Billing Medicare SBIRT Services

HCPCS Code G2011	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 5–14 minutes	
HCPCS Code G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes	
HCPCS Code G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes	

Medicare Telehealth Includes SBIRT Services

You can provide SBIRT services via telehealth if you meet all requirements.

Substance Use Disorder Bundled Physician Fee Schedule Payments

HCPCS Code G2086	Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month	
HCPCS Code G2087	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month	
HCPCS Code G2088	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (list separately in addition to code for primary procedure)	

Note: Don't bill HCPCS codes G2086–G2088 more than once per month per patient. These codes describe treatment for 1 or more SUDs.

Opioid Use Disorder: Part D Treatment Drugs

Medicare drug plan (Part D) sponsors **must** cover OUD Part D treatment drugs, when medically necessary, by including them on the formulary or by exception. Coverage isn't limited to single entity products (for example, Buprenorphine) but must include combination products when medically necessary (for example, Buprenorphine Naloxone and long-acting Naltrexone).

CMS sponsors must have a transition policy to prevent interruptions in Part D therapeutic treatment drugs when new patients transition into the benefit. This transition policy, along with CMS's non-formulary exceptions and appeals requirements, helps make sure all your patients have timely access to medically necessary OUD Part D drug therapies.

A pharmacy can dispense a Part D drug only upon prescription if the drug is helping treat a medically accepted indication. Medicare Prescription Drug Benefit Manual, Chapter 6 has more information.

Since January 1, 2021, you can prescribe a Medicare Part D Schedule II, III, IV, or V controlled substance electronically according to the electronic prescription drug program requirements.

Methadone isn't an OUD Part D drug because a retail pharmacy can't dispense it for treatment. 42 CFR 8.12(h)(2) has more FDA-authorized OUD investigational use medication information, and 42 CFR 8.1 has more OUD medication-assisted treatment information.

Note: Methadone is a Part D drug when indicated for pain. State Medicaid Programs may include the methadone costs in their bundled payment to qualified Opioid Treatment Programs (OTPs) or hospitals dispensing OUD methadone. Section 10.8 of Medicare Prescription Drug Benefit Manual, Chapter 6 has more information.



Opioid Treatment Programs

Since January 1, 2020, we pay certified OTPs Medicare Part B bundled OUD treatment services payments. Covered services include FDA-approved oral, injected, and implanted opioid agonist and antagonist medication-assisted treatment medications (including methadone, buprenorphine, and naltrexone) and their administration (if applicable), substance use counseling, individual and group therapy, toxicology testing, intake, and periodic assessments. Opioid Treatment Programs (OTPs) Medicare Billing & Payment booklet and Opioid Treatment Program Directory have more information.

There are 3 add-on codes to cover the cost of Naloxone:

HCPCS Code G2215	Take-home supply of Nasal Naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure. (This will include both a drug component and a non-drug component for overdose education).
HCPCS Code G2216	Take-home supply of Injectable Naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
HCPCS Code G1028	**Beginning January 1, 2022, we cover HCPCS Code G1028:** Take-home supply of nasal Naloxone; 2-pack of 8mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

Note: Payment for HCPCS codes G1028, G2215, and G2216 is limited to once every 30 days unless an additional take home supply of the medication is medically reasonable and necessary.

After the conclusion of the COVID-19 Public Health Emergency (PHE), OTPs can furnish counseling and therapy services via audio-only interaction (for example, phone calls) in cases where audio and or video communication isn't available to the patient, including circumstances in which the patient isn't capable of or doesn't consent to using devices that permit a 2-way audio and or video interaction, provided all other applicable requirements are met.

There's no copayment for OTP services for people with Medicare.



Medicaid SBIRT

States may cover SBIRT as a Medicaid state plan service. Several Medicaid statutory authorities may cover SBIRT, including, but not limited to:

- 42 CFR 440.50: Physicians' services
- 42 CFR 440.60: Services of other licensed practitioners
- 42 CFR 440.130(c): Preventive services
- 42 CFR 440.130(d): Rehabilitative services

Section 1905(r) of the Social Security Act states the Early and Periodic, Screening, Diagnostic, and Treatment (EPSDT) benefit provides a comprehensive selection of eligible children's preventive, diagnostic, and treatment services if they're under age 21. Medicaid includes this mandatory benefit to make sure children get early detection and care to treat or avoid health problems.

States must arrange for children to get health screening services at regular intervals and diagnostic services when needed. They must also provide services or items within the Medicaid-covered benefits listed in section 1905(a) of the Social Security Act if that service or item is necessary and corrects or ameliorates defects and physical and mental illnesses or conditions.

A physician or other licensed practitioner of healing arts, within the scope of their practice under state law, must recommend preventive and rehabilitative services.

When state Medicaid plans cover SBIRT, the states establish which practitioners may provide services and their qualifications. Practitioner qualifications offering SUD treatment include, but aren't limited to those:

- Licensed or certified to perform SUD services by the state where they perform the services
- Qualified to perform specific SUD services
- Supervised by a licensed practitioner of healing arts (in some instances, when a qualified unlicensed professional provided the services)
- Working within their state scope-of-practice act

Documenting Medicaid SBIRT Services

You must comply with the state's Medicaid SBIRT documentation policy. You can often find the state's documentation policy in its Medicaid Provider Manual. Your state Medicaid agency has more documentation information.

Billing Medicaid SBIRT Services

If a state chooses to cover SBIRT under its Medicaid Program, the state may choose which codes to bill brief intervention services; for example, HCPCS codes:

HCPCS Code G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes	
HCPCS Code G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes	
HCPCS Code G0442	Annual alcohol misuse screening, 15 minutes	
HCPCS Code G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes	
HCPCS Code G0444	Annual depression screening, 15 minutes	
HCPCS Code H0049	Alcohol and/or drug screening	
HCPCS Code H0050	Alcohol and/or drug services, brief intervention, per 15 minutes	

Check with your state Medicaid agency about which billing codes to use.

Medicaid National Correct Coding Initiative (NCCI) Policy Manual, Chapter 12, Section C(16), available in the Medicaid NCCI Reference Documents webpage, has billing codes G0396 and G0397 with evaluation and management codes and behavioral health codes information.

Medicaid Telemedicine Includes SBIRT

If the state allows it, you may provide SBIRT via telemedicine.

Medicare Learning Network®

Dually Eligible Medicare-Medicaid Beneficiaries

For people enrolled in both Medicare and Medicaid Programs (dually eligible), Medicare-participating providers should bill Medicare and their Medicare Administrative Contractor (MAC) will transfer the claim to Medicaid after paying the Medicare-approved amount. Medicare providers must enroll in their state Medicaid Program(s) to get paid. States must accept the claim and decide if they'll pay the cost-sharing amounts.

States accept claims for all Medicare-covered services for certain dual eligible beneficiaries and pay cost-sharing amounts according to the state plan payment method.

Note: Nominal Medicaid cost sharing may apply for certain dually eligible beneficiaries. The state Medicaid Programs pay some cost sharing. However, you may not balance-bill dually eligible beneficiaries when Medicare and Medicaid payments fall below the approved Medicare rate.

Beneficiaries Dually Eligible for Medicare & Medicaid fact sheet has more information.

Find your MAC's website for more information.

Resources

- OTPs Medicare Enrollment
- Stopping the Misuse of Fentanyl and Other Synthetic Opioids

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Exhibit K

Baldwin's Ohio Administrative Code Annotated
4731 Medical Board (Refs & Annos)
Chapter 4731-11. Controlled Substances (Refs & Annos)

OAC 4731-11-14

4731-11-14 Prescribing for subacute and chronic pain

Currentness

(A) Prior to treating, or continuing to treat subacute or chronic pain with an opioid analgesic, the physician shall first consider and document non-medication and non-opioid treatment options.

(1) If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain and improve the patient's ability to function.

(2) The physician shall comply with the requirements of rule 4731-11-02 of the Administrative Code.

(B) Before prescribing an opioid analgesic for subacute or chronic pain, the physician shall complete or update and document in the patient record assessment activities to assure the appropriateness and safety of the medication including:

(1) History and physical examination including review of previous treatment and response to treatment, patient's adherence to medication and non-medication treatment, and screening for substance misuse or substance use disorder;

(2) Laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results. If evidence of substance misuse or substance use disorder exists, diagnostic testing shall include urine drug screening;

(3) Review the results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code;

(4) A functional pain assessment which includes the patient's ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and the physical activity of the patient;

(5) A treatment plan based upon the clinical information obtained, to include all of the following components:

(a) Diagnosis;

(b) Objective goals for treatment;

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(c) Rationale for the medication choice and dosage; and

(d) Planned duration of treatment and steps for further assessment and follow-up.

(6) Discussion with the patient or guardian regarding:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose; and

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

(7) The physician shall offer a prescription for naloxone to the patient receiving an opioid analgesic prescription under any of the following circumstances:

(a) The patient has a history of prior opioid overdose;

(b) The dosage prescribed exceeds a daily average of eighty MED or at lower doses if the patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodol, tramadol, or gabapentin; or

(c) The patient has a concurrent substance use disorder.

(C) Prior to increasing the opioid dosage to a daily average of fifty MED or greater the physician shall complete and document the following in the patient's medical record:

(1) The physician shall review and update the assessment completed in paragraph (B) of this rule, if needed. The physician may rely on an appropriate assessment completed within a reasonable time if the physician is satisfied that he or she may rely on that information for purposes of meeting the further requirements of this chapter of the Administrative Code;

(2) The physician shall update or formulate a new treatment plan, if needed;

(3) The physician shall obtain from the patient or the patient's guardian written informed consent which includes discussion of all of the following:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose.

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

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(4) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall document consideration of the following:

(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtaining a medication therapy management review by a pharmacist; and

(d) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted.

(5) The physician shall consider offering a prescription for naloxone to mitigate risk of overdose.

(D) Prior to increasing the opioid dosage to a daily average of eighty MED or greater, the physician shall complete all of the following:

(1) Enter into a written pain treatment agreement with the patient that outlines the physician's and patient's responsibilities during treatment and requires the patient or patient guardian's agreement to all of the following provisions:

(a) Permission for drug screening and release to speak with other practitioners concerning the patient's condition or treatment;

(b) Cooperation with pill counts or other checks designed to assure compliance with the treatment plan and to minimize the risk of misuse or diversion;

(c) The understanding that the patient shall only receive opioid medications from the physician treating the chronic pain unless there is written agreement among all of the prescribers of opioids outlining the responsibilities and boundaries of prescribing for the patient; and

(d) The understanding that the dosage may be tapered if not effective or if the patient does not abide by the treatment agreement.

(2) Offer a prescription for naloxone to the patient as described in paragraph (B) of this rule.

(3) Except when the patient was prescribed an average daily dosage that exceeded eighty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall obtain at least one of the following based upon the patient's clinical presentation:

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(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtain a medication therapy management review; or

(d) Consultation with a specialist in addiction medicine or addiction psychiatry if aberrant behavior indicating medication misuse or substance use disorder may be present.

(E) The physician shall not prescribe a dosage that exceeds an average of one hundred twenty MED per day. This prohibition shall not apply in the following circumstances:

(1) The physician holds board certification in pain medicine, board certification in hospice and palliative care, board certification in hematology, or board certification in oncology;

(2) The physician has received a written recommendation for a dosage exceeding an average of one hundred twenty MED per day from a board certified pain medicine physician or board certified hospice and palliative care physician who based the recommendation on a face-to-face visit and examination of the patient. The prescribing physician shall maintain the written recommendation in the patient's record; or

(3) The patient was receiving an average daily dose of one hundred twenty MED or more prior to the effective date of this rule. The physician shall follow the steps in paragraph (E)(2) of this rule prior to escalating the patient's dose.

(F) During the course of treatment with an opioid analgesic at doses below the average of fifty MED per day, the physician shall provide periodic follow-up assessment and documentation of the patient's functional status, the patient's progress toward treatment objectives, indicators of possible addiction, drug abuse or drug diversion and the notation of any adverse drug effects.

(G) During the course of treatment with an opioid analgesic at doses at or above the average of fifty MED per day, the physician shall complete and document in the patient record the following no less than every three months:

(1) Review of the course of treatment and the patient's response and adherence to treatment.

(2) The assessment shall include a review of any complications or exacerbation of the underlying condition causing the pain through appropriate interval history, physical examination, any appropriate diagnostic tests, and specific treatments to address the findings.

(3) The assessment of the patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities;

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(4) Rationale for continuing opioid treatment and nature of continued benefit, if present.

(5) The results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code.

(6) Screening for medication misuse or substance use disorder. Urine drug screen should be obtained based on clinical assessment of the physician with frequency based upon presence or absence of aberrant behaviors or other indications of addiction or drug abuse.

(7) Evaluation of other forms of treatment and the tapering of opioid medication if continued benefit cannot be established.

(H) This rule does not apply to the physician who prescribes an opioid in any of the following situations:

(1) The medication is for a patient in hospice care.

(2) The patient has terminal cancer or another terminal condition, as that term is defined in rule 4731-11-01 of the Administrative Code.

(I) This rule does not apply to inpatient prescriptions as defined in rule 4729-17-01 of the Administrative Code.

Credits

HISTORY: 2020-21 OMR pam. # 4 (A), eff. 10-31-20; 2018-19 OMR pam. # 6 (E), eff. 12-23-18.

Periodic review date(s): 12-23-23

Rules and appendices are current through April 15, 2022. Emergency rules are more current.

OAC 4731-11-14, OH ADC 4731-11-14

End of Document

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Exhibit L

THE STATE MEDICAL BOARD OF OHIO
DISCIPLINARY GUIDELINES

(Revised July 2019)

Disciplinary Guidelines are primarily for the Board's reference and guidance. They are subject to revision at the Board's discretion without notice to the public. Disciplinary Guidelines are intended to promote consistency in Board-imposed sanctions, but are not binding on the Board. The Board recognizes that individual matters present unique sets of circumstances which merit individual consideration by the Board.

CATEGORY I: IMPROPER PRESCRIBING, DISPENSING, OR ADMINISTERING OF DRUGS

A. Prescribing, dispensing, or administering of any drug for excessive periods of time and/or in excessive amounts.

Maximum Penalty: Permanent revocation of certificate or permanent denial of application

Minimum Penalty: Definite suspension, min. 90 days; discretionary probation as appropriate, to include prescribing course

B. (Reserved)

C. (Reserved)

D. Failing to keep patient records of substances prescribed, dispensed or administered; and/or failing to perform appropriate prior examination and/or failure to document in the patient record performance of appropriate prior examination.

Maximum Penalty: Permanent revocation of certificate or permanent denial of application

Minimum Penalty: Reprimand; discretionary probation as appropriate, to include medical-recordkeeping course

E. (Reserved)

F. Inappropriate purchasing, controlling, dispensing, and/or administering of any drug.

Maximum Penalty: Permanent revocation of certificate or permanent denial of application

Minimum Penalty: Definite suspension, min. 60 days; discretionary probation, as appropriate

Exhibit M

OHIO AUTOMATED RX REPORTING SYSTEM

PMP Awarxe™

Ohio PDMP AWARXE

User Support Manual

STATE OF OHIO BOARD OF PHARMACY

11.6 Clinical Application

In work-flow use

Narx Scores are intended to be delivered into workflow automatically as discrete data and be easily viewable within a patient's record. Many systems choose to place the scores in the patient header, or alongside the patient's vital signs.

Narx Scores are best viewed at the beginning of a patient encounter, as such they should be obtained at or near the time a patient is registered.

General Considerations

- The primary purpose of providing Narx Scores is to raise provider awareness to the associated PDMP data available for review.
- Concerning Narx Scores are intended to trigger a *discussion,* **not a decision**. If a Narx Score raises concern the recommended course of action is to evaluate the PDMP data, review any additional pertinent data, and discuss any concerns with the patient.
- Just as there is no single blood pressure that can be considered *normal* for all people, there is no Narx Score that is *normal*. A Narx Score must be applied to the clinical scenario before evaluating appropriateness. For example, a blood pressure of 120/80 can simultaneously be:
    - Inappropriate for a 2-month-old infant
    - Appropriate for a 20-year-old woman
    - Inappropriate for an elderly patient with an average daily blood pressure of 200/100
- Narx Scores are distributed within the PDMP population as follows:
    - 75% of patients score below 200
    - 5% of patients score above 500
    - 1% of patients score above 650
    -

Example Use Cases

Narx Scores can be used to great effect in certain clinical scenarios. Again, the recommended course of action is to seek additional information and discuss concerns with the patient.

Case A – An 17y/o male basketball player with other significant history presents with a severe ankle sprain. His Narx Scores are:

Narcotic	Sedative	Stimulant
000	000	000

Important consideration: If considered for an opioid due to the severity of injury, this may be the patient's first exposure to the effects of an opioid. Recommend thorough review of the risks and benefits with the patient and consideration of an informed consent process.

Case B – an 81 y/o female presents with decreased level of consciousness following a fall where she suffered a closed head injury. Her Narx Scores are:

Narcotic	Sedative	Stimulant
341	501	000

Important Consideration: Many elderly patients are on chronic opioids and benzodiazepines. The use of opioids and benzodiazepines for this patient may have contributed to her fall. The patient may be taking enough medication to develop anxiety seizures due to benzodiazepine withdrawal, complicating the medical picture.

Case C – A 36 y/o male patient with mild chronic back pain frequently treated with opioids presents for a medication refill. On review of the PDMP record the patient has been to 17 different prescribers in the last year. His Narx Scores are:

Narcotic	Sedative	Stimulant
671	240	000

Important Consideration: Many patients obtain medications through multiple different providers. This can be due to the patient being seen in a clinic that is staffed by different providers, or can be due to *access to care* issues requiring visits to urgent care centers or emergency departments.

Score Based Guidance

Score/Range	**Notes**	**Recommendations***
000	This may be the first prescription of this type for the patient.	Discuss risks/benefits of using a controlled substance. Consider informed consent.
010-200	Approximately 75% of scores fall in this range.	Review use patterns for unsafe conditions.
	Occasionally, patients in this score range have a remote history of high usage (> 1 year ago).	Discuss any concerns with patient. See guidance below

		If previously high usage exists with recent abstinence, consider risk/benefits of new prescriptions
201-650	Approximately 24% of scores fall in this range.	Review use patterns for unsafe conditions. Discuss any concerns with patient. See guidance below.
> 650	Approximately 1% of scores fall in this range. Some patient records may have a score in this range and *still be within prescriber expectations.* Many patient records include some level of multiple provider episodes, overlapping prescriptions, or elevated milligram equivalency.	Review use patterns for unsafe conditions. If multiple providers involved in unsafe prescribing discuss concern with patient and consider contacting other providers directly. If multiple pharmacies involved in unsafe prescribing discuss concern with patient and consider pharmacy lock-in program. If overlapping medications of same or different type, discuss concern with patient and consider taper to lower dose and/or discontinuation of potentiating medications. If patient has evidence of a substance use disorder, consider inpatient admit or referral for outpatient evaluation and treatment.

Exhibit N

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC

POLICY FOR THE RETENTION OF MEDICAL RECORDS

PURPOSE:

To provide standards for the retention of all documentation related to patient care within Comprehensive Pain Management Institute, LLC ("CPMI") and to ensure that medical records are current, detailed, and organized to allow effective patient care, maintain confidentiality, and facilitate quality review.

RESPONSIBILITY:

Physicians, Advanced Practice Providers ("APPs"), Nurses, Practice Administrators, Managers, and all other employees of CPMI.

POLICY:

All medical records shall be considered corporate assets of CPMI. CPMI will maintain an organized system of the retention of medical records. These records will be secure from loss, unauthorized access, unauthorized reproduction, corruption, damage or destruction. Medical records must be maintained and retained on an ongoing basis to ensure accuracy, detail, and organization. This policy shall provide for a process to ensure the ongoing creation, maintenance and storage of medical records as well as the archiving and/or purging of medical records and the data contained therein.

MEDICAL RECORDS:

Every physician and APP is aware of the need to maintain adequate medical records for each patients. Ohio, which also recognizes the need for adequate medical records, has passed statutes and rules regulating the content, retention and accessibility of medical records.

1. Patient medical records shall be made readily available for the provision of healthcare services and healthcare assessment.

2. CPMI shall ensure that medical records are stored and maintained to prevent the unauthorized access, use or disclosure and ensure confidentiality. CPMI shall store all medical records onsite in accordance with its HIPAA Plan and related policies. CPMI shall ensure that it has appropriate administrative, operational, and technical safeguards in place to prevent unauthorized use, disclosure, or access to medical records.

3. CPMI may store medical records offsite so long as the storage facility site is fully compliant with HIPAA and storage of medical record and other confidential information is within the facility's core business services.

4. The retention periods set forth in this policy are set to minimize storage expense and ensure compliance with state and federal law regarding record retention.

5. All medical records shall be destroyed in an appropriate manner consistent with this policy.

6. CPMI will keep all medical records for patients over the age for 21 years for a period of seven (7) years from the date of the last healthcare encounter.

7. CPMI will keep all medical records for unemancipated minors until 18 years of age plus seven (7) years after the last healthcare encounter.

8. Under no circumstances will any medical record be destroyed (1) before seven (7) years after the last healthcare encounter, or (2) in the event CPMI issues a hold on the destruction of patient medical records. In the event CPMI issues a hold on the destruction of patient medical records, CPMI shall not destroy patient medical records until the destruction hold has been lifted.

9. Records must be destroyed in a manner to ensure that they are no longer recognizable as records (e.g. shredding, pulverizing, etc.). CPMI will document the types and quantities of records destroyed as well as the date of destruction. Where feasible, CPMI will establish a record destruction schedule.

APPROVED _____ DATE _____

REVISIONS: _____
_____
_____
_____

Exhibit O



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Strategy to Combat Opioid Abuse, Misuse, and Overdose

A Framework Based on the Five Point Strategy

"The five-point HHS strategy to end the opioid crisis, unveiled under President Trump in 2017, uses the best science and evidence to directly address this public health emergency. Now, HHS is expanding the scope and improving the effectiveness of the strategy. The dedicated men and women of HHS will continue to support communities and families across America until, together, we have brought an end to this crisis."

SECRETARY OF HEALTH AND HUMAN SERVICES
ALEX M. AZAR II

"With this strategic framework, HHS is building upon the 5-point Strategy To Combat the Opioid Crisis using robust, scientific evidence as its foundation to set forth specific, concrete actions that can be taken by the Secretary and the agencies within HHS to end the worst public health crisis of our time."

ASSISTANT SECRETARY FOR HEALTH AND SENIOR ADVISOR FOR OPIOID POLICY
ADM BRETT P. GIROIR

BETTER ADDICTION PREVENTION, TREATMENT, AND RECOVERY SERVICES

Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid misuse and addiction, and to enable individuals to achieve long-term recovery.

Prevention

- Implement science-based education campaigns to improve the public's understanding of substance use disorders as well as evidence-based treatments and prevention strategies, and to eliminate stigma associated with the disease.
- Increase the use of digital and social media technologies to amplify public health messages regarding prevention.
- Increase and support the use of school- and community-based prevention programs that are evidence-based to prevent misuse of opioids and other substances.
- Engage community and faith-based organizations to use evidence-based messages on prevention, treatment, and recovery.
- Identify individuals who are at risk of opioid use disorder and make available prevention and early intervention services and other supportive services to minimize the potential for the development of opioid use disorder (OUD).
- Educate the public and healthcare professionals regarding drug-drug interactions between opioids and other medications, including the interactions between opioids and benzodiazepines, alcohol, and gabapentin.
    - Working with the Department of Justice (DOJ), and the United States Postal Service (USPS), improve technologies and processes to detect illegal imports and human trafficking of illicit opioids.
    - Facilitate proper disposal of unused opioid prescription medications and other prescription drugs such as benzodiazepines and gabapentin.

Treatment

- Enable individuals, families, and caregivers to find, access, and navigate evidence-based, affordable treatments for opioid use disorder and home and community-based services and social supports.
- Identify and disseminate best practices related to medication-assisted treatment (MAT) and companion psychosocial treatment such as coordinated, holistic, culturally appropriate, person- and family-centered treatment of OUD, including the utilization of a broad range of providers, ancillary professionals, and team-based care.
- Test and implement new payment models that facilitate and incentivize coordinated care, and build in incentives for adoption of payment models across programs.

- Support broader adoption of Assisted Outpatient Treatment and Assertive Community Treatment models and provide technical assistance to states and tribes.
- Increase the number of behavioral health providers knowledgeable about substance use disorders, including psychiatrists, primary care providers with specialized addiction training, peer recovery specialists, social workers, and others.
- Support stakeholder efforts to make a full range of MAT available on demand to all individuals with OUD who meet the eligibility criteria for the specific MAT therapy.
    - Increase the number of providers, including nurse practitioners, physicians, and physicians assistants who are able and willing to provide MAT.
    - Advance telehealth direct care and consultation approaches to MAT.
    - Target workforce development, provider training, and recruitment incentives to underserved areas.
    - Advance innovative service delivery models that can address documented barriers to provider willingness to provide MAT.
    - Pursue a framework and work across different payers to reduce and remove coverage limitations on MAT.
- Track, screen, prevent, and refer to treatment patients with OUD and substance use disorder (SUD) who have infectious complications, including HIV, viral hepatitis, and endocarditis, particularly among persons who inject drugs. This can be done through Syringe Services Programs (SSPs) and other evidence-based strategies.
- Enable family-centered treatment that endeavors to keep families and caregivers together in their homes and communities, including utilizing out of home care only when in the best interest of the child.
- Provide support for pregnant and postpartum women to enter and adhere to family-centered OUD treatment, reduce the risk of relapse, and prevent, and reduce and manage medical complications in the newborn and other children, using approaches that minimize stigma and other barriers to care, and to support the long-term recovery of the women.
- In partnership with professional organizations, develop and implement a comprehensive educational plan for physicians, advanced practice nurses, pharmacists, and other healthcare professionals and providers in training, to improve the national professional expertise in the identification and treatment of addiction as well as safe pain management, treatment, and recovery.
- Enhance communication and formal feedback from state, tribal, and local providers, officials, and other stakeholders to continually improve federal funding, programs, and services.
- Work with states to address the complex challenges of those at risk of, or suffering from, SUD through Medicaid flexibilities as well as novel payment models for integrated care.

Recovery

- Provide culturally and linguistically appropriate education and support to individuals, families, and caregivers to understand the importance of recovery and to find and access a range of evidence-based services.

- Identify innovative ways to expand and fund recovery services as part of a continuum of services to support stable and long-term recovery.
- Support the development of recovery communities, recovery coaches, and recovery community organizations to expand the availability of and access to recovery support services.
- Enhance discharge coordination for people leaving inpatient treatment facilities who require linkages to home and community-based services and social supports, including case management, housing, employment, food assistance, transportation, medical and behavioral health services, faith-based organizations, and sober/transitional living facilities.
- Enhance the ability to provide MAT and transition of care for people exiting the criminal justice system, and in particular following incarceration.
- Expand peer workforce and programming as interventionists in various settings, including hospitals, emergency departments, law enforcement departments, jails, OUD treatment programs, and in the community.
- Strengthen the education process demonstrating the value of peer and recovery supports through Recovery Community Centers and other recovery oriented systems and services.
- Increase collaboration with law enforcement and first responders to enhance their capability of responding to and/or providing emergency treatment to those with OUD.
- Develop best practices, such as toolkits, guidelines and policy briefs, on the development of recovery housing that meets the needs of those with OUDs who may or may not be on MAT.

BETTER DATA

Strengthen public health data reporting and collection to improve the timeliness and specificity of data, and to inform a real-time public health response as the epidemic evolves.

- Collect and disseminate as close to “real-time” as possible, actionable data that can be used to target interventions, deployment of resources locally and regionally, and to assess impacts of federal, state, and local efforts.
- Enhance the speed of data collection and publication of results from HHS surveys on illicit drug use and abuse.
- Work with the Drug Enforcement Administration (DEA) and the U.S. Customs and Border Protection (CBP) to collect data about, and compile periodic and timely reports of, illicit drug seizures.
- Collect data that indicate durable outcomes, such as opioid deaths and non-fatal overdoses; as well as surrogate outcome markers, such as opioid prescriptions, new drug patterns, related harms, patients receiving MAT, and Neonatal Abstinence Syndrome (NAS) incidence, with minimal lag time in order to modify, expand, or change federal strategies to meet the ongoing needs.

- Collect, analyze, and disseminate data that provide insights into causes, risk and protective factors, comorbidities, and disparities of opioid misuse and other substance use, misuse, and addiction that can be used to devise long term solutions to the underlying causes and drivers.
- Collect state-, county-, and zip-code specific data when feasible.
- Improve linkages between disparate data systems, including among HHS operating divisions, to inform interventions as well as analytics and modeling.
- Effectively communicate the meaning of the data and its implications within HHS and externally.
- Conduct a comprehensive assessment of current data and key metrics, and implement strategies to address gaps and identify policy and research questions.
- Create incentives for states to develop, implement, and utilize Prescription Drug Monitoring Programs (PDMP) that are accessible by providers (prescribers and pharmacies) across state lines and integrated into the electronic health record.

BETTER PAIN MANAGEMENT

Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

- Provide prescribers with actionable information on the appropriate use of opioids and other pain treatment modalities, such as the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, which also ensure patients pain management needs are met.
- Develop evidence-based guidance on appropriate management of acute pain including non-opioid approaches and, when appropriate, short-term opioid management.
- Develop further evidence-based guidance on the management of chronic pain, including non-opioid approaches, pre/peri-operative treatment, and when appropriate, opioid management.
- Develop payment policies and other incentives to encourage best practices for the appropriate prescribing of opioids and the use of a full range of non-opioid pain treatments.
- Develop regulatory strategies, guidance, and policies to promote the appropriate use of opioids, including professional and patient labeling, and packaging at the time of marketing approval and in the post-marketing period.
- Assist states to monitor and support best practices by providers, including through the use of comprehensive prescription drug monitoring programs, other data integration mechanisms across states, and clinical decision support in electronic health records.
- Encourage the use of multidisciplinary team models for the management of pain.

- Promote best practices for safe and well-tolerated opioid tapering for people on potentially excessive and unsafe doses, based on established guidelines.
- Work with healthcare professional stakeholders to develop guidance on screening and treatment for co-occurring mental and substance use disorders and unresolved trauma in people living with chronic pain.
- Educate and empower patients, families, caregivers, and communities to understand the risks and benefits of opioid pain medication and non-opioid mechanisms to manage both acute and chronic pain.
- Work with healthcare professional stakeholders to develop guidance for prescribers of when to refer to or link to treatment for OUDs.
- Identify individuals who are at risk of developing chronic pain after an acute pain episode, and make available mental health, substance use, and other supportive services to minimize the potential for the development of chronic or persistent pain.

BETTER TARGETING OF OVERDOSE REVERSING DRUGS

Target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations.

- Develop models to estimate the amount of naloxone required by communities to be able to reverse cases of opioid overdose.
- Explore development of over the counter naloxone, including an assessment of its impact on availability of naloxone in the community.
- Ensure widespread availability of naloxone, including through standing orders, co-prescription with other opioids, collaborative practice agreements, pharmacist prescriptive authority, targeting of high-risk populations such as people leaving incarceration, residential treatment, and recent opioid-related emergency department visits and hospitalizations.
- Expand availability and affordability of naloxone through grants, including grants to first responders, and the approval of generic products.
- Strengthen education and training on overdose prevention and naloxone administration to ensure that individuals likely to respond to an overdose can take the appropriate steps to reverse an overdose. Develop and assess intervention models across settings that leverage the overdose reversal as a bridge to treatment to reduce long-term dependence on naloxone as the only form of addressing harmful opioid use.

BETTER RESEARCH

Support cutting-edge research that advances our understanding of pain, overdose and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms.

- Support and evaluate novel integrated treatment delivery demonstration projects to bring together all HHS and other entities, including the criminal justice system, in regional projects with short-term and long-term objectives.
- Support the development of non-pharmacologic, non-opioid and/or non-addictive pain therapeutics.
- Support the development of novel opioid antagonists to combat highly potent synthetic opioids, including new antagonists with longer duration of action.
- Support development and evaluation of immunotherapies including vaccines against select opioids.
- Determine risk factors, including genomic, metabolomics, prenatal substance exposure, work history, social, behavioral, and psychological factors for SUD, OUD, and identify how these factors may affect responses to treatment. Explore the development of "personalized treatment" based on these factors to maximize efficacy.
- Develop technologies and systems to alert potential naloxone providers, such as family members, emergency medical services personnel, and others when a person is at imminent risk of overdose death.
- Assess current treatments and develop new treatments, including non-pharmacological treatments, for NAS, as well as appropriate care for all infants with sustained prenatal opioid exposure.
- Improve research and disseminate findings on safe and effective treatment for OUD during pregnancy, including the risks and benefits of pharmacotherapy to both the mother and infant.
- Develop longitudinal data systems to assess the ongoing potential developmental, social, educational, physical, and other disabilities of infants born to mothers with SUD, with a focus on infants with NAS.
- Expand service delivery and intervention implementation research and service delivery innovations in order to identify how best to quickly incorporate scientific advances into community and clinical practice.
- Utilize community based participatory research strategies when evaluating data in diverse communities including tribal communities.

Exhibit P

---------- Forwarded message ----------
From: **David Deppen** <ddeppen@practice-pro.net>
Date: 2013-03-11 11:39 GMT-04:00
Subject: RE: needle EMG coding
To: Leon Margolin <leon3087@gmail.com>

Here are the codes and the Utilization guidelines right from Medicare's policy for EMG and NCS:

95885: Needle electromyography, each extremity; done with nerve conduction study, limited
95886: Needle electromyography, each extremity; done with nerve conduction study, complete, 5 or more muscles studied, innervated by three or more nerves or four or more spinal levels

Utilization Guidelines
Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.

The number of nerves tested should be the minimum necessary to address the clinical issue being evaluated. In almost all studies this will appropriately include evaluation of 1 or more nerves that have normal test results.

The following bullets summarize the reasonable maximum number of studies per diagnostic category necessary for a physician to arrive at a diagnosis in 90% of patients with that final diagnosis. In simple straightforward cases, fewer tests will be necessary, particularly when the most critical tests are normal. In the small number of cases that require testing in excess of these numbers, the physician must be able to justify the additional testing with supplementary documentation.

Carpal Tunnel (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests

Carpal Tunnel (bilateral)
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95909 Sensory NCS – 6 tests

Radiculopathy
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95907 Sensory NCS – 2 tests
· CPT codes 95907 H-Reflex – 2 tests

Mononeuropathy
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 3 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Polyneuropathy/Mononeuropathy Multiplex
· Needle EMG - 3 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Myopathy
· Needle EMG - 2 tests
· CPT codes 95907 Motor NCS with or w/o F-wave – 2 tests
· CPT code 95907 Sensory NCS – 2 tests

Motor Neuronopathy
· Needle EMG - 4 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95907 Sensory NCS – 2 tests

Plexopathy
· Needle EMG - 2 tests
· CPT codes 95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95909 Sensory NCS – 6 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Neuromuscular Junction
· Needle EMG - 2 tests
· CPT codes 95907 Motor NCS with or w/o F-wave – 2 tests
· CPT code 95907 Sensory NCS – 2 tests

Tarsal Tunnel (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests

Tarsal Tunnel (bilateral)
· Needle EMG - 2 tests
· CPT codes 95908/95909 Motor NCS with or w/o F-wave – 5 tests
· CPT code 95909 Sensory NCS – 6 tests

Weakness, Fatigue, Cramps or Twitching (focal)
· Needle EMG - 2 tests
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests

Weakness, Fatigue, Cramps or Twitching (general)
· Needle EMG - 4 tests
· CPT codes 95907/95908Motor NCS with or w/o F-wave – 4 tests
· CPT code 95908 Sensory NCS – 4 tests

Pain, Numbness or Tingling (unilateral)
· Needle EMG - 1 test
· CPT codes 95907/95908 Motor NCS with or w/o F-wave – 3 tests
· CPT code 95908 Sensory NCS – 4 tests
· CPT codes 95934/95936 H-Reflex – 2 tests

Exhibit Q



PRACTICEPRO

4494 Derr Rd
Springfield, OH 45503-1445

Caresource
Special Investigations Unit
PO Box 1940
Dayton, Ohio 45401

Ms. Katherine M Leff,

We are the billing company for Dr. Leon Margolin and his medical practice, Comprehensive Pain Management Institute, LLC. We are a pain management specific billing company that has over 30 years of experience billing every aspect of pain management services.

Dr. Margolin made us aware of the current investigation by Caresouce concerning the CPT code 95912. This code is defined in the 2017 CPT Manual as: Nerve Conduction Studies, 11-12 studies. Based on the testing that is done, this would be the correct code to bill for Dr. Margolin.

Caresource has a very complex automated claims review system in place to verify that billing that does not meet medical policy denies upon receipt. At no time during the almost 4 year period in question did Caresource ever deny this billing as not meeting medical policy. As a billing company we find that most often the Caresource system will deny claims in error for not meeting medical policy when in fact they do. We know that this is a system in place to prevent items from being paid that should not, but in this circumstance there was never a time that these claims were denied by Caresource.

The information sent to us states that 30 records were reviewed and due to a 100% error rate on your findings, there is a request for all reimbursement to be refunded for this code. Based on our review of the almost 2000 charts, we have found that there are hundreds of patients on the list that did have a needle EMG study done or were tested for diagnoses such as carpal tunnel or neck pain that includes carpal tunnel evaluation. The list of the patients does not seem to support the conclusions of the letter. Reviewing 2% of the charts would not give you enough data to request a refund from almost 2000 patients.

In conclusion, we see that Dr. Margolin billed the proper correct code for the testing he performs in office. Caresource's automated claims review system at no time denied these claims as being not medically necessary based on medical policy. Caresource reviewed a very small amount of the total charts billed for this investigation.

David Deppen
Billing Manager
Practice-Pro, LLC

Exhibit R

PRACTICESHIELDS

October 14, 2019

To whom it may concern:

I am a former police detective, former State of Ohio Medical Board Investigator, former Director of Compliance for Cincinnati Pain Physicians, CME trainer, healthcare regulatory expert witness, and healthcare regulatory consultant. (See attached CV) As a healthcare regulatory consultant, I only assist clients that demonstrate a lack of criminal intent.

On September 12, 2019, I conducted an extensive independent review and audit of Dr. Margolin's pain management practice located at 5245 E. Main St. in Columbus, OH. Dr. Margolin is one only a few pain physicians in Ohio that is double specialty boarded in pain. Dr. Margolin has dedicated his life and education to learning the newest and most advanced methods to treat his pain patients in a medically sound, regulatory compliant, and patient focused manner.

The practice review and audit included a review of medical records for regulatory compliance and standards of care, general practice and patient observations, staff observations with patient interactions, policy and procedure reviews, and State of Ohio Pain Management License practice compliance inspection.

I can testify to the high level of compliance demonstrated by Dr. Margolin's medical practice in regards to the State of Ohio Pain Clinic (PMC) license requirements, Ohio's Revised and Administrative Codes, and exceeding minimum standards of care (The standard in which all pain practices should be operated).

Dr. Margolin not only complies with all state requirements and standards of care, Dr. Margolin had already implemented several of the recommendations listed in HHS Pain Management Best Practices Inter-Agency Task Force Final Report. Examples of compliance- Page 17- Clinical Best Practices lays the ground work for quality and complaint patient care. Patients must be thoroughly evaluated including the medical and probable biopsychosocial factors contributing to a pain condition. Dr. Margolin utilizes EMG and NCV studies to determine the medical factors contributing to their pain condition. Clinical best practices goes on to emphasize the importance of screening for Substance Use Disorder and in the second paragraph states "Finally, quality care must be adequately reimbursed." Dr. Margolin screens all patients for substance use disorder because not only is it recommended and required by best practices and state law, it is the safer for the patient, their family, and the community. Page 30- 2.2.1 Overdose Prevention Education and Overdose Risk. Dr. Margolin educates his patients on the dangers of opioids

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not only in person, but also in their opiate agreement, and other patient forms every patient visit as part of their assessment. Dr. Margolin offers Naloxone prescriptions to his patients as well. Pages 39-40 sections 2.5.1 and 2.5.2 go only to further list and justify SUD screening and psychological evaluation and treatment. Dr. Margolin has long practiced these recommendations even before the expert report was completed. These examples only highlight a few ways that Dr. Margolin's polices and procedures were above compliant from the start. The report actually models Dr. Margolin's current pain practice and compliments his compliance.

I would like to mentioned the State of Ohio Pain Clinic (PMC) license requirement to document organic pathology prior to prescribing opioid medications. Dr. Margolin fulfills this requirements by obtaining records, imaging reports and performing electro diagnostic studies (EMG and NCV) that provide immediate objective results that document organic pathology.

Dr. Margolin made compliance with the state and national guidelines a high priority. Dr. Margolin contacted AANEM and received a written response from Millie Suk, JD, MPP I AANEM Health Policy Director stating that "AANEM does not have any "best practices" established for pain management" and that AANEM endorses AAPMR policies. Dr. Margolin contacted AAPMR and its certifying body ABPMR and performed a voluntary practice improvement project under ABPMR guidance that showed a high level of compliance with the state and national guidelines, clear medical necessity and significant impact on patient care. This project received high reviews from the experts Dr. Wainepal and Dr. Kimura.

I would also like to mention Dr. Margolin's SBIRT protocol that is very thorough, efficient and compliant with the MLN (ICN 904084) (MLN requires physician to implement SBIRT as required by the state law (42CFR 410.20), the State of Ohio Pain Clinic (PMC) license requirements and HB 93 state law.

Dr. Margolin's practice treats high risk vulnerable patients that frequently require 30 min or more for procedures related to screening for substance use and alcohol. These procedures include face to face time spent by Dr. Margolin and his nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS review (of note Dr. Margolin's practice obtains OARRS for every patient visit which is the highest level of compliance with the SMBO policy and HB-93 law), and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

His SBIRT records document the time spent, rationale for ordering tests (i.e. urine screens), relevant history, assessment, plan of care for each encounter. Dr. Margolin identifies and manages the risk factors very efficiently (of note frequent consultation with a qualified pain psychologist, pharmacology doctors and other specialists).

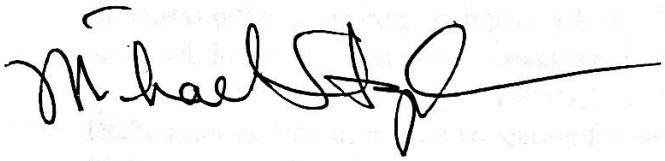
Dr. Margolin's excellence in implementation of the SBIRT protocol as related to screening for substance use and alcohol is evident by the high number of referrals from major hospitals such as OSU, Riverside, Grant, Adena Health and University Hospitals in Cleveland and even other pain management practices. It's my understanding is that Dr. Margolin is going to present his experience in this field at the State and national meetings and educational events.

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Finally, it should be noted that Dr. Margolin's office only sees an average of 15 patients per provider per day. This average patient number is extremely low compared to his peers that see upwards of 40-50 patients a day and does not indicate a physician that is interested more in profit than patient care.

If you have any questions or would like additional information, feel free to contact me on my cell at (513) 464-6721 or via email: Michael.Staples@practiceshields.com

Regards,



Michael Staples, CMBI

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MICHAEL W. STAPLES, CMBI
(513) 464-6721 • Michael.Staples@practiceshields.com

Director of Compliance
Regulatory and Legal Heath Care Compliance

Over 20 years' experience in criminal investigations, regulatory license investigations, scope of medical practice investigations, health care regulatory and legal compliance, management, conflict resolution, drug diversion investigations, and drug diversion education.

Demonstrated success record in:

- Successful investigation and prosecution of licensed health care professionals.
- Successful investigation and administrative action of licensed health care professionals for standards of care and administrative violations.
- Successful investigation and prosecution of criminal drug diverters.
- Experienced with identifying, preventing, and deterring health care drug diversion.
- Dedication to drug diversion education for health care professionals.
- Proven record of regulatory compliance excellence.

CORE COMPETENCIES

• Criminal/Administrative Investigations • Regulatory Compliance • Public Speaking
• Drug Diversion Education • Drug Diversion Investigations • Safe Prescribing Practices

HIGHLIGHTED CAREER ACHIEVEMENTS

- 2+ years' experience as Director of Compliance for a large pain management office.
- 9+ years' experience as a Police Detective focusing on Criminal Drug Crimes.
- 9+ years' experience as a Medical Board Enforcement Investigator focusing on Controlled Substance Prescribing Investigations, prescriber education, scope of practice and minimum standards of care investigations.
- Earned National recognition as a Certified Medical Board Investigator "C.M.B.I." from the National Federation of Medical Boards.
- Staples, M & Practice Shields, LLC. "Comprehensive Controlled Substance Prescribing in the age of increased regulations, legal challenges, and diversion." Presented in conjunction with West Virginia Interventional Pain Physicians accredited with Commendation from the West Virginia State Medical Association for 17.25 Category 1 CME. February, 2019
- Staples, M & Practice Shields, LLC. "Comprehensive Controlled Substance Prescribing in the age of increased regulations, legal challenges, and diversion." Presented in conjunction with Tri Health Hospital for 15 Category 1 CME. February, 2019
- Staples, M. & Harding, K "APRNs and Schedule II Prescribing in Ohio." Presented in Conjunction with the Ohio Board of Nursing. Available for 6 Hours of Continuing Education Credit. Ohio Board of Nursing, Columbus, Ohio. March 31, 2014.
- Staples, M., Harding, K, & Galante, C. "APRNs and Schedule II Prescribing in Ohio." Presented in Conjunction with the Ohio Board of Nursing and Ohio State Board of Pharmacy.

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Available for 6 Hours of Continuing Education Credit. Ohio Board of Nursing, Columbus, Ohio. November 25, 2013.

- Staples, M. "It Takes an Office: Protecting your Practice from Drug Diversion." Mercy Health Systems CME, June 15, 2015. https://youtu.be/tiFrhirb93M
- Former Director of Education and Training for Ohio Chapter of NADDI.
- Certified as a National Certified Investigator and Inspector Training (NCIT) both basic and specialized. Known as CLEAR Certification.
- Expert Report Admitted Cuyahoga County Common Pleas Court, State of Ohio, Case- CR-16-607224A-D State of Ohio vs. Rogaciano Trocio, MD, Maria Siwik, RN, Virginia Paulino, and Janet Paulino

PROFESSIONAL EXPERIENCE

Interventional Pain Specialists, Inc, 2019-Present
Crestview Hills, Kentucky
Compliance Officer

Regulatory and Legal Compliance Management
HIPPA Compliance Office
Medical Records Review
Staff Education
Policy and Procedure Implementation
Drug Diversion Reduction
Standards of Care Reviews

Cincinnati Pain Physicians, LLC, 2017 – 2019
Cincinnati, Ohio
Director of Compliance

- Regulatory and Legal Compliance Management
- Identification of Drug Diversion in patient population
- Policy and Procedure Implementation
- Medical Record's Review
- Staff education
  Prevention of Drug Diversion in practice
- Standards of Care Reviews

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Practice Shields, LLC
Fairfield, Ohio 2017 – 2018
Founder and Owner

- Dedication to ensuring regulatory compliance for health care practices and prescribers
- Health Care Practice and Prescriber Education
- D.R.A.P. Accreditation Program (Drug Resistant Accredited Practice)
- Practice compliance audits
- Expert Testimony
- Standards of Care Reviews
- Practice Drug Diversion Defense Techniques

State Medical Board of Ohio, 2007 – 2017
Columbus, Ohio
Enforcement Investigator

- Investigations of Ohio Regulatory Rules and Laws
- Standards of Care Investigations
- Testimony at Federal, State, Local, and Administrative Hearings
- Prescriber Controlled Substance Education
- Drug Diversion Investigations
- CME Diversion program development and implementation
- Member of drug abuse and diversion task forces

City of Monroe Police Department, 1998 – 2007
Monroe, Ohio
Police Detective

- Criminal Drug Investigations
- Warren County Drug Task Force Participant
- Federal, State, and Local Court Testimony
- CVSA Lie Detection Operator
- Butler County Child Abuse Task Force Member
- Established a strict reporting system for allegations of stolen controlled medications

EDUCATION and CERTIFICATION

Certified Medical Board Investigator (CMBI)
Basic and Specialized CLEAR Certification
OSU-Newark, Criminal Justice
Central Ohio Technical College, Criminal Justice
UC-Clermont Pre-Law
1995 Butler Tech Police Academy, Police Certification 1998

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Exhibit S

October 18, 2020

To Whom It May Concern,

I am a certified coder and medical auditor through the AAPC I have been a medical coder since 2012 with five years of auditing experience. Please see my review enclosed.

Compliance in the health care industry is the process of meeting regulations, recommendations, and expectations of Federal and State agencies that pay for health care services and regulate the industry. This summary of findings is given to assist in identifying any problem areas. I reviewed in depth all reports for the patient examples used in the SBIRT article Margolin, L. "Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients." Journal of Diabetes and Treatment Volume 5, Issue 01. I reviewed EMG reports for all patients (see enclosed item for patient list 2) I also reviewed in depth all patient records for NARX score analysis. (see enclosed item for patient list 3)

All findings and recommendations are based on standards for billing and coding, regulatory standards: CPT/American Medical Association - Professional Edition, ICD-9-CM/ICD-10-CM, Optum Professional, Office of Inspector General references (www.oig.gov), Guidelines for Ethical Behavior Relating to Clinical Practice Issues in Neuromuscular and Electrodiagnostic Medicine, www.cgsmedicare.com, MLN /Local coverage determination L36029 controlled substance monitoring and drugs of abuse testing. www.aafp.org, and American Academy of Professional Coders Medical Auditing (www.aapc.com). 1995 guidelines were used in this audit and the Marshfield audit tool was applied to level the visit.

Target codes for review included SBIRT (Screening and Brief Intervention) protocol for management of high-risk patients. Services for SBIRT include but are not limited to HCPCS and CPT medical codes, G0396, G0397/ 99408,99409 Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g, AUDIT,DAST) and brief intervention based on time, OARRS, Urine drug testing 80305-80307/G0434. Nerve conduction studies 95907-95913, Autonomic studies 95923, 95924, 93922 and 93040 which are diagnostic test and minimally invasive procedures such as 76942, 64450, 64418, 64405, 64425. 20533 (injections and needle placement) which are services that help patients with chronic pain to improve functionality and reduce pain.

A focus on G0396 and G0397 for compliance and reimbursement was assessed. CSM introduced two G codes in 2008 for specific use for assessment and intervention services. CMS Pub 100-04 Medicare Claims Processing. Transmittal 1423 states,

"Instead, we have created two parallel G-codes to allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not provided as screening services, but that are performed in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST) and brief intervention, 15 to 30 minutes) and HCPCS code G0397 (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST) and intervention greater than 30 minutes). Contractors shall consider payment for HCPCS codes G0396

and G0397 only when appropriate, reasonable and necessary (i.e., when the service is provided to evaluate patients with signs/symptoms of illness or injury) as per section 1862(a)(1)(A) of the Act."

The provider can utilize these codes in treating patients, when appropriate, reasonable and necessary and that patients should have signs and symptoms of illness. This is based on assessments, testing, reviewing risk factors, NARX scores and behavioral patterns,

Local coverage determination L36029 states, A physician who is writing prescriptions for medication to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of SUD or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general." Dr. Margolin's practice established the SBIRT protocol standard of testing to correspond with NARX score (the analysis of the patient risk) that are also in line with the local coverage determination, that states, "Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical assessment." Rational for testing patients are determined by the length of abstinence, from 1 test per week for patients with 0-30 consecutive days of abstinence, 1-3 tests per month for abstinence of 31-90 days and 1-3 test in three months for patients that are greater than 90 days of abstinence. I agree with Dr. Margolin's use of L36029 for SBIRT /G codes as described in this article as recommended by ICN MLN904084.

The determination also states that medical necessity is established on "patient-specific elements identified during clinical assessment." This happens through the patient's evaluation and management visit, the medical decision-making process that includes reviewing tests, consulting with other health providers, establishing a treatment plan, and medication management and the OARRS report. This is based on an individual's needs.

Nerve conduction studies 95910-95913, autonomic studies 95923, 95924, 93922 and ECG 93040 are diagnostic studies that help detect illnesses associated with nerve functionality. Many patients on chronic opioid therapy have chronic pain conditions such as chronic nerve pain (neuropathy) or sciatic nerve problems, musculoskeletal diseases, auto-immune diseases and other conditions. Patients that are in chronic pain turn to use of illicit pain medicines. These conditions can be a result of alcoholism and drug abuse. Autonomic studies are a collection of motor, sensory and autonomic data. Dr. Margolin uses this tool to help determine sources of pain, and to see if the autonomic nervous system is affected. This could affect internal functions such as blood pressure, heart rate, sweating, Guidelines for clinical practice of neuromuscular and electrodiagnostic studies is standardized by AANEM

Each patient in the article was examined in depth for compliant documentation standards, comprising of risk stratification, informed consent, diagnostic studies, additional records and treatment, as well as medical necessity which is the overarching criterion for treatment of a patient. Each chart was reviewed in detail for completeness of evaluation and management, including history, physical exam, labs, mental screenings, EMGs, pain assessment, NARX score, counseling and educational materials. Charts that included EMGs had informed consents and appear to be compliant and follow national standards and guidelines.

The cost to treat chronic pain patients is high. Dr. Margolin is combating the conflict between state and federal regulations that provide guidelines for treatment of these patients and payer denial of the

services (G codes) that put patients at higher risks. I would like to acknowledge the depth of assessment and documentation that Dr. Margolin submits establishing medical necessity for treatment of his patients. Quality patient care is the highest standard. The SBIRT protocol exemplifies this standard and is compliant, detailed, and methodical.

Finally, Dr. Margolin's utilization of the above codes appear to be applied correctly regarding billing and coding guidelines and abide by the standards of use as set in local coverage determinations through Medicare. I believe their use is innovative and cost effective for the payer and patient while still providing quality care. Good documentation is necessary for continuity of care. This is a top priority to Dr. Margolin and is evident in the high level of records that is kept for each patient. This along with his rationale and medical decision-making, support the use of the codes billed for reimbursement.

Please feel free to reach out to me with any questions or concerns. You may reach me at tleslie@mdbillingky.com.

Sincerely,

Tina Leslie

Tina Leslie CPC, CPMA, CEMC, CEDC, CHTS-TR,
tleslie@mdbillingky.com

Enclosures (2)

1. Copy of patient list 1 and list 2
2. Copy of patient list 3 NARX scores
3. Copy of the SBIRT article Margolin, L. "Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients." Journal of Diabetes and Treatment Volume 5, Issue 01

Exhibit T

William H. Vasilakis, Psy.D.

130 Tarkiln Road
Lancaster, OH 43130
1-740-503-5455

PROFESSIONAL EXPERIENCE

Hocking Valley Community Hospital
Logan Ohio
Work with geriatric population, counsel veterans and perform Gastric Bypass evaluation, pain management evaluations. Current

Apex Counseling
Ph: 614-751-1090
General counseling, psychological testing, forensic evaluations and custody evaluations, Pain management (Spinal Stimulator Evaluations), Work with LHI (Logistics Health Institution) evaluating candidates for military service. Current

Integrity Psychological Counseling, Inc 2005-2012
42 Hill Road South Pickerington, Oh 43137
Private Practice specializing in forensic evaluation, dual diagnosis, addictions, counseling, competency evaluations, psychological evaluations, Impaneled with Tricare for referrals with current service personal and veterans PTSD diagnosis and counseling with veterans of WWII, Vietnam, Desert Storm Legal work for Fairfield County Court System.
Bariatric & Gastric Bypass Evaluation, Spinal Stimulator Exams

Senior Life Consultants 2006-2011
6465 Reflections Drive, Suite 110
Dublin, OH 43017
Nursing Home evaluations, counseling geriatric population, consultation with physicians competency evaluations

Circleville Juvenile Correctional Facility 2006 - 2007
640 Island Road Circleville OH 43113
Clinical Experience: Psychology Supervisor.
Responsible for program development, scheduling, supervision of staff and caseloads, overall clinical management of institution, responsible for QI implementation and testing, and supervision of units.

River Valley Counseling 2001 - 2005
131 N. Ewing Street, Lancaster, OH 43130
Clinical Experience: Adult and adolescent individual and family psychotherapy, specialize in dual diagnoses; bariatric evaluations, spinal stimulator evaluations and evaluations for rehab, assessments for work injuries. BWC evaluations

Fairfield Medical Center 2001 -2012

401 North Ewing Street, Lancaster, OH 43130
Affiliate Staff Psychologist: Consultations, evaluations, therapy and triage of patients admitted to the Behavioral Health Unit.

Drug & Alcohol Recovery Center of Fairfield County 2000 -2001
1856 Cedar Hill Road, Lancaster, 01143130
Clinical Experience: Clinical Director: Responsible for program development, supervision of staff caseloads, crisis work, responsible for Q.I. implementation, and overall clinical management of agency.

Maryville Academy City of Youth 1996 - 1999
1150 North River Road, Des Plaines, Illinois 60016

Clinical Experience: Caseload involved assignment to two diagnostic group homes with youth and adolescents ages 7 years to 18 years. Tasks included psychological testing, individual therapy, develop group therapy for both group homes, court appearances on behalf of the youth, and staff training, and recommended alternate and additional placement and crisis intervention.
Doctoral Internship Jan. 1995 to Jan. 1996

Alexian Brothers Medical Center-Niehoff Mental Health Unit
995 Beisner Road, Elk Grove, Illinois 60007
Supervisor John Noto, PH.D.
Clinical Experience: Psychological testing, psychological reports, individual assessments, diagnosis, in-patient admissions, case management, supervision of practicum students, led groups for substance abuse and dual-diagnosis.

Samaritan House-Outpatient Adolescent Addictions 1994 - 1994
999A Leichester Road, Elk Grove, Illinois 60007
Supervisor: John Noto, Ph.D.
Clinical experience: Led adolescent addiction therapy groups, parent education groups, psychological testing, led multi-family educational groups, drug screens.

Alexian Brothers Medical Center-Addictions Treatment Center. 1993 - 1993
800 Beisterfield Road, Elk Grove, Illinois 60007
Supervisor Joan Stiech, RN CSADC
Clinical Experience: Coed psychotherapy groups, individual therapy, drug screens, intake und admissions, lecturer in addiction lectures series.

EDUCATIONAL BACKGROUND:

CHICAGO SCHOOL OF PROFESSIONAL PSYCHOLOGY 2009- 2009
Degree Conferred: Certificate of Forensic Psychology

ADLER SCHOOL OF PROFESSIONAL PSYCHOLOGY

65 East Wacker, Chicago, Illinois 60601
Degree Conferred: Doctor of Psychology, (Psy.D.) Clinical Psychology 1991 - 1996
Certification : Substance Abuse Counseling

NORTHEASTERN ILLINOIS UN1VERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: M.A. Community & Family Counseling Sep. 1984 to Oct. 1986
Degree Conferred: M.A. History Jan. 1981 to Dec. 1983

NORTHEASTERN ILLINOIS UNIVERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: B.A. Psychology. Sep. 1977 to Jun. 1980

HARPER COLLEGE
1200 W. Algonquin Rd., Palatine, Illinois, 60067
Degree Conferred: A.A. Liberal Arts Jan. 1975 to Aug. 1977

LICENSURE AND CERTIFICATIONS
State of Ohio #5481
Certificate: Forensic Psychology
Certificate Substance Abuse Counseling
(Alder School of Professional Psychology) Apr. 1994 to Dec. 1994

PRESENTATIONS
-Psychological Needs of the Substance Dependent Patient
-Pain Management Team, Fairfield Medical Center, Lancaster, OH
-Identifying Drug Abusers and Pain Management Technique in Patients
-With a History of Drug Abuse, Pain Management Physicians, Fairfield Medical Center, Lancaster, OH
-Peer Pressure and Anger Management; Thomas Ewing Junior High School, Lancaster, Ohio
-"Catch Me If You Can—Obsessive Compulsive Disorder", and
-"Stress and Anxiety Disorder in the Adult Population" 12th Annual
-Early Childhood Conference, Ohio University, Lancaster Campus, Sponsored By the Children's Committee,
a subcommittee of Fairfield County Family,
Adult and Children First Counsel
-"Competency Evaluation: presented to the Ohio State Bar Association, Lancaster, OH
-"Childhood Depression", interview for Medical Minute presented by WLOH Radio, Lancaster, OH
-"Signs and Symptoms of Childhood Depression: written for Lancaster Eagle Gazette through Fairfield Medical Center.
-Interview, Fairfield Focus, WLOH Radio, Lancaster, OH
-"Out of the Box" Workshop, presented with Dr. Miller and Dr. Wing

Ohio University Inn, Athens. OH
-"Emotional and Psychological Health: How to Support Employees", Women's Division, Lancaster Chamber of Commerce, Presented at Fairfield Medical Center, Lancaster, OH.

Book Written under Pseudonym T.L. Shull: Do They Have a Pill for That? Publisher I Universe Press, March 2019.

Exhibit U

APEX

· Counseling Services ·

10/13/2020

To whom it may concern:

I am a licensed psychologist, who has certification in Addiction Medicine and have taken training in pain management. I had been a clinical director of a recovery program in Lancaster, Ohio (please find my resume enclosed).

I have evaluated and followed up many of Dr. Leon Margolin's patients (including all the patients in the patient list enclosed), however, I am not an employee, colleague, or social friend of Dr. Margolin. I did not receive any payment for this review.

As described in my prior letters (dated October 10, 2019 and May 16, 2019), based on my experience of more than 20 years in the field of pain and addiction, I fully endorse the use of the SBIRT (G codes) and addressing psychological factors in EMG testing for the patients in the list enclosed. I think Dr. Margolin has created one of the best SBIRT programs in the state of Ohio which is medically necessary and fully compliant.

I fully endorse his publication in collaboration with the Cleveland Clinic Foundation published in a peer-reviewed journal:

https://www.gavinpublishers.com/assets/articles_pdf/1595045423article_pdf1130015263.pdf

There are several independent publications by American Medical Association, HHS, National Institute for Drug Abuse, Society for Addiction Medicine and other agencies that have recently endorsed similar findings. Dr. Margolin's SBIRT program is even more relevant and needed during the COVID-19 pandemic.

For example, Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, National Institutes of Health (USA) recently (September, 2020) published the enclosed article calling for increase in screening of the pain and addiction patients, especially since this population is at increased risk for COVID-19.

American Medical Association (AMA) published the enclosed urgent brief on August 4th, 2020 marking Ohio as an area of a sharp increase in opioid mortality:

"Policymakers need to act to remove barriers to evidence-based care for patients with pain and those with a substance use disorder or the epidemic will continue to worsen." (AMA report below page 4):
https://www.ama-assn.org/system/files/2020-07/opioid-task-force-progress-report.pdf

5310 East Main Street
Columbus, OH 43213

PHONE (614) 751-1090
FAX (614) 751-1091

The opioid crisis has become an epidemic within the COVID-19 (see enclosed):

https://www.painmedicinenews.com/Multimedia/Article/08-20/Panel-COVID-19-Compounds-Opioid-Public-Health-Emergency/59293

It is absolutely clear to me that any denial of the SBIRT (G codes) or other services rendered by Dr. Margolin or marking them as "unallowed" and any recoupment of funds from Dr. Margolin's practice would not only contradict the acceptable national and state guidelines but in effect constitute a public health hazard that puts hundreds if not thousands of Ohioans at the risks of disability and death.

Such policies must be stopped to prevent danger to thousands of people in Ohio and nationwide as reflected by the HHS, AMA, National Institute for Drug Abuse (NIDA) policies and publications. Ohio is one of the most affected area devastated by the crisis, therefore urgent actions are required.

Sincerely,
William Vasilakis, Psy.D.
Dr. William Vasilakis, Psy.D

Clinical Psychologist #5481

5310 East Main Street
Columbus, OH 43213

PHONE (614) 751-1090
FAX (614) 751-1091

APEX

· Counseling Services ·

Addendum – October 10, 2019:

I would also like to clarify that each time the patient is defined as "low risk" or a "good candidate for narcotic medication" this assessment is based on the history and the data reported by the patient. There it is mandatory to continue SBRIT (G0397) protocol attached.

Literature shows that some patients will develop aberrant drug seeking behavior despite an initial recommendation to be a "good candidate for narcotic medication" or "low risk", that's why the guidelines mandate the SBRIT (G0397) monitoring that Dr. Margolin implemented in his practice.

Based on my clinical experience of 20+ years in this field of pain and addiction psychology, serving as the head of the Department of Addiction Medicine in the Lancaster Hospital, I think Dr. Margolin has created one of the best SBIRT programs in Ohio and maybe nationwide. Dr. Margolin's practice is located in the epicenter of the opioid epidemic and sub-specialized in the screening for drug and alcohol of high risk patients that require high frequency of such screening. Dr. Margolin receives referral for the screening for drug and alcohol of high risk patients from hospitals including OSU, Riverside, Mount Caramel, and University Hospital in Cleveland, OH and even from other pain management clinics in the area because of the outstanding quality of his SBRIT (G0397) protocol for screening high risk patients for drugs and alcohol.

My understanding is that he has presented his experience at the 2019 national meeting and is invited to present his SBIRT experience at the Case Western School of Medicine continuous medical education event.

Respectfully,

William H. Vasilakis, Psy.D.

William H. Vasilakis, Psy.D.

Clinical Psychologist

5310 East Main Street
Columbus, OH 43213

PHONE (614) 751-1090
FAX (614) 751-1091

Patient Name: **INS:** **DOB:** **Date:**

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC (CPMI)
5245 E. Main Street, Columbus, OH; 43213
Ph. 614-557-6075, F. 614-453-8222

Screening And Brief Intervention Review Sheet

In compliance with the SMBO guidelines the CPMI provider reviewed:

- SOAPP R
- Review of PADT tool that includes 4As of chronic pain treatment (Analgesia, Activities of Daily Living, Aberrant Drug Related Behavior, Adverse Events) , patient progress towards objective for the duration of treatments.
- Review of Assessment Of Patient Receiving Protracted Prescription Medication For The Treatment Of Intractable Pain Form (Pursuant to State Medical Board of Ohio Administrative Rule 4731-21-02)
- Review Withdrawal Assessment form
- Review OARRS report
- ORT / COMM assessment tools on selected charts
- Results of the screening, history, physical examination, responses to and assessment of the particular items required for chronic prescription of controlled medications (including PADT tool enclosed), and alternatives to treatment reviewed and discussed with the patient

Total time spent - greater than 30 minutes

❑ at least 15-30 / other _____ minutes

Comments:

_____

_____

_____

_____

Leon Margolin MD, PhD / Jing Liu CNP

Exhibit V

CHAPTER 18 ELECTRODIAGNOSTIC EVALUATION OF ACUTE AND CHRONIC PAIN SYNDROMES

DOUGLAS G. CHANG AND ELAINE S. DATE

INTRODUCTION

Before a clinician can treat pain effectively, the utmost must be done to identify what condition is being treated, and identify what may be causing pain. For this purpose, electrodiagnostic studies are important in the evaluation of acute and chronic pain syndromes. They give valuable, quantitative information on the physiologic health and functioning of nerve and muscle. They help localize injuries, quantify the extent of injury, suggest age of injury, and give valuable prognostic information that can change treatment protocols. They can monitor interval progression. All of this complements the static, anatomic structural information provided by radiological imaging studies. In other words, radiological imaging can identify anatomy that may or may not be the cause of symptoms. Electrodiagnostic studies can quantify symptoms (e.g., show evidence of spinal nerve root compression) but cannot identify the anatomic cause (e.g., infection, tumor, or disk herniation). Together, electrodiagnostic and radiologic studies are extensions of the physical exam and serve to refine the differential diagnosis suggested by a clinical presentation.

Common reasons for ordering electrodiagnostic studies include symptomatic complaints (weakness, pain, numbness and/or tingling in an extremity) and physical examination findings (focal neurological deficits, abnormal reflexes, strength or sensory losses). Typical clinical scenarios involve radiculopathies, entrapment syndromes, trauma, and metabolic pathology seen in diabetes and alcoholism. Other important scenarios include rheumatologic disease, neuromuscular disease, and various infectious and neoplastic neuropathies. Further details about these conditions can be found in several electrodiagnostic textbooks.[1,2,3,4,5,6]

Practically, electrodiagnostic studies should be thought of when the diagnosis is in doubt, either during the initial patient presentation or as the result of nonresponse to treatment. The studies can evaluate the possibility of additional lesions (e.g., concomitant nerve entrapment syndromes, peripheral neuropathies, and so-called "double crush syndromes"), be used to follow the interval progression of both operative and nonoperative treatments, and provide pre-operative baselines. The objectives of this chapter are to introduce basic principles of electrodiagnosis. Hopefully, this will provide information on when to order electrodiagnostic tests, and help interpret and utilize the resulting electrodiagnostic reports.

TERMINOLOGY

Electrodiagnostic studies involve two components: nerve conduction studies (NCS) and needle electromyography (EMG). Al

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Exhibit W

LCD for Nerve Conduction Studies and Electromyography (L35897)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Archive site.



Please Note: This document version is not currently in effect. There may be more recent version(s) available in the Public Version(s) section below or on the CMS Medicare Coverage Database (MCD).

Contractor Information



CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	MAC - Part A	15101 - MAC A	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part B	15102 - MAC B	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part A	15201 - MAC A	J - 15	Ohio
CGS Administrators, LLC	MAC - Part B	15202 - MAC B	J - 15	Ohio

LCD Information



LCD ID
L35897

LCD Title
Nerve Conduction Studies and Electromyography

Source Proposed LCD
DL35897 Nerve Conduction Studies and Electromyography

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CMS National Coverage Policy

Code of Federal Regulations:
42 CFR Section 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who uses the results in the management of the beneficiary's specific medical problem.

Federal Register:
Federal Register Vol. 62, 59047, Supervision of Diagnostic Tests, describes the degree of physician supervision required for diagnostic tests.

CMS Publications:
CMS Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2:
160.23 Sensory Nerve Conduction Threshold Tests (sNCTs)
Program Memorandum Carriers Transmittal B-01-28 Change Request 850, describes tests that may be performed by PTs with ABPTS certification
CMS IOM 100-2. Medicare Benefit Policy Manual Chapter 15 Section 80 Requirements for Diagnostic Tests p. 88-91. 2009.
Transmittal 2663 Change Request 8169 April Update to the CY 2013 Medicare Physician Fee Schedule Database (MPFSDB)

Date Information



Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 09/26/2019

Revision Ending Date
10/23/2019

Retirement Date
N/A

Notice Period Start Date
01/19/2017

Notice Period End Date
03/05/2017

Coverage Guidance



Coverage Indications, Limitations and/or Medical Necessity

CGS Administrators expects healthcare professionals who perform electrodiagnostic (ED) testing will be appropriately trained and/or credentialed, either by a formal residency/fellowship program, certification by a nationally recognized organization, or by an accredited post-graduate training course covering anatomy, neurophysiology and forms of electrodiagnostics (including both NCS and EMG) acceptable to this contractor, in order to provide the proper testing and assessment of the patient's condition, and appropriate safety measures. It would be highly unlikely that this training and/or credentialing is possessed by providers other than Neurologists, or Physical Medicine & Rehabilitation physicians.

The electrodiagnostic evaluation is an extension of the neurologic portion of the physical examination. Both require a detailed knowledge of a patient and his/her disease. Training in the performance of electrodiagnostic procedures in isolation of knowledge about clinical diagnostic and management aspects of neuromuscular diseases, may not be adequate for proper performance of an electrodiagnostic evaluation and correct interpretation of electrodiagnostic

test results. Without awareness of the patterns of abnormality expected in different diseases and knowledge that the results of nerve conduction studies (NCS) and electromyography (EMG) may be similar in different diseases, diagnosis solely by EMG-NCS findings may be both inadequate and ultimately be detrimental to the patient.

Guidelines about proper qualifications for qualified health care professionals performing electrodiagnostic evaluations have been developed and published by AANEM (American Association of Neuromuscular and Electrodiagnostic Medicine) and other medical organizations, including the AMA, the American Academy of Neurology, the American Academy of Physical Medicine and Rehabilitation, American Neurological Association, the American Board of Physical Therapy Specialties (ABPTS) in Clinical Electrophysiology, and the Department of Veterans Affairs.

Both EMGs and NCSs are usually required for a clinical diagnosis of peripheral nervous system disorders. Performance of one type of testing does not eliminate the need for the other. The intensity and extent of testing with EMG and NCS are matters of clinical judgment developed after the initial pre-test evaluation, and later modified during the testing procedure.

Decisions to continue, modify or conclude a testing rely on knowledge of anatomy, physiology and neuromuscular diseases. Ongoing real-time assessment of data is required during the clinical diagnostic evaluation and especially during EMG examination.

Nerve conduction studies (NCS) are used to measure action potentials resulting from peripheral nerve stimulation which are recordable over the nerve or from an innervated muscle. With this technique, responses are measured between two sites of stimulation, or between a stimulus and a recording site.

Nerve conduction studies are of two general types: sensory and motor. Either surface or needle electrodes can be used to stimulate the nerve or record the response. Axonal damage or dysfunction generally results in loss of nerve or muscle potential response amplitude; whereas, demyelination leads to prolongation of conduction time and slowing of conduction velocity.

Obtaining and interpreting NCS results requires extensive interaction between the performing qualified health care professional and patient, and is most effective when both obtaining raw data and interpretation are performed concurrently on a real-time basis.

Results of the NCS reflect on the integrity and function of:

(I) the myelin sheath (Schwann cell derived insulation covering an axon), and
(II) the axon (an extension of neuronal cell body) of a nerve.

Interruption of axon and dysfunction of myelin will both affect NCS results.

It is often also valuable to test conduction status in proximal segments of peripheral nerves. This assessment can be accomplished by H-reflex, F-wave and blink reflex testing. These proximal segments include the first several centimeters of a compound nerve emerging from the spinal cord or brainstem. H-reflex, F-waves and Blink reflex testing accomplish this task better than distal NCS.

Electromyography (EMG) is the study and recording of intrinsic electrical properties of skeletal muscles. This is carried out with a needle electrode. Generally, the needles are of two types: monopolar or concentric. EMG is undertaken together with NCS. Unlike NCS, however, EMG testing relies on both auditory and visual feedback to the electromyographer. This testing is also invasive in that it requires needle electrode insertion and adjustment at multiple sites, and at times anatomically critical sites. As in NCS during EMG studies the electromyographer depends on ongoing real-time interpretation based knowledge of clinical diagnosis being evaluated to decide

whether to continue, modify, or conclude a test. This process requires knowledge of anatomy, physiology, and neuromuscular diseases.

EMG results reflect not only on the integrity of the functioning connection between a nerve and its innervated muscle but also on the integrity of a muscle itself. The axon innervating a muscle is primarily responsible for the muscle's volitional contraction, survival, and trophic functions. Thus, interruption of the axon will alter the EMG. A few prime examples of conditions in which EMG is potentially helpful are disc disease producing spinal nerve dysfunction, advanced nerve compression in peripheral lesions, Amyotrophic Lateral Sclerosis (ALS), polyneuropathy, etc. After an acute neurogenic lesion, EMG changes may not appear for several days to weeks in the innervated muscles. Primary muscle disease such as polymyositis will also alter a normal EMG pattern. Myotonic disorders may show a pattern of spontaneous repetitive discharges on needle exploration.

In summary, axonal and muscle involvement are most sensitively detected by EMGs, and myelin and axonal involvement are best detected by NCSs.

Physical Therapists Performing EMGs
Program Memorandum Transmittal B-01-28/Change Request 850 sets forth revised levels of physician supervision required for diagnostic tests payable under the Medicare Physician Fee Schedule. Effective July 1, 2001, certain codes in the range of CPT 95860-95937 were assigned new supervision levels (21, 22, 6a, 66, 77 or 77a). This implementation date would make it possible for physical therapists to acquire the certification required to perform these services without supervision. A physical therapist who is presently certified by the American Board of Physical Therapy Specialties can perform procedures assigned level of 21, 22, 66, 6a, 77, or 77a without supervision. These numeric levels assigned to the CPT codes are listed in the Medicare Physician Fee Schedule Database (MFSDB). Physical therapists who do not possess the ABPTS (American Board of Physical Therapy Specialties) certification by July 1, 2001, may continue to furnish those tests that require the certification if they have been furnishing such diagnostic tests prior to May 1, 2001.
Payment will be based on the Medicare Physician Fee Schedule level of supervision designation.

Nerve conduction code 95905 does not have one of the above designations and is therefore not allowed by Physical Therapists.

Nerve conduction codes 95907-95913 had their Physician Supervision of Diagnostic Procedures Indicators adjusted to 7A effective 01/01/2013 (CR 8169). Therefore if authorized by state law Physical Therapists are allowed the technical portion and professional component of the test according to the description of 7A which is included in the Billing and Coding Guideline attached.

The TC component of the Neuromuscular junction testing code 95937 had its Physician Supervision of Diagnostic Procedures Indicator changed to "7A" This change is effective January 1, 2013.

Needle electromyographic (EMG) codes 95860-95872 and 95885-95887 have the designation of 6A for the technical portion of the test.Therefore if authorized by state law Physical Therapists are allowed the technical portion of the test according to the description of 6A which is included in the Billing and Coding Guideline attached.

A. Nerve Conduction Studies
The dichotomy into axonal and demyelinating neuropathies provides a practical means of correlating electrical abnormalities with major pathophysiologic changes in the nerve. Electrical studies can be of help in localization of an abnormality, and in distinguishing one variety of neuropathy from another: for example, diffuse vs. multifocal; axonal vs. demyelinating. Such distinction has diagnostic value. Specific classification of nerve injuries into neuropraxia and axonotmesis can be made on the basis of conduction studies and electromyography. Such classification has a bearing on prognosis and treatment.

1. Focal neuropathies or compressive lesions such as carpal tunnel syndrome, ulnar neuropathies or root lesions, for localization.
2. Traumatic nerve lesions, for diagnosis and prognosis.
3. Diagnosis or confirmation of suspected generalized neuropathies, such as diabetic, uremic, metabolic or immune.
4. Repetitive nerve stimulation in diagnosis of neuromuscular junction disorders such as myasthenia gravis, myasthenic syndrome.
5. There may be other instances, not detailed here, where NCS may be of use. Not all possible or potential indications are addressed here.

The broad diagnostic scope of NCS is recognizable by the foregoing description. There may be instances where questions about an indication, or need for a study, will arise. The clinical history and examination, carried out before the study, must always describe and document clearly and comprehensibly the need for the planned test. A "rule-out" diagnosis is typically not acceptable. The Contractor is cognizant of the fact that patients are not always referred with a definite diagnosis in mind. Often, pain, paresthesia, or weakness in an extremity is the reason for an NCS or EMG. These common symptoms result not only from axonal and myelin dysfunction but also from systemic, non-neurological illnesses. EMG and NCV may help in making this distinction. Therefore, symptom-based diagnoses such as "pain in limb" weakness, disturbance in skin sensation or "paresthesia" are acceptable provided the clinical assessment unequivocally supports the need for a study. To cite but one example of many, an EMG or NCS is irrelevant as a first order diagnostic test for limb pain resulting from immediate antecedent trauma or acute bone injury.

Both EMGs and NCSs are required for a clinical diagnosis of peripheral nervous system disorders. EMG results reflect on the integrity of the functioning connection between a nerve and its innervated muscle and also on the integrity of a muscle itself. Performance of one does not eliminate the need for the other. The intensity and extent of testing with EMG and NCS are matters of clinical judgment developed after the initial pre-test evaluation, and later modified during the testing procedure.

Decisions to continue, modify or conclude a test also rely on a knowledge base of anatomy, physiology and neuromuscular diseases. There is a requirement for ongoing real-time clinical diagnostic evaluation, especially during EMG examination. Also, EMG examination is invasive. Needle placement in the exact muscle of interest is essential. It requires needle exploration near vital structures as the pleura, femoral neurovascular bundle, peritoneum, intraspinal spaces, carotid artery, orbit and brachial plexus. Risk of infection from AIDS, Hepatitis B-E, Creutzfeldt-Jakob encephalopathy, and hemorrhage from anticoagulation can be managed by proper techniques.

The electrodiagnostic evaluation is actually an extension of the neurologic portion of the physical examination. Both require a detailed knowledge of a patient and his/her disease. Training in the performance of electrodiagnostic procedures, in isolation without awareness and ability to diagnose and manage neuromuscular diseases, is not always adequate for electrodiagnostic consultation. Recognition and experience in the management of disparate diseases that produce common electrodiagnostic findings may be necessary. For example, EMG-NCS findings may overlap in the following pairs of disorders: inflammatory myopathies and ALS, ALS and multi-level radiculopathies, myotonia of channelopathies (periodic paralyses) and myotonic dystrophies, focal neuropathies as Carpal Tunnel Syndrome and proximal plexopathies. Other instances where knowledge of disease behavior is crucial are Chronic Inflammatory Demyelinating Neuropathy (CIDP) and Multifocal Motor Neuropathy. These entities display electrodiagnostic features that resemble generalized polyneuropathies. Neuromuscular transmission disorders require separation based on clinical presentation and electrical features. Treatment will depend on differentiating among them. Without awareness of the disease spectrum, diagnosis solely by EMG-NCS findings may be either wrong or detrimental to the patient.

The following definitions are from the American Association of Neuromuscular & Electrodiagnostic Medicine Recommended Policy for Electrodiagnostic Medicine (page 2)

http://www.aan.com/globals/axon/assets/4061.pdf

"The stimulation of nerves is similar across all NCSs; the characteristics of motor, sensory, and mixed NCSs are different and are discussed separately below. In each case, an appropriate nerve is stimulated and recording is made either from the appropriate nerves or from muscle supplied by the motor nerve.

a. Motor. Motor NCSs are performed by applying electrical stimulation at various points along **the course of a motor nerve** while recording the electrical response from an appropriate muscle. Response parameters include amplitude, latency, configuration, and motor conduction velocity.
b. Sensory. Sensory NCSs are performed by applying electrical stimulation near a nerve and recording the response from a distant site along the nerve. Response parameters include amplitude, latency, and configuration.
c. Mixed NCSs are performed by applying electrical stimulation near a nerve containing both motor and sensory fibers (a mixed nerve) and recording from a different location along that nerve that also contains both motor and sensory nerve fibers. Response parameters include amplitude, latency, configuration, and motor conduction velocity."
d. CPT code 95905 -Nerve conduction studies performed using automated devices (for example devices such as NC-stat® System) cannot support testing of other locations and other nerves as needed depending on the concurrent results of testing and they should not be billed to Medicare with the current CPT codes.

When the beneficiary has a high pre-test or a prior probability for having the diagnosis of Carpal Tunnel Syndrome, the NC-stat® System (alone) will be allowed, one service per arm, using CPT code 95905. The diagnosis codes G56.01, G56.02, or G56.03 should be used. All other diagnosis codes will be denied as not medically necessary.

Nerve conduction studies performed independent of needle electromyography (EMG) may only provide a portion of the information needed to diagnose muscle, nerve root, and most nerve disorders. When the nerve conduction study (NCS) is used on its own without integrating needle EMG findings or when an individual relies solely on a review of NCS data, the results can be misleading, and important diagnoses may be missed.

In most instances, both NCS and usually EMG are necessary to perform diagnostic testing. While a provider may choose to perform just a NCS, when performed alone it is usually considered not medically necessary. The only exception to this is a situation when a provider may consider it appropriate to perform a NCS without doing an EMG for the diagnosis of carpal tunnel syndrome with a high pre-test probability.

B. Electromyography
Neurogenic disorders can be distinguishable from myopathic disorders by a carefully performed EMG. For example, both polymyositis and ALS (Amyotrophic Lateral Sclerosis) produce manifest weakness. The former carries a very different prognosis and treatment than the latter. An EMG is very valuable in making this distinction. Similarly, classification of nerve trauma into axonal vs. demyelinating categories, with corresponding differences in prognoses, are possible with EMG. Below is a list of common disorders where an EMG, in tandem with properly conducted NCS, will be helpful in diagnosis:

1. Nerve compression syndromes, including carpal tunnel syndrome and other focal compressions.
2. Radiculopathy - cervical, lumbosacral.
3. Mono/polyneuropathy - metabolic, degenerative, hereditary.
4. Myopathy - including poly-and dermatomyositis, myotonic and congenital myopathies.
5. Plexopathy - idiopathic, trauma, infiltration.
6. Neuromuscular junction disorders - myasthenia gravis. Single fiber EMG is of special value here.
7. At times, immediately prior to botulinum toxin injection, for localization.
8. At times, immediately prior to injection of phenol or other substances for nerve blocking or chemodenervation.

There may be other instances, not detailed here, where EMG may be of use.

Use of EMG with Botulinum Toxin Injection
EMG may be used to optimize the anatomic location of botulinum toxin injection. It is expected there will be one study performed per anatomic location of injection, if needed.

Limitations:

Nerve Conduction Studies
Each descriptor (code) from codes 95907, 95908, 95909, 95910, 95911, 95912, and 95913, can be reimbursed only once per nerve, or named branch of a nerve, regardless of the number of sites tested or the number of methods used on that nerve. For instance, testing the ulnar nerve at wrist, forearm, below elbow, above elbow, axilla and supraclavicular regions will all be considered as a single nerve. Motor and sensory nerve testing are considered separate tests. CPT code 95905 is payable only once per limb studied and cannot be used in conjunction with any other nerve conduction codes.

Routine testing for polyneuropathy of diabetes or endstage renal disease (ESRD) is not considered medically necessary and is NOT covered. Testing for the sole purpose of monitoring disease intensity or treatment efficacy in these two conditions is also not covered.

Psychophysical measurements (current, vibration, thermal perceptions), even though they may involve delivery of a stimulus, are considered to be part of the physical exam and may not be billed as a separate service.

Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT) – is not covered by Medicare. This procedure is different and distinct from assessment of nerve conduction velocity, amplitude and latency. It is also different from short-latency somatosensory evoked potentials. Codes designated for eliciting nerve conduction velocity, latency or amplitude, and those designed for short latency evoked potentials are not to be used for sNCT. The sNCT has a unique code **G0255**: Effective October 1, 2002, CMS initially concluded that there was insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law. Therefore, sNCT was noncovered. Based on a reconsideration [in March, 2004] of current Medicare policy for sNCT, CMS concludes that there continues to be insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test as reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law. CMS Publication 100-3, Medicare National Coverage Issues Manual, Chapter 1, Section 160.23

Examination using portable hand-held devices, or devices which are incapable of real-time wave-form display and analysis, and incapable of both NCS and EMG testing; will be included in the E/M service. They will not be paid separately. Examples include; The Axon II or delta fiber analysis testing and/or machines with other names.

Nerve conduction studies must provide a number of response parameters in a real-time fashion to facilitate provider interpretation. Those parameters include amplitude, latency, configuration and conduction velocity. Medicare does not accept diagnostic studies that do not provide this information or those that provide delayed interpretation as substitutes for Nerve conduction studies. Raw measurement data obtained and transmitted trans-telephonically or over the Internet, therefore, does not qualify for the payment of the electrodiagnostic service codes included in this LCD.

Medicare does not expect to receive claims for nerve conduction testing accomplished with discriminatory devices that use fixed anatomic templates and computer-generated reports used as an adjunct to physical examination routinely on all patients.

Electromyography
It is expected that providers will use CPT code 95870 for sampling muscles other than the paraspinals associated

with the extremities, which have been tested. Medicare would not expect to see this code billed when the paraspinal muscles corresponding to an extremity are tested and when the extremity EMG code 95860, 95861, 95863 or 95864 is also billed. The necessity and reasonableness of the following uses of EMG studies have not been established:

- exclusive testing of intrinsic foot muscles in the diagnosis of proximal lesions
- definitive diagnostic conclusions based on paraspinal EMG in regions bearing scar of past surgeries (e.g., previous laminectomies)
- pattern-setting limited limb muscle examinations, without paraspinal muscle testing for a diagnosis of radiculopathy
- EMG testing shortly after trauma, before EMG abnormalities would have reasonably had time to develop
- surface and macro EMG's
- multiple uses of EMG in the same patient at the same location of the same limb for the purpose of optimizing botulinum toxin injections.
  For outpatient settings other than Comprehensive Outpatient Rehabilitation Facility (CORF)s, references to "physicians" throughout this policy include non-physicians, such as nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners, with certain exceptions, may certify, order and establish the plan of care as authorized by State law. (See Sections 1861[s][2] and 1862[a][14] of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; 58 FR 18543, April 7, 2000.) Each practitioner must provide only those services within the scope of practice for each state.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information



Associated Information

Documentation Requirements

The patient's medical records must clearly document the medical necessity for the test. It is not necessary to include documentation with each claim submission. Data gathered during NCS, however, should be available which reflect the actual numbers (latency, amplitude, etc.), preferably in a tabular (not narrative) format. The reason for referral and a clear diagnostic impression are required for each study. In cases where a review becomes necessary, either a

hard copy of waveforms or a complete written report with an interpretation of the test must be submitted upon request.

Normal findings and abnormalities uncovered during the study should be documented with the muscles tested, the presence and type of spontaneous activity, as well as the characteristics of the voluntary unit potentials and interpretation.

Sources of Information

1.AANEM. Position Statement, Proper performance and interpretation of electrodiagnostic studies. Approved June 2014. Available at aanem.org
2. AANEM. Position Statement, Risks in electrodiagnostic medicine. Approved July 2014. Available at aanem.org
3. AANEM. Recommended Policy for Electrodiagnostic Medicine. Updated on 08/30/2014. Available at aanem.org
4. ABPTS, 2016 Clinical Electrophysiology Specialist Certification Candidate Guide. Available at: abpts.org.
5. Brown E. An Evidence Based Technology Assessment of the NC-stat® Device; March 19, 2007.
6. Morse, J. Office of the Medical Director, Department of Labor and Industries. Washington State Department of Labor and Industries. Technology Assessment: NC-stat System, NeuroMetrix, Inc. June 8, 2006. Available at: http://www.lni.wa.gov/claimsins/files/omd/tancstat0506.pdf

Bibliography

N/A

Revision History Information



Revision History Table

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
14	09/26/2019	Revision#:R14 Revision Effective date: 09/26/2019 Revision Explanation: Converted policy into new template and moved all coding into related billing and coding article based on CR 10901. 09/20/2019 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (Code Migration)
13	10/01/2018	Revision#:R13 Revision Effective date: N/A Revision Explanation: Annual Review, no changes made. Added 21 Century Cures Act 04/15/2019 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (Added 21 Century Cures Act)
12	10/01/2018	Revision#:R12 Revision Effective: N/A Revision Explanation: Annual review no changes made.	• Other (Annual review, no changes made.)

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
11	10/01/2018	Revision#:R11 Revision Effective: 10/01/2018 Revision Explanation:10/01/2018 ICD-10-CM code updates: deleted codes G51.3, G71.0, M79.1 from Group One and added codes G51.31, G51.32, G51.33, G71.01, G71.02, G71.09, M79.11, M79.12, and M79.18. Description change to M50.01, M50.11, M50.21, M50.31, and M50.81 in Group One. 08/27/2018-*At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	• Revisions Due To ICD-10-CM Code Changes
10	10/01/2017	Revision#:R11 Revision Effective: N/A Revision Explanation: Annual review no changes made.	• Other (Annual Review)
9	10/01/2017	Revision#:R10 Revision Effective: 10/01/2017 Revision Explanation: ICD-10 annual review update, added the following new codes E11.10, e11.11, G12.23, G12.24, G12.25, M33.03, M33.13, M33.93, M48.061, and M48.062.	• Revisions Due To ICD-10-CM Code Changes

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
		08/23/2017-*At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.* Revision#:R9 Revision Effective: N/A Revision Explanation: Annual review no changes made.	
8	03/06/2017	Revision#:R8 Revision Effective: 03/06/2017 Revision Explanation: Releasing policy after taking back to CAC as a draft after reviewing policy and found some ICD-10 codes missing and others that were not appropriate for the LCD.	• Provider Education/Guidance

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
7	10/01/2016	Revision#:R7 Revision Effective: 10/01/2016 Revision Explanation: ICD-10 Code updates added codes: G56.03, G56.13, G56.23, G56.33, G56.43, G56.83, G56.93, G57.03, G57.13, G57.23, G57.33, G57.43, G57.53, G57.63, G57.73, G57.83, G57.93, G61.82, M50.021, M50.022, M50.023, M50.121, M50.122, M50.123, M50.221, M50.222, M50.223, M50.321, M50.322, M50.323, M50.821, M50.822, M50.823. Deleted codes: M50.02, M50.12, M50.22, M50.32, M50.82. Revised description codes: S54.8X1A, S54.8X2A. Combined the CPT code groups and the ICD-10 code groups for clarification. Added that any code in list that has the 7th character of D or S also can be used in paragraph above the ICD-10 codes.	• Revisions Due To ICD-10-CM Code Changes
6	10/01/2015	Revision#:R6 Revision Effective: 10/01/2015 Revision Explanation: ICd-10 code M48.06 was left off in error and has been added.	• Typographical Error
5	10/01/2015	Revision#:R5 Revision Effective: N/A Revision Explanation: annual review no changes made.	• Other (Annual Review)
4	10/01/2015	Revision#:R4 Revision Effective: N/A Revision Explanation: Clarified in last paragraph above Nerve Conduction Studies section A that PTs can bill global for codes designated with 6A if certified and within scope of practice.	• Provider Education/Guidance
3	10/01/2015	Revision#:R3 Revision Effective: 10/01/2015 Revision Explanation: Added G62.9 to list of codes that support medical necessity.	• Reconsideration Request

Revision History Number	Revision History Date	Revision History Explanation	Reason(s) for Change
2	10/01/2015	Revision#:R2 Revision Effective: 10/01/2015 Revision Explanation: Corrected ICD-9 code left in error in the text to G56.01 and G56.02 concerning 95905	• Typographical Error
1	10/01/2015	Revision#:R1 Revision Effective: 10/01/2015 Revision Explanation: added notice period dates.	• Provider Education/Guidance

Associated Documents



Attachments

There are no attachments for this LCD.

Related Local Coverage Documents

Article(s)

A57307 - Billing and Coding: Nerve Conduction Studies and Electromyography

A55432 - Response to Comments: Nerve Conduction Studies and Electromyography

LCD(s)

DL35897 - Nerve Conduction Studies and Electromyography

Related National Coverage Documents

This LCD version has no Related National Coverage Documents.

All Versions

Updated on 04/30/2020 with effective dates 10/24/2019 - 04/28/2021

Updated on 10/15/2019 with effective dates 10/24/2019 - N/A

Updated on 09/20/2019 with effective dates 09/26/2019 - 10/23/2019

Updated on 04/15/2019 with effective dates 10/01/2018 - 09/25/2019

Updated on 04/10/2019 with effective dates 10/01/2018 - N/A

Updated on 08/27/2018 with effective dates 10/01/2018 - N/A

Updated on 04/30/2018 with effective dates 10/01/2017 - 09/30/2018

Updated on 08/23/2017 with effective dates 10/01/2017 - N/A

Updated on 01/13/2017 with effective dates 03/06/2017 - 09/30/2017

Updated on 09/12/2016 with effective dates 10/01/2016 - 03/05/2017

Updated on 06/21/2016 with effective dates 10/01/2015 - 09/30/2016

Updated on 04/19/2016 with effective dates 10/01/2015 - N/A

Updated on 02/25/2016 with effective dates 10/01/2015 - N/A

Updated on 12/30/2015 with effective dates 10/01/2015 - N/A

Updated on 04/14/2015 with effective dates 10/01/2015 - N/A

Updated on 04/02/2015 with effective dates 10/01/2015 - N/A

Updated on 04/02/2015 with effective dates 10/01/2015 - N/A

Additional Information



Keywords

N/A

Exhibit X

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

Baldwin's Ohio Revised Code Annotated
Title XXIII. Courts--Common Pleas (Refs & Annos)
Chapter 2317. Evidence
Miscellaneous Provisions

R.C. § 2317.54

2317.54 Informed consent; health care facility liability precluded, when; form for written consent

Effective: September 30, 2021
Currentness

No hospital, home health agency, ambulatory surgical facility, or provider of a hospice care program or pediatric respite care program shall be held liable for a physician's failure to obtain an informed consent from the physician's patient prior to a surgical or medical procedure or course of procedures, unless the physician is an employee of the hospital, home health agency, ambulatory surgical facility, or provider of a hospice care program or pediatric respite care program.

Written consent to a surgical or medical procedure or course of procedures shall, to the extent that it fulfills all the requirements in divisions (A), (B), and (C) of this section, be presumed to be valid and effective, in the absence of proof by a preponderance of the evidence that the person who sought such consent was not acting in good faith, or that the execution of the consent was induced by fraudulent misrepresentation of material facts, or that the person executing the consent was not able to communicate effectively in spoken and written English or any other language in which the consent is written. Except as herein provided, no evidence shall be admissible to impeach, modify, or limit the authorization for performance of the procedure or procedures set forth in such written consent.

(A) The consent sets forth in general terms the nature and purpose of the procedure or procedures, and what the procedures are expected to accomplish, together with the reasonably known risks, and, except in emergency situations, sets forth the names of the physicians who shall perform the intended surgical procedures.

(B) The person making the consent acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.

(C) The consent is signed by the patient for whom the procedure is to be performed, or, if the patient for any reason including, but not limited to, competence, minority, or the fact that, at the latest time that the consent is needed, the patient is under the influence of alcohol, hallucinogens, or drugs, lacks legal capacity to consent, by a person who has legal authority to consent on behalf of such patient in such circumstances, including either of the following:

(1) The parent, whether the parent is an adult or a minor, of the parent's minor child;

(2) An adult whom the parent of the minor child has given written authorization to consent to a surgical or medical procedure or course of procedures for the parent's minor child.

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Any use of a consent form that fulfills the requirements stated in divisions (A), (B), and (C) of this section has no effect on the common law rights and liabilities, including the right of a physician to obtain the oral or implied consent of a patient to a medical procedure, that may exist as between physicians and patients on July 28, 1975.

As used in this section the term "hospital" has the same meaning as in section 2305.113 of the Revised Code; "ambulatory surgical facility" has the same meaning as in section 3702.30 of the Revised Code; "hospice care program" and "pediatric respite care program" have the same meanings as in section 3712.01 of the Revised Code, and "home health agency" has the same meaning as in section 3740.01 of the Revised Code. The provisions of this division apply to hospitals, doctors of medicine, doctors of osteopathic medicine, and doctors of podiatric medicine.

CREDIT(S)

(2021 H 110, eff. 9-30-21; 2019 H 166, eff. 10-17-19; 2017 H 49, § 130.31, eff. 9-29-18; 2012 H 303, eff. 3-20-13; 2008 H 125, eff. 6-25-08; 2002 S 281, eff. 4-11-03; 2002 S 124, eff. 9-17-02; 1986 S 22, eff. 3-1-87; 1977 H 213; 1976 H 1426; 1975 H 682)

Notes of Decisions (63)

R.C. § 2317.54, OH ST § 2317.54
Current through File 100 of the 134th General Assembly (2021-2022).

End of Document

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Exhibit Y

KeyCite Yellow Flag - Negative Treatment
Distinguished by In re Flint Water Cases, 6th Cir.(Mich.), August 5, 2020

912 F.3d 907
United States Court of Appeals, Sixth Circuit.

Shari GUERTIN, Individually and as Next Friend of Her Child, E.B., a Minor; Diogenes Muse-Cleveland, Plaintiffs-Appellees,
v.
STATE of Michigan, et al., Defendants,
City of Flint, Michigan, Howard Croft, Darnell Earley, and Gerald Ambrose (17-1699); Liane Shekter-Smith, Daniel Wyant, Stephen Busch, Michael Prysby, and Bradley Wurfel (17-1745); Nancy Peeler (17-1752); Robert Scott (17-1769); Eden Wells and Nick Lyon (17-1698), Defendants-Appellees.

Nos. 17-1698/1699/1745/1752/1769
|
Argued: June 6, 2018
|
Decided and Filed: January 4, 2019

Synopsis

Background: City residents brought § 1983 action against State of Michigan, City of Flint, and related government officials, alleging they sustained personal injuries and damages due to drinking and bathing in water supplied by defendants to customers without the addition of chemicals to counter river water's known corrosivity. The United States District Court for the Eastern District of Michigan, No. 5:16-cv-12412, Judith E. Levy, J., 2017 WL 2418007, dismissed claims in part. Residents appealed.

Holdings: The Court of Appeals, Griffin, Circuit Judge, held that:

[1] residents stated a bodily-integrity substantive due process claim against city's former emergency managers and former public works director;

[2] residents stated a bodily-integrity substantive due process claim against Michigan Department of Environmental Quality (MDEQ) officials;

[3] residents failed to state a bodily-integrity substantive due process claim against Michigan Department of Health and Human Services (MDHHS) employees;

[4] State, city, and related officials were not entitled to qualified immunity from residents' substantive due process claims; and

[5] city was not an arm of the State despite being under State's emergency management and, thus, was not entitled to Eleventh Amendment sovereign immunity from residents' substantive due process claims.

Affirmed in part and reversed in part.

McKeague, Circuit Judge, issued opinion concurring in part and dissenting in part.

Procedural Posture(s): On Appeal; Motion to Dismiss for Failure to State a Claim.

West Headnotes (53)

[1] Civil Rights Nature and elements of civil actions

Under § 1983, an individual may bring a private cause of action against anyone who, under color of state law, deprives a person of rights, privileges, or immunities secured by the Constitution or conferred by federal statute.

42 U.S.C.A. § 1983.

2 Cases that cite this headnote

[2] Public Employment Qualified immunity

Qualified immunity shields public officials from undue interference with their duties and from potentially disabling threats of liability.

7 Cases that cite this headnote

[3] Public Employment Qualified immunity

Qualified immunity is not a mere defense to liability; the doctrine provides immunity from suit.

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permit of constitutional differentiation"). And more broadly, it is beyond debate that an individual's "interest in preserving her life is one of constitutional dimension." *Nishiyama v. Dickson Cty.*, 814 F.2d 277, 280 (6th Cir. 1987) (en banc), *abrogated on other grounds as recognized in* *Jones v. Reynolds*, 438 F.3d 685, 694–95 (6th Cir. 2006).

[20] Bodily integrity cases "usually arise in the context of government-imposed punishment or physical restraint," but that is far from a categorical rule. *Kallstrom*, 136 F.3d at 1062 (collecting cases). Instead, the central tenet of the Supreme Court's vast bodily integrity jurisprudence is balancing an individual's common law right to informed consent with tenable state interests, regardless of the manner in which the government intrudes upon an individual's body. *See, e.g.*, *Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 269–70, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990). Thus, to show that the government has violated one's right to bodily integrity, a plaintiff need not "establish any constitutional significance to the means by which the harm occurs[.]" *Boler v. Earley*, 865 F.3d 391, 408 n.4 (6th Cir. 2017). That is because "individuals possess a constitutional right to be free from forcible intrusions on their bodies against their will, absent a compelling state interest." *Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 506 (6th Cir. 2012).

A few examples illustrate the breadth of this tenet. Consider *Washington v. Harper*, which addressed the State of Washington's involuntary administration of antipsychotic medication to an inmate without a judicial hearing. 494 U.S. 210, 213–17, 110 S.Ct. 1028, 108 L.Ed.2d 178 (1990). There, the Supreme Court had "no doubt" that the inmate "possess[ed] a significant liberty interest in avoiding unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment." *Id.* at 221–22, 110 S.Ct. 1028. This "interest in avoiding the unwarranted administration of antipsychotic drugs is not insubstantial. The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." *Id.* at 229, 110 S.Ct. 1028 (citing *Winston v. Lee*, 470 U.S. 753, 105 S.Ct. 1611, 84 L.Ed.2d 662 (1985), and *Schmerber*, 384 U.S. 757, 86 S.Ct. 1826, 16 L.Ed.2d 908). And this is especially so when the foreign substance "can have serious, even fatal, side effects" despite some therapeutic benefits. *Id.* But the extent of this interference, reasoned the Court, is circumscribed by the government's interest (there, administering ***920** medication in the custodial setting). *Id.* at 222–27, 110 S.Ct. 1028. Examining those interests, the Court permitted the physical intrusion upon a showing of certain circumstances—danger to self or others, and in the inmate's medical interest. *Id.* at 227, 110 S.Ct. 1028; *see also* *Riggins v. Nevada*, 504 U.S. 127, 135–38, 112 S.Ct. 1810, 118 L.Ed.2d 479 (1992) (applying *Harper* to the forced administration of drugs in trial and pretrial settings and focusing upon the state's "overriding justification and a determination of medical appropriateness" to justify the intrusion); *Sell v. United States*, 539 U.S. 166, 177–86, 123 S.Ct. 2174, 156 L.Ed.2d 197 (2003) (similar).

The Supreme Court's seminal "right to die" case, *Cruzan v. Director, Missouri Department of Health*, provides further explication. At issue in *Cruzan* was whether the parents of an individual in a persistent vegetative state could insist that a hospital withdraw life-sustaining care based on her right to bodily integrity. 497 U.S. at 265–69, 110 S.Ct. 2841. Writing for the Court, Chief Justice Rehnquist extensively detailed the line between the common law, informed consent, and the right to bodily integrity: "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment," *id.* at 269, 110 S.Ct. 2841, "generally encompass[es] the right of a competent individual to refuse medical treatment," *id.* at 277, 110 S.Ct. 2841, and is a right that "may be inferred from [the Court's] prior decisions." *Id.* at 278–79, 110 S.Ct. 2841 (citing *Jacobson v. Massachusetts*, 197 U.S. 11, 25 S.Ct. 358, 49 L.Ed. 643 (1905); *Breithaupt v. Abram*, 352 U.S. 432, 77 S.Ct. 408, 1 L.Ed.2d 448 (1957); *Harper*, 494 U.S. 210, 110 S.Ct. 1028, 108 L.Ed.2d 178; *Vitek v. Jones*, 445 U.S. 480, 100 S.Ct. 1254, 63 L.Ed.2d 552 (1980); and *Parham v. J.R.*, 442 U.S. 584, 99 S.Ct. 2493, 61 L.Ed.2d 101 (1979)). And, although the Court assumed as much, "the logic of [these] cases ... embrace[s] ... a liberty interest" in "artificially delivered food and water essential to life." *Id.* at 279, 110 S.Ct. 2841. As with *Harper*, the Court's

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Exhibit Z

NCD - Wrong Surgical or Other Invasive Procedure Performed on a Patient (140.6)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Tracking Information

Publication Number

100-3

Manual Section Number

140.6

Manual Section Title

Wrong Surgical or Other Invasive Procedure Performed on a Patient

Version Number

1

Effective Date of this Version

01/15/2009

Implementation Date

07/06/2009

Description Information

Benefit Category

Diagnostic Tests (other)
Federally Qualified Health Center Services
Home Health Services
Inpatient Hospital Services
Outpatient Hospital Services Incident to a Physician's Service
Physicians' Services
Rural Health Clinic Services
Skilled Nursing Facility

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

A. General

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report" [1], which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This

concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items. Among surgical events on the list is "Wrong surgical procedure performed on a patient." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

Indications and Limitations of Coverage

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs a different procedure on a Medicare beneficiary because that particular surgical or other invasive procedure is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

A surgical or other invasive procedure is considered to be the wrong procedure if it is not consistent with the correctly documented informed consent for that patient. Emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent are not considered erroneous under this decision. Also, the event is not intended to capture changes in the plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

D. Other

N/A

(NCD last reviewed January 2009.)

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[1]http://www.qualityforum.org/pdf/reports/sre.pdf

Claims Processing Instructions

TN 1755 (Medicare Claims Processing)
TN 1764 (Medicare Claims Processing)
TN 1778 (Medicare Claims Processing)

Transmittal Information

Transmittal Number

102

Coverage Transmittal Link

http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R102NCD.pdf

Revision History

06/2009 - Effective Date: 01/15/2009. Implementation Date: 07/06/2006. (TN 101) (CR6405)

07/2009 - Effective Date: 01/15/2009. Implementation Date: 07/06/2006 (TN 102) (CR6405). Transmittal 101, Change Request 6405, dated June 12, 2009 is being rescinded and replaced, to correct manual references to the Benefit Policy Manual. All other information remains the same.

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process.The following are existing associations with NCAs, from the National Coverage Analyses database.

- Original Consideration for Wrong Surgery Performed on a Patient (CAG-00401N)

Additional Information

Other Versions

Title	Version	Effective Between
Wrong Surgical or Other Invasive Procedure Performed on a Patient	1	01/15/2009 - N/A

Exhibit AA

AANEM PRACTICE TOPIC

GUIDELINES FOR ETHICAL BEHAVIOR RELATING TO CLINICAL PRACTICE ISSUES IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

NAOMI A. ABEL MD,[1] EDUARDO A. DE SOUSA MD, FAAN,[2] RAGHAV GOVINDARAJAN MD,[3] MATTHEW P. MAYER MD,[4] and DAVID A. SIMPSON DO, MS[5]

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[2] Department of Neurology, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, USA
[3] Department of Neurology, University of Missouri, Columbia, Missouri, USA
[4] Department of Pediatric Rehabilitation Medicine, University of Missouri–Kansas City, Children's Mercy Kansas City, Kansas City, Missouri, USA
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Received 10 June 2015; Revised 9 September 2015; Accepted 14 September 2015

ABSTRACT: The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) developed guidelines to formalize the ethical standards that neuromuscular and electrodiagnostic (EDx) physicians should observe in their clinical and scientific activities. Neuromuscular and EDx medicine is a subspecialty of medicine that focuses on evaluation, diagnosis, and comprehensive medical management, including rehabilitation of individuals with neuromuscular disorders. Physicians working in this subspecialty focus on disorders of the motor unit, including muscle, neuromuscular junction, axon, plexus, nerve root, anterior horn cell, and the peripheral nerves (motor and sensory). The neuromuscular and EDx physician's goal is to diagnose and treat these conditions to mitigate their impact and improve the patient's quality of life. The guidelines are consistent with the Principles of Medical Ethics adopted by the American Medical Association and represent a revision of previous AANEM guidelines.

Muscle Nerve **52**: 1122–1129, 2015

THE PATIENT–PHYSICIAN RELATIONSHIP IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

The Patient–Physician Relationship. The relationship between the patient and the physician is a key component to assure that excellent care is provided. The quality of this relationship can impact not only the success of the outcome of the interaction between patient and physician, but also the outcome of the patient's treatment. The physician has a fiduciary duty to first safeguard the interests of the patient. The physician must practice competently, respect patient autonomy and confidentiality, maintain patient safety, and protect the patient's best interests.

Beginning and Ending the Relationship. The physician is free to decide whether to perform an EDx or neuromuscular evaluation on a particular patient. The physician should not decline the evaluation on the basis of the patient's race, color, religion, national origin, gender, disability, age, or other personal characteristics. The physician also should not decline an evaluation on the basis of the patient's known or suspected medical diagnosis. The physician should decline performance of the EDx or neuromuscular evaluation if he or she believes it to be unnecessary or not beneficial to the patient.

If possible, it is best for the EDx physician and the referring physician to concur on who should inform the patient (or designated surrogate) of the results of the EDx or neuromuscular evaluation. The physician should discuss with the patient the reason for the evaluation and the methods to be employed. The physician should advise the patient as to who will be providing the patient with the results of the test. If the patient has a diagnosis that does not require EDx or neuromuscular testing, the physician should so inform the patient and cancel the study or give the patient the right to cancel the study (see subsection "Cooperation and Communication with Healthcare Professionals").

Once the evaluation has begun, the physician should complete the evaluation process unless the patient ends the relationship before the evaluation can be completed, or if medical contraindications to completing the evaluation become apparent during the evaluation. After completion, the physician should return the patient to the care of the referring physician. If the patient does not have a referring physician, the physician should take

Abbreviations: AANEM, American Association of Neuromuscular and Electrodiagnostic Medicine; EDx, electrodiagnostic; EMG, electromyography; FDA, Food and Drug Administration; HIV, human immunodeficiency virus; IRB, institutional review board; LAR, legally authorized representative; NCS, nerve conduction study; OSHA, Occupational Safety and Health Administration; TJC, The Joint Commission

Key words: electrodiagnostic medicine; ethics; genetic testing; informed consent; neuromuscular medicine

This document, by the AANEM Ethics and Peer Review Committee, was originally drafted by the 1994 Committee: Robert G. Miller, MD (chair); Neil A. Busis, MD; William W. Campbell, MD, MSHA; Andrew A. Eisen, MD; Donna L. Frankel, MD; Mark Hallett, MD; Janice M. Massey, MD; and Lois M. Nora, MD, JD. The association also acknowledges the contributions of J. Russell Burck, PhD; Yasoma B. Challenor, MD; Steven H. Horowitz, MD; Glenn A. Mackin, MD; Lawrence R. Robinson, MD; and Jay V. Subbarao, MD.Developed and reviewed by the AANEM Ethics and Peer Review Committee. Approved by the AANEM Board of Directors, May 2015. This manuscript did not undergo further peer review by *Muscle & Nerve*.

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responsibility for urgent care of the patient until an appropriate referral can be made.

Informed Consent in Clinical Evaluation. The physician must obtain valid verbal or written consent from the patient. When the patient cannot give consent or lacks decisional capacity, a verbal or written consent must be obtained from the patient's appropriate legally authorized representative (LAR), who acts as a surrogate decision-maker. If the LAR is unavailable and the situation is urgent, the physician may proceed without consent. The physician must disclose information that the average person would need to know to make an appropriate medical decision. This information must include the benefits and risks of the proposed tests and should include the costs of the proposed tests if the patient desires this information. If the patient is referred for evaluation of a painful symptom, the physician should explain that the EDx studies are directed toward evaluation of certain measurable peripheral nerve abnormalities, not whether pain is present or absent. The patient must give consent voluntarily. If reasonable explanation fails to elicit a patient's consent to carry out the EDx examination, the physician should not undertake the evaluation. The patient may withdraw a prior consent; if this occurs at any point during testing, the physician should not continue with the examination. Physicians must comply with applicable state and federal laws governing informed consent requirements.

Federal Food and Drug Administration (FDA) and institutional review board (IRB) rules should be followed when conducting experimental or investigational studies of procedures, pharmaceuticals, or medical devices that involve human subjects (see section "Clinical Research").

Patient Communication, Comfort, and Preparation. The physician has a duty to communicate with the patient. The physician should convey relevant information in terms the patient can understand and allow adequate opportunity for the patient to raise questions and discuss matters related to a neuromuscular and/or EDx evaluation. Physicians should make every effort to ensure that patients are adequately prepared for planned neuromuscular evaluation and EDx procedures and that they are made as comfortable as possible during the examination. Physicians should be attentive to signs of patient discomfort and safety concerns and resolve them before proceeding. Physicians may decide whether to admit family members or significant others into the examination room during testing to provide support. Informing the patient of the findings of the examination should be coordinated with the referring physician (see previous subsection "Beginning and Ending the Relationship"). Moreover, suggestions for changes in clinical management should generally be made to the referring physician rather than the patient, unless the referring physician has requested that the physician participate in the direct clinical management of the patient.

Medical Risk to the Physician. Physicians have needs and concerns that are relevant for ethical decision-making in the context of evaluation. At the same time, a physician should provide appropriate, compassionate care to all patients, including patients with infectious and other communicable diseases [e.g., human immunodeficiency virus (HIV) or antibiotic-resistant infections]. A physician should not deny care to a patient solely because of real or perceived medical risk to the physician. Physicians must utilize appropriate universal precautions during the examination of any patient to minimize their own medical risk.

Ethical Considerations and the Management of Neuromuscular Disease. Some neuromuscular disorders are progressive or debilitating and may impact a patient's autonomy or competence. Many neuromuscular disorders have limited treatments, which may lead patients to seek unproven interventions. Others may have effective but costly treatments that their insurance may not cover or which patients may not be able to afford. Still others are known to shorten a patient's life expectancy with the prospect of a challenging final few months of life, leading the patient to seek alternatives for end-of-life care. In addition, genetically diagnosed diseases may include issues that affect relatives and future decision-making and have social implications.

Discussion of Disease Implications. First and foremost, physicians must provide patients with their best diagnostic and management skills. They also have a duty to discuss openly with their patients the implications of their EDx diagnosis and related illnesses. This discussion may require a great deal of sensitivity and compassion on the physician's part, particularly if the diagnosis is one that will severely impact the patient's quality or length of life. The physician's counsel should be honest yet allow the patient to preserve some level of realistic hope. The physician has a duty to help the patient understand, decide upon, and seek reasonable treatment, should this be available, and to help avoid ineffective treatments.

Progressive Disorders. For progressive disorders the physician should provide or refer the patient to services that will help maintain or prolong the patient's autonomy and independence. When the neuromuscular diagnosis is expected to limit life expectancy, the physician has a duty to provide this information to the patient as well as to provide

Exhibit BB

UNIVERSITY OF IOWA HOSPITALS & CLINICS

University of Iowa Health Care

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December 28, 2018

Leon Margolin MD, PhD
5245 E Main St
Columbus, OH 43213

Dear Dr. Margolin,

Thank you for asking me to review your project on chronic pain management, which is of considerable interest not only to physiatrists but also to other related specialties in general and neurology in particular. I am pleased to evaluate your proposal as a neurologist with special interest in clinical electrophysiology, which I practiced over 50 years.

The project you are undertaking relates to the role of nerve conduction studies (NCS) and needle electromyography (EMG) on clinical assessments of chronic pain patients. I find the study well designed using appropriate methodology to gain a positive impact on clinical practice. I am pleased to learn that the American Board of PM&R has approved this project that was highly evaluated by Dr. Wainapel, an expert in this field. As a neurologist, I too consider the project of considerable value and interest to other specialists and the third party payers.

From my personal experience, I consider NCS as one of the most important tests for evaluation of neuropathy and EMG as an essential tool for clinical study of radiculopathy, two very common conditions where chronic pain management plays an important role. As such these electrodiagnostic methods have demonstrated strong medical necessity on patient care dealing with chronic pain. I wish you continued success in this important endeavor.

Regards,

Jun Kimura, MD
Professor Emeritus
Department of Neurology
University of Iowa
Professor Emeritus
Kyoto University

Exhibit CC

Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

November 14, 2018

Dear Dr Margolin,

I have reviewed your study on the role of neuromuscular electrodiagnostic testing (including nerve conduction studies and needle electromyography) in the context of your chronic pain practice, found its methodology to be well considered, and its positive impact on clinical outcome provocative and quite compelling. I commend you for making a significant contribution to the specialty area of chronic pain management. These findings would likely be of considerable interest to physiatrists, other specialists treating chronic pain patients, and to the third party payors responsible for authorizing payment for electrodiagnostic testing.

Yours truly,

Stanley F.Wainapel MD, MPH, Clinical Director, Department of Rehabilitation Medicine

Montefiore Medical Center

Professor of clinical Rehabilitation Medicine, Albert Einstein college of Medicine

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Physiatric Consultation
Physical Therpy
Occupational Therapy
Speech Language Pathology

Exhibit DD

APEX

· Counseling Services ·

May 16, 2019

To Whom It May Concern:

I am a licensed psychologist, who has certification in addictions medicine and have taken training in pain management. I had been a clinical director of a recovery program in Lancaster, Ohio before transitioning to a hospital.

I have been working with the Comprehensive Pain Management Institute, LLC (CPMI) for several years now, but I am not employed by them and receive no compensation for services from them or Dr. Margolin for analysis.

I reviewed Dr. Margolin's voluntary practice improvement, submitted and approved to ABPMR.

After evaluating the patients I noticed that most of the patients in the sample (as well as many other high risk patients treated by CMPI) have psychological co-morbidities such as: anxiety, depression or concerns of aggressive/manipulative behavior (such as demanding a sharp increase in medications in response to an invasive test). The tests include EMG but because of higher risk patients, there is a chance of increasing psychopathology, like verbal aggression, therefore, a patient is required to give verbal consent.

These risks are clearly and objectively documents in the records as reflected in the initial follow-up evaluations. This includes urine drug screens, prescription monitoring program reports (OARRS), SOAPP-R, PADT, ORT and other assessment tools and referring provider records. All the patients on the list were treated in the framework of screening and brief intervention (SBIRT) approach which requires diagnostic testing. This includes nerve conduction studies within the framework of the Interventional Pain Management according to the state and federal guidelines.

Taking these factors into consideration, in my professional opinion Dr. Margolin made the correct clinical judgement within the framework of Interventional Pain Medicine by avoiding the needle EMG testing (for patients in sample two and in general of all CPMI patients) in case of lack of cooperation or clear understanding by the patient and/or concern of the aberrant behaviors described above.

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PROFESSIONAL EXPERIENCE

Hocking Valley Community Hospital
Logan Ohio
Work with geriatric population, counsel veterans and perform Gastric Bypass evaluation, pain management evaluations. Current

Apex Counseling
Ph: 614-751-1090
General counseling, psychological testing, forensic evaluations and custody evaluations, Pain management (Spinal Stimulator Evaluations), Work with LHI (Logistics Health Institution) evaluating candidates for military service. Current

Integrity Psychological Counseling, Inc 2005-2012
42 Hill Road South Pickerington, Oh 43137
Private Practice specializing in forensic evaluation, dual diagnosis, addictions, counseling, competency evaluations, psychological evaluations, Impaneled with Tricare for referrals with current service personal and veterans PTSD diagnosis and counseling with veterans of WWII, Vietnam, Desert Storm Legal work for Fairfield County Court System.
Bariatric & Gastric Bypass Evaluation, Spinal Stimulator Exams

Senior Life Consultants 2006-2011
6465 Reflections Drive, Suite 110
Dublin, OH 43017
Nursing Home evaluations, counseling geriatric population, consultation with physicians competency evaluations

Circleville Juvenile Correctional Facility 2006 - 2007
640 Island Road Circleville OH 43113
Clinical Experience: Psychology Supervisor.
Responsible for program development, scheduling, supervision of staff and caseloads, overall clinical management of institution, responsible for QI implementation and testing, and supervision of units.

River Valley Counseling 2001 - 2005
131 N. Ewing Street, Lancaster, OH 43130
Clinical Experience: Adult and adolescent individual and family psychotherapy, specialize in dual diagnoses; bariatric evaluations, spinal stimulator evaluations and evaluations for rehab, assessments for work injuries. BWC evaluations

Fairfield Medical Center 2001 -2012

401 North Ewing Street, Lancaster, OH 43130
Affiliate Staff Psychologist: Consultations, evaluations, therapy and triage of patients admitted to the Behavioral Health Unit.

Drug & Alcohol Recovery Center of Fairfield County 2000 -2001
1856 Cedar Hill Road, Lancaster, 01143130
Clinical Experience: Clinical Director: Responsible for program development, supervision of staff caseloads, crisis work, responsible for Q.I. implementation, and overall clinical management of agency.

Maryville Academy City of Youth 1996 - 1999
1150 North River Road, Des Plaines, Illinois 60016

Clinical Experience: Caseload involved assignment to two diagnostic group homes with youth and adolescents ages 7 years to 18 years. Tasks included psychological testing, individual therapy, develop group therapy for both group homes, court appearances on behalf of the youth, and staff training, and recommended alternate and additional placement and crisis intervention.
Doctoral Internship Jan. 1995 to Jan. 1996

Alexian Brothers Medical Center-Niehoff Mental Health Unit
995 Beisner Road, Elk Grove, Illinois 60007
Supervisor John Noto, PH.D.
Clinical Experience: Psychological testing, psychological reports, individual assessments, diagnosis, in-patient admissions, case management, supervision of practicum students, led groups for substance abuse and dual-diagnosis.

Samaritan House-Outpatient Adolescent Addictions 1994 - 1994
999A Leichester Road, Elk Grove, Illinois 60007
Supervisor: John Noto, Ph.D.
Clinical experience: Led adolescent addiction therapy groups, parent education groups, psychological testing, led multi-family educational groups, drug screens.

Alexian Brothers Medical Center-Addictions Treatment Center. 1993 - 1993
800 Beisterfield Road, Elk Grove, Illinois 60007
Supervisor Joan Stiech, RN CSADC
Clinical Experience: Coed psychotherapy groups, individual therapy, drug screens, intake und admissions, lecturer in addiction lectures series.

EDUCATIONAL BACKGROUND:

CHICAGO SCHOOL OF PROFESSIONAL PSYCHOLOGY 2009- 2009
Degree Conferred: Certificate of Forensic Psychology

ADLER SCHOOL OF PROFESSIONAL PSYCHOLOGY

65 East Wacker, Chicago, Illinois 60601
Degree Conferred: Doctor of Psychology, (Psy.D.) Clinical Psychology 1991 - 1996
Certification : Substance Abuse Counseling

NORTHEASTERN ILLINOIS UN1VERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: M.A. Community & Family Counseling Sep. 1984 to Oct. 1986
Degree Conferred: M.A. History Jan. 1981 to Dec. 1983

NORTHEASTERN ILLINOIS UNIVERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: B.A. Psychology. Sep. 1977 to Jun. 1980

HARPER COLLEGE
1200 W. Algonquin Rd., Palatine, Illinois, 60067
Degree Conferred: A.A. Liberal Arts Jan. 1975 to Aug. 1977

LICENSURE AND CERTIFICATIONS
State of Ohio #5481
Certificate: Forensic Psychology
Certificate Substance Abuse Counseling
(Alder School of Professional Psychology) Apr. 1994 to Dec. 1994

PRESENTATIONS
-Psychological Needs of the Substance Dependent Patient
-Pain Management Team, Fairfield Medical Center, Lancaster, OH
-Identifying Drug Abusers and Pain Management Technique in Patients
-With a History of Drug Abuse, Pain Management Physicians, Fairfield Medical Center, Lancaster, OH
-Peer Pressure and Anger Management; Thomas Ewing Junior High School, Lancaster, Ohio
-"Catch Me If You Can—Obsessive Compulsive Disorder", and
-"Stress and Anxiety Disorder in the Adult Population" 12th Annual
-Early Childhood Conference, Ohio University, Lancaster Campus, Sponsored By the Children's Committee,
a subcommittee of Fairfield County Family,
Adult and Children First Counsel
-"Competency Evaluation: presented to the Ohio State Bar Association, Lancaster, OH
-"Childhood Depression", interview for Medical Minute presented by WLOH Radio, Lancaster, OH
-"Signs and Symptoms of Childhood Depression: written for Lancaster Eagle Gazette through Fairfield Medical Center.
-Interview, Fairfield Focus, WLOH Radio, Lancaster, OH
-"Out of the Box" Workshop, presented with Dr. Miller and Dr. Wing

Ohio University Inn, Athens. OH
-"Emotional and Psychological Health: How to Support Employees", Women's Division, Lancaster Chamber of Commerce, Presented at Fairfield Medical Center, Lancaster, OH.

Book Written under Pseudonym T.L. Shull: Do They Have a Pill for That? Publisher I Universe Press, March 2019.

Exhibit EE