

AANS/CNSSection on Disorders of the Spine and Peripheral Nerves Statement of Financial Position For the Six Months Ending December 31, 2013



Current Year 12/31/2013	Prior Year 12/31/2012
916,613	675,856
125,925	66,575
2,889,948	2,595,829
0	
3,932,487	3,338,260
25 222	20 500
The second secon	32,500 99,600
	0
222,800	132,100
2 322 232	
	3,087,544
4,322	52,000
298,932	66,616
3,709,687	3,206,160
3,932,487	3,338,260
	916,613 125,925 2,889,948 0 3,932,487 85,000 97,800 40,000 222,800 3,405,215 1,217 4,322 298,932 3,709,687

		Final	Final	Final	Final	Bu	Budget
SPINE AND PERIPHERAL NERVE SECTION SECTION INCOME		OK PAGE	1			and on	000 04
Dues (AANS)		9065	52,550	52,903	104	069	006,94
Mailing List Sales SPONSORSHIP REVENUE	Historical Sponsons	2000			i	00	400
H. Alan Crockard Int'l Fellowship	Darbuy Spine	5,000	30 000	000'9	30.0	30,000	30,000
Sanford Larson Research Award Ronald Apfelbaum Research Award	Aesculap	15,000	15,000	15,000	15,0	000	15,000
David Cahil Fellowship	Synthes	30,000	00000	30,000		o c	30,000
Raiph Cloward Fellowship	Meditoric Nuvasive 2013 and on Integral	15,000	15,000	15,000	16,0	16,000	15,000
David Kilne Lectureship	Integra	5,000	5,000	0000	9'0	000	3,000
David Kline Lectureship Dinner	Wallace Foundation/Spine Section	50,000	20	52,000		0	0
Sontiag International Fellowship	Meditonic -> Nuvasive 2013 and on	5,000	5,000	5,000	UE	000	30,000
Regis W. Haid, Jr., MD Adult Deformity Research Award Rehma of Un-expended Kilne Research Award (ok to knop per Integra)	Globus Medical	20	0	0	9	6,895	0
Committuitors for Operating Expenses Miscellaneous Revenue		7.977	7,893	8,439 104	ó	0	0
Total Income	-	214,342	166,623	252,331	162,	162,084	223,987
SECTION EXPENSES (AANS)		1,971	1,499	1,724	4	1,197	2,000
Augh Visual		648	470	604		498	498
Contributions & Affiliations		000'06	187,500	76,000	191	385	140,000
Decorating		4,827	3,994	5,914	7,	023	6,500
Gifts & Gratuities	C leading		0	٥		164	0
LONORARIO (AANS)	DePly Spine	5,000	6,000	0	מ	000'9	6,000
Sanford Larson Research Award	DePuy Spine	30,000	30,00	30,000	30	30,000	30,000
Ronald Aprelbaum Research Award	Aesoulap	15,000	15,000	000,61	. G	000	30,000
David Cahil Fellowship Pales Cinward Fellowship	Synthes Medtronic -> Nuvasive 2013 and bit	30,000	30,000	30,000	300	30,000	30,000
David Kilne Research Award	Integra	15,000	15,000	15,000	15.	000	15,000
Clinical Trials Fellowship Award**	Wallace Foundation/Spine Section	9,000	0	9000'9	er.	457	5,000
Sonntag international Fellowship	Meditronic → Nuvasive 2013 and on	10,000	5,000	000'9	en c	000	5,000
Mayfield Clinical Award**	Spine & PV Section	3,000	4,000	2,000	N CN	2,000	2,000
Outcomes Committee Award**	Spine & PN Section	2,000	2,000	2,000	CN C	2,000	2,000
Regis W. Hatd, Jr., MD Adult Deformity Research Award	Globus Medical	0 097	1.500	00	1	1,500	9000
Clinical Trials Awards	The second secon	1,834	0	0		0	0
Plaques for 14 Awards @ \$326 each**	Spine & PN Section	270	135	336		387	350
Office & other Supplies		0	-	, cv		m	25
Postage & Distribution		1,284	1,145	1,073		0	006,1
Printing Navelater Professional Fees		0	0	2		01	0
Staff Travel		0	0 0	0 0	-	103	2200
Telephone		48/	0	19,966	•	0	6,500
Voluntaer rayer Website		3,354	436	806		00	12,500
Other Personnel Service Feets		7,877	7,893	8,439	9	6,189	7,187
Niscellaneous		12,398	0 000	7,500	16.	027.303	50.000
Guidelines Development		7,968	15,952	0	ì	0	0
Sub-Total Expenses		285,638	418,170	312,848	406	06,249	456,110

5,000 20,000 30,000 30,000 20,000 5,000 26,000 30,000 30,000 12,000 0 0,000 0,000 0,000 0,000 0,000 0,000 0,000 0,000 0,000 0,000 0,00 0,000 0,000 0,000 0,000 0 0,000 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

345 345 345 30,000 30,000 30,000 15,000 5,000 5,000 30,000 30,000 30,000 30,000 30,000

26,000

30,000

3,258

FY '14 Budget

YTD YTD

FY 13 Final

7.500
7.500
1.000
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750
9.750

6,864 4 440 500 6 440 5 6 440

Website Other Parsonnel Service Fees	0 0	7 883	8.439	6,189	7,187	8.791	3,486	12,898
Staff Coordination	12,398	0	7,500	0	0	0	0	0
Miscellaneous Guidalines Development	297	10,010	4,420	27,303	50,000	36,973	00	900'09
Spine Section History Project	7,968	15,952	0.0000	000 240	AEG 44.61	AND BREI	6.078	524 485
Sub Total Expenses	285,638	418,170	312,848	400,245	420,110	440,000	0.000	and and
	Kado AZA	// FEA EA71	(RD 5173)	(9A4 185)	(232, 123)	(182,265)	128.916	(206,889)
Net=Total Income - Total Expenses	(ORPY)	(250,105)	W. Larrey					
					Ann and	Tour sea	470 540	450 940
Investment Revenue	(183,399)	120,394	175,898	82,875	115,095	786.412	179,510	130,040
	Chech 2007	Man April	115 364	VAES 240V	1117 (1971)	30 132	307 432	(78.541)
Net Income Including Investment Revenue	(54,045)	(131,150)	1105,511	(Alexael)	(520,111)			
								-
SPINE AND PERIPHERAL NERVE ANNUAL MEETING (CNS) ANNUAL MEETING INCOME (CNS)	228,710	230,295	216,570	222,890	249,235	224,440	0	230,810
Neglistration	427,225	372,240	360,165	331,125	369,800	304,925	0	761,600

ANNUAL MICETING INCOME (CNS) ANNUAL MICETING INCOME (CNS) Registration Exhibits Continuous/Sportsorbitps Continuous/Sportsorbitps Continuous/Sportsorbitps Continuous/Sportsorbitps	2287/10 427,725 337,650 2,380 47,890	230,295 372,240 389,159 2,006 44,110	216,570 360,165 342,500 2,000 38,000	222,890 331,125 347,500 2,600 47,460	249,235 369,800 350,000 2,100 44,920	224,440 304,925 367,500 2,300 44,590	00000	230,810 761,600 2,000 42,660
	1 043 835	1 037 804	959.225	951.575	1,016,055	944.155	0	1,057,070

			040 400	DAY DAY	207 770	975 094	c	917 558
Scientific Program/Special Courses	233,994	237,007	018,162	234,240	271.120	426,012	0 0	00000
	0	0	0	0	20,560	12,145	0	21,012
Abstractivariagement	0	0	0	0	24,762	26,846	D	23,700
Program Book	0	0	0	0	95,079	65,673	0	81,695
Opening Reception	145 927	141.475	156.186	154.398	0	0	0	0
Social Events	0	0	0	0	54,506	59,015	0	94,758
Committee Dinners/Events	43.188	49.057	48.660	49,600	86,437	70,517	0	115,461
Exhibit Hall Program	47.826	50,598	54,585	52,149	63,912	62,369	0	56,037
AlM Registration	63.870	67.929	52,463	60,624	20,200	13,128	0	0
Annual Meeting Promotion	12.213	9,423	12,810	18,024	17,537	16,751	0	19,133
Onside Coordination & Citizens	1,016	2,145	0	2,528	4,212	4,608	0	2,070
Annual Meeting Framming Come	000'08	100,000	100,000	100,000	0	100,000	0	100,000
Start Cordination	628,034	657,635	676,514	671,560	664.927	208,976	0	731,422
ioni tespono		100 1000	CON 24.2	200000	024 470	1927 470	10	305 848
Net=Total Income - Total Expenses	415,601	380,189	282,711	610,085	331,160	271,102	5	20000
Net Income Including Annual Meeting	160,906	249,016	398,092	121,706	234,101	269,311	307,432	229,107
Chodeard Fellowship Payment for FY0B received in FY10 Sanford Larson Award Payment for FY0B received in FY10 Adhebaum Award Sporachip for FY10 received in FY11 Chodeard Fellowship Sporachip for FY12 received in FY13 (January) Sanford Larson Award Sporachship for FY12 received in FY13 (January)	(000'05) (000'5)	5,000 30,000 (15,000)	15,000	(5,000) (30,000) 15,000			77 600	
2nd half of Apfelbaum Award pald in FY14 - Liau Stonned Parment on 2. Clinical Trials Proposal Award Checks - raissued in FY14 - checks were lost in the mail			00000	1000 000		1,000	(1,000)	1
Total Adjustments	(35,000)	20,000	15,000	(20,000)	5	loon'i	(Orania)	
	125 906	269,016	413,092	101,706	234,101	270,311	298,932	229,107

Spine Table of Contents/Section Editors:

- I. Basic Science of the Spine (Marjorie Wana)
 - a. Spinal Anatomy (Kai-ming Fu)
 - b. Spinal Biomechanics including Instrumentation (Joe Cheng/ Charley Sansur)
 - c. Pathophysiology of Axial Spinal Pain, Radiculopathy, Myelopathy (John O'Toole ,

Marjorie Wana)

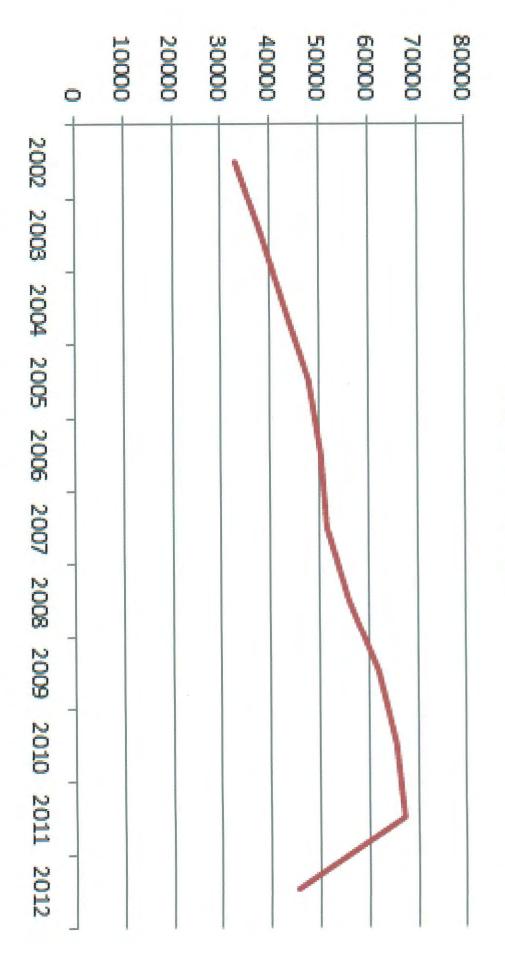
- d. Spinal Cord Injury- Shekar Kurpad
- e. Complication Avoidance In the Spine (Infection, DVT, PE) (Charley Sansur)
- II. Spine Imaging and Assessments (Erica Bisson, Meic Schmidt)
 - a. Radiographs, CT and MRI Meic Schmidt
 - b. Electrophysiological studies including Intraoperative Monitoring- Uribe, Mummaneni
 - Evaluation and Treatment of Osteoporosis (Labs: Vit D, Ca++, PTH, PCT, etc). (Pat Jacob, David Ibrahimi – former shaffrey fellow)
- III. Non-Surgical Management of Spinal Disorders (John Hurlbert, Sanjay Dhall)
 - a. Nonsurgical management (PT, Injections, Bracing) (Hurlbert and friend)
 - b. Acute and Chronic Pain Management (Daniel Lu and Mrs. Lu)
- IV. Spinal Trauma (Michael Groff, Okonkwo)
 - a. Assessment of Spinal Instability and Classification, David Okonkwo, <u>Dan hoh</u>
 - b. Cervical Injuries (including OC and CT Jxn)- Saniay Dhall, Resnickl
 - c. Thoracolumbar Spine Injuries-James Harrop
- V. Degenerative Spinal Disorders (Frank LaMarca, Joe Cheng)
 - a. Disc Herniations- Scott Meyer, Jack Knightly
 - b. Stenosis, Spondylolisthesis / Spondylolysis (Park, LaMarca)
 - c. Degenerative Disc Disease/Artificial Discs and Motion Strom/Frempong/Upadhyaya
 - d. Revision Spine Surgery Dom/Ziewacz
- VI. Congenital Spinal Disorders (Ratliff, Daryl Fourney)
 - a. Inflammatory spinal diseases (AS, DISH, etc.) (Mike Rosner/Tyler Koski)
 - b. Skeletal Dysplasias (achondroplasia) (Kojo Hamilton)
- VII. Spinal Deformities (Praveen Mummaneni)
 - a. Evaluation of the Patient with Deformity (Spinal balance/sacropelvic parameters)

(Mummaneni, Charles Kuntz)

- i. Including high grade spondylolisthesis
- b. Cervical Deformity (Frank La Marca, Paul Park)
- Thoracolumbar deformity (Justin Smith, Meic Schmidt)
- d. Proximal junctional kyphosis (Ames, Uribe)
- e. Two and three column osteotomies (Mike Wang, Chestnut)
- f. Sacropelvic fixation anterior and posterior options (Kanter, Okonkwo)
- VIII. Intrinsic Abnormalities (Kai-ming Fu, Charley Sansur)
 - a. Syringohydromyelia/Tethered Cord (Sandami)
 - b. Vascular Malformations (Lawton/Sansur)
- IX. Spinal Tumors and Infections (Daryl Fourney, John O'toole)

- a. Primary and Metastatic Extradural Spinal Tumors (Groff)
- b. Primary Intradural Spinal Tumors (La Marca and Park)
- c. Spinal Infection (Mike Wang)
- X. Sports Medicine and Spine (Adam Kanter and Jack Knightly)
 - a. Athletic Spinal Injuries and Return to Play (Kanter and Knightly)
- XI. Associated Spinal Topics (Joe Cheng and Juan Uribe)
 - a. Bone Graft Options (Joe Cheng)
 - b. Guidelines, Spinal Outcomes, and Registries O'toole, Cheng
 - c. ethics, costs, patient access, etc. Steinmetz

CPT 22612



Proposed Coverage Criteria for Minimally Invasive Sacroiliac Joint Fusion

Coverage Indications, Limitations, and/or Medical Necessity

Introduction

The sacroiliac joint (SIJ) is an important cause of chronic lower back pain. SI joints are paired diarthrodial articulations of the sacrum and ilium. The SI joint serves as the biomechanical mediator between the spine and pelvis. The subchondral bone, capsule, and surrounding ligaments of the SIJ are innervated by spinal nerves.¹

Because SIJ pain can be confused with lumbar and hip pain, proper diagnosis of SIJ pain is key to appropriate patient management. Patients with SIJ pain typically report pain in the buttocks, with possible radiation into the groin or upper legs. Specific physical examination tests that stress the SIJ (including distraction testing, compression testing, thigh thrust, the FABER (Patrick's) test, Gaenslen's maneuver, testing for sacral sulcus tenderness) are typically performed; in combination, these tests are predictive of SI joint pain.2 Other physical examination tests may be performed as well. Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration). The diagnosis of SIJ pain is confirmed by performing a fluoroscopy guided percutaneous SI joint block with local anesthetic (e.g., lidocaine). The published data show that an acute reduction in pain of 50% or more compared to immediately prior to the block is a positive test and indicates that the injected joint is the pain generator.3 Occasionally, steroids are injected with local anesthetic in the hope of achieving more prolonged (e.g., days to weeks) pain relief. Because other pathologic processes can coexist with SIJ pain, the physician should ensure that the SIJ is the primary source of the patient's pain and that non-SIJ causes of pelvic or lower back pain are of less overall importance on the basis of history, physical exam and/or imaging; examples of alternative diagnoses include pelvic fracture, tumor, infection, skeletal deformity, hip arthritis, and degeneration of the L5/S1 disc or other base-of-spine pathologies.

Occasionally, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of a typical history, physical examination showing bilateral SIJ pain with maneuvers (listed above) that stress the SIJ, and bilateral acute pain relief upon bilateral, fluoroscopy-guided SI joint block.

Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroidal anti-inflammatory agents, opioids), physical therapy, steroid injections into the SIJ and radiofrequency ablation of the SIJ. While a short period of rest is reasonable for acute SIJ pain, prolonged rest plays no role in chronic SIJ pain and may lead to negative health consequences. Most patients respond adequately to conservative treatment. However, a small number of patients do not have satisfactory pain relief and may be functionally disabled (e.g., cannot sit or stand for more than five minutes, cannot perform housework, cannot walk up or down stairs, require a wheelchair, require chronic opioid treatment). Patients with a diagnosis of SIJ pain who experience pain for a minimum of six months and who do not respond to an adequate course of non-surgical treatment may be considered for SIJ fusion.

Coverage Rationale for Minimally Invasive SIJ Fusion

Although open fusion of the SIJ can provide pain relief, recovery times are long and the complication rate is high. 4-8 Patients can experience significant intraoperative bleeding and require prolonged postoperative rehabilitation. Therefore, it should only be performed on patients who are not candidates for minimally invasive SI joint fusion. 9

Minimally invasive fusion of the SIJ has been performed with several types of implants, including triangular, porous, titanium coated implants, 10-12 hollow modular screws, 13-15 titanium cages, 16 and allograft dowels. These devices are placed either inside or across the SIJ using a minimally invasive surgical approach. Minimally invasive SIJ fusion provides pain relief by acutely stabilizing the painful SI joint with subsequent fusion. In contrast to open fusion, minimally invasive SIJ fusion typically does not

require joint decortication or biologically active substances placed into the joint. In addition to publication of multiple retrospective case series, ^{10–12} published results from a prospective multicenter trial of minimally invasive SIJ fusion have substantiated high rates of pain relief, improvement in functional measures (SF-36, ODI and EQ-5D) and a low rate of revisions (<5%) and other serious adverse events. ¹⁷ In addition, two publications comparing minimally invasive SIJ fusion to open fusion have shown marked differences between the two procedures. The first study was a multicenter retrospective review of 263 patients undergoing either open or minimally invasive SIJ fusion; the latter was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased length of stay (5.1 vs. 1.3 days) as well as improved relief of pain at 1 year (-2.7 points on 0-10 scale vs. -6.2 points) and at 2-years (-2.0 vs. -5.6 points) follow-up. ¹⁸ All these differences are statistically significant. In the second study, patients from a single center who had minimally invasive SIJ fusion had substantially lower blood loss compared to those undergoing open SIJ fusion (mean 41 vs. 681 cc), lower operative times (mean 68 vs. 128) and lower length of stay (2.0 vs. 3.3 days). ¹⁹ Changes in ODI were similar in both groups.

The complication rate for minimally invasive SI joint fusion is low. Importantly, the rate of removal or revision is less than 2%. Revisions can be required in the immediate postoperative period or after many months. Early revisions may include the need to reposition an implant that is impinging on a sacral nerve or removal of an implant due to infection.

In cases of bilateral SI joint pain, bilateral SIJ fusion may occasionally be indicated. Serial bilateral SIJ fusion may be preferred, as this would allow early weight-bearing on the non-operated side to promote overall faster recovery. However, simultaneous bilateral fusion may be appropriate in selected cases.

Indications/Limitations of Coverage

Patients who have all of the following criteria may be eligible for minimally invasive SIJ fusion:

- Significant SIJ pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ (see list provided above) and cause the patient's typical pain.²
- Confirmation of the SIJ as a pain generator with at least a 50% acute decrease in pain upon fluoroscopically guided diagnostic SIJ block using local anesthetic, with or without steroids;
- Failure to respond to at least 6 months of non-surgical treatment consisting of appropriate
 pharmacotherapy for pain (e.g., non-steroidal anti-inflammatory drugs and/or opioids) and one or
 more of the following: rest, physical therapy, SIJ steroid injection. Failure to respond means
 continued pain that interferes with activities of daily living and/or results in functional disability;
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been ruled out (e.g., L5/S1 compression, hip osteoarthritis).

Minimally invasive SIJ fusion is NOT indicated for patients with the following:

- Less than 6 months of back pain:
- Failure to pursue conservative treatment of the SIJ;
- Pain not confirmed with a diagnostic SIJ block;
- Existence of other pathology that could explain the patient's pain.

In rare instances, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon fluoroscopically guided SI joint block with local anesthetic.

Bilateral SIJ fusion, if required, is usually performed serially to allow the patient to bear weight early in the postoperative period on the non-operated side to promote easier overall recovery. However, simultaneous bilateral fusion may be appropriate in certain patients, based on collaborative decision-making between the patient and surgeon.

It is expected that a person would not undergo more than one SIJ fusion per side per lifetime except in the rare case that a revision is needed.

Coding

Minimally invasive SI joint fusion is coded using CPT code 27280X.

When bilateral fusions are performed, use CPT code 27280X on two line items with the RT (right side) and LT (left side) modifiers on each line item to indicate bilateral fusion; do not use modifier -50 to indicate a bilateral procedure.

Revision and/or removal of the SI joint implants is coded using 22899 (unlisted procedure, spine) or 27299 (unlisted procedure, pelvis or hip joint) depending on the type of approach and procedure performed, whether within the global period of the fusion, or not.

ICD-9 Codes that Support Medical Necessity

ICD-9 code	Description
720.2	Sacroiliitis not elsewhere classified; inflammation of sacroiliac joint NOS
721.3	Lumbosacral spondylosis without myelopathy
724.6	Disorders of sacrum
739.4	Nonallopathic lesions, not elsewhere classified in the sacral region; sacrococcygeal region or sacroiliac region
846.9	Sprains and strains of the sacroiliac region, unspecified site of sacroiliac region
847.3	Sprains and strains of sacrum

Documentation Requirements

For patients undergoing minimally invasive SI joint fusion, the following must be documented in the medical record and be available upon request:

- A complete history documenting pain likely to be from the SIJ;
- A physical examination documenting elicitation of pain on physical examination maneuvers that stress the SIJ;
- Performance of a fluoroscopically guided SI joint block on the affected side (or both sides) which shows at least a 50% acute reduction in pain;
- A course of conservative treatment to include appropriate pharmacotherapy (e.g., non-steroidal anti-inflammatory drugs and/or opioids) and one of the following: (1) an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment, (2) SI joint steroid injections into the affected joint with inadequate response or return of pain after treatment, or (4) radiofrequency ablation of the affected SI joint with either inadequate response or return of pain after treatment;
- SI joint pain has continued for a minimum of six months;
- Other diagnoses that could be playing an important role in the patient's pain have been evaluated and ruled out as important causes of the patient's pain;
- If bilateral fusion is to be performed, bilateral pain, pain with physical examination maneuvers and bilateral response to SIJ anesthetic block should be documented;

 Within two months prior to surgery, the surgeon documents that SIJ fusion is the only treatment that is likely to provide long-term SIJ pain relief.

Surgeon Qualifications

- Minimally invasive SIJ fusion is a surgical procedure performed only by orthopedic or neurologic surgeons who have successfully completed a residency in that specialty as well as at least one specialized training course in the procedure. Training should include device placement in cadavers under supervision of a surgeon experienced in the procedure.
- Surgeons performing minimally invasive SIJ fusion should be specifically credentialed and/or privileged by at least one hospital to perform the procedure.

References

- 1. Szadek, K. M., Hoogland, P. V., Zuurmond, W. W., de Lange, J. J. & Perez, R. S. Nociceptive nerve fibers in the sacroiliac joint in humans. *Reg. Anesth. Pain Med.* **33**, 36–43 (2008).
- Szadek, K. M., van der Wurff, P., van Tulder, M. W., Zuurmond, W. W. & Perez, R. S. G. M. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. J. Pain 10, 354–368 (2009).
- Broadhurst, N. A. & Bond, M. J. Pain provocation tests for the assessment of sacroiliac joint dysfunction. J. Spinal Disord. 11, 341–345 (1998).
- 4. McGuire, R. A., Chen, Z. & Donahoe, K. Dual fibular allograft dowel technique for sacroiliac joint arthrodesis. *Evid.-Based Spine-Care J.* **3**, 21–28 (2012).
- Buchowski, J. M. et al. Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint. Spine J. Off. J. North Am. Spine Soc. 5, 520–528; discussion 529 (2005).
- 6. Belanger, T. A. & Dall, B. E. Sacroiliac arthrodesis using a posterior midline fascial splitting approach and pedicle screw instrumentation: a new technique. *J. Spinal Disord.* **14,** 118–124 (2001).
- 7. Waisbrod, H., Krainick, J. U. & Gerbershagen, H. U. Sacroiliac joint arthrodesis for chronic lower back pain. *Arch. Orthop. Trauma. Surg. Arch. Für Orthop. Unf.-Chir.* **106**, 238–240 (1987).
- 8. Moore, M. R. in *Mov. Stab. Low Back Pain Essent. Role Pelvis* 563–572 (Churchill Livingstone, 1997).
- 9. Lorio, M. P. et al. Utilization of Minimally Invasive Surgical Approach for Sacroiliac Joint Fusion in Surgeon Population of ISASS and SMISS Membership. *Open Orthop. J.* 8, 1–6 (2014).
- 10. Sachs, D. & Capobianco, R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv. Orthop.* **2013,** 536128 (2013).
- 11. Rudolf, L. MIS Sacroiliac (SI) Joint Fusion in the Context of Previous Lumbar Spine Fusion: 50 Patients with 24 Month Follow up. in *Int. Soc. Adv. Spine Surg.* 107 (2013).
- 12. Gaetani, P. et al. Percutaneous arthrodesis of sacro-iliac joint: a pilot study. J. Neurosurg. Sci. 57, 297–301 (2013).
- 13. Al-Khayer, A., Hegarty, J., Hahn, D. & Grevitt, M. P. Percutaneous sacroiliac joint arthrodesis: a novel technique. *J. Spinal Disord. Tech.* **21**, 359–363 (2008).
- Khurana, A., Guha, A. R., Mohanty, K. & Ahuja, S. Percutaneous fusion of the sacroiliac joint with hollow modular anchorage screws: clinical and radiological outcome. *J. Bone Joint Surg. Br.* 91, 627– 631 (2009).
- Mason, L. W., Chopra, I. & Mohanty, K. The percutaneous stabilisation of the sacroiliac joint with hollow modular anchorage screws: a prospective outcome study. *Eur. Spine J.* (2013). doi:10.1007/s00586-013-2825-2
- 16. Wise, C. L. & Dall, B. E. Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. *J. Spinal Disord. Tech.* **21**, 579–584 (2008).
- 17. Duhon, B. S. et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Med. Devices Auckl. NZ* 6, 219–229 (2013).
- Graham-Smith, A., Capobianco, R. A. & Cher, D. J. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. *Ann. Surg. Innov.* Res. 7, 1–12

- Ledonio, C. G. T., Polly, D. W., Jr & Swiontkowski, M. F. Minimally Invasive Versus Open Sacroiliac Joint Fusion: Are They Similarly Safe and Effective? Clin. Orthop. (2014). doi:10.1007/s11999-014-3499-8
- Miller, L., Reckling, W. C. & Block, J. E. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System®: a minimally invasive treatment for degenerative sacroilitis and sacroiliac joint disruption. *Med. Devices Evid. Res.* 77 (2013). doi:10.2147/MDER.S44690

2014 CNS Annual Meeting - Boston MA

AANS/CNS Spine Section Session

Timing for 2014: 2:00-4:30PM

2014 Program

Moderators Chris Shaffrey, MD Tyler Koski, MD

2:00-3:29 PM Symposium Spinal Balance

2:00-2:14 PM

Why does spinal balance matter in the case of basic degenerative spinal pathology? Speaker: Robert Heary MD

2:15-2:29 PM

Importance of pelvic parameters in assessing spinal balance.

Speaker: Praveen Mummaneni, MD

2:30-2:44 PM

Does coronal balance matter when addressing adult spinal pathology?

Speaker: Peter Angevine, MD

2:45-2:59 PM

When and how does global spinal balance affect the cervical spine

Speaker: Frank La Marca, MD

3:00-3:14 PM

Challenges of addressing spinal balance with minimally invasive surgical techniques

Speaker: Juan Uribe, MD

3:15-3:29 PM

Proximal Junctional kyphosis: can anything be done?

Speaker: Dan Sciubba, MD

3:30-4:30 PM

Abstract Presentations (7 abstract presentations at 7 minutes each)

3:31-3:38 PM

3:39-3:46 PM

3:47-3:54 PM

3:55-4:02 PM

4:03-4:10 PM

4:11-4:18 PM

4:20-4:27 PM

4:28-4:30 PM Q&A

The Appropriateness of Surgical Treatment Approaches for Lumbar Degenerative Scoliosis Study

Bioparagraphs of Panelists

Samuel Bederman, MD, PhD, FRCSC

Assistant Professor, Orthopaedic Surgery The University of California, Irvine

Dr. Bederman completed his residency in Orthopaedic Surgery, two spine fellowships, a M.S. in Biostatistics, and a Ph.D. in Health Services Research. Currently, he teaches at the Department of Orthopaedic Surgery at the University of California, Irvine. He investigates clinical outcomes and health services, spanning both economic/health policy matters as well as innovative surgical techniques within spinal deformity surgery. He is currently conducting research on how patient and physician behavior affect the use of spine surgery; one component of this study entails examining physician agreement on indications for referral to spine surgeons. His thesis focus was on the preferences of patients and physicians for decisions on degenerative lumbar spine surgery and included the use of consensus methods to determine appropriateness for surgical referrals. He treats approximately 150 patients with lumbar degenerative scoliosis per year, including operating on 50 individuals. Dr. Bederman was nominated by American Academy of Orthopaedic Surgeons.

Sigurd Berven, MD

Professor, Orthopaedic Surgery

UC San Francisco

Dr. Berven completed a Combined Orthopaedic residency and a Spine Surgery fellowship at UC San Francisco. Currently, he teaches Orthopaedic Surgery at UC San Francisco. He conducts basic science research on the mechanisms of the intervertebral disc degeneration, which underlies many of the common degenerative spinal disorders. He is also Co-Director of UCSF's Clinical Outcomes Research Program in Orthopaedic Surgery, which studies clinical outcomes in spinal deformity. To date, Dr. Berven has over 100 peer-reviewed publications. He served as the chair of the Adult Deformity Committee in the Scoliosis Research Society and is the co-director of the Clinical Outcomes Research Program in Orthopaedic Surgery. He treats approximately 210 patients with lumbar degenerative scoliosis per year, including operating on 70 individuals. Dr. Berven was nominated by American Academy of Orthopaedic Surgeons.

Harsimran S. Brara, MD, FACS

Assistant Area Medical Director, Chief of Service, Neurosurgery and Spine Surgery Los Angeles Medical Center, Southern California Permanente Medical Group Dr. Brara completed his residency in Neurosurgery and a fellowship in Complex Reconstructive Spinal Surgery. Currently, he practices at Southern California Permanente Medical Group (an integrated healthcare system) in Los Angeles, CA. He serves on the Kaiser Permanente National Spinal Sourcing Team and Medical Technology Deployment and Strategy Team. He is also a Regional Co-lead for spinal surgery; regional Co-leads are responsible for overseeing population care management and quality improvement activities across the Southern California region. On an annual basis, he treats approximately 250 patients with lumbar degenerative scoliosis, including operating on 50 individuals. Dr. Brara was recommended by Jed Weissberg, MD, Senior Vice President of Hospitals, Quality and Care Delivery Excellence, Kaiser Foundation Health Plan and Hospitals.

Julie Fritz, PhD, PT, ATC

Professor, Department of Physical Therapy, University of Utah Clinical Outcomes Research Scientist, Intermountain Healthcare, Inc.

Dr. Fritz received her M.S. in Physical Therapy and doctorate in Health and Rehabilitation Sciences. Currently, she teaches at the University of Utah and conducts research on the effectiveness of management strategies for low back pain and knee osteoarthritis at Intermountain Healthcare (an integrated healthcare system) in Salt Lake City, UT. She is a full-time researcher who spends approximately half her time working with research subjects and clinicians in routine clinical practice. She has led many research projects focused on elderly adults with lumbar spine disorders, including a randomized controlled trial on degenerative scoliosis and spinal stenosis. Other relevant research projects include examining comparative effectiveness of spinal surgery, how patterns of care delivery influence outcomes. She is an expert reviewer of policy work and health services research for the American Physical Therapy Association (APTA). Dr. Fritz was nominated by the APTA.

Standiford Helm, II, MD, MBA

Medical Director

The Helm Institute for Pain Management

Dr. Helm completed his residency in Anesthesiology. Currently, he works at a private practice focused on pain management in Laguna Hills, CA. He has participated in a variety of activities related to the efficacy and safety of pain management strategies for low back pain. Dr. Helm was one of the principals involved in the development of the current pain guidelines by the American Society of Interventional Pain Physicians (ASIPP). He served as president of ASIPP and has extensive experience writing guidelines and serving on multidisciplinary panels. He spends about 40% of his time treating adults over age 50 with back pain, including approximately 50 individuals per year whose primary problem is scoliosis. Dr. Helm was nominated by ASIPP.

Kenneth Lyles, MD

Professor of Medicine and Medical Director of Medicine Site-Based Research, Duke University Medical Center

Staff Physician, Geriatric Research, Education, and Clinical Center, VA Medical Center Dr. Lyles completed his residency in Medicine and fellowships in Endocrinology and Metabolism and Geriatrics and Gerontology. Currently, he teaches at Duke University Medical Center, practices at the VA Medical Center in Durham, NC. He conducts research on ways that osteoporotic fractures affect people and how to reduce their impact and prevent further fractures, and has authored more than 110 articles in this area. At both Duke University and at the Durham VA, his clinical work focuses on the care and management of patients, particularly older adults, with osteoporosis. He served on an expert panel for the Assessing Care of Vulnerable Elders (ACOVE) project at RAND and multiple committees on osteoporosis. He treats 15-20 patients with lumbar degenerative scoliosis per year. Dr. Lyles was nominated by the American Geriatrics Society.

John O'Toole, MD. MS

Associate Professor and Attending

Department of Neurosurgery, Rush Medical Center

Dr. O'Toole completed his residency in Neurological Surgery, a fellowship in Spinal Surgery, and a M.S. in Clinical Research. Currently, he teaches and practices at Rush University in Chicago, IL. He conducts research on clinical outcomes for spinal surgery and new spinal surgical techniques and devices. Dr. O'Toole has been involved in developing or reviewing several guidelines and appropriateness criteria related to spinal disorders. He has also served on numerous professional committees and published numerous peer-reviewed articles on lumbar spinal surgery. Currently, he is a member of the North American Spine Society Evidence-Based Guideline Development Committee and chairman of the AANS/CNS Spine Section Guidelines Committee. He treats approximately 50 operative and 200 non-operative patients with lumbar degenerative scoliosis per year. Dr. O'Toole was nominated by the American Association of Neurological Surgeons.

Charles A. Reitman, MD

Professor, Orthopedic Surgery Baylor College of Medicine

Dr. Reitman initially completed a certificate program in Physical Therapy. He subsequently completed his residency in Orthopedic Surgery followed by a fellowship in Spine Surgery. Currently, he practices at Baylor College of Medicine in Houston TX. His primary research interests are focused on understanding spinal stability, particularly in the cervical spine. He serves as the Evidence Compilation & Analysis Chair on the Board of Directors and as Chair of

the Appropriate Use Criteria Committee for North American Spine Society (NASS). He treats a diversity of spinal conditions, including approximately 50 patients with lumbar degenerative scoliosis per year. Dr. Reitman was nominated by NASS.

Christopher Shaffrey, MD, FACS

Professor of Neurological Surgery, Spine Division Director University of Virginia Medical Center

Dr. Shaffrey completed residencies in Neurosurgery and Orthopaedic Surgery and a fellowship in Pediatric and Adult Spinal Surgery. Currently, he practices at the University of Virginia Medical Center and conducts research on adult deformity outcomes and non-operative treatment for adult spinal deformity in Charlottesville, VA. He has more than 200 publications and 700 national and international presentations and served on numerous neurosurgery and spinal surgery committees. He is on the board of directors for the American Association of Neurologic Surgeons (AANS), American Board of Neurological Surgery and the Scoliosis Research Society (SRS). He is on the editorial boards of numerous journals including Journal of Neurosurgery, Spine and Spinal Deformity. He treats approximately 500 patients with lumbar degenerative scoliosis per year, including operating on 100 individuals. Dr. Shaffrey was nominated by the AANS and the SRS.

Gwendolyn Sowa, MD, PhD

Associate Professor

University of Pittsburgh School of Medicine

Dr. Sowa completed her residency in Physical Medicine and Rehabilitation and holds a doctorate in Biochemistry. Currently, she practices at the University of Pittsburgh School of Medicine/University of Pittsburgh Medical Center (an academic practice) and conducts research on molecular level disc and spine degeneration and biomarkers associated with treatment outcomes in Pittsburgh, PA. She is the Co-Director of the Ferguson Laboratory for Orthopaedic Research, and has extensive experience researching and serving on multidisciplinary groups focused on low back pain. Currently, she serves on a multidisciplinary panel for the International Spine Intervention Society, to develop appropriate use criteria for fluoroscopically-guided diagnostic and therapeutic sacroiliac joint injections. She treats approximately 100 patients with lumbar degenerative scoliosis per year. Dr. Sowa was nominated by American Academy of Physical Medicine & Rehabilitation.

Christopher Standaert, MD

Clinical Professor, Department of Rehabilitation Medicine, Department of Neurological Surgery, Department of Orthopaedics and Sports Medicine, University of Washington Dr. Standaert completed his residency in Physical Medicine and Rehabilitation and a Fellowship in Spine and Musculoskeletal Medicine. Currently, he practices at the University of Washington where he is a Clinical Professor in the Department of Rehabilitation Medicine, Department of

Neurological Surgery, and Department of Orthopaedics and Sports Medicine. He is also the site principal investigator for a study examining outcomes and longitudinal data for lumbar epidurals for spinal stenosis. He has prior experience serving as a panelist on an appropriate use criteria panel related to surgical care for degenerative spondylolisthesis. He has also done work related to appropriate use criteria for cervical fusion with the North American Spine Society (NASS). Prior to joining the University of Washington, he worked in community practice for nine years in Washington and Massachusetts. He treats approximately 100 patients with lumbar degenerative scoliosis per year. Dr. Standaert was nominated by NASS.

2014 Awards

- Applications down compared to last year, (similar to 2011)
- Apfelbaum will increase from 15K to 20K
- Current industry sponsors include
- Depuy Synthes, Nuvasive, Globus, Integra and Aesculap

Current Awards

- RESEARCH
- Larson- 30K
- Haid- 30K
- Apfelbaum 15K going to 20K
- Kline- 15K
- FELLOWSHIPS
- Cahill and Cloward Domestic 30K each
- Sonntag and Crockhard-International 5K each

Peer Organization Funding levels

Awards Travel fellowships

名言の回り 155/308

AANS/NREF

N O N

Z

2

SOK DYDTOMO

V

TOPESON TOPESON

いり

Future Planning for Research and Fellowships

- Funding Amount
- Organization of Awards
- Endowment planning

Research Awards

- 1) Apfelbaum Award (\$15,000) Roger Hartl, MD Cornell Medical Center, roh9005@med.cornell.edu
- "Annular repair using high-density collagen gel seeded with annular fibroblasts: an in vivo study"
- 2) Larson Award (\$15,000)- Ben Elder, MD Johns Hopkins, <u>belder4@jhmi.edu</u>
 "Preventing painful spinal compression fractures after radiation therapy to spinal metastasis"
- 3) Larson Award (\$15,000)- Rory Murphy, MD Washington University, St. Louis, rmurphy23@wustl.edu
- "The performance of a chronically implanted macro sieve electrode (MSE) in rodents with spinal cord injury"
- 4) Haid Award (\$15,000)- Andrew Torre-Healy, MD Cleveland Clinic, <u>athealy@msn.com</u> "Biomechanics of support options in long thoracolumbarosacral constructs"
- 5) Haid Award (\$15,000)- Kai-Ming Fu, MD Cornell Medical Center, kaimingfu@gmail.com "Minimally invasive vs. open deformity correction: A multi-center cohort analysis."
- 6) Kline Award (\$15,000) Yuval Shapira, MD University of Calgary, yuvalshap@gmail.com "Schwann cell therapy to reduce axonal attrition and misdirection in the injured nerve"

Fellowships

1) Cahill Fellowship (\$30,000)- Jay Turner, MD Barrow Neurological Institute, jay.turner@bnaneuro.net

Location: The Schulthess Klinik (Zurich) and The Sand Diego Center for Spinal Disorders (San Diego, CA)

- 2) Cloward Fellowship (\$30,000)- Khoi Than, MD University of Michigan, khoi@med.umich.edu
 Location: UCSF
- 3) Crockard International Fellowship (\$5,000)- Ahmed Ibrahim, MBBS, PhD, University College London, <u>aibrahim@gmail.com</u>
 Location: University of Toronto
- 4) Sonntag International Fellowhip (\$5,000)- Oscar Ramirez, MD Hospital Universitario de la Samaritana, Bogota, Columbia, <u>oscarcastro22@hotmail.com</u>
 Location: UCSF

Washington Update

February 2014





Healthcare Reform Update

Congressional Activities

AANS and CNS continue to lead efforts to "reform the reform". Neurosurgery's priority issues remain:

Repeal/Modification

- Independent Payment Advisory Board (IPAB)
- PQRS penalties
- Value-based purchasing modifier
- Public reporting of physician performance data
- Repeal of the medical device tax

Implementation

- Funding for pediatric specialist loan forgiveness
- Funding for emergency care regionalization projects
- Funding for trauma-EMS program

Additional Legislation

- SGR reform
- Medicare private contracting
- Medical liability reform
- Eliminating GME funding caps (and preserving current GME Medicare funding)

IPAB Repeal Legislation Moving Forward

Repealing the IPAB is one of organized neurosurgery's top legislative priorities. To this end, the AANS and CNS, along with the American Society of Anesthesiologists, are leading a physician coalition dedicated to repealing the IPAB. The coalition represents more than 450,000 physicians across 26 specialty physician groups. The IPAB was created by the Patient Protection and Affordable Care Act and is a government board whose primary purpose is to cut Medicare spending.

On Jan. 23, 2013, Reps. Phil Roe, MD (R-TN) and Allyson Schwartz (D-PA) introduced H.R. 351, the Protecting Seniors' Access to Medicare Act of 2013, which would repeal the Independent Payment Advisory Board (IPAB). The bill currently has 221 bipartisan cosponsors. On Feb. 14, 2013, Sen. John Cornyn (R-TX) introduced the companion bill, which has the same name and bill number (S. 351). The senate bill has 36 bipartisan cosponsors, including two Democrats. In early January 2013, the House of Representatives adopted rules for the 113th Congress that included a provision limiting IPAB's authority.

Legislation to Repeal, Defund or Delay the ACA

Efforts continue to repeal, defund or delay the Affordable Care Act, particularly in light of the disastrous roll-out. Examples include:

- S. 1592 to provide for a delay of the individual mandate under the Patient Protection and Affordable Care Act until the American Health Benefit Exchanges are functioning properly, Marco Rubio (R-FL).
- S. 1617 -- to ensure that individuals can keep their health insurance coverage, Ron Johnson (R-WI).
- S. 1642 -- To permit the continuation of certain health plans, Mary Landrieu (D-LA).
- S. 1693 -- to amend the Patient Protection and Affordable Care Act to extend the initial open enrollment period, Jeanne Shaheen (D-NH).

- S. 1699 -- to permit individuals to renew certain health insurance coverage offered in the individual or small group markets and to provide that such individuals would not be subject to the individual mandate penalty, Mark Udall (D-CO).
- S. 1711 -- to enable states to opt out of certain provisions of the Patient Protection and Affordable Care Act, John Barrasso, MD (R-WY).
- S. 1726 -- to prevent a taxpayer bailout of health insurance issuers, Marco Rubio (R-FL).
- S. 1735 -- to exclude from the definition of health insurance coverage certain medical stop-loss insurance obtained by certain plan sponsors of group health plans, Lamar Alexander (R-TN).
- H.R. 45 would repeal the ACA in its entirety and restore the provisions of law amended or repealed by the ACA as if it had not been enacted, Michelle Bachman (R-MN). Passed House of Representatives on Nov. 15 by a vote of 229-195 on May 16, 2013.
- H.R. 2009 would prohibit the Internal Revenue Service (IRS) from implementing or enforcing any
 provisions of the ACA, Tom Price, MD (R-GA). Passed House of Representatives on Nov. 15 by a
 vote of 232-185 on Aug. 2, 2013.
- H.R. 2667 -- would delay for one year certain ACA reporting requirements for insurers and employers as well as the penalties for employers who do not offer affordable coverage, Tim Griffin (R-AR).
 Passed House of Representatives by a vote of 264-161 on July 17, 2013.
- H.R. 2668 would delay the ACA individual mandate by one year, and shift by one year the schedule of penalties for individuals who do not comply with the mandate. It also incorporated the provisions in H.R. 2667 (see above) to delay the employer mandate and related reporting requirements, Bill Young (R-FL). Passed House of Representatives by a vote of 251-174 on July 17, 2013.
- H.R. 2775 No Subsidies Without Verification Act, Diane Black (R-TN), which was signed into law by President Obama.
- H.R. 2300—To repeals the Patient Protection and Affordable Care Act and the health care provisions
 of the Health Care and Education and Reconciliation Act of 2010 and provide for incentives to
 encourage health insurance coverage, Tom Price, MD (R-GA)
- H.R. 3121 To repeal the Patient Protection and Affordable Care Act and related reconciliation provisions, to promote patient-centered health care, Phil Roe, MD (R-TN).
- H.R. 3299 -- to protect the privacy of personally identifiable information in relation to enrollment activities of health insurance exchanges, Denis Ross (R-FL).
- H.R. 3350 -- to authorize health insurance issuers to continue to offer for sale current individual health insurance coverage in satisfaction of the minimum essential health insurance coverage requirement, Fred Upton (R-MI). Passed House of Representatives on Nov. 15 by a vote of 261-157.
- H.R. 3362 -- to require transparency in the operation of American Health Benefit Exchanges, Lee Terry (D-NE). Passed House of Representatives on Jan. 16 by a vote of 259-154.
- H.R. 3367 -- to delay the application of the health insurance provider annual fee until 2016 and to provide a process to return to consumers any amounts attributable to the expected application of the annual fee to 2014 or 2015, Charles Boustany, MD (R-LA).
- H.R. 3373 -- to prohibit incurring further obligations with respect to the healthcare.gov website without offsetting savings, Bill Johnson (R-OH).
- H.R. 3376 -- to provide a 12-month exemption from the health insurance mandate for individuals whose employer-sponsored health plan coverage or individual health insurance coverage is terminated for a plan year beginning during 2014, Billy Long (R-MO).
- H.R. 3406 -- to ensure that individuals can keep their health insurance coverage, Ron DeSantis (R-FL).
- H.R. 3419 -- o exempt certain small businesses from the employer health insurance mandate and to modify the definition of full-time employee for purposes of such mandate, Jack Kingston (R-GA).
- H.R. 3425 -- to delay the individual health insurance mandate and any penalties for violating the individual mandate until after there is a certification that the healthcare.gov website is fully operational, Daniel Lipinski (D-IL).

- H.R. 3429 -- to protect personal and financial information by requiring certain certifications by entities awarded funds under the Patient Protection and Affordable Care Act for the operation of a navigator program or certain other exchange activities, Cathy McMorris Rogers (R-WA).
- H.R. 3489 -- to repeal the funding mechanism for the transitional reinsurance program in the individual market, Pat Tiberi (R-OH).
- H.R. 3504 -- to provide improved consumer protection and rate review for health insurance coverage in the individual market, Jan Schakowsky (D-IL).
- H.R. 3517 -- to delay the individual health insurance mandate and any penalties for violating the
 individual mandate until after there is a certification that the healthcare.gov or other applicable state
 exchange website is fully operational, Kurt Schrader (D-OR).
- H.R. 3522 -- to authorize health insurance issuers to continue to offer for sale current group health insurance coverage in satisfaction of the minimum essential health insurance coverage requirement, Bill Cassidy, MD (R-LA).
- H.R. 3541 -- to prevent a taxpayer bailout of health insurance issuers, Tim Griffin (R-AR).
- H.R. 3598 -- to permit insurers to offer catastrophic coverage plans to anyone, Jeff Fortenberry (R-NE).
- H.R. 3607 -- to enable states to opt out of certain provisions of the Patient Protection and Affordable Care Act, Mick Mulvaney (R-SC).
- H.R. 3621 -- to provide for access to health insurance coverage of life-sustaining treatments furnished by certain providers, Sean Duffy (R-WI).
- H.R. 3811 would require the HHS Secretary to notify affected individuals within two business days
 of a breach of their personally identifiable information maintained by an exchange, Joe Pitts (R-PA).
 Passed House of Representatives on Jan. 10 by a vote of 291-122.

At this point, it is not likely that any of this legislation will be considered by the Senate, particularly if the Healthcare.gov website improves. This is particularly true since President Obama appears to be dealing with all the problems by merely delaying implementation dates via executive directives.

AANS/CNS Continue to Support Efforts to Repeal Medical Device Tax

At present, H.R. 523, the Protect Medical Innovation Act of 2013, which would repeal the tax, has 270 cosponsors. The Senate companion measure, S. 232, has 38 cosponsors.

On Sept. 28, 2013, the AANS and CNS joined 975 organizations in writing a letter to congressional leaders, urging Congress to repeal the medical device excise tax, which was included in the Affordable Care Act. Repealing this tax is a top legislative priority for organized neurosurgery, as we believe it is adversely impacting patient care and medical innovation. Along with this effort, the AANS and CNS joined AdvaMed in sponsoring an advertisement (http://bit.ly/14VNzZp) in *Politico*. On Sept. 29, the House of Representatives adopted, by a margin of 248-174, an amendment repealing the medical device tax to H.J.Res. 59. This stopgap spending measure would have temporarily continued to fund the federal government through Dec. 15, 2013. Senate Majority Leader Harry Reid (D-NV) vowed to oppose attempts to use this government spending legislation as a vehicle for repealing this tax, and ultimately, Congress passed a temporary spending measure that did not include any provisions that would delay, defund or repeal elements of the ACA.

To bolster its claim that the tax is having a On February 18 2014, the Advance Medical Technology Association (AdvaMed) released the findings of a new survey of its membership on the first year impact of the device tax on industry. The survey found that industry employment was reduced by approximately 14,000 jobs, and companies decided to forgo hiring an additional 19,000 who otherwise would have been hired, bringing the total direct employment impact of the tax on the device industry to about 33,000. The survey also found that almost one-third of respondents had reduced research and development efforts as a result of the tax. In terms of investment dollars, three-quarters of respondents said they had taken one or more of the following actions in response to the tax: deferred or cancelled capital investments; deferred or cancelled plans to open new facilities; reduced

investment in start-up companies; found it more difficult to raise capital (among startup companies); and/or, reduced or deferred increases in employee compensation. A copy of the survey is on the web at: http://bit.ly/1dHPvtc.

Regulatory Activities

The Obama Administration continues to issue implementing regulations, including those related to Medicaid expansion, health insurance exchanges, insurance market and rate rules, and others. To date the following states have made decisions regarding health insurance exchanges:

- State -- The state plans to run its own exchange: CA, CO, CT, DC, HI, ID, KY, MD, MA, MN, NV, NM, NY, OR, RI, VT, WA
- Federal -- The state will not set up an exchange, and the federal government will run a fallback exchange instead: AL, AK, AZ, FL, GA, IN, KS, LA, ME, MS, MO, MT, NE, NH, NJ, NC, ND, OH, OK, PA, SC, SD, TN, TX, VA, WI, WY
- Partnership -- The state will run some functions of the exchange but will leave certain ones to the federal government: AR, DE, IL, IA, MI, UT, WV

In terms of expanding Medicaid coverage, AL, FL, GA, ID, LA, MS, MO, MT, NE, NC, OK, SC, SD, TX, and WI will not be expanding Medicaid coverage to those individuals making under 133% of federal poverty level. AK, IN, KS, ME, NH, PA, TN, UT, VA and WY have not yet decided. All others have announced plans to expand Medicaid coverage.

The following outlines key elements of the law that have been implemented (or authorized to be implemented, though some have not been put into effect yet – e.g., IPAB) so far and those scheduled to come on-line in 2013:

2010

- Review of health plan premium increases
- Creation of Medicaid and CHIP Payment Advisory Commission
- Establishment of Comparative Effectiveness Research Institute
- Establishment of Prevention and Public Health Fund
- Medicare Beneficiary Drug Rebate
- Small Business Tax Credits to expand insurance coverage
- Adult Dependent Coverage to Age 26
- Consumer Protections in Insurance
- Insurance Plan Appeals Process
- Coverage of Preventive Benefits
- Health Care Workforce Commission

2011

- Minimum Medical Loss Ratio for Insurers
- Closing the Medicare Drug Coverage Gap
- Increasing Medicare Payments for Primary Care and Rural General Surgeons
- Establishing Center for Medicare and Medicaid Innovation
- Implementing a National Quality Strategy
- Medical Malpractice Grants
- Funding Health Insurance Exchanges
- Reduced Medicaid Payments for Hospital-Acquired Infections
- Establishment of Medicare Independent Payment Advisory Board

2012

Accountable Care Organizations in Medicare

- Uniform Coverage Summaries for Consumers
- Fraud and Abuse Prevention
- Medicare Value-Based Purchasing
- Reduced Medicare Payments for Hospital Readmissions

2013

- State Notification Regarding Exchanges
- Closing the Medicare Drug Coverage Gap
- Medicare Bundled Payment Pilot Program
- Medicaid Coverage of Preventive Services
- Increased Medicaid Payments for Primary Care
- Limits on Itemized Deductions for Medical Expenses
- Flexible Spending Account Limits
- Medicare Tax Increase
- Tax on Medical Devices
- Extension of CHIP
- Reductions in Disproportionate Share Hospital Payments

2014

- Expanded Medicaid Coverage
- Presumptive Eligibility for Medicaid
- Individual Requirement to Have Insurance
- Health Insurance Exchanges
- Health Insurance Premium and Cost Sharing Subsidies
- Guaranteed Availability of Insurance
- No Annual Limits on Coverage
- Essential Health Benefits
- Multi-State Health Plans
- Temporary Reinsurance Program for Health Plans
- Basic Health Plan
- Employer Requirements (employer mandate delayed for one-year)
- Medicare Advantage Plan Loss Ratios
- Wellness Programs in Insurance
- Fees on Health Insurance Sector
- Medicare Payments for Hospital-Acquired Infections

For more information about the overview of the law and the implementation timeline go to: http://bit.ly/18VYVzi and http://bit.ly/14w3Dgi. To view a premium calculator, go to: http://bit.ly/1935Gjo

Pressing forward with Implementation

The number of glitches in the rollout of the ACA enrollment process continues. An a sample of the glitch timeline is as follows:

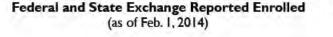
- Sept. 2013: Glitches Expected Before ACA Roll-Out. Policy experts warn that glitches can be expected on the health insurance exchanges' Oct. 1 launch due to the complexity of the exchanges and the involvement of many different agencies.
- Oct. 1, 2013: ACA Debut Plagued with Problems. High traffic causes both federal and state-run exchanges to crash.
- Oct. 6, 2013: Officials Acknowledge Flaws with Healthcare.gov. The administration cites overwhelming traffic, design flaws, and software problems as root causes of exchange glitches.

- Oct. 23, 2013: Glitches Prompt Administration to Clarify Late Enrollment Penalties. The administration announces that individuals have until March 31, 2014, rather than the original date of Feb. 15, 2014, to avoid penalties for late enrollment.
- Oct. 24, 2013: House Energy and Commerce Committee Questions Contractors.

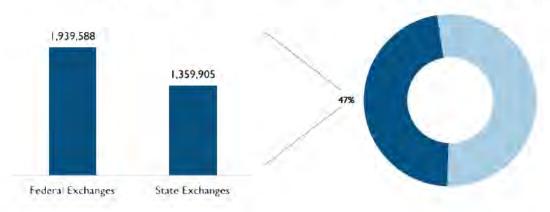
 Contractors testify that there was insufficient testing before the health exchanges' launch and that it was not their decision to go live on Oct. 1.
- Oct. 30, 2013: House Energy and Commerce Committee Questions HHS Secretary Kathleen Sebelius. Sebelius told the Committee to hold her accountable for the issues surrounding the HealthCare.gov website.
- Nov. 13, 2013: ACA Enrollment Numbers Released. According to HHS, only 106,185 people
 have applied for and chosen private insurance through the new marketplaces, which falls short of
 administration's initial enrollment target for October.
- Nov. 21, 2013: 2015 Enrollment Delayed. HHS announces that it will delay the start of the 2015 enrollment period by a month until Nov. 15, 2014 *after* the elections.
- Nov. 27, 2013: SHOP Enrollment Delayed. Obama Administration announces one-year delay in online small business insurance (SHOP) marketplace until Nov. 2014.
- Dec. 20, 2013: Individual Mandate Delayed. Individuals whose health plans were canceled will not be required to purchase one of the "metal" plans, but will be permitted to satisfy the mandate with a catastrophic plan.
- Jan. 14, 2014: PCIP Coverage Expanded. Individuals enrolled in the Pre-Existing Condition Insurance Plan (PCIP) who have not yet found new health insurance coverage may keep their PCIP coverage for two additional months, through March 31, 2014.

Despite the fact that the exchange enrollment process has been a disaster, more individuals are enrolling in the healthcare exchanges.

With Two Months Until Deadline, ACA Enrollment Nears 50% of Goal February 12, 2014

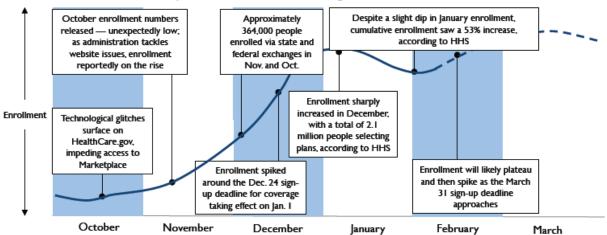


Federal and State Exchange Reported Enrolled as Percentage of Goal (7M)



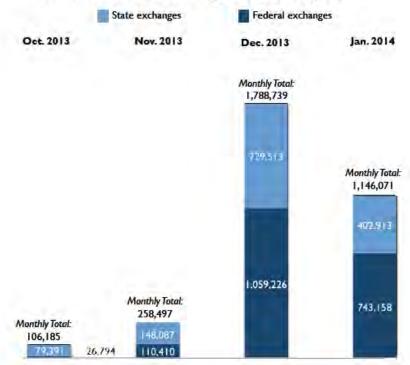
Exchange Enrollment Numbers Will Likely Spike February 13, 2014 Closer to Deadlines

Projected ACA Insurance Exchange Enrollment Patterns



Despite January Drop, ACA Enrollment More Robust in 2014

Health Insurance Exchange Enrollment by Month

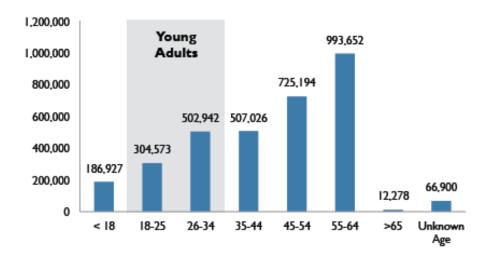


Analysis

- In January, there was a 35% drop from December's enrollment numbers
- · Yet, in January, total ACA enrollment saw a 53% increase
- The rise in December enrollment is due in large part to Dec. 24 deadline for Jan. I coverage and technical repairs to HealthCare.gov
- · The cumulative, four-month ACA enrollment total is 3,299,492 people

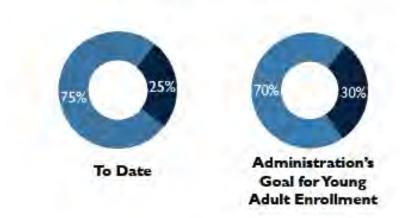
Breakdown of Insurance Exchange Enrollees by Age

Oct. 2013 - Jan. 2014



Percentage Young Adult Enrollment to Date Compared with Goal

Percentage Young Adult Enrollment



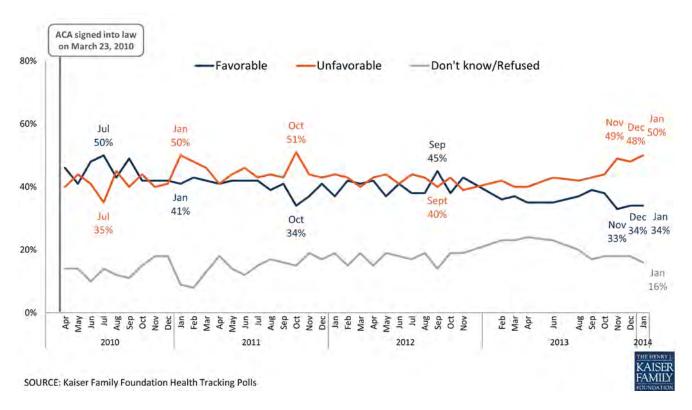
The Effects on Workers and Business

Recently, the CBO dealt President Obama another blow when it reported that workers will work fewer hours as a result of the ACA. "The reduction in CBO's projections of hours worked represents a decline in the number of full-time-equivalent workers of about 2.0 million in 2017, rising to about 2.5 million in 2024 ... The decline in full-time-equivalent employment stemming from the ACA will consist of some people not being employed at all and other people working fewer hours; however, CBO has not tried to quantify those two components of the overall effect."

Additionally, a new <u>report</u> by the Obama administration estimates that health insurance premiums of 11 million small-business employees will increase under the federal healthcare law, handing Republicans another potent talking point about how Obamacare is inflicting damage on workers. The report also found that premiums are expected to fall for the other 6 million small-business employees and that the impact on premiums in large employer health plans will be "negligible."

Public Opinion Plummets

Approximately one-half of the country views the ACA unfavorably, and only one-third view the health reform law in a favorable light.



Republican support for the law has always been low, while Democrat support has been high. Due to the problems associated with the roll-out, dropped insurance plans and other problems that have become apparent, even Democrat support is waning.

Given all the glitches, it is difficult to predict how implementation will continue to unfold, and whether and how this will continue to be a political issue to be decided at the Nov. 2014 ballot box. The AANS and CNS will continue to monitor implementation, and weigh-in as determined appropriate by leadership.

Judicial Activities

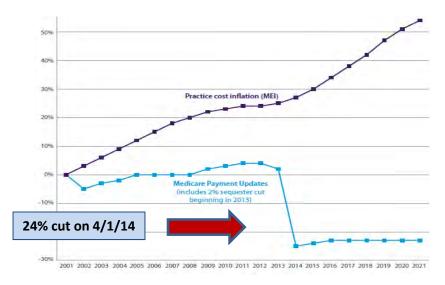
Several years ago, the Goldwater Institute filed a lawsuit (*Coons v. Geithner*) challenging, among other things, the constitutionality of the Independent Payment Advisory Board (IPAB) on separation-of-powers grounds. The federal district court had dismissed the suit, and on February 19, 2013, the Goldwater Institute filed an appeal with the 9th Circuit Court of Appeals. The suit is pending action by the Court of Appeals, which was scheduled to hear oral arguments on Jan. 28, 2014. The court, however, has postponed arguments and another hearing date has not yet been set.



Medicare Physician Payment Update

Background

Every year for more than a decade, physicians have faced a significant Medicare payment cut -- the result of a flawed sustainable growth rate (SGR) formula. Now, once again, physicians face an SGR-driven pay cut of approximately 24 percent effective April 1, 2014. In addition to the SGR-related cuts, physicians face and additional 2 percent budget sequestration cut per year for the next 9 years.



As if these cuts weren't bad enough, physicians also face a host of penalties stemming from the Affordable Care Act (ACA), including those related to PQRS, eRx, EHR, IPAB and others. Under a worst case scenario situation, neurosurgeons could face cuts in excess of 85 percent over the next decade.

Year	SGR	Deficit Reduction Sequester	PQRS	e-Rx	EHR	Value Based Payment Modifier
2013		-2		-1.5		
2014	-24.7	-2		-2		
2015	3.6	-2	-1.5		-1	-1
2016	2.6	-2	-2		-2	-2
2017	2.0	-2	-2		-3	?
2018	1.5	-2	-2		-3	?
2019	1.0	-2	-2		-4	?
2020	0.9	-2	-2		-5	?
2021	1.0	-2	-2		-5	?
2022	1.3	-2	-2		-5	?

AANS/CNS Principles for SGR Reform

Given the reduction in the cost of repealing the SGR, policymakers and stakeholders are cautiously optimistic that Congress will be able to repeal the SGR this year. The AANS and CNS, along with our colleagues in other medical groups – including the Alliance of Specialty Medicine – have been advocating for the following general SGR principles:

- Repeal the SGR, followed by at least 5-year period of payment stability and annual updates based on MEI
- No payment differentials between primary care physicians and all other doctors
- Maintain a viable fee-for-service option
- Payments based on quality improvement should be based on positive incentives, rather than penalties
- Physicians should not be evaluated based on flawed ranking systems or head-to-head comparisons
- Any new quality-based physician payment system must replace the current PQRS, EHR, VBPM programs
- Physicians, rather than the government, should determine the most appropriate and clinically relevant quality improvement metrics
- Legal protections should be provided to physicians who follow clinical practice guidelines and quality improvement program requirements
- IPAB should be repealed
- Patients and physicians should be allowed to privately contract on case-by-case basis, with beneficiaries receiving the Medicare allowable

The Evolution of Repeal Legislation

Since this time last year when the key congressional leaders pledged to repeal the SGR once and for all, the three committees with jurisdiction over Medicare --- the Senate Finance, House Energy and Commerce and House Ways and Means Committees – have been working to develop bipartisan legislation. The first bill was passed unanimously by the House Energy and Commerce Committee back in July 2013. The Senate Finance and House Ways and Means Committees followed suit in December. All three bills were structurally similar, and aimed at moving Medicare physician payment from a pay for quantity to pay for quality system.

Following the tri-committee action, the House Doc Caucus issued a letter outlining a list of key demands that they required to get their support for any legislation. They secured the commitment of Speaker Boehner and other House leaders that SGR repeal legislation would only be brought to the House floor for a vote if it had the support of the caucus. Meanwhile, as negotiations were nearing a conclusion, the AANS and CNS sent a letter to Congress outlining the principles of the Doc Caucus, the AMA and neurosurgery, in an effort to shape the final draft. The final deal, as outlined below, represented progress over earlier drafts.

Bicameral-Bipartisan Legislation Introduced

On Feb. 6, 2014, the <u>Senate Finance</u>, <u>House Energy and Commerce</u> and <u>House Ways and Means</u> Committees released bipartisan legislation to repeal Medicare's sustainable growth rate (SGR) physician payment system. The SGR Repeal and Medicare Payment Modernization Act (S. 2000/H.R. 4015), establishes a new streamlined value-based incentive payment system called the Merit-Based Incentive Payment System, or MIPS. The new program consolidates the three existing Medicare incentive programs — Physician Quality Reporting System (PQRS), Electronic Health Records (EHR) and Value-Based Payment Modifier (VBPM) — and allows physicians to opt-out of the fee-for-service

system in favor of participating in alternative payment models (APMs), such as accountable care organizations, patient-centered medical homes and other similar arrangements.

The Details

Below is a brief summary of the major provisions of the "SGR Repeal and Medicare Payment Modernization Act." Click here for a copy of the legislation and a section-by-section summary:

- SGR Repeal and Medicare Payment Modernization Act
- Section-by-Section Summary
- Frequently Asked Questions
- Timeline for implementation of key provisions

The main provisions are as follows:

Stabilizes Fee Updates:

- Prevents the 24.1% pay cut on April 1, 2014 and any future SGR-related cuts.
- Repeals the SGR, and stabilizes payments by providing annual positive updates of 0.5% per year for five years (2014-18).
- Freezes payments from 2019-23.
- In 2024 and beyond, physicians participating in APMs will receive a 1.0% annual pay increase and all others will receive a 0.5% base pay increase.

Consolidates Current Medicare Quality Programs:

- Creates a new Merit-Based Incentive Payment System (MIPS) program, which eliminates the
 existing penalties for PQRS, EHR and VBPM programs at the end of 2017.
- Under MIPS, physicians will receive bonuses or penalties based on a composite score on a 0-100 scale. The components of the score are based on a consolidation of the existing quality programs as follows:
 - 30% PQRS
 - 30% resource use
 - 15% clinical practice improvement activities
 - 25% EHR meaningful use
- The MIPS payment pool is <u>not</u> budget neutral and all physicians are eligible to receive bonus payments (although if all physicians do in fact meet the quality threshold, most will only receive the annual update and only those who are the highest performers will receive a small bonus) if they exceed the performance threshold (which is a mean of all composite scores over rolling 3 year period); <u>Maximum</u> bonuses and penalties (the bonuses and penalties are assessed based on a linear scale and those that are clustered around the mean will receive a smaller bonus/penalties and those who are the top and bottom performers will receive the higher bonus/penalties) are as follows:
 - 4.0% in 2018
 - 5.0% in 2019
 - 7.0% in 2020
 - 9.0% in 2021 and beyond
- Establishes an <u>additional</u> bonus pool of funds (\$500 million per year) to distribute to the highest performing physicians.

- Physicians can opt-out of the fee-for-service MIPS program and participate in alternative payment models (APM) instead. Under this two-sided risk program, physician could earn annual 5.0% bonus payments from 2018-23.
- Participation in qualified clinical data registries, maintenance of certification programs and other clinical improvement activities are recognized in this new program.
- Physician specialty societies will have an enhanced opportunity to identify and submit quality measures that are relevant to their specialties, without having to first go through the current National Quality Forum and other measure endorsement processes.

Accurate Valuation of Services Under the Physician Fee Schedule:

- Builds on current ongoing efforts to identify potentially misvalued services and the following list of codes will be subject to this ongoing effort:
 - Majority of spending under the fee schedule
 - Substantial changes in procedure time
 - Changes in site-of-service
 - More appropriately bundled together
- CMS can change values in order to "smooth RVUs within a group of services".
- GAO is required to study the AMA/Specialty Society Relative Value Update Committee (RUC) process and report its finding w/in one year.

Promoting Evidence-Based Care:

- Requires CMS to use appropriate-use criteria (as developed by specialty societies) when ordering and providing advanced diagnostic imaging services.
- CMS will develop qualified clinical decision support tools for ordering physicians to use when ordering imaging services.
- In 2020, outlier physicians will be required to undergo prior authorization when ordering imaging services.

Access to Information on Physicians and Expanded Data Availability:

- CMS is required to publish quality, resource use (current law), utilization and payment (new requirement) data on the Physician Compare website.
- CMS is required to make claims data available to qualified clinical data registries; registries must pay for the costs associated with providing this data.

Other Provisions:

- Physicians who opt out of Medicare to engage in private contracting with their patients will no longer be required to renew their opt-out status every two years and HHS must publicly release number and characteristics of opt-out physicians beginning in 2015.
- Requires EHR interoperability by 2017.
- Prohibits any guideline or other quality/resource standard from being used to establish the standard of care or duty of care owed by a healthcare provider to a patient in any medical malpractice or medical product liability action or claim.

AANS/CNS (tepid) Support

Because on balance it meets many of neurosurgery's core principles, and is likely the best deal we are likely to achieve, the AANS and CNS are supporting passage of the bill -- provided, however, that Congress is able to identify acceptable budget offsets to cover the estimated \$150 billion price tag. The chart below depicts how the legislation stacks up against neurosurgery's top principles:

Neurosurgery Reform Principle	Final Tri-Committee Bill			
Neurosurgery Keroriii Frincipie	Yes	No	In Part	
Repeal the SGR	X			
Annual positive payment updates based on Medicare Economic Index (MEI)			X ¹	
Five-year period of payment stability with updates based on MEI			X ²	
No payment differentials between specialists and primary care physicians	х			
Eliminate current PQRS, EHR and VBPM programs and penalties	X³			
Provide choice of payment models, including fee-for-service	х			
Positive, rather than negative, incentives for any quality improvement payment programs			X ⁴	
Quality programs must not be budget neutral and all physicians must have an opportunity to earn bonus payments			X ⁵	
Quality measures developed by physicians	х			
Allow patients and physicians to privately contract on a case-by-case basis		X ⁶		
Legal protections for physicians	X ⁷			
Repeals the Independent Payment Advisory Board		х		

_

¹ Positive 0.5% payment update each year for five years (2014-18); beginning in 2013, reinstitutes 0.5% update for MIPS program and 1.0% for APM program.

² Positive 0.5% payment update for five years (2014-18).

³ Eliminates penalties, but incorporates existing programs into new composite quality formula.

⁴ Under new Merit-Based Incentive Payment System (MIPS) and APM programs, physicians can earn bonus payments; however, those physicians that do not meet performance thresholds or who fail to participate at all, will receive penalties that compare to those imposed under current law.

⁵ Technically all physicians will be able to achieve the quality threshold; however there is still a finite amount of money available for quality incentive payments. If all physicians meet or exceed the threshold, only those in the top tier will be eligible for the additional annual \$500 million bonus payment pool; all others will merely receive the annual payment update.

⁶ Allows indefinite automatic extension of the 2-year Medicare private contracting opt-out election.

⁷ Any guideline or other quality standard does not establish the standard of care or duty of care owed by a physician to a patient in any medical malpractice or medical product liability action or claim.

In a <u>letter to Congress</u>, the AANS and CNS noted that the legislation includes a number of elements that are essential for physician payment reform:

- Repeals the SGR and provides physicians a five-year period of payment stability with positive updates;
- Consolidates the current PQRS, EHR and VBPM programs and eliminates the penalties associated with these programs;
- Provides physicians a choice of payment models, including fee-for-service;
- Includes positive incentives for quality improvement payment programs that allow all physicians the opportunity to earn bonus payments;
- Enhances the ability of physicians, rather than the government, to develop quality measures and clinical practice improvement activities; and
- Clarifies that quality improvement program requirements do not create new standards of care for purposes of medical malpractice lawsuits.

Although the legislation incorporates many of neurosurgery's recommendations, the AANS and CNS nevertheless continue to have ongoing concerns about several aspects of the bill, which may adversely affect Medicare beneficiaries' access to specialty care. In our letter, we pointed out our disappointment that the bill does not include positive base payment updates every year, noting that medical practice costs will rise in excess of 25 percent over the next decade and "physicians will continue to lose ground to inflation — and this is on top of the past decade of flat Medicare payments." Additionally, we objected to a section of the bill that instructs the Centers for Medicare and Medicaid Services to make additional cuts to so-called "misvalued" codes, which will redistribute an additional \$1 billion from specialty services across the entire Medicare physician fee schedule over the next three years. Finally, the AANS and CNS encouraged Congress to exercise ongoing oversight over the MIPS program "to ensure that the performance metrics employed are in fact reflective of the views of the medical profession and the scoring system is fair and accurate."

The AANS and CNS also joined the Alliance of Specialty Medicine in writing a similar <u>letter of support</u>.

Prospects for Reform

While there is clear bipartisan, bicameral support for repealing and replacing the SGR, there are still a number of real challenges. The price tag for repeal, while lower than in past years, ranges from \$130-\$150 billion, and finding bipartisan budget offsets will still be a challenge. Options for budget offsets include hospital cuts and other providers, GME cuts, and others that are controversial. Furthermore time is running out for action, with only a month remaining before the 24 percent cut takes place. The prospect for yet another short-term "patch" to prevent the cut is therefore a real possibility – the length of which could be 9 months or longer.

While some medical groups (see e.g., a <u>coalition of state medical associations</u> that includes Arizona, California, Florida, Louisiana, Oklahoma, New York, North Carolina, South Carolina, and Texas) followed a similar approach to neurosurgery -- supporting the bill, while at the same time pointing out its flaws -- organized medicine is largely pressing Congress to act swiftly and pass the "SGR Repeal and Medicare Payment Modernization Act" prior to the expiration of the current SGR "patch" at the end of March. There is widespread, bipartisan support for repeal, from the <u>editorial pages</u> of major news outlets, to <u>health policy though leaders</u>, to <u>Medicare beneficiary organizations</u> and most physician organizations, including the <u>American Medical Association</u> and <u>American College of Surgeons</u>.

The American College of Surgeons is running a grassroots drive, with a toll-free number for surgeons to use to contact Congress:



1-877-996-4464

The AMA has also set up a special grassroots website, for patients and physicians. There individuals can send emails, call Congress and get advocacy materials to help support their grassroots advocacy program.



www.FixMedicareNow.org

Action to Consider

The ACS, AMA and others are also considering paid and earned media and other tools to achieve repeal within the next 30 days. To that end, the ACS in particular, wants to know if the AANS and CNS are inclined to support any or all of the following:

- 1. Announce publicly that neurosurgery will "score" co-sponsorship of the SGR bills as a key vote in terms of our political support
- 2. Participate in a conference call and effort among the surgical societies' communications staff to coordinate a uniform message
- 3. Coordinated and unified grassroots "blitz" calls
- 4. Encourage neurosurgeons to schedule in-district meetings with their elected officials
- 5. Promote a countdown clock to 4/1/14
- 6. Tweeting members of Congress to publicly call on them to co-sponsor S. 2000/H.R. 4015
- 7. Support a special surgical SGR repeal website
- 8. Financially support banner ads to direct people to a surgical SGR repeal website
- 9. Prioritize lobbying/grassroots efforts towards the 259 signers of Maffei-Flores letter, which called for repeal of the SGR; then target the remaining members of Congress
- 10. Participate in coordinated lobby visits
- 11. Participate in targeted PAC giving and sponsor political events based on SGR repeal
- 12. Establish work groups to coordinate strategy and activities on a number of fronts, including grassroots, lobbying visits and communications

Medicare Private Contracting

Unfortunately the SGR repeal legislation did not include a provision to allow private contracting on a case-by-case basis. Nevertheless, the AANS and CNS continue to work with the Coalition of State Medical and National Specialty Societies to promote legislation to allow private contracting in Medicare without penalty to either patient or physician. Under current law, physicians who wish to privately contract must opt out of Medicare for 2 years and Medicare will not pay any portion of the physician's services. After gaining some limited momentum last year, the Medicare Patient Empowerment Act is again moving forward in the 113thCongress -- S. 236 is sponsored by Sen. Lisa Murkowski (R-AK) and has 4 cosponsors, and Rep. Tom Price, MD (R-GA) introduced H.R. 1310, which has 22 cosponsors. The MPEA would allow physicians and patients, on a case-by-case basis, enter into private contracts. The physician would not be forced out of Medicare and the beneficiary would be reimbursed for those services in the amount that Medicare would have otherwise paid.

The AANS and CNS have endorsed both bills. Neurosurgeons are encouraged to go to the My Medicare-My Choice website (http://bit.ly/Xv1Xno) to sign the petition supporting the MPEA.



Coding and Reimbursement Committee Update

Medicare Physician Fee Schedule

2014 Medicare Physician Fee Schedule Final Rule

On Nov. 27, 2013, the Centers for Medicare & Medicaid Services (CMS) posted the 2014 Medicare Physician Fee Schedule (MPFS) Final Rule. Disregarding the temporary SGR-related 0.5% increase from January 1, 2014 through March 31, 2014, the net overall impact of changes in the 2014 MPFS final rule on neurosurgery's Medicare reimbursement is zero. Fortunately, CMS accepted neurosurgery's recommendation to maintain the current value for two laminectomy codes — CPT codes 63047 and 63048 — which were flagged for review by CMS as potentially misvalued. The agency nevertheless believes that two other laminectomy codes — CPT 63045 and 63046 — may be overvalued, and the AMA/Specialty Society Relative Value Scale Update Committee (RUC) has been asked to re-review CPT Codes 63047 and 63048 together with 63045 and 63046. On January 27, 2014, AANS and CNS sent a letter to CMS objecting to inclusion of 63045 and 63046 in the family of codes with 63047 and 63048.

CPT Coding

February 2014 CPT Meeting

The CPT Panel met February 6 through 8, 2014. Patrick Jacob, MD, AANS Advisor to CPT, Henry Woo, AANS Alternate Advisor, and Washington office staff attended. The AMA publishes a summary following each meeting which is available at: http://bit.ly/15jiazu. The following code proposals were discussed:

- Intracranial Lysis and Embolectomy Codes. Drs. Jacob and Woo presented the latest draft of new thrombolysis and mechanical embolectomy codes to several CPT panel members prior to the February 2014 panel meeting who questioned the current level of literature for mechanical embolectomy codes, which were added to the proposal at the request of the Society of Interventional Radiology (SIR). The genesis for the new code proposal was the elimination of CPT Code 37201, a non-coronary thrombolysis code that had been used by endovascular surgeons for stroke thrombolysis. The code was eliminated two years ago through the bundling initiative for unrelated renal angiography codes at the RUC and the neurosurgeon use of the code was inadvertently overlooked, requiring neurosurgeons to report the service as an unlisted procedure code. At the February 2014 meeting panel reviewers agreed to present the codes to the full editorial panel for discussion only to provide further guidance in the development of the proposal but stated they still could not support the code proposal at this time because of their concerns about the literature. Based on feedback received, Drs. Jacob and Woo will revise the code change proposal to resubmit by July 10, 2014 for the October 2014 CPT meeting.
- Transcatheter Placement of Carotid Stents. SIR presented a proposal to add code a new code
 and to revise current Category I codes 37215 and 37216, Transcatheter placement of intravascular
 stent(s), cervical carotid artery, percutaneous codes, and Category III codes 0075T 0076T to include
 the open approach in addition to the percutaneous in the use of these codes and for reporting
 antegrade stent placement in the innominate and intrathoracic carotid artery.
- Minimally Invasive Sacroiliac Joint Fusion. The AANS and CNS presented a proposal for a new Category I code to replace the Category III code 0334T to describe percutaneous/minimally invasive sacroiliac joint arthrodesis. The manufacturer had presented a proposal at the February 2013 CPT

panel meeting and subsequently asked the AANS and CNS to help develop a new code proposal. Following a review of additional literature vetted by the AANS/CNS Coding and Reimbursement Committee and the AANS/CNS Spine Section, the decision was made to co-sponsor the proposal, as the literature meet the minimum AMA standard for a category I code.

- Vertebroplasty/Kyphoplasty. CMS has asked that fluoroscopy and CT guidance be bundled into Vertebroplasty and Kyphoplasty CPT codes 22520-22525. SIR developed the proposal and the AANS and CNS co-sponsored and helped with the presentation.
- Category I for Additional Level Cervical Disc Arthroplasty. The North American Spine Society
 (NASS) submitted a code change proposal to elevate the Additional Level Cervical Disc Arthroplasty
 category III code 0092T to a category I "add-on" to report performance of total disc arthroplasty at an
 additional level, and revision of current Category III code 0092T to allow reporting for three or more
 levels. The AANS and CNS supported the proposal.
- Transforaminal Endoscopic Discectomy. Representatives for Joimax, Inc., the manufacturers of a transforaminal endoscopic lumbar decompression system presented a code change proposal to report lumbar nerve root, foraminal and laminotomy, facetectomy and foraminotomy decompressions under continuous endoscopic visualization. The panel reviewers did not support the proposal and put it on the table for discussion, suggesting that perhaps a workgroup to discuss the definitions of open, percutaneous, and endoscopic spinal decompression should be formed. Accompanying the sponsors was Daniel T. Laich, DO, a neurosurgeon from Chicago. The panel had rejected a proposal from the sponsors at the October 2013 CPT Editorial Panel meeting.
- Decompression with Implantation of an Interlaminar Stabilization Device. Sponsors of a proposal for a new Category I code for Implantation of an Interlaminar Stabilization Device decided to withdraw their proposal from February 2014 panel meeting. In October 2013, the AANS/CNS Washington Office received a request from Tim Hunter, Vice President, Health Economics, Reimbursement and Public Policy with Musculoskeletal Clinical Regulatory Advisers (MCRA), regarding a category I code change proposal for the device. The proposal was referred to the AANS/CNS Coding and Reimbursement Committee and Spine Section leadership and the company was given some suggestions for changing the proposal. The sponsors plan to resubmit the proposal for the July 10, 2014 deadline for the October 2014 CPT panel meeting and have asked for further assistance from AANS and CNS.

Neurostimulator Programing Editorial Change

During a presentation at the January 2014 RUC meeting by the American Society of Anesthesiologists (ASA), American Urological Association (AUA), American Congress of Obstetricians and Gynecologists (ACOG), and several other societies for sacral nerve stimulation primarily for incontinence, the societies proposed to change neurostimulator programing codes to time based codes. The AANS and CNS objected, maintaining that spinal cord stimulation programming was significantly more intense than nerve root stimulation and purely time based codes did not account for the difference. The AANS and CNS joined 7 other societies in sending a letter to the CPT Editorial Panel to ask for an editorial change to the codes for the 2015 CPT cycle and suggesting workgroup be formed to create a new set of neurostimulator programing codes that would account for intensity differences.

CPT Editorial Panel Literature Requirements Workgroup

AANS and CNS CPT Advisors Patrick Jacobs, MD and Joseph Cheng, MD, are participating in a new CPT Literature Requirement Workgroup. The CPT panel has established a workgroup to consider supporting literature requirements for Category I and Category III CPT codes. The workgroup will build on a revision to the policy established by a previous workgroup in 2010 and 2011 and comments received at a February 2013 CPT Summit Fly-In meeting for physician specialty society and industry stakeholders. Drs. Jacob and Cheng have been active in pushing for clarity in literature standards and in

urging CPT to establish consequences for stakeholders giving misleading or disingenuous information to the panel or violating panel lobbying procedures.

Nomination of R. Patrick Jacob, MD for CPT Panel

On February 17, 2014, AMA announced the opening of two CPT Editorial Panel seat beginning in May 2014. The AANS and CNS will nominate R. Patrick Jacob, MD for a seat on the panel. Dr. Jacob has served as a CPT advisor for over 12 years and has been member of the CPT Assistant Editorial Board since its creation in 2007. All application documents are due to the AMA by March 7, 2014.

RUC Issues

January 2014 RUC Meeting

The RUC met January 26 through February 1, 2014. Greg Przybylski, MD, RUC member, Edward Vates, MD, RUC alternate, Alexander Mason, MD and John Ratliff, MD, RUC members, and AANS/CNS Washington Office Staff attended. Below are items of interest to neurosurgery:

- Post Time Workgroup. In October 2013, the RUC established a Post Time Workgroup chaired by Greg Przybylski, MD, to develop standardized "packages" for immediate post-operative time for global surgical procedures. The effort was similar to a previous RUC initiative that established packages for pre-time physician work. The workgroup presented their recommendations to the RUC in October 2013. On December 2, 2013, the American College of Surgeons raised concerns about the packages and wrote a letter from 26 specialty societies, including AANS and CNS, asking that the issue be revisited. At the January 2014 RUC, the Post Time Workgroup held an open meeting to review the issues. As a result, the RUC will keep post-time packages but have revised the packages to allow for greater flexibility. In addition, the RUC affirmed that the packages are minimum times and specialties may provide a rationale for requesting additional time.
- RAW Pre-service Time Screen. The RUC identified codes reviewed prior to April 2008 with pretime greater than pre-time package 4 Facility Difficult Patient/Difficult Procedure (63 minutes) for
 services with 2012 Medicare Utilization over 10,000. The screen identified 21 services with more preservice time than the longest standardized pre-service package. The RUC reviewed these services
 and requests action plans from the specialty societies on how to address the pre-service time for
 these services. The Relativity Assessment Workgroup (RAW) will review action plans in April 2014.
 Codes for Neurosurgery on the list include: 63030, 63042 and 22612 and the AANS/CNS Coding
 and Reimbursement Committee leaders are developing action plans for these codes.
- CMS Request to Review CPT codes 63045 through 63048. As stated above, in the 2014 MPFS
 Final Rule, CMS requested that CPT codes 63045 and 63046 be reviewed along with 63047 and
 63048, as one family of codes. RUC staff has advised interested stakeholders to write to the RUC
 Research Subcommittee to suggest that the codes be reviewed without a survey and the AANS/CNS
 Coding and Reimbursement Committee is drafting the letter.

April 2014 RUC Meeting

The next RUC meeting will take place from April 23 to April 26, 2014. The AANS and CNS Coding and Reimbursement Committee is conducting four sets of surveys for codes passed at the February 2014 CPT meeting; specifically new vertebroplasty/kyphoplasty codes with image guidance; additional level cervical disc arthroplasty codes; minimally invasive sacroiliac joint fusion codes; and revised transcatheter placement of carotid stent codes. Survey data is due to the RUC by April 1, 2014.

Coverage Issues

The AANS/CNS Washington Office continues to receive requests for comment on coverage policy from Medicare, private payors, state neurosurgical societies, and individual neurosurgeons. The AANS/CNS Rapid Response Team (RRT), led by Joseph Cheng, MD, is working to improve processes to help

neurosurgeons address these issues as they arise in their states and regions and has developed an outreach letter to send to payors to inform them of the clinical expertise available to them through organized neurosurgery. The AANS/CNS Section on Cerebrovascular Surgery has created a Rapid Response Team for CV issues headed by Henry Woo, MD. Some recent activity is highlighted below:

Aetna Thrombolysis Policy

On December 9, 2013, Aetna posted the results of an October 2013 review of its non-coverage policy for thrombolysis in which they decided not to change the policy. Aetna continues to consider the procedure investigational and contends that the effectiveness has not been established. The next review for the policy is scheduled for October 2014. The current Aetna non-coverage policy is on the web at: http://bit.ly/155Syne.

Aetna Revises Non-coverage for Spine Cages

In response to comments from the neurosurgery-led Council of Surgical Spine Societies (COSSS) and other organizations, on December 24, 2013, Aetna issued an updated policy for spine surgery, stating spine cages for cervical fusion are considered medically necessary for members with any the following indications for use: 1) multilevel corpectomy for tumors, compressed fractures, retropulsed bone fragments, or central canal stenosis with myelopathy; 2) multilevel pseudarthrosis in persons with prior fusion; or 3) Jehova's Witness with poor bone stock. In addition, Aetna will cover sacroiliac joint fusion for tumors involving the sacrum and for sacroiliac joint infection.

The policy revises a previous proposal not to coverage spinal fusion with cages based on an August 31, 2013 review. COSSS sent a letter on December 11, 2014 requesting a change in the proposed policy not to cover cages and pointed out that literature cited by Aetna designating the use of cervical cages as experimental and investigational, was outdated, incomplete, and did not reflect standard best practice. A copy of the COSSS letter is available on the web at: http://bit.ly/N4uhva. A copy of the updated Aetna policy is available at: http://bit.ly/116UXZ1.

Washington State Health Care Authority

On March 21, 2014, the Washington State Health Care Authority HTA Program Health Technology Clinical Committee will hold a public meeting to consider coverage for Facet Neurotomy and Non-pharmacological Treatments for Treatment-resistant Depression which includes electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), deep brain stimulation (DBS), transcranial direct current stimulation (tDCS), and vagus nerve stimulation (VNS). The AANS and CNS did not plan to comment on Neurotomy and leaders of the AANS/CNS Stereotactic and Functional Section and the Washington State Association of Neurological Surgeons are developing a statement on the depression treatment issue to be presented for the March 21, 2014 meeting. A final technology assessment report will be released on or before February 28 and more information is available at: http://www.hca.wa.gov/hta/Pages/trd.aspx

Wellpoint

Wellpoint continues to seek the opinion of the AANS and CNS on coverage issues, including the following topics:

• **BMP**. On August 30, 2013, Wellpoint contacted the AANS and CNS requesting input on the use of Recombinant Human Bone Morphogenetic Protein (rhBMP). In particular, they would like feedback regarding the use of rhBMP-2 for spinal indications in light of the recently released meta-analyses of patient-level clinical trial data from Medtronic, Inc. (Fu, 2013; Simmonds, 2013). Dr. Cheng and the Spine Section RRT are working on a response.

- Lumbar Spinal Fusion Policy. On February 18, 2014, the AANS and CNS provided Wellpoint with comments on Lumbar Spinal Fusion Policy.
- Lumbar Laminectomy, Hemi-Laminectomy and Laminotomy. On January 18, 2014, the AANS and CNS provided comments on lumbar laminectomy, hemi-laminectomy and laminotomy procedures. Dr. Cheng and the Spine Section RRC are working on a response.
- Navigated Transcranial Magnetic Stimulation (nTMS). On September 16, 2013, Wellpoint
 contacted the AANS and CNS requesting input on navigated transcranial magnetic stimulator (nTMS)
 procedures. Wellpoint proposes policy indicating navigated transcranial magnetic stimulation (nTMS)
 as investigational for all purposes. Manish Aghi, MD, is leading the response for the Tumor Section.
- **DBS**. On January 17, 2014, AANS and CNS submitted comment to Wellpoint on Deep Brain Stimulation (DBS) policy.
- Intraoperative Neurophysiologic Monitoring. On January 22, 2014, Wellpoint asked for input on Intraoperative Neurophysiologic Monitoring. The request has been referred to the Spine Section and the Tumor Section.

CMS Issues Final Non-Coverage Decision for PILD

On Jan. 9, 2014, CMS issued a final decision not to cover percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS). CMS has determined that PILD is not reasonable and necessary and Medicare will only pay for it when provided in a clinical study under certain conditions through its Medicare Coverage with Evidence Development (CED) policy. On Nov. 11, 2013, the AANS, CNS and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves sent a letter opposing coverage, stating, "overall our field of neurosurgery has not embraced the use of this procedure due to concerns regarding its effectiveness as compared to our current surgical options." The letter further notes that the "present literature...is of low quality and demonstrates that this technique is not indicated in patients with a significant element of bony stenosis, lateral recess stenosis, or foraminal stenosis." A copy of the final decision is available on the web at: http://go.cms.gov/1j7AALW The AANS-CNS Letter is available at: http://bit.ly/1dsKy6P.

Other Medicare Issues

New Technology Add-on Payment Town Hall Meeting

On February 12, 2014, CMS held a Town Hall Meeting to discuss fiscal year (FY) 2015 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Manufacturers presented comments, recommendations, and data regarding their product's ability to meet the substantial clinical improvement criterion for the add-on payment. Of interest to neurosurgery, NeuroPace presented a request for the RNS System implantable medical for treating individuals with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The company had applied last year but did not receive FDA approval in time to be eligible. CMS will review the comments presented and include their suggestions in the 2015 Medicare Hospital Inpatient Prospective Payment Proposed Rule to be released at the end of April. As was the case last year, the AANS and CNS will likely support the contention that the RNS system represents a significant clinical improvement for patients who are refractory to medical and surgical treatment. More information is available at: http://go.cms.gov/M9TDHd.

Medicare Appeals Backlog

In December 2013, HHS Office of Medicare Hearings and Appeals (OMHA) made an announcement that it was temporarily suspending assignment of Level III Medicare appeals to administrative law judges (ALJs). The "rationale" provided was that the ALJs are overwhelmed with their current dockets and have

no additional capacity, and therefore, OMHA is holding the claims until the dockets are clear to handle the cases (and associated paperwork). There is a current backlog of over 400,000 appeals. AANS and CNS joined numerous state and local medical societies in sending a letter organized by the AMA protesting the growing Medicare appeals backlog and urging the agency to develop a comprehensive panel for eliminating the backlog.

CMS Changes Policy for Releasing Physician Specific Data

On Jan. 17, 2014, the Centers for Medicare and Medicaid Services (CMS) issued a notice in the *Federal Register* setting forth a new policy regarding requests made under the Freedom of Information Act (FOIA) for information on amounts paid to individual physicians under the Medicare program. The change comes following a May 2013 ruling by U.S. District Judge Marcia Morales Howard in Jacksonville, Fla., dissolving a 1979 federal injunction that had barred the release of Medicare payment data identifying specific physicians on the grounds that physicians' privacy concerns no longer outweighed the public interest in releasing the data. As a result, CMS proposes to make a case-by-case determination as to whether an exemption from FOIA applies to a given request. The new rule takes effect on March 18, 2014. The AANS and CNS have not supported the public release of this information in its raw form. Without context, claims data will do nothing to help answer questions related to quality, cost, and fraud and abuse. A copy of the Federal Register notice is available at: http://l.usa.gov/leXPuzf

Nominations for the Medicare Payment Advisory Commission

The General Accountability Office (GAO) announced on January 21, 2014 openings on the Medical Payment Advisory Commission (MedPAC). MedPAC an independent agency established in 1997 to advise Congress on issues affecting the Medicare program. AANS and CNS have nominated Gregory J. Przybylski, MD. A copy of the Federal Register notice is available at: http://l.usa.gov/1gqQJw3.

Two Midnight Rule Delay

The AANS and CNS continue to work with the AMA and other specialties to urge CMS to scrap the "two midnights" rule that requires admitting physicians to attest that a patient hospital stay is expected to span two midnights in order to classify the stay as inpatient. CMS announced January 30, 2014, that the agency would delay full implementation of the two-midnight policy until at least September 30, 2014. The policy indicates that if a physician expects a Medicare beneficiary's treatment to cross two midnights and admits the beneficiary based on that belief, CMS generally will then consider the inpatient admission to be appropriate, with proper documentation in the medical record. This is the third time CMS has delayed full implementation of the policy, which is part of the 2014 Inpatient Prospective Payment System rule.

Meanwhile, Medicare administrative contractors (MACs) are conducting "probe and educate" audits of inpatient admissions spanning less than two midnights. MACs are allowed to review samples of 10 to 25 claims per hospital for compliance with the policy. Sampled claims that fail to meet the two-midnight requirements will be denied but may be billed again under Medicare Part B as if the patient were an outpatient. Therefore, although CMS will not fully enforce the two-midnight policy until at least September 30, CMS will extend the "probe and educate" period to review small samples of claims with dates of admission between October 1, 2013, and September 30, 2014, for compliance.

Hospital Systems Initiate Challenge to CMS' "Two-Midnights" Policy

The American Hospital Association (AHA) announced January 22, 2014, that four hospital systems have filed appeals asking the Provider Reimbursement Review Board (PRRB) to grant expedited judicial review for the hospitals' challenge to the new payment policies for Medicare Part A inpatient claims. According to AHA, the hospital systems contend the rule's 0.2% payment cut for fiscal year 2014 inpatient prospective payment system hospitals is unlawful. "The Providers seek judicial review of pure questions of law regarding the substantive and procedural validity of the 0.2% reduction," AHA said.

"Because the [PRRB] lacks the power to grant the Providers' requested relief, it should grant expedited judicial review." The hospitals contend that the reduced inpatient payment they receive under the final rule is arbitrary and capricious because CMS relied on indefensible assumptions and offered no reasoned explanation for them. They also argue that the payment cut fails to comply with Administrative Procedure Act's requirements for proper notice and comment and was not codified in regulation as the law requires, AHA said.

AMA Amicus Brief

The AANS and CNS have joined the AMA in submitting an amicus brief in the appeal of *Bagnall v. Sebelius*. This case concerns Medicare beneficiaries who were hospitalized, but did not meet the three-day inpatient stay requirement for subsequent Skilled Nursing Facility (SNF) coverage because they were classified as under observation. Increasingly, hospital patients are finding that they have been considered "Observation Outpatients," although they have been cared for in the hospital for many days and nights. On November 3, 2011, the Center for Medicare Advocacy, and co-counsel National Senior Citizens Law Center, filed a nationwide class action lawsuit to challenge this illegal policy and practice. *Bagnall v. Sebelius* (No. 3:11-cv-01703, D. Conn) states that the use of observation status violates the Medicare Act, the Freedom of Information Act, the Administrative Procedure Act, and the Due Process Clause of the Fifth Amendment to the Constitution.

HHS OIG Work Plan

In January 2014, the HHS Office of Inspector General (OIG) issued its "Work Plan" for Fiscal Year 2014 that provides brief descriptions of activities that OIG plans to initiate or continue with respect to HHS programs and operations in fiscal year 2014. The Work Plan describes the primary objective, the year in which the office expects one or more reports to be issued as a result of the review, and indicates whether the work was in progress at the start of the fiscal year or will be a new start during the year. Among the new items list in the work plan is a review to be completed in 2015 to determine the impact of recently developed inpatient admission criteria on hospital billing, Medicare payments, and beneficiary payments. This review will also determine how billing varied among hospitals in FY 2014. Previous OIG work found overpayments for short inpatient stays, inconsistent billing practices among hospitals, and financial incentives for billing Medicare inappropriately. The OIG states that the new criteria represent a substantial change in the way hospitals bill for inpatient and outpatient stays, an interesting statement given that some CMS officials have claimed that the "two midnights" requirement merely clarifies current policy. A copy of the OIG FY2014 Work Plan is available at: http://go.usa.gov/Bj4z.

ICD-10-CM

The AANS and CNS continue to support repeal of ICD-10 but are also working to educate and prepare neurosurgeons for compliance should the October1, 2014 ICD-10 conversion take place as scheduled. It is imperative that neurosurgeons prepare for the change, as significant disruption to claims processing is almost certain. The agency continues to state that there will be no transition period. Some key recent developments are below:

• AMA Letter to Kathleen Sebelius. Citing dramatically high costs and interference with quality improvements, the AMA on February 12, 2014, continued efforts to stop ICD-10 implementation in a letter urging HHS Secretary Kathleen Sebelius to reconsider the mandated transition to the new code set, currently scheduled for October 1, 2014. In the letter, the AMA outlines the considerable drawbacks of requiring physicians to comply with the new code set. The letter states, "Physicians are being asked to assume this burdensome requirement at the same time they are being required to adopt new technology, re-engineer workflow and reform the way they deliver care; all of which are interfering with their ability to care for patients and make investments to improve quality." According to an AMA study released on February 12, 2014, the cost to meet the ICD-10 requirements is dramatically higher than previously estimated. A small physician practice, for instance, can expect to spend anywhere from \$56,639 to \$226,105 to prepare for the new code set. More information on the report and AMA's letter is available at: http://bit.ly/1gFI5W9.

- Congressional Letter to CMS Regarding ICD-10. Four Republican senators have expressed concerns to CMS Administrator Marilyn Tavenner that her agency is not testing new Medicare and Medicaid billing codes extensively enough. In a letter sent on February 18, 2014, they asked that Tavenner explain the testing plan and warned that inadequate testing could allow for "system-wide errors and delay" similar to the problems that disabled HealthCare.gov early on. "Given the size and scope of the potential transition to ICD-10, the brevity and limited scope of this test is worrisome," they wrote. "This change will impact millions of physicians and patients, and hundreds of billions of dollars in payments that flow through Medicare and Medicaid. Other major federal IT projects such as the implementation of Healthcare.gov have demonstrated the importance of thorough pretesting every aspect of new systems, both the front-end and back-end components." Testing is planned for the week of March 3, 2014. The letter was signed by Sens. Tom Coburn, MD (R-OK), John Barrasso, MD (R-WY), John Boozman, OD (R-AZ), and Rand Paul, MD, (R-KY) who have introduced a bill that would prohibit HHS from moving forward with the ICD-10 transition. A copy of the letter is available at: http://1.usa.gov/1gTytsf.
- CMS Issues ICD-10 Education Video. CMS has released a new MLN Connects™ video on ICD-10 Coding Basics. Sue Bowman from the American Health Information Management Association (AHIMA) provides a general introduction to ICD-10 coding, including:
 - Similarities to and differences from ICD-9
 - ICD-10 code structure
 - Coding process and examples
 - 7th Character
 - Placeholder "x"
 - Excludes notes
 - Unspecified codes
 - External cause codes

The video is available at: http://bit.ly/1e83JiO



Agency for Healthcare Research and Quality

Quality Improvement Update



Administrative Issues

Quality Improvement Workgroup Members

Jack Knightly, MD, Chair John Ratliff, MD, Vice-Chair

Members:

David Adelson, MD Peter Angevine, MD

Tony Asher, MD Hunt Batjer, MD Maya Babu, MD

Gary Bloomgarden, MD Kevin Cockroft, MD Aaron Cohen-Gadol, MD

Jeffrey Cozzens, MD Fernando Diaz, MD Zoher Ghogawala, MD Robert Harbaugh, MD

Odette Harris, MD Bob Heary, MD Michael Kaiser, MD

Alexander A. Khalessi, MD, MS

John A. Kusske, MD

Staff Liaison:

Rachel Groman, Hart Health Strategies

Zachary Litvack, MD

Marlon Mathews, MD (CSNS Resident Fellow)

Matt McGirt, MD Paul Penar, MD Ralph Reeder, MD Dan Resnick, MD

Richard B. "Ben" Rodgers, MD

Gail Rosseau, MD Clemens Schirmer, MD

Karl Sillay, MD Mike Steinmetz, MD Krystal Tomei, MD Kevin Walter, MD Philip Weinstein, MD Richard Wohns, MD Christopher Zacko, MD Edie Zusman, MD

Ex-Officio:

John Wilson, MD (WC, Chair)

Medicare Physician Quality Improvement System (PQRS)

Bonus/Penalties 2014-16

2014 marks the last year that physicians are eligible for an incentive payment under the PQRS. Physicians who successfully report on measures in 2014 are eligible to receive a 0.5% bonus. Those who fail to satisfy reporting requirements in 2014 are subject to a 2.0% penalty in 2016 and going forward. 2014 is also the last year that a PQRS-MOC bonus of 0.5% is authorized under law.

Incentive payments made through the PQRS are subject to the mandatory reductions in federal budgetary resources known as sequestration, required by the Budget Control Act of 2011. Therefore, PQRS incentive payments made to physicians and group practices will be reduced by 2%. For example, if a physician has \$100,000 in allowed charges and is eligible to receive a \$500 incentive (0.5% of \$100,000), the \$500 would be reduced by 2% (\$500 x 0.02= \$10), so the total incentive

payment with sequestration would be \$490. This 2% reduction is being applied to any PQRS incentive payment for a reporting period that ends on or after April 1, 2013.

The most recent PQRS participation data available from CMS remains the 2011 PQRS Experience Report, released in October 2013. CMS claims there were 4,476 eligible neurosurgeons who could have participated in PQRS in 2011. Of the eligible neurosurgeons in 2011, 21.4% participated in PQRS. In 2011, 17% of neurosurgeons received a PQRS Incentive. The median incentive amount was \$1,601.85 and the maximum amount received by an individual neurosurgeon was \$9,461.25. Approximately, 82% of physicians who participated in 2011 PQRS via a registry received an incentive.

New Reporting Requirements and Applicable Measures

CMS dramatically increased the reporting requirements for 2014, but continues to offer less burdensome reporting requirements for those seeking to do the bare minimum to avoid the penalty (but not qualify for the incentive).

For the 2014 incentive, CMS increased the reporting requirement to at least 9 measures across at least 3 National Quality Strategy (NQS) domains for 50% of applicable Medicare Part B FFS patients (versus 3 measures in 2013). The reporting requirement for measures groups remains the same: 1 measures group for 20 or more unique patients, a majority of whom must be Medicare Part B. In terms of avoiding the 2016 penalty, physicians must report in 2014 on at least 3 measures for 50% of applicable Medicare Part B patients or 1 measures group for 20 or more unique patients, a majority of whom must be Medicare Part B. CMS no longer offers the "administrative claims-based" reporting method for avoiding the penalty, which required no action on the part of physicians and was offered solely to help physicians transition during the first year of penalties.

For claims-based and traditional PQRS registry reporting, CMS continues to maintain PQRS measures applicable to neurosurgical practices, including perioperative measures, measures related to stroke and cancer care, measure related to epilepsy, and measure groups related to low back pain and ischemic vascular disease.

Registry Participation

Starting in 2014, and as required under the American Taxpayer Relief Act (ATRA), CMS will begin to recognize qualified clinical data registries (QCDR) as a new PQRS reporting mechanism. A QCDR will collect and submit data on <u>its own quality measures</u> to CMS on behalf of its participants versus traditional PQRS registries, which can only submit data on PQRS measures. To be considered a QCDR for purposes of the PQRS, an entity must self-nominate by <u>January 31, 2014</u> and successfully complete a qualification process that includes providing CMS with detailed specifications and evidentiary rationale for measures collected by the registry by <u>March 31, 2014</u>; submitting a validation strategy; demonstrating a plan to risk adjust measure data; and providing feedback reports to participants at least 4 times a year.

To qualify for the 2014 PQRS incentive using the QCDR reporting option, physicians must report at least 9 measures covering at least 3 NQS domains for at least 50% of all applicable patients (both Medicare and private payer). At least one measure must evaluate outcomes. For 2014, the QCDR option cannot be used for reporting measures groups or reporting measures under the Group Practice Reporting Option (GPRO), although CMS is hoping to change that policy in the future.

While neurosurgery and other specialties long advocated for more flexible reporting options, such as the QCDR, there is concern that the QCDR criteria is overly burdensome and the timeline challenging, which may limit the number of entities able to take advantage of this mechanism. After careful consideration, the N²QOD concluded it is not in a position to apply for 2014, but will instead continue

to work to seek clarification and potentially ease some of the current requirements in preparation for applying in the future. In the interim, the N²QOD will reapply to serve as a traditional PQRS registry, which will allow it to submit PQRS measures data, such as the perioperative measures group, to CMS on behalf of its participants for 2014. Other groups that plan to apply include: American Society of Clinical Oncology (ASCO), Society of Thoracic Surgeons (STS), American College of Surgeons (only their bariatric registry), American Society of Anesthesiologists (ASA), American Academy of Ophthalmology (AAO) and the gastroenterologists (ACG and AGA). STS and ACS are working with CMS to see if they can get an extension of data submission since their data collection schedule does not align with the February 2015 data submission deadline.

As required under the ATRA, the Government Accountability Office (GAO) released a <u>study</u> in late December 2013, which found that the new rules surrounding QCDRs might be too vague to provide meaningful data. While the intent of the QCDR was to increase opportunities for specialists to participate in the PQRS, the GAO concluded agency that the flexible approach may "provide minimal impetus to (clinical data registries) to take full advantage of their specific opportunities to promote the quality and efficiency of care." The GAO also cited CMS for not providing details on how it would interpret or enforce the program's requirements. Other recommendations for HHS included:

- Focusing requirements for QCDRs on improving quality and efficiency;
- Requiring registries to demonstrate quality and efficiency improvements;
- Drawing on expert judgment to monitor qualified registries;
- Reducing barriers to the development of qualified registries; and
- Addressing privacy concerns so that clinical registry data can be linked to payers' administrative data to examine cost/efficiency; and
- Through its meaningful-use program, influencing the extent to which EHR systems are
 designed, standardized, and implemented to collect data needed by registries to assess
 physician performance. Unless clinical data registries can overcome variations in content,
 storage and other specifications, they will not be able to take full advantage of an EHR's ability
 to collect and transmit data.

In preparing this report, the GAO reviewed studies assessing the impact of registries, interviewed officials from organizations operating existing registries, including the AANS, and interviewed officials from CMS and HHS' Office of the National Coordinator for Health Information Technology (ONC).

2013 PQRS Interim Feedback Now Available

In late December 2013, CMS made available to physicians who reported at least one PQRS quality measure in 2013 via claims feedback regarding their first and second quarter data submissions (January 2013 – June 2013). This feedback is accessible via the online PQRS Interim Feedback Dashboard. The data can be viewed as a Taxpayer Identification Number (TIN) summary or in individual National Provider Identifier (NPI) detail and allows practices to monitor the status of their claims-based measures and measures group reporting to see where they are in meeting the PQRS reporting requirements. The Dashboard is available through the Physician and Other Health Care Professionals Quality Reporting Portal, with Individual Authorized Access to the CMS Computer System (IACS) sign-in.

The Dashboard allows neurosurgeons to access interim PQRS data on a quarterly basis. Prior Dashboard data are available for up to two years. The interim feedback reports do not provide the final data analysis for full-year reporting, nor do they indicate PQRS incentive eligibility. It also should be noted that data submitted via a qualified registry, electronic health record (EHR), or through the GPRO in 2013, is not available through the dashboard, but instead through the annual PQRS feedback report, which will be issued in the fall of 2014.

Public Reporting: Physician Compare

The ACA required CMS to establish a Physician Compare website by January 1, 2011. This website is intended to provide patients with basic data about physicians, including information about their participation status in the PQRS, e-prescribing and EHR incentive programs. Under the ACA, CMS is required to implement a plan by 2013 for making physician *performance* data (including quality, efficiency, and patient experience data) available to the public.

In 2013, CMS started to publicly post performance data for a defined set of measures that apply to the PQRS Group Practice Reporting Option (GPRO) and ACOs participating in the Shared Savings Program. In the first year, 66 group practices and 141 ACOs now have quality data publicly reported on Physician Compare. In 2014, it will expand public reporting to include additional performance data on GPRO and ACO participants, including patient experience data (in fact, in late February, CMS announced the release of additional measure data, mostly primary care-focused). The provider performance ratings, which are only now reported at the group practice or ACO level, are displayed using stars, with actual scores listed next to the stars. CMS contractors have been gathering feedback from clinicians and consumers on the use of a star system. Despite concerns raised about arbitrary cutoffs and the lack of statistically significant differences between each tier, CMS concluded the star system was easiest to comprehend and aligned with other federal reporting programs.

By 2015, CMS will publicly report on select 2014 PQRS individual measures collected through an EHR, registry, or claims. Physicians will have 30 days to review data before it is posted. Neurosurgery remains opposed to this rapid expansion and believes that until CMS can work out technical kinks with the website and prove that the reported data is an accurate reflection of physician quality and is truly meaningful and valuable to the public, physician performance data should not be released to the public.

CMS recently revamped the *Physician Compare* website to include a new intelligent search function, and other changes meant to improve the usability and accuracy of the site. The AANS and CNS has been working with CMS contractors to further improve ongoing issues with the accuracy of the site and physician profiles. In January 2014, QIW reviewers helped provide input on specific keyword listings for "neurosurgery" to improve the accuracy and reliability of the search function.

Availability of Medicare Data for Performance Measurement

The ACA also authorizes CMS to make Medicare data available to "qualified entities" for the evaluation of the performance of providers by January 1, 2012. In earlier rulemaking, CMS did not make many of neurosurgery's requested changes. However, it did allow for using claims data in addition to registry data and for partnering with additional entities to meet the requirements.

The "SGR Repeal and Medicare Payment Modernization Act" (S. 2000/H.R. 4015) would expand upon this provision by requiring CMS to not only publish on its Physician Compare website data on quality and resource use, but also utilization and payment data. It would also require CMS to make claims data available to QCDRs, but registries would have to pay for the costs associated with providing this data.

On a separate but related note, in mid January 2014, CMS released a rule titled, "Modified Policy on Freedom of Information Act Disclosure of Amounts Paid to Individual Physicians Under the Medicare Program," which institutes a new policy for releasing data on how much Medicare reimburses individual doctors. The agency said it will make individual determinations under the Freedom of Information Act (FOIA), weighing the privacy interest of the individual against the public interest. This revised policy takes effect March 18, 2014. While the policy aims to avoid a wholesale, cookie-cutter

approach to releasing data, it is sparse on details and has been criticized as ambiguous and failing to make clear the standards CMS will use to evaluate data requests.

The previous policy, which had been based on court orders, was that the public interest was insufficient under FOIA to allow the disclosure of amounts that Medicare pays to individual physicians. As a result, CMS was legally barred from disclosing identifiable annual Medicare reimbursement payments of individual physicians or disclosure of payments in a manner that could identify individual physicians. However, in May 2013, a federal court vacated a 33-year-old injunction that had prohibited the government from releasing any Medicare physician reimbursement data that would identify specific physicians, prompting the need for a revised federal policy.

Leading up to this new policy, the AANS and CNS joined the AMA and nearly 95 state medical and national specialty societies in writing <u>a letter</u> to CMS in September 2013, cautioning against the inappropriate release of Medicare physician claims data. In the letter, we noted that if not approached thoughtfully, the "public release of Medicare claims data can have unintentional adverse consequences for patients. Patient de-selection can occur for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or economic and cultural characteristics that make them less adherent to established protocols." While Medicare data can help promote meaningful, accurate, and innovative ways to improve the overall quality of patient care, we believe that it is essential that CMS establish appropriate ways to utilize this data.

The January policy change follows other CMS efforts to make more data available to the public. Since 2010, the agency has released an unprecedented amount of aggregated data in machine-readable form, with much of it available at www.healthdata.gov. These data range from previously unpublished statistics on Medicare spending, utilization, and quality at the state, hospital referral region, and county level, to detailed information on the quality performance of hospitals, nursing homes, and other providers. In May 2013, CMS released www.healthdata.gov. In June 2013, CMS released www.healthdata.gov.

Physician Resource Use Reports and Value-Based Modifier

Under the ACA, Congress directed CMS to refine and expand its current efforts to provide confidential feedback reports comparing the cost and quality of care across physicians, known as the Physician Resource Use Feedback Program. The budget neutral Value-Based Payment Modifier (VBM) applies to payments of group of physicians of 100 or more starting in 2015 (based on 2013 reporting) and all physicians by 2017 (likely based on 2015 reporting).

In the 2014 Medicare Physician Fee Schedule Final Rule, CMS finalized rules for the 2016 VBM. Despite widespread objections, CMS dramatically increased the number of physicians who will be affected by the VBM in 2016 (based on 2014 reporting) by expanding it to groups of 10 or more EPs. The amount of the penalty has also been increased. Groups that do not satisfy PQRS GPRO reporting requirements will now be subject to a 2.0% cut under the VBM, which will be applied on top of the 2.0% PQRS cut for 2016. Groups that satisfy PQRS reporting requirements will avoid these automatic cuts, but will be subject to a "quality-tiering" approach under which CMS will calculate a payment adjustment based on the group's quality and cost performance. Since this is the first year that quality-tiering is mandatory, smaller groups (with 10-99 EPs) will be held harmless from downward adjustments and can only receive a positive or neutral adjustment. Groups of 100 or more, which will be in their second year of the program, may receive a downward adjustment (up to -2.0%) based on quality/cost performance. CMS also approved a new "50% rule" whereby groups that do not register to participate in the GPRO can still avoid VBM penalties if at least 50% of their EPs satisfy PQRS requirements as individuals.

For each group practice, CMS will calculate a quality and cost composite score based on the following measures:

1) Quality composite

- PQRS measures reported by the group practice
- 3 outcomes measures automatically calculated by CMS: 1) Acute Prevention Quality Indicators composite (bacterial pneumonia, UTI, dehydration); 2) Chronic Prevention Quality Indicators composite (COPD, HF, DM); 3) All-cause Readmissions

2) Cost composite

- Total per Capita Costs for All Beneficiaries: evaluates all Part A and Part B costs associated with a beneficiary over a year
- Total per Capita Costs for Select Conditions (HF, CAD, COPD, DM)
- <u>NEW FOR 2016</u>: Medicare Spending per Beneficiary: evaluates Part A and B costs during the 3 days before and 30 days after an inpatient hospitalization

At the behest of the AANS/CNS and other groups, CMS did finalize a "specialty benchmarking method" for 2016, which should better account for the specialty composition of the group in order to ensure more fair peer group comparisons.

Setting the value-based bonuses and penalties

The tiered modifier structure for 2016 is listed below. The upward payment adjustment factor ("x") will be determined after the performance period has ended and, due to the budget neutral nature of this program, is based on the aggregate amount of downward payment adjustments:

CY 2016				
Cost/Quality	Cost/Quality Low Quality Average Quality High (High Quality	
Low Cost	+0.0%	+1.0x*	+2.0x*	
Average Cost	-1.0%	+0.0%	+1.0x*	
High Cost	-2.0%	-1.0%	+0.0%	

^{*} Groups of physicians eligible for an additional +1.0x if reporting PQRS quality measures and average beneficiary risk score is in the top 25% of all beneficiary risk scores.

The AANS and CNS have been highly critical of these VBM policies, including the speed of implementation; the relevancy and accuracy of the measures (particularly the cost measures), attribution methods, risk adjustments and other statistical methodologies; and concerns related to per capita versus episode-based assessments of resource use. These concerns remain, particularly after seeing the latest round of Quality and Resource Use Reports (QRURs), based on 2012 data, made available to all groups of physicians with 25+ EPs. CMS will distribute QRURs to all groups and solo practitioners in the late summer of 2014. The reports, which are supposed to provide a confidential preview of the methodologies that will be applied under the VBM, are confusing and provide little value in regards to quality and cost information. In an effort to address these issues, CMS continues to hold focus sessions with specialty staff and physicians to learn how to improve the QRURs and to educate physicians on the reports.

In response to concerns that the cost measures used to calculate the VBM are too broad and not reflective of care within the control of certain physicians, CMS has noted that it is working to develop more specific episode-based cost measures, but until this work is completed and the measures well tested, it must rely on per capita and other total spending measures. Fortunately, Tony Asher has

been selected to serve on the CMS Episodes of Care project, which is working to develop some of these measures. He has been appointed to the cerebrovascular disease Clinical Working Group, which includes stroke. The AMA PCPI is overseeing this project.

Bundled Payments

The Middle Class Tax Relief and Job Creations Act of 2012 mandates that HHS conduct a study that examines options for bundled or episode-based payments, to cover physicians' services currently paid under the physician fee schedule for one or more prevalent chronic conditions (such as cancer, diabetes, and congestive heart failure) or episodes of care for one or more major procedures (such as medical device implantation). In conducting the study, the Secretary shall consult with medical professional societies and other relevant stakeholders. Ultimately the "vast majority" of services and patients will be included in episodes and most likely will cover about 80% of Medicare costs. The term "bundling" can refer to a variety of ways by which payment units are broadened to include more services.

CMS has chosen the AMA/Brandeis software to test bundles. For chronic conditions, the episode would be a calendar year. For procedures, the episode would begin with a principal procedure being coded and the episode would include 3 days prior and 90 post-discharge. For acute medical events without a procedure (such as a heart attack without an associated procedure or pneumonia) the episode would be 30 days from the event. For post-acute care in a facility, the episode would be the length of stay in the facility. For system-related failure the episode would be the length of stay—admission through discharge. System failure care is not included in other episodes.

Bundled Payments for Care Improvement (BPCI) Initiative

On Jan. 31, 2013, the Centers for Medicare & Medicaid Services (CMS) through CMMI, announced the health care organizations selected to participate in the Bundled Payments for Care Improvement initiative (BPCI). This initiative is separate from the episode grouper project CMS is working on that will eventually influence the value based payment modifier. The BPCI is testing new models at a smaller scale that may potentially inform the physician value modifier and other payment models (e.g., expanding bundling, ACOs).

Under the BPCI, organizations will enter into payment arrangements that include financial and performance accountability for episodes of care. The initiative includes four bundled payment models covering various elements of hospital, physician and post-acute services and payments targeting 48 diseases and conditions. Spine and stroke are part of the 48 diseases and conditions. Based on conversations with participating sites, it does not appear that risk-adjustment is involved (or sufficient) and CMS will determine rates based on historic Medicare data so there is no room for negotiation. There is concern the models will lead to cherry picking and physicians will only enroll healthy patients and send sick patients to tertiary care or academic facilities. For more information, click here.

Legislation

In late December 2013, Reps. Diane Black (R-TN) and Richard Neal (D-MA) proposed legislation that would expand bundled payments within the Medicare program. The Comprehensive Care Payment Innovation Act would establish a voluntary bundled payment model, building off of the BPCI. The new program would go into effect January 1, 2015. Under the proposed legislation, hospitals and other providers would receive a lump payment from Medicare for all services furnished from three days prior to an inpatient admission to 90 days after discharge. Covered services include acute inpatient care, physician services, outpatient hospital services and post-acute care such as home health and skilled nursing. Providers could choose the bundled payment program from six conditions, including lumbar spine fusion and angioplasty with a stent. The bundled payments would also be tied to quality.

Health Information Technology

e-Prescribing Program

The eRx Incentive Program ended in 2013, but e-prescribing will continue through the EHR Incentive Program.

Electronic Health Record Incentive Program (Meaningful Use)

The American Recovery and Reinvestment Act (ARRA) included \$19 billion in federal grants to encourage eligible professionals (EPs) to adopt EHR systems. Once an EP starts the program, he/she must continue to meet higher stages of meaningful use over time, each of which have their own set of goals, summarized below:

Stage of Meaningful Use	Applicable Years	Focus of Requirements
Stage 1	2011-2014	Data capture/sharing, using EHR to track key conditions
Stage 2	2013-2016	Advanced clinical processes, more rigorous information exchange, increased requirements for e-Rx and incorporating lab results, more patient engagement
Stage 3	2017	TBD, but will likely focus on improved outcomes, use of decision support tools, patient access to self-management tools, testing of innovative, locally generated measures, 100% compliance with certain measures

The dates listed above are reflective of a decision made in mid-December by CMS to extend Stage 2 an extra year, and delay Stage 3 an additional year.

Earning potential depends on an EP's start date. EPs who satisfy reporting requirements under this program are eligible to receive an incentive payment equal to 75% of their total allowed Medicare Part B covered charges during the reporting year, up to a cap. The table below illustrates the maximum amount a physician can earn each year and over a period of years depending on his/her start date. Please note that the 2% cut due to sequestration applies to the EHR Incentive Program, as well (see PQRS section discussion).

Maximum	Annual Incentive Payment by Stage of Meaningful Use						
Payment by Start Year	2011	2012	2013	2014	2015	2016	2017
2011	1	1	1	2	2	2	3
\$44,000	\$18,000	\$12,000	\$8,000	\$4,000	\$2,000	-	-
2012		1	1	2	2	2	3
\$44,000		\$18,000	\$12,000	\$8,000	\$4,000	\$2,000	-
2013			1	1	2	2	3
\$39,000			\$15,000	\$12,000	\$8,000	\$4,000	-
2014	Last year to begin to		1	1	2	2	
\$24,0000	qualify for an incentive		\$12,000	\$8,000	\$4,000	-	

New Policies for 2014

It is important to note that the 2014 reporting year marks the beginning of a restructured EHR Incentive Program and other important changes. For one, 2014 is the last opportunity for an EP to qualify for incentive. However, EPs who start the program in 2014, do not have to meet Stage 2 requirements until they have first met Stage 1 requirements for 2 years. Furthermore, EPs who are not meaningful users by the end of 2014 will be subject to a -1.0% penalty in 2015. This first year penalty can increase to as high as -5.0% by 2019. Also in 2014, all EPs, regardless of their stage of meaningful use, must report at least 9 clinical quality measures (CQMs), out of a total of 64, covering a minimum of 3 National Quality Strategy (NQS) domains in addition to the objectives that must be satisfied (see below). This is a dramatic increase from the pervious requirement of 3 CQMs and meant to align with new PQRS reporting requirements. Finally, starting in 2014, EPs also must use EHRs certified under the new 2014 Edition criteria, which is supposed to encourage better interoperability, electronic health information exchange, and patient engagement. EHR technology certified to the previous 2011 Edition will no longer be acceptable for the purposes of meeting the "Certified EHR Technology" definition.

As a result of these changes, the revised requirements are as follows:

Stage 1 Requirements

- 14 core objectives
- 5 out of 10 menu set objectives
- 9 out of 64 approved clinical quality measures (CQMs) covering at least 3 National Quality Strategy domains

Core Objectives	Menu Set Objectives
Computerized order entry	Drug-formulary checks
E-Prescribing	Incorporate clinical lab test results as structured data
Report ambulatory clinical quality measures to CMS/States	Generate lists of patients by specific conditions
Implement one clinical decision support rule	Send reminders to patients per patient preference for preventive/follow up care
Provide patients with an electronic copy of their	Provide patients with timely electronic access to their
health information, upon request	health information
Provide clinical summaries for patients for each	Use certified EHR technology to identify patient-
office visit	specific education resources and provide to patient, if
	appropriate
Drug-drug and drug-allergy interaction checks	Medication reconciliation
Record demographics	Summary of care record for each transition of care/referrals
Maintain an up-to-date problem list of current and	Capability to submit electronic data to immunization
active diagnoses	registries/systems
Maintain active medication list	Capability to provide electronic syndromic
	surveillance data to public health agencies
Maintain active medication allergy list	
Record and chart changes in vital signs	
Record smoking status for patients 13 years or older	
Protect electronic health information	

Click <u>here</u> for more detailed information about each objective. Click <u>here</u> for more information about the CQMs.

Stage 2 Requirements

- 17 core objectives
- 3 out of 6 menu set objectives
- 9 out of 64 approved clinical quality measures (CQMs) covering at least 3 National Quality Strategy domains

Stage 2 makes mandatory some EHR measures that are optional for stage 1, such as whether the EHR can incorporate clinical laboratory test results. Other measures stay the same but have higher thresholds, such as a requirement that EHRs send more than 50% of applicable prescriptions electronically, up from more than 40%.

CMS offers a new resource, <u>An Eligible Professional's Guide to Stage 2 of the EHR Incentive Programs</u>, which provides a comprehensive overview of Stage 2. It also offers a breakdown of <u>Stage 1 versus Stage 2</u>.

Stage 3 Requirements

Last December, the HIT Policy Committee released a pre-rulemaking proposal on Stage 3. The Stage 3 objectives, for the most part, reiterate the Stage 2 goals, with higher thresholds for demonstrating meaningful use. The AANS and CNS submitted comments in response to this proposal, pointing out the unique challenges of specialty care and voicing our concerns that the proposed Stage 3 requirements would be overly burdensome for specialists, thereby preventing neurosurgeons from complying with the program's requirements. The AANS and CNS also highlighted concern that the Stage 3 recommendations are being made without considering how providers — especially neurosurgeons and other specialists — have fared with meeting the criteria used in Stages 1 and 2 of the EHR Incentive Program. Additionally, we cited the need for CMS to better align the agency's various quality improvement programs, given the fact that these programs will become punitive in future years. Finally, we highlighted the N²QOD, noting that comprehensive "registry data can be used to develop specialty specific quality and outcomes measures that will be more meaningful than current 'check box' measures contained in the EHR Incentive Program." Click here for a copy of our comments.

In an effort to further accelerate and advance interoperability and health information exchange, CMS decided to delay any Stage 3 Meaningful Use rulemaking until the fall of 2014, with a final rule expected in the first half of 2015. The Stage 3 delay is a request neurosurgery has made to CMS numerous times. In the interim, CMS reached out to stakeholders, through a request for information (RFI) for advice on how new payment models affect implementation of EHRs. Neurosurgery signed onto a joint letter with the American College of Surgeons and other surgical specialties voicing our continued concerns with the EHR Incentive Program and its associated timelines.

Participation Rates

In January 2014, the GAO issued a report titled, "Number and Characteristics of Providers Awarded Medicare Incentive Payments for 2011-2012." According to the report, hospitals and health care professionals, such as physicians, were awarded a total of approximately \$6.3 billion in Medicare EHR incentive payments for 2012, which is more than twice the \$2.3 billion awarded to hospitals and professionals for 2011. Almost half of eligible hospitals and less than a third of eligible professionals received Medicare EHR incentive payments for 2012. 183,712 professionals were awarded payments for 2012, which represents 31% of the EPs and an increase compared to 2011, when 58,331 professionals, or 10% of those eligible, were awarded incentive payments. Nationwide, 75% of professionals that were awarded an incentive payment for 2012 were new to the program. **Not**

surprisingly, general practice physicians were 1.5 times more likely than specialty practice physicians to have been awarded an incentive payment for 2012. In addition, professionals with the lowest total amount of Medicare Part B charges were 3.3 times more likely to have been awarded an incentive payment for 2012 compared to 2011, which was a slightly greater increase than for professionals overall.

In February 2014, the AMA hosted a meeting with specialty societies to discuss Clinical Quality Measure (CQM) reporting requirements and other challenges specialties face in satisfying EHR criteria. The AMA is collecting feedback from societies on specific impediments to adopting EHRs and meeting meaningful use requirements. It will use this data to urge CMS to further delay implementation of the program. AMA staff also noted at this meeting that the encouraging numbers cited above are deceiving in that they do not reflect physicians who may have registered for or later dropped out of the program due to challenges.

Following the meeting, the AMA prepared a letter to HHS requesting relief from the prescriptive nature of this program. The AANS and CNS signed on to this letter, which requested that HHS extend the timeline for implementing 2014 Edition Certified EHR software, delay Stage 1 and 2 program requirements through 2015, and add flexibility to the requirements. The letter did not include detailed data about participation barriers. The goal was to send it in time to coincide with the start of the Health Information and Management Systems Society (HIMSS) annual meeting when HHS and the rest of the health care industry convenes on HIT matters. A more substantive letter based on specialty society feedback will follow. The AANS and CNS, along with NERVES, are in the process of collecting anecdotal evidence from its members to add to this letter.

Legislation

In an effort to try and address the impending penalties, specifically for small group practices, the AANS and CNS signed onto a letter asking Congress to delay penalties. As a result, Rep. Diane Black re-introduced her bill in March. This legislation would make common sense reforms, including:

- Creating a hardship exemption for solo practitioners and physicians in and near retirement to avoid exacerbating workforce shortages;
- Shortening the gap between the performance period and the application of the penalty:
- Expanding options for participation in the incentive program and improving quality measures through incorporation of specialty-led registries;
- Increasing participation among rural health care providers:
- Tailoring requirements to meet specific needs of certain specialties; and
- Establishing an appeals process before application of penalties.

The AANS and CNS with the Alliance, also recently met with a key member of the HIT Policy Committee to discuss specialty specific issues and a possible specialty pipeline for achieving meaningful use.

The "SGR Repeal and Medicare Payment Modernization Act" (S. 2000/H.R. 4015) also includes language promoting interoperability. "Congress declares it a national objective to achieve widespread exchange of health information through interoperable certified Electronic Health Record technology nationwide by December 31, 2017," the bill's language states. If the HHS Secretary determines that widespread interoperability hasn't been established by the end of 2017, then he or she must submit a report to Congress by the end of 2018 identifying barriers to meeting the goal. The report also must make recommendations that lawmakers can take to meet the goal such as adjusting Medicare payments and recommending the decertification of electronic health records as ineligible for those payments. The bill also aims to create a website allowing providers to compare how well various electronic health record products work.

Additional ACA Provisions Targeted Toward Quality and Efficiency

The ACA authorizes the creation of a new Center for Medicare and Medicaid Innovation (CMMI) to test new payment and treatment models that improve coordination, quality and efficiency. The ACA provides \$10 billion over 10 years for new demonstration projects and pilot programs to test payment models designed to catalyze transformation of the delivery system, moving it away from fee for service and toward care coordination. In a recent hiccup, the Congressional Budget Office released a 2013 briefing paper that concluded CMS' demonstrations aimed at enhancing the quality of health care and improving the efficiency of health care delivery in Medicare's fee-for-service programs have not reduced Medicare spending. In nearly every program involving disease management and care coordination, spending was either unchanged or increased relative to the spending that would have occurred in the absence of the program, when the fees paid to the participating organizations were considered. Despite these concerns, the program is moving forward full-speed-ahead, although some in Congress are pressing for more oversight and details about this program's funded projects.

CMMI recently announced nearly \$1 billion in awards to innovations that are focused on improving the quality and reducing the cost of specialty care. Building on other CMMI initiatives that cater to primary care, these awards will support innovations in 4 specific areas:

- 1. Rapidly reduce Medicare, Medicaid, and CHIP costs in outpatient and inpatient care (e.g., diagnostic radiology, physician administered drugs, acute and post-acute care services)
- 2. Improve care for patients with specialized care needs, such as HIV patients, high cost pediatric populations, and behavioral health patients.
- 3. Quickly transform clinician models for specific types of providers, including specialists. (e.g., oncologists, cardiologists, and pediatric providers who provide care to children with complex medical needs)
- 4. Models that link clinical care delivery to preventive health and population health outcomes (cardiovascular diseases, hypertension, diabetes, and HIV/AIDS were singled out).

Preference will be given to proposals that are nationally scalable, engage multiple payers, and test new payment models in support of the desired care delivery model. Awards, expected in January 2014, but have not yet been announced.

Shared Savings Program and Accountable Care Organizations

The ACA created the authority to establish ACOs — coordinated networks of providers that would be rewarded by Medicare for collaborating to redesign care processes that result in improved coordination, quality and cost-efficiency. Medicare ACOs became operational in 2012. Additionally, because of all the criticism levied on the Obama Administration for an overly restrictive ACO rule, CMS created the Pioneer ACO Model. The Pioneer ACO Model was designed specifically for organizations with experience offering coordinated, patient-centered care, and operating in ACO-like arrangements. CMS has selected 32 organizations selected to participate in the Pioneer ACO Model. The Pioneer ACO program has felt some growing pains, as nearly 10 of the 32 Pioneer ACOs either are dropping out of the demo or are considering doing so, and the four or five have said they will drop out and move to a separate CMS ACO program, called the Medicare Shared Saving Program (MSSP). The MSSP does not punish ACOs for failing to meet cost and performance goals.

In late January 2014, CMS released preliminary financial data for the first two rounds of the MSSP with mixed results. Of the 114 ACOs in the program, only 54 of the ACOs saved money and only 29 of those saved enough money to receive bonus payments. While the 54 ACOs that saved money accounted for a net savings of \$128 million for Medicare, it's uncertain if those savings were offset by

any losses from the remaining organizations. Overall, the results were similar to last year's Pioneer ACO results.

The AANS and CNS continue to support efforts to experiment with innovative models of healthcare delivery, but question the ability of the shared savings model to bring value to a system that is currently plagued by more fundamental problems, such as the flawed SGR. Finally, we are concerned that ACOs are nothing more than capitated managed care plans that ultimately will restrict patient access to vital medical services.

Hospital Quality Initiatives

The AANS and CNS continue to monitor various hospital quality initiatives as they apply to neurosurgeons. Topics include the hospital readmissions, payment reductions for hospital acquired conditions (e.g., surgical site infections), SCIP measures (e.g., clipping vs. shaving) and the application of quality requirements to outpatient departments. In April, CMS released the 2014 Proposed Inpatient Prospective Payment Rule. In addition to setting Medicare reimbursement rates for hospitals, the regulation includes additional proposed quality measures to strengthen the Hospital Value-Based Purchasing (VBP) Program and Inpatient Quality Reporting Program (IQR). In response to the proposal, the AANS and CNS submitted comments, which urged CMS to:

- Halt the expansion of the hospital readmission reduction program;
- Exclude patients with brain tumors or trauma from the postoperative pulmonary embolism/deep vein thrombosis quality measure requirements;
- Reconsider its proposal for including in 2017: Hospital 30-day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure and Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measures.

Both of the stroke measures were developed by Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) for CMS. CMS states in this rule that it plans to adopt both measures even though the measures are not endorsed by the National Quality Forum (NQF) and are not recommended by the Measures Application Partnership (MAP). Neurosurgery voiced its concerns with the measures when they were up for NQF review.

According to the rule, CMS believes it is imperative to adopt these measures as they aim to address a prevalent and costly health problem in the nation. In addition, CMS states the measures align with the Agency's priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and to reduce short term, preventable readmission and mortality rates. In addition, CMS states the measures align with the Agency's priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and to reduce short term, preventable readmission and mortality rates.

The Washington Office worked in conjunction with the AHA/ASA to get the following organizations to comment on the CMS Inpatient stroke mortality and readmission measures proposed for 2017. The list of organizations who commented on the issue was multi-disciplinary and started a new AHA/ASA relationship in the quality area.

- American Association of Neurology (AAN)
- American College of Physicians (ACP)
- American College of Surgeons
- American Medical Association
- American Hospital Association

- Premier
- Highmark
- National Stroke Association
- American Association of Medical Colleges (AAMC)
- Federation of American Hospitals (FAH)
- Essential Hospitals

Comparative Effectiveness Research

CER was considerably expanded with the passage of ACA, which established the new Patient Centers Outcomes Research Institute (PCORI). The AANS and CNS continue to participate in high-level discussions related to CER and the PCORI by commenting on their reports/proposals and through our position on the steering committee of the Partnership to Improve Patient Care (PIPC).

Patient-Centered Outcomes Research Institute (PCORI)

In March, PCORI conducted a workgroup meeting to discuss, "Treatment Options for Back Pain". The aim of the multi-stakeholder group was to advise PCORI on highest priorities of funding within this topic. "Treatment Options for Back Pain" is one of five focused funding areas for which RFAs will be announced this spring. Individuals at this roundtable meeting included representatives of osteopathic medicine, health services researcher, anesthesia pain management, employers, physical therapy, radiology, the NIH, occupational therapy, chiropractic care, and patient advocates. Matt McGirt, MD and Joseph Weistroffer, MD (AAOS) were the only surgeon representatives. The session was moderated by Paul Shekelle, MD, PhD, Director of RAND and Quality Improvement at UCLA.

After an all-day meeting, five areas emerged (which seemed almost predetermined by PCORI): 1. Methods for classifying patients for treatment planning; 2. Effectiveness of treatment options; 3. Relapse prevention and self-management; 4. Prioritizing Outcomes and; 5. Healthcare Systems

Dr. McGirt made a strong argument that it would be a mistake to ignore several areas surrounding lumbar surgery in PCORI low back pain funding priorities. He highlighted that despite the competing effectiveness and decision making that patients undergo for alternative treatments early during their presentation of back pain (which was most of the meetings focus), a substantial number receive and fail non-invasive medical treatments and present for consideration of surgical intervention. This surgical phase is the most costly, involves the most risk taking, is irreversible, and MUST be studied. He highlighted the feasibility and utility of longitudinal outcomes registries to capture the patient experience throughout an extended episode of back care, to identify prognostic patient-level factors to refine surgical indications and to develop informed and shared decision aids. He also highlighted the rapidly rising utilization of fusion and the need to fund comparative effectiveness of this intervention, etc. Joseph Weistroffer (AAOS) was highly supportive.

In sum, neurosurgery was successful in narrowing category #2 (Effectiveness of treatment options) to three high focus treatments in: opioids, spinal injections, and surgery/fusion. In category #5 (Healthcare Systems), neurosurgery was successful in getting the use of outcomes registries to inform patient decision making listed as a priority. The PCORI board of governors will meet to vote and refine the list of priorities.

In November 2013, PCORl's Board approved a two-year commitment of more than \$1 billion in funding for CER. That figure, which covers 2014 and 2015, marks a significant per-year jump from the approximately \$400 million PCORI awarded by the end of 2013. The commitment includes a projected \$528 million for research awards in 2014.

In December, PCORI announced its <u>latest round of research funding</u>, \$191 million for 82 projects. PCORI's Board of Governors approved over \$95 million for 53 CER studies and \$93.5 million to support the establishment of <u>PCORnet</u>, a new national patient-centered clinical research network to facilitate CER.

In January 2014, PCORI announced plans to pursue a new path to research funding as it moves into 2014 and enters a three-year period of research allocations averaging approximately \$500 million annually. This new pathway combines aspects of both PCORI's investigator-initiated and targeted research approaches. Applications for this initiative must propose studies that will directly compare outcomes between two or more approaches to addressing an important clinical challenge. PCORI refers to these as "pragmatic clinical trials" or "large simple trials," which will typically require larger and sometimes longer funding commitments than the current three-year awards. PCORI will therefore make funding available for these trials in the range of \$5 million to \$15 million in total costs, with terms of up to five years. Funding announcements for this initiative won't appear until February 2014. Thereafter, the announcements are expected to appear semi-annually. In its preannouncement, PCORI identified the following two topics as priorities the following two topics: "Strategies for preventing the progression of episodic acute back pain into chronic back pain;" and "Treatment strategies for symptomatic osteoarthritis, including joint replacement."

Finally, the Partnership to Improve Patient Care (PIPC), of which the AANS and CNS are founding members, recently distributed an updated draft document outlining PIPC's vision for its work in 2014. Once approved, PIPC will incorporate these messages into its website and other public statements. The document reiterates the goal of the group, which is "to raise awareness about the value of well-designed comparative clinical effectiveness research, the important role of continued medical innovation as part of the solution to cost and quality challenges in health care, and the need to ensure that comparative clinical effectiveness research conducted by the PCORI is centered on patient and provider needs." It continues to emphasize the needs of the individual patient, but with a heavier emphasis on the challenges posed by value-based payment models.

Registry Regulatory Burdens

In an effort to address neurosurgery's ongoing concerns regarding the Privacy and Commons Rules and the need for further clarification on the ability to collect prospective patient data for quality improvement purposes, organized neurosurgery has been interacting with HHS' Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP is governed by the Federal Advisory Committee Act and provides expert advice and recommendations to the Secretary, Kathleen Sebelius on issues and topics pertaining to the protection of human research subjects. SACHRP submitted recommendations to the Secretary in October 2012, recommending the Secretary eliminate irrelevant non-research related information (e.g., standard surgical risks) from the informed consent document. However, SACHRP did not directly address exemptions that relate to research for quality improvement purposes, which continues to pose a significant challenge. Therefore, in response, the AANS and CNS submitted comments to the Secretary and provided oral comments at the March 2013 SACHRP meeting requesting they address informed consent for quality improvement purposes.

Neurosurgery also has joined a coalition with other physician organizations that have registries to address common regulatory and legislative issues. The purpose is to work together to address common registry problems at the federal level. The coalition also recently drafted a White Paper on the issue and emailed it to OCR and OHRP staff.

In August, the coalition met with OCR/OHRP staff. It was very productive and a summary of the main points we discussed is as follows:

- 1. OCR and OHRP have addressed many of the issues raised in our White Paper (e.g., sites submitting data to registries can rely on central IRB waivers obtained by registries), but, we believe it would be very helpful to consolidate and publish your guidance in one place (or one place for each agency). The NIH-published guidance on Research, Repositories, Databases, and the HIPAA Privacy Rule (http://1.usa.gov/GAzmYK) may be a good option for adding the clarifications we've requested. It does not currently address Common Rule issues, so it is not clear whether Common Rule guidance could be added to that document.
- 2. OCR confirmed that if a registry, acting as a business associate of its participating sites, collects PHI primarily for health care operations purposes (e.g., data aggregation and benchmarking), it may de-identify that PHI and use if for any purpose permitted by the business associate agreement, including the secondary purpose of research. This is consistent with OCR's FAQ on HIO's that we discussed (http://1.usa.gov/17B3oFU). We continue to believe it would be very helpful in explaining this issue prospective sites if OCR would add clinical data registries to this FAQ, in addition to HIOs, to make it crystal clear that the FAQ applies to registries acting as business associates of participating sites.
- 3. We discussed OHRP's guidance in its correspondence with Dr. Asher (AANS/CNS) that when a hospital, physician, or other health care provider supplies data collected in the course of clinical care to a clinical trial or clinical data outcomes registry, the data source is not engaged in research. This point is covered in a more general way in the OHRP "Guidance on Engagement of Institutions on Human Subjects Research" at: http://1.usa.gov/19pwTXL. We believe it would be very helpful if OHRP could add a specific reference to clinical registries in the guidance document. That would help registries persuade hospitals and other data sources that the Common Rule does not apply if they are simply submitting data to registries in the course of clinical care and not conducting research themselves.
- 4. We appreciate that OHRP is open to reconsidering its position that benchmarking constitutes research (as stated in correspondence with Dr. Asher). From our perspective, benchmarking consists of gathering PHI from multiple data sources, aggregating and analyzing the data to develop average or standard performance levels/metrics across all sources and then reporting back to each source how its performance compares to the group average. The benchmarks themselves do not necessarily contribute to generalizable knowledge. Registries may make secondary use of the data to perform research, but the purpose of the benchmarking itself is improve quality care at the participating sites.
- 5. In terms of follow-up options with OHRP, we believe guidance documents will be most useful in persuading hospitals and other data sources that the Common Rule does not apply to the submission of data to registries. But we understand that developing and issuing such guidance is a long-term proposition for OHRP. In the meantime, we would appreciate the opportunity to start a new chain of correspondence that applies to registries generally, but covers most of the same issues as the Asher correspondence. The only substantive difference is we would hope that OHRP would clarify that the benchmarking alone does not constitute research. We will provide you with an opening letter raising these issues as soon as we can.
- 6. We sensed there may be some willingness on OHRP's part to discuss further the idea of exempting registries or registry participants from the Common Rule (to the extent it would otherwise apply) if they are only collecting identifiable patient data (and have no direct contact with patients through clinical trials or otherwise) and are complying with the relevant HIPAA privacy and security rules. We continue to believe this would be enormously helpful in persuading hospitals and other data sources to participate in clinical data registries and would welcome further conversation on this issue.

Follow-up correspondence was sent to the OCR-OHRP folks reflecting the above. Unfortunately, they have been slow to respond and have taken a "don't call us, we'll call you" approach. Given this roadblock, the registry coalition has recently considered using political capital on the Hill to push this along. Although we really only need clearer guidance from federal agency officials on things like exceptions to the common rule for cases when you're simply collecting data and not dealing with patients, the coalition felt a push from Congress may help. Senator Durbin's office suggested inserting it, along with other related language such as legal protections for registry data, as report language in the forthcoming HHS appropriations bill. Durbin is also happy to urge Senator Harkin, the Chairman of the HHS appropriations committee to include the language.

NeuroPoint Alliance

The NPA has implemented a number of projects related to the collection, analysis and reporting of clinical data relevant to neurosurgical practice, including MOC, PQRS and the National Neurosurgery Quality and Outcomes Database (N²QOD). NPA has partnered with the Vanderbilt Institute for Medicine and Public Health (VIMPH) to provide an online data-entry system and to perform back-end statistical analysis of the data and provide individualized feedback reports to practices. To date, 39 groups have signed contracts to participate in the initial N²QOD spine module. Nearly 50 have gone through IRB review. Additional plans are in the works to develop more subspecialty modules including Spinal Deformity, Cerebrovascular and Tumor, and an "essentials" module to encourage more physicians to participate in this initiative. NPA leaders and Washington Office staff are working to position the NPA as a one-stop portal for purposes of MOC, PQRS and quality reporting. NPA was a PQRS approved registry for 2013 and it has applied for this status in 2014 as well. The NPA will evaluate whether or not it will apply for Qualified Clinical Data Registry (QCDR) status in future years. It was decided that neurosurgery could not likely comply with all the QCDR requirements at this time.

ABIM Choosing Wisely Campaign

In an effort to address overuse of testing, the American Board of Internal Medicine Foundation launched the *Choosing Wisely* campaign in the spring of 2012. *Choosing Wisely* is part of a multi-year effort to help physicians be better stewards of finite health care resources. Originally conceived and piloted by the National Physicians Alliance through a Putting the Charter into Practice grant, nine medical specialty organizations, along with Consumer Reports, have identified five tests or procedures commonly used in their field, whose necessity should be questioned and discussed. The campaign is now going through a second phase and a total of 26 specialties have signed on and identified additional areas of overuse. The AANS and CNS have been invited to participate in this campaign and we are currently developing a submission for this campaign, which we hope to finalize following the April 2014 AANS annual meeting.

For more information, click here.

CMS Quality Strategy

In January 2014, the AANS/CNS responded to a request for comments on the CMS Quality Strategy for 2013 and beyond, meant to optimize health outcomes by improving clinical quality and transforming the health system. Organized neurosurgery encouraged CMS to move away from process metrics that only indirectly reflect quality of care and instead move towards patient specific outcome metrics that reflect the global quality of care delivered by a provider or network and noted that the organizations best equipped to define those metrics are the clinicians that treat those patients. We also emphasized the value of clinical data registries and greater flexibility and variation in complying with quality reporting mandates.

Quality Improvement Organizations

The AANS and CNS continue to actively participate in a number of quality improvement organizations, including the Physician Consortium for Performance Improvement (PCPI), Surgical Quality Alliance (SQA), and National Quality Forum (NQF). It has been decided to terminate our participation with AQA, due to their lack of relevance and value. Projects include:

- Updating the perioperative measure set
- Helping to develop efficiency and overuse measures, including imaging
- Fostering the use of clinical registries in a standardized, yet flexible and non-burdensome manner
- Helping to expand and update the stroke measure set
- Ensuring standards for physician profiling and public reporting, including helping to develop an SQA document titled, "Recommendations for Issuing Public Reports on Surgical Care."

We have also recently nominated a number of neurosurgeons to participate on several quality-related projects, including:

- Paul Penar, MD was nominated to Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation's (CORE) Technical Advisory Panel (TEP). CMS has contracted with Yale/CORE to develop administrative claims-based, risk-adjusted measures of all-cause admissions for patients with chronic disease (heart failure, diabetes, and multiple chronic conditions). The purpose of the project is to develop admission measures that can be used to assess and improve the quality of care provided to Medicare beneficiaries.
- Shelly D. Timmons, MD was appointed to the NQF Phase II Regionalized Emergency Medical Care Services (REMCS) Taskforce. The taskforce is responsible for providing guidance to measure developers on the Office of Assistance Secretary for Preparedness and Response's prioritized areas of ED crowding, including a specific focus on boarding and diversion, emergency preparedness, and surge capacity.
- Michael G. Kaplitt, MD was appointed to the NQF Neurology Endorsement Project. He was the sole neurosurgeon on the panel. The panel is responsible for re-evaluating existing neurology measures and reviewing new measures. Measures reviewed related to stroke, Parkinson's, and epilepsy. CMS put forward two stroke readmission and mortality measures and due to weak evidence they were voted down. Neurosurgery was not supportive of the measures.
- Jeffrey W. Cozzens, M.D., FACS, was recently selected as an expert panelist to serve on an Agency for Healthcare Research and Quality (AHRQ) ICD-10-CM/PCS Quality Indicators (QI) Neurology Group. The workgroup process will lead to recommendations regarding how the existing AHRQ QIs should be re-specified using ICD-10-CM/PCS codes, retaining the original clinical intent of each indicator while taking advantage of the greater specificity of ICD-10-CM/PCS to improve the indicator's validity.
- Tony Asher, MD has been selected to serve on the CMS Episodes of Care project. The CMS grouper project is primarily being designed for the Physician QRUR reports. He has been appointed to the Cerebrovascular disease Clinical Working Group (which includes stroke). The AMA PCPI will oversee this project.
- Joseph Neimat, MD was appointed to serve on an AAN Epilepsy Measures Update and Development Work Group in November 2013.

- In January 2014, John Ratliff, MD, was selected to serve on the NQF Cost and Resource Use Measure Endorsement/Maintenance Standing Committee.
- In January 2014, Paul Penar, MD was nominated to serve on the NQF Surgery Workgroup and Zo Ghogawala, MD was nominated to serve on the NQF Musculoskeletal Workgroup. The ACS submitted a letter of support for both nominations and NASS submitted a letter of support for Dr. Ghogawala.



NPA/N²QOD Update

- 1) On March 19, 2014, The N2QOD will have been open for data collection for exactly 2 years. As of last month, over 8,000 and 2,000 patients were enrolled in the lumbar and cervical modules, respectively. 52 centers are now participating. We are the largest spine registry in North America. It is almost certain we have the highest 12 month follow-up rates (77-80%) of any existing cooperative spine registry.
- 2) Our Scientific Committee determined that detailed ad hoc analyses of the data base (now containing over 1.5 million independent variables) would start after 2 full years of data collection (to allow for the data to mature sufficiently). We will therefore start our deep analysis of the data in March. The analyses will start with descriptions of our methodologies and statistical models, along with analyses of the variability observed in patient responses to therapy. The first investigations will be conducted by VIMPH quality scientists working with clinical investigators from the leading N2QOD centers (the N2QOD Clinical Analysis Project-or CAP). We will open up the database to independent scientific analysis (individual N2QOD investigators) later in 2014.
- 3) The registry is a CMS "qualified clinical registry" for the purposes of PQRS reporting. Members have started using the registry for this purpose, and we are receiving more inquiries from various practice groups. We will not participate in the QCDR option for the time being due to the requirement of reporting on 50% of eligible Medicare and Private Payer patients. The SGR legislation may present more possibilities for us.
- 4) The ABNS is revising its MOC program, particularly MOC part IV. The board has voted to allow participation in registries meeting basic requirements for relevance to neurosurgical practice and quality improvement (these requirements are under development) to satisfy MOC Part IV requirements. Other options will be made available for MOC Part IV participation, including large local and regional quality improvement programs. All of the NPA's registry programs will be made compliant with the ABNS requirements.
- 5) The ABNS has worked out an agreement with the ACGME to accept resident case data. NPA will assist the ABNS with the collection, analysis and reporting of that data back to residency program directors.
- 6) A CV module has been developed and will be released in early second quarter 2014. Tumor and essential modules, along with a general practice module, are being developed. The modules in development will allow individual surgeons to participate in local quality improvement and, if they wish, PQRS and MOC.
- 7) A comprehensive SRS module is being developed by NPA and will be a joint effort between 25 practice centers and Outcome Science (Quintiles). This three year project is being funded by BrainLab and possibly other industry groups. A scientific committee has been developed under the leadership of Dr. Jason Sheehan.

- 8) An independently funded EC-IC bypass project has been initiated and is being coordinated by Dr. Ghogawala. This module is being administered with IT support from Acesis Corporation (California).
- 9) We are finalizing our new contract with VIMPH. We have developed an outstanding cooperative relationship with quality scientists at Vanderbilt. The new contract will facilitate growth of the network and our registry projects. Important new collaborative projects specified in the contract include the development of a patient risk calculator (to educate patients and clinicians regarding personalized likelihoods of outcomes with spine surgery), methods to improve data collection efficiencies (including patient portals and EHR integration) and focused resources to facilitate scientific inquiry relate to the database.
- 10) The NPA continues its conversations with other leadership groups in our specialty, particularly the Senior Society, regarding important methods to consolidate data gathering and reporting programs (such as the Portal Project).



GUIDELINES

Administrative Issues

Current Committee Members

Tim Ryken, MD, Chair Sepideh Amin-Hanjani, MD, Co Vice-Chair Kevin Cockroft, MD, Co Vice-Chair Steven Kalkanis, MD, Co Vice-Chair

P. David Adelson, MD (Past JGC Co-Chair)

Manish Aghi, MD (Tumor Section)
Peter Angevine, MD (CV Section)
Paul Arnold, MD (Trauma Section)
Maya Babu, MD, MBA (CSNS)
Lissa Baird (Pediatric Section)
Than Brooks, MD (Spine)
Jeff Bruce, MD (Tumor Section)
Steve Casha, MD (Tumor Section)
Sean Christie, MD (Spine Section)

Jeff Cozzens, MD (CRC)

Aaron Filler, MD (Peripheral Nerve)

Ann Marie Flannery, MD (Pediatric Section)
Isabelle Germano, MD (Tumor Section)
Odette Harris, MD (Trauma Section)
Gregory Hawryluk, MD (Trauma Section)

Brian Hoh, MD (CV Section)
Dan Hoh, MD (Spine Section)

Kathryn Holloway, MD (Stereotactic Section)

Steve Hwang, MD (Spine)
Jack Jallo, MD (Trauma Section)
Terrence Julien, MD (Tumor Section)
John Kestle, MD (AANS Appointee/Peds)

Alex Khalessi, MD (CV Section)
Paul Klimo, MD (Pediatric Section)

Abhaya Kulkarni, MD (AANS Appointee/Peds)

Sean Lavine, MD (CV Section) Elad Levy, MD (CV Section)

Mark Linskey, MD (Past JGC Chair)

Zachary Litvack, MD

William Mack, MD (CV Section)
Christopher Madden, MD (Trauma)

Marlon Matthews, MD (CSNS Resident Fellow)

Cathy Mazzola, MD (Pediatric Section)

Todd McCall, MD (CNS)
Jeffrey Olson (Tumor Section)
John O'Toole (Spine Section)
Chirag Patil (Tumor Section)
Erika Peterson. MD (Pain Section)

Julie Pilitsis, MD (Pain/Stereotactic Section)

J. Adair Prall, MD (Trauma Section)
Patricia B. Raksin, MD (Trauma Section)
Daniel K. Resnick, MD (Spine Section)

Josh Rosenow, MD (Pain/Stereotactic Section)

John Shin, MD (Spine)

Konstantin Slavin, MD (Stereotactic Section)
Martina Stippler, MD (Trauma Section)
Krystal Tomei, MD (CNS Appointee)
Marjorie Wang, MD (Spine Section)
Chris Winfree, MD (Pain Section)

Chris Winfree, MD (Pain Section)

Brad Zacharia, MD (CSNS)

Christopher Zacko, MD (Trauma Section)

Gabriel Zada, MD (Tumor Section)
Gregory Zipfel, MD (CV Section)

Consultant:

Beverly Walters, MD

Ex Officio:

John A. Wilson, MD

Staff Liaisons:

Laura Mitchell Rachel Groman

The JGC also now has its own CNS-hosted website at: http://www.cns.org/advocacy/jgc/default.aspx. Additional information regarding initial planning and development of evidence-based guidelines can be located at: http://www.cns.org/guidelines/.

Current and Completed Projects

Cerebrovascular

• AHA Stroke Projects. There are several AHA guidelines and scientific statements of interest to neurosurgery that recently have been, or soon will be, updated.

The Scientific Statements include:

- Secondary Stroke Prevention
- Intracerebral Hemorrhage
- Subarachnoid Hemorrhage
- Management of Acute Stroke and Primary Stroke Prevention
- Cervical Arterial Dissection Related to Cervical Manipulation (endorsed by the AANS/CNS in December 2013)

The following guidelines have recently undergone review:

- Early Management of Patients With Acute Ischemic Stroke
- Cerebral Venous Thrombosis
- Definition of Stroke
- Palliative and End of Live Care in Stroke (Scientific Statement)
- Evaluation and Management of Malignant Infarcts
- Risk of Cervical Arterial Dissection after Chiropractic manipulation (Scientific Statement)
- Management of Cerebral & Cerebellar Infarction with Swelling
- Cervical Dissection and Palliative Care (Scientific Statement)
- Prevention of Stroke in Women
- Prevention of Stroke in Patients with Stroke or Transient Ischemic Attach (Secondary Prevention)
- Primary Prevention of Stroke (AAND and CNS endorsement pending)
- Neurocritical Care Society. The AANS/CNS is in the process of creating a collaborative guidelines relationship with the NCS, similar to the process developed with AHA, where neurosurgery would prospectively identify guidelines projects of interest for review and potential endorsement, and look to have a formal AANS/CNS designee on the writing group. Drs. Huang and Amar, who is already the CV Section's liaison to the NCS, have been proposed as representatives to sit on the core NCS guidelines committee. The NCS is interested in neurosurgery's involvement and is vetting the proposal.

In the meantime they have several projects at, or nearing completion that they would be interested in having our review for endorsement, as follows, in order of most time sensitive:

- Multimodality monitoring in neuroICU
- Large Hemispheric Infarction (consensus statement)
- EVD management (consensus statement)
- Coagulation reversal
- DVT prophylaxis

Spine/Peripheral Nerve

- Guidelines for the Surgical Management of Cervical Degenerative Disease
- Position Statement on Percutaneous Vertebral Augmentation
- Treatment of Osteoporotic Spinal Compression Fractures
- Cervical and Thoracic Spine Disorders Guideline

- AAOS/ADA Antibiotic Prophylaxis for Bacteremia in Patients with Total Joint Replacements Guideline
- Lumbar Fusion Guideline
- Cervical Spine Trauma Guideline
- AAOS Guideline on Diagnosis of Carpal Tunnel Syndrome

Trauma

- Thoraco-Lumbar Trauma Guideline (expected to come before JGC in spring of 2015)
- Traumatic Brain Injury
- Management of Coagulopathy and DVT Prophylaxis in TBI Patients
- American College of Occupational and Environmental Medicine (ACOEM) chapter on traumatic brain injury within its evidence-based Occupational Medicine Practice Guideline

Tumor

- Guidelines for the Treatment of Newly Diagnosed Glioblastoma
- Metastatic Brain Tumor Guidelines
- ASTRO Guideline on Radiotherapeutic and Surgical Management for Brain Metastases
- Metastatic Spinal Tumor Guideline
- Management of Progressive Glioblastoma
- Non-Functioning Pituitary Adenoma Guideline (expected to come before the JGC in the fall of 2014)
- Low-Grade Glioma (expected to come before the JGC shortly)

Stereotactic/Functional

 Deep Brain Stimulation for Patients with Obsessive Compulsive Disorder (JGC comments submitted to authors January 2014)

Pediatrics

 Pediatric Hydrocephalus (following a JGC review and support, the AANS and CNS endorsed in January 2014).

Pain

- The American Association of Occupational and Environmental Medicine (ACOEM) request to review chapter on "Opioids"
- ACOEM request to review chapter on "Low Back and Neck Pain"

Cross-Sectional Projects

- Appropriateness Criteria for Diagnostic Imaging
- CSNS Brain Death Guidelines (currently stalled; completion date unknown)



Drugs and Devices Update

Physician Industry Relations

Sunshine Act Reporting Instructions Issued

On February 7, 2014, CMS published updated instructions on the CMS Open Payments website, explaining that registration and reporting will take place in two phases for the first Sunshine Act reporting period. First, starting on February 18, 2014, manufacturers and applicable group purchasing organizations (GPOs) may begin to register for "Phase 1" of reporting, which will run until March 31, 2014. In Phase 1, applicable manufacturers will submit corporate profile information and "aggregate 2013 payment data" to CMS's Enterprise Portal. Second, beginning in May 2014 and running for at least 30 days, manufacturers will enter "Phase 2" of the registration and reporting cycle. During this period, they will register for the Open Payments system, submit "detailed 2013 payment data," and attest to the accuracy of the data. Finally, after both phases are complete, expected by August 1, 2014, manufacturers, physicians, and teaching hospitals will be able to review the reported data and correct any inaccuracies. More information is available at: http://bit.ly/1dCfMoe.

FDA Updates System for Applying to Serve on Advisory Committees

On January 22, 2014, the FDA released a 10-page slide presentation defining conflicts of interest for individuals who would like to serve on agency advisory committees and launched an online portal for applications. Advisory committees have come under scrutiny because of the important influence that their decisions have on agency reviews of drugs for approval. Even though the FDA is not required to follow the panels' opinions on whether a particular drug should be approved for sale, the agency often does. Some consumer advocacy groups such as Public Citizen support disqualifying individuals with ties to any drug or device manufacturers from service. However, FDA officials have said that they are mindful of concerns about conflicts of interest, but that for certain topics, it can be difficult to find experts with sufficient knowledge who have no links at all to industry. More information and access to the online portal for applications is available on the FDA website at: http://l.usa.gov/limXbny

Congressional Activity

GAO Report on VA Purchase of Surgical Implants

On January 13, 2014, the Government Accountability Office (GAO) released a report to Congress titled *VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement* [GAO-14-146]. The Veterans Health Administration (VHA) spending on surgical implants was about \$563 million in fiscal year 2012, an increase of 28 percent since 2008. Clinicians at Veterans Affairs Medical Centers (VAMCs) determine veterans' needs and request implant purchases either from a contract or from the open market (i.e., not from an existing contract). VHA requirements--which implement relevant federal regulations--include providing justifications for open-market purchases. However, GAO found that VHA was often not following stated procedures.

GAO examined (1) factors that influence clinicians' decisions to use particular implants when multiple, similar items are available; (2) selected VAMCs' compliance with pertinent VHA requirements for documenting open- market purchases; and (3) VA's and VHA's oversight of VAMC compliance with implant purchasing requirements. In the report, the GAO criticizes the VA for not seeking market-rate prices for implants or accurately documenting those purchases, which would help the FDA document

recalls or other safety problems. In addition, the GAO report raised concern about implant vendors being involved with patient care. The GAO recommended the VA identify implants and establish a timeline to expand the volume that can be purchased from VA-negotiated contracts and improve compliance with and oversight of purchasing requirements. The VA has concurred with these recommendations. A copy of the report is available at: http://l.usa.gov/lhyx1Pn.

House Veterans' Affairs Hearing on Surgical Implants

On January 15, 2014, the House Committee on Veterans' Affairs Subcommittee on Oversight and Investigations held a hearing titled "Vendors in the OR - VA's Failed Oversight of Surgical Implants." The purpose of the hearing was to look at issues raised in the recent GAO report regarding purchase of surgical implants, documentation for those purchases, and the way in which VA hospitals interact with implant vendors. At the hearing, GAO staff highlighted points made in their report. Veterans Affairs officials discussed action taken since 2012 to try to improve surgical implant procurement. Philip Matkovsky, Assistant Deputy Under Secretary for Health for Administrative Operations at the VA addressed the issue of industry vendors in the operating room, which was of concern to the GAO and some of the committee members. He stated that the presence of industry vendors is not unusual in health care and that the VA had patient consent procedures in place to inform patients of such presence and strict rules stating that a vendor may provide technical advice but may not participate in the actual surgical procedure. More information is available at: http://l.usa.gov/1fjYKzU.

AANS and CNS Support Exempting FDA User Fees From Sequestration

AANS and CNS joined 125 other stakeholders in sending a letter to Representatives Leonard Lance (R-NJ) and Anna G. Eshoo (D-CA) in support of the FDA Safety over Sequestration Act H.R. 2725. The legislation exempts the FDA user fees – paid by pharmaceutical, biologic, medical device, and other manufacturers to help support the FDA's review of new drugs, biologics, devices and diagnostics – from being sequestered in fiscal year 2014 and beyond. The FDA relies heavily on private user fees to supplement federal appropriations for its product review activities. The letter encourages Congress to protect these user fees from sequestration. A copy of the letter is on the web at: http://bit.ly/18wlNUa.

President Signs Bill to Increase FDA Oversight for Compounding Pharmacies

On Nov. 27, 2013, the President signed into law H.R. 3204, the Drug Quality and Security Act, P.L. 113–54. This law allows, but does not require manufacturers of compounded drugs to register and report to the FDA on outsourcing facilities and will create a national supply chain drug-tracking program. It also distinguishes compounders engaged in traditional pharmacy practice producing one product for an individual, from those manufacturing large volumes of compounded drugs without individual prescriptions. Compounders who wish to practice outside the scope of traditional pharmacy practice can register with the FDA as "outsourcing facilities," and will be subject to FDA oversight, similar to the process for traditional pharmaceutical manufacturers. Those who do not choose to register with the FDA will continue to be primarily regulated by state boards of pharmacy. In addition, the law requires the FDA to provide a list of FDA-regulated outsourcing facilities on the agency's website.

This law comes in the wake of the meningitis outbreak that stemmed from contaminated steroid pain injections produced in a Framingham, Mass. pharmacy that killed 64 people and caused illness in more than 750 individuals. More information is available on the FDA website at http://1.usa.gov/1oyRqVq A copy of the bill is available at: http://1.usa.gov/1nBRpfM.

AdvaMed Survey on Device Tax Impact

On February 18 2014, The Advance Medical Technology Association (AdvaMed) released the findings of a new survey of its membership on the first year impact of the device tax on industry. The survey found

that industry employment was reduced by approximately 14,000 jobs, and companies decided to forgo hiring an additional 19,000 who otherwise would have been hired, bringing the total direct employment impact of the tax on the device industry to about 33,000. The survey also found that almost one-third of respondents had reduced research and development efforts as a result of the tax. In terms of investment dollars, three-quarters of respondents said they had taken one or more of the following actions in response to the tax: deferred or cancelled capital investments; deferred or cancelled plans to open new facilities; reduced investment in start-up companies; found it more difficult to raise capital (among start-up companies); and/or, reduced or deferred increases in employee compensation. A copy of the survey is on the web at: http://bit.ly/1dHPvtc.

Food and Drug Administration Activities

New Director for FDA CDRH Division of Neurological and Physical Medicine

Recently Carlos Peña, PhD, MS has been appointed as the Director for the Division of Neurological and Physical Medicine Devices in the Office of Device Evaluation at the FDA Center for Devices and Radiological Health (CDRH). Prior to his new position, Dr. Pena served in the Office of the Commissioner and before that he was a reviewer for neurological devices at CDRH. Dr. Pena is well known to the AANS/CNS Drugs and Devices Committee and has been responsive and helpful in the past.

FDA Guidance on Electronic Medical Device Reporting

On February 14, 2014, FDA announced the availability of the guidance entitled "Questions and Answers About eMDR—Electronic Medical Device Reporting." FDA has published a final rule that requires device manufacturers and importers to submit mandatory reports of individual medical device adverse events, also known as medical device reports (MDRs), to the Agency in an electronic format that FDA can process, review and archive. Device manufacturers are required to report adverse events with devices when they become aware of them. The FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. The guidance provides general information regarding how to prepare and send an electronic postmarket medical device report to the FDA CDRH. The full notice can be found at: http://1.usa.gov/1c4RdAK More information regarding reporting of medical device adverse events is on the FDA website at: http://1.usa.gov/1oWnGBP.

FDA Pediatric Rare Diseases Meeting

FDA held a public workshop on January 8, 2014, entitled "Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases," organized by CDRH and the Office of Orphan Products Development (OOPD). The meeting was held in conjunction with a Center for Drug Evaluation and Research (CDER) workshop entitled "Complex Issues in Developing Drug and Biological Products for Rare Diseases." The purpose of the workshop is to discuss issues related to the following broad topics associated with medical devices for the diagnosis and treatment of pediatric patients affected by rare diseases: Current approaches toward use of medical devices for pediatric clinical practice; Humanitarian Device Exemption (HDE) marketing pathway, including the Humanitarian Use Device (HUD) designation process; Pediatric Specialty-Specific Practice Areas; Clinical Trials and Registries; and Pediatric Needs Assessment and Possible Approaches to Advancing Pediatric Medical Device Development. The input from this public workshop will help in developing a strategic plan to encourage and accelerate the development of new medical devices and therapies for pediatric patients affected by rare diseases. More information is on the FDA website at: http://1.usa.gov/1bnnlEK

Orthopaedic Devices Advisory Panel Meeting

On December 12, 2013, the FDA Orthopaedic Devices Panel discussed and made recommendations regarding the classification of spinal sphere devices. These devices are spheres manufactured from

metallic (e.g., cobalt chromiummolybdenum (CoCrMo)) or polymeric (e.g., polyetheretherketone (PEEK)) materials, intended to be inserted between the vertebral bodies into the disc space from L3-S1 to help provide stabilization and to help promote intervertebral body fusion. During the arthrodesis procedure, they are to be used with bone graft. These devices are not intended for use in motion-sparing, non-fusion procedures. Spinal sphere devices are considered preamendment devices because they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments became effective. Spinal sphere devices are currently regulated under the heading of "Intervertebral Fusion Device with Bone Graft, Solid-Sphere, Lumbar", Product Code NVR, as unclassified devices and reviewed under the 510(k) premarket notification authority.

The panel generally agreed with FDA's assertion that insufficient information exists to establish a reasonable assurance of safety and effectiveness for spinal sphere devices for use in intervertebral body fusion procedures. Furthermore, the panel unanimously agreed that spinal sphere devices for use in fusion procedures present an unreasonable risk of illness or injury to the patient. In addition to the risks to health identified by FDA that include removal/revision, pain and neurologic impairment, the Panel recommended incorporating all known risks generally associated with spinal interbody fusion procedures and unanimously determined that, given the lack of available evidence and the unreasonable risk profile of spinal sphere devices for use in fusion procedures, these devices should be classified as Class III devices, requiring submission and approval of a premarket application (PMA). The Federal Register notice is available at: http://1.usa.gov/1hXP0Ph. And more information on the meeting is available on the FDA website at: http://1.usa.gov/1fewdgE.

Biosimilars

AANS and CNS joined 10 other societies from the Alliance of Specialty Medicine on January 17, 2014 in sending a letter to the Washington State legislature in support of legislation, HB 2326 and SB 6091, that would allow a treating physician to require that a prescription for a biological medicine be dispensed as written and that if a substitute biosimilars is permitted, both the physician and the patient be notified. On February 18, 2014, the bill was referred to the Washington State House Rules Committee. A copy of the bill is available at: http://1.usa.gov/1jg2NOx and more information is available at: http://1.usa.gov/1gl0sPH.



Emergency Neurosurgical Services Update

Legislative Activities

Staff Meets with Energy & Commerce Committee Staff to Discuss Trauma Reauthorization

AANS/CNS staff met with Energy & Commerce Majority Committee staff in early February to discuss efforts to reauthorize trauma and emergency care programs that were passed as a part of the Affordable Care Act. The Trauma and Emergency Care System Grants authorize \$24 million per year for trauma systems and regionalization of emergency care development. Unfortunately, this authorization expires in September 2014, so the AANS/CNS, along with several other organizations, is working to have legislation introduced before they expire. Reps. Michael Burgess, MD (R-TX) and Gene Green (D-TX) have once again agreed to act as the lead sponsors on this effort. Advocacy efforts also continue to secure appropriations for the programs discussed above.

Bill Introduced to Include "Burn" in the Definition of Trauma

Late last year, Rep. Bill Johnson (R-OH) introduced HR 3548, the "Improving Trauma Care Act of 2013." This legislation would amend the Public Health Service Act to change the definition of trauma. In addition to the current definition: "The term trauma means an injury resulting from exposure to a mechanical force," the following language would be added, "or, another extrinsic agent, including an extrinsic agent that is thermal, electrical, chemical, or radioactive." Championed by the American Burn Association, this bill has the support of the American College of Emergency Physician, American College of Surgeons, and the Trauma Center Association of America. The AANS and CNS have been asked to support this legislation.

Traumatic Brain Injury (TBI) Reauthorization Passed by House Energy & Commerce Committee

On December 10, 2013, the House Energy & Commerce Committee passed the TBI Reauthorization Act, H.R. 1098. Introduced by Rep. Bill Pascrell (D-NJ) in March 2013, this bill would reauthorize funding through 2018 for the Centers for Disease Control and Prevention (CDC) to conduct brain injury surveillance, prevention, public education and awareness; funding for research conducted by the National Institutes of Health; and to improve service delivery and access through state and protection and advocacy grant programs.

The AANS and CNS are currently working with several other national organizations involved in injury and violence prevention to have a companion bill introduced in the Senate.

Omnibus Appropriations Bill Passed and Signed by President Obama

On January 17, 2014, President Obama signed a \$1.1 trillion omnibus spending package to fund federal agencies for the rest of the fiscal year. The measure, which encapsulates all 12 of the annual appropriations measures for federal departments, results in a 2.6 percent increase in discretionary spending from the \$986.3 billion sequester-set level of Fiscal Year (FY) 2013. Prior to the proposed measure, spending had been set to fall again to \$967 billion under the sequester, but the plan adheres to the new caps on defense spending (\$520.5 billion) and domestic discretionary spending (\$491.8 billion) set under last month's House-Senate budget deal.

The omnibus allocates \$156.8 billion in discretionary funding to the Labor-HHS-Education bill—\$100 million less than the amount enacted in FY 2013—and, significantly, staves off further cuts to various departments including the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).

More specifically, the NIH would receive \$29.9 billion for FY 2014, a bump of \$1 billion from 2013 levels. However, this funding falls short of fully restoring NIH funding to pre-sequester levels 2012. The CDC would receive \$6.9 billion, \$567 million more than the FY 2013 program level, and the FDA would get almost \$2.6 billion, an increase of \$91 million from last year's enacted level. Funding for certain HHS programs include:

- \$1.3 billion for CDC's public health preparedness and response activities (about \$91 million above FY13, but below the President's request), including \$640 million for PHEP grants (\$17 million above FY13);
- \$254.5 million for the Hospital Preparedness Program, a \$103.5 million cut from FY13;
- \$156.7 million for CDC's Influenza Planning and Response, slightly above FY13.

In addition, the bill would provide no new funding for the implementation of the Affordable Care Act (ACA). The proposal also cuts \$10 million from the budget for the Independent Payment Advisory Board (IPAB), one of the most contentious provisions in the health care law.

Other

Emergency Docs Give America's Emergency Care a D+

A new report card from the American College of Emergency Physicians (ACEP) is sharply critical of emergency care in the U.S., giving it an overall grade of D+. This grade is down from a C+ in 2009. The overall grade was based on scores in several categories, including access to emergency care, which made up 30 percent of the total score and included access to treatment, providers and specialists, hospital capacity and financial obstacles. Dr. Alex Rosenau, President of ACEP, explained that the lower grade in 2014 reflects a misguided focus on cutting funding and resources for emergency departments because of the popular but erroneous view that emergency care is expensive, even though it represents less than 5 percent of overall U.S. healthcare expenditures. For more information, please go to http://www.emreportcard.org/

CMS Proposed Rule on National Emergency Preparedness Requirements

On December 27, 2013, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to "establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It would also ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations." You can read the full rule, Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, in the Federal Register here. Comments are due February 25, 2014.

"Health Care Preparedness Funding: Are We Inviting Disaster?" Health Affairs Blog

Expanding on the theme of the December 2013 issue of *Health Affairs* — *The Future of Emergency Medicine: Challenges and Opportunities* — author Dan Hanfling writes that building the capacity and capability required for a prepared community takes an investment in time and money. Hanfling notes that "while the proposed CMS rules focusing on emergency preparedness are an important step forward, coming as it does after well over a decade of intensive focus on this issue, there is more that could be done. Centers for Medicare & Medicaid Services (CMS) could help to incentivize hospital

participation in regional health care coalitions, the substrate that currently defines hospital preparedness planning and response." <u>Click here</u> to read his post.

Institute of Medicine Report on Preparedness

The Institutes of Medicine (IOM) has released a report in December 2013 from their June Forum on Medical and Public Health Preparedness for Catastrophic Events. The workshop was held to discuss disaster preparedness, response, and recovery relative to the needs of children and families, including children with special healthcare needs. The workshop reviewed existing tools and frameworks that can be modified to include children's needs; identified non-traditional child-serving partners and organizations that can be leveraged in planning to improve outcomes for children; highlighted best practices in resilience and recovery strategies for children; and raised awareness of the need to integrate children's considerations throughout emergency plans. You can find a copy of the report here.

VA Adds Five Conditions Linked to Service-related Traumatic Brain Injury

The Department of Veterans Affairs has issued new regulations effective January 16, 2014, easing the burden of proof required for veterans to receive health care and compensation for certain illnesses, including Parkinsonism, dementia, and depression, which have been linked to traumatic brain injury. In addition, the policy includes unprovoked seizures and hormone deficiency diseases related to the hypothalamus, pituitary or adrenal glands. Under the new rules, if a veteran with an established service-related moderate to severe brain injury develops one the five conditions within stated time period, the condition will be considered service-related. A copy of the final rule is available at: http://1.usa.gov/1d500dV and more information is at: http://1.usa.gov/KaVwm0

Centers for Disease Control

The Centers for Disease Control (CDC) released its fifth preparedness report, The 2013-2014 National Snapshot of Public Health Preparedness, which outlines the preparedness and response activities of CDC and state and local public health partners, despite diminishing resources. This snapshot also includes PHEP awardee fact sheets that present available data to display trends and document progress related to 3 of the 15 preparedness capabilities: public health laboratory testing, emergency operations coordination, and emergency public information and warning. Fact sheets also highlight Technical Assistance Review scores and CDC resources that supported state, local, and insular areas' preparedness activities. The complete report and individual sections of the report can be found here.

Staff Meets with National Institute of Neurological Disorders and Stroke (NINDS) at NIH

On January 16, as part of the National Coalition for Heart Disease and Stroke, AANS/CNS staff met with several NIH personnel, including Story Landis, Ph.D., director of the NIH National Institute of Neurological Disorders and Stroke (NINDS), to receive an update on current research funding programs currently under way at NINDS.

The NIH received a \$1 billion increase in funding from FY 2013 levels in the recent Omnibus Appropriations bill. However, this funding falls short of fully restoring NIH funding to pre-sequester levels 2012. They have lost a significant amount of "buying power" are still not back to previous funding levels, but they recognize this is great first step. Several new trail studies have begun, including: clinical stroke, blood pressure, glucose levels, intervention, and long-term follow up.

The NIH Stroke Network has begun multi-site clinical trials across the country. <u>Click here</u> for more information.

In addition, more clinical research has begun in stroke disparities between African Americans and Hispanic Americans. They are looking at system barriers and time and distance between patients and hospitals. These results are expected to be announced in the new few months.

They noted that while it is unfortunate that private industry has begun to halt stroke research, the NINDS is trying to reengage them.

NINDS participants also included: Walter Koroshetz, M.D., Deputy Director; Petra Kaufmann, M.D., Director, Office of Clinical Research; Scott Janis, Ph.D., Program Director, Office of Clinical Research; Claudia Moy, Ph.D., Program Director, Office of Clinical Research; Salina Waddy, Ph.D., Program Director, Office of Clinical Research; Rajesh Ranganathan, Ph.D., Director, Office of Translational Research which oversees and manages therapy development projects; Pat Walicke, M.D., Ph.D., Program Director, Office of Translational Research; Francesca Bosetti, Ph.D., Program Director, Neural Environment Cluster with portfolio of basic stroke-related science; Jim Koenig, Ph.D., Program Director, Neural Environment Cluster with portfolio of basic stroke-related science; Roderick Corriveau, Ph.D., Program Director, Neurodegeneration Cluster with portfolio in vascular cognitive impairment; Marian Emr, Director, Office of Communication and Public Liaison; Paul Scott, Ph.D., Director, Office of Science Policy and Planning; Katie Pahigiannis, Ph.D., Program Analyst, Office of Science Policy and Planning who manages stroke communications among Federal agencies, legislature and within NINDS.

For more information on NINDS activities, please go to http://www.ninds.nih.gov/index.htm.



Medical Liability Reform Update

Health Coalition on Liability and Access

The Health Coalition on Liability and Access, of which Katie Orrico is Vice Chair and Chair of its Legislative Committee, has planned for an active year. Information about HCLA and the *Protect Patients Now* initiative is available at http://bit.ly/114rbdH. HCLA's Legislative Agenda includes the following:

- Maintaining support for the HEALTH Act as the fundamental basis of proven medical liability reform. The HEALTH Act has a hard \$250,000 cap.
- Adopting additional reforms -- liability protections for volunteers, pretrial screening, certificate
 of merit, expert witness, protection for physicians following practice guidelines -- to
 complement the HEALTH Act and which may garner bipartisan support.
- Promoting modifications to the ACA including: Amending the medical liability reform demonstration project language and adding new language stating that nothing in the Act shall create new causes of action.
- Monitoring efforts to repeal the antitrust exemption for medical liability insurers.

Congressional Activities

Efforts to reform the medical legal system have been a high priority for the 113th Congress, as evidenced by the fact that Rep. Phil Gingrey, MD (R-GA) has not yet reintroduced the HEALTH Act. Nevertheless, a number of bills have been introduced so far this year. They include:

House

- H.R. 36, the Health Care Safety Net Enhancement Act of 2013, was introduced by Reps.
 Charlie Dent (R-PA) and Pete Sessions (R-TX) on Jan. 3, 2013. The bill currently has 65 cosponsors, including four democrats. This bill provides medical liability protections to all physicians that provide EMTALA-related emergency care. This would include physicians who initially see the patient upon arrival at an emergency department to physicians who provide stabilization and post-stabilization services, including surgery. The bill would provide protection by moving these physicians under the protection of the Federal Tort Claims Act.
- H.R. 1473, the Standard of Care Protection Act, was introduced by Reps. Phil Gingrey (R-GA) and Henry Cuellar (D-TX) on April 30, 2013. The bill has 16 cosponsors, but the language has been included in the tri-committee SGR replacement legislation (S. 2000/H.R. 4015). Medicare, the Patient Protection and Affordable Care Act and other federal healthcare programs create quality measures and payment methodologies, which may have the potential for expanding the risk of lawsuits against medical providers despite the fact that these guidelines were never intended to measure negligence. This legislation would help ensure laws regarding federal healthcare programs are not used, outside their intended purpose, to create new standards of care for medical liability lawsuits.
- H.R. 1733, Good Samaritan Health Professionals Act, was introduced by Rep. Marsha Blackburn (R-TN) on April 25, 2013. It has 16 cosponsors. This bill would provide medical liability protections for physicians who provide volunteer medical services during a disaster.
- H.R. 3722, was introduced by Rep. Tom Latham (R-IA) on December 12, 2013. This sports
 medicine medical liability reform bill would provide protections for certain sports medicine
 professionals who provide medical services in a secondary state. These professionals would

- be covered by their malpractice insurance, and if any lawsuit were filed, the laws in their states would apply.
- Reps. Andy Barr (R-KY) and Ami Bera, MD (D-CA) are working on legislation that would
 provide physicians who follow practice guidelines some protections from lawsuits. The bill is
 still undergoing refinement, and is expected to be introduced in the upcoming month or so.

Senate

- S. 44, the Medical Care Access Protection Act of 2013, was introduced by Sen. Rob Portman (R-OH). This bill adopts a "stacked cap" approach, similar to that in place in Texas. It has 2 cosponsors.
- S. 961 the Health Care Safety Net Enhancement Act of 2013, was introduced by Reps. Charlie Dent (R-PA) and Pete Sessions (R-TX) on May 15, 2013. The bill currently has two co-sponsors. This bill provides medical liability protections to all physicians that provide EMTALA-related emergency care. This would include physicians who initially see the patient upon arrival at an emergency department to physicians who provide stabilization and post-stabilization services, including surgery. The bill would provide protection by moving these physicians under the protection of the Federal Tort Claims Act.
- S.1769, the Standard of Care Protection Act, was introduced by Reps. Pat Toomey (R-PA) and Tom Carper (D-DE) on November 21, 2013. but the language has been included in the tricommittee SGR replacement legislation (S. 2000/H.R. 4015). Medicare, the Patient Protection and Affordable Care Act and other federal healthcare programs create quality measures and payment methodologies, which may have the potential for expanding the risk of lawsuits against medical providers despite the fact that these guidelines were never intended to measure negligence. This legislation, like its companion in the House, would help ensure laws regarding federal healthcare programs are not used, outside their intended purpose, to create new standards of care for medical liability lawsuits.

State Activities

California

The trial lawyers have filed a proposed ballot measure that would increase MICRA's cap on speculative, non-economic damages from \$250,000 to more than \$1.1 million. A broad-based coalition is fighting against this effort. More information is available at: http://www.micra.org/.

Federal Rules Initiative

The AANS and CNS, along with the AMA and a handful of other medical specialties, have been working with Professors Kenneth Lazarus and Paul Rothstein of Georgetown University Law Center on the Federal Rules Initiative Group. This initiative is an effort to protect the litigating interests of physicians. Amendments to the Federal Rules impact federal court cases and also generally serve as a model for state rule enactments. Recent changes were made governing the discovery of expert testimony and the utilization of summary judgment remedies.

Miscellaneous

Medical Liability Report

The 2014 edition of "Medical Liability Reform – Now!" is now available online at www.ama-assn.org/go/mlrnow. "Medical Liability Reform – Now!" provides medical liability reform (MLR) advocates with the information you need to advocate for and defend MLR legislation. It includes background on the problems with the current system, proven solutions to improve the liability climate and a discussion of innovative reforms that could complement traditional MLR provisions.

National Practitioner Data Bank

The National Practitioner Data Bank is doing a study on medical liability issues for hospitals and reporting back next fall.

Agency for Healthcare Research and Quality

The AHRQ patient safety and medical liability demo programs have wrapped up and there will be a report soon. The planned next step is to create a national framework for a communication and resolution program. It will not be done legislatively, nor will it need funding. It's more of a best practices model – not a requirement. This will be completed in early fiscal year 2015 and the focus is on hospitals not physicians.

Health Affairs

The January issue of *Health Affairs* included a cluster of papers exploring alternatives to malpractice litigation. This cluster was supported by a grant from Ascension Health. These papers reflect a research-based effort, administered through the Agency for Healthcare Research and Quality (AHRQ), to identify new approaches to litigation. *Health Affairs* is subscription based (www.healthaffairs.org). Below are the abstracts:

- How Policy Makers Can Smooth The Way For Communication-And- Resolution Programs. Communication-and-resolution programs (CRPs) in health care organizations seek to identify medical injuries promptly; ensure that they are disclosed to patients compassionately; pursue timely resolution through patient engagement, explanation, and, where appropriate, apology and compensation; and use lessons learned to improve patient safety. CRPs have existed for years, but they are being tested in new settings and primed for broad implementation through grants from the Agency for Healthcare Research and Quality. These projects do not require changing laws. However, grantees' experiences suggest that the path to successful dissemination of CRPs would be smoother if the legal environment supported them. State and federal policy makers should try to allay potential defendants' fears of litigation (for example, by protecting apologies from use in court), facilitate patient participation (for example, by ensuring access to legal representation), and address the reputational and economic concerns of health care providers (for example, by clarifying practices governing National Practitioner Data Bank reporting and payers' financial recourse following medical error).
- Communication-And-Resolution Programs: The Challenges And Lessons Learned From Six Early Adopters. In communication-and-resolution programs (CRPs), health systems and liability insurers encourage the disclosure of unanticipated care outcomes to affected patients and proactively seek resolutions, including offering an apology, an explanation, and, where appropriate, reimbursement or compensation. Anecdotal reports from the University of Michigan Health System and other early adopters of CRPs suggest that these programs can substantially reduce liability costs and improve patient safety. But little is known about how these early programs achieved success. We studied six CRPs to identify the major challenges in and lessons learned from implementing these initiatives. The CRP participants we interviewed identified several factors that contributed to their programs' success, including the presence of a strong institutional champion, investing in building and marketing the program to skeptical clinicians, and making it clear that the results of such transformative change will take time. Many of the early CRP adopters we interviewed expressed support for broader experimentation with these programs even in settings that differ from their own, such as systems that do not own and control their liability insurer, and in states without strong tort reforms.
- Implementing Hospital-Based Communication-And-Resolution Programs: Lessons Learned In New York City. In 2010 five New York City hospitals implemented a communication-and-

resolution program (CRP) in general surgery. The program's goals were to improve reporting of serious adverse events to risk management, support clinical staff in discussing these events with patients, rapidly investigate why injuries occurred, communicate to patients what was discovered, and offer apologies and compensation when the standard of care was not met. We report the hospitals' experiences with implementing the CRP over a twenty-two-month period. We found that all five hospitals improved disclosure and surveillance of adverse events but were not able to fully implement the program's compensation component. These experiences suggest that strong support from top leadership at the hospital and insurer levels, and adequate staff resources, are critical for the success of CRPs. Hospitals considering adopting a CRP should ensure that their organizations can tolerate risk, their leaders are willing to reinforce CRP implementation, and resources are in place to educate clinical staff about how the program can benefit them.

- Ascension Health's Demonstration Of Full Disclosure Protocol For Unexpected Events During Labor And Delivery Shows Promise. Communicating openly and honestly with patients and families about unexpected medical events—a policy known as full disclosure—improves outcomes for patients and providers. Although many certification and licensing organizations have declared full disclosure to be imperative, the adoption of and adherence to a full disclosure protocol is not common practice in most clinical settings. We conducted a case study of Ascension Health's implementation of a full disclosure protocol at five labor and delivery demonstration sites. Twenty-seven months after implementation, the rate of full disclosure had increased by 221 percent. Practitioners saw insurers' acceptance of the full disclosure protocol, consistent and ongoing leadership by local practitioners and hospitals, the establishment of a well-trained local investigation and disclosure team, and disclosure training for practitioners as key catalysts for change. Lessons learned from this multisite initiative can inform liability insurers and guide providers who are committed to ensuring that full disclosure becomes the only response to unexpected medical events.
- Structuring Patient And Family Involvement In Medical Error Event Disclosure And Analysis. The study of adverse event disclosure has typically focused on the words that are said to the patient and family members after an event. But there is also growing interest in determining how patients and their families can be involved in the analysis of the adverse events that harmed them. We conducted a two-phase study to understand whether patients and families who have experienced an adverse event should be involved in the post event analysis following the disclosure of a medical error. We first conducted twenty-eight interviews with patients, family members, clinicians, and administrators to determine the extent to which patients and family members are included in event analysis processes and to learn how their experiences might be improved. Then we reviewed our interview findings with patients and health care experts at a one-day national conference in October 2011. After evaluating the findings, conference participants concluded that increasing the involvement of patients and their families in the event analysis process was desirable but needed to be structured in a patient-centered way to be successful. We conclude by describing when and how information from patients might be incorporated into the event analysis process and by offering recommendations on how this might be accomplished.
- Let's Make A Deal: Trading Malpractice Reform For Health Reform. Physician leadership is required to improve the efficiency and reliability of the US health care system, but many physicians remain lukewarm about the changes needed to attain these goals. Malpractice liability—a sore spot for decades—may exacerbate physician resistance. The politics of malpractice have become so lawyer-centric that recognizing the availability of broader gains from trade in tort reform is an important insight for health policy makers. To obtain relief from malpractice liability, physicians may be willing to accept other policy changes that more directly improve access to care and reduce costs. For example, the American Medical Association might broker an agreement between health reform proponents and physicians to enact federal legislation that limits malpractice liability and simultaneously restructures fee-for-service payment,

heightens transparency regarding the quality and cost of health care services, and expands practice privileges for other health professionals. There are also reasons to believe that tort reform can make ongoing health care delivery reforms work better, in addition to buttressing health reform efforts that might otherwise fail politically.

• Greatest Impact Of Safe Harbor Rule May Be To Improve Patient Safety, Not Reduce Liability Claims Paid By Physicians. "Safe harbor" legislation that provides liability protection to physicians when they follow designated guidelines is often proposed as a way to reform the malpractice system while improving patient safety. However, published evidence provides little policy guidance on implementing safe harbors. With the support of an Agency for Healthcare Research and Quality planning grant, we conducted an empirical analysis of closed liability claims in Oregon to determine the potential effects of hypothetical safe harbor legislation. We found that such legislation would have changed the liability outcome in favor of the physician defendant in only 1 percent of 266 claims from the period 2002–09 that we reviewed. Nevertheless, if safe harbors can induce greater physician adherence to care guidelines, they have the potential to improve patient safety. Implementing safe harbor legislation, however, requires overcoming a number of hurdles, including selecting and updating approved guidelines, obtaining broad stakeholder support, and withstanding challenges to the legal validity of the legislation. More experimentation with safe harbors is needed to determine their effects on the performance of the liability system and on health care quality and costs.



Neurosurgical Education and Training

Regulatory Activity

IOM Study on Governance and Financing of Graduate Medical Education

Pursuant to a Congressional request in December 2011, the Institute of Medicine has embarked on a review of the GME system. An IOM committee will: (1) assess current regulation, financing, content, governance, and organization of U.S. graduate medical education (GME) and (2) recommend how to modify GME to produce a physician workforce for a 21st century U.S. health care system that provides high quality preventive, acute, and chronic care, and meets the needs of an aging and more diverse population. The study began June 1, 2012 and will conclude 16 months from this date.

The report has been delayed and is now scheduled for release in May 2014 (or thereabouts). Information about the study is available at: http://bit.ly/HMpyZf.

Government Accountability Office (GAO) Studies

Requested by Sens. Tom Coburn (R-OK), Michael Enzi (R-WY) and Richard Burr (R-NC), the GAO is conducting two studies related to GME and workforce.

The first report was released on August 15, 2013 and is entitled: *Health Care Workforce: Federally Funded Training Programs in Fiscal Year 2012*. The report catalogues all the federally funded training programs for health care providers for FY 2012. It is available at: http://l.usa.gov/1bno1IN.

The second report is entitled: *HRSA Action Needed to Publish Timely National Supply and Demand Projections*. This report examines the actions the Health Resources and Services Administration has taken to project the future supply of and demand for physicians, physician assistants, and advanced practice registered nurses since publishing its 2008 report. It is available at: http://l.usa.gov/Ns1kJL.

Letter Sent to OMB in Support of Pediatric Subspecialty Loan Repayment Program

In January, the AANS/CNS, along with 33 other aligned national organizations, sent a letter to the Director of the Office of Management & Budget (OMB), Sylvia Mathews Burwell, to ask that \$5 million in funding for the Pediatric Subspecialty Loan Repayment Program be included in President Obama's Fiscal Year 2015 budget. Passed as a part of the Affordable Care Act, the law authorizes \$30 million annually as a financial incentive for students to choose careers in a pediatric medical subspecialty by agreeing to give these specialists \$35,000 in school loan repayments for each year of service in a health professional shortage area. Unfortunately, no funding was appropriated in the FY 2014 Omnibus law.

COGME Seeks Nominations

The Health Resources and Services Administration (HRSA) is seeking nominations of qualified individuals for appointment to the Council on Graduate Medical Education (COGME). COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs.

Under the authorities that established the COGME and the Federal Advisory Committee Act, HRSA is seeking individuals with the qualifications to represent one or more of the following categories:

- Practicing Primary Care Physicians
- Specialty Physician Organizations
- Foreign Medical Graduates
- Medical Student Associations
- Schools of Osteopathic Medicine
- Private Teaching Hospitals
- Business
- Health Insurers

Organized neurosurgery, led by the Society of Neurological Surgeons, will be nominating Nate Selden, MD for a position on COGME. Nominations are due by March 31, 2014.

Legislation

Legislation to Provide Additional Residency Slots Gains Co-Sponsors

On March 14, 2013 Reps. Aaron Schock (R-IL) and Allyson Schwartz (D-PA) re-introduced H.R. 1201, the Training Tomorrow's Doctors Today Act. The bill currently has 52 co-sponsors. Additionally, S. 577, the Resident Physician Shortage Reduction Act, was also introduced on March 14 in the Senate by Sens. Bill Nelson (D-FL) and Charles Schumer (D-NY) and has 12 co-sponsors. The companion bill, H.R. 1180, was introduced in the House by Reps. Joseph Crowley (D-NY) and Michael Grimm (R-NY) and has 91 co-sponsors.

Capped in 1997 by the Balance Budget Act, this legislation would increase the number of Medicare supported residency positions by 3,000 each year for the next five years for a total of 15,000 new residency slots. One-half of these positions are required to be used for shortage specialty residency programs, of which neurosurgery qualifies.

GME funding continues to be a potential target for budget savings or to help pay for the repeal of the SGR.

Workforce Grant Program Legislation Introduced

On June 12, 2013, Sens. Jack Reed (D-RI) and Roy Blunt (R-MO) introduced S. 1152, the Building a Health Care Workforce for the Future Act. The bill has two cosponsors. This legislation would strengthen the healthcare workforce through improving core competencies and providing grants to states for medical scholarship programs to encourage health professionals to stay and practice in the state. Importantly, the legislation recognizes the shortage of specialty physicians (as well as primary care physicians). For this reason, the AANS and CNS, through our participation in the Alliance of Specialty Medicine, supported this legislation. A copy of the letter is available at: http://bit.ly/17ITE2g.

Senate Committee Approves Children's Hospital GME Bill

On Nov. 12, 2013, by unanimous consent, the Senate passed S. 1557, the Children's Hospital GME Support Reauthorization Act of 2013. The bill would reauthorize the Children's Hospital Graduate Medical Education Payment Program for five years at \$300 million per year. The program provides funding to help train pediatricians and other residents at approximately 55 freestanding children's hospitals in 30 states. These hospitals train more than 45 percent of general pediatricians, 51 percent of pediatric specialists, and the majority of pediatric researchers. A similar measure passed the House of Representatives on Feb. 4, 2013, by a vote of 352 to 50.

The bill has gone back to the House for consideration, as the Senate version has a handful of minor differences than the version passed by the House.

Effort to Prevent GME Cuts Continues

The AANS and CNS continue to work with the AAMC and the GME coalition to prevent cuts in GME funding. To this end, on November 20, 2013, over 40 organizations <u>sent a letter</u> to the Senate stating in part:

As you work to address the federal budget, Medicare physician payment reform, and sequestration, we strongly urge you to protect Medicare beneficiary access to health care services by preserving existing Medicare financing for Graduate Medical Education (GME). We recognize the need to take action to ensure the long-term fiscal stability of our nation. However, we are gravely concerned that reductions in Medicare support for GME would worsen an already critical national physician workforce shortage and limit teaching hospitals' ability to maintain vital, life-saving services, such as 24-7 trauma and burn units that often are unavailable elsewhere in communities.

We will continue to resist efforts to use GME funds to finance other federal programs or for deficit reduction.

Neurocritical Care

Despite repeated written and verbal requests over the past 3 years, Leapfrog has, until recently, refused to meet with representatives from organized neurosurgery to discuss their neurocritical care standards. Frustrated with this lack of response, this summer, the AANS' attorney sent another letter to Leapfrog, noting that the current Leapfrog policy is anticompetitive under the Sherman Antitrust Act and also raises serious patient safety issues. We once again requested an opportunity to meet with Leapfrog to address its current policy to our mutual satisfaction.

Leapfrog finally responded and directed neurosurgery to submit an official "Leapfrog Refinement" form, which we did. On Feb. 24, 2014, a delegation from neurosurgeon, including Bob Harbaugh, MD, Josh Medow, MD, Shelly Timmons, MD, Alex Valadka, MD, Chris Zacko, MD and Katie Orrico, met with representatives of the Leapfrog Group at John's Hopkins University. The meeting was extremely productive, and barring some unforeseen problem, we are cautiously optimistic that our proposed changes to the Neuro ICU Leap will be accepted. The timeline for action is as follows:

- March 2014: Neurocritical Care Scientific Committee meets; Dr. Peter Pronovost will recommend that the committee adopt our suggested revisions
- November 2014: Revised Leap will be published for 30-day comment period
- January 2015: Revised Leap will be pilot tested among 25-30 hospitals for a 30-day period
- April 2015: Revised Leap will go into effect



AMA Update

AMA Delegation

Because neurosurgical membership in the AMA dropped below 1,000, the AANS lost one of its delegate/alternate positions in the AMA House of Delegates. Our current delegation is thus:

Maya Babu, MD, AMA Board of Trustees (Resident/Fellow member)
Philip W. Tally, MD, CNS Delegate (Neurosurgery Delegation chair)
John K. Ratliff, MD, AANS Delegate
Zachary N. Litvack, MD, CNS Alternate Delegate/Young Physician Delegate
Ann R. Stroink, MD AANS Alternate Delegate
Krystal L. Tomei, MD, AANS Young Physician Delegate

AMA Elections

Dr. Tally is running for a seat on the AMA's Council on Medical Service (CMS), which serves a very specific and important role within the AMA by studying and evaluating the social and economic aspects of medical care. Through its reports, the CMS recommends AMA policies and actions for consideration by the AMA House of Delegates on the socioeconomic factors that influence the practice of medicine. This 11-member council is elected by members of the House of Delegates. Drs. Ann Stroink and John Ratliff are serving as Dr. Tally's campaign co-chairs, and Katie Orrico will provide staff support. At the November meeting, Dr. Tally received important endorsements by the Specialty and Service Society (SSS) and the Neuroscience Caucus and just recently received an endorsement of the Young Physician Section of the AMA.

Communications and Public Relations Update





Administrative Issues

The goal of the Communications and Public Relations (CPR) Committee is to provide a strategic, formalized process to coordinate and prioritize Washington Committee/Office communications and public relations efforts.

Committee Members

Deborah Benzil, MD, Chair

Cory Adamson, MD (Young Neurosurgeons)
Peter Angevine, MD (Coding and Reimbursement)
Tony Asher, MD (NeuroPoint Alliance)
Deborah Benzil, MD (AANS Neurosurgeon)
Rick Boop, MD (Journal of Neurosurgery)
Sander Connelly, MD (Neurosurgery)
William Curry, MD (Tumor Section)
Art Day, MD (Society of Neurological Surgeons)
Rick Fessler, MD (Drugs and Devices Committee)
James Harrop, MD (CNS Quarterly)
Jason Hauptman, MD (CSNS Resident Fellow)
Kathryn Holloway, MD (Stereotactic Section)
Rashid M. Janjua, MD

Staff Liaison:

Alison Dye, Sr. Manager for Communications

Jack Knightly, MD (QIW)
Alon Mogilner, MD (Pain Section)
David Okonkwo, MD (Trauma Section)
Julie Pilitsis (CSNS Newsletter)
Brian Ragel, MD (CNS)
Clemens Schirmer, MD, PhD
Gary Simonds, MD (CSNS)
Mike Steinmetz, MD (Spine Section)
Brian Subach, MD (AANS)
Shelly Timmons, MD (Emergency NS Task Force)
Craig Van der Veer, MD (NeurosurgeryPAC)
Christopher Winfree, MD (Guidelines Committee)

Ex-Officio:

John Wilson, MD (WC, Chair) William Couldwell, MD (AANS President) Daniel Resnick, MD (CNS President)

Communication Activities

New CPR Chair, Deborah Benzil, MD, Calls for Guest Blog Posts

As previously reported, Deborah L. Benzil, MD, FAANS, was recently appointed to serve as the new chair of the CPR Committee. Dr. Benzil, who serves as the *AANS Neurosurgeon* liaison to the CPR, and is the current associate editor for *AANS Neurosurgeon*, has an extensive communication background and has already begun to take the committee to the next level.

One of the purposes of our social media platforms is to serve as an echo chamber for neurosurgical initiatives and achievements by creating a nexus where policy meets practice. In an effort to enhance this idea and grow our readership, Dr. Benzil has been reaching out to individuals to garner much needed guest blog posts. To this end, if you willing to author a blog post, have one you would like us to consider, or if you have had an op-ed published, we would welcome the opportunity to place those types of pieces on Neurosurgery Blog.

Entering the World of Video

Over 80 percent of all internet user watch online video clips. Furthermore, <u>statistics show</u> that videos are over 6 times more effective than print. To this end, as part of our ever-growing digital advocacy strategy, we will be working diligently to build an online video presence. Multimedia content will help us develop a more personal and meaningful connection with viewers. This important step will allow for organized neurosurgery campaigns to take complex issues and make them relevant to a large audience in order to make a difference in the outcome of a policymaking process. Starting at the CSNS meeting in April we will be executing this concept by videotaping short interview segments with key physician leaders on various topics. Additionally, we are also investigating the idea of producing high quality content much like the Texas Medical Association's video, "<u>Grandma and the Big Bad SGRI</u>," which would be centered around top legislative issues.

Neurosurgery Blog 2013 Year in Review

Each week, Neurosurgery Blog is updated on a regular basis and reports on how healthcare policy affects patients, physicians and medical practice and to illustrate that the art and science of neurosurgery encompasses much more than brain surgery. As of February 18, 2013, we have disseminated 78 blog posts on topics including the SGR, the Independent Payment Advisory Board (IPAB), medical liability reform, and health reform in general. Since our last CPR report in December, the following new blog posts have been published:

- Neurosurgeons Making Headlines on Spine Care
- CNS Spotlight: 2014 Winter Congress Quarterly Released
- Death and the Doctor: Under-valued Skills
- All I Wanted for Christmas!
- "Nuclear Option" Only Adds a Can of Worms to the IPAB Debate

In 2013, we addressed a variety of topics on Neurosurgery Blog. The following posts represent the top five blogs of the year based on number of views:

- Ms. Sanger-Katz: Come Spend a Week in My Scrubs
- The Primary Care Shibboleth: Debunking the Myth
- Budget Sequestration Hits Neurosurgeons
- AANS Spotlight: AANS Neurosurgeon Highlights Personal Stories of Humanitarian Neurosurgery
- IOM Releases New Report on Sports Concussion in Youth

We invite you to visit the blog and subscribe to it, as well as connect with us on our various social media platforms list below, so that you can keep your pulse on the many health-policy activities happening in the nation's capital and help promote our digital efforts.

- Neurosurgery Blog: More Than Just Brain Surgery www.neurosurgeryblog.org
- Neurosurgery's Twitter Feed: @Neurosurgery https://twitter.com/neurosurgery
- Neurosurgery's Facebook Page http://bit.ly/NeuroFacebook
- Neurosurgery's LinkedIn Group http://bit.ly/NeuroLinkedIn

Reaching Millions of Key Health Policy Influencers Online

Neurosurgery's Washington office continues to use social media platforms to expand the reach of its message by reaching key health policy influencers online. Our new media tools serve as a conduit to deliver two types of communiqués: (1) neurosurgery's positions on key health policy issues, and (2) news about neurosurgery that could range from op-eds to endeavors in new medical innovations to bring greater attention to the achievements of, and issues facing, the AANS and CNS. Recently, organized

neurosurgery reached millions of influencers when Forbes re-tweeted a question we posed during a healthcare reform Twitter chat. As a result, our question was re-tweeted nineteen times, including by Forbes contributors Avik Roy and Rick Ungar, and reached an audience of 2,138,430 people within a day. As of February 18, 2013, organized neurosurgery has amassed an external subscriber audience of 6,054 across all of our online communications platforms. Click here, for a complete list of individuals we have engaged with on Twitter.

Traditional Media Outreach

In addition to aforementioned new media efforts, the DC office continues to implement traditional media/communication efforts including Op Eds, letters to the editor, radio "tours" and desk side briefings with reporters. As such, we have been able to generate media hits in the following outlets:

- American Medical News
- Becker's ASC Review
- Becker's Spine Review
- British Medical Journal
- Bureau of National Affairs (BNA)
- California Healthline
- Diane Rehm Show
- The Hill
- Health Leaders Media
- Inside Health Policy

- Inside CMS
- MedPage Today
- medwire News
- NBC News
- The Plain Dealer
- Politico
- Portland Business Journal
- The Salt Lake Tribune
- The Wall Street Journal
- The Washington Post

Since December 2012, the Washington Office has generated 72 traditional media hits reaching a circulation/audience of 6.2 million. One of these aforementioned hits occurred on Dec. 12, 2013, when **Brian R. Subach**, MD, FAANS, a practicing spine-neurosurgeon from northern Virginia, was invited to serve as a panelist on National Public Radio's (NPR's) <u>Diane Rehm Show.</u> The program, "<u>Concerns About The Increase In Spinal Fusion Surgery.</u>" was an outgrowth of an article in <u>The Washington Post</u> and subsequent <u>letter to the editor</u> that Dr. Subach submitted. The Washington Office assisted Dr. Subach with his op ed and preparation for the radio program. As a reminder, for individuals who want to keep tabs on our media outreach please visit our <u>Press Room</u> on the website. There you will find our statements and releases, letters to the editor, and media hits.

Member Outreach

The AANS and CNS have continued to update our members by disseminating a monthly DC enewsletter to better inform them of key health policy activities happening in Washington. To date, we have we have produced twenty three "Neurosurgeons Taking Action" newsletters, which reach a distribution list of 10,350 individuals and covered a variety of topics including the Independent Payment Advisory Board (IPAB), replacing the sustainable growth rate (SGR) formula, and a host of other topics of concern to organized neurosurgery. Accessing past issues is easy as they are archived directly on the AANS website and are available at: http://bit.ly/MgL646. Additionally, the DC office regularly submits items to AANS and CNS for website postings and continues to provide content for AANS and CNS newsletters and publications and. Since our last report, we have contributed to the following items:

- CNS Winter Congress Quarterly "Working for You in Washington"
- February AANS Neurosurgeon "Washington Watch" article

CNS Website Update

Currently, the Washington Office communications staff is working with the CNS headquarters staff to update the legislative activities pages of the CNS website. Among other things, changes will entail a complete revamp of the Washington Office section on the CNS website including archiving old materials

by year and only having 2013 content on the main pages, renaming and adding new navigation sidebars to better reflect our activities, adding links to our blog and social media platforms, and enhancing our pages with key links and introductory copy to provide viewers with context as to what each page offers. Once this project is completed, we will send out a notice in our monthly e-newsletter communications.

Coalition Efforts

• The Alliance of Specialty Medicine and Health Coalition on Liability and Access. The AANS and CNS have continued to work closely with other healthcare organizations, including the Alliance of Specialty Medicine (Alliance), the Health Coalition on Liability and Access (HCLA) to provide assistance in promoting those organizations and/or their health policy and advocacy to the media. Past Washington Committee Chairman, Alex Valadka, serves as the spokesperson for the Alliance and is also called on by HCLA to speak on the topic of medical liability reform. Washington Office staff member, Alison Dye, also serves as HCLA's communications chair.

Working with these groups, we have been able to generate media hits in the following outlets:

- American Medical News
- The Congressional Quarterly
- CQ Healthbeat
- FierceHealthcare
- Health Affairs
- Inside Health Policy

- MedPage Today
- Modern Healthcare Magazine
- Modern Physician
- Roll Call
- The Hill

Since our December report, we have garnered multiple media hits. All of which, have been stories regarding the ongoing SGR repeal process.

Partners for Healthy Dialogues. Organized neurosurgery has continued to participate with the
Partners for Healthy Dialogues campaign, an initiative aimed at educating physicians and patients
about the Sunshine Act and the benefits of appropriate industry and physician interaction and
collaboration. As part of our ongoing efforts, we regularly publish educational material on our social
media platforms and participate in monthly outreach calls. Additional details can be found at:
http://bit.ly/GXAZR4.

Accomplishments

Making Progress

Neurosurgery continues to see a significant expansion of its digital media outreach. This highly effective online echo chamber, allows us the ability to share neurosurgery news and AANS/CNS health policy positions to a growing audience of healthcare media and key policy influencers in a very rapid manner. Listed below are some key metrics pertaining to neurosurgery's digital media efforts:

- From March 15, 2012 to Feb. 15, 2014, Neurosurgery's Twitter has "touched" 7,283,651 million twitter users with its communications.
- From Sept. 15, 2012 to Feb. 15, 2014, Neurosurgery generated 29,208 hits via its bit.ly links.
- From Sept. 10, 2012 to Feb. 15, 2014, Neurosurgery Blog has garnered 17,295 hits.
- From Oct. 15, 2012 to Feb. 15, 2014, Neurosurgery's Facebook page has "touched" 247,816 Facebook users with its communications.
- From Oct. 15, 2012 to Feb. 15, 2014, Neurosurgery's LinkedIn Group has "touched" 22,984 LinkedIn users with its communications.

PR Success Stories

 Making Millions of Digital Media impressions. To date, neurosurgery's digital media communications platforms reached nearly 7.6 million individual impressions. This number takes on great significance with the understanding that neurosurgery doesn't market its social media messages to a broad, national audience but rather to a targeted audience of media, Capitol Hill staff and policy influencers.

- Thousands of influencers can be reached with just one "tweet." When Roll Call Newspaper tweeted out a Guest Opinion piece by our own Alex Valadka, MD, on Twitter, the article was retweeted 10 times by key health policy influencers, including House Speaker John Boehner (R-OH), and reached an audience of 297,525 people within a day.
- Washington Office Health Policy E-Newsletter Disseminated to Thousands. Every month, the
 Washington Office disseminates a health policy newsletter to better inform them of our key health
 policy activities happening in DC. As of February 18, 2014, we have we have produced twenty three
 "Neurosurgeons Taking Action" newsletters which reach a distribution list of 10,350 individuals each
 month.
- Neurosurgery priority issues can be disseminated rapidly to large audiences. The AANS and CNS reached millions of influencers when Forbes re-tweeted a question we posed during a health reform Twitter chat. As a result, our question was re-tweeted nineteen times, including by Forbes contributors Avik Roy and Rick Ungar, and reached an audience of 2,138,430 people within a day.
- Reaching Millions through traditional Media. Since January 2012, the Washington Office has generated 72 traditional media hits reaching a circulation/audience of 6.2 million. In addition to working alone on these media efforts organized neurosurgery also continues to work closely with other healthcare organizations to provide assistance in promoting those organizations and/or their health policy and advocacy to the media by using neurosurgery spokespersons.

Hypothermia and Human Spinal Cord Injury: Updated Position Statement and Evidence Based Recommendations from the AANS/CNS Joint Section on Disorders of the Spine Peripheral Nerves

John E. O'Toole, Marjorie C. Wang, and Michael G. Kaiser

Recommendation:

Grade I - There is insufficient evidence to recommend for or against the practice of either local or systemic therapeutic hypothermia as a treatment for acute spinal cord injury.

Grade C - There is level IV evidence based on one retrospective comparative cohort study and one prospective cohort study to suggest that systemic modest hypothermia might be applied safely to this population.

Future Directions for Research:

Further research is essential to determine if the preclinical promise of systemic hypothermia for acute spinal cord injury can be realized in humans. If prospective randomized controlled trials prove too challenging to conduct in this patient population, prospective comparative cohort studies (ideally at multiple centers) should be conducted to define the effectiveness and safety of this intervention.

Background:

Both local and systemic hypothermia have been of interest for decades as potential therapies for acute spinal cord injury (SCI). ^{1,2} In 2007 the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) Joint Section on Disorders of the Spine and Peripheral Nerves and Joint Section on Trauma released a position statement and evidence-based review on hypothermia after SCI. ⁷ In that review, Resnick et al found a lack of evidence to either support or refute the use of local or systemic hypothermia for acute SCI in humans. The reviewers advocated for controlled clinical trials investigating the safety and efficacy of this intervention prior to its adoption in clinical practice. In an effort to keep the position statement current, an *ad hoc* committee was formed to generate an updated evidence-based recommendation founded upon a review of the literature from the intervening time period since the 2007 statement.

Methodology:

Literature Search:

A computerized search of the National Library of Medicine database was performed using PubMed with the search terms "hypothermia AND spinal cord injury." The search was limited to the years 2005 to present since the prior review covered 1965-2005. One hundred and thirty-one references were obtained. The titles and abstracts of

these references were then reviewed, and all publications not pertaining to the clinical use of hypothermia after acute SCI in humans were eliminated including laboratory, preclinical, and vascular surgical reports. Only papers published in English were included. Case series and case reports as well as systematic reviews/meta-analyses were included, but general review papers were excluded. The bibliographies of selected papers were also reviewed for additional references. This yielded four publications of relevance.

Grading of the Evidence and Elaboration of Recommendations:

Publications were graded according to the attached Levels of Evidence for Therapeutic Studies (Table 1) similar to that used by the North American Spine Society and other professional societies. Each member of the committee individually graded the publications and these grades were then compared. Differences were adjudicated by discussion and consensus voting. These grades were then synthesized with the evidence from the 2007 position statement to elaborate a recommendation using the attached guide (Table 2).

Scientific Foundation of Recommendation:

The four new publications included one case report, one retrospective feasibility case series, one retrospective comparative case series and one pooled retrospective and prospective case series. ³⁻⁶ The details and critique of the evidence can be found in the attached evidentiary table (Table 3).

Briefly, the case report from Cappuccino et al ³ described the treatment of a professional football player who sustained a blunt cervical SCI (ASIA A) during play that was treated with systemic hypothermia one day after undergoing anterior-posterior decompression and fusion for C3-4 dislocation. He eventually recovered to ASIA D by four months postoperatively, and the authors felt the degree of recovery was more than would be expected in the absence of hypothermia. Unfortunately, this single case example (level IV evidence) provides inadequate evidence to judge the safety or efficacy of hypothermia in this clinical situation.

The remaining three studies were all published from the same institution and all included the same retrospectively reviewed cohort of 14 patients with complete (ASIA A) acute cervical SCI treated with operative decompression and stabilization followed by 48 hours of modest (32-34°C) systemic hypothermia via an intravascular cooling catheter. ⁴⁻⁶ The first report from Levi et al in 2009 ⁶ was a technical feasibility and early safety study that provides level IV evidence that the authors' method of hypothermia was reproducible and that systemic hypothermia can be used safely in acute SCI patients.

The second report from Levi et al in 2010 ⁵ examined this same cohort of patients but compared them to a similar group of SCI patients who did not undergo systemic hypothermia in an attempt to establish baseline safety for this intervention. The authors found no statistically significant difference in complications between the groups except for an increased incidence of pleural effusions and anemia in the hypothermia group. The authors concluded that systemic hypothermia for acute SCI is safe and that phase 2 and 3 trials are feasible. This study suffers from limitations, outlined in the evidentiary table

that downgraded its level of evidence to IV. It therefore provides low-level evidence that hypothermia may be applied safely to acute spinal cord injury patients.

The final report from this group, Dididze et al in 2013 ⁴, presented a pooled analysis of the previously reported retrospective cohort of 14 patients with an additional prospectively treated cohort of 21 patients all undergoing systemic hypothermia in which they investigated clinical outcomes and complications. Comparison of pre- and post-treatment ASIA scores at 12 months revealed that 43% of patients improved at least 1 ASIA grade at follow-up (35% when excluding 4 patients that spontaneously improved in first 24 hours). Most common complications were pulmonary, as seen previously. Overall, 14% had venous thromboembolic events (VTE) (24% in prospective group, none in the smaller retrospective cohort). The authors conclude that systemic endovascular hypothermia for cervical acute SCI is safe and results in higher rates of neurological improvement than seen in previously reported population studies on SCI. As with the prior publications, the absence of a true control group precludes the formulation of definitive inferences on the actual safety or efficacy of systemic hypothermia for acute cervical SCI. This study provides low-level (level IV) evidence for the safety of modest systemic hypothermia in this patient population.

Conclusions:

Scientific studies have documented a potential benefit of systemic hypothermia in animal models of acute spinal cord injury; however there remains a paucity of clinical evidence to recommend for or against the practice of either local or systemic hypothermia for acute SCI in humans. The level IV evidence suggesting the safety of modest systemic hypothermia is promising, but controlled, comparative clinical studies investigating safety and efficacy must be performed prior to the introduction of hypothermia in the routine clinical care of patients with acute SCI.

Table 1. Levels of Evidence

	Therapeutic Studies
Level I	 High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic Review of Level I RCTs (and study results were homogenous)
Level II	 Lesser quality RCT (e.g. <80% follow-up, no blinding, or improper randomization) Prospective comparative study Systematic review of Level II studies or Level 1 studies with inconsistent results
Level III	 Case control study Retrospective comparative study Systematic review of Level III studies
Level IV	Case SeriesCase Reports
Level V	Expert Opinion

Table 2. Grades of Recommendation

Grade of Recommendation	Alternate Language	Levels of Evidence		
A	Recommended	Two or more consistent Level I studies		
В	Suggested	One Level I study with additional supporting Level II or III studies	Two or more consistent Level II or III studies	
С	May be considered; is an option	One Level I, II or III study with supporting Level IV studies	Two or more consistent Level IV studies	
I (Insufficient or Conflicting Evidence)	Insufficient evidence to make recommendation for or against	A single Level I, II, III or IV study without other supporting evidence	More than one study with inconsistent findings*	

Table 3. Evidentiary Table on Hypothermia and Spinal Cord Injury, 2005-2013

Authors and Year	Description of Study	Comments	Class
Levi et al, J Neurotrauma 2009	Retrospective case series on a subset of patients in a single-institution phase 1 feasibility study for modest (32-34°C) hypothermia in patients with complete (ASIA A) blunt traumatic spinal cord injury (SCI). A total of 14 patients with cervical SCI were included. All patients underwent operative decompression/stabilization. No patient received steroids. An intravascular cooling catheter in the femoral vein was used for 48 hours of cooling. Outcomes included temperature control and complications. Temperature was well controlled using the catheter. Complications included: 12/14 atelectasis, 8/14 pneumonia, 2/14 ARDS, 3/14 arrhythmia, 1/14 thrombocytopenia, 1/14 sepsis and 0/14 VTE.	This phase 1 feasibility study was intended to demonstrate the reproducibility of applying hypothermia to acute spinal cord injury patients. The authors provided limited information regarding methodology, including the ascertainment and definition of complications. Heterogeneity of the cohort exists regarding timing of surgery and demographics. No statistical information is provided. Despite these limitations, the study demonstrates the reproducibility of the technique.	IV
Cappuccino et. al., Spine 2010	A case report of a professional football player who sustained a blunt cervical SCI (ASIA A) during play that was treated with systemic hypothermia one day after undergoing anterior-posterior decompression and fusion for C3-4 dislocation. He also received methylprednisolone and iced saline on the field. A femoral vein intravascular cooling catheter was used to induce the modest hypothermia for 48 hours and normothermia for several days after. He demonstrated improvement in motor function to at least anti-gravity strength in the legs. He eventually recovered to ASIA D by four months postop. No complications were noted. The authors felt the degree of recovery was more than would be expected in the absence of hypothermia.	No validated outcome measures. This solitary case example does not allow any conclusions to be drawn regarding the safety or efficacy of systemic hypothermia for traumatic SCI.	IV
Levi et al, Neurosurgery	(Same cohort reported in Levi 2009). Retrospective	Small sample size of cases (possibly	Potential
2010	comparative case series on a subset of patients in a	nonconsecutive) and controls likely	III,

single-institution phase 1 feasibility study for modest makes study underpowered to detect downgraded (32-34°C) hypothermia in patients with complete (ASIA significant differences in complication to IV A) blunt traumatic spinal cord injury (SCI). A total of 14 rates. Confounding the differences in patients with cervical SCI were included. All patients the clinical results are the fact that 3 underwent operative decompression/stabilization. No patients in control group received patient received steroids. An intravascular cooling methylprednisolone and only 50% (vs catheter in the femoral vein was used for 48 hours of 85% in hypothermia group) underwent cooling. Outcomes included pre- and post-treatment early surgery (<24hr). Unclear ASIA scores for 12 months and complications. A cohort methodology for collection and of 14 patients with similar age and SCI treated prior to definition of complications. hypothermia protocol initiation were selected as Heterogeneous group in regards to historical controls for comparison of complications. 6/14 timing of surgery, demographics. This study provides low-level evidence that patients in hypothermia group and 3/14 in control group improved their ASIA score at follow-up (no statistically endovascular systemic hypothermia significant difference). No statistically significant may be applied safely to acute cervical difference in complications except for more pleural SCI patients. effusions and anemia in hypothermia group. The authors conclude that systemic hypothermia for acute SCI is safe and phase 2 and 3 trials are feasible. Pooling of same retrospective cohort of 14 patients from The absence of a control group IV Levi 2009 and Levi 2010 with prospective cohort of 21 precludes the drawing of inferences on the true safety or efficacy of systemic patients at same single-institution for modest (32-34°C) hypothermia after complete (ASIA A) blunt traumatic hypothermia for acute cervical SCI. spinal cord injury (SCI). All patients operative The heterogeneity of the cohort (with decompression/stabilization. No patient received respect to surgical timing and steroids. An intravascular cooling catheter in the femoral demographics), potential nonvein was used for 48 hours of cooling. Outcomes consecutive allocation to treatment. included pre- and post-treatment ASIA scores for 12 and failure to define method of months and complications 43% of patients improved at complication ascertainment makes least 1 ASIA grade (35% when excluding 4 patients that valid comparisons to previously spontaneously improved in first 24 hours). Most published studies difficult. This study common complications were respiratory as seen provides low-level evidence for the previously. Overall, 14% had VTE (24% in prospective safety of systemic hypothermia in this

patient population.

group, none in smaller retrospective cohort). The authors

Dididze et al, Spinal Cord

2013

conclude that systemic endovascular hypothermia for cervical acute SCI is safe and results in higher rates of neurological improvement than seen in previously reported population studies on SCI.

References:

- 1. Ahmad F, Wang MY, Levi AD: Hypothermia for Acute Spinal Cord Injury-A Review. **World Neurosurg**
- 2. Batchelor PE, Skeers P, Antonic A, Wills TE, Howells DW, Macleod MR, et al: Systematic review and meta-analysis of therapeutic hypothermia in animal models of spinal cord injury. **PLoS One 8:**e71317
- 3. Cappuccino A, Bisson LJ, Carpenter B, Marzo J, Dietrich WD, 3rd, Cappuccino H: The use of systemic hypothermia for the treatment of an acute cervical spinal cord injury in a professional football player. **Spine (Phila Pa 1976) 35:**E57-62
- 4. Dididze M, Green BA, Dalton Dietrich W, Vanni S, Wang MY, Levi AD: Systemic hypothermia in acute cervical spinal cord injury: a case-controlled study. **Spinal Cord 51:**395-400
- 5. Levi AD, Casella G, Green BA, Dietrich WD, Vanni S, Jagid J, et al: Clinical outcomes using modest intravascular hypothermia after acute cervical spinal cord injury. **Neurosurgery 66:**670-677
- 6. Levi AD, Green BA, Wang MY, Dietrich WD, Brindle T, Vanni S, et al: Clinical application of modest hypothermia after spinal cord injury. **J Neurotrauma 26:**407-415, 2009
- 7. Resnick DK, Kaiser MJ, Fehlings M, McCormick PC: Hypothermia and Human Spinal Cord Injury: Position Statement and Evidence Based Recommendations from the AANS/CNS Joint Sections on Disorders of the Spine and the AANS/CNS Joint Section on Trauma, in: AANS/CNS, 2007

2014 AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting Advanced Registration Comparison

Description	1/26/2011	1/18/2012	1/23/2013	1/24/2014	2/2/2011	1/25/2012	1/30/2013	1/31/2014
		1 Week to Cut-off						
	2011	2012	2013	2014	2011	2012	2013	2014
Spine Section Member	151	117	138	105	170	151	153	125
NASS Member	23	6	11	9	25	6	15	12
Orthopedic Surgeon/ACOS Member	4	1	6	12	5	2	6	15
Nonmember	25	25	37	28	36	27	38	37
Non-Physician, Nonmember	1			2	3	1	1	4
Nurse	4	2	4	4	5	5	5	4
Physician Assistant	4	4	9	9	7	5	11	10
Resident	30	14	34	32	31	25	45	39
Medical Student	7	6	11	12	7	6	16	14
Non-Member Faculty	15	3	3	4	16	5	4	4
Brazilian Spine Society				5				5
Chinese Orthopedic Association	1							
SRS Member	Ī			1				1
Total Medical Attendees	264	178	253	222	305	233	294	264

2014 Annual Meeting of the AANS/CNS Section on Disorders of the Spine

Special Courses	Friday, Jar	uary 31, 2	2014	Friday, Fel	oruary 7, 2	2014	Friday, Feb	ruary 14,	2014	Friday, Feb	ruary 21,	2014
Title	Tickets Sold	Faculty	Total	Tickets Sold	Faculty	Total	Tickets Sold	Faculty	Total	Tickets Sold	Faculty	Total
Special Course I - Neurosurgical												
Spine: Business and Compensation	9	1	10	9	3	12	17	3	20	33	3	36
Special Course II - Cases and												
Complications with the Masters	9	3	12	12	8	20	17	9	26	22	10	32
Special Course III - Spinal Deformity:												
What the Surgeon Needs to Know	6	4	10	10	8	18	12	8	20	16	10	26
Special Course IV - Advanced MIS												
Techniques/Managing MIS												
Complications	5	2	7	9	6	15	11	6	17	12	6	18
Special Course V - Managing												
Metastatic Spine Tumors	2	0	2	4	4	8	5	5	10	8	5	13
Special Course VI - Spinal Trauma in												
the Elderly	4	5	9	5	9	14	12	5	17	12	5	17
Special Course VII - Hands On Spine:												
Indications, Techniques, and												
Complication Avoidance for the NP/PA	3	1	4	2	9	11	11	3	14	11	4	15
Innovative Technologies in Spine and												
Peripheral Nerve Surgery	9	1	10	11	5	16	16	6	22	20	7	27
Total	47	17	64	62	52	114	101	45	146	134	50	184

Luncheon Seminars	Friday, Jan	uary 31,	2014	Friday, Fe	bruary 7, 2	2014	Friday, Feb	ruary 14,	2014	Friday, Feb	ruary 21,	2014
Title	Tickets Sold	Faculty	Total	Tickets Sold	Faculty	Total	Tickets Sold	Faculty	Total	Tickets Sold	Faculty	Total
Luncheon Symposium I - Revision												
Spine Surgery	8	1	9	8	4	12	11	5	16	11	5	16
Luncheon Symposium II- Update of												
Spine Guidelines	6	0	6	9	3	12	11	3	14	15	3	18
Luncheon Symposium III - Lateral												
Retroperitoneal Interbody Fusion:												
Technique and Outcomes	3	2	5	5	3	8	5	3	8	7	3	10
Total	17	2	19	22	10	32	27	11	38	33	11	44

2013 Annual Meeting of the AANS/CNS Section on Disorders of the Spine Special Courses

Title Tickets Sold Faculty Total

Special Course I - Neurosurgical			
Spine: Business and Compensation	25	7	32
Special Course II - Cases and			
Complications with the Masters	18	10	28
Special Course III - Spinal Deformity:			
What the Surgeon Needs to Know	23	8	31
Special Course IV - Advanced MIS			
Techniques/Managing MIS			
Complications	18	8	26
Special Course V - Management of			
Spinal Trauma in the Elderly			
Complications	8	14	22
Special Course VI - AO: Aging Spine			
Spine	12	9	21
Special Course VII - Peripheral Nerve			
Exposures and Nerve Repair			
Techniques	51	2	53
Total	155	58	213

Title	Tickets Sold	Faculty	Total
Luncheon Symposium I - Revision			
Spine Surgery	16	4	20
Luncheon Symposium II- Spine			
Tumors	13	7	20
Luncheon Symposium III - Update of			
Spine Guidelines	39	6	45
Luncheon Symposium IV - Lateral			
Retroperitoneal Interbody Fusion:			
Technique and Outcomes	28	5	33
Luncheon Symposium V - My Worst			
Outcome: Complications Avoidance			
and Management	25	6	31
Total	121	17	138

2012 Annual Meeting of the AANS/CNS Section on Disorders of the Spine Special Courses

Title	Tickets Sold	Faculty	Total
Special Course I - Neurosurgical			
Spine: Business and Compensation	32	6	38

Total	243	67	310
Techniques (Comp to residents)	47	8	55
Nerve Exposures and Nerve Repair			
Special Course VIII - *Peripheral			
Cervical Spine Trauma Guidelines	52	6	58
Trauma, Spinal Cord Injury, and			
Special Course VII - Updates on Spine			
the Brazilian Spine Society)	21	15	36
Surgery in Brazil (in conjunction with			
Special Course VI - Brazil: Spine			
Perioperative Pain Issues	22	8	30
Special Course V - Management of			
Complications	26	8	34
Techniques/Managing MIS			
Special Course IV - Advanced MIS			
Special Course III - Spinal Deformity	31	8	39
Complications with the Masters	12	8	20
Special Course II - Cases and			

Title	Tickets Sold	Faculty	Total
Luncheon Symposium I - Revision			
Spine Surgery	16	4	20
Luncheon Symposium II- Spine			
Tumors	13	7	20
Luncheon Symposium III - Update of			
Spine Guidelines	39	6	45
Luncheon Symposium IV - Lateral			
Retroperitoneal Interbody Fusion:			
Technique and Outcomes	28	5	33
Luncheon Symposium V - My Worst			
Outcome: Complications Avoidance			
and Management	25	6	31
Total	121	17	138

2011 Annual Meeting of the AANS/CNS Section on Disorders of the Spin $\,$ Special Courses

Title	Tickets Sold	Faculty	Total

Special Course I - Coding Update and			
Review	12	7	19
Special Course II - Masters in Spinal			
Surgery: What Has Experience Taught			
Me?	25	7	32
Special Course III - Spinal Deformity	39	13	52
Special Course IV - Advanced MIS			
Techniques/Managing MIS			
Complications	38	11	49
Special Course V - Management of			
Perioperative Pain Issues	14	7	21
Special Course VI - Update on Spinal			
Surgery in Turkey	17	15	32
Special Course VII - Cervical			
Myelopathy (co-sponsored by CSRS)	15	8	23
Special Course VIII - Peripheral Nerve			
Exposures and Nerve Repair			
Techniques	47	8	55
Special Course IX - Evaluation and			
Management of Spine Trauma Patient	22	9	31
Total	229	85	314

Title	Tickets Sold	Faculty	Total
Luncheon Symposium I - Revision			
Spine Surgery	20	4	24
Luncheon Symposium II-			
Neurosurgeon as CEO: Business			
Aspects of Spinal Surgery	29	4	33
Luncheon Symposium III - Cranial-			
Cervical Junction	18	6	24
Luncheon Symposium IV - Geriatric			
Spine	18	7	25
Luncheon Symposium V - Spinal			
Arthroplasty	17	5	22
Total	102	18	120

2010 Annual Meeting of the AANS/CNS Section on Disorders of the Spine

Special Courses

Title	Tickets Sold	Faculty	Total
Special Course I - Coding Update and			
Review	19	5	24
Special Course II - Masters in Spinal			
Surgery: What Has Experience Taught			
Me?	25	6	31
Special Course III - Spinal Deformity	32	18	50
Special Course IV - Advanced MIS			
Techniques/Managing MIS			
Complications	18	6	24
Special Course V - Management of			
Perioperative Pain Issues	7	4	11
Special Course VI - Pediatric			
Craniocervical	12	2	14
Special Course VII - Update on Spinal			
Surgery in Taiwan and the Far East**			
(+12 comp)	0	5	5
Special Course VIII - Peripheral Nerve			
Exposures and Nerve Repair			
Techniques* (+31 comp)	11	5	16
Special Course IX - Evaluation and			
Management of Spine Trauma Patient	14	8	22
Total	138	59	197

Luncheon Seminars

Title	Tickets Sold	Faculty	Total
Luncheon Symposium I - Revision			
Spine Surgery	20	4	24
Luncheon Symposium II-			
Neurosurgeon as CEO: Business			
Aspects of Spinal Surgery	26	4	30
Luncheon Symposium III - Treatment			
of Primary and Metastatic Spine			
Tumors	16	5	21
Luncheon Symposium IV - Geriatric			
Spine	15	7	22
Luncheon Symposium V - Spinal			
Arthroplasty	15	6	21

Total	92	18	110

2009 Annual Meeting of the AANS/CNS Section on Disorders of the Spine Special Courses

Special Courses			
Title	Tickets Sold	Faculty	Total
Special Course I - Spinal Coding Update			
and Review	17	7	24
Special Course II - New Developments in			
Arthroplasty	23	6	29
Special Course III - Biomechanics: Its Use			
in Surgical Decision Making	22	2	24
Special Course IV - Pediatric			
Craniocervical	12	2	14
Special Course V - Surgical Management			
of the Aging Spine: Deformity, Stenosis,			
Listheseis, Disc	43	6	49
Special Course VI - Evaluation and			
Mangement of the Patient with a Spinal			
Infection	14	8	22
Special Course VII - Peripheral Nerve			
Exposures and Nerve Repair Techniques	41	7	48
Special Course VIII - Evaluation and			
Mangement of the Spine Trauma Patient	17	6	23
Total	189	44	233

Luncheon Seminars

Title	Tickets Sold	Faculty	Total
Luncheon Symposium I - Revision Spine			
Surgery and Management of			
Complications	41	7	48
Luncheon Symposium II - Critical Review			
and Analysis of the SPORT Trials:			
Implications for your Practice	31	6	37
Luncheon Symposium III - Treatment of			
Primary and Metastatic Spine Tumores	27	9	36
Total	99	22	121

2008 Annual Meeting of the AANS/CNS Section on Disorders of the Spin Special Courses

Title	Tickets Sold	Faculty	Total
Special Course I - Spinal Coding Update			
and Review	19	6	25
Special Course II - Spine and Nerve Oral			
Board and Recertification Review	14	9	23
Special Course III - Learning Adult Spinal			
Deformity Surgery	26	7	33
Special Course IV - Advances in the			
Treatment of Thoracic and Lumbar Spine			
Trauma	15	10	25
Special Course V - Advances in Minimally			
Invasive and Outpatient Spine Surgery	38	9	47
Special Course VI - Evaluation and			
Management of the Spine Trauma Patient	14	8	22
Special Course VII - Peripheral Nerve			
Exposures and Nerve Repair Techniques	48	9	57
Special Course VIII - Evaluation and			
Management of the Post-Operative Spine	18	8	26
Total	192	66	258

Title	Tickets Sold	Faculty	Total
Luncheon Symposium I - Revision Spine			
Surgery and Complication Avoidance	32	5	37
Luncheon Symposium II - Evolution of			
Minimally Invasive Spine Surgery			
Techniques	29	5	34
Luncheon Symposium III - Treatment of			
Primary Metastatic Spine Tumors	24	5	29
Total	85	15	100