October 2025

Annual Provider Notice

RE: Compliance Update and CPT information

Dear Valued Client:

The Office of Inspector General (OIG) recommends clinical laboratories send notices to physicians and providers who use their services at least once a year to inform the recipients of the laboratory's policies for test ordering and billing and provide information regarding laws and regulations that govern laboratory services. To meet the compliance recommendations set forth this notice serves as the annual written notice describing the following:

Specimen Integrity – In order to ensure patient safety and provide accurate results on the correct patient, our laboratory requires that all samples be labeled with at least two unique patient identifiers that match the accompanying requisition. Improperly labeled specimens will result in testing delays or rejection.

Please make sure that all specimens collected in your office are labeled at the time of collection, in the presence of the patient. The patient's full name and date of birth are the preferred identifiers, though the following identifiers may also be used: (1) unique patient identifier, such as medical record number and (2) barcode labels embedded with at least two unique identifiers. Location-based identifiers are *not acceptable* as these are *not unique*. Specimen identifiers must match exactly as they appear on the test requisition.

If the specimen is hand-labeled, a ballpoint pen should be utilized. Felt-tip pens and gel pens are prone to smudging and may result in illegible identifiers. Specimens should be labeled in such a way that does not prevent the visual inspection of the sample (e.g.: a sample window and fill lines should be visible when labeled). Additionally, barcodes should be oriented vertically to maintain scan ability.

Supplies – ARMO provides certain supplies necessary to collect and transport specimens to our laboratory for analysis, at no charge. Supplies provided by ARMO are only to be used for specimens submitted to our laboratory for analysis. The type and quantity of supplies ordered should correspond to the type and volume of testing referred. The laboratory

monitors the volume of supplies provided to clients as required by anti-kickback statutes and other regulatory guidelines.

Medical Necessity - When ordering tests for which payment under federal health care programs will be sought, such as Medicaid and Medicare, ARMO reminds physicians (or other individuals authorized by law to order tests) that tests must meet the following conditions: (1) included as covered services, (2) reasonable, (3) medically necessary for the treatment and diagnosis of the patient and (4) not for screening purposes. The Center for Medicare Services (CMS) requires that certain procedures be "medically necessary" when ordered by a physician to be covered by Medicare. CMS has published National Coverage Determinations (NCD) for these tests. In addition, each carrier has established Local Coverage Determinations (LCD) for additional tests. Complete copies of these determinations can be found on the Medicare carriers (Novitas Solutions) website www.novitas-solutions.com, or you may contact your marketing representative.

Referring physicians will be notified as appropriate of their role and responsibility to provide medical necessity and ICD-10-CM coding information in accordance with Medicare and other program requirements. Referring physicians shall provide diagnosis information that supports the medical necessity of the services ordered. Narrative descriptions and "rule out" diagnosis are not sufficient.

ARMO may submit claims to Medicare which it believes will be denied solely in the limited circumstances where: (1) the beneficiary has signed an appropriate ABN, the laboratory has the signed ABN on file, and the claim is submitted with the GA modifier; or (2) where the beneficiary insists the claim be submitted and the claim reflects ARMO's belief that the service is non-covered but is being submitted at the beneficiary's insistence.

ARMO makes reasonable efforts to inform referring physicians of medical necessity rules changes that may affect referred specimens. Written notice shall be given to referring physicians who request medically unnecessary tests. This notice will be documented and retained in laboratory records.

Advance Beneficiary Notice (ABN) – ABNs are used when there is a likelihood that an ordered service will not be paid. If medical necessity requirements are not met and ARMO has genuine doubt regarding payment, the beneficiary will be clearly informed, in writing, the likelihood of the specifically stated service(s) being denied. The beneficiary can sign an agreement to pay on the ABN if the services are desired. If the beneficiary does not agree to pay on the ABN, services will not be provided unless the consequences prevent this option.

Custom Panels – The OIG discourages the use of custom panels as part of the OIG's Compliance Program guidance for clinical laboratories. Concerns exist surrounding the possibility of excessive use of custom panels, which results in performance and billing of medically unnecessary testing. In order to create a custom panel, ordering physicians are required to sign an attestation statement indicating that the panels will only be ordered

when all tests are medically indicated for the patient. In all cases, each panel component test is separately orderable.

Standing Orders – Standing Orders are not usually acceptable documentation that tests are reasonable and necessary. They are only to be used in connection with an extended course of treatment specific to an individual patient. The order must be verified in writing and include duration, frequency, and diagnosis information.

Standing orders may not be in place for longer than 1 year without review. ARMO ensures all standing orders are documented, marked for notice on the record, and reviewed at least annually. For continuation of standing orders, ARMO will obtain and maintain confirmation in writing that provides the duration, frequency, and diagnosis information from the entity for which the standing order applies.

Reflex Testing – Reflex testing occurs when the initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. In order to avoid unnecessary reflex testing, reflex testing will only be performed on the specific tests that are identified in the directory of services or requisition when appropriate. ARMO will only bill for medically necessary reflex tests.

CPT or HCPCS Codes – On an annual basis, all tests are reviewed to make certain that the annual Current Procedural Terminology (CPT) coding changes are implemented. These changes may affect the way the laboratory bills Medicare and other federal and state health care programs as well as any other third-party payer.

The CPT codes in the laboratory's test directory are provided on request for informational purposes only and reflect our interpretation of CPT coding requirements based on the American Medical Association (AMA) and our understanding of payor guidelines. These are provided as a guide to assist with billing, though CPT coding is the sole responsibility of the billing party. Clients are encouraged to confirm CPT codes with Medicare administrative contractors (MACs) as requirements may vary.

Please review this notice and should you have any questions, please do not hesitate to contact us.

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