

MOBILE ELECTRODIAGNOSTIC LABORATORIES PROVIDE SUBSTANDARD PATIENT CARE

BACKGROUND

While basic rules for independent diagnostic testing facilities (IDTFs) have been established by the Centers for Medicaid and Medicare (CMS) in 2000, recent changes to the law have clarified the standards Medicare will use when paying IDTFs under the Medicare Physician Fee Schedule. In order to be paid by Medicare, IDTFs are required to enroll as a Medicare Part B supplier. An IDTF must comply with a number of requirements including the use of qualified supervising physicians, qualified nonphysician personnel, performance of only specifically ordered tests, and compliance with all applicable state laws to obtain and maintain billing privileges. IDTF may be at a fixed location, a mobile entity, or an individual non-physician practitioner. IDTFs are independent of a physician's office or hospital; however, the IDTF rules apply when an IDTF furnishes diagnostic procedures in a physician's office.¹ The regulations regarding IDTF were largely unchanged for many years until an OIG audit conducted in 2003-2004 found that a potential \$71 million in improper payments were made to IDTFs.² AANEM is concerned that despite changes made to Medicare reimbursement rules as a result of the OIG findings, the potential for fraud and abuse in IDTF practices, particularly with mobile laboratories performing nerve conduction studies (NCSs), remains. In addition, many companies acting as an IDTF do not enroll as Medicare Part B supplier and bill only private payers. These groups are not being held to Medicare standards.

NCS Mobile Laboratories

As the name suggests, a mobile NCS lab allows for electrodiagnostic (EDX) testing equipment to be moved from site to site. A typical mobile diagnostic laboratory company advertises that it will send a technician and equipment to a physician's office (for example, a family practice, cardiologist, pulmonologist, etc.) and provide state-of-the-art testing that the ordering practitioner is not qualified to perform. Some companies advertise such practices as "teleneurology." The company's promotions often state that the arrangement will allow patients to avoid waiting for a consultation with a specialist and promises increases in revenue for the practitioner's office. The companies promote that the results will be sent to the company and read later. Often they will state that the tests will be read by a certified neurologist or physical medicine and rehabilitation physician. This combination makes the mobile diagnostic laboratories testing offer of interest to many health care providers who do not possess the appropriate education or training to perform NCSs.

In many cases, the number and type of tests is the same for every patient, with a pre-determined battery of tests performed based on the signs or symptoms indicated in the referral. In some cases, the ordering physician may have determined a suspected diagnosis; however, the area of the pain typically determines which template is used to test the nerves in that area. The test is not adapted during the procedure based on findings that occur during the study. There is generally no physician qualified to perform the test onsite.

CHARACTERISTICS OF SUBSTANDARD CARE AND AANEM'S RECOMMENDATIONS

It is the opinion of the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) that many mobile diagnostic laboratories testing companies are offering substandard electrodiagnostic (EDX) services. Because substandard and inaccurate diagnoses delay appropriate care, these types of services are negatively impacting the quality of EDX examinations delivered to patients across the United States. The mobile diagnostic laboratories testing companies that are offering substandard EDX examinations include many if not all of the following characteristics that violate AANEM standards:

NCSs are ordered without a trained EDX physician determining that NCS testing is necessary and without the EDX physician conducting a history and physical examination of the patient to determine a differential diagnosis and determine which nerves need to be studied.

AANEM's Recommendations: A typical EDX evaluation should involve: (1) an appropriately trained EDX physician taking a focused neuromuscular history and performing a directed physical examination; (2) the development of a differential diagnosis; (3) the design of an appropriate EDX examination (based on the history and physical and suspected diagnosis) followed by an examination of muscles and nerves utilizing NCSs and needle electromyography (EMG); and (4) the determination of a final diagnosis. The standard of care in clinical practice dictates that each of these components cannot be predetermined or standardized.³ The history and physical examination and the determination of which nerves to study utilizing NCSs and which muscles to sample by EMG should be performed by a trained EDX physician. A qualified EDX physician should receive training in neurology and/or physical medicine and rehabilitation residencies and/or fellowships that provide detailed medical education including anatomy, pathology of muscle and nerve,

neuromuscular physiology, electrophysiology, and clinical aspects of neurological and musculoskeletal conditions, with particular emphasis on diagnosis and treatment of neuromuscular diseases as they pertain to clinical EDX medicine.³

Predetermined NCSs or EMGs are performed based on the referring physicians suspected diagnosis or symptoms in a given body part (e.g. low back pain or neck pain with or without radicular symptoms) and the study does not change during the procedure based on the findings.

AANEM's Recommendations: Interpreting NCSs without performing a focused history and physical and without the EDX physician having oversight over the design and performance of testing is inappropriate.⁴ The EDX evaluation is an extension of the neurologic portion of the physical examination and requires detailed knowledge of the patient and his or her disease. The EDX testing must be tailored for each individual patient. In addition, it is often necessary to modify or add to the procedure during the examination depending on the findings as they unfold. Only in this way can appropriate data be collected and the proper conclusions drawn. This is accomplished only when a qualified EDX physician meets with the patient to learn about present and past medical conditions, performs a physical examination, and designs and then performs the EDX examination. If a technician is utilized for the NCS portion of the examination, the qualified, supervising physician needs to be alerted immediately during testing when any results appear to be unusual or unexpected so that there is opportunity to reassess the differential diagnosis and develop alternative testing strategies.

The NCS testing is performed by technicians without adequate physician supervision. The supervising or interpreting physician is not able to assist the technician if problems or questions are encountered during the testing.

AANEM's Recommendations: Medicare rules as defined at 42 CFR 413.65 state that direct supervision is recommended for all NCS testing performed by uncertified technologists. For certified technologists, general supervision is allowed but AANEM believes that direct supervision is required of all technologists regardless of certification to provide the best quality patient care. In direct supervision, the physician may be absent from the room when the procedure is performed, but should be immediately available. In the case of mobile diagnostic laboratories testing, the physician providing the supervision typically has no understanding of the tests being performed and, therefore, the supervision provided is inadequate. A physician supervising the technologist must have special training in the diagnosis and treatment of neurological and neuromuscular diseases and in the application of particular neurophysiological techniques to study these disorders.⁵ Supervising physicians should receive training in neurology and/or physical medicine and rehabilitation residencies and/or fellowships that provide detailed medical education including anatomy, pathology of muscle and nerve, neuromuscular physiology, electrophysiology, and clinical aspects of neurological and musculoskeletal conditions, with particular emphasis on diagnosis and treatment of neuromuscular diseases as they pertain to clinical electrodiagnostic medicine.³

AANEM's opinion on appropriate supervision of NCSs is supported by the 2010 Outpatient Prospective Payment System Final Rule (the "2010 OPPTS").⁸ Comments in the 2010 OPPTS provide guidance on the qualifications required to be a supervising physician. Although these rules specifically discuss tests performed in a hospital setting, the same quality of care should be provided to patients outside of a hospital setting. According to the 2010 OPPTS, the supervising physician (1) must have, within his or her scope of practice and hospital granted privileges, the knowledge, ability and hospital privileges to perform the services being supervised; (2) must be prepared to step in and perform the services, not just to respond to an emergency; and (3) need not be of the same specialty as the procedure or service being performed, but (as stated above) must have the ability to perform the procedure and have the privileges to do so. In most cases, the mobile diagnostic laboratory company physician who has experience in EDX testing, is off site and, therefore, cannot step in and perform the service if needed. The practitioner in whose office the test is being performed cannot perform the test because most, if not all, do not have the appropriate education and training as described in the preceding paragraph or the necessary experience in performing NCSs.

Interpretation of the NCS data is not done at the time of the study (in "real time") or at the location of the patient ("on site") but at a later time (and often at a location far removed from the patient and testing site).

AANEM's Recommendations: When properly performed, the waveforms from the NCSs should be reviewed as they are obtained (on site) prior to the patient being dismissed (in real time). The American Medical Association's (AMA) 2014 *Current Procedural Terminology Professional Codebook* includes a description of how NCSs should be performed "Waveforms must be reviewed on site in real time..." In addition, it states that the "Reports must be prepared on site by the examiner, and consists of the work product of the interpretation of numerous test results... along with summarization of clinical and electrodiagnostic data, and physician or other qualified health care professional interpretation."⁸ This is necessary to ensure the quality of the waveforms and to ascertain whether further NCSs should be performed, as well as to determine what, if any other diagnostic tests are necessary. Before results can be interpreted as normal or abnormal, it is important that the physician consider other factors that could be causing an apparent abnormality, such as electrical interference, improper setting, malfunctioning equipment, poor electrode placement⁷ or connections, sub-maximal stimulation intensity, volume conductance, anomalous innervations, or even whether the room was too cold. Interpretation of NCS data absent face-to-face patient interaction results in substandard care.

Often the number of tests is greater than what would reasonably be necessary to arrive at a given diagnosis.

AANEM's Recommendations: AANEM has developed a chart of the maximum number of NCS tests necessary in 90% of cases. Many mobile laboratories provide testing that exceeds these numbers (see pp12-13 of the *Recommended Policy for Electrodiagnostic Medicine*).⁵ Mobile laboratories using a predefined set of testing

on each patient or that are exceeding the number of tests necessary to reach a medical diagnosis are likely overbilling. The greatest drains on healthcare resources are unnecessary tests, treatment, and/or surgery.⁶ Providing the appropriate number of EDX tests ensures quality and is an effective tactic in reducing the expense of healthcare.

Needle EMG studies are not performed on the patient.

AANEM's Recommendations: In most circumstances, a needle EMG and NCSs should be performed together. When NCSs are performed without needle EMG, the additional and complementary information provided by the needle EMG results (except in limited circumstances) is not available. Without the information provided by the needle EMG examination, valuable data that may be essential in establishing an accurate diagnosis is missing. For example, performing both studies together is critically important when evaluating patients with suspected radiculopathy, plexopathy, and motor nerve or motor neuron disease.² See AANEM's position paper, *Proper Performance and Interpretation of Electrodiagnostic Studies*.⁴

CONCLUSION

The AANEM believes that NCSs or EMG exams performed by mobile diagnostic laboratories testing companies not meeting the above criteria are offering services below the standard of care. The EDX examinations performed by these companies often lead to questionable diagnoses and are providing poor quality patient care. AANEM is strongly opposed to any EDX laboratory or practice that denigrates the quality of EDX testing or practices in an abusive or fraudulent manner.

AANEM recommends that payers require companies that are performing studies in the manner listed above but have failed to register as an IDTF be held to the same standards of IDTFs listed in the federal rules.

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