Social Security Act § 1833(e)**
  No payment shall be made for services or items that lack sufficient supporting information to determine medical necessity.

- **42 CFR § 410.32(a)**
  Diagnostic tests must be ordered by the treating physician or other qualified practitioner, and the results must be used in the management of a specific medical problem. Routine or screening use is not covered unless specifically allowed by preventive services regulations.

**Documentation Expectation**

Providers must ensure that the following are clearly documented in the medical record:

- Clinical justification for each test ordered
- Accurate and specific ICD-10-CM coding
- Signed orders that align with Medicare-defined coverage conditions

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**Exhibit 1A. CMS National Coverage Policy**

The following provisions from the Social Security Act and Code of Federal Regulations (CFR) govern Medicare coverage for clinical laboratory testing. These form the legal and regulatory foundation for determining whether a laboratory service is reimbursable under Medicare:

**1. Social Security Act § 1862(a)(1)(A)**

"No payment may be made under Part A or Part B for any expenses incurred for items or services—(A) which, except as provided in subsection (l), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

**Full Text**: https://www.ssa.gov/OP_Home/ssact/title18/1862.htm

**Social Security Act § 1833(e)**

"No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person…"

**Full Text**: https://www.ssa.gov/OP_Home/ssact/title18/1833.htm

**3. 42 CFR § 410.32(a) – Diagnostic Test Order Requirements**

Medicare regulations state that diagnostic laboratory tests must be ordered by the treating physician or practitioner who is responsible for the patient's care. The order must be based on a specific medical problem, and the results must be used in managing that condition.

"...Diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."

Routine or blanket screening tests are not covered unless specifically authorized by preventive services regulations or statutory exceptions.

**Full Regulation**: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.32

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**Implications for Providers**

To meet CMS standards, all laboratory test orders must:

- Originate from the treating provider
- Be supported by a clearly documented clinical rationale
- Include a specific diagnosis code (ICD-10-CM) that aligns with covered indications
- Reflect appropriate frequency and test selection as defined in applicable NCDs or LCDs

Failure to comply with these policies may result in:

- Denied claims
- Medicare recoupment
- Civil or administrative penalties under the False Claims Act

**Reference Information and Regulatory Resources**

The following official resources provide authoritative guidance for laboratory test ordering, documentation, medical necessity, compliance, and billing practices. Providers are encouraged to reference these links to stay current with applicable CMS, OIG, and regulatory requirements.

**ICD-10 Coding and Medicare Documentation Requirements**

- ICD-10-CM Resources (CMS)
  https://www.cms.gov/medicare/icd-10

- Medicare Program Integrity Manual (MPIM), Chapter 3
  *Signature requirements and documentation standards*
  https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals
  *(See "Medicare Program Integrity Manual" under Publication 100-08)*

**Medical Necessity and Coverage Determinations**

- National Coverage Determinations (NCDs) Index
  https://www.cms.gov/medicare-coverage-database/view/ncd.aspx

- Local Coverage Determination (LCD) – Urine Drug Testing (L38345, Novitas)
  https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38345

- LCD for Molecular Pathology Procedures (L39063, Novitas)
  https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39063

**Administrative Forms and Billing References**

- Advance Beneficiary Notice (ABN) – CMS-R-131
  https://www.cms.gov/medicare/medicare-general-information/bni/abn

- Medicare Clinical Laboratory Fee Schedule (CLFS)
  https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched

**Regulatory and Compliance Framework**

- Anti-Kickback Statute (42 U.S.C. § 1320a–7b)
  https://www.law.cornell.edu/uscode/text/42/1320a-7b

- OIG Supplemental Compliance Guidance for Hospitals (2005)
  https://oig.hhs.gov/documents/compliance-guidance/810/012705hospsupplementalguidance.pdf

- OIG Compliance Program Guidance for Clinical Laboratories (1998)
  https://oig.hhs.gov/documents/compliance-guidance/712/cpglab.pdf

**Program Integrity and Enforcement**

- Special Advisory Bulletin: Effect of Exclusion from Federal Programs (OIG, 1999)
  https://oig.hhs.gov/documents/special-advisory-bulletins/886/effects_of_exclusion.pdf

- National Practitioner Data Bank (NPDB)
  https://www.npdb.hrsa.gov

- State Medicaid Director Letter: Screening and Enrollment (SMDL #09-001)
  https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD011609.pdf