



FSIPP NEWSLETTER

WINTER 2016

Editor-in-Chief: Deborah H. Tracy, MD

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PRESIDENT'S MESSAGE

By Larry Dalton, DO



The Mission Statement of the Florida Society of Interventional Pain Physicians (FSIPP) has been our driving force since the founding of FSIPP in 2001. Our previous presidents: Andrea Trescot, MD, Lora Brown, MD, Harold Cordner, MD, Deborah Tracy, MD, and Sanford Silverman, MD have all dedicated their time and effort to this mission and have grown our society into the largest and most dynamic Pain Society in the State of Florida. The mission statement is as follows, "To promote the development and practice of safe, high quality, cost-effective interventional pain management techniques for the diagnosis and treatment of pain

and related disorders, and to ensure patient access to interventional pain medicine (or management) doctors and these treatments in the State of Florida."

We currently have three arms or our organization: FSIPP, FSIPP Political Action Committee (PAC) and the FSIPP Educational and Research Foundation. The Society itself coordinates the daily operations of these organizations. Our Executive Director, Michelle Byers is a dynamic force who does a great job with the management logistics required but also is a successful fundraiser. The Society's Annual Educational Meeting continues to grow with large

membership attendance and this year will be held May 20-22 in Orlando. FSIPP has a representative on the Carrier Advisory Committee (CAC) for Medicare First Coast Service Options, the Medicare provider for Jurisdiction 9 in the State of Florida. Participation in the CAC has allowed our Society to educate the Medicare Policy Staff and affect the preservation of coverage in the development of Local Coverage Determinations.

Over the past 2 years FSIPP leadership has provided testimony to the FDA, AMA, FMA, Florida House and Senate Committees, Florida Board of Medicine, and the Board of Pharmacy. The FSIPP PAC is responsible for our advocacy efforts. We have contracted a full time lobbyist to help get the job done. This representation has had a positive impact on our ability to continue to perform interventional procedures, influenced the regulations that govern pharmacists on filling controlled substances, and ensuring access to abuse deterrent medications for our patients. We have retained General Council to represent our membership steadfastly at the Florida Board of Medicine Meetings and General Council to insure all regulatory issues are addressed.

Our newest arm is the Florida Society of Interventional Pain Physicians Educational and Research Foundation. This foundation is designed to foster further educational opportunities for physicians, allied health providers and the public about the practice interventional pain medicine as a specialty. It will also allow our society to develop revenue sources to help encourage research in our field.

Aside from the FSIPP Annual Educational Conference, we have started regional FSIPP meetings with resounding success. These meetings have encouraged a deeper level of communication between our members and have allowed the leadership to appreciate the collective will and represent the membership more effectively. Next year we are planning a mid-year educational seminar for those members who may not be able to attend the May Annual Meeting.

As you can see, the Florida Society of Interventional Pain Physicians is constantly working to fulfill its mission in multiple ways. We thank you for your continued membership and support. FSIPP will continue to represent our membership and our specialty with multiple instruments and tools at our disposal.

FSIPP Update from the Executive Director

Michelle Byers-Robson, FSIPP Executive Director



First of all, it has been an absolute pleasure getting to know all of you since taking over the position as the FSIPP Executive Director in June of 2015. I have had some pretty big shoes to fill following in the footsteps of Lorry Davis who did a great job starting and building FSIPP into what it is today. I see my job as continuing all of the wonderful initiatives of Lorry and the FSIPP Board of Directors, as well as growing the Membership, Outreach, Education and Legislative support so that we can truly embody the mission of FSIPP as well as our parent organization, ASIPP through 2016 and beyond.

My primary goals in taking over the Executive Directorship were to: improve the financial health of FSIPP and the FSIPP PAC, maintain and grow FSIPP Membership, produce the best FSIPP Annual Meeting yet, increase and improve communication and collaboration between the FSIPP Membership. Below is a snapshot of where we currently stand with respect to these goals.

FSIPP Financial Health

On the income side, we added an option of corporate sponsorship on an annualized basis IN ADDITION to sponsorship of our annual meeting. We have had several very large companies agree to support FSIPP on an annual basis including Nevro and Boston Scientific and Advanced Labs. We have also pursued annualized advocacy and educational grants with several pharmaceutical companies. Additionally, we have significantly reduced expenses.

FSIPP Membership

FSIPP closed the 2015 year with 203 total members. As you know, we initiated our membership drive in January, 2016. This has resulted in the collection of a substantial number of membership dues to support FSIPP and PAC throughout the year. In addition to our membership renewal revenue, we have also realized the addition of 16 new members in the first two weeks of January alone!

FSIPP Annual Meeting

FSIPP Annual Meeting – REGISTER NOW!! The FSIPP Annual Meeting will take place May 20-22, 2016 at the Orlando World Resort in Orlando, Florida. The FSIPP annual meeting has historically been one of the largest and best state society meetings for ASIPP. We are committed to making this year one of the best FSIPP has ever offered! Take advantage of both our reduced registration rates for our members AS WELL AS our early registration rates! Registration: www.FSIPP.org.

FSIPP Improved Collaboration and Outreach

Finally, in 2015, FSIPP initiated a Regional Dinner Program to improve our collaboration and communication with our membership through the year. These dinners have given us an opportunity to communicate directly with our membership on a local level to discuss current and regional issues with interventional pain management. We have supported these dinners through our pharmaceutical and device company partners who have graciously agreed to fund the cost of the dinners in exchange for a short company presentation. We have held 5 regional dinners: Jacksonville, Naples, Tampa, Miami and Ft. Lauderdale with attendance of over 25 local members! Additional dinners will be offered in 2016 including two already planned in January.

Things To Come In 2016 And Beyond

The newly formed FSIPP Educational Foundation will begin to offer education and outreach to pain practitioners, interventional pain practitioners, pharmacists and primary care physicians in 2016. The mission and goal of the FSIPP Educational Foundation is to expand our outreach and knowledge of best practices in Pain Management.

As always, I and the entire FSIPP Board of Directors, appreciate your comments, concerns, ideas and input throughout the year – we WELCOME your ideas and feedback! Have a wonderful 2016.

SAVE THE DATE



FLORIDA SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
...THE voice for interventional pain physicians.

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2016 ANNUAL MEETING, CONFERENCE AND TRADE SHOW

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ON FSIPP ANNUAL MEETING REGISTRATION***

Radiation Exposure: "Over-Radiated from Fluoroscopy"

By Jonathan Daitch, MD



I certainly was receiving a large dose of radiation exposure from providing interventional injections under fluoroscopy. I do all of my interventional pain injections in a surgery center. I perform about 80 cases per week under fluoroscopy. For the first five months of 2015, based on my outside dosimeter badge, I was receiving nearly 1000 mRems of radiation exposure per month. That was putting me nearly over my yearly limit in just five months!! The recommended limit is 5000 mRems per year. I received an urgent call from our radiation physicist sternly warning me. I took heed, since the state of Florida could have come in and halted my work.

We analyzed what the most effective steps might be at limiting excessive radiation and obtained a real-time x-ray dosimeter badges from our GE representative. That allowed us to analyze what changes were helping the most in real time.

The first measure we implemented was to remove my sacred wireless foot pedal and gave complete control to the x-ray tech for taking fluoroscopy pictures. The second step was to use a laser pointer and have the x-ray tech localize the entry site prior to my approaching the patient. Since, I was mainly using a long pointer, I found myself standing quite close to the patient while identifying the target. The laser pointer solved that problem. The third step we took was going from using low dose radiation to pulsed radiation with our fluoroscope. Using pulse radiation cuts the fluoroscopy exposure by 50%. The fourth step, was utilizing a mobile radiation screen between myself and the X-ray tube when I was taking lateral fluoroscopy shots, such as with caudals, cervical MNBBs, or during kyphoplasties.

Finally, I have been more vigilant about taking a step back prior to taking any fluoroscopy pictures (especially lateral shots). With these five changes I have dropped my radiation exposure 20 fold. Now I am getting only 50 mRems per month. I feel we are more safety conscious, and it is certainly better for my own health and everyone else in the room.

I also spoke with Dr. Deborah Tracy, who is the queen of minimal radiation dose and picked her brain. She is even standing behind a clear leaded shield for all fluoroscopy cases. Her exposure numbers are per quarter are quite impressive, so even further reduction is possible. Overall, I'm thankful I had this wakeup call and revelation. I hope some of you can benefit from my experience.

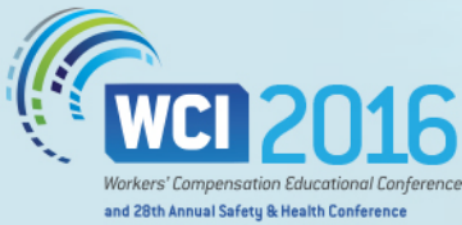
I have summarized some of the actions that can improve radiation safety and have also added the list below of others as well.

- Time
- Collimation
- Source-to-tabletop distance
- Patient-to-image intensifier distance
- Low mA
- Preferential kVp
- Placement of X-ray tube
- Pulsed fluoroscopy, ↓exposure 50%
- "Last image hold" fluoroscopy
- 5 Minute Alarm
- Shielding
- Avoiding Magnification



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Topical Compounded Ketamine: Hype or Hope?

By Miguel de la Garza, MD



Recently, pharmaceutical compounding has been extremely controversial due to cases of inappropriate laboratory methodologies for sterile compounding, inappropriate billing practices, overt fraud are patient deaths. Many physicians are weary to use compounded agents at this time. However, compounding offers target specific solutions for treating pain that cannot be achieved in other ways. This article will focus on a rational approach to integrating topical compounding solutions in a multidisciplinary pain practice and will examine available evidence or use of topical compounded ketamine administration.

Topical compounded medications offer site specific administration, low systemic absorption and may reduce the doses of concurrent systemic administration of medications, thus reducing side effects. To select a specific medication for compounding, one must first understand the pathophysiology of pain to be treated. Then, relevant patient specific conditions including comorbidities, stage of illness, where the pain is occurring and other contributing factors related to a patient-specific condition are considered. Next, a specific agent or drug which will focus on treating the pathophysiology is selected while the specific site of application, the route of delivery (topical) and delivery system will be selected. Consultation with your compounding pharmacist is a good idea. He or she must consider the absorption, distribution, metabolism and excretion (ADME) of each agent and how each will affect each other in the compounded vehicle. Many hydrophobic and hydrophilic agents cannot be mixed together without special considerations.

Ketamine is a popular transdermal compounded agent. Ketamine has diverse effects and acts primarily as an antagonist of the NMDA receptor, this action accounts for most of its effects. Ketamine is poorly understood due to its relatively complex pharmacological profile.

- Non-competitive antagonist of the NMDA receptor (NMDAR)
- Negative allosteric modulator of the nACh receptor
- Weak agonist of the μ -opioid and κ -opioid receptors
- Agonist of the D2 receptor
- Weak mACh receptor antagonist
- Inhibitor of the reuptake of serotonin, dopamine, and norepinephrine
- Voltage-gated sodium channel and L-type calcium channel blocker, and HCN1 cation channel blocker
- Inhibitor of nitric oxide synthase
- σ receptor 1 and 2 agonist

Despite the lack of understanding regarding the true mechanism of action, the role for acute and chronic refractory neuropathic pain is supported by the literature. There is a low therapeutic index when administered systemically. Increases in blood pressure, heart rate, altered mental status, dysphoria, seizures, coma, neuronal toxicity and even death may result from ketamine administration. But, retrospective review of literature provides evidence of Ketamine induced pain reduction in central pain syndromes (parental and oral), complex regional pain syndrome (epidural), fibromyalgia, ischemic pain, nonspecific neuropathic pain, phantom limb pain, post herpetic neuralgia (parenteral and oral), and acute or chronic severe neuropathic pain. Overall, "the evidence for efficacy of [systemic] ketamine for treatment of chronic pain is moderate to weak. However, in situations where standard analgesic options have failed ketamine is a reasonable "third line" option." There were no studies which examined topical administration.

Topical administration of ketamine may offer significant benefits for pain control without deleterious systemic effects. Recent research has suggested that ketamine may alter the "docking station" for vesicles containing neurotransmitters, such as glutamate. The vesicles travel through the primary afferent neuron and have an effect at the presynaptic level, before binding to the intermediate receptors. Thus, the peripheral effects of ketamine in a topical administration will show different pharmacological modes of action than systemic administration.



FLORIDA | Board of Medicine

NEWS FROM THE FLORIDA BOARD OF MEDICINE REGARDING "PILL MILLS"

In 2009, the Florida legislature adopted a new law to address the state's growing problem with prescription drug abuse and diversion. Chapter 893.055 established new guidelines for operating pain management clinics and approved development and utilization of a Prescription Drug Monitoring Program ("PDMP") database to collect controlled substance prescription records from dispensers.

Prior to passage of the law, the Federal Centers for Disease Control labeled Florida the epicenter of prescription drug diversion because it had weak regulatory oversight of pain management practices, limited regulation of physician dispensing habits and, most importantly, no prescription drug monitoring program. Florida became known as the "Pill Mill" capital of the country.

According to DEA statistics, the state had over 900 unregulated pain management clinics in 2010. The data also showed that these clinics employed 90 of the top 100 oxycodone dispensing physicians in the country. Of the top 50 oxycodone dispensing clinics in the U.S., 49 were located in Florida and were selling more than 1 million oxycodone pills a month. Before new regulations were enacted by the Florida legislature, it was projected from state medical examiners reports that about 10 persons each day died of prescription drug overdose, primarily due to oxycodone abuse.

Florida's prescription drug monitoring program, E-FORCSE (the Electronic-Florida Online Reporting of Controlled Substances Evaluation), began operation in 2011. The database is managed by the Department of Health, and its yearly \$500,000 operating budget is raised through a non-profit, tax exempt, Direct Support Organization foundation whose board of directors is appointed by the State Surgeon General.

Because of the new PDMP law, dispensers of controlled substances must report all transactions within seven days. The law also permits all licensed health care practitioners including physicians, dentists, osteopaths, podiatrists, pharmacists, physician assistants, ARNPs and optometrists to register and use the database in treatment planning prior to prescribing a controlled substance. Law enforcement agencies may also access the system for information to assist in investigation of active cases.

Since E-FORCSE became fully operational the oxycodone death rates have been reduced by 41%. Practitioners who use the database have the ability to check patients prescription history which can help prevent over-prescribing and identify those persons who may be doctor shopping.

As of July 1, 2015 over 163 million dispensing records have been collected by the PDMP. Also, more than 32,000 practitioners have registered for the program of which 14.5% of all licensed MDs or 10,206 are utilizing E-FORCSE. Of this total, 7,348 MDs queried the program with over 6.7m queries.

For more statistics, you may view the 2014-2015 Prescription Drug Monitoring Program Annual Report by visiting http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/_documents/2015-pdmp-annual-report.pdf

For more information about E-FORCSE visit its website at www.e-forcse.com. For technical assistance call (877) 719-3120. To obtain information on how to support the program contact the PDMP Foundation at executive.director@flpdmpfoundation.com.

ACNE Syndrome

By Andrea Trescot, MD



Abdominal cutaneous nerve entrapment syndrome (ACNES) [also known as "intercostal neuralgia", "rectus abdominis nerve entrapment syndrome", chronic abdominal wall pain (CAWP), and many others] is abdominal pain due to entrapment of the abdominal cutaneous nerves (ACN). These are the most distal branches of intercostal nerves, which terminate in the rectus abdominis muscle and the skin of the anterior abdominal wall. One investigator stated that any patient with the triad of chronic abdominal pain, a positive Carnett's test (see below) and normal laboratory/radiologic examinations suffers from ACNES until proven otherwise.

Despite the fact that ACNES was initially described in the 19th Century and is relatively easy to identify and treat, it is still widely under-diagnosed and viewed as a diagnosis of exclusion. As a result, patients with abdominal wall pain frequently have multiple studies and surgeries in the interval before correct diagnosis (1 month to 30 years, average 25 months), examples of what one author has termed "visceral thinking." The average cost of unnecessary evaluations before correct diagnosis was \$6,727 per patient (using 2001 prices) in one study, and evaluation costs decreased more than 50% after a pain clinic consultation, when compared to the costs of a diagnostic evaluation for the same symptoms in a primary care clinic (mean cost \$541 per pain clinic patient versus \$1,133 per primary care clinic patient). The true incidence and prevalence of ACNES is unknown. It has been estimated that for every 150 patients in a family practice, there are 1 to 2 patients who have abdominal wall pain.

Clinical Presentation

Patients with ACNES will present with sharp, constant or intermittent pain over any part of the anterior abdominal wall. If the pain is on the right, they may be misdiagnosed as having appendicitis or cholecystitis; if on the left, they may be thought to have diverticulitis. Patients with ACNES are most commonly in 30 to 50 year age range, though this condition has been reported in children and octogenarians, and the pain is more often on the right side. This condition often occurs at 22 to 23 weeks of pregnancy, especially in muscular young mothers, where the growth of the baby stretches the abdominal musculature. The pain is usually increased by activities that increase abdominal wall tension (e.g., coughing, lifting weights/groceries/children, turning in bed), and patients can usually point with one finger to where it is most intense.

They are often told that they have "fibromyalgia", "irritable bowel syndrome", depression, or Munchausen's syndrome, and they may be confronted as malingerers or drug seekers. Since they are unable to prove the legitimacy of their pain because of their often-normal tests, these patients may have a hard time establishing a trusting relationship with a physician.

Anatomy

The lowest 6 pairs of thoracic intercostal nerves innervate the abdominal wall. The anterior rami travel between the internal oblique and transversus abdominis muscles in the transversus abdominis plane (TAP) as thoracoabdominal intercostal (T7-T11) or subcostal (subgastric) (T12) nerves and then turn 90° anteriorly to pierce the rectus abdominis muscle (RAM). Each of the five lowest intercostal nerves divides into several branches that, accompanied by an artery and vein, traverse the RAM at each level. The ACN passes through a firm fibrous ring in the rectus muscle, accompanied by small branches of the inferior epigastric artery and vein, cushioned by fatty tissue. The T7 ACN innervates the skin at the level of xiphoid, the T10 at the umbilicus, and the L1 in the groin as the iliohypogastric nerve.



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ACNE Syndrome

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Entrapment

The most common thoracoabdominal nerve entrapment site is near the lateral border of the RAM, though other sites over the RAM and at the branch points of the lateral and posterior cutaneous branches are possible. Usually patients have only one site of entrapment (92%), but multiple sites are possible. Local inflammation and scarring prevents the ACN from gliding through the sheath opening, which causes painful nerve overstretching, frequently associated with a specific body position. Increased intra-abdominal pressure from any cause can initiate herniation of the neurovascular bundle and its accompanying fat through the fibrous ring. Scars due to trauma or surgery may create additional points of entrapment of subcutaneous branches and are frequent precursors to ACNES.

Physical Exam

Physical examination is directed by the history, and is initially performed in a standing position. It begins with observation of abdominal muscle tone and the presence of surgical scars or hernias. With the patient supine, ask the patient to put one finger on the most painful spot, then displace it slowly with your finger while palpating for a small half-moon indentation on the fascial surface to find the point of the ACN entrapment at it exits from the RAM. This maneuver can help locate the site of origin of the pain, especially when hyperesthesia or allodynia is present; this technique is also useful in identification of a little "pit" (crescent defect of a fascia opening) or a "ball" of a firm fat surrounding the ACN at its exit through the fascia. Palpating fingers should literally "walk" through the painful area looking for irregularities and the point of maximum tenderness. There is usually a particularly sharp pain localized to a small depression over the lateral RAM. Then, ask the patient to perform a partial "sit up" to contract the RAM while you palpate the point of maximum tenderness (Carnett's test). The presence of highly localized pain and tenderness and the increase in pain with abdominal wall tensing makes a visceral source of pain much less likely. A good response to at least one injection of local anesthetic is included in the diagnostic criterion by many authors.

Injection Techniques

Landmark-Guided Technique

The patient is placed supine with the involved side close to the injector; in thin patients, palpation is usually sufficient to identify the target, while a peripheral nerve stimulator (PNS) may be helpful in those who are overweight. Following aseptic precautions, the fingers of the non-injecting hand straddle the tender site, and a 25-gauge 2-inch needle is inserted at about a 30-degree angle through the skin, 2-3 cm from the point of maximal pain (more in an obese patient). The needle should never be directed perpendicular to the abdominal wall; tangential needle position ensures that the needle moves with the abdominal wall, making penetration less likely. The needle is slowly advanced toward the painful spot through two ill-defined layers – the superficial loose fat of "Camper's fascia" and deeper fibrous fat of "Scarpa's fascia". The needle will finally encounter the resistance of the RAM sheath, and the patient usually feels a reproduction of their ACNES pain. The inferior and superior epigastric vessels are superficial to the posterior rectus sheath and can be inadvertently damaged with deep needle advancement.

Ultrasound-Guided Technique (US)

The US anatomy of the abdominal wall has been well characterized. Orient yourself by placing the transducer transversely, just off the midline, at the approximate level of the point of maximum tenderness. The RAM is seen as a hypoechoic area surrounded by its hyperechoic fascia. Above the arcuate line, the posterior rectus sheath consists of the aponeurosis of the transversus abdominis muscle and the transversalis fascia, often seen on ultrasound as a hyperechoic "double layer". Move the transducer laterally to identify the hyperechoic semilunar line; often the ACN is seen as a hyperechoic dot within the muscle medial to the semilunar line. The accompanying artery may also be visible and may help to find the nerve, but veins at this level are usually too small to produce detectable blood flow.

Complications

As with other interventional procedures, complications can include poor target localization with ineffective treatment during a landmark-based technique (especially in obese patients), intra-abdominal or intra-thoracic needle penetration, intramuscular hematoma, anesthetic toxicity, bleeding, and increased

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ACNE Syndrome

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intra-thoracic needle penetration, intramuscular hematoma, anesthetic toxicity, bleeding, and increased pain. Although there are no reports specifically describing this in ACNES patients, chemodeneration and RF neuroablation can cause scar formation and deafferentation with possible pain increase. Denervation or injury to the lower abdominal nerves may cause an abdominal bulge, due to motor weakness of the abdominal wall.

Summary

ACNES is a commonly overlooked cause of abdominal pain. Patients usually have undergone extensive evaluations and multiple surgeries before being sent to a pain management specialist. Diagnosis is simple and can be done at the bedside, and treatment can be very successful.

The above excerpt is heavily editing due to limited space.
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PUBLISHING APRIL 2016

Peripheral Nerve Entrapments, Clinical Diagnosis and Management

Editor: Andrea M. Trescot



Features over 50 videos and examination and injection techniques

Contains Pain Problem Index

Includes anatomy and complication of each injection

Nerve entrapments can occur throughout the body and cause headaches, chest pain, abdominal pain, pelvic pain, low back pain, and upper and lower extremity pain. As an example, one of the most common forms of nerve entrapment syndrome, Carpal Tunnel Syndrome, affects roughly 1 in 20 people in the United States, and is only one of several types of entrapment syndrome possible for the median nerve. Offered in a single volume, *Peripheral Nerve Entrapments: Clinical Diagnosis and Management* is a comprehensive guide to possible nerve entrapment syndromes and their management. Each chapter covers a single nerve, or group of closely related nerves, and goes over the clinical presentation, anatomy, physical exam, differential diagnosis, contributing factors, injection techniques, neurolytic/surgical techniques, treatments of perpetuating factors, and complications. Chapters are also extensively illustrated and include 3D anatomical images. The additional online material enhances the book with more than 50 videos - one for each nerve. This enables readers to easily navigate the book. In addition to a conventional index, it includes a "Pain Problems Index" for searching by symptom.

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FSIPP

FLORIDA SOCIETY
OF
INTERVENTIONAL PAIN PHYSICIANS

THE VOICE FOR INTERVENTIONAL PAIN PHYSICIANS



Our Mission

To promote the development and practice of safe, high quality, cost-effective interventional pain management techniques for the diagnosis and treatment of pain and related disorders, and to ensure patient access to interventional pain medicine (or management) doctors and these treatments in the State of Florida.

FSIPP Proudly Acknowledges

Advocacy and Educational Grant



Educational Grant





FLORIDA | Board of Pharmacy

FSIPP Achieves Support From The Florida Board Of Pharmacy

FSIPP Achieves Support From The Florida Board Of Pharmacy To Enable Legitimate Pain Patient Access To The Prescribed Controlled Substances And Must Take The Following Steps Before Denying A Fill:

To determine whether the prescription for a controlled substance is a valid prescription

1. Obtain government issued ID
2. Check the PDMP
3. Call the physician

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Definitions: For purposes of this rule the following definitions shall apply:

- (a) Valid Prescription. A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.
- (b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.
- (c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.

(2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

- (a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.
- (b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.
- (c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

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FSIPP Achieves Support From The Florida Board Of Pharmacy

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(3) Minimum Standards Before Refusing to Fill a Prescription.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;
2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

(5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of Section 456.42(2), F.S. (2015), and pursuant to applicable federal law. For more information related to the federal requirements, access <http://www.deadiversion.usdoj.gov/ecommm/index.html>.

(6) Mandatory Continuing Education: All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:

- (a) Ensuring access to controlled substances for all patients with a valid prescription;
- (b) Use of the Prescription Drug Monitoring Program's Database;
- (c) Assessment of prescriptions for appropriate therapeutic value;
- (d) Detection of prescriptions not based on a legitimate medical purpose; and,
- (e) The laws and rules related to the prescribing and dispensing of controlled substances. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period.

(7) Summary Record: Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History—New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.



VAUGHN & ASSOCIATES, L.L.C.
Lawyers for Healthcare Providers

What's New In Interventional Pain For 2016

By David Vaughn, Esq., CPC

1. Reimbursement.

a. Medicare UDT Reimbursement. The most important change in reimbursement is the massive cut in UDT reimbursement from Medicare. Most labs are reporting approximately 70% reduction in Medicare reimbursement. I will cover that issue more in-depth below.

b. Medicare Conversion Factor. Medicare's conversion factor ("CF") decreased only minimally, from \$35.9335 to \$35.8279. The CF is the price Medicare pays for a single RVU in the Medicare Physician's Fee Schedule ("Fee Schedule").

c. Professional Fees ("Pro Fee") for Core Interventional Procedures. ASIPP puts out its analysis of Medicare's reimbursement changes each year, both as to the Pro Fee and the ASC facility fee. In looking at that analysis, insofar as the Pro Fees are concerned, the physician's fees for the bread and butter procedures (facets, epidurals, SIJ, TPI, etc.) did not materially change regardless of the place of service. In fact, each of the above procedures had minor increases in reimbursement. The only significant procedures undergoing a change of Pro Fee reimbursement of 5% or more were kyphoplasty and vertebroplasty, in which case the Pro Fee in the facility increased slightly in excess of 5% for most of those codes. While there were some other procedures experiencing greater than 5% increase or decrease, they were not commonly performed procedures by most interventionalists.

d. E&M Reimbursement. Medicare's E&M reimbursement did not materially change whether in the office or the facility.

e. Facility Reimbursement. In contrast to the benign changes for Pro Fees, the facility fees will experience material changes in some procedures. There were numerous procedures in which the facility fees changed, for better or worse, more than 40%. Examples include 62263 (percutaneous lysis of adhesions, 2 or 3 days, minus 42.9%; 62270 and 62272 (spinal puncture) plus 60.2%; 62281 and 62282 (neurolytic epidurals) minus 42.9%; 62360 (implant subcutaneous reservoir for epidural drug infusion) plus 542% (appears they are including the cost of the reservoir in the facility fee); 64410 (phrenic nerve block) plus 182%; 64415 (brachial plexus block) plus 125%; 64420 (single intercostal block) plus 60%; 64600 (destruction of trigeminal nerve) minus 42.9%; 64620 (destruction of intercostal nerve) minus 42.9%. Some of the core procedures experiences lesser, yet still material, reimbursement changes. For example, facility fees for cervical and lumbar translaminal and transforaminal epidurals (62310, 62311, 64479, and 64483) decreased 11.2%; while epidurals with catheters (62318, 62319) increased 24.8%. Facet blocks (64490, 64493) increased 24.8%. SIJ injections (G0260) decreased 11.2%.

2. Medicare Lab Coding and Reimbursement.

a. Complete Revamp of UDT Coding. Medicare completely revamped UDT coding. All of Medicare's prior G codes were deleted, and that includes G0434 (multiplexed kit), G0431 (analyzer), and all the new G codes that Medicare just adopted for 2015 (G6030-G6058) for specific drug classes. In lieu of these approximate 30 G codes, Medicare adopted 7 new G codes, 3 of which are for screening and 4 of which are for confirmations.

b. 3 New Screening Codes. The 3 new Medicare screening codes are:

i. G0477 (test read by direct optical observation, such as dipsticks, cups, cards, and cartridges) which pays \$14.86 (unadjusted for geographic locality). This code is billed once per date of service, regardless of how many drug classes are tested. This code bundles (so you cannot separately bill) sample validation codes, such as for pH, creatinine, etc.

ii. G0478 (test read by instrument assisted direct optical observation), which pays \$19.81. This code is billed once per date of service, regardless of how many drug classes are tested. Sample validation services are bundled.

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iii. G0479 (test read by chemistry analyzers, such as immunoassay, enzyme assay), which pays \$79.25. This code is billed once per date of service, regardless of how many drug classes are tested. Sample validation services are bundled.

c. 4 New Confirmation Codes. The four new confirmation codes are all defined exactly the same, with the only difference being how many drug classes are tested. The more drug classes tested, the higher the Medicare reimbursement. For example, all 4 confirmation codes are defined as requiring sophisticated testing equipment such as LC/MS and GC/MS, which are able to identify individual drugs and distinguish between structural isomers. Each of the 4 codes bundles specimen validity tests, and each excludes immunoassays and enzyme assays (i.e., desktop analyzers). The number of tests required for each code and the reimbursement for each code is as follows (note that the code changes for every additional 7 drug classes tested):

- i. G0480 - 1-7 drug classes, including metabolites, which pays \$79.94
- ii. G0481 - 8-14 drug classes, including metabolites, which pays \$122.99
- iii. G0482 - 15-21 drug classes, including metabolites, which pays \$166.03
- iv. G0483 - 22 or more drug classes, including metabolites, which pays \$215.23

d. Refusal to Recognize the AMA CPT Codes. Medicare continues the position it adopted in 2015 that it will not recognize or pay for the AMA's new presumptive and definitive UDT codes adopted in CPT 2015.

3. CPT Coding Changes.

a. What Did Not Change. There were no changes to code descriptors for usual and customary interventional procedures or core E&M services. Thus, TPI's, joint injections, epidurals, facets, RF's, kypho/vertebroplasty, fluoro, stims, pumps, and E&M visits in the hospital and office did not undergo changes in definition.

b. What Did Change. The major changes affecting pain in the CPT Code are:

i. Instructions for Coding Facet RF Procedures. The AMA instructs that facet RF procedures are coded "per joint, not per nerve." Additionally, the AMA advises that RF of T12-L1 should be coded as thoracic, not lumbar (64633). Finally, the AMA cautions that facet RF codes should not be reported for either pulsed RF or any RF procedure where the temperature is less than 80 degrees Celsius (i.e., low grade RF).

ii. Instructions for Coding RF of the SIJ. The AMA instructs as follows when coding for RF of the SIJ, "For destruction by neurolytic agent, individual nerves, sacroiliac joint, use 64640." In the past many interventionists have coded RF of the SIJ using a facet RF code for L5-S1. According to this new instruction, all nerves which are denervated for the SIJ should be coded as 64640, and none of them should be coded using the facet RF codes.

iii. Stim Analysis and Programming. 95972 (stimulator programming and analysis up to one hour) has been changed to delete the "one hour" verbiage. It now applies regardless of how much time is involved. 95973, (each additional 30 minutes of programming) has been deleted.

iv. Spinal Accessory Block Code Deleted. 64412 was deleted because Medicare found massive incorrect coding for this code; the AMA now instructs providers to bill this procedure as 64999.

v. New Prolonged E&M Codes for Clinical Staff Supervised by a Physician. Although I don't think this will have much application in a typical pain practice, the CPT Code added codes 99415 (additional 45-74 minutes of

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of face-to-face patient time by clinical staff) and 99416 (each additional 30 minutes) for incident to billing of services by clinical staff such as RN's, LPN's, or MA's (excludes NP's or PA's, who have their own separate codes). The time does not have to be continuous, but can be discontinuous. The prolonged E&M codes are billed in addition to the normal E&M code billed. For example, assume the usual 99213 visit is billed, which typically requires 15 minutes. If clinical staff spends an extra 45 minutes face-to-face with the patient, in addition to the 15 minutes required by 99213, the physician can bill 99213 and 99415 to account for 60 minutes of clinical staff face-to-face time, assuming the physician is in the office and immediately available. These codes are limited to the office or outpatient setting, not the inpatient setting.

4. OIG Work Plan for 2016.

a. Orthotics. For 2016, the OIG will institute 2 new items of inquiry on orthotics. The first inquiry will center on whether Medicare is paying too much for orthotics. The second inquiry will focus on whether the orthotics are medically necessary. The OIG reminds providers that each of the DME MAC's have LCD's which provide a narrow window of clinical indications justifying medical necessity for orthotics, as well as documentation requirements for the Detailed Written Order ("DWO") and the Proof of Delivery ("POD"). Each provider needs to be sure that all 3 of these components (i.e., clinical indications, DWO, and POD) are correctly documented, since audits are coming.

b. Prolonged Services. The OIG will start auditing prolonged service E&M codes to see if they are medically necessary. The OIG warns that these add-on E&M codes should be "rare and unusual."

c. Payments for Illegal Aliens. Medicare does not authorize its contractors to pay for medical services to illegal aliens. However, the MACs have not been doing a good job of patrolling this. The OIG notes that Medicare contractors have paid out \$91.6mm in improper payments for medical services for illegal aliens, and the OIG will now start to recoup those payments.

5. PQRS.

a. Individual Measures. Whether reporting via claims or through a registry, the Final Rule states that one must report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

b. Measures Group. For the measures group, you must report for 20 patients, the majority of which are Medicare. There is one measures group that applies to pain management physicians for 2016, which is "Preventive Care Measures Group" which contains the following measures:

#39 Screening for Osteoporosis for Women Aged 65 - 85 Years of Age

#48 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

#110 Preventive Care and Screening: Influenza Immunization

#111 Pneumonia Vaccination Status for Older Adults

#112 Breast Cancer Screening

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#113 Colorectal Cancer Screening

#128 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

#134 Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan

#226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

#431 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

c. **New Cross-Cutting Measures.** There are 3 new cross-cutting measures for 2016: Unhealthy Alcohol Use #431 (reportable via registry and measures groups); Breast Cancer Screening #112 (reportable via claims and registry); and Falls: Risk Assessment #154 (reportable via claims and registry).

d. **New Chronic Pain Measures.** There are 3 new opioid related measures, as follows: Opioid Therapy Follow-up Eval #408 (registry only); Signed Opioid Treatment Agreement #412 (registry only); and Interview for Risk of Opioid Misuse #414 (registry only).

6. Value Modifier ("VM"). In the 2016 Medicare Physician Fee Schedule Final Rule ("Final Rule"), Medicare confirms that the 4% VM penalty will be assessed if one does not report the PQRS measures. CMS also notes that the penalty for VM is at TIN level; whereas, the penalty for PQRS is at the individual NPI level. The failure to properly report PQRS in 2016 will result in a penalty in 2018. The VM penalty will be limited to 2% for a group with 2-9 EP's and 4% for a group with 10 or more EP's.

7. MACRA and MIPS. MACRA (Medicare Access and Chip Reauthorization Act) was enacted on April 16, 2015, and establishes MIPS (Merit-based Incentive Payment System). MIPS will combine VM, PQRS and EHR effective on January 1, 2019. MIPS will apply to physicians, CRNA's, PA's, NP's, CNS's, and their groups. The 4 factors upon which payments and penalties will be based at that time are quality, resource use, clinical practice improvement, and meaningful use of EHR technology.

8. Potentially Misvalued Codes. In the 2016 Final Rule, Medicare provides a list of potentially overvalued codes which it is going to study for possible reimbursement reduction in 2017. The pain codes listed are trigger point injections (20552-20553), psych testing (96101), and physical therapy codes (97032, 97035, 97110-97116, 97140, 97530, and 97535).

9. New E&M Codes for Advanced Care Planning. Last year the AMA created two new codes for advanced care planning: 99497 and 99498; however, Medicare did not list those codes as active codes for 2015 and did not pay for them. For 2016, these two codes have been assigned an "active code" status in the Medicare Physician Fee Schedule and are separately payable under the Physician Fee Schedule.

10. Incident To Billing.

a. **Who is the Billing Physician.** The 2016 Final Rule clarifies that the billing physician is the physician directly supervising the service, which is not necessarily the same physician who is the initial or usual physician. The Final Rule states, "the physician or other practitioner who bills for the incident to service must also be the physician or other practitioner who directly supervises the service." The Final Rule further clarifies that "where the supervising practitioner is not the same as the referring, ordering or treating practitioner, only the supervising practitioner may bill Medicare for the incident to service."

b. **Excluded Personnel Cannot be Billed as Incident To.** The Final Rule also prohibits billing incident to for services performed by auxiliary personnel who have been excluded from federal programs, or who have had their enrollment revoked for any reason.

Sponsor Succeeds In FDA Approval For Sacroplasty



Stryker's VertaPlex® HV First PMMA to Receive Clearance for Treating Sacral Insufficiency Fractures

KALAMAZOO, Mich., Oct. 15, 2015 /PRNewswire/ -- The Instruments division of Stryker Corporation announced today

that its Interventional Spine business unit has received clearance from The U.S. Food and Drug Administration (FDA) to market its expanded indications of VertaPlex HV for the treatment of sacral insufficiency fractures. Stryker set a new standard in 2008 with the release of VertaPlex HV, addressing specific viscosity and working time preferences for treating vertebral compression fractures. On June 12, 2015, VertaPlex HV became the first PMMA to receive 510(k) clearance for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty.

"Careful intraoperative technique and VertaPlex HV PMMA is an excellent and safe solution in the management of sacral fractures. This new FDA approved indication will benefit countless lives," said Jeffrey W. Miller, MD, Director of Neuroendovascular Surgery at Bronson Methodist Hospital in Kalamazoo, MI, and principal investigator of the Stryker sponsored study for 510(k) submission. "I have already witnessed dramatic patient improvement in my own practice by incorporating sacral vertebroplasty/sacroplasty as part of my intraoperative protocol."

Sacral insufficiency fractures are an often under diagnosed condition in the elderly population, typically presenting with severe low back pain resulting in immobility. The diagnosis can be complicated by the fact that radiographic assessment of the sacrum is difficult and lower spine (lumbar) imaging is frequently not specifically targeted at the sacrum. Sacral vertebroplasty, a procedural extension of percutaneous vertebroplasty, involves the injection of bone cement into the sacrum with the aim of alleviating pain and facilitating more rapid mobilization than conservative therapy alone allows.

Due to the inherent porosity of sacral bone and comorbidity of osteoporosis, cement extravasation may be a risk for treatment of sacral insufficiency fractures. In this porous, osteoporotic environment, higher viscosity cement can help reduce cement spreading and forming denser cement clusters¹.

"As our population ages, we will see more sacral insufficiency fractures that will require intervention," said Douglas Yim, MD, Visiting Associate Professor, Associate Program Director of Interventional Radiology at Johns Hopkins School of Medicine, Baltimore, MD. "Having a reliable and consistent high viscosity cement like VertaPlex HV will allow greater margin of safety for patients undergoing sacroplasty." Please contact us for more information at <http://www.stryker.com>.