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Brandon Wm. Cady, President and Chief Executive Officer
Robert Mandel, MD, MBA, Senior Vice President, Chief Medical Officer
AIM Specialty Health
8600 West Bryn Mawr Avenue
South Tower – Suite 800
Chicago IL 60631

RE: AIM Clinical Appropriate Guidelines: Musculoskeletal Program - Interventional Pain Management

Dear Mr. Cady and Dr. Mandel:

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and 51 state societies (including the Puerto Rico Society of Interventional Pain Physicians), we would like to thank you for publishing AIM Musculoskeletal Program Interventional Pain Management guidelines to achieve the multiple functions of establishing criteria, standardizing medical practice patterns, advocating patient safety concerns, enhancing quality of care, and promoting the most efficient and cost-effective use of services.

We also appreciate the guideline development process you have described in the document with applicable accreditation standards. These include the requirement that the guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the guidelines under the review and be based on the most up-to-date clinical principles and best practices. However, we would respectfully disagree with some of the assumptions related to evidence-based medicine, current clinical expertise, and involvement of appropriate providers. We believe that there was no involvement of stakeholder providers, and further, the available evidence may not have been utilized appropriately. Consequently, we would like to make comments and request revisions for these guidelines as these should be widely applied by multiple carriers, affecting not only the quality of care, but access to care with increasing practice expenses.

We would like to specifically comment on epidural injection procedures, diagnostic selective nerve root blocks, and paravertebral facet joint injection/nerve block/neurolysis. In addition, we are also writing about percutaneous adhesiolysis (also known as neuroplasty), a procedure which has not been included in the A.M. Guideline. The majority of the insurers who are following your guidance have not approved this procedure. All our comments are based on evidence-based principles and available literature derived predominantly from randomized controlled trials and systematic reviews. In cases where there is a lack of randomized controlled trials, the evidence is derived from observational literature or consensus. We will so state when this level of evidence or consensus applies.

ASIPP is a not-for-profit professional organization founded in 1998, now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States.
Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (1).

Interventional pain management techniques are minimally invasive procedures, including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (2).

Interventional pain management (09) also has been provided a mandatory membership to Carrier Advisory Committees (CACs) in each state in the United States (3).


The following are our concerns about the AIM Musculoskeletal Program – Interventional Pain Management guidelines, with its associated precertification process and various other issues. We will focus our comments on epidural injection procedures; diagnostic selective nerve root blocks; paravertebral facet injection/nerve block/neurolysis procedures; and percutaneous adhesiolysis, which has not been analyzed by AIM in their guideline development process for musculoskeletal program of interventional pain management.

EPIDURAL INJECTION PROCEDURES AND
DIAGNOSTIC SELECTIVE NERVE ROOT BLOCKS

Epidural injection procedures and diagnostic selective nerve root blocks are described under this heading.

In 2014, the US Food and Drug Administration (FDA) issued a drug safety communication about epidural injection of glucocorticoids, citing the risk of rare but serious adverse effects. However, this was related to transforaminal epidural injections, mainly in the cervical spine (1-5). The guidelines describe indications for epidural steroids only for radicular pain either for workup or for therapeutic modality when noninvasive treatment strategies have failed. However, the literature also is replete with multiple other indications for this therapy, including: central spinal stenosis with or without claudication; foraminal stenosis with or without radicular pain; discogenic pain (after an appropriate diagnostic workup eliminating facet joint pain, sacroiliac joint pain and other conditions); and, finally, post surgery syndrome (6-46). The majority of the studies showed positive evidence for fluoroscopic epidural injections when performed appropriately with repeated procedures in patients who were responsive to the initial 2 procedures. Further, the misunderstanding of placebo and flawed methodology has been discussed extensively (11,13,45,47). The comprehensive evidence provided by Kaye et al (7) utilizing best evidence synthesis from Level I to V showed the following, after reviewing 52 trials that met inclusion criteria:
The evidence in managing lumbar disc herniation or radiculitis is Level II for long-term improvement, either with caudal, interlaminar, or transforaminal epidural injections with no significant difference among the approaches.

The evidence is Level II for long-term management of cervical disc herniation with interlaminar epidural injections.

The evidence is Level II to III in managing thoracic disc herniation with an interlaminar approach.

The evidence is Level II for caudal and lumbar interlaminar epidural injections with Level III evidence for lumbar transforaminal epidural injections for lumbar spinal stenosis.

The evidence is Level II for cervical spinal stenosis management with an interlaminar approach.

The evidence is Level II for axial or discogenic pain without facet arthropathy or disc herniation treated with caudal or lumbar interlaminar injections in the lumbar region; whereas it is Level II in the cervical region treated with cervical interlaminar epidural injections.

The evidence for post lumbar surgery syndrome is Level II with caudal epidural injections and for post cervical surgery syndrome it is Level II with cervical interlaminar epidural injections.

Further, not only clinical efficacy evidence, but also significant evidence of cost utility has been provided thus far for caudal and lumbar interlaminar epidural injections for disc herniation, discogenic pain, and spinal stenosis, and caudal epidural injections for post surgery syndrome (48,49). The cost utility analysis was performed using highly regarded surgical literature from an analysis of Spine Patient Outcomes Research Trial (SPORT) data (50,51). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall the cost effectiveness of disc herniation surgery (50) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (51). More importantly, these studies showed direct costs without medication to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis, with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost, lowest indirect costs at 60% and highest indirect cost of 40%, the cost utility of caudal epidural injections is estimated to be $3,628 with multiplication of the procedural cost by 1.67. This procedure can be used to treat disc herniation, discogenic pain, spinal stenosis, and post surgery syndrome with some variations (48). Further, cost utility analysis of lumbar interlaminar epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, and axial or discogenic low back pain, utilizing the extrapolation method of surgical interventions of direct cost, showed an average cost of $3,301 per QALY (49).

Thus, the guidance and evidence assessment provide not only the clinical effectiveness, but also value with lower expenses than surgical interventions per one year of QALY and well below $20,000 or $50,000 threshold utilized by many authorities.

EXCLUSIONS
The policy describes thoracic epidural injections as an exclusion for thoracic pathology. There is significant and emerging evidence of effectiveness of thoracic epidural injections (6,7,18). Consequently, we request that thoracic epidural injections should be a covered procedure. Denial of coverage for this may lead to access issues denying appropriate care in patients who require thoracic epidural injection procedures.
REQUESTED CHANGE:

We request that the policy be revised to specify the following:

- Based on the available evidence, epidural injections are considered appropriate in axial or discogenic spinal pain and post surgery syndrome after elimination of facet joint and sacroiliac joint pain in addition to disc herniation and spinal stenosis in lumbosacral, cervical and thoracic spine (6-9,31-34).

REFERENCES


**FACET JOINT INJECTIONS/MEDIAL BRANCH BLOCKS**

1. Paravertebral Facet Injection/Nerve Block/Neurolysis

Overall, this is a well written policy in reference to diagnostic facet joint nerve blocks and radiofrequency thermoneurolysis. However, even though intraarticular injections are covered, therapeutic medial branch blocks seem to be non-covered procedures. The policy excludes therapeutic medial branch blocks. Further, the policy also excludes thoracic diagnostic injections and radiofrequency thermoneurolysis in the thoracic region.

2. Thoracic Diagnostic Facet Joint Nerve Blocks

Thoracic diagnostic facet joint nerve blocks have been evaluated in 2 appropriately performed prevalence studies with dual diagnostic blocks. Systematic reviews have shown moderate or Level II evidence based on best evidence synthesis (1-5). Consequently, we request that diagnostic facet joint nerve blocks be allowed.

3. Thoracic Radiofrequency

Evidence of effectiveness of thoracic radiofrequency neurotomy, is emerging, with sources showing Level IV evidence (6,7). Consequently, this should be considered for coverage to avoid unnecessary denials, appeals, and access issues.

4. Therapeutic Medial Branch or Dorsal Ramus Blocks

Therapeutic medial branch blocks or L5 dorsal ramus blocks have been performed with increasing frequency. Essentially, based on CPT coding, therapeutic medial branch blocks are interchangeable with intraarticular injections. However, there is a wide variation in their effectiveness with medial branch or dorsal ramus blocks showing superior effectiveness. In fact, the evidence for therapeutic medial branch blocks or L5 dorsal ramus blocks is equivalent or often even better than radiofrequency neurotomy as illustrated in multiple systematic reviews, derived from multiple randomized controlled trials (1,6,8-16).

Based on the comprehensive best evidence synthesis (classified at 5 levels from Level I to Level V) assessment of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain (6), with inclusion of 21 randomized controlled trials and 5 observational studies, the following evidence was presented:

- In the lumbar spine, there is Level II evidence for radiofrequency neurotomy and lumbar facet joint nerve blocks, whereas the evidence is Level III for lumbosacral intraarticular injections.
- In the cervical spine, there is Level II evidence for cervical radiofrequency neurotomy and cervical facet joint nerve blocks, and Level IV evidence for cervical intraarticular injections.
- In the thoracic spine, there is Level II evidence for thoracic facet joint nerve blocks and Level IV evidence for radiofrequency neurotomy.
Further, cost utility analysis has been assessed for lumbar and cervical facet joint nerve blocks showing favorable evidence. Based on the similar assessment, the results of cost utility analysis in the cervical spine showed with procedural costs of $2,552 and overall costs of $4,261 per one year improvement in QALY (17).

For the lumbar spine, the results of cost utility analysis showed procedural costs of $2,654.08 and overall costs of $4,432 per one year of QALY (18).

The cost utility analysis was performed from highly regarded surgical literature from analysis of Spine Patient Outcomes Research Trial (SPORT) data (19,20). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall cost effectiveness of disc herniation surgery (19) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (20). More importantly, these studies showed direct costs without medication costs to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost lowest at 60% and highest indirect cost of 40%, the cost utility of facet joint injections is estimated to be $4,261 per one year improvement in QALY in cervical spine with facet joint nerve blocks, and $4,432 per one year of QALY in lumbar spine with facet joint nerve blocks with multiplication of the procedural cost by 1.67.

In addition to proven clinical and cost effectiveness:

- Therapeutic facet joint nerve blocks are covered by all Medicare carriers, an overwhelming majority of Medicaid carriers, and multiple commercial insurers.

- Facet joint nerve blocks elicit higher acceptance rate from patients with less fear compared to radiofrequency neurotomy, which seems to elicit more fear and the false notion of burning the nerves as promoted by many.

- It is crucial to consider the role of facet joint pain in lumbar and cervical postsurgery syndrome. Studies have shown significant prevalence of pain of facet joint origin in postsurgery patients (21-24). Further, a significant proportion of patients after post-surgery syndrome with hardware or bone fusion are not candidates for radiofrequency neurotomy; however, they can be treated with facet joint nerve blocks.

- Effectiveness of radiofrequency is not observed in all patients. Consequently, if 80% to 85% of the patients respond to radiofrequency neurotomy after appropriate diagnostic blockade, a 15% to 20% population is without response. Thus, without further treatment, after failure of radiofrequency neurotomy which is approximately 15% to 20% of the patients, these patients will be left without any further options. However, an overwhelming majority of these patients (after failure of radiofrequency neurotomy), seem to respond to facet joint nerve blocks.

- A significant proportion of obese patients also suffer with facet joint related pain. In these patients, radiofrequency neurotomy may be difficult. In these patients, facet joint nerve blocks can be performed with somewhat of an easier technical challenge providing significant improvement with lower risk (4,5,25).

- In patients with a pacemaker, radiofrequency neurotomy is difficult or associated with some risk, despite development of bipolar radiofrequency which is considered to be safe
but not foolproof. In these patients, facet joint nerve blocks will be much safer and easier to perform with patient comfort.

These are multiple and additional benefits of medial branch blocks and it will reduce the access to patient care once medial branch blocks are removed from armamentarium of treatment modalities.

We believe that your exclusion of therapeutic medial branch blocks is based on inappropriate interpretation of the evidence, with overall diminution in access and finally contributing to increased disability and health care costs rather than reducing these as you seem to believe it would (26-31).

REFERENCES


**PERCUTANEOUS EPIDURAL ADHESIOLYSIS**

Epidural adhesiolysis is not listed as a covered procedure, despite substantial evidence available by way of multiple randomized controlled trials specifically in post lumbar surgery syndrome and spinal stenosis (1-3), along with recalcitrant pain with degenerative disc disease (1-8). Overall, significant improvement has been shown in a greater proportion of patients with spinal stenosis, post surgery syndrome, and disc herniation at one and 2-year follow-ups based on pragmatic protocols and administration of the procedures. It should also be considered that these patients have already failed a multitude of interventions including interventional techniques with epidural injection and surgical interventions in many cases.
In addition, cost utility analysis also has been performed, which showed favorable cost utility (9). The cost utility analysis was performed from highly regarded surgical literature from analysis of Spine Patient Outcomes Research Trial (SPORT) data (10,11). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall cost effectiveness of disc herniation surgery (10) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (11). More importantly, these studies showed direct costs without medication costs to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost lowest at 60% and highest indirect cost of 40%, the cost utility of percutaneous adhesiolysis is estimated to be $4,425 with multiplication of the procedural cost by 1.67, with significant cost savings overall.

The evidence synthesis utilizing strict criteria of methodologic quality assessment and clinically relevant outcomes shows Level II evidence for percutaneous adhesiolysis after failure of other modalities of treatments.

REFERENCES
Thank you for consideration of our comments. Hopefully, you will consider these comments and revise the guidelines which will improve access and care patterns and value for the purchased insurance.

If you have any further questions, please feel free to contact us.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS

Laxmaiah Manchikanti, MD
Chairman of the Board and Chief Executive Officer, ASIPP, SIPMS
Paducah, KY 42003
drm@asipp.org

Francis Riegler, MD
President, ASIPP
Palmdale, CA 93551
frieqler@upmgmt.com

Hans C. Hansen, MD
President-Elect, ASIPP
Conover NC 28613
hhansen@painreliefcenters.com

Aaron K. Calodney, MD
Immediate Past President, ASIPP
Tyler TX 75713-0459
aaroncalodney@me.com

Sudhir Diwan, MD
First Executive Vice President of Regional Affairs, ASIPP
New York, NY 10022
sudhir.diwan63@gmail.com

Frank J.E. Falco, MD
First Executive Vice President, ASIPP
Newark, DE 19713
cssm01@aol.com

Harold Cordner, MD
Second Executive Vice President, ASIPP
Sebastian, FL 32958
gassdoc@aol.com

Sanjay Bakshi, MD
Vice President of Strategic Planning, ASIPP
New York, NY 10022
drbakshi58@gmail.com

Sukdeb Datta, MD, MBA
Vice-President of Strategic Alliances, ASIPP
New York NY 10016
sukdeb@hotmail.com; sdattamd@gmail.com

Standiford Helm, II, MD
Treasurer, ASIPP
Laguna Woods, CA
dhelm@thehelmcenter.com

Vijay Singh, MD
Chairman of Executive Committee, ASIPP
Lifetime Director, ASIPP
Iron Mountain, MI 49801-6722
vj@wmpnet.net

DIRECTORS:

Salahadin Abdi, MD, PhD
Academic Director, ASIPP
Houston TX 77010
sabdi@mdanderson.org

Sheri L. Albers, DO
Director-at-Large, ASIPP
Sacramento, CA 95864
sla2oz@aol.com

Steve Aydin, DO
Young Physician Director, ASIPP
Franklin Lakes, NJ 07417
steve.avdin@gmail.com

Cyrus E. Bakhti, MD
Lifetime Director, ASIPP
Roanoke, VA 24016
cbakhit@pmcr.org
Ramsin Benyamin, MD  
Director Emeritus, ASIPP  
Bloomington, IL 61701  
ramsinbenyamin@yahoo.com

Mark Boswell, MD, PhD  
Academic Director, ASIPP  
Round Rock, TX 78664  
boswellmv@earthlink.net  
mbooswell@advancedpaincare.us

Kaylea Boutwell, MD  
Young Physician Director, ASIPP  
Chesterfield MO 63017  
kbvoutwell@prsstl.com

Kenneth D. Candido, MD  
Academic Director, ASIPP  
Chicago, IL 60657  
kdcandido@yahoo.com

George C. Chang Chien, DO  
Young Physician Director, ASIPP  
Arcadia, CA 91006  
gechangchien@gmail.com

Christopher Gharibo, MD  
Academic Director, ASIPP  
New York, NY 10015  
cgharibo@usa.net

Scott E. Glaser, MD  
Director-at-Large, ASIPP  
Burr Ridge IL 60527  
sglaser@painchicago.com

Jay Grider, DO, PhD  
Academic Director, ASIPP  
Lexington, KY 40535  
jsgrid2@email.uky.edu

Joshua Hirsch, MD  
Academic Director, ASIPP  
Boston, MA 02114  
hirsch@snisonline.org

Sachin "Sunny" Jha, MD  
AMA Alternate Delegate  
Chicago, IL 60607  
sunnyjha@gmail.com

Alan D. Kaye, MD, PhD  
Editor-in-Chief  
Pain Physician Journal  
New Orleans, LA  
akaye@lsuhsc.edu

Michael C. Lubrano, MD, MPH  
Resident/Fellow, Director, ASIPP  
San Francisco, CA  
Michael.Lubrano@ucsf.edu;  
Lubrano.Michael@gmail.com

Dharam Mann, MD  
Director-at-Large, ASIPP  
Whiting, NJ 08759  
amanpainmd@gmail.com

Devi E. Nampiaparimpil, MD  
Young Physician Director, ASIPP  
New York, NY 10001  
devicechchi@gmail.com

Annu Navani, MD  
Director-at-Large, ASIPP  
Campbell, CA 95008  
anavani@spineandsportsctr.com;  
anavaani@cssctr.com

Vikram B. Patel, MD  
AMA RUC Advisory Committee  
AMA CPT Advisory Committee  
Algonquin, IL 60102  
vikpatel1@yahoo.com

Sanford Silverman, MD  
Director-at-Large, ASIPP  
Pompano Beach, FL 33064  
sanfordsliverman@cpmedicine.com

Lee Snook, MD  
AMA Delegate  
Sacramento CA 95821  
lsnook@pain-mpcmc.com

Amol Soin, MD  
President, SIPMS  
Young Physician Director, ASIPP  
Centerville, OH 45458  
ohiopainclinic@gmail.com
STATE SOCIETIES OF INTERVENTIONAL PAIN PHYSICIANS:

Kenneth Varley, MD
President and CEO, Alabama Society of Interventional Pain Physicians
Birmingham, AL 35242
kennethv@southernpain.com

Andrea Tresco, MD
President and CEO, Alaska Society of Interventional Pain Physicians
Eagle River, AK 99577
DrTresco@gmail.com

Jonathan D. Carlson, MD
President, Arizona Society of Interventional Pain Physicians
Glendale, AZ 85305
jcarlsonmd@gmail.com

John Swiecegood, MD
President and CEO, Arkansas Society of Interventional Pain Physicians
Fort Smith, AR 72917
swice99@gmail.com

Jason Pope, MD
President, California Society of Interventional Pain Physicians
Petaluma, CA 94954
ipeterson@centerforpainrelief.com

Kenneth C. Lewis, MD
President and CEO, Colorado Society of Interventional Pain Physicians
Fruita, CO 81521
kclewis007@earthlink.net

Dean Mariano, DO
President, Connecticut Pain Society
Meriden, CT 06451
marianodean@me.com

Selina Xing, MD
President and CEO, Delaware Society of Interventional Pain Physicians
Newark, DE 19713
s65sing@yahoo.com

Orlando G. Florete, Jr., MD
President, Florida Society of Interventional Pain Physicians
Jacksonville, FL 32207
dhabilino@theipm.com
Vincent Galan, MD  
President, Georgia Society of Interventional Pain Physicians  
Stockbridge, GA 30281  
vgalan@msn.com

Jeffrey S. Wang, MD  
President, Hawaii Society of Interventional Pain Physicians  
Honolulu, HI 96813  
hpmc_hawaii@yahoo.com

Holly Zoe, MD  
President, Idaho Society of Interventional Pain Physicians  
Idaho Falls, ID 83404  
hlyzoe@yahoo.com

Ramsin Benyamin, MD  
President, Illinois Society of Interventional Pain Physicians  
Bloomington, IL 61701  
ramsinbenyamin@yahoo.com

Mahendra Sanapati, MD  
President, Indiana Society of Interventional Pain Physicians  
Evansville, IN 74414  
msanapati@aol.com

Bradley Wargo, DO  
President and CEO, Iowa Society of Interventional Pain Physicians  
Ames, IA 50010  
drbwargo@gmail.com

Mayank Gupta, MD  
President and CEO, Kansas Society of Interventional Pain Physicians  
Overland Park, KS  
mayankempire@yahoo.com

Ramana Pasupuleti, MD  
President, Kentucky Society of Interventional Pain Physicians  
Bowling Green, KY 42104  
rampasupuleti@yahoo.com

Paul Hubbell, MD  
President and Executive Director, Society of Interventional Pain Physicians of Louisiana  
Metairie, LA 70002  
phubbell@bellsouth.net

Stephen Ramberger, MD  
President, Maine Society of Interventional Pain Physicians  
Brunswick, ME 04011  
45stephan@comcast.net
Raj Jari, MD  
President, Maryland Society of Interventional Pain Physicians  
Nottingham, MD 21236  
rjari@yahoo.com

Thomas Simopoulos, MD  
President and CEO, Massachusetts Society of Interventional Pain Physicians  
Boston MA 02445  
tsimopoul@bidmc.harvard.edu

Anand C. Thakur, MD  
President and CEO, Michigan Society of Interventional Pain Physicians  
Clinton Township, MI 48037  
acthakur@yahoo.com

Andrew Will, MD  
President and CEO, Minnesota Society of Interventional Pain Physicians  
Edina, MN 55439  
andrew.will@painmanagementandrehab.com

Timothy Beacham, MD  
President, Mississippi Society of Interventional Pain Physicians  
Greenville, MS 38703  
Tbeacham06@gmail.com

Kaylea Boutwell, MD  
President, Missouri Society of Interventional Pain Physicians  
Chesterfield, MO 63017  
kboutwell@prsstl.com

Scott Jahnke, DO  
President and CEO, Montana Society of Interventional Pain Physicians  
Kalispell, MT 59901  
highwater@montanasky.net

Daniel Wik, MD  
President, Nebraska Society of Interventional Pain Physicians  
Norfolk, NE 68701  
dmwik@yahoo.com

Daniel E. Fabito, MD  
President, Nevada Society of Interventional Pain Physicians  
Henderson, NV 89015  
jfabito@gmail.com

George Lantz, DO  
President, New Hampshire Society of Interventional Pain Physicians  
Rye, NH 03870  
glantz@nhpain.com
Eric Freeman, DO
President, New Jersey Society of Interventional Pain Physicians
Edison, NJ 08820
DrEFree@comcast.net

Pamela O. Black, MD
President and Executive Director, New Mexico Society of Interventional Pain Physicians
Albuquerque, NM 87109
pobrack@att.net

Edward S. Rubin, MD
President, New York Society of Interventional Pain Physicians
Garden City NY 11530
edsrubin@aol.com

Mark Hines, MD
President, North Carolina Society of Interventional Pain Physicians
Huntersville, NC 28078
markhines@adelphia.net

Rup K Nagala, MD
President and CEO, North Dakota Society of Interventional Pain Physicians
Oakes, ND 58474
rnagala@hotmail.com

Ricardo Buenaventura, MD, MBA
President and CEO, Ohio Society of Interventional Pain Physicians
Centerville, OH 45459
rbuena@sbcglobal.net; rbuena@sbcglobal.net; dr.rbuena@gmail.com

Rico Guerra, MD
President and CEO, Oklahoma Society of Interventional Pain Physicians
Oklahoma City, OK 73135
rguerra@okheart.com

Peter Kosek, MD
President, Oregon Society of Interventional Pain Physicians
Eugene, OR 97401
pkosek@peacehealth.org

Vahid Grami, MD, MPH
President and CEO, Pennsylvania Society of Interventional Pain Physicians
Riverside, PA 17868
vahidgrami@yahoo.com

Renier Mendez, MD
Chief Executive Officer and President, Puerto Rico Society of Interventional Pain Physicians
Bayamon, PR 00961
drenier@msn.com
Adrian Hamburger, MD
President, Rhode Island Society of Interventional Pain Physicians
Westerly, RI 02891
doctor@westerlyspine.com

Ezra B. Riber, MD
President and CEO, South Carolina Society of Interventional Pain Physicians
Columbia, SC 29204
Sc99fan@aol.com

John Cook, MD
President and CEO, South Dakota Society of Interventional Pain Physicians
Dakota Dunes, SD 57049
cookerj@aol.com

Graf Hilgenhurst, MD
President and Executive Director, Tennessee Society of Interventional Pain Physicians
Smyrna, TN 37167-8412
ghilgenhurst@aol.com

Larry C. Driver, MD
President, Texas Pain Society
Houston, TX 77004
ldriver@mdanderson.org

Craig Davis, MD
President and Executive Director, Utah Society of Interventional Pain Physicians
West Jordan, UT 84088
craiguf@gmail.com

Evan Musman, DO
President and Executive Director, Vermont Society of Interventional Pain Physicians
South Burlington, VT 05403
Doc@VermontPainManagement.com

Douglas Wisor, MD
President, Virginia Society of Interventional Pain Physicians
Richmond, VA 23294
Dwisor@treatlingpain.com

Arthur S. Watanabe, MD
President, Washington Society of Interventional Pain Physicians
Bellingham, WA 98226
aswatanabe@earthlink.net

Timothy Deer, MD
President, West Virginia Society of Interventional Pain Physicians
Charleston, WV 25301
DocTDear@aol.com
David A. Bryce, MD  
President, Wisconsin Society of Interventional Pain Physicians  
Madison, WI, 53711  
tonys09@gmail.com

Dan Alzheimer, MD  
President and CEO, Wyoming Society of Interventional Pain Physicians  
Big Horn, WY 82833  
roxdan78@hotmail.com