Minutes for Spine Section Executive Committee Meeting May 4, 2009 San Diego, CA

Members Present: Michael Groff, Chris Shaffrey, Ehud Mendel, Jean Coumans, Charles Kuntz, John Hurlbert, Chris Wolfla, Daryl Fourney, Joe Cheng, Michael Steinmetz, Eric Woodard, Robert Spinner, Allen Maniker, Michael Rosner, Dan Resnick, Praveen Mummaneni,

Guests: None

The meeting was called to order by Dr. Shaffrey at 12:00PM

1. Secretary's report

M. Groff

- a. Update of email list and contact info
- b. Review and approval of minutes
- c. Review EC grid
- 2. Treasurer's Report

J. Hurlbert

a. Review and approve budget

Total assets down by \$9K but impact of recession was largely mitigated by our plan to self fund fellowships which had put our assets into very stable funds.

We expect outside funding of fellowship to be received in December. Peter G. and Marg W. will review contact list of sponsors and confirm their commitment to contribute to the funding of the fellowships.

Unspent funds for the History Proj (aprox \$48K) will be carried forward to the next year.

- b. Review Annual meeting reconciliation. Net revenue was approximately \$496K.
- 3. Committee Reports
 - a. Annual Meeting

C. Kuntz/ P. Mummanneni

Meeting was hugely successful. The number of medical registrants is at an all time high at this point in the tracking process. The meeting was profitable. The scientific content was excellent.

b. CPT

J. Cheng/J Knightly

Spinal Stimulator codes were lowered.

Asked to combine plating with acdf code. Over all reimbursement for doing these codes together will likely be decreased as a result of this review.

Efforts to publicize these changes to the membership will help them understand that we are working hard to minimize any negative impact.

Survey should go to the membership at large for suggestions and as part of an awareness campaign.

c. Exhibits

P. Mummanneni/B. Subach

No report.

d. Future sites

I. Kalfas/E. Woodard

2011 plans for meeting in Las Vegas have been compromised by a change of ownership and law suite. A motion was made by Dr. Kalfas to resume negotioatons with the Desert

Ridge Marriot in Phoenix. It was seconded by Drs. Kuntz and Hurlburt, affirmative vote to proceed.

e. Research and Awards

P. Gerszten/Marg. Wang

Funding commitments are in place and will be confirmed.

f. Education

Mike Wang

No report

g. Guidelines

M. Kaiser

The Thoracolumbar guidelines group is meeting in Chicago in July.

h. Outcomes

Z. Ghogawala

They are down to three finalists for the clinical trial award. Winner to be determined in July. IOM solicitation for challenge grant will be satisfied with either a cervical myelopathy proposal or a LBP study looking at conservative vs operative treatment

i. Peripheral nerve TF

A. Maniker

Peter Richter for Klein lecturer this year. Rob Spinner taking over. Dr. Cheng proposal for AANS EPM nerve course.

j. Publications

L. Holly

Paper selection at annual meeting. Abstract submission for oral platform requires 1000 word abstract. Commitment to provide mini-manuscript before the meeting. Opportunity to publish at JNS:Spine.

k. Public Relations

M. Steinmetz

Slide show presentation at section booth. Healthy spine campaign operative and non-operative care.

1. Membership

Marg. Wang

Medical students are givin free membership.

There were six Orthopedic surgeons registrants at this years annual meeting. AANS prefers ortho members not be full members rather ex oficcio. Steve Glassman, Chris Bono. David Poly, Larry Lenke are potential surgeons to recruit.

Ad hoc committee to suggest best way to incorporate ortho members comprised of Tanvir Mark McLaughlin, Resnick was created.

Eblast to non-paying members

m. Washington Committee

R. Heary

n. Fellowships

P. Mummanini/G. Trost

Cast approval of spine fellowships is still pending

o. Web Site

J. Chang

Annual meeting videio on line. Resident awards.

p. CME

E. Mendel/D. Fournay

No report

q. Nominating Committee

D. Resnick

No report

r. Rules and Regs

T. Choudhri

No report

s. Newsletter

M. Steinmetz/ Eckholtz

Eblast news letter forthcomming

t. ASTM

G. Trost/J Coumans

u. NREF Z. Gokoslan/E. Woodard

We are not on the exec committee.

v. AANS PDP K. Foley/ P. Johnson

No report

w. Young Neurosurgeons comm. E. Potts/D. Sciubba

No report

x. FDA drugs and devices J. Alexander

No report

y. AMA Impairment G. Trost

No new developments

z. Inter-Society Liaison M. Rosner

We are assisting in the SRS pre meeting course. CSRS letter to respond to. LSRS developing we should encourage membership.

4. New Business

a) CNS Meeting service plan was reviewed. A motion to accepts was made and seconded by Drs. Resnick and Wolfla respectively. The motion was approved by a unanimous vote

5. Old Business

a) Outcomes Registry

Need to develop or identify outcome instruments. Wolfla, Knightly Consideration of < \$15K contribution and seat on the board of directors (E. Woodard) and NPA reach an contract with ABNS. NPA. Neuro Port Alliance.

- b) Intersociety Liason (ondra/heary cf Rosner)
- c) History Project is nearing completion

There being no further business the meeting was adjourned at 2:20PM

Respectfully submitted, Michael W. Groff, Secretary.

2009 Annual Meeting

Total Gross Revenue - \$1,043,635 Final Expenses - \$546,647 Final Net Revenue - \$496,988

AANS/CNS Section on Disorders of the Spine Statement of Financial Position As of August 31, 2009

	Current Year Prior \\ 08/31/09 08/31	
ASSETS		
Checking & Short Term Investments	\$718,176	\$445,024
Accounts Receivable, net of Allowance for Uncollectible Accounts	54,750	29,650
Prepaid Expenses		12,398
Long-Term Investment Pool, at Market	1,668,563	1,779,543
TOTAL ASSETS	\$2,441,489	\$2,266,615
LIABILITIES AND NET ASSETS		
Liabilities Deferred Contribution Revenue Deferred Dues Total Liabilities	45,000 18,033 \$63,033	18,733 \$18,733
Net Assets Unrestricted Unrestricted - Fellowships	\$2,255,728 \$100,000	\$2,229,822
Net Revenue (Expense)	22,728	18,060
Total Net Assets	\$2,378,456	\$2,247,882
TOTAL LIABILITIES AND NET ASSETS	\$2,441,489	\$2,266,615

AANS/CNS Section on Disorders of the Spine Statement of Activities For the Two Months Ending August 31, 2009

	FY '08 Final	FY '09 Final	YTD FY '10	FY '10 Budget
REVENUES Membership Dues Mailing List Sales Fellowship/Award Sponsorship	53,925 885 174,000	49,300 2,065 120,000	8,867 295	52,550 185,000
Miscellaneous Revenue Contributions for Operating Expenses Annual Meeting Revenue	7,405 961,534	7,977 1,043,635	1,813	9,072 935,385
TOTAL REVENUES & SUPPORT	1,197,749	1,222,977	10,974	1,182,007
EXPENSES Audio Visual Bank Fee Contributions & Affiliations Decorating Food & Beverage Fellowships Grants	1,888 518 75,000 3,626 144,507	1,971 648 90,000 205 4,827 151,604	28 260	2,000 706 75,000 250 5,000
Honoraria & Awards Office & other Supplies Photocopy Postage & Distribution Printing/Typesetting Speaker Expenses	543 1 1,058	592 0 1,284 1,966	56	196,500 600 25 1,500
Telephone Volunteer Travel Website Staff Coordination Miscellaneous	11 1,188 5,521 7,405	487 60 3,354 7,977 12,398	1,813	500 1,500 15,500 9,072
Guidelines Development Spine Section History Project Annual Meeting Expense	616,907	297 7,968 628,034	1,335 12,403 25,000	33,600 40,000 703,725
TOTAL EXPENSES	858,173	913,672	40,895	1,085,478
Investment Earnings NET REVENUE	(32,160) 307,416	(183,399) 125,906	52,649 22,728	84,463 180,992

AANS/CNS Section on Disorders of the Spine Annual Meeting For the Two Months Ending August 31, 2009

	FY '08 Final	FY '09 Final	YTD FY '10	FY '10 Budget
Revenues Misc Contribs: Unrestricted Registration Fees Exhibitor Fees Closing Banquet/Event Revenues Exhibitor Sponsorship Revenue Special Event Revenues	302,000 271,359 382,200 5,975	337,500 276,610 427,225 2,300		253,310 404,800 275,000 2,275
Total Revenues	961,534	1,043,635		935,385
Expenses Scientific Program Abstract Management	208,701	233,994		245,175 34,400
Opening Reception Social Events/General Committee Dinners/Events	164,674	145,927		72,000 33,000 63,400
Exhibit Program Exhibit Marketing	46,813	43,188		51,500 10,750
Advanced Registration On-Site Registration Preliminary Program	40,131	47,826		46,200 6,400 25,700
Annual Meeting Promotion	61,390	63,870		19,200
On-Site Coordination Annual Meeting Planning Cmte	15,081 117	12,213 1,016		12,350 3,650
Miscellaneous Expenses	80,000	80,000	25,000	80,000
Total Expenses	616,907	628,034	25,000	703,725
Net Excess (Loss)	344,627	415,601	(25,000)	231,660



UBS Financial Services Inc. 257 EAST MAIN STREET BARRINGTON, IL 60010

APP1001898341 0909 X245 GS 0

Investment Account

September 2009

Account name: AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS

Account type: PACE Multi

Account number: GS 08240 25

Your Financial Advisor:

BODOLAY, JOHN L 847-277-2129 Phone: 847-277-2100/800-824-2521

Visit our website:

www.ubs.com/financialservices

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS CNS SECTION ON DISORDERS OF THE SPINE 5500 MEADOWBROOK INDSTRL CT ROLLING MEADOWS IL 60008-3800

Value of your account

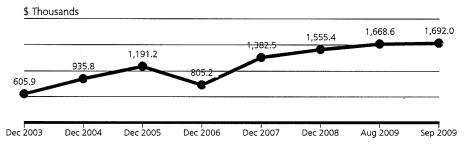
Value of your account	\$1,668,569.25	\$1,691,995.71
Your liabilities	0.00	0.00
Your assets	1,668,569.25	1,691,995.71
	on August 31 (\$)	on September 30 (\$)

As a service to you, your account value of \$1,691,995.71 includes accrued interest, pending return of principal, and the following assets that are not held by UBS:

Insurance Products \$1,057,573.52

Information about these assets not held by UBS, including their value, was provided by an external source for which UBS is not responsible. These assets are not covered by SIPC. See the section *Your assets* for details.

Tracking the value of your account



Sources of your account growth during 2009

Value of your account	£4 CO4 OOF 74
	\$07,001.05
Change in market value	\$87,601.83
outside assets and accruals	\$38,260.70
Change in value of	
Dividend and interest income	\$11,552.96
Your investment return:	
Net amount you invested	- \$866.31
Value of your account at year end 2008	\$1,555,446.53

on Sep 30, 2009

\$1,691,995.71



Account name:
Account number:

AMERICAN ASSOCIATION OF

GS 08240 25

Your account balance sheet

The value of your account includes assets held at UBS and certain assets held away from UBS. See page 1 for more information.

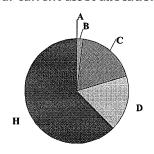
Summary of your assets

Tot	al assets	\$1,691,995.71	100.00%
Н	Other	1,057,573.52	62.51%
G	Real estate	0.00	0.00%
F	Broad commodities	0.00	0.00%
E	Alternative strategies	0.00	0.00%
D	Fixed income	290,035.73	17.14%
c	Equities	312,232.90	18.45%
В	Cash alternatives	31,274.70	1.85%
A	Cash and money balances	878.86	0.05%
	·	Value on September 30 (\$)	Percentage of your account

Value of your account

\$1,691,995.71

Your current asset allocation



Eye on the markets

	Percentage change			
Index	September 2009	Year to date		
S&P 500	3.73%	19.26%		
Russell 3000	4.19%	21.19%		
MSCI - Europe, Australia & Far East	3.85%	29.58%		
Barclays Capital Aggregate Bond Index 10+ Yrs.	2.14%	2.65%		

Interest rates on September 30, 2009

3-month Treasury bills: 0.12% One-month LIBOR: 0.25%



Investment Account
September 2009

Account name: Account type: Account number: AMERICAN ASSOCIATION OF

PACE Multi GS 08240 25 **Your Financial Advisor:** BODOLAY, JOHN L 847-277-2129 847-277-2100/800-824-2521

Change in the value of your account

	September 2009 (\$)	Year to date (\$)	
Opening account value	\$1,668,569.25	\$1,555,446.53	
Withdrawals and fees, including securities transferred out	0.00	-866.31	
Dividend and interest income	1,461.22	11,552.96	
Change in value of outside assets/accruals	4,558.06	38,260.70	
Change in market value	17,407.18	87,601.83	
Closing account value	\$1,691,995.71	\$1,691,995.71	

Dividend and interest income earned

For purposes of this statement, taxability of interest and dividend income has been determined from a US tax reporting perspective. Based upon the residence of the account holder, account type, or product type, some interest and/or dividend payments may not be subject to United States (US) and/or Puerto Rico (PR) income taxes. The client monthly statement is not intended to be used and cannot be relied upon for tax purposes. Clients should refer to the applicable tax reporting forms they receive from UBS annually, such as the Forms 1099 and the Forms 480, for tax reporting information. It is the practice of UBS to file the applicable tax reporting forms with the US Internal Revenue Service and PR Treasury Department, and in such forms accurately classify dividends and/or interest as tax exempt or taxable income. Please consult your individual tax preparer.

	September 2009 (\$)	Year to date (\$)	
Taxable dividends	1,461.22	10,467.54	
Total current year	\$1,461.22	\$10,467.54	
Prior year adjustment	0.00	1,085.42	
Total dividend & interest	\$1,461.22	\$11,552.96	

Summary of gains and losses

Values reported below exclude products for which gains and losses are not classified.

	Realized gains a	Unrealized		
	September 2009 (\$)	Year to date (\$)	gains and losses (S	
Short term	0.00	0.00	5,321.79	
Long term	0.00	0.00	-118,562.35	
Total	\$0.00	\$0.00	-\$113,240.56	

Cash activity summary

See the section Account activity this month for details. UBS Bank USA deposit account balances are included in the opening and closing balances value, are insured by the FDIC within applicable limits, but are not protected by SIPC. See Important information about your statement at the end of this document for details about those balances.

Closing balances	\$878.86	\$878.86
Net cash flow	\$0.00	-\$863.46
Total subtractions	-\$1,461.22	-\$12,416.42
Funds withdrawn for securities bought	-1,461.22	-11,550.11
Professional management fees and related services	0.00	-866.31
Total additions Subtractions	\$1,461.22	\$11,552.96
Dividend and interest income	1,461.22	11,552.96
Additions		
Opening balances	\$878.86	\$1,742.32
	September 2009 (\$)	Year to date (\$)



Account name:
Account number:

AMERICAN ASSOCIATION OF

GS 08240 25

Your investment objectives:

You have identified the following investment objectives for this account. If you have questions about these objectives, disagree with them, or wish to change them, please contact your Financial Advisor or Branch Manager. You can find a full description of the alternative investment objectives in *Important information about your statement* at the end of this document.

Your return objective:

Capital appreciation

Your risk profile:

Primary - Moderate Secondary - None selected

Your PACE investment objectives:

Your PACE return objective:

Income and capital appreciation

Your PACE risk profile:

Moderately conservative



Investment Account
September 2009

Account name: Account type:

AMERICAN ASSOCIATION OF

Account type: PACE Multi
Account number: GS 08240 25

Your Financial Advisor: BODOLAY, JOHN L 847-277-2129 847-277-2100/800-824-2521

Your PACE assets

Some prices, income and current values shown may be approximate. As a result, gains and losses may not be accurately reflected. Gains and losses for zero-coupon investments are not shown. See Important information about your statement at the end of this document for more information.

Investment return is the current value minus the amount you invested. It does not include any cash dividends that were not reinvested.

Total reinvested is the total of all reinvested dividends. It does not include any cash dividends. It is not a tax lot for the purposes of determining holding periods or cost basis. The shares you receive each time you reinvest dividends become a separate tax lot.

Cost basis is the total purchase cost of the security, including reinvested dividends. The cost basis may need to be adjusted for return of capital payments in order to determine the adjusted cost basis for tax reporting purposes.

Unrealized gain or loss is the difference between the current value and the cost basis. The unrealized gain or loss may need to be adjusted for return of capital payments in order to determine the realized gain or loss for tax reporting purposes.

Cash alternatives

Holding	Number of shares	Purchase price per share (\$)	Client investment (\$)	Cost basis (\$)	Price per share on Sep 30 ((\$)	Value on Sep 30 (\$)	Unrealized gain or loss (\$)	Investment return (\$)	Holding period
UBS PACE MONEY MARKET INVESTMENT FUND CLASS P									<u>'</u>
Trade date: Oct 3, 08	31,125.680	1.000	31,125.68	31,125.68	1.000	31,125.68			ST
Total reinvested	149.020	1.000		149.02	1.000	149.02			
Security total	31,274.700		31,125.68	31,274.70		31,274.70		149.02	
Equities									
Holding	Number of shares	Purchase price per share (\$)	Client investment (\$)	Cost basis (\$)	Price per share on Sep 30 (\$)	Value on Sep 30 (\$)	Unrealized gain or loss (\$)	Investment return (\$)	Holding period
COLUMBIA MARSICO FOCUSED EQUITIES FUND CLASS A									
Trade date: Jan 28, 05	323.511	17.560	5,680.85	5,680.85	17.990	5,819.96	139.11		LT
Trade date: Aug 10, 07	675.676	22.200	15,000.00	15,000.00	17.990	12,155.41	-2,844.59		LT
Trade date: Sep 4, 07	1,720.430	23.250	40,000.00	40,000.00	17.990	30,950.53	-9,049.47		LT
Total reinvested	66.964	23.250		1,556.92	17.990	1,204.68	-352.24		
EAI: \$176 Current yield: 0.35%									
Security total	2,786.581		60,680.85	62,237.77		50,130.59	-12,107.19	-10,550.27	
COLUMBIA ACORN FUND CLASS A					:				
Trade date: May 18, 04	322.087	22.370	7,205.10	7,205.10	22.690	7,308.15	103,05		LT
Trade date: Aug 10, 07	359.595	30.590	11,000.01	11,000.01	22.690	8,159.21	-2,840.80		LT
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Account name:
Account number:

AMERICAN ASSOCIATION OF

GS 08240 25

Your PACE assets • Equities (continued)

Holding	Number of shares	Purchase price per share (\$)	Client investment (\$)	Cost basis (\$)	Price per share on Sep 30 (\$)	Value on Sep 30 (\$)	Unrealized gain or loss (\$)	Investment return (\$)	Holding period
Total reinvested	591.686	27.925		16,523.35	22,690	13,425.35	-3,098.00		
Security total	1,273.368		18,205.11	34,728.46		28,892.71	-5,835.75	10,687.60	
EATON VANCE LARGE CAP VALUE FUND CLASS A									
Trade date: Aug 10, 07	1,082.399	21.490	23,260.75	23,260.75	15.900	17,210.14	-6,050.61		LT
Trade date: Sep 4, 07	1,351.960	22.190	30,000.00	30,000,00	15.900	21,496.16	-8,503,84		LT
Total reinvested	175.389	19.496		3,419,52	15.900	2,788.68	-630.84		
EAI: \$655 Current yield: 1.58%				•					
Security total	2,609.748		53,260.75	56,680.27		41,494.99	-15,185.29	-11,765.77	
HARTFORD CAPITAL APPRECIATION FUND CL A	177 A 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1								
Trade date: Oct 24, 07	545.027	44.520	24,264.60	24,264.60	28.730	15,658.62	-8,605.98		LT
Total reinvested	259.730	39.472		10,252.30	28.730	7,462.04	-2,790.26		
EAI: \$252 Current yield: 1.09%									
Security total	804.757		24,264.60	34,516.90		23,120.66	-11,396.24	-1,143.94	
ING GLOBAL REAL ESTATE									
FUND CLASS A									
Trade date: Feb 28, 06	441.169	18.780	8,285.15	8,285.15	14.690	6,480.77	-1,804.38		LT
Total reinvested	149.741	20.287		3,037.83	14.690	2,199.69	- 838.14		
EAI: \$221 Current yield: 2.55%									
Security total	590,910		8,285.15	11,322.98		8,680.46	-2,642.52	395.31	
ing international value Fund class a									
Trade date: Sep 4, 07	1,476.221	21.990	32,462.10	32,462.10	11.850	17,493.22	-14,968.88		LT
Total reinvested	1,839.226	15.739		28,948.10	11.850	21,794.82	-7,153.28		
EAI: \$1,144 Current yield: 2.91%									
Security total	3,315.447		32,462.10	61,410.20		39,288.04	-22,122.16	6,825.94	
JANUS FORTY FUND A									
Trade date: Sep 26, 07	216.153	38.890	8,406.40	8,406.40	30.520	6,596.99	-1,809.41		LT
Trade date: Oct 9, 07	736.116	40.754	30,000.00	30,000.00	30.520	22,466.25	-7,533.75		LT
Total reinvested	55.173	22.668		1,250.70	30.520	1,683.88	433.18		
Security total	1,007.442		38,406.40	39,657.10		30,747.12	-8,909.98	-7,659.28 continued ne	ext page



Investment Account September 2009

Account name: Account type: Account number: AMERICAN ASSOCIATION OF

PACE Multi GS 08240 25 **Your Financial Advisor:**BODOLAY, JOHN L 847-277-2129
847-277-2100/800-824-2521

Your PACE assets . Equities (continued)

Holding	Number of shares	Purchase price per share (\$)	Client investment (\$)	Cost basis (\$)	Price per share on Sep 30 (\$)	Value on Sep 30 (\$)	Unrealized gain or loss (\$)	Investment return (\$)	Holding period
JOHN HANCOCK CLASSIC									
VALUE FUND CLASS A									
Trade date: Mar 13, 06	364.258	25,490	9,284.94	9,284.94	14.340	5,223.46	-4,061.48		LT
Trade date: Aug 10, 07	698.016	27.220	19,000.00	19,000.00	14.340	10,009.55	-8,990.45		LT
Trade date: Sep 4, 07	723.589	27.640	20,000.00	20,000.00	14.340	10,376.26	-9,623.74		LT
Total reinvested	687.525	19.598		13,474.50	14.340	9,859.11	-3,615.39	•	
EAI: \$851 Current yield: 2.40%									
Security total	2,473.388		48,284.94	61,759.44		35,468.38	-26,291.06	-12,816.56	
TOUCHSTONE MID CAP									
GROWTH FUND CLASS A									
Trade date: Aug 10, 07	1,130.956	25.110	28,398.31	28,398.31	18.180	20,560.78	-7,837.53		LT
Trade date: Sep 4, 07	1,167.315	25.700	30,000.00	30,000.00	18.180	21,221.78	-8,778.22		LT
Total reinvested	694.576	22.468		15,606.05	18.180	12,627.39	-2,978.66		
Security total	2,992.847		58,398.31	74,004.36		54,409.95	-19,594.41	-3,988.36	
PACE portfolio total			\$342,248.21	\$436,317.48		\$312,232.90	-\$124,084.60	-\$30,015.31	

Total estimated annual income: \$3,299

Fixed income

Holding	Number of shares	Purchase price per share (\$)	Client investment (\$)	Cost basis (\$)	Price per share on Sep 30 (\$)	Value on Sep 30 (\$)	Unrealized gain or loss (\$)	Investment return (\$)	Holding period
PIMCO REAL RETURN									
FUND CLASS A									
Trade date: Feb 7, 08	2,462.130	11.290	27,797.45	27,797.45	10.760	26,492.52	-1,304.93		LT
Total reinvested	287.254	10.107		2,903.50	10.760	3,090.85	187.35		
EAI: \$767 Current yield: 2.59%									
Security total	2,749.384		27,797.45	30,700.95		29,583.37	-1,117.58	1,785.92	
PIMCO TOTAL RETURN FUND									
CLASS A									
Trade date: May 18, 04	4,759.903	10.570	50,312.17	50,312.17	10.920	51,978.14	1,665.97		LT
Trade date: Jan 28, 05	2,201.020	10.680	23,506.89	23,506.89	10.920	24,035.14	528.25		LT
Trade date: Aug 10, 07	8,763.389	10.270	90,000.00	90,000.00	10.920	95,696.21	5,696.21		LT
								continued n	ext page



Account name: Account number:

AMERICAN ASSOCIATION OF

GS 08240 25

Your PACE assets . Fixed income (continued)

Holding	Number of shares	Purchase price per share (\$)	Client investment (\$)	Cost basis (\$)	Price per share on Sep 30 (\$)	Value on Sep 30 (\$)	Unrealized gain or loss (\$)	Investment return (\$)	Holding period
Total reinvested	8,126.637	10.419		84,671.69	10.920	88,742.88	4,071.19		
EAI: \$13,357 Current yield: 5.13%									
Security total	23,850.949		163,819.06	248,490.75		260,452.36	11,961.62	96,633.31	
PACE portfolio total			\$191,616.51	\$279,191.70		\$290,035.73	\$10,844.04	\$98,419.22	

Total estimated annual income: \$14,124

Your assets not enrolled in PACE

Some prices, income and current values shown may be approximate. As a result, gains and losses may not be accurately reflected. See *Important information about your statement* at the end of this document for more information.

Cash

Cash and money balances

Holding	Opening balance on Sep 1 (\$)	Closing balance on Sep 30 (\$)	Price per share on Sep 30 (\$)	Average rate	Dividend/Interest period	Days in period	
UBS CASHFUND INC.	878.86	878,86	1.00	0.01%	Aug 24 to Sep 22	30	

Other

Assets held outside UBS Financial Services Inc.

These assets are held outside UBS Financial Services Inc. and are included in your statement as a service to you. Information about these assets, including their value, is provided by the issuer and UBS Financial Services Inc. does not guarantee the accuracy of the information and is not responsible for it. The value

shown is not necessarily the value you would receive from the issuer if you sold the assets. These assets are not covered by SIPC.

Annuities

AS OF 09/29/2009

Holding	Issue date	Contract number	Death benefit (\$)	Rate	Amount (\$)	Value (\$)
SYMETRA LIFE INSURANCE COMPANY SELECT 5 FIXED ANNUITY-NON-NY	Oct 23, 08	V000068637		Variable	1,000,000.000	1,057,573.52



Investment Account September 2009

Account name: Account type: Account number: AMERICAN ASSOCIATION OF

PACE Multi GS 08240 25 **Your Financial Advisor:** BODOLAY, JOHN L 847-277-2129 847-277-2100/800-824-2521

Your total assets

		Value on Sep 30 (\$)	Percentage of your account	Cost basis (\$)	Estimated annual income (\$)	Unrealized gain or loss (\$)
Cash	Cash and money balances	878.86	0.05%	878.86		
Cash alternatives	PACE	31,274.70	1.85%	31,274.70		
Equities	PACE	312,232.90	18.45%	436,317.48	3,299.00	-124,084.60
Fixed income	PACE	290,035.73	17.14%	279,191.70	14,124.00	10,844.04
Other	Annuities	1,057,573.52	62.51%			
Total		\$1,691,995.71	100.00%	\$747,662.74	\$17,423.00	-\$113,240.56
Your total PACE assets**		\$633,543.33	37.44%	\$746,783.88	\$17,423.00	-\$113,240.56

^{**} Your total PACE assets are included in the Total reported above.

Account activity this month

	Date	Activity	Description	Amount (\$)
Dividend and interest income				
Taxable dividends	Sep 1	Dividend	PIMCO TOTAL RETURN FUND CLASS A AS OF 08/31/09	1,177.64
	Sep 1	Dividend	PIMCO REAL RETURN FUND CLASS A AS OF 08/31/09	179.96
	Sep 10	Dividend	EATON VANCE LARGE CAP VALUE FUND CLASS A AS OF 09/09/09	103.34
	Sep 16	Dividend	UBS PACE MONEY MARKET INVESTMENT FUND CLASS P AS OF 09/15/09	0.28
	Total ta	xable dividen	ds	\$1,461.22
	Total di	vidend and in	terest income	\$1,461.22

Security transactions

For more information about the price/value shown for restricted securities, see *Important information about your statement* at the end of this document.

Date	Activity	Description	Quantity	Value (\$)	Price (\$)	Proceeds from securities transactions (\$)	Funds withdrawn for securities bought (\$)	Accrued interest (\$)
Sep 1	Reinvestment	PIMCO TOTAL RETURN FUND CLASS A DIVIDEND REINVESTED AT 10.78 NAV ON 08/31/09 AS OF 08/31/09	109.243				-1,177.64	
Sep 1	Reinvestment	PIMCO REAL RETURN FUND CLASS A DIVIDEND REINVESTED AT 10.50 NAV ON 08/31/09 AS OF 08/31/09	17.139				-179.96	

continued next page



Account name: Account number:

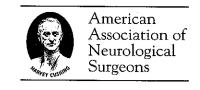
AMERICAN ASSOCIATION OF

GS 08240 25

Account activity this month (continued)

Security transactions (continued)

Date	Activity	Description	Quantity	Value (\$)	Price (\$)	Proceeds from securities transactions (\$)	Funds withdrawn for securities bought (\$)	Accrued interest (\$)
Sep 10	Reinvestment	EATON VANCE LARGE CAP VALUE FUND CLASS A DIVIDEND REINVESTED AT 15.60 NAV ON 09/09/09 AS OF 09/09/09	6.624				-103.34	
Sep 16	Reinvestment	1000TH UBS PACE MONEY MARKET INVESTMENT FUND CLASS P DIVIDEND REINVESTED AT 1.00 NAV ON 09/15/09 AS OF 09/15/09	280,000				-0.28	
Total							-\$1,461.22	



5550 Meadowbrook Drive Rolling Meadows, IL 60008

member services: 888.566.AANS phone: 847.378.0500 fax: 847.378.0600 web: www.AANS.org www.NeurosurgeryToday.org

April 24, 2009

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Executive Director Thomas A. Marshall tam@aans.org R. John Hurlbert, MD PhD Foothills Med. Ctr./Clinical Neurosci. 1403 29th St. N.W. Rm. C 1249 Calgary, AB T2N-2T9 Canada

Dear Doctor Hurlbert:

The enclosed financial statements for the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves are for the Quarter Ended March 31, 2009, and comparative information for the Quarter Ended March 31, 2008.

After your review of the financial statements, if you have any questions, please do not hesitate to contact me at 847-378-0561 or rpc@aans.org.

Sincerely.

Rebecca Calloway-Blyth Section Accountant

A ally Blytz

Enclosures

Cc: Christopher I. Shaffrey, MD

James R. Bean, MD P. David Adelson, MD Paul C. McCormick, MD Daniel K. Resnick, MD Laurie Behncke Ronald W. Engelbreit

AANS/CNS Section on Disorders of the Spine Statement of Financial Position As of March 31, 2009

	Current Year 03/31/09	Prior Year 03/31/08
ASSETS		
Checking & Short Term Investments	\$287,920	\$539,270
Accounts Receivable, net of Allowance for Uncollectible Accounts	1,900	5,800
Prepaid Expenses	12,398	12,398
Long-Term Investment Pool, at Market	1,547,898	1,301,800
TOTAL ASSETS	\$1,850,116	\$1,859,268
LIABILITIES AND NET ASSETS		
Liabilities Accounts Payable and Current Liabilities Deferred Dues	(\$30,000) 40,575	42,150
Total Liabilities	<u>\$10,575</u>	<u>\$42,150</u>
Net Assets Unrestricted Unrestricted - Fellowships	\$2,144,822 \$85,000	\$1,922,406
Net Revenue (Expense)	(390,281)	(105,287)
Total Net Assets	\$1,839,541	<u>\$1,817,118</u>
TOTAL LIABILITIES AND NET ASSETS	\$1,850,116	\$1,859,268

AANS/CNS Section on Disorders of the Spine Statement of Activities For the Nine Months Ending March 31, 2009

	FY '07 Final	FY '08 Final	YTD FY '08	YTD FY '09	FY '09 Budget
REVENUES					
Membership Dues Mailing List Sales	55,975 1,475	53,925 885	40,675 885	37,275 1,770	49,500
Fellowship/Award Sponsorship Miscellaneous Revenue	129,390 108	174,000	90,000	60,000	177,000
Contributions for Operating Expenses Annual Meeting Revenue	9,368 915,425	7,405 <u>961,534</u>	5,360	6,574	7,847 <u>961,675</u>
TOTAL REVENUES & SUPPORT	1,111,741	1,197,749	136,920	105,619	1,196,022
EXPENSES					
Audio Visual	1,011	1,888	1,561	1,491	2,000
Bank Fee	484	518	448	566	502
Contributions & Affiliations	75,000	75,000			75,000
Decorating	594	0.000	4.004	205	250
Food & Beverage Fellowships	3,636 140,092	3,626	1,301	3,399	5,000
Grants	500,000	144,507	137,500	159,770	188,500
Honoraria & Awards	300				
Marketing & Advertising	000				
Office & other Supplies	229	543	354	399	600
Photocopy	0	1	1	0	50
Postage & Distribution	1,214	1,058	833	953	1,500
Printing/Typesetting					
Speaker Expenses	_				
Telephone Volunteer Travel	2	11	0	451	50
Website	1,462 3,192	1,188 5,521	1,188	60	1,500
Staff Coordination	9,461	7,405	3,021 5,360	2,587 6,574	15,500 7,977
Miscellaneous	0,701	7,700	3,300	0,574	1,511
Guidelines Development	15,948			•	33.600
Spine Section History Project	,			7,968	50,000
Annual Meeting Expense	583,402	616,907	60,000	60,000	632,465
TOTAL EXPENSES	1,336,028	858,173	211,568	244,424	1,014,494
Investment Earnings	154,713	(32,160)	(30,640)	(251,476)	84,838
NET REVENUE	(69,574)	307,416	(105,287)	(390,281)	266,366

AANS/CNS SECTION ON DISORDERS OF THE SPINE

NOTES TO FINANCIAL STATEMENTS
March 31, 2009

General & Administrative

Bank Fees - Budget \$502, Actual \$566

Due to more members paying their dues by credit card, the bank fees are higher than anticipated.

Telephone - Budget \$50, Actual \$451

The Telephone expenses from the CNS meeting were more than anticipated.

Section on the Disorders of Spine and Peripheral Nerves Annual Meeting Budget

NET REVENUE & EXPENSES SUMMARY Revenue	2009 Phoenix Actual	2009 Phoenix Budget	2008 Orlando Actual	2007 Phoenix Actual	
Registration	227,695	211,325	225,639	195,415	
Exhibits	427,225	407,500	382,200	407,800	
Contributions/Sponsorships	337,500	285,000	302,000	274,500	
Social Events	2,300	6,050	5,975	4,950	
Special Courses/Luncheon Symposia	48,210	47,250	45,720	32,760	
Miscellaneous	-	-	-	-	
Total Gross Revenue	\$ 1,042,930	\$ 957,125	\$ 961,534	\$ 915,425	

Expenses

Scientific Program/Special Courses	232,609	267,198	210,200	192,351
Social Events	145,927	183,251	164,674	138,139
Marketing	63,870	74,550	61,390	65,360
Exhibit Hall Program	43,188	53,411	46,813	49,121
AM Registration	47,694	43,305	40,131	33,882
Onsite Coordination & Offices	12,213	17,600	15,081	12,757
AM Planning General	1,016	4,350	117	4,225

Total Expenses	\$ 546,515	\$ 643,665	\$ 538,406	\$ 495,835
Net Revenue	\$ 496,415	\$ 313,460	\$ 423,128	\$ 419,590

Because the AANS provides financial services to the section, the CNS invoices the section via the AANS each quarter for its meeting management fee (as per signed agreement) of \$80,000. These meeting management fees have been paid quarterly in 2008 as well as 2009. Therefore, although budgeted as an expense, the fee expense is not captured in this summary under actual expense as the fee is recorded and reported by the AANS. This needs to be considered when addressing actual net revenue for 2009 (and 2008).

JW Marriott Desert Ridge Resort

2011, 2013 and 2015 Offers:

Confirmed:

- 2011 \$369 guest room rate
- 2013 \$379 guest room rate
- 2015 \$389 guest room rate
- One (1) Complimentary Room Night for every forty-five (45) revenue-generating room nights. \$14,402.00 value.
- One (1) Complimentary Presidential Suite provided Tue. 3/8 Sun. 3/13/11. \$17,500.00 value.
- Eighteen (18) Suite Upgrades provided at the group room rate. \$86,400.00 value.
- Fifteen (15) rooms (registration/av vendors, staff, etc.) provided at 50% off the group room rate. \$10,395.00 value.
- Five (5) Complimentary Round-Trip Airport Transfers \$1860.00 value.
- Complimentary meeting/exhibit space.
- Banquet food/beverage pricing confirmed/guaranteed 12 months prior to arrival.
- Conference rate valid 3 days pre/post main meeting dates, space available basis,
- 30% guest room attrition,
- Internet service provided in guest rooms for all attendees provided complimentary in 2011, 2013 and 2015. \$55,512.00 value.
- Cancellation Terms

CANCELLATION			
2011			
	10%	\$ 48,576	Now to 1 yr out
	20%	\$ 97,152	1 yr to 6 mths out
			6 mths to 3 mths
	40%	\$ 194,304	out
	80%	\$ 388,608	2 months out
2013			
	10%	\$ 49,984	Now to 3.5 yrs out
			3.5 yrs out - 2.5
	20%	\$ 99,968	yrs out
			2.5 yrs out - 1 yr
	40%	\$ 199,936	out
	80%	\$ 399,872	1 yr out or less
2015			
	10%	\$ 51,216	Now - 2yrs out
	20%	\$ 102,432	2 yrs - 1.5 yrs out
	40%	\$ 204,864	1.5 -1 yr out
	80%	\$ 409,728	1 yr or less

		Agreement	2009 Funds
Amount	Agreement?	Terms	Received
\$ 5,000.0	0 in process	2006-2009	
\$ 30,000.0	0 in process	2006-2009	
\$ 15,000.0	0 in process	n/a	
\$ 30,000.0	0 yes	2009-2010	
\$ 15,000.0	0 in process	2008-2009	6/30/09
\$1500 + Travel	in process	n/a	12/18/08
\$ 50,000.0	0 not on file	n/a	8/14/08
\$ 30,000.0	0 yes	2005-2011	11/12/08
\$ 5,000.0	0 yes	2005-2011	11/12/08
\$ 5,000.0	0		
•	\$ 5,000.00 \$ 30,000.00 \$ 15,000.00 \$ 30,000.0 \$ 15,000.0 \$ 50,000.0 \$ 50,000.0 \$ 5,000.00	\$ 5,000.00 in process in process \$ 30,000.00 in process \$ 15,000.00 ves \$ 15,000.00 in process \$ 15,000.00 in process \$ 15,000.00 in process \$ 15,000.00 in process \$ 50,000.00 not on file \$ 30,000.00 ves	Amount Agreement? Terms \$ 5,000.00 in process 2006-2009 \$ 30,000.00 in process 2006-2009 \$ 15,000.00 in process n/a \$ 30,000.00 yes 2009-2010 \$ 15,000.00 in process n/a \$ 50,000.00 not on file n/a \$ 30,000.00 yes 2005-2011 \$ 5,000.00 yes 2005-2011

^{*}the section elected to award 2 Sonntag Int'l Fellowships in FY09

Subject: Re: SNS/CAST - Spine Applications
Date: Thursday, August 20, 2009 9:48 AM
From: Praveen Mummaneni <vmum@aol.com>

Reply-To: <vmum@aol.com>

To: Piepgras piepgras.david@mayo.edu

Cc: Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu, Trost (Gregory) trost@neurosurg.wisc.edu, Steven Giannotta giannott@usc.edu, volker sonntag@bnaneuro.net, R.H.Rosenwasser, M.D.,F.A.C.S.,F.A.H.A. robert.rosenwasser@jefferson.edu, Dennis Spencer dennis.spencer@yale.edu, fboop@semmes-murphey.com, Michael Groff, MD mgroff@bidmc.harvard.edu, Dan Resnick resnick@neurosurg.wisc.edu, gerald.rodts@emory.org

Dr. Piepgras, thank you for the update.

By way of this email,

I will ask greg trost to help update the spine section website to match the cast list of approved fellowships (greg is copied on this email).

http://www.societyns.org/fellowships/sns-cast_accredit_fellowships.html

I will ask chris shaffrey who the aans contact person is to update their website as well to reflect the cast approved spine fellowships.

I will ask dan resnick and rusty rodts who the cns contact person is to update their website to reflect cast approved fellowships. .

Warm regards, Praveen.

Sent from my Verizon Wireless BlackBerry

----Original Message----

From: "Piepgras, David G., M.D." <piepgras.david@mayo.edu>

Date: Thu, 20 Aug 2009 08:24:03

To: <vmum@aol.com>

Cc: Shaffrey, Chris I *HS<CIS8Z@hscmail.mcc.virginia.edu>; Trost

(Gregory)<trost@neurosurg.wisc.edu>; Steven Giannotta<giannott@usc.edu>; volker

sonntag<volker.sonntag@bnaneuro.net>; R.H.Rosenwasser,

M.D.,F.A.C.S.,F.A.H.A.<robert.rosenwasser@jefferson.edu>; dennis

spencer<dennis.spencer@yale.edu>; <fboop@semmes-murphey.com>

Subject: SNS/CAST - Spine Applications

Dear Praveen:

I apologize for being slow in responding but was away for a time and am now catching up I hope.

I believe the entire list of CAST accredited Spine Fellowships (a total of 19 programs) is now up-to-date on the SNS web site and should be fine to post on your Section web site. Let me know if there are questions and thanks for your patience.

It might be a good idea if Greg Trost as your Section fellowship liaison looked over the list from time to time in the future to provide feedback to CAST regarding the "health" of the accredited spine fellowships. If there was concern about major changes in a specific spine fellowship such as sponsoring institution, major ongoing deficiencies in faculty or case material, the CAST Secretary (Dr. Steve Giannotta) or our spine representative (now Dr. Volker Sonntag) would appreciate being notified so we could follow-up appropriately.

Sincerely,

Dave

David G. Piepgras, M.D.
SNS/CAST Chair
Department of Neurologic Surgery
Mayo Clinic, Gonda 8-209
200 First Street SW
Rochester, MN 55905

Tel: 507-284-2254 or 3331

Fax: 507-284-5206

E-mail: piepgras.david@mayo.edu

-----Original Message-----

From: Shaffrey, Chris I *HS [mailto:CIS8Z@hscmail.mcc.virginia.edu]

Sent: Sunday, July 05, 2009 12:28 PM

To: vmum@aol.com; Piepgras, David G., M.D.

Cc: trost@neurosurg.wisc.edu; cis8z@virginia.edu;

weinsteinp@neurosurg.ucsf.edu; resnick@neurosurg.wisc.edu

Subject: RE: Fwd: SNS - Cast Application

Thank you Praveen and Dr. Peipgras.

Dr. Peipgras, please let Praveen and me know who it the best person within SNS/CAST to facilitate the change. Praveen/Greg, It is very important that this get updated on Section website. This information is also contained in a very old format On the AANS (http://www.aans.org/education/fellowdir.aspxand) and CNS (link to AANS site). It is important that this get updated in all sites.

Christopher I Shaffrey, MD, FACS Harrison Distinguished Professor Neurological and Orthopaedic Surgery University of Virginia Phone: (434) 243-9714

From: vmum@aol.com [vmum@aol.com]

Sent: Friday, July 03, 2009 11:13 PM

To: piepgras.david@mayo.edu

Cc: trost@neurosurg.wisc.edu; cis8z@virginia.edu;

weinsteinp@neurosurg.ucsf.edu; resnick@neurosurg.wisc.edu

Subject: RE: Fwd: SNS - Cast Application

Dr. Piepgras,

thank you for your note indicating the approval of the UCSF spine fellowship by CAST.

I have forwarded your message to our chair (mitch berger) and our program director (nick barbaro).

At this time, Greg Trost has taken over from me as the new fellowships liason for the Joint Spine Section.

Greg would like to post the new CAST approved neurosurgery spine fellowships on the spine section website (www.spinesection.org)

The CAST website does not contain an updated list of approved spine

fellowships.

I searched the SNS/CAST website just now at:

http://www.societyns.org/fellowships/sns-cast_accredit_fellowships.html

The only fellowships for spine that are listed are:

Spine

Barrow Neurologic Institute Phoenix, AZ

Spine

University of South Florida Tampa, FL

Spine

University of Cincinnati Cincinnati, OH

Spine

UCLA

Los Angeles, CA

Spine

Thomas Jefferson University Philadelphia, PA

Spine

University of Miami Miami, FL

Could you please send the updated new list of 25 programs to Greg Trost (who is copied on this email) to update our list and also please ask your webmaster to update the CAST/SNS website?

thank you

Praveen

Praveen V. Mummaneni, M.D.
Associate Professor
Dept. of Neurosurgery
Co-Director: UCSF Spine Center
University of California, San Francisco

From: "Vincent_Traynelis@rush.edu" < Vincent_Traynelis@rush.edu>

Subject: RE: CSRS

Date: August 25, 2009 5:37:43 PM EDT

To: "Shaffrey, Chris I *HS" <CIS8Z@hscmail.mcc.virginia.edu>

Cc: "Groff,Michael (HMFP - Neurosugery)" <mgroff@caregroup.harvard.edu>, "resnick@neurosurg.wisc.edu"

Thanks, Chris.

"Shaffrey, Chris I *HS" <CIS8Z@hscmail.mcc.virginia.edu>

08/25/2009 03:39 PM

- To "'mgroff@bidmc.harvard.edu" <mgroff@bidmc.harvard.edu>, "zgokasl1@jhmi.edu" <zgokasl1@jhmi.edu>
- cc "resnick@neurosurg.wisc.edu" <resnick@neurosurg.wisc.edu>,
 "Vincent_Traynelis@rush.edu" <Vincent_Traynelis@rsh.net>, "tjsurg@aol.com"
 <tjsurg@aol.com>

Subject RE: CSRS

Please send E blast.

From: mgroff@bidmc.harvard.edu [mailto:mgroff@bidmc.harvard.edu]

Sent: Tuesday, August 25, 2009 11:13 AM **To:** zgokasl1@jhmi.edu; Shaffrey, Chris I *HS

Cc: resnick@neurosurg.wisc.edu

Subject: RE: CSRS

Would you like me to get the info together and ask Eric Potts to eblast?

mike

From: Ziya Gokaslan [mailto:zgokasl1@jhmi.edu] Sent: Tuesday, August 25, 2009 11:08 AM

To: 'Vincent_Traynelis@rush.edu'

Cc: 'resnick@neurosurg.wisc.edu'; Groff,Michael (HMFP - Neurosugery); 'cis8z@hscmail.mcc.virginia.edu'

Subject: Re: CSRS

I agree! We will do so. Ziya

From: Vincent_Traynelis@rush.edu <Vincent_Traynelis@rush.edu>

To: Ziya Gokaslan; resnick@neurosurg.wisc.edu <resnick@neurosurg.wisc.edu>
Cc: Tjsurg@aol.com <Tjsurg@aol.com>; Wlezien@aaos.org <Wlezien@aaos.org>

Sent: Tue Aug 25 09:24:04 2009

Subject: CSRS

Dan and Ziya,

As past and future Chairs of the Spine Section I would like to encourage you to let the Section membership know of Todd's generous offer to waive registration fees to this year's CSRS meeting. This would be an excellent thing to promote in the newsletter or any other media (e-mail blast?). It is a true benefit of membership in the Spine Section and as you know an outstanding educational forum for all who attend.

Vince

Washington Committee Drugs & Devices Committee May 4, 2009

Due to concerns regarding non-surgeons performing increasingly complex spine surgical procedures, the Drugs and Devices Committee is requesting that the AANS/CNS Joint Section on Disorders of the Spine & Peripheral Nerves develop a position statement on the qualifications required to perform spinal surgery. Recent anecdotal reports have surfaced involving lumbar spinal fusions, usually done in a minimally invasive fashion, being performed by radiologists. Additionally, there is a report of an anesthesiologist, pain management specialist, who has been performing open spinal fusion surgeries and sending the patients home on the day of surgery with no reasonable follow-up and no aftercare.

As a result of this increasing trend of spinal surgery being performed by non-surgeons, the Drugs & Devices Committee is asking the Spine Section to come up with a formal position statement on who is most qualified to perform spinal surgery. This should pertain to both open and minimally invasive spinal surgeries.

Respectfully submitted,

Robert F. Heary, M.D.

AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerve Guidelines Committee Report October 2009

1. CSM Guidelines

i. Published in JNS: Spine August 2009: 11(2).

2. Update of Lumbar Fusion Guidelines

- a. Multidisciplinary Committee selected.
 - i. Literature search completed with assistance of NASS
 - ii. Chapters assigned
 - iii. Anticipated completion of evidentiary tables Jan/Feb 2010

3. Metastatic Spine Guidelines

- a. The majority of initial drafts will be completed following the 2009 CNS meeting.
- b. Initial review to the Joint Guidelines Committee by the 2010 Joint Section Meeting.
- c. Topic Outline:
 - Introduction and Methodology and Functional Outcome Assessment for Metastatic Spinal Disease FIRST DRAFT COMPLETED
 - ii. Radiographic Assessment Instability and Risk of Pathologic Fracture
 - LITERATURE REVIEW INITIATED
 - iii. Non-chemotherapeutic Medical Management (i.e. Steroids, Bis-phosphonate)EVIDENTIARY TABLES COMPLETED
 - iv. Role of Surgery in Symptomatic Metastatic Spinal Cord Compression:Posterior approaches EVIDENTIARY TABLES COMPLETED
 - v. Role of Surgery in Symptomatic Metastatic Spinal Cord Compression:Anterior and Combination approaches EVIDENTIARY TABLES COMPLETED
 - vi. Role of Combination Surgery and Radiotherapy in Symptomatic Metastatic Spinal Cord Compression FIRST DRAFT COMPLETED
 - vii. Role of Combination Surgery and Radiotherapy in Asymptomatic Metastatic Spinal Cord Compression

FIRST DRAFT COMPLETED

- viii. Role of Intraoperative Radiation Therapy Techniques for Metastatic Spine Disease
 - LITTERATURE REVIEW COMPLETED
 - ix. Role of Radiosurgery and Intensity Modulated
 Radiotherapy for Metastatic
 Spine Disease
 - LITTERATURE REVIEW COMPLETED
 - x. Role of Vertebral Augmentation (Kyphoplasty, Vertebroplasty) in Metastatic Spine Disease FIRST DRAFT COMPLETED
 - xi. Role of Pre-operative Embolization for Spinal Metastatic Disease FIRST DRAFT COMPLETED
- xii. Role of Implantable Pain Devices for Metastatic Spine Disease (REVIEWED VERY MINIMAL DATA MAY OMIT AND DEFER TO PAIN EXPERTS)

Treatment Recommendations for Specific Diagnoses (SEVERAL SECTIONS ARE COMPLETED BUT MOST IN LITTERATURE REVIEW – Final Structure Dependent on amount of data available)

d. Funds dispersed to date - \$0

4. Thoracolumbar Trauma Guidelines

- a. Initial committee meeting in Chicago -8/1/09
- b. Topic list finalized
 - i. Introduction and methodology
 - ii. Classification of thoracic and thoracolumbar spine fracture-dislocations
 - iii. Radiographic evaluation of traumatic thoracic and thoracolumbar spine trauma
 - iv. Assessment of neurological impairment of thoracic and thoracolumbar spinal cord injuries
 - v. Pharmacologic treatment of acute of thoracic and thoracolumbar spinal cord injury
 - vi. Deep venous thrombosis and thromboembolism in thoracic and thoracolumbar spinal cord injury
 - vii. Clinical and radiographic predictors of patient based outcomes following thoracic and thoracolumbar trauma

- viii. Non-operative treatment alternatives for patients presenting with thoracic and thoracolumbar trauma
- ix. Timing of surgical intervention for thoracic and thoracolumbar trauma
- x. Operative versus non-operative treatment for thoracic and thoracolumbar trauma
- xi. Surgical approaches for the management of thoracic and thoracolumbar burst fractures
 - 1. Neurologically intact
 - 2. Neurologically impaired
- xii. Surgical approaches for the management of thoracic and thoracolumbar fracture-dislocations
 - 1. Neurologically intact vs. impaired.
- xiii. Is arthrodesis necessary for instrumentation of patients presenting with thoracic and thoracolumbar trauma
- c. Anticipated completion of evidentiary tables Jan/Feb 2010
- d. Second meeting Spring 2010
 - i. Formulate recommendations and review initial drafts
- e. Funds dispersed to date \$8705 (Joint Spine Section)

5. Cervical Spine Trauma Guidelines

- a. Anticipated update of current guidelines in 2010
- b. Mark Hadley/Beverly Walters in charge

6. Lumbar Fusion Guidelines in the Medicare Population

a. Lumbar Fusion Task Force Initiative

Respectfully submitted,

Mike Kaiser, MD New York, NY Tim Ryken, MD Iowa City, Iowa



FOR IMMEDIATE RELEASE

Contact: Katie Orrico (202) 446-2024

Neurosurgeons Oppose Limiting Patient Access and Government Interference in Medical Care

House Health Care Reform Bill Jeopardizes Future of American Medicine

WASHINGTON, DC – The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) announced their opposition to H.R. 3200, the "America's Affordable Health Choices Act of 2009," currently under consideration by the House of Representatives.

"America's neurosurgeons strongly support improving our nation's healthcare system by ensuring insurance coverage for all our citizens. Unfortunately, as it is currently constructed, this bill goes far beyond what is necessary to fix what is broken with our healthcare system," stated Troy M. Tippett, MD, President of the AANS. "Rather than pursuing a carefully targeted set of reforms, the House bill could amount to a complete government takeover of healthcare."

P. David Adelson, MD, President of the CNS echoed these sentiments, stating, "Clearly, we want to ensure that every patient has insurance and timely access to quality healthcare provided by the doctor of his or her choice. However, this legislation will ultimately limit patient choice, will put the government between the doctor and the patient, interfering with patient care decisions, and because of its tremendous cost – immediately and in the future – will be a burden to all Americans."

Specifically, the AANS and CNS have concerns about the following key elements of the legislation:

- Ultimately, the public health insurance option will lead to a single-payer, government run healthcare system;
- Due to its high price-tag, the health system envisioned is unsustainable;
- Under the public health insurance option, the government is empowered to implement rules that would restrict patients' choice of physician and limit timely access to quality specialty care;
- The bill fails to recognize the looming workforce shortages in surgery by requiring that all unused medical residency training slots be allocated to primary care and placing the emphasis on national workforce policy on primary care, to the exclusion of surgical and other specialty care;
- The bill inappropriately expands the government's involvement in determining the quality of medical care and residency training programs;
- The bill permits the government to arbitrarily reduce reimbursement for valuable, life-saving specialty care for elderly patients, threatening treatment options;
- Patient-centered healthcare is threatened by provisions related to comparative effectiveness research, changes to office-based imaging and curtailing the development of physician-owned specialty hospitals; and
- The bill potentially stifles medical innovation and valuable continuing medical education programs.

In addition, the House bill fails to include an essential element – medical liability reform. "Numerous studies have demonstrated that effective federal medical liability reforms will significantly lower healthcare costs by reducing defensive medicine and eliminating frivolous lawsuits from the system," Dr. Tippett noted. "Congress cannot call this health care reform without addressing this problem."

The AANS and CNS look forward to working with Congress to make changes in the legislation to ensure that we enact meaningful health system reform, without dismantling the current system, which works well for most Americans.

The American Association of Neurological Surgeons (AANS), founded in 1931, and the Congress of Neurological Surgeons (CNS), founded in 1951, are the two largest scientific and educational associations for neurosurgical professionals in the world. These groups represent approximately 7,600 neurosurgeons worldwide. Neurological surgery is the medical specialty concerned with the prevention, diagnosis, treatment and rehabilitation of disorders that affect the entire nervous system, including the spinal column, spinal cord, brain and peripheral nerves.

AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES



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A Section of the American Association of Neurological Surgeons and Congress of Neurological Surgeons

Dorothy G. Smith Clinical Affairs, Speakers Bureau Manager Integra LifeSciences 315 Enterprise Drive Plainsboro, NJ 08536 dsmith@integra-LS.com

17 October 2008

Re: AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Annual David Kline Lectureship

Dear Ms. Smith:

Thanks to Integra LifeSciences for your continued support of the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and the Annual David Kline Lectureship.

Per your request of 14 October 2008, the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves formally requests from Integra LifeSciences support in the amount of \$5000.00 for the travel, lodging, and honorarium for the 2009 David Kline lecturer at the Section program at 2009 AANS Annual Meeting.

I will have the Section W-9 form sent to you shortly from the AANS home office.

Thank you again for your support of the Section. If you have any questions or require any additional information, please contact me at your convenience.

Sincerely,

Christopher Wolfla, MD

in E. Well

Treasurer

Subject: meeting budget

Date: Thursday, July 2, 2009 10:32 AM **From:** paul matz <matzpg@yahoo.com>

To: Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu, Praveen Mummaneni vmum@aol.com, R. Hurlbert jhurlber@ucalgary.ca, Dan Resnick@neurosurg.wisc.edu, Michael Groff, MD mgroff@bidmc.harvard.edu, Charlie Kuntz charleskuntz@yahoo.com

Cc: Regina N. Shupak rns@1CNS.ORG, Behncke Laurie llb@1CNS.ORG

Recently, I reviewed the proposed budget for the meeting. With the recession, the revenues will likely be diminished due to lower contributions from exhibitors (15% reduction). This is projected and not definite but we have to expect the worst. The cost increases will be about 10-15% from the past. My questions to the group are as follows:

- 1) We have budgeted \$6000 for speaker honoraria. Usually, is this a sufficient amount? Usually it is \$1000/speaker with foreign speakers sometimes getting \$2000.
- 2) We have had diminished attendance at the Tuesday night Executive Committee dinner. Most folks fly in late on Tuesday if they have a Wednesday commitment. Should we continue a dinner? Something less expensive (a later cocktail reception)? Any thoughts?
- 3) Finally, a large amount of the program printing charges has to do with printing the names and addresses of JSSPN members. Do we want to still do this? It may be better simply to state that the names/addresses are available on the Section website or some less cumbersome means. Do members still use the directory?

Let me know your thoughts.

Thanks,

Paul Matz

Paul G. Matz Neurosurgery and Neurology, LLC 232 South Woods Mill Road Suite 400E Chesterfield, MO 63017

Phone 314-878-2888 Fax 314-878-4026 email: matzpg@yahoo.com

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Membership Committee 10/9/09

There were 86 unpaid section members when the delinquent eblast was sent in June.

Currently, 44 members remain unpaid. Most are unpaid for 2009 only but a few still owe for 2008 and 2009.

5 orthopedic surgeons have joined since the beginning of 2009.

-There have been 34 new members since the last Spine Section meeting

Outcomes Committee Report Spine Section Executive Committee Meeting Versailles Ballroom, Riverside Hilton, October 24th, 2009, 3 pm – 7 pm New Orleans

Committee Members:

Zoher Ghogawala zoher.ghogawala@yale.edu Mike Kaiser mgk7@columbia.edu Subu Magge subu.n.magge@lahey.org John O'Toole John_Otoole@rush.edu Jean Coumans jcoumans@partners.org Maxwell Boakye mboakye@stanford.edu

A. Clinical Trials Proposal Awards \$ 500

- 1. We received 8 clinical trial proposals from 8 different institutions that met all the requirements. All trial proposals were de-identified to ensure a fair and blinded review. All competitive trial proposals were reviewed by at least 2 reviewers from the committee and NIH scoring criteria were followed. Proposals were reviewed according to:
 - a) significance
 - b) design and approach
 - c) innovation
 - d) overall potential to have impact on clinical care

The scores of both reviewers were averaged.

B. Clinical Trials Award – \$ 50,000

1. The Outcomes reviewed all three revised clinical trial proposals and scored each of them. Revised proposals were due April 15, 2009. All proposals were reviewed by 5 separate reviewers and the score averaged.

The three top proposals were:

Marjorie Wang, MD (faculty) - WINNER

Medical College of Wisconsin (institution)

"Cervical Spondylotic Myelopathy: Can outcome be predicted by diffusion tensor imaging?"

Design: Prospective Single Center Study to evaluate novel technology

Outcome: SF-36 Physical Component Summary Score, mJOA, Neck Disability

Index

Scientific Principle – Non-invasive imaging of spinal cord tissue integrity and architecture might help stratify patients with cervical spondylosis and help predict outcome.

Richard Lebow, MD (resident) – Joseph Cheng, MD (faculty sponsor)

Vanderbilt (institution)

"The effect of a continuous perioperative dexmedetomidine infusion on time-todischarge in patients undergoing multi-level spinal fusion: a double-blinded, placebo controlled study."

Design – RCT, 100 patients (4 sites)

Outcome – Length of Stay, VAS, SF36, cytokine serum levels

Scientific Principle – Controlling the inflammatory response might affect healing and improve pain control after fusion surgery

<u>Deb Bhowmick, MD (resident) William Welch, MD (faculty sponsor)</u>

University of Pennsylvania (institution)

"Hypertonic saline therapy for the treatment of acute spinal cord injury"

Design: RCT, 68 pts (2 sites)

Outcome: Death, complication, ASIA scores

Scientific Principle – Hypertonic saline might result in the osmotic removal of extra cellular fluid in the CNS and possibly increase blood flow to damaged spinal cord resulting in better outcome after acute spinal cord injury.

The award will be given in 2 parts: \$25,000 initially once a satisfactory letter from Dr Wang's biostatistician has been received. The second \$25,000 will be awarded once a progress report has been received summarizing progress on each of the specific aims listed in the grant proposal. The second \$25,000 will be awarded only if 50% of the proposal accrual has been reached.

- 2. We have \$ 100,000 dollars to support 2 more awards over the next 2 years.
- 3. We are awaiting a progress report from our first Clinical Trials Award Winner:

Khalid Abbed, MD, Yale University, Assistant Professor

Proposal: To compare minimally invasive T-LIF versus open T-LIF for grade I spondylolisthesis with symptomatic spinal stenosis.

Design: pilot study - 100 pts, 3 sites, non-randomized.

Outcome Instruments: SF-36 PCS and ODI

C. Spine Section Web Site

In addition, we are keeping the section website current with a section on all active clinical trials registered with the NIH site clinicaltrials.gov that relate to spinal diseases. There are currently 96 clinical trials relating to spinal disorders

registered with ClinicalTrials.gov – all are listed on our section website. This is up 71% from last year.

Appendix – E-blast (to be sent out by AANS in Nov, 2009)

2009 AANS/ CNS Spine Section Clinical Trial Awards

Spine Clinical Trial Proposal - \$ 500 Spine Clinical Fellowship Award - \$ 50,000

The AANS/CNS Spine Section is pleased to announce the continuation of a clinical trials fellowship award to promote well-designed neurosurgical clinical research. Neurosurgical residents/ fellows/clinical instructors/ and assistant professors are eligible to apply for the Clinical Trial Proposal. Applications for the Clinical Fellowship Award will only be accepted from junior faculty members of an accredited neurosurgical department. The objective of this award is to create an infrastructure necessary for executing well-designed multi-center studies, to promote the advancement of evidence-based neurosurgical practices, with an emphasis on spine. **DEADLINE FOR SUBMISSION is January 1, 2010.** The application process can be found on the section website and is summarized below:

Step 1. Clinical Trials Proposal Award - \$ 500

This award would be presented annually by the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves to <u>no more than three</u> neurosurgical residents or BC/BE neurosurgeons/ fellows in North America who submit an outstanding clinical trials proposal (5 pages maximum) that demonstrates clinical relevance, sound methodological design, and feasibility. Preference would be given to a team that designs a multi-center trial. Winners would be given an honorarium of \$ 500 plus reimbursement to attend the annual AANS/CNS Spine Section Meeting (presenter only).

Step 2. Clinical Trials Fellowship Award - \$ 50,000

All submitted proposals sponsored by junior faculty will be considered for the Clinical Trials Fellowship Award. Those individuals whose proposals are meritorious would be formally critiqued by the Joint Section Outcomes Committee and invited to submit a revised proposal for the one year \$ 50,000 Clinical Trials Fellowship Award. This grant is intended to support a pilot study based on the submitted proposal. The recipient will receive \$ 25,000 at the onset of the research project. Involvement of an independent biostatistician for epidemiological support is required. A written progress report within 6 months of receiving the award, including a comprehensive data analysis submitted by the biostatistician, is mandatory. In general, the progress report should contain evidence for enrollment of 50% of the accrual goal. Satisfactory completion of the progress report is required in order to receive the second allotment of \$ 25,000.

AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES



A Section of the American Association of Neurological Surgeons and Congress of Neurological Surgeons



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Section Membership Report

		Count
SP Member Type		
Current Members		
SP01S	Spine Section Active Member	1,013
SP15D	Spine Section Associate Member	7
SP25S	Spine Section Senior Member	239
SP40S	Spine Section International Member	41
SP45D	Spine Section Honorary Member	1
SP60D	Spine Section Adjunct Member	19
SP60P	Spine Section Pending Adjunct Member	3
SP65R	Spine Section Resident Member	118
		1,441
Resigned, Deceased,	or Suspended Members - 2009	
SP97S	Spine Section Resigned Member	7
SP98S	Spine Section Deceased Member	3
		10

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Gregory A. Brandenberg MD F A01S

AANS Member CNS Member Type Member Type ID Name Inv# Batch Inv Amt Amt Paid Amt Due Email Section: Spine Section Jafri Malin Abdullah MD PhD A40S 146772 CN05S 50.00 0.00 50.00 deptneurosciencesppspusm@yahoo.com 5-000167833 SP081201DU01 A01S CN01S 90555 Chad D. Abernathey MD 5-000154752 SP071205DU01 50.00 0.00 50.00 1971gtx@mchsi.com 5-000167299 SP081201DU01 50.00 0.00 50.00 121910 Bret B. Abshire MD A01S 5-000167622 SP081201DU01 50.00 0.00 50.00 bretabshire@yahoo.com X99S 96107 Maged Lotfy Abu-Assal MD 5-000155504 SP071205DU01 50.00 0.00 50.00 magedaassal@yahoo.com 50.00 0.00 50.00 5-000167977 SP081201DU01 117649 Mark S. Adams MD A01S 5-000167605 SP081201DU01 50.00 0.00 50.00 markadamsa@aol.com 161502 Maher A. Al-Hejji MD X99S CN65R 0.00 50.00 5-000155470 SP071205DU01 50.00 none 5-000168003 SP081201DU01 50.00 0.00 50.00 157369 Ghanem Al-Sulaiti MD A05S CN65R 0.00 50.00 5-000167749 SP081201DU01 50.00 dralsulaiti@yahoo.ca E. Francois Aldrich MD A01S 101188 0.00 50.00 5-000167472 SP081201DU01 50.00 aldrich3@starpower.net X99S CN01S 56473 Anthony N. Avellanosa MD 0.00 50.00 5-000167957 SP081201DU01 50.00 none 101171 Jose Avila-Ramirez MD A01SC 0.00 50.00 5-000168015 SP081201DU01 50.00 afauiela@hotmail.com 90061 Charles Jules Azzam MD A01S CN01S 0.00 50.00 5-000167215 SP081201DU01 50.00 charlesazzam@aol.com CN01S 96966 Giancarlo Barolat MD A01S 0.00 5-000167420 SP081201DU01 50.00 50.00 gbarolat@verizon.net 144944 Maxwell Boakye MD A01S CN65T 0.00 50.00 5-000167701 SP081201DU01 50.00 mboakye@stanford.edu CN01S 123196 Samuel R. Bowen II MD A01S 50.00 0.00 50.00 5-000167644 SP081201DU01 bbowen@bnspc.com

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Page 1 of 10

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arthlink.net		5-000167695	SP081201DU01	50.00	0.00	50.00
Kerry E. Brega MD	X99S	CN01S				
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Travis H. Calvin Jr. MD	A35S	CN25S				
acrmc.org		5-000154414	SP071205DU01	50.00	0.00	50.00
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Bo-Young Cho	X99D					
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Kyung Gi Cho MD PhD	A40SD					
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Dean Chou MD	X99S	CN65T				
eurosurg.ucsf.edu		5-000167986	SP081201DU01	50.00	0.00	50.00
Christopher H. Comey MD	A01S	CN01S				
omcast.net		5-000167510	SP081201DU01	50.00	0.00	50.00
Benjamin Gould Cox Jr. M	D X99S	CN25S				
@verizon.net		5-000167947	SP081201DU01	50.00	0.00	50.00
Brian G. Cuddy MD FACS	A01S	CN01S				
harleston-neurosurgery.com		5-000167457	SP081201DU01	50.00	0.00	50.00
David L. Cunningham MD	A35S					
ahoo.com		5-000167800	SP081201DU01	50.00	0.00	50.00
Guy O. Danielson III MD	S01S	CN01S				
ahoo.com		5-000154597	SP071205DU01	50.00	0.00	50.00
		5-000168026	SP081201DU01	50.00	0.00	50.00
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opical.com.br		5-000167746	SP081201DU01	50.00	0.00	50.00
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edocs.com	-	5-000168023	SP081201DU01	50.00	0.00	50.00
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Page 2 of 10

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			5-000168008	SP081201DU01	50.00	0.00	50.00
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90755	Ravindra N. Goyal MD FA	CS A01S	CN25S				
rngoyal@at				SP081201DU01	50.00	0.00	50.00
95126	Paul A. Grabb MD	X99S	CN01S				
	hotmail.com			SP081201DU01	50.00	0.00	50.00

Page 3 of 10

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bgreen@n	ned.miami.edu		5-000167158	SP081201DU01	50.00	0.00	50.00
117650	Kern H. Guppy MD PhD	A01S	CN01S				
kguppy@y	yahoo.com		5-000167606	SP081201DU01	50.00	0.00	50.00
403179	Mark N. Hadley MD FAC	S A01S	CN01S				
mhadley@)uabmc.edu		5-000167740	SP081201DU01	50.00	0.00	50.00
98085	Andrea L. Halliday MD PA	A A01S	CN01S				
ahalliday@	Deugenespine.com		5-000167436	SP081201DU01	50.00	0.00	50.00
19217	Robert F. Heary MD	A01S	CN01S				
heary@un	ndnj.edu		5-000167062	SP081201DU01	50.00	0.00	50.00
130442	Langston T. Holly MD	A01S	CN01S				
lholly@m	ednet.ucla.edu		5-000167679	SP081201DU01	50.00	0.00	50.00
52431	L. Nelson Hopkins III MD	A01S	CN01S				
lnhbuffns(@aol.com			SP071205DU01	50.00	0.00	50.00
			5-000167139	SP081201DU01	50.00	0.00	50.00
116466	Tomokatsu Hori MD	A40S	CN05S				
thori@nij.	twmu.ac.jp		5-000167829	SP081201DU01	50.00	0.00	50.00
52514	Michael G. Hughes MD	S01S	CN01S				
dawnef@a	meritech.net			SP071205DU01	50.00	0.00	50.00
			5-000168025	SP081201DU01	50.00	0.00	50.00
161392	Kevin Morgan Jackson MI	A60S	CN65R				
kjaxmd@s	sbcglobal.net		5-000167882	SP081201DU01	50.00	0.00	50.00
156028	Thad R. Jackson MD	A01S	CN65T				
tjack0@uk	xy.edu		5-000167873	SP081201DU01	50.00	0.00	50.00
144155	Sam P. Javedan MD	A01S	CN65R				
lsjavedan@	@comcast.net		5-000167700	SP081201DU01	50.00	0.00	50.00
97171	Hae-Dong Jho MD PhD	A01S	CN97S				
drjho@drj	ho.com		5-000167422	SP081201DU01	50.00	0.00	50.00
90768	Jose L. Joy MD PA	A01S					
joseljoymo	d@msn.com		5-000167339	SP081201DU01	50.00	0.00	50.00
409805	Adam S. Kanter MD	A60S	CN65R				

Page 4 of 10

Printed: 4/17/2009 2:11:42PM sjm

Member ID	Name	AANS Member Type	CNS Member Type				rage 5 or
Email			Inv#	Batch	Inv Amt	Amt Paid	Amt Du
kanteras@	upmc.edu		5-000167919	SP081201DU01	50.00	0.00	50.00
102797	John F. Keller MD	A01S	CN01S				
jkeller412(@aol.com		5-000154943	SP071205DU01	50.00	0.00	50.00
			5-000167488	SP081201DU01	50.00	0.00	50.00
123518	Ahmed M. Khan MD	A01S	CN01S				
ahkhan@th	nocc.org		5-000155103	SP071205DU01	50.00	0.00	50.00
			5-000167654	SP081201DU01	50.00	0.00	50.00
95123	Joseph T. King Jr. MD	A01S	CN01S				
joseph.king	gjr@va.gov		5-000167405	SP081201DU01	50.00	0.00	50.00
98236	Phillip Kissel MD	A01S	CN01S				
pkissel@pl	kisselneurosurgery.com		5-000167459	SP081201DU01	50.00	0.00	50.00
104277	Nachshon Knoller MD	A40S	CN97S				
knoller@sł	neba.health.gov.il		5-000167827	SP081201DU01	50.00	0.00	50.00
55889	William Kraut MD FACS	A35S	CN25S				
wjkraut@v	erizon.net		5-000167819	SP081201DU01	50.00	0.00	50.00
90721	Joseph Philip Krzeminski M	MD A01S	CN01S				
jkrz@aol.c	om		5-000167329	SP081201DU01	50.00	0.00	50.00
23358	Robert H. Le Grand Jr. MD	A01S	CN01S				
aa5fd@wc	c.net		5-000167066	SP081201DU01	50.00	0.00	50.00
123039	Thomas T. Lee MD	A01S					
thomastlee	md@aol.com		5-000167632	SP081201DU01	50.00	0.00	50.00
50017	Matt John Likavec MD	A01S	CN01S				
mlikavec@	metrohealth.org		5-000167085	SP081201DU01	50.00	0.00	50.00
50699	Kenneth I. Lipow MD	A01S	CN01S				
cyberken@	optonline.net		5-000167126	SP081201DU01	50.00	0.00	50.00
90836	Sean Raymond Logan MD	A01S	CN01S				
slogan9398	a@aol.com		5-000167353	SP081201DU01	50.00	0.00	50.00
51133	Nelson T. Macedo MD	A35P	CN01S				
nmacedo@	suddenlink.net		5-000167132	SP081201DU01	50.00	0.00	50.00
103029	Lloyd I. Maliner MD	A01S	CN01S				
lmaliner@r	nhs.net		5-000167517	SP081201DU01	50.00	0.00	50.00
53215	Jack Earl Maniscalco MD	X99S	CN01S				
manisca@	tampabay.rr.com		5-000167950	SP081201DU01	50.00	0.00	50.00

Page 5 of 10

Printed: 4/17/2009 2:11:42PM sjm

Member ID	2:11:42PM sjm A Name	ANS Member Type	CNS Member Type				Page 6 of 10
Email			Inv#	Batch	Inv Amt	Amt Paid	Amt Due
	Dhilin I Marra MD	A01S	CN97S				
101376	Philip J. Marra MD	AUIS		SP081201DU01	50.00	0.00	50.00
pmarrama	ittigator.com		3 000107171	51 0012012 001	20.00	0.00	
110432	Jeffrey E. Masciopinto MD	A01S					
jeff.masci	opinto@deancare.com			SP071205DU01	50.00	0.00	50.00
			5-000167579	SP081201DU01	50.00	0.00	50.00
22863	Frederick McEliece MD	X99S	CN01S				
none			5-000167938	SP081201DU01	50.00	0.00	50.00
56853	Hamid M. Mehdizadeh MI) A15D	CN01S				
none			5-000155191	SP071205DU01	50.00	0.00	50.00
			5-000168030	SP081201DU01	50.00	0.00	50.00
103017	B. Theo Mellion PhD MD	A01S	CN01S				
tmellion@				SP081201DU01	50.00	0.00	50.00
102070	D' I - I G M - I I MD FA	CC 401C	CNOIC				
102979	Richard C. Mendel MD FA	CS AUIS	CN01S 5-000167508	SP081201DU01	50.00	0.00	50.00
docamen	de1480ffs.com		3-000107308	31 001201D001	30.00	0.00	30.00
90206	Ronald Michael MD	A01S					
insn@msr	n.com		5-000167236	SP081201DU01	50.00	0.00	50.00
145268	Fardad Mobin MD	A01S					
mobinmd(@gmail.com		5-000167703	SP081201DU01	50.00	0.00	50.00
50293	Daniel W. Moore MD FAC	CS A01S	CN01S				
	7@bellsouth.net		5-000167113	SP081201DU01	50.00	0.00	50.00
	n / 1/ 1/0	77000	CNICED				
402391	Ramon L. Navarro MD	X99S	CN65R 5-000168004	SP081201DU01	50.00	0.00	50.00
mavarro(a	hsjdben.org		3-000108004	3F001201D001	50.00	0.00	50.00
135940	Robert T. Numoto MD	X99S	CN05S				
spine@jik	ei.ac.jp		5-000168000	SP081201DU01	50.00	0.00	50.00
60297	Stephen K. Ofori-Kwakye	MD A01S					
stephenof	ori@msn.com		5-000167197	SP081201DU01	50.00	0.00	50.00
119009	Seong-Hoon Oh MD	A40SD	CN05S				
	yahoo.co.kr			SP081201DU01	50.00	0.00	50.00
104	Telle A. Oudenen MD	4010					
jaordon@	Julio A. Ordonez MD	A01S	5-000166966	SP081201DU01	50.00	0.00	50.00
			2 232 200 00		2 2 . 0 0		
106871	Hyung-Chun Park MD PhD	A40SD					
phchun@i	inha.ac.kr			SP071205DU01	50.00	0.00	50.00
			5-000168038	SP081201DU01	50.00	0.00	50.00

Page 6 of 10

Printed: 4/17/2009 2:11:42PM sjm Page 7 of 10

Member ID	Name	AANS Member Type	CNS Member Type				
Email			Inv #	Batch	Inv Amt	Amt Paid	Amt D
98133	Noel I. Perin MD FRCS	A01S	CN01S				
nip3311@	aol.com		5-000167444	SP081201DU01	50.00	0.00	50.0
98229	Joel D. Pickett MD	A01S	CN01S				
joelpickett	@comcast.net		5-000167458	SP081201DU01	50.00	0.00	50.0
105222	J. Adair Prall MD	A01S	CN01S				
adairprall(@centura.org		5-000167564	SP081201DU01	50.00	0.00	50.
98224	Gregory J. Przybylski MD	A01S	CN01S				
gprzybyl@	optonline.net		5-000154911	SP071205DU01	50.00	0.00	50.0
			5-000167456	SP081201DU01	50.00	0.00	50.
11759	Donald E. Richardson MD	A25S	CN01S				
nsurg@ma	ic.com		5-000167786	SP081201DU01	50.00	0.00	50.0
155	Bernard Robinson MD	A01S	CN01S				,
bernierob1	@aol.com		5-000166975	SP081201DU01	50.00	0.00	50.0
11932	Gaylan L. Rockswold MD	A25S	CN01S				
gaylan.roc	kswold@co.hennepin.mn.us			SP071205DU01	50.00	0.00	50.
			5-000167787	SP081201DU01	50.00	0.00	50.0
412756	Andrew C. Roeser MD	X99S					
andyroeser	@yahoo.com			SP071205DU01	50.00	0.00	50.0
			5-000167844	SP081201DU01	50.00	0.00	50.
19178	Michael J. Rutigliano MD	MB A01S					
rutiglianon	nj@msx.upmc.edu		5-000167053	SP081201DU01	50.00	0.00	50.
157	Lenard J. Rutkowski MD	A01S					
ljrutkowsk	imd@hotmail.com		5-000166976	SP081201DU01	50.00	0.00	50.0
90469	David P. Sachs MD FACS	A01S	CN01S				
alysendave	e@aol.com		5-000167279	SP081201DU01	50.00	0.00	50.0
54445	Pritam S. Sahni MD	X99S	CN01S				
sahni@mv	n.net		5-000167951	SP081201DU01	50.00	0.00	50.0
98111	John Sarris MD	A01S					
esarris4@c	comcast.net		5-000167441	SP081201DU01	50.00	0.00	50.0
157287	Thomas C. Schermerhorn M	MD A60S	CN65R				
jbreithaupt	@mhc.net		5-000167877	SP081201DU01	50.00	0.00	50.0
13144	Stanton Schiffer MD	A25S	CN97S				
	acbell.net			SP081201DU01	50.00	0.00	50.0

Printed: 4/17/2009 2:11:42PM sjm

Member ID	Name	AANS Member Type	CNS Member Type				
Email			Inv #	Batch	Inv Amt	Amt Paid	Amt Due
59386	Daniel Schmelka MD	A01S	CN01S				
dschmelka	a@altru.org		5-000167185	SP081201DU01	50.00	0.00	50.00
95006	John H. Schneider Jr. MD	A01S	CN01S				
john@wy	omingspine.com		5-000167382	SP081201DU01	50.00	0.00	50.00
50312	Ricardo Segal MD	X99S	CN97S				
rsegal@ha	adassah.org.il		5-000167991	SP081201DU01	50.00	0.00	50.00
136092	Pennie S. Seibert	X99O					
penseiber	t@msn.com		5-000168010	SP081201DU01	50.00	0.00	50.00
415452	Anthony K. Sestokas PhD	X99D					
tonys@su	rgmon.com			SP071205DU01	50.00	0.00	50.00
			5-000167929	SP081201DU01	50.00	0.00	50.00
146748	Scott A. Shapiro MD	A01S	CN01S				
sshapiro@	jiupui.edu		5-000167716	SP081201DU01	50.00	0.00	50.00
422996	Homoz Sheikh MD	X99D					
hsheikh@	mednet.ucla.edu			SP071205DU01	50.00	0.00	50.00
			5-000167931	SP081201DU01	50.00	0.00	50.00
418665	Gregory Truitt Sherr MD	A50R					
sherr031@	vumn.edu			SP071205DU01	50.00	0.00	50.00
			5-000167843	SP081201DU01	50.00	0.00	50.00
160	Henry M. Shuey MD FAC	S A01S	CN01S				
sushu98@	comcast.net		5-000166977	SP081201DU01	50.00	0.00	50.00
152641	Marco T. Silva MD	A01S	CN65T				
mtsmd@y	rahoo.com		5-000167869	SP081201DU01	50.00	0.00	50.00
90912	Thomas N. Spagnolia MD	Ph A01S	CN01S				
tspagnolia	@hotmail.com		5-000167364	SP081201DU01	50.00	0.00	50.00
90396	Steven M. Stranges MD	A35S	CN01S				
stranges@	charter.net			SP071205DU01	50.00	0.00	50.00
			5-000167820	SP081201DU01	50.00	0.00	50.00
90598	Scott W. Strenger MD FAC	CS A01S	CN01S				
sstrenger@	@aol.com		5-000167305	SP081201DU01	50.00	0.00	50.00
102795	Mitchell L. Supler MD	A01S	CN01S				
mlsupler@	gaol.com		5-000168027	SP081201DU01	50.00	0.00	50.00
57018	Yoshiro Takaoka MD PhD	X99S	CN01S				

Page 8 of 10

Printed: 4/17/2009 2:11:42PM sjm

Member ID	Name	AANS Member Type	CNS Member Type				
Email			Inv #	Batch	Inv Amt	Amt Paid	Amt Du
yxt2@po.o	cwru.edu		5-000167958	SP081201DU01	50.00	0.00	50.0
95090	William R. Taylor MD	A01S	CN01S	,			
wtaylor@ı	ucsd.edu		5-000167400	SP081201DU01	50.00	0.00	50.0
157266	Francesca D. Tekula MD	A01S	CN65T				
francesca_	tekula@ciocenter.com		5-000167876	SP081201DU01	50.00	0.00	50.00
98260	Larry L. Teuber MD	X99S	CN01S				
lteuber@n	ssa.com		5-000167978	SP081201DU01	50.00	0.00	50.00
90767	B. Gregory Thompson Jr.	MD A01S	CN01S				
gregthom(@med.umich.edu		5-000167338	SP081201DU01	50.00	0.00	50.00
90880	Richard M. Toselli MD	T01S	CN01S				
tosellir@y	ahoo.com		5-000168033	SP081201DU01	50.00	0.00	50.00
19107	Gerald F. Tuite Jr. MD	A01S	CN01S				
geraldtuite	@yahoo.com		5-000167041	SP081201DU01	50.00	0.00	50.00
186	David D. Udehn MD	A01S	CN01S				
kidens@m	ac.com		5-000166981	SP081201DU01	50.00	0.00	50.00
116712	Todd W. Vitaz MD	A01S	CN01S				
tvitaz@nik	xy.com		5-000167601	SP081201DU01	50.00	0.00	50.00
151991	Amir A. Vokshoor MD	A01S					
avokshoor	@yahoo.com		5-000167722	SP081201DU01	50.00	0.00	50.00
96495	Dennis G. Vollmer MD	A01S	CN01S				
dennis.g.vo	ollmer@uth.tmc.edu		5-000167418	SP081201DU01	50.00	0.00	50.00
130222	Nicholas F. Voss MD	A01S					
nvoss@nei	urospineofdothan.com		5-000167673	SP081201DU01	50.00	0.00	50.00
50324	Shiro Waga MD	X99S	CN05S				
bprtj569@			5-000167992	SP081201DU01	50.00	0.00	50.00
57760	Joseph R. Walker MD	A01S	CN01S				
	@charter.net			SP071205DU01	50.00	0.00	50.00
			5-000167168	SP081201DU01	50.00	0.00	50.00
102769	Monte B. Weinberger MD	T01S	CN01S				
weinberger	r6@comcast.net		5-000168034	SP081201DU01	50.00	0.00	50.00
14944	Philip R. Weinstein MD	A35S	CN01S				
veinsteinp	@neurosurg.ucsf.edu		5-000167813	SP081201DU01	50.00	0.00	50.00

Page 9 of 10

Printed: 4/17/2009 2:11:42PM sjm

Grand Totals

Member **AANS Member CNS** ID Name Type Member Type Inv# Batch Inv Amt Amt Paid Amt Due Email 145351 Gregory C. Wiggins MD A01S CN01S gcwiggins@yahoo.com 5-000167706 SP081201DU01 50.00 0.00 50.00 59683 David Bruce Woodham MD A01S CN01S dbkobs@aol.com 5-000167192 SP081201DU01 50.00 0.00 50.00 137179 Julie E. York MD A01S CN01S julieyork@comcast.net 5-000155130 SP071205DU01 50.00 0.00 50.00 5-000167686 SP081201DU01 50.00 0.00 50.00 Peter A. Zahos MD FACS 102927 A01S CN01S pzahos@solarishs.org 5-000167503 SP081201DU01 50.00 0.00 50.00 19132 Ahmad Zakeri MD A01S CN01S ahmadzakeri@aol.com 5-000154479 SP071205DU01 50.00 0.00 50.00 5-000167045 SP081201DU01 50.00 0.00 50.00 95046 Andrew Stephen Zelby MD A01S CN01S azelby@yahoo.com 5-000167386 SP081201DU01 50.00 0.00 50.00 Totals for Section: Spine Section 166 \$8,300.00 \$0.00 \$8,300.00

166

\$8,300.00

\$0.00 \$8,300.00

Page 10 of 10



SYNTHES Spine 1302 Wrights Lane East West Chester, Pennsylvania 19380 Telephone 601-719-5000

September 30, 2009

Ms. Michele Lengerman Director of Marketing Congress of Neurological Surgeons 10 N. Martingale Road, Suite 190 Schaumburg, IL 60173

Dear Michele:

Thank you for your time on the phone today. As we discussed, during the past few months, my colleagues and I have had the opportunity to meet with some of the leadership and members of CNS and the Spine Section. Our objective was to share the mission and values of Synthes Spine, and, importantly, to better understand how these align with the CNS and Jt. Spine Section mission of delivering high quality, evidence-based, ethical spine care through education, research and advocacy.

As I mentioned, we believe that our mutual spine care goals would be better served through a redirection of exhibit related funds to projects commissioned by CNS and the Jt. Spine Section. As such, our proposal is to reinforce Synthes Spine as a major supporter of both societies and to discontinue our presence as an exhibitor at the annual meetings. I should add that this proposal only applies to Synthes Spine. Synthes CMF is, for this purpose, a separate entity, and they plan to continue as a CNS annual meeting exhibitor.

Eliminating the commercial element from our relationship is a unique and bold move, and it's important to us that this be viewed by your constituents in the spirit of advancing the care of spine patients. As you can imagine, there's a very real possibility of misinterpretation and negative perception, so we are asking for your support in communicating an appropriate message. We are also seeking your commitment to a few items that, I believe, would customarily be provided to a high level exhibitor.

These are the details of our proposal:

Our sponsorship of CNS in 2010 will be \$75,000.
Our sponsorship of the Jt. Spine Section in 2010 will be \$75,000.
For both the CNS and Jt, Spine Section annual meetings, we are seeking recognition in
the inside front cover of the program (at our expense) or some other meaningful way that

we mutually agree upon; 5 complimentary badges for each of the annual meetings; access to rooms in the HQ hotel (or exemption from the housing bureau restriction); invitations to events to which high level exhibitors would customarily be invited; and maintenance of our point/priority status. (Should we re-enter the exhibit hall in future years, we don't want to loose our status and find ourselves with a booth in the kitchen).

- Synthes Spine will have no input into the activities/projects to be funded by either entity, other than stipulating that they be related to research, education or advocacy in spine care. To the extent that any reporting is permissible (from a compliance perspective) we would like to understand the level of reporting that we can expect.
- □ It's important to us, and to the society, to have balance in the content of the annual meeting program. Specifically, in the invited presentations (such as pre-meeting symposia, breakfast clinics etc..), and only as permitted within ACCME regulations, we'd like to continue to receive requests from the society to participate in workshops, as well as provide names of potential speakers, based on the qualifications and topics as determined by CNS or the Jt. Spine Section.

Michele, this is such an unprecedented time in spine care. There's so much that needs to be done in areas of outcomes research, surgeon education and patient advocacy. We genuinely believe that this is the right time to take a unique position toward addressing the issues that matter most to surgeons and patients. I look forward to hearing your thoughts on this proposal as well as the next steps toward formalizing our mutual understanding. Thank you!

Fondest regards,

Sharon Schulzki

Sharon V. Schulzki Executive Vice President Sales & Marketing Synthes N-Spine

Cc: Laurie Behnke Rusty Rodts, MD Chris Shaffrey, MD Ziya Gokaslan, MD Subject: RE: WA State SIMP Draft Policy for Comment-URGENT

Date: Friday, July 31, 2009 6:43 PM

From: Chris Shaffrey <CIS8Z@hscmail.mcc.virginia.edu>

To: Katie O. Orrico korrico@neurosurgery.org, Dan Resnick resnick@neurosurg.wisc.edu, R. Hurlbert

jhurlber@ucalgary.ca, zgokasl1@jhmi.edu, Michael Groff, MD mgroff@bidmc.harvard.edu, Bob Heary heary@umdnj.edu

Cc: Cathy Hill chill@neurosurgery.org

Agree.

From: Katie O. Orrico [mailto:korrico@neurosurgery.org]

Sent: Friday, July 31, 2009 6:04 PM

To: Resnick (Daniel); 'jhurlber@ucalgary.ca'; 'zgokasl1@jhmi.edu'; 'mgroff@bidmc.harvard.edu'; Shaffrey, Chris I *HS; 'heary@umdnj.edu'

Cc: Cathy Hill

Subject: RE: WA State SIMP Draft Policy for Comment-URGENT

Here are Dan's comments....

I would suggest that we agree in concept but ask that the requirement be waved if an effective SIMP (as demonstrated in the literature) is not available. Such programs do not exist in North America, and requiring such a program is unrealistic. The two Washington State references we used last time would seem to suffice for evidence.

Katie O. Orrico, Director
Washington Office
American Association of Neurological Surgeons/
Congress of Neurological Surgeons
725 15th Street, NW, Suite 500

Washington, DC 20005 Direct Dial: 202-446-2024

Fax: 202-628-5264 Cell: 703-362-4637

korrico@neurosurgery.org

-----Original Message-----

From: Resnick (Daniel) [mailto:resnick@neurosurg.wisc.edu]

Sent: Friday, July 31, 2009 6:00 PM

To: Katie O. Orrico; 'jhurlber@ucalgary.ca'; 'zgokasl1@jhmi.edu';

'mgroff@bidmc.harvard.edu'; 'CIS8Z@hscmail.mcc.virginia.edu'; 'heary@umdnj.edu' Cc: Cathy Hill
Subject: Re: WA State SIMP Draft Policy for Comment-URGENT

Hi Katie- I sent a response to Pam that I thought was cc'd to you and Rachel- if you did not get it let me know and I'll try and remember what I said.

---- Original Message ---From: Katie O. Orrico <korrico@neurosurgery.org>
To: (jhurlber@ucalgary.ca) <jhurlber@ucalgary.ca>; (zgokasl1@jhmi.edu)
<zgokasl1@jhmi.edu>; (mgroff@bidmc.harvard.edu) <mgroff@bidmc.harvard.edu>; Christopher I. Shaffrey (CIS8Z@hscmail.mcc.virginia.edu)
<CIS8Z@hscmail.mcc.virginia.edu>; heary@umdnj.edu <heary@umdnj.edu>; Resnick (Daniel)
Cc: Cathy Hill <chill@neurosurgery.org>; Katie O. Orrico <korrico@neurosurgery.org>
Sent: Fri Jul 31 12:49:21 2009
Subject: FW: WA State SIMP Draft Policy for Comment-URGENT

Chris, Dan, et al,

See below and attached. We need Section comment on this if you choose to do so. NASS will help coordinate the response, as they have been doing on this Washington State business. See 2 comments, one from Gunnar Andersson and Ted Wagner. That is it so far. The deadline for comments is next week. Let me know what you want to do.

*	*	*	*	*	*	*	*	**

Katie

Dear Pam

Having read Gunnar Andersson's comments, I suggest that the first page should read that those surgeons who are trained to diagnose and operate on patients must

consider many different pathologies such as congenital, infectious, deformity, neoplasm, endocrine[osteoporosis], and degenerative. These patients present with a wide variety of complaints i.e.. numbness weakness, balance, deformity and pain. The best outcome from spine surgery will only occur if the diagnosis accurate and the surgery is appropriate for the diagnosis.

This paragraph is only a suggestion,

Ted Wagner

* * * * * * * * * *

For starters the frontpage to the document is missleading suggesting that spinal surgery is a procedure to treat chronic low back pain. In fact most spine surgery is performed for other reasons. Further when reading the document the first few paragraphs excludes the most common reasons for which one of many spineprocedures (spinal fusions) are performed. It is surprising that the introductory page does not reflect the content of the report. Gunnar

Katie O. Orrico, Director

Washington Office

American Association of Neurological Surgeons/

Congress of Neurological Surgeons

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korrico@neurosurgery.org

From: Pam Hayden [mailto:phayden@spine.org]

Sent: Wednesday, July 29, 2009 3:46 PM

To: Charles Branch, MD; Charles Mick, MD; Christopher Bono; Dan Resnick; David A. Wong, MD, MSc; David W. Polly; Gunnar Andersson, MD; Hansen Yuan, MD; Jack Zigler, MD; Jeffrey Wang, MD; Jens Chapman, MD; Jerome Schofferman, MD; John Devine, MD; Johnn Heller, MD; Joseph Cheng, MD; Marjorie Eskay-Auerbach, MD, JD; Matthew Gornet, MD; Oheneba Boachie, MD; Praveen Mummaneni, MD; Ray Baker, MD; Richard D. Guyer, MD; Richard Wohns, MD; Steve Garfin; Steven Glassman, MD; Thomas Zdeblick; Tom Faciszewski, MD; Tom Faciszewski, MD (home); Wagner; Wendy Hess; William Watters

Cc: Belinda Duszynski; Cathy Hill; Dawn Brennaman; Eric Muehlbauer; Katie O. Orrico; Kristy Radcliffe; Nick Schilligo; Peggy Wlezien; Rachel Groman; Robert

Haralson, MD; Tressa Goulding

Subject: FW: WA State SIMP Draft Policy for Comment-URGENT

Importance: High

Dear Washington State Multisociety Work Group,

As you may remember, one of the requirements placed on coverage of lumbar fusion and lumbar artificial disc replacement in WA State was the completion of a structured, intensive multidisciplinary program (SIMP). Per the below e-mail from the WA State Office of the Medical Director

Labor and Industries, attached are the draft documents re: the proposed SIMP that were presented at the WA State Industrial Insurance Medical Advisory Committee (IIMAC) on July 23 and links to the proposed rule language (in the e-mail below). It has just come to our attention that these are out for public comment until 5PM on August 14. These are presented for your consideration and comment. I would be happy to coordinate a multi-society comment once again, should you wish to participate. Outlined below is a timeline for comment:

All Comments to Pam Hayden

Comment Letter Circulated Weds. August 5 Final Letter Submitted to Societies for Sign-on Tuesday, August 11 Comments Submitted to WA State Thursday, August 14 For your information WA State has also provided the following link that explains the decision that Washington State's Health Technology Assessment program made regarding lumbar fusions, which was the impetus for the documents you're now reviewing. Their decisions are legally binding on several state agencies that purchase health care. I've sent you only the page on lumbar fusions. http://www.hta.hca.wa.gov/ lumbar.html http://www.hta.hca.wa.gov/lumbar.html

Please submit your comments to me by 12:00PM Central, Weds. August 5.

We look forward to your comments,

Pam Hayden

Pamela M. Hayden

12:00PM Central, Weds. August 5

Director, Research & Quality Improvement

North American Spine Society

8320 St. Moritz Drive

Spring Grove, IL 60081

630.230.3690

Fax 630.230.3790

From: Javaher, Simone P (LNI) [mailto:stil235@LNI.WA.GOV]

Sent: Wednesday, July 29, 2009 1:51 PM

To: Pam Hayden

Cc: Dawn Brennaman; Lifka, Jami M (LNI) Subject: RE: SIMP Draft Policy for Comment

There are four documents in circulation and on which you can comment, but the process differs for some of them. Here's what you need to know:

The SIMP policy, patient education aid, and lumbar fusion guideline are all in draft form and are open for public comment through 5:00pm on August 14, 2009. Comments for these documents can be sent directly to me. Please bear in mind that the patient education aid is a very early draft and will likely undergo many changes before it's complete. The SIMP policy is a final draft, which means we are trying to limit any further changes to correction of errors or omissions, or clarifying language that will make it easier to understand. You can send any comments you like, but this is their status.

A portion of the SIMP policy is being put into administrative rule, meaning our Washington Administrative Code (WAC), and the process for providing feedback must follow the Administrative Procedures Act. This means all public comments must be submitted to our rule coordinator, Jami Lifka. Her email address is jami.lifka@Lni.wa.gov. The deadline for these comments is also 5:00pm on August 14, 2009.

I am attaching the non-rule documents and am attaching the links to the proposed rule language. If you submit comments, please be sure to include the Washington State Register number: WSR 09-10-081 as a reference.

http://www.lni.wa.gov/rules/AO09/06/0906Proposal.pdf

http://www.lni.wa.gov/rules/AO09/06/0906CR102.pdf

I hope this meets your needs.

Simone Javaher

Ms. Simone P. Javaher, BSN, MPA

Office of the Medical Director

Labor and Industries

Olympia,- WA

Phone: 360-902-5762

Email: stil235@Ini.wa.gov

From: Pam Hayden [mailto:phayden@spine.org]

Sent: Wednesday, July 29, 2009 11:28 AM

To: Javaher, Simone P (LNI)

Cc: Dawn Brennaman

Subject: SIMP Draft Policy for Comment

Importance: High

Dear Ms. Javaher,

It has come to NASS' attention that at the July 23 meeting of the IIMAC, there was a presentation and update on the SIMP and that a draft policy was one of the handouts. It is our understanding that public comments are being taken on the draft policy until August 14. This is a topic that NASS and others would be interested in providing public comment on. Can you please confirm this information and kindly direct me to where I may find a copy of the materials for the SIMP (draft policy and patient materials, etc.) as well as where to submit comment.

I thank you in advance.

Best wishes,

Pam Hayden

Pamela M. Hayden

Director, Research & Quality Improvement

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AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS –

CONGRESS OF NEUROLOGICAL SURGEONS 2009 LEGISLATIVE AGENDA

☑ IMPROVE TRAUMA SYSTEMS AND ACCESS TO NEUROSURGICAL EMERGENCY CARE

There are significant gaps in our trauma and emergency health care delivery systems, and trauma is the leading killer of Americans under the age of 44. The AANS and CNS are committed to working with Congress to develop and implement creative approaches to improve the emergency care system, including implementing a system to regionalize emergency care. As recommended by the IOM in its ground-breaking 2006 report, "the objective of regionalization is to improve patient outcomes by directing patients to facilities with optimal capabilities of any given type of illness or injury." In addition, the AANS and CNS actively support increased funding for the HRSA Trauma-EMS Program, which provides grants to states to improve critically needed statewide trauma care systems.

☐ CHAMPION AN IMPROVED MEDICARE PHYSICIAN REIMBURSEMENT SYSTEM

Physicians face a 22 percent cut in Medicare reimbursement on January 1, 2010. Congress needs avoid bandaid solutions for fixing the physician payment system and once-and-for-all replace Medicare's Sustainable Growth Rate (SGR) formula with a stable mechanism for updating and reimbursing physicians. The new system must be fundamentally fair for *all* physicians, and any additional payments that are made to primary care physicians must not be budget neutral within the physician payment pool. The AANS and CNS are committed to working with Congress to pass a long-term solution to avert this significant cut and identify innovative approaches for reforming the Medicare payment system.

☑ ENHANCE MEDICARE AND OTHER QUALITY IMPROVEMENT PROGRAMS

While Congress has taken the first steps towards implementing informed quality improvement programs, the current Physician Quality Improvement Program (PQRI) is not working and needs to be drastically reworked to better incorporate a system for clinical data collection and reporting. A "one-size-fits-all" approach will not accomplish the lofty goals that we all hope will be the end result of these quality-based initiatives – better patient outcomes. The AANS and CNS support a pay-for-participation system under which data regarding physician quality is collected in a non-punitive environment and analyzed using accurate risk-adjustment mechanisms; public reporting of data only occurs at the aggregate level and not at the individual level; and physicians receive performance feedback continually and in a timely manner.

☑ INCREASE FUNDING FOR HEALTH CARE RESEARCH

Neurosurgeons are committed to advancing the public health by fighting diseases, developing treatments, and finding cures through continued medical research. Institutions such as the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ) are leading the way to help improve our nation's health and save lives. Organized neurosurgery also embraces the need for well-designed *clinical* comparative effectiveness research (CER), which can be a valuable tool to "learn what works in health care" and support good clinical decision making. CER must focus on communicating research results to patients and physicians, and must not be used for determining medical necessity or making centralized coverage and payment decisions. The AANS and CNS urge Congress to provide adequate funding for these vital public health research programs.

✓ Preserve Quality Resident Training and Safe Patient Care

Concerns about resident fatigue must be balanced with the need to adequately train neurosurgical residents and ensure quality patient care. The AANS and CNS believe that further reductions in resident work hours will have a negative impact on resident training and education and will produce a generation of neurosurgeons who will not be as skilled or committed as their predecessors and will fall short of public expectations. In addition, adherence to strict work hours can lead to medical errors attributable to more frequent patient handoffs,

fragmentation and loss of continuity of care. The Accreditation Council for Graduate Medical Education (ACGME) is effectively addressing these issues and legislation on this matter is therefore unnecessary.

✓ ALLEVIATE THE MEDICAL LIABILITY CRISIS

The AANS and CNS support legislation to provide common sense, proven, comprehensive medical liability reform. Federal legislation modeled after the laws in California or Texas, which includes reasonable limits on non-economic damages, represents the "gold standard," but other solutions should also be explored. A first step would be to apply the Federal Tort Claims Act to EMTALA-mandated services. EMTALA, the Emergency Medical Treatment and Labor Act, is a federal mandate to provide emergency care and puts neurosurgeons at an increased liability risk. Congress should also study alternatives to civil litigation, including: early disclosure and compensation offer; the administrative determination of compensation model; and health courts.

✓ ADVANCE MEASURES TO IMPROVE NEUROSURGICAL WORKFORCE

While neurosurgery continues to fill its residency slots across the nation, the federally *funded* positions have not kept pace with the growth in U.S. population, particularly the Medicare population. The future supply of all surgical specialists is woefully inadequate to provide the care that our Nation will require. Training a health care workforce to successfully serve the needs of the nation requires stable, long-term predictable funding given the length of time required to educate and train physicians – 6-8 years for neurosurgical training. The AANS and CNS support preserving Medicare funding for Graduate Medical Education (GME) and eliminating the residency funding caps that were established by the Balanced Budget Act of 1997. In addition, Medicare should *fully* fund residency programs through at least the initial board eligibility – in neurosurgery's case 6 years.

☑ SAFEGUARD PATIENT ACCESS TO SPECIALTY CARE IN HEALTH CARE REFORM

Health care reform must ensure that every patient has access to appropriate quality care, by the appropriate doctor, at the appropriate time. The AANS and CNS believe it is imperative that all health care reform proposals ensure that patients have timely access to the doctor of their choice.

☑ PROTECT PATIENT-CENTERED HEALTHCARE

Diagnostic imaging is an integral component of neurosurgical care, and the ability of neurosurgeons to provide in-office diagnostic imaging services to their patients ensures they get the best possible and timely care available. Ambulatory Surgery Centers (ASCs) and physician-owned specialty hospitals provide cost-effective care; have low infection, complication and mortality rates; and produce a marked increase in patient satisfaction. The AANS and CNS urge Congress to protect patient access to these services.

For More Information Contact: Adrienne A. Roberts, Senior Manager for Legislative Affairs

AANS/CNS Washington Office 725 15th Street, N.W., Suite 500

Washington, DC 20005 Office: 202-628-2072

Email: aroberts@neurosurgery.org

The American Association of Neurological Surgeons was founded in 1931 and is dedicated to advancing the specialty of neurological surgery in order to promote the highest quality of patient care. The Congress of Neurological Surgeons was founded in 1951 and exists to enhance health and improve lives worldwide through the advancement of education and scientific exchange. The AANS and CNS are the two largest scientific and educational associations for neurosurgical professionals in the world and represent approximately 4,000 neurosurgeons in the United States. Neurosurgery is the surgical specialty concerned with the prevention, diagnosis, treatment and rehabilitation of disorders that affect the spinal column, spinal cord, brain, and peripheral nerves.

From: "Katie O. Orrico" <korrico@neurosurgery.org>
Subject: New AANS/CNS Washington Office Employee

Date: August 31, 2009 5:09:49 PM EDT

Dear Neurosurgical Leader:

I am pleased to announce the addition of a new member to our Washington Office team. Susanne C. Hartman will begin as the new Senior Manager for Communications in the AANS/CNS Washington Office beginning tomorrow, September 1. Susanne has over 20 years of experience in all areas of communications. She has worked in the media as a television and radio producer, culminating with a job as the Executive Producer for the Fox affiliate in Philadelphia, Pennsylvania. She has experience working for non-profit organizations including serving as a Regional Director of Communications for the American Heart Association and Vice President of Marketing and Communications for the Prevent Cancer Foundation. Finally, she knows what it is like to work directly with/for doctors, having served as the News Officer in the Department of Communications for the University of Pennsylvania's Health System and School of Medicine and the Manager for Media Relations at Temple University Health System's PR Department. At both U. of Penn and Temple, Susanne covered, among other things, the cardiology and thoracic surgery "beat" areas.

Susanne hails from the mid-west, and graduated with a B.S. degree, with a dual major in radio/TV and political science from Kansas State University. She is extremely outgoing, is an excellent writer and, from what I can tell, possesses a work ethic that will meet the challenges of organized neurosurgery!

The primary purpose of this new position is to carry out external and internal communications on health policy and advocacy issues of concern to organized neurosurgery. Susanne's job will include writing articles for the AANS and CNS publications; drafting and editing grassroots alerts, position statements and other advocacy materials; developing and maintaining relationships with the trade and national media; pitching stories to the media; drafting and editing press releases and letters to the editor; assisting with the development, organization and posting of advocacy/health policy web content for the AANS and CNS websites; and assisting with spokesperson media training.

I am confident that Susanne will be a huge asset to organized neurosurgery. She will be attending the CNS Annual Meeting in New Orleans, at which time you will get to meet her (if not sooner by phone/email).

Please let me know if you have any questions.

Katie

Katie O. Orrico, Director Washington Office American Association of Neurological Surgeons/ Congress of Neurological Surgeons 725 15th Street, NW, Suite 500 Washington, DC 20005 Direct Dial: 202-446-2024

Fax: 202-628-5264 Cell: 703-362-4637 korrico@neurosurgery.org

Comments

of the

American Academy of Facial Plastic and Reconstructive Surgery American Academy of Ophthalmology American Academy of Otolaryngology-Head and Neck Surgery **American Association of Neurological Surgeons American Association of Orthopaedic Surgeons** American College of Obstetricians and Gynecologists **American College of Osteopathic Surgeons** American College of Surgeons **American Osteopathic Academy of Orthopedics** American Society of Breast Surgeons **American Society of Cataract and Refractive Surgery American Society of Colon and Rectal Surgeons** American Society for Metabolic & Bariatric Surgery **American Society of Plastic Surgeons Congress of Neurological Surgeons** Society for Vascular Surgery Society of American Gastrointestinal and Endoscopic Surgeons **Society of Gynecologic Oncologists** Society of Surgical Oncology The Society of Thoracic Surgeons

on the

Senate Finance Committee Policy Options

Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs

May 14, 2009

Contact: Kristen V. Hedstrom, MPH

Assistant Director, Legislative Affairs American College of Surgeons 1640 Wisconsin Ave, NW Washington, DC 20007

202-672-1503

khedstrom@facs.org

Executive Summary

Sustainable Growth Rate

- To reform Medicare's payment system and find more innovative models of Medicare physician payment, Congress must first immediately eliminate the SGR.
- Surgery does not support another short-term "patch" that only temporarily prevents Medicare payment cuts and does not directly address the problems with the SGR.
- Congress must incorporate a realistic budget baseline that provides physicians with positive updates.
- During the transition period to a new payment system, Congress should replace the SGR with a system of separate service category growth rates (SCGR). The four SCGR categories (primary care; other evaluation and management services; major surgery; and all other physician services) would recognize the differences among the various types of services and account for their varied rates of growth, while providing additional dollars for primary care.

Primary Care and General Surgery Bonus

- Surgery supports increased payments for primary care physicians, however the threshold for determining which providers receive a primary care bonus should be set to ensure that only true primary care services are eligible.
- Surgery opposes any measure that would finance increased payments for primary care and general surgery by an across-the-board reduction in payments for all other services.

Workforce

• In order for surgical residency programs to expand in response to increased patient demand, additional patient and educational resources will be necessary. A redistribution of unused residency training positions may begin to address the workforce shortages in primary care and general surgery. Consideration should also be given to lifting residency caps as an option for addressing the emerging workforce shortages in other medical specialties.

Physician Quality Reporting Initiative (PQRI) Improvement and Requirements

- Surgery supports the proposal to allow physicians who participate in Maintenance of Certification (MOC) programs to qualify for PQRI bonus payments, with the following suggested changes:
 - ABMS member board MOC programs or equivalent should qualify
 - Participation in programs required for obtaining initial board certification should qualify
 - ➤ MOC practice assessment must not be limited to NQF approved measures
 - The audit process should not be overly burdensome and costly
- Surgery supports the recommended improvements to the PQRI program including the establishment of an appeals process and more timely feedback reports.
- Quality reporting for physicians should remain voluntary and not be mandatory and surgery therefore opposes the implementation of penalties for those physicians who do not participate in PQRI.

• Surgery urges Congress to expand the PQRI to recognize physicians who prospectively report to a clinical data registry or other similar quality improvement database.

Improving Quality Measurement

- Surgery welcomes the additional resources for quality improvement activities. However, we
 are concerned about the proposal's continued heavy reliance on only NQF-endorsed
 measures.
- Cost should not trump quality and Congress should carefully consider the implications for measuring efficiency.
- Surgery recognizes the value of public reporting, but urges Congress to carefully consider the unintended consequences associated with releasing individual physician data to the public.

Encouraging Health Information Technology (HIT) Use and Adoption

• Surgery is concerned about the current HIT timelines for bonuses and penalties established in the American Recovery and Reinvestment Act (ARRA). Given continued problems with interoperability and lack of certified HIT systems, we urge Congress to amend the current bonus and penalty timelines so the entire surgical community can participate fully.

Comparative Effectiveness Research

• Surgery embraces the need for well-designed clinical comparative effective research and supports the proposal to establish a comparative effectiveness research system that builds on the framework laid out in the Comparative Effectiveness Research Act of 2008.

Medicare Shared Savings Program

- Surgery supports the development and testing of shared savings payment models for physician, hospital and other provider services.
- If implemented, participation in shared savings programs should be voluntary, non-punitive and not restrict patient choice.
- Congress should amend the Stark physician self-referral and antitrust laws and/or regulations
 to allow provider collaboration and flexibility in the development of shared savings
 programs.

Transparency and Evidence-Based Decision-Making for Imaging Services

- Surgery supports the continued ability of physicians to own, operate and refer patients to inoffice imaging services and agree that the Stark in-office ancillary exception should be
 amended to require the referring physician to provide patients with a written disclosure of
 financial interests and a list of alternate suppliers.
- In those circumstances involving multiple referrals, after the initial disclosure to a particular patient, physicians should only be required to make a disclosure annually to that patient.
- Surgery is fundamentally opposed to the use of radiology benefit managers (RBMs) or other draconian pre-certification requirements for imaging services in Medicare.
- The timeframe for developing and implementing imaging appropriateness criteria is overly ambitious and needs to be changed.

- Any appropriateness criteria system must also apply to radiologists when they make recommendations for additional imaging tests.
- Surgery supports a non-punitive approach to eliminate unnecessary imaging based on education and confidential feedback programs; however we are opposed to the penalty system outlined in the proposal.

Hospital and Readmission Bundling

- Surgery is concerned with the unintended consequences that a hospital readmission and postacute bundling policy may carry, particularly the potential avoidance of patients with complex medical conditions.
- When the readmission policy is phased out and the bundled payment policy is implemented, a workable and reasonable readmission policy must remain an essential piece of the initiative.
- Congress must also develop a coherent risk adjustment policy as the primary method for
 preventing the practice of deselecting patients, addressing the readmission issue, and
 ultimately providing the highest quality and most appropriate level of patient care with these
 methods of payment.
- Congress should exclude readmissions for a different diagnosis than the original admission in either the hospital readmission or post-acute bundling policy.

Physician Payment Sunshine

- Surgery strongly supports disclosure and transparency of physician and industry relationships through a single, federal reporting system that preempts state law.
- Physicians should have the opportunity to review and correct information about their financial relationships before those disclosures are made publically available.
- Congress should not include reporting of industry funding for continuing medical education (CME).

Physician Owned Hospitals

 Surgery believes that physician owned hospitals are an important component of our health care delivery system and Congress should not prohibit their development and further expansion.

Medical Liability Reform

• Congress should incorporate certain medical liability reforms in comprehensive health care reform, including: (1) alternatives to civil litigation, such as health courts and early disclosure and compensation offers; (2) protections for physicians who follow established evidence-based practice guidelines; (3) protections for physicians volunteering services in a disaster or local or national emergency situation; and (4) provisions modeled after the laws in California or Texas.

May 14, 2009

The Honorable Max Baucus Chairman, Senate Finance Committee 215 Dirksen Senate Office Building Washington, DC 20510

Dear Chairman Baucus:

We, the undersigned surgical organizations, write in response to the Senate Finance Committee's proposal entitled *Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs.* We appreciate the leadership that you and your colleagues in Congress have dedicated to enacting comprehensive reform of our nation's health care system and we look forward to working collaboratively with you as more substantive details of the proposal are developed.

Much attention has been paid to the need to provide more Americans with access to health care coverage, to increase Americans' access to care, and to improve the value of care delivered in our health care system. Expanding coverage to more Americans and improving the quality of care will mean little if Americans are not able to access the care they need—particularly in potentially life-threatening situations. Without real reform of our Medicare physician payment system, the reform that our health care delivery system needs cannot be achieved. To that end, the surgical community stands united in the effort to bring fundamental and long-term change to the Medicare physician payment system and overall comprehensive reform.

Sustainable Growth Rate (pgs. 16–17)

The surgical community appreciates the Committee's recognition that the sustainable growth rate (SGR) is a failed system for calculating Medicare reimbursement for physician services. We support this effort to reform Medicare's payment system and to find more innovative models of Medicare physician payment and we believe the first step towards this goal is to immediately eliminate the SGR. During the time necessary to transition out of the SGR to more accountable and integrated models of reimbursement of care, we appreciate your commitment to prevent further cuts in Medicare reimbursement. However, we do not support another short-term "patch" that does not directly address the problems with the SGR and believe a realistic budget baseline for future Medicare payment updates, which accurately reflects the anticipated costs of providing physicians with positive updates under a new update system in lieu of SGR-related cuts, should be incorporated into the federal budget. For full-scale health reform to be successful, Medicare's physician reimbursement system must be set on a path toward full-scale and permanent reform.

While there are many good models that could improve quality, better integrate care, and offer a better value in health care, none have been widely tested, and they will require pilot testing, demonstration projects and further study before broader implementation. As a result, the coming years will be critical. We appreciate the Committee's stated openness to considering other options and to that end, suggest a Medicare payment proposal that we believe should be implemented during the transition from the SGR toward these more innovative models of payment and health care delivery.

As an alternative, interim measure, we propose that Congress replace the SGR with a system of separate service category growth rates (SCGR). The SCGR would recognize the differences among the various types of services that physicians provide to their patients, while providing additional dollars for primary care. Unlike the SGR, which bases reimbursement on the overall spending on all physician services, the SCGR would establish a system that determines reimbursement based on the spending and volume growth among like services. As a result, the SCGR would create four categories based on type-of-service:

- 1) Primary and preventive care;
- 2) Other evaluation and management (E/M) codes;
- 3) Major procedures (10 and 90 day global and related anesthesia services); and
- 4) All other physician services including minor procedures, radiology services, diagnostic tests, etc.

The SCGR, like the SGR, would base the targets for each category on trends in physician spending, fee-for-service (FFS) enrollment, law and regulations, but unlike the SGR, it would replace the GDP component with a statutorily specified allowance. With the exception of E/M, the annual target allowance for the specific categories should be 3.1 percent; to further promote primary care and preventive care, the target for primary care should be adjusted to 5.1 percent and the target for other E/M should be adjusted to 4.1 percent. The targets for 2010 and following years would be actual spending in the prior year for each service category times the SCGR factors. The surgical community also believes that more than three years is needed to ensure appropriate testing and study of innovative payment models and therefore suggest that the SCGR would sunset after five years in anticipation of Medicare moving into fully-tested innovative payment models at that time.

The surgical community believes that the SCGR would have distinct advantages as a transition model to more innovative reforms. First of all, it recognizes that all physician services are not alike, and lower growth services, such as primary care and surgery, would no longer simply be subject to the blunt cuts of the SGR. Under the second option offered in the options document, we are concerned there would simply be a transferring of this blunt instrument from a national to a more local level, but still treating all physician services the same—just on a smaller scale. Second, under the SCGR, efforts to promote specific services, such as primary care, would be greatly simplified, and the proposal would promote increased payments for primary care without requiring corresponding Medicare cuts for other services. Most importantly, the SCGR would support efforts to promote improved quality and better value by recognizing that these goals will look different and will be achieved in different ways for different services. Also, as Medicare studies various payment models, the SCGR could enable Congress and CMS to study and better understand how these physician quality improvement efforts affect spending for hospitals, skilled nursing, home health and other service areas in the Medicare program. In addition, the SCGR could also provide a mechanism to study alternative payment mechanisms.

While reimbursement does not stand on its own as a determining factor for the professional decisions of physicians, if not appropriately addressed, it will over time exacerbate the growing workforce and access problems we are seeing in surgery. Likewise, if Medicare's payment system is not reformed and set on a path to sustainability, it is hard to envision a scenario where there would be enough physicians and surgeons to cover the need that will present as more Americans are added to the rolls of the insured.

Primary Care and General Surgery Bonus (pg. 10)

The surgical community shares your concern regarding the need for a stable physician workforce in primary care and general surgery—particularly in rural areas. One means toward securing a stable workforce is to ensure more stable and appropriate reimbursement. While we support increased payments for our physician colleagues in primary care, we believe that the threshold for determining which providers receive a primary care bonus should be set at an appropriate level to ensure that only true primary care services are eligible. Furthermore, we oppose any measure that would finance increased payments for primary care and general surgery by an across-the-board reduction in payments for all other services. Such measures, while seeking to promote important physician services, could have a negative effect on patients' ability to access other needed services, including surgical care.

It should be noted that these physicians are not the only ones for whom Medicare reimbursement has failed to keep pace with the rising cost of practicing medicine. In fact, since 1989, Medicare reimbursement for many surgical procedures has been significantly reduced. For example, a three vein coronary artery bypass graft surgery (CPT 33512), for which Medicare paid an average of \$3,957 in 1989, is now reimbursed at an average of \$2,374—a cut of 40 percent in 20 years. Medicare payment reductions have affected a wide range of surgical care including cataract removal (CPT 66984), removal of spinal lamina (CPT 63047), and total hip replacement (CPT 27130), which have been cut 59.38 percent, 51.15 percent, and 43.96 percent, respectively.

As Medicare payments have continued their steady decline over the past few years, significant steps have been taken to improve reimbursement for primary care. In fact, the most recent five-year review by the AMA/Specialty Society Relative Value Update Committee (RUC), approved by the Centers for Medicare & Medicaid Services (CMS), resulted in more than \$4 billion in the fee schedule being shifted to evaluation and management (E/M) codes from other services, including surgical care, in 2007. In addition, the most recent review resulted in a 37 percent increase in the work values associated with an intermediate office visit (CPT 99213), the most frequently billed physician service in Medicare. In its March 2009 report, MedPAC noted that Medicare payments for primary care have increased 10.6 percent between 2006 and 2009, which can be attributed largely to the work of the physician community through its work on the RUC.

The surgical community firmly believes that Medicare payment reform is critical to the larger health reform effort. We also believe that the declining reimbursements are not simply a physician problem, but instead, impact the Medicare program system-wide. Therefore, we suggest that, rather than apply budget-neutrality to only physician services, the Committee should share the burden of the broken payment system across the entire Medicare program. While we acknowledge that cost, at least as calculated by CBO, is great, the surgical community believes the cost of inaction or only partial action could be much greater over the years ahead.

Workforce (pgs. 33-35)

Workforce shortages affect nearly all surgical specialties and occur in both rural and urban areas. The *Archives of Surgery* published an analysis last April that showed a decline of more than 25 percent of general surgeons between 1981 and 2005 in proportion to the U.S. population. Looking to the future, between 2005 and 2020, the Bureau of Health Professions projects an increase of only 3 percent among practicing surgeons, with declines projected in thoracic surgery (–15 percent), urology (–9 percent), general surgery (–7 percent), plastic surgery (–6 percent),

and ophthalmology (–1 percent). Further, according to the Association of American Medical Colleges (AAMC) specialties like cardiothoracic surgery experienced an absolute decline in practitioners and a Government Accountability Office study released May 4, 2009 reports a 40 percent decline in applications for cardiothoracic surgery residency positions from 2004-2008. It should be noted that according to the AAMC October 2008 report, the anticipated physician workforce shortage in 2025 is nearly identical for primary care as surgery, with a projected shortage of 46,000 in primary care and 41,000 in surgery. Some experts believe that had a cap not been imposed on graduate medical education (GME), the U.S. would not be faced with such severe surgical workforce shortages.

Addressing this problem presents a unique challenge for surgery. Physicians entering practice will not grow in spite of an increase in medical school graduates. Residency training is the limiting factor in the pipeline for the shortage. The training is rigorous and lengthy and it will take longer to fill the surgical pipeline than to increase the number of other specialists. In order for surgical residency programs to expand in response to increased patient demand, additional patient and educational resources will be necessary. Quality should be a major factor in determining which education and resident training programs should be funded and how additional residency slots will be allocated. Other factors, such as geographic need and minority participation, are also important considerations.

We agree that efforts to expand the number of insured Americans must be accompanied by proposals that will ensure an adequate health care workforce to meet the anticipated increase in demand for health care services. A redistribution of unused residency training positions will begin to address the workforce shortages in areas like primary care and general surgery. However, consideration should also be given in how to address anticipated workforce shortages in other specialties, like cardiothoracic surgery, and subspecialties such as pediatric neurosurgery. Estimating future workforce shortages is not a perfect science and therefore reallocating unused slots - which those specialties may never regain - has the potential to exacerbate already apparent and emerging workforce shortages in some medical specialties unless an option to lift residency caps is included.

The surgical community encourages the Committee to examine other policy options that will create incentives for medical students to pursue training in specialty areas with demonstrated or anticipated workforce shortages, taking into account the severe workforce shortages in surgical specialties. Such solutions should ensure the quality of surgical training and a workforce that meets our nation's unique geographic and population needs.

Physician Quality Reporting Initiative (PQRI) Improvement and Requirements (pgs. 5-7)

Surgical specialties are committed to providing the highest quality surgical/specialty care to Medicare beneficiaries and have been actively engaged in the process of developing evidence-based and clinically relevant quality measures and establishing clinical data registries through their own specialty and/or through the AMA's Physician Consortium for Performance Improvement (PCPI). We applaud and support the Committee's recommendation to make participation in a qualified Maintenance of Certification (MOC) program a new PQRI reporting mechanism. This represents a major step towards recognizing alternative quality improvement activities. MOC exemplifies continuous advancement of physician quality care by emphasizing self-assessment and practice-based learning to ensure that physicians maintain competencies of patient care, professionalism, and overall medical knowledge.

Despite our support for this option, we have four main concerns that we would like to see addressed. First, your proposal defines a qualified MOC program. We recommend that any final proposal specify that a MOC program created and sponsored by a member board of the American Board of Medical Specialties (ABMS) or equivalent qualify for this PQRI option. Second, not all physicians are required to participate in MOC programs, particularly those physicians who have just graduated from a residency training program but have not yet obtained board certification. We therefore encourage you to recognize clinical data collection and other education requirements related to obtaining board certification as activities that qualify for the PQRI bonus. Third, the proposal states that the MOC practice assessment component must use "NQF measures, where appropriate, to derive a set of clinical metrics that are at least equivalent in both the methods and measures used to those of the PQRI program." We ask the Committee to consider what effect this requirement will have on those participants who choose the MOC reporting option over the more traditional reporting options. Physicians who meet the MOC reporting requirement would be held to much more stringent and burdensome requirements than physicians who choose the basic "three measures reported 80% of the time" option, since they must not only collect data through MOC, but reflect on their results and implement a quality improvement intervention.

We recognize that Congress needs a mechanism to ensure that meaningful, valid metrics are being collected and that physicians are not just getting paid to report low-bar measures. However, requiring these MOC programs to incorporate NQF endorsed measures may pigeonhole those specialties whose MOC programs already incorporate more robust metrics (many of which rely on clinical data, rather than administrative data). Including the NQF-endorsed measure requirement seems to defeat the whole purpose of moving towards more robust, and more clinically-rich, data sources, since it still relies on the same, limited claims-based measure set. Our final concern involves the MOC audit requirement. While probably necessary to some extent, we ask that the requirement not be so burdensome and costly that it discourages Board participation. In any event, most Boards will need to spend time and resources to put one in place that meets the standards of this program, so these facts must be understood if an audit program is established.

We would like to commend the Committee for including recommendations submitted by the surgical community to establish an appeals process and require CMS to provide more timely reports to providers. However, we remain concerned about the continued administrative burden and the lack of evidence substantiating that the PQRI is having a positive impact on quality and the Committee's proposal to extend the PQRI beyond 2010 with a phase-out of positive incentives and the implementation of penalties for those who do not participate.

Ultimately, the surgical community is concerned about the increasing number of "quality and efficiency" measures imposed on physicians without evidence of improved health outcomes, health status, and reduced system costs. We have found that the administrative burden of participating in PQRI has outweighed the current incentive, a problem that is particularly acute for solo practitioners. The proposal presumes the existence of a functioning and well-developed quality measurement infrastructure that for the majority of physicians is not yet established; rather, it is currently under development. Without acknowledgment of the critical differential between the vast majority of specialties and primary care physicians, hospitals, managed care plans and the like, the expectations embedded in this proposal are premature and will not yield

the kind of reporting and performance sought. Therefore, we maintain that quality reporting should remain voluntary and not punitive.

Because of the detailed clinical data that can be collected through clinical registries, we appreciate recent efforts by CMS to incorporate registries as a reporting mechanism in PQRI. However, we are concerned about the continued overwhelming reliance on claims data for quality improvement and public reporting even though we recognize that claims-based reporting makes it easier for many physicians to participate in the PQRI. Claims data, although based on procedure and diagnosis coding, are limited in scope and are rife with inaccuracies and attribution errors. Claims data also is inadequate in capturing meaningful physician performance if limited to one setting (e.g., inpatient or outpatient). Therefore, we urge the Committee to consider expanding the PQRI, so that it recognizes physicians who engage in other quality improvement activities, such as prospective reporting to a clinical data registry or other similar quality improvement database. Clinical data registries, especially those linked to electronic medical records, offer the benefit of claims data, while also allowing for more accurate attribution and the collection of more detailed data over time, such as quality of life, patient experience, and outcomes data. In addition, continuous data collection through registries also is an excellent method for identifying specific patient characteristics that could serve as predictors of improved outcomes and for identifying and validating meaningful process measures.

Improving Quality Measurement (pgs. 21-23)

Building on the provision set forth in the Medicare Improvements for Patients and Providers Act (MIPPA), the committee proposes to provide additional resources to HHS, working in cooperation with AHRQ and CMS, to further strengthen and improve quality measurement and development processes. Surgeons welcome this proposal and recommend that these resources be used to fill gaps in clinical research that will allow us to build a better supply of evidence-based clinical practice guidelines; to fund clinical data registries and other innovative quality improvement activities; to develop valid risk adjustment mechanisms that will allow us to take full advantage of clinical outcomes data; and to conduct studies on whether currently used measures have any impact on quality and cost.

We also appreciate that the proposal recognizes the need for measures to focus on a range of important areas, including patient outcomes, functional status, patient experience/satisfaction, and care coordination. However, we urge the Committee to carefully consider the implications of measuring efficiency. Cost should not trump quality and information accrued from measures should be presented in a manner that is meaningful and actionable to both physicians and eventually patients.

We have concerns about the proposal's continued heavy reliance on only NQF-endorsed measures. The NQF is certainly the most balanced, structured, and fluid of all the current multistakeholder groups. However, its ever-expanding size and scope often make it difficult for the NQF to focus on unique quality improvement activities that are most relevant to smaller specialties, such as outcomes measures that rely on clinical data sources.

Finally, the proposal calls on the HHS Secretary to "develop a strategy for improving the public reporting of quality and performance information." While we recognize the value of public reporting and the need to improve the manner in which information is distributed to various stakeholders, Congress must very carefully consider the unintended consequences associated

with releasing individual physician data to the public prematurely. If measures are not meaningful and data are not adjusted accurately (and few valid risk-adjustment mechanisms currently exist) or presented in an understandable manner, it may create further confusion among patients, limit patients' access to care as physicians avoid high-risk patients or otherwise game the system and/or unfairly harm the reputation of a physician and increase one's exposure to medical liability. Public reporting, if adopted prematurely, creates perverse incentives and discourages the very collaborative spirit and trust that is currently needed among health professionals. Furthermore, the measures on which public reporting would be based have not yet been tested and their true effect on quality/cost is unknown.

Encouraging Health Information Technology Use and Adoption (pgs. 19-21)

Health information technology (HIT) has the potential to increase efficiency and quality of care, and to lower health care costs significantly. The surgical community strongly supports the development of an electronic health information network that is reliable, interoperable, secure, and protects patient privacy. Congress made significant strides towards the implementation of HIT with the passage of the *American Recovery and Reinvestment Act of 2009* (ARRA) (PL11-5), and we are appreciative for the opportunities available for physicians to receive enhanced Medicare payments to support the adoption and effective utilization of HIT. Given HIT's potential positive impact on the health care system, the proposal's recommendation to expand the eligibility for the electronic health record Medicare incentive payments to include nurse practitioners and physicians assistants seems appropriate.

As HIT moves forward within comprehensive health care reform, the surgical community is concerned, however, about the current HIT timelines for bonuses and penalties established in ARRA. Smaller physician practices, which include the majority of the physicians practicing medicine in this country, continue to face barriers to purchasing HIT systems. The financial incentives and penalties are based on the adoption and "meaningful use" of **certified** HIT systems. However, current, certified HIT systems have only been fully developed for primary care settings, and have not yet been fully adapted for specialty/surgical care. Physicians are hesitant to make the considerable investment until the systems are certified and meet their unique needs and appropriate interoperability standards have been developed.

Some surgical specialties are taking steps toward achieving interoperable HIT solutions for their members and have been placed on the Certification Commission for Health Information Technology (CCHIT) roadmap for HIT certification. CCHIT is the only recognized certification body. However, the majority of surgical specialties are not on the roadmap because of the significant obstacles that must be overcome to be identified by CCHIT as one of the planned expansion areas and the lack of CCHIT financing and staff. Furthermore, due to the time it takes to move through the CCHIT process, even those specialties currently on the roadmap will face significant challenges meeting the HIT timelines.

Because of the existing HIT challenges and limitations, it will be very difficult for the majority of specialty/surgical physicians to purchase certified systems designed for their specialty, become meaningful users, and qualify for the majority of the vitally necessary financial incentives under the currently established timelines. We recognize that HIT will play an important role in achieving and maintaining high quality care and performance and, therefore, urge you to amend the current HIT bonus and penalty timelines included in the ARRA so the entire surgical community can participate fully.

Comparative Effectiveness Research (pgs. 24-25)

The surgical community embraces the need for clinical comparative effectiveness research (CER) and we commend your work to advance legislation on CER. We believe that well-designed comparative effectiveness research can be a valuable tool in meeting our health care challenges and supporting high quality clinical decision-making. Proposals to expand government-supported CER, if appropriately structured, can benefit patients by supporting health care decisions that best meet individual needs, improve overall quality of care and support continued medical progress.

At the same time, such research can be misapplied in ways that restrict patient access to optimal care, undermine physician/patient decision-making, and discourage continued medical progress. We are very pleased that the CER provision in your latest policy options document acknowledges the value of well-designed CER, the importance of continued medical innovation as part of the solution to cost and quality challenges in health care, and the need to ensure that proposals to expand the government's role in CER are centered on patient and provider needs. Surgeons are thrilled that the American Recovery and Reinvestment Act (ARRA) has provided significant "seed" money to begin conducting CER; however we are concerned that there is no appropriate structure or framework in place to oversee the CER enterprise and ensure that this research adheres to certain important principles. We ask that you consider the following principles and ensure that the legislation:

- focuses on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations;
- provides information on clinical value and patient health outcomes, not cost-effectiveness assessments;
- recognizes the diversity, including racial and ethnic diversity, of patient populations and subpopulations and communicates results in ways that reflect the differences in individual patient needs;
- examines all aspects of health care including care management, medical interventions, benefit design, and processes of care for all patients;
- establishes a governance structure that ensures appropriate experts are appointed to research advisory panels (e.g., physicians who are involved in treating the disease or disorder under consideration) and adequate physician representation on any CER Board;
- ensures full transparency and adequate opportunity for surgeons to have input into the development of CER priority topics, research project methodology, and final CER findings;
- provides physicians with certain medical liability protections (e.g., an affirmative defense that the doctor complied with the guidelines and therefore cannot be liable) when they follow clinical practice guidelines that are based on CER recommendations.

The surgical community believes that the Comparative Effectiveness Research Act of 2008 represents a strong starting point that is consistent with organized surgery's principles, and we support the proposal in the Committee's paper to build off this framework as you advance health care reform legislation.

Medicare Shared Savings Program (pgs. 17-19)

The surgical community believes that a reformed health care delivery system should encourage providers to collaborate and provide patient-centered care with the goal of improving quality and creating cost savings and shared savings programs can appropriately align incentives between stakeholders to improve the quality of care for patients leading to reductions in costly complications, the creation of quality guided resource utilization, and the achievement of sustained savings. We support the development of incentive programs that allow physicians to participate in the sharing of savings generated by quality improvement efforts. Care must be refocused around the needs of patients, and systems of delivery should allow and encourage – rather than discourage – collaboration and accountability among health care providers and across sites of care. The surgical community therefore recommends that Congress require the Secretary of HHS or the Government Accountability Office to fully evaluate the shared saving programs and report back to Congress within 5 years of enactment of this provision before a more expanded, permanent shared savings program is implemented.

The term "shared savings" has been used to describe a variety of potential payment models, including accountable care organizations (ACO). The success of the ACO concept will depend largely on how this entity is organized, as well as how the structure would effectively provide care for uncommon, yet costly diseases. The reality is that the incidence of various disease processes in the general population is quite variable, and therefore the "minimum population size" on which an ACO might take risk in an actuarially sound manner varies widely by the type of disease in question. An ACO would have to enroll millions of patients to develop significant expertise in the management of these disease entities, and the structure and financing of ACOs must not provide incentives to retain the care of these types of patients within care organizations without the experience and expertise to provide the best patient care. We recognize the need for improved coordination of care and reduction of resource utilization, but we suggest that improvements in health information technology, particularly interoperability and outcomes data feedback, are central to improved care coordination and more effective resource utilization.

We agree that if implemented, participation in shared savings programs should be voluntary, non-punitive and not restrict patient choice. We also agree with the inclusion in the criteria the requirements that the entity have in place both contracts with a core group of specialist physicians and processes to promote evidence-based medicine, report on quality and costs measures, and coordinate care.

As various shared savings programs models continue to be tested and explored, the surgical community urges the Committee to strongly consider policy changes that will allow for flexibility in the development these programs. Specifically, we support a new, targeted exception to the physician self-referral (Stark) laws to permit provider arrangements, such as those between hospitals and physicians that foster high quality, cost-effective care through economic incentives. Another hurdle is the antitrust laws and/or the enforcement policies of the Department of Justice and Federal Trade Commission. Changes must be implemented to ensure that providers who wish to collaborate by forming an ACO do not run afoul of the antitrust laws. A number of attempts at shared savings programs involving cardiothoracic surgeons, including one sponsored by the Virginia Cardiac Surgery Quality Initiative, have been derailed due to concerns by the Office of the Inspector General and the Department of Justice regarding violations of physician self referral and civil monetary penalty laws. These programs have demonstrated the ability to

generate improved outcomes through reductions in post-operative complications and thus to reduce costs. We believe that it is good public policy to enable these types of programs.

Transparency and Evidence-Based Decision-Making for Imaging Services (pgs. 7-9)

Transparency in Self-Referrals

In order to increase transparency, the Committee proposes to amend the Stark in-office ancillary exception (IOAE) for certain imaging services by requiring the referring physician to provide a written disclosure of financial interests and provide patients with a list of alternate suppliers.

The surgical community agrees that increased transparency is of value to the health care system when the quality and quantity of information provided to patients is *accurate*, *understandable*, *and actionable*. We agree that physicians should discuss all options regarding alternative facilities and that the patient should be fully informed of his/her choices and allowed to make the final determination as to where to receive care. Furthermore, the surgical community believes that surgical specialists that are experienced in diagnostic radiologic methods are fully competent to supervise the performance of and interpret imaging studies in their offices for the evaluation and management of certain conditions. Many surgeons perform the immediate and timely interpretation of imaging studies, correlate these studies with clinical findings, and assume the responsibility for determining the treatment of their patients. The quality and accuracy of imaging studies and interpretations performed by these surgeons are consistently high.

As the details of the proposal are further developed, the surgical community urges the Committee members to consider, with respect to frequency of disclosure, the utility and burden of providing patients with a list of alternate suppliers "at the time of referral." In particular, we are concerned about multiple referrals to the same patient, the usefulness of subsequent disclosures, and the burden to the patient and physician. Providing the list to the same patient in multiple instances will neither improve quality nor lower costs, and it risks confusing the patient and adding administrative costs. We propose that, after the initial disclosure to a particular patient, physicians would then be required to make a disclosure annually to that patient. With a clarification regarding the frequency of disclosure and provision of alternate providers to a single patient, the surgical community agrees that transparency and informed decision-making can increase the integrity of our health care system.

Promotion of Adherence to Appropriateness Criteria for Imaging Services

The surgical community understands that imaging services represent one of the fastest growing categories of services in the Medicare physician fee system and this growth is unsustainable and we are therefore committed to working with Congress to identify and reduce unnecessary diagnostic imaging services.

A considerable amount of imaging is utilized because of defensive medicine practices and risk avoidance due to medical liability concerns. Indeed, one study by Elliot Fisher, MD, MPH, concluded that the overuse of imaging services was driven by medical liability fears and was associated with an increase in total Medicare spending of more than \$15 billion between 2000 and 2003. This being the case, any legislation aimed at curbing inappropriate imaging services must recognize that the current medical liability system is driving physicians to order more tests to protect themselves, whether the tests are clinically necessary or not.

Another reason for increased imaging utilization relates to the underlying quality of the scan. It is not uncommon for a surgeon to evaluate a patient who comes in with an MRI or other image only to discover that the scan is of poor quality. This then requires the surgeon to order another scan before he or she can make a definitive decision to proceed or not with a particular surgical procedure. We are hopeful that the imaging accreditation provisions of the Medicare Improvements for Patients and Providers Act (MIPPA) will adequately address the gaps in quality of imaging equipment, which we believe will require surgeons to order fewer scans due to poor quality.

With regard to the specific options outlined in the paper, we have the following comments. At the outset, the surgical community is fundamentally opposed to the use of radiology benefit managers (RBMs) or other draconian pre-certification requirements for imaging services in Medicare. Surgeons are already burdened with enough paperwork and mind numbing regulations, and to add yet another layer of rules, requirements and hoops through which a surgeon must jump to care for his or her patient is unacceptable. We therefore appreciate that the options paper recognizes a different approach to managing medical imaging volume.

Having said that, however, we have a number of concerns and questions that we believe need to be addressed before this new system becomes law:

- The timeframes for implementing this new program are overly ambitious.
 - ➤ One year is simply not enough time for the national standards organizations, physician specialty societies and other stakeholders to develop valid appropriateness criteria, the process by which physicians would report their use of imaging and a system to ascertain whether they have adhered to such criteria. This could not be accomplished until the end of 2011 at the earliest.
 - ➤ While we certainly favor a confidential education and feedback program, the program should not begin until 2013, which would allow the appropriateness criteria to be developed and available for use in 2012.
 - ➤ We are opposed to the penalty structure outlined in the proposal, but should Congress nevertheless implement such a structure, penalties cannot be imposed until 2014 at the earliest until physicians have had the opportunity to reflect on their confidential feedback and adjust their ordering patterns.
- How will physicians access the appropriateness criteria and report required data? Who are the vendors? Which registries will be used? Will individual specialty societies that have created their own clinical data registries be able to incorporate this in their own systems or will physicians be expected to report to yet another data management system? Congress must keep in mind that not every physician has the necessary EMR/HIT system to participate.
- Who determines which criteria apply, particularly if there are different opinions offered by different specialties?
- Will the appropriateness criteria and penalties also apply to radiologists who often make additional imaging recommendations to encourage the ordering physician to do additional

(and usually more expensive) tests? When this happens, the ordering surgeon may not agree that an additional test is necessary, but if he or she fails to follow the advice of the radiologist the surgeon may face a potential medical liability problem.

- As stated above, surgeons support a non-punitive approach to help eliminate unnecessary imaging and we support the proposal to establish an education and confidential feedback program on patterns of imaging and adherence to appropriateness criteria. Organized surgery is fundamentally opposed to the 5 percent reduction on all outlier physicians' fees. If a penalty system is put in place, it should be altered and somehow only tied to the value of the imaging services, rather than all services ordered by an individual physician. In addition, the penalty should not be for an entire year, but rather for a shorter period of time, particularly if tied to an education and feedback program.
- Because, as stated above, surgeons are sometimes forced to order scans that may not be
 deemed clinically appropriate, we suggest that any data collection and education and
 feedback program also seek additional information from the ordering physicians such as
 whether or not they ordered the test for defensive medicine reasons and/or because the
 quality of the original scan was poor, necessitating an additional test.

The surgical community is willing to assist Congress in finding an appropriate mechanism to reduce unnecessary diagnostic imaging. At the same time, however, we need to make sure that the solutions to this problem do not unduly interfere with physician and patient treatment decision making in a way that delays or restricts patient access to necessary services.

Hospital and Readmission Bundling (pgs. 13-16)

The surgical community understands that current methods of reimbursement by government programs and private insurance offer little incentive to help control the cost of delivering care and supports efforts of all stakeholders to develop and evaluate payment methodologies that will incentivize coordination of care among providers and help curb health care inflation. However, the surgical community is concerned with the unintended consequences that a hospital readmission and post-acute bundling policy may carry.

The patient must be the focal point of any initiative and therefore the system must not create incentives to treat healthier patients and limit access to sicker patients. One possible consequence is deliberate deselecting of complex or risky patients. As is already occurring, we are concerned that physicians may find it even more difficult to treat their most complex, vulnerable patients. We are also concerned that physicians may be subjected to facility pressure to discharge a patient earlier or later than medically necessary and/or to an inappropriate post-acute setting. We encourage the Committee to ensure that the payment policy facilitates a provider's ability to decide the most appropriate facility in which the patient should receive care.

Additionally, when the readmission policy is phased out and the bundled payment policy is implemented, a workable and reasonable readmission policy must remain an essential piece of the initiative. Unavoidable, planned, scheduled, or extreme cases of high risk readmissions will still need to be addressed in the development of a bundled payment methodology between the hospital and post-acute provider. Developing a coherent risk adjustment policy is the primary method for preventing the practice of deselecting patients, addressing the readmission issue, and

ultimately providing the highest quality and most appropriate level of patient care with these methods of payment.

The surgical community applauds the Committee's recognition of the need for risk adjustment to adequately account for a "patient's severity of illness and differences in case types" when calculating the readmission benchmark and the recognition of readmissions that are planned, scheduled, unavoidable, and/or related to extreme cases of high risk. We encourage the Committee to include provisions for both readmissions and bundled payments that require risk-adjustment for patient demographics, co-morbidities, severity of illness, and procedure-specific characteristics that account for the differences that contribute to outcome and costs of treatment. The surgical community understands that risk adjustment is a costly and complicated task and, therefore, proposes that the Committee require the federal agencies to work with the individual specialty societies when developing, implementing, and evaluating the metrics for risk adjustment. As is always the case, when stakeholders are involved in the decision making process, the support and participation follows.

The surgical community would like to highlight the importance of excluding readmissions for a different diagnosis than the original admission in either the hospital readmission or post-acute bundling policy. It is important to avoid the unintended consequences of restricting choice and/or encouraging denial of care based on a payment policy. We encourage the Committee to ensure that an all-cause approach to readmissions and bundled payments is not taken.

Ultimately, we must have safeguards to protect both the patient and the equity and role of providers. Policies should not create a system where each entity is imputing blame on the other. Before proceeding with hospital readmission and post-acute bundling policy, we urge the Committee to consider the necessary resources, structure, and cultural changes necessary to reasonably implement such a policy.

Necessary Safeguards to Protect Patient Access to Quality Care:

- The patient should be the primary focus of all initiatives.
- The patient should be empowered to be a fully participating stakeholder in their health care process.
- The patient's access to quality care should always be a priority over cost savings.
- No stakeholder should be incentivized to limit care or provide unnecessary care.
- The physician should be the patient's primary advocate for their unique medical needs.
- All stakeholders should disclose potential conflicts of interest when providing patient care.
- Patients should maintain access to a variety of necessary providers and facilities.

Necessary Safeguards to Protect and Facilitate Provider Alignment:

- One provider should not have control over another provider.
- The burden to improve quality and affect cost savings should be on all providers and stakeholders.
- The process should be transparent so that all financial incentives and any revisions are known by all stakeholders.
- The initiative should align providers to collaboratively work together.
- All stakeholders should be represented when developing initiatives to align payment and incentives.

- The payment should be agreed upon prior to delivering care.
- All stakeholders should be represented when creating a method of distribution for payment.
- The compensation for work should be fair and reasonable for all providers.
- Payment should be risk adjusted for patient and procedure specific characteristics.
- The implementation should be equitable for all patients and providers.
- Competition should be maintained in the health care system.
- A provider should have the autonomy to provide care that addresses each patient's unique medical needs.

Physician Payment Sunshine (pgs. 25-27)

The surgical community strongly supports disclosure and transparency of physician and industry relationships and believes that a reliable system of transparency will reinforce ethical standards that have long governed the practice of medicine. We support the Committee's requirement that the reporting and disclosure requirements would preempt state law. To reduce reporting errors and minimize public confusion, the surgical community believes that a national standard of reporting is preferable to the patchwork of state laws that would be created should the requirements allow states to go beyond what would be covered under federal law. The surgical community believes it is critically important that physicians have the opportunity to review and correct information about their financial relationships before those disclosures are made publically available. To that end, we support the Committee's provision that allows the submission of corrections and requires stakeholder input on the development of the reporting procedure. Finally, we believe the proposal should not be expanded to include reporting of industry funding for continuing medical education (CME). CME has long advanced the educational foundations and cutting edge science of our medical system, and issues relating to disclosure have not been thoroughly vetted. The complexity of this issue was evident during MedPAC's deliberations last year and we believe this issue must be thoughtfully considered and debated.

Physician-Owned Hospitals (pgs. 27-29)

The surgical community believes that physician-owned hospitals are an important component of our health care delivery system. Physician owners in physician-owned hospitals have greater control over the facility and the quality and efficiency of care (e.g., scheduling of surgeries, surgical equipment, staffing, etc.) which lead to higher quality patient care. Furthermore, these facilities tend to have greater patient satisfaction, reduced costs, and lower infection rates.

While the document contains a number of thoughtful options to reform our health care delivery system, it proposes language that will have significant and harmful affects on the 218 existing physician-owned hospitals and the eighty-six projects under development. Significantly, it will prevent physicians from owning hospitals in this country in the future.

Currently, hospitals that have physician ownership are located in 31 states across the country and provide diversity of location, specialty, and ownership. Of the 218 hospitals that are currently active, 18 are general acute-care facilities, 150 are multispecialty (includes surgical, women's and children's hospitals), 18 are rehabilitation hospitals, 19 specialize in cardiac care and 13 focus on orthopaedics. More than half (117) are joint ventures with not-for-profit, general acute

care hospitals and health systems. The remaining entities are a mixture of joint ventures with for-profit hospitals and corporate investors or are owned entirely by physicians. Although the debate over physician ownership may have started with specialized facilities in a few states, it now affects hospitals of all variations. Because of this wide geographic impact, the proposed legislation will disrupt access to medical care in many communities.

Resulting from a study of physician-owned hospitals required by the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, the Federal government in 2005 reported that structural measures of quality, such as staff specialization, clinical staff per patient, and complication rates, all suggest good performance on the part of physician-owned hospitals and demonstrate very high quality of care. Mortality rates were also shown to be significantly lower in physician-owned hospitals than in other community hospitals. For all medical procedures analyzed by the U.S. Department of Health and Human Services (HHS), there was a measurable statistical significance. In addition, complication rates at physician-owned hospitals are measurably lower than at general hospitals. According to the HHS study, patients are 3 to 5 times more likely to experience complications at general hospitals than at physician-owned hospitals. All of the HHS results were adjusted for patient acuity.

In a survey conducted in 2008 by Lake Research Partners, an independent third party, it was determined that "The American public believes doctors would do a good job running hospitals in their community, and they want doctors to make decisions about patient care and how hospitals are run. They believe doctors should be allowed to own hospitals where they work and that Congress ought to vote to allow this practice to continue." Two-thirds (67 percent) of the American public believes physicians would do an excellent or good job running a hospital in their community. Additionally, physicians are the American public's first choice (over hospital administrators) of the person(s) they would prefer to see in charge of hospitals in their communities. (March 2008 telephone survey of 1,000 adults nationwide, conducted by Celinda Lake of Lake Research Partners).

Not only do physician-owned hospitals deliver high quality medical care to the patients they serve, they also provide much needed jobs, pay taxes, and generate significant economic activity for local businesses. In its 2005 study, HHS concluded that, considering uncompensated care and tax payments, physician-owned hospitals returned a net community benefit as a percent of total revenue almost 8 times higher than non-profit hospitals, averaging 7.23 percent in net benefit as compared to .87 percent for non-profit hospitals. Physician-owned hospitals have a huge economic impact at the national, state, and local levels.

The surgical community believes legislation limiting physician ownership is bad for health care, bad for business, and bad for Medicare beneficiaries who receive care at the many physician-owned and operated hospitals throughout the country and urge the Committee to not include any legislative language that would discriminate against physician-owned hospitals.

Liability System Reform

While the surgical community is acutely aware of the current challenges in passing federal medical liability reform legislation, we nevertheless believe that there are a number of approaches that would be worthwhile to pursue. To alleviate the medical liability crisis and ensure patient access to surgical services, the Committee should consider incorporating the following medical liability reform ideas in comprehensive health care reform legislation:

- Studying alternatives to civil litigation, including: early disclosure and compensation offers; the administrative determination of compensation model; and health courts;
- Providing medical liability protections for physicians who follow established evidencebased practice guidelines;
- Protections for physicians volunteering services in a disaster or local or national emergency situation; and
- Modeled after the laws in California or Texas, which includes reasonable limits on non-economic damages.

Reform of our nation's health care system covers a range of important issues, from covering the uninsured to expanding patient access to care, from improving the quality of care to containing the growth of our nation's rising health care costs. A myriad of problems and challenges calls for not one but many steps and solutions to put us on the path to extending the possibility and promise of quality health care to all Americans. We must proceed deliberately and thoughtfully to ensure that the policy changes we make today do not lead to unintended consequences that could undermine Americans' access to quality care. The surgical community looks forward to working with the Committee in the weeks to come to reform our nation's health care system and to preserve and improve Americans' ability to access high quality surgical care and health care services.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery American Academy of Ophthalmology American Academy of Otolaryngology-Head and Neck Surgery American Association of Neurological Surgeons American Association of Orthopaedic Surgeons American College of Obstetricians and Gynecologists American College of Osteopathic Surgeons American College of Surgeons American Osteopathic Academy of Orthopedics American Society of Breast Surgeons American Society of Cataract and Refractive Surgery American Society of Colon and Rectal Surgeons American Society for Metabolic & Bariatric Surgery American Society of Plastic Surgeons Congress of Neurological Surgeons Society for Vascular Surgery Society of American Gastrointestinal and Endoscopic Surgeons Society of Gynecologic Oncologists Society of Surgical Oncology The Society of Thoracic Surgeons

Subject: [WARNING: MESSAGE ENCRYPTED] Comparative Effectiveness Recommendations Released

Date: Wednesday, July 1, 2009 9:46 AM

From: Katie O. Orrico <korrico@neurosurgery.org>

TO: Washington Committee, QIW, Guidelines Committee, AANS EC, CNS Officers, Spine Section Leaders, CSNS EC, Others

Yesterday the Institute of Medicine issued its Comparative Effectiveness Report, following on the heels of the Federal Coordinating Council (FCC) for CER, which had issued its report on June 29th. Below is a memo from Rachel summarizing the reports. Attached are several documents related to the reports (and this memo in a word document file). The "CER report brief 6.22.09.pdf" file is the IOM report in brief and has topics relevant to neurosurgery highlighted. Based on both of these reports, it looks as if there should be a pretty good opportunity for NPA to get some seed funding from the feds. Of course the devil will be in the details, which we will not know right away until the Secretary of HHS synthesizes these reports and moves forward. As noted below, the AANS and CNS had commented to both the IOM and FCC encouraging the funding for prospective clinical data registries and for an evaluation of certain spine treatments.

Katie

MEMORANDUM

To: AANS/CNS Leaders

From: Rachel Groman Date: June 30, 2009

Re: Comparative Effectiveness Research Priorities

As required by the American Recovery and Reinvestment Act of 2009 (ARRA), the Institute of Medicine (IOM) and the Federal Coordinating Council (FCC) for Comparative Research (CER) today released separate reports that provide guidance from medical professionals and the public to Congress and the Secretary of HHS on how to prioritize and conduct research to compare different health services and approaches to care. The IOM and FCC reports will help to inform HHS Secretary Sebelius' submission of an operational plan for the combined \$1.1 billion allocated for CER, which includes the \$400 million allocated to the Office of the Secretary at HHS.

Institute of Medicine Report

The IOM's report, Initial National Priorities for Comparative Effectiveness Research,

presents a working definition of CER, develops a priority list of research topics to be undertaken with ARRA funding using broad stakeholder input, and identifies the necessary requirements to support a robust and sustainable CER enterprise.

The IOM defines CER as follows:

CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

To develop its list of priorities, the IOM sought advice from a broad range of stakeholders and received nominations for more than 2,606 topics. Comments were received in 3 forms: approximately 90 letters; 54 oral presentations at a day-long hearing in Washington; and a Web-based nomination form. The AANS and CNS took advantage of each of these opportunities to comment. Using a three-step voting process, the committee then identified 100 high-priority topics. To evaluate a topic's importance, the committee formulated criteria that would identify not only those diseases and conditions with the greatest aggregate effect on the health of the U.S. population, but also less common conditions that severely affected individuals in vulnerable subgroups of the population. The IOM divided the topics into quartiles, the first of which is considered the highest priority group.

Among its highest priorities, the IOM recommended to, "Establish a **prospective registry** to compare the effectiveness of treatment strategies for low back pain without neurological deficit or spinal deformity," based on an AANS/CNS recommendation. Other topics relevant to neurosurgery include:

- In the second group of priority areas, the IOM recommended, "Comparative effectiveness of effective treatment strategies (e.g., artificial cervical discs, spinal fusions, pharmacologic treatment with physical therapy) for cervical discs and neck pain."
- In the third group of priority areas, it recommended to "Establish a **prospective registry** to compare the effectiveness of surgical and nonsurgical strategies for treating cervical spondylotic myelopathy (CSM) in patients with different predictors of improved outcomes," based on an AANS/CNS recommendation.
- In the third group of priority areas, it recommended to "Compare the effectiveness of traditional and newer imaging modalities (e.g., routine imaging, MRI, CT, PET) when ordered for neurological and orthopedic indications by primary care practitioners, emergency department physicians, and specialists.
- In the fourth group of priority areas, it recommended to "Compare the effectiveness (e.g., pain relief, functional outcomes) of different surgical strategies for

symptomatic cervical disc herniation in patients for whom appropriate nonsurgical care has failed."

The AANS and CNS will continue to work to promote the use of the NeuroPoint Alliance (NPA) to assist with conducting these studies.

This list of priorities provides a starting point for what the report says should be a sustained effort to conduct CER. As this research initiative progresses, the priorities are expected to evolve as well. List below are IOM recommendations aimed at a sustainable, trustworthy national CER initiative:

- The HHS Secretary should establish a mechanism—such as a coordinating advisory body—with the authority to strategize, organize, monitor, evaluate, and report on the implementation and impact of the CER Program.
- The CER Program should fully involve consumers, patients and their caregivers in key aspects of CER, including strategic planning, priority setting, research proposal development, peer review, and dissemination.
- The CER Program should devote sufficient resources to research and innovation in the methods of CER, including the development of methodological guidance for CER study design such as the appropriate use of observational data and more informative, practical, and efficient clinical trials.
- The CER Program should help to develop large-scale, clinical and administrative data networks to facilitate better use of data and more efficient ways to collect new data to yield CER findings.
- ➤ The CER Program should promote widespread participation and provide incentives to data holders to participate in CER.
- The CER Program should develop and support the workforce for CER to ensure the nation's capacity to carry out the CER research mission. Important next steps include:
- Long-term, sufficient funding for career development including expanding grants for graduate and postgraduate training opportunities in comparative effectiveness methods as well as career development grants and mid-career merit awards.
- The CER Program should promote rapid adoption of CER findings and conduct research to identify the most effective strategies for disseminating new and existing CER findings to health care professionals, consumers, patients, and their caregivers

and for helping them to implement these results in daily clinical practice.

Federal Coordinating Council for Comparative Effectiveness Research Report

Like the IOM, the FCC was charged by Congress with the task of identifying key areas of CER where funding could make the greatest impact to improve health outcomes for our nation. Unlike the IOM report, the FCC report does not recommend specific research priority areas. Instead, it lays out a definition of CER, proposes criteria for determining which research projects should be a priority, and presents a strategic framework to identify gaps and future priorities. It also catalogues current federal activities on CER, which had not been previously inventoried. The FCC heard many perspectives, including public input from hundreds of diverse stakeholders such as the AANS and CNS, which influenced the entire report.

The FCC defines CER as follows:

Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and subgroups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

The FCC focused specifically on the unique role that the Office of the Secretary funds could play in complementing and leveraging funding currently allocated to the Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH), and other government agencies. The FCC's recommendations include the following:

 Investments should be made in data infrastructure such as linking current data sources to enable answering CER questions, development of distributed electronic data networks and partnerships with the private sector.

- It is critically important to be able to share the results of comparative effectiveness research with doctors and patients and make better investments in how information is disseminated;
 - Research should focus on the needs of priority populations such as racial and ethnic minorities, persons with disabilities, persons with multiple chronic conditions, the elderly, and children; and
 - Research should be in specific high-impact health arenas such as medical and assistive devices, surgical procedures, behavioral interventions and prevention.

Katie O. Orrico, Director
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INSTITUTE OF

REPORT BRIEF • JUNE 2009

Initial National Priorities for Comparative Effectiveness Research

Clinical research provides health care providers with information on the natural history of disease, clinical presentations of disease, and diagnostic and treatment options. Consumers, patients, and caregivers also require this information to decide how to evaluate and treat their conditions. All too often, the information necessary to inform these medical decisions is incomplete or unavailable, resulting in more than half of the treatments delivered today without clear evidence of effectiveness. This uncertainty contributes to great variability in managing clinical problems, with costs and outcomes differing markedly across the country.

and outcomes differing markedly across the country.

Comparative effectiveness research (CER) is a way to identify what works for which patients under what circumstances. Congress, in the American Recovery and Reinvestment Act (ARRA) of 2009, appropriated \$1.1 billion to jump-start the nation's efforts to accelerate CER. ARRA tasked the Institute of Medicine (IOM) to recommend national priorities for research questions to be addressed by CER and supported by ARRA funds. The IOM committee identified three report objectives: 1) establish a working definition of CER, 2) develop a priority list of research topics to be undertaken with ARRA funding using broad stakeholder input, and 3) identify the necessary requirements to support a robust and sustainable CER enterprise.

WHAT IS CERT

As the committee developed its priority list of research topics, it repeatedly referred to its definition of CER:

CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

The key elements of this definition are the direct comparison of effective interventions, the study of patients in typical day-to-day clinical care, and the aim of tailoring decisions to the needs of individual patients.

CER can take many forms. Systematic reviews of the literature are the starting

CER can take many forms. Systematic reviews of the literature are the starting point for practice guidelines. They summarize a body of evidence, identify information gaps, and generate new ideas for research questions. Large established databases, including electronic health records, provide a window into current health care practices and their outcomes. These databases, however, seldom specify the rationale for medi-



The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.



For more information visit www.iom.edu/cerpriorities.

Advising the Nation. Improving Health.

Subject: Specialty, Primary Care Debate Resurfaces With Members' Letter

Date: Monday, April 27, 2009 8:00 AM

From: Katie O. Orrico <korrico@neurosurgery.org>

TO: WC, AANS EC, CNS Officers, CSNS EC and Coding and Reimbursement Committee, Section Leaders, Others

See below article published in last Wednesday's *Inside Healthcare Policy*. At the urging of the surgical "coalition," Rep. Shelley Berkley (D-NV) and Mark Kirk (R-IL) are circulating the attached letter hoping to gain the support of other members. The final tally will be made this week and then the letter will be sent to Speaker Pelosi and Minority Leader Boehner. Yours truly is the "official" representing surgical groups quoted at the end of the article. Following an article is a list of current Members of Congress who have signed the letter.

Katie

Specialty, Primary Care Debate Resurfaces With Members' Letter

A letter circulated by two House members seeking support to block cuts to specialty physicians' Medicare reimbursement as a way to bump up primary care doctors' pay has highlighted the ongoing tug-of-war between medical specialties and primary care. Emphasizing their continued cooperation to achieve health care reform, stakeholders are treading carefully on both sides of the issue and insist they're not trying to fuel a turf war over Medicare Part B physician payments.

Rep. Shelley Berkley (D-NV), a member of the Ways and Means health subcommittee, and Rep. Mark Kirk (R-IL), a member of the Appropriations Committee, sent a dear colleague letter asking other members to back a letter to House Speaker Nancy Pelosi (D-CA) and Minority Leader John Boehner (R-OH) to protect specialty physicians' Medicare reimbursement.

While the draft letter hasn't been sent to Pelosi and Boehner, the American Association of Family Physicians (AAFP) is already on the defensive, telling Inside CMS it is "far too premature to disregard any option" to pay for additional Medicare payment for primary care physicians. Broad recognition that primary care is "undervalued" makes it important to keep every option open for reforming primary care payment, the AAFP official said.

But, at the same time, the AAFP official said: "The notion that this should be balanced on the backs of the subspecialties is not one we support." Support for boosting primary

care is only fragmented when there is concern that physicians payment reform must be budget neutral only within Part B, the official said.

Primary care physician associations have suggested reforming the budget neutral calculation to improve primary care payment without cutting into specialties. The proposal suggests using savings primary care doctors say they can achieve in other parts of Medicare, such as within Part A by reducing hospital admissions that could be handled by a primary doctor.

Kirk told Inside CMS that he and Berkley "feel that the voice of the specialty physicians is not strong enough yet, hence the letter."

"Obviously older Americans need doctors most," Kirk said. "They have the most chronic and long-term issues for obvious reasons, so we want to make sure they're protected because they have little place to go but Medicare."

Asked about primary care, Kirk said, "I'm for it," but specialty care should be protected as well. The letter, which Kirk expects to receive much more support now that Congress has returned from recess, is intended to demonstrate there is bipartisan backing for finding a fix to the sustainable growth rate and protecting specialty and primary care, Kirk said.

An aide to Berkley told Inside CMS her office is trying to "find a way to satisfy both needs" and cutting specialty physician payments to bolster primary care would harm beneficiaries in need of those services. Berkley's husband, Lawrence Lehrner, is a specialty doctor, practicing as a nephrologist in Las Vegas, according to the congresswoman's personal biography.

The Berkley aide said the letter, which calls on the House leadership to stop the upcoming 21 percent physician payment cut as well as reform the payment system to provide access to primary and specialty doctors, doesn't pit primary doctors against specialty doctors. Instead, the aide said, it indicates the House members are trying to "find ways to get around that requirement to offset" payment reform.

A lobbyist for physician interests said a new budget neutral calculation would satisfy Congress' desire for a win-win situation, but the lobbyist was skeptical it would pan out. Renewed talk about the six "bucket" system, proposed in the 2007 Children's Health and Medicare Protection Act (CHAMP) that passed the House, indicates some support for allowing primary care to grow at its own rate while letting other practice areas "take the brunt of the cuts," the physician lobbyist told Inside CMS.

Neurological surgeons are among those working with Berkley and Kirk on the

issue. An official representing surgical groups said the surgical medical sector supports improving primary care, but is "absolutely opposed" to doing that "in a budget neutral manner within the physician payment pool of dollars."

"There may be other places to look for extra financing, but we are not specifying how this is done," the surgeons representative said about the specialty's work with Congress on the payment reform. -- Ashley Richards (arichards@iwpnews.com)

Current Signatures

Rep. Shelley Berkley

Rep. Mark Kirk

Rep. Tammy Baldwin

Rep. Judy Biggert

Rep. John Boozman

Rep. Rick Boucher

Rep. Charles W. Boustany

Rep. Dan Burton

Rep. Chris Carney

Rep. Andre Carson

Rep. Michael Castle

Rep. Elijah Cummings

Rep. Kathy Dahlkemper

Rep. Charlie Dent

Rep. Lincoln Diaz-Balart

Rep. Samm Farr

Rep. Randy Forbes

Rep. Barney Frank

Rep. Elton Gallegly

Rep. Jim Gerlach

Rep. Steve Kagen

Rep. Dale Kildee

Rep. Suzanne Kosmas

Rep. Chris Lee

Rep. John Lewis

Rep. Frank LoBiondo

Rep. Michael E. McMahon

Rep. Carolyn Maloney

Rep. Kenny Marchant

Rep. Dennis Moore

Rep. Patrick Murphy

Rep. Richard Neal

Rep. John Olver

Rep. Ron Paul

Rep. Todd Russell Platts

Rep. Tom Price

Rep. Sylvester Reyes

Rep. Ileana Ros-Lehtinen

Rep. C.A.Dutch Ruppersberger

Rep. Aaron Schock

Rep. Kurt Schrader

Rep. Bobby Scott

Rep. Pete Sessions

Rep. Peter Visclosky

Rep. Robert J. Wittman

Rep. David Wu

Rep. Don Young

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korrico@neurosurgery.org

Congress of the United States Washington, DC 20515

STOP THE CUTS AND REFORM MEDICARE'S PAYMENT SYSTEM THIS YEAR Preserve Americans' Access to the Care They Need

Dear Colleague:

Please join us in sending the attached letter to Speaker Nancy Pelosi and Republican Leader John Boehner asking for their support in taking action this year to prevent cuts to reimbursements to physicians carring for seniors, provide a positive Medicare update for 2010, and to initiate payment reform to ensure that Medicare beneficiaries and all Americans continue to have access to physician services.

Medicare physician payments are scheduled to be cut 21.5 percent in 2010 and by more than 40 percent over the next decade. These cuts are required by the flawed Sustainable Growth Rate (SGR) formula used to calculate Medicare physician reimbursement. In 2002, the SGR led to a 5.4 percent reduction in Medicare physician payments, and only Congressional action has prevented further reductions in the following years. Although we have prevented further cuts, the rate of reimbursement has not kept up with physician cost of practice.

Recently, some have proposed financing increased Medicare payments for some physicians and services by cutting payments to other physician specialties. With Medicare payments already not keeping pace with the rising practice costs, such proposals could potentially threaten patient access to the life-saving care provided by other physician specialties. While Congress must work together to help Americans better manage their care, Congress must also ensure that a new reimbursement structure not threaten patients' access to the life-saving care provided by other physicians.

Please join us in calling on Speaker Pelosi and Leader Boehner to take action this year to stop the 21.5 percent cut in 2010 and to initiate much-needed reform of Medicare's payment system that will not just preserve but also improve Americans' access to the full-range of care provided by America's physicians.

To sign on, please contact Matt Coffron with Congresswoman Shelley Berklay at 5-5965 or Shauna McCarthy with Congressman Mark Kirk at 5-4835.

Sincerely,

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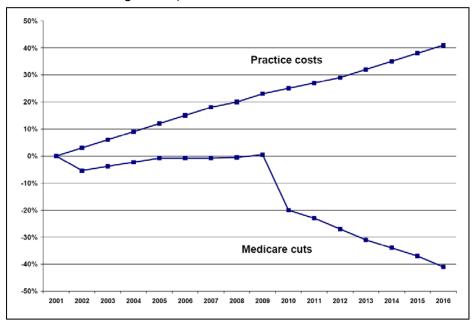
Washington Update May, 2009



CODING AND REIMBUSREMENT

Medicare Physician Payment Update

Absent legislative change in 2009 projected reimbursement trends are as follows (with a 21% cut in 2010 and a total of over 40% through 2016):



The principle obstacle to reform is **cost**. The Congressional budget office's estimated costs of reform continue to escalate and CBO now expects various reform proposals to cost the following:

- \$439 billion to replace system w/MEI updates (\$556 billion if beneficiary premiums held harmless)
- \$318 billion to replace system w/ a pay freeze for 10 years
- \$50 billion for short-term modest update for a year

If CMS would retroactively remove Part B drugs administered by physicians from the SGR formula – retroactively – this would put \$100 billion back into the physician payment baseline. Efforts to urge CMS to do this continue, but with a legal opinion from CMS counsel against this position, prospects for this option may be dim.

The Baucus White Paper

To date, only one detailed proposal (in the Senate) has been proposed. On November 12, 2008, Senator Max Baucus (D-MT), Chairman of the Senate Finance Committee, released an 89-page outline of his comprehensive vision for health care reform entitled, "Call to Action: Health Reform 2009." Included in this White Paper are a number of proposals related to Medicare physician payment. *Most disturbing about the document is Sen. Baucus' proposal to provide increased payments to primary care providers in a budget-neutral fashion at the expense of specialty physicians.* Key aspects of the Baucus plan include:

- Strengthening role of primary care and chronic care management
- Refocusing payment incentives towards quality, including: expand use of clinical data registries; move from bonus to punitive reimbursement tied to quality
- Promoting provider collaboration and accountability, including: bundling, gainsharing
- Improving the health care infrastructure, including: HIT, comparative effectiveness research

The complete document is available at: http://finance.senate.gov/healthreform2009/home.html
Page 1 of 51

MedPAC Recommends 1.1 % Physician Payment Update for 2010

In its March 2009 report, the Medicare Payment Advisory Commission (MedPAC) recommended a physician payment update of 1.1%. A copy of the March report is available at http://www.medpac.gov/documents/Mar09_EntireReport.pdf

House and Senate Pass Budget Resolutions

The House and Senate approved separate versions of the fiscal year (FY) 2010 Congressional Budget Resolution on April 2, by votes of 233-196 and 55-43, respectively. The budget resolutions lay out five-year Congressional plans for taxes and spending.

The House Budget Resolution contains provisions that would facilitate passage of legislation to replace the flawed sustainable growth rate (SGR) formula. Specifically, it would provide budgetary protection for such legislation that is consistent with the view that the current Medicare physician spending budget baseline, which assumes payment cuts totaling 40 percent over the several years, is unrealistic. Congress will still have to enact additional legislation to replace the SGR. The House Budget Resolution also includes a provision known as a "budget neutral reserve fund" that represents support for health system reform legislation. Of note, it would require the costs of health system reform to be fully offset by other spending cuts or revenue increases. Additionally, the resolution contains budget reconciliation instructions that would require both the Committee on Ways and Means and the Committee on Energy and Commerce to report legislation by September 29 that produces savings of \$1 billion over 5 years. These savings could be used to advance health system reform legislation. Reconciliation bills are significant because they are not subject to a filibuster in the Senate and need only 51 votes for passage.

The Senate version of the Budget Resolution contains a budget-neutral reserve fund to avert projected Medicare physician payment cuts. However, it does not provide funding to stop the cuts or provide budgetary protection to legislation that would replace the SGR. The Senate resolution also contains a budget neutral reserve fund for health system reform legislation.

The AANS and CNS, along with the AMA and other national specialty societies recently sent a to congressional leaders involved in reaching consensus on a fiscal year 2010 congressional budget resolution. The budget resolution passed April 2 by the U.S. House of Representatives included provisions that would facilitate the passage of legislation to replace Medicare's sustainable growth rate (SGR) and establish a path toward long-term physician payment reform. The Senate-passed budget resolution did not include the same budgetary protections for eliminating the SGR. It is anticipated that a final budget resolution will be considered on the House and Senate floors by the end of this month.

The House and Senate are currently negotiating the final conference agreement.

Congressional Budget Office Warns of Access Problems

In late March, the Congressional Budget Office (CBO told the House Budget Committee that the effect of a 21% reduction in Medicare physician payment rates in January 2010 and a cumulative cut of 40% by 2014 would likely result in reduced physician participation in Medicare. CBO said that while some doctors would stop participating, others would no longer accept new Medicare patients, and others would compensate by increasing the volume and/or intensity of services. CBO also said that if beneficiaries are compelled to receive care at emergency departments, the quality and continuity of care received could decline, possibly leading to poorer health outcomes.

The CSNS is finalizing a Medicare survey that will be conducted each year and will ascertain neurosurgeons' Medicare participate status.

Organized Medicine's Activities

The AANS and CNS continue to work with Congress and others to improve payment policies. Since December, working with the American College of Surgeons and the Alliance of Specialty Medicine, we have held over 20 meetings with Congressional staff outlining our current position on various Medicare issues.

- American Medical Association. The American Medical Association continues to work on achieving a unified position on Medicare physician payment reform within organized medicine. Given the divide between primary care and the specialists, unity remains elusive. Within the past several months, the AMA has convened several meetings of staff and physician leaders and the House of Delegates has met (although no definitive policy or strategy was forthcoming form this meeting, other than the endorsement of the medical home principles). At these meetings, the AMA is currently evaluating a number of proposals for reform, including:
 - Gainsharing and Accountable Care Organizations
 - Pay-for-Performance on Quality Measures
 - Bundling (Physician episodes of care/bundling of hospital and physician payments)
 - Patient-Centered Medical Homes
 - SGR Targets (Service or specialty-specific/state or regional/other)
 - Other Payment Policy Changes (e.g., balance billing, GPCIs, HIT)

Again, no consensus on the major issues (i.e., no budget neutral shift of money from specialty physicians to primary care doctors and no acceptance of a short term fix) has been reached.

Thanks to the AANS and CNS, however, we were successful at finally getting the AMA on record in opposition of this budget neutral shift of funds from specialists to primary care. Leaders from the AANS and CNS (Drs. Bean, Tippett, Adelson and Ms. Orrico), along with representatives from the American College of Surgeons, American Association of Orthopaedic Surgeons and the American Society of Cataract and Refractive Surgeons met with approximately 10 members of the AMA Board of Trustees. This high-level meeting produced an op-ed by Dr. Joseph Heyman, Chairman of the AMA Board, published in the February 2, 2009 *AMNews*. In this piece, entitled, "Physicians need one voice to fight for payment reform," Dr. Heyman writes:

The American Medical Association absolutely opposes applying budget-neutrality rules that confine off-sets to the physician payment pool. Congress should not rob Dr. Peter, the surgeon, to pay Dr. Paul, the primary care physician.

We will continue to work with the AMA to achieve reforms that work for neurosurgery.

- American College of Surgeons. The AANS and CNS are working with the American College of Surgeons on a comprehensive strategy for promoting the value of surgical care and the need to ensure that payment systems and other health policies do not favor primary care at the expense of surgical care. Thus far, we have developed "Surgery's United Agenda for Medicare Physician Payment Reform," which is endorsed by 15 major surgical organizations. Specifically, the agenda advocates for, among other things:
 - Repeal of the current sustainable growth rate (SGR) and establishment of a new baseline for the physician payment system;
 - Replacement of the current SGR with a system of multiple conversion factors; and
 - Assurance that any additional payments that are made to primary care physicians are not budget neutral within the physician payment pool.

Organized surgery is currently in the process of finalizing the actual legislative proposal outlining the multiple conversion factor approach. The new proposal will have 4 separate categories: primary care E&M; all other E&M; major surgery (defined as procedures with 90 and 10 day global periods and associated add-on codes); and all other services.

To help promote our agenda, on March 24, 2009, organized surgery launched a new communications campaign. Spearheaded by the American College of Surgeons and involving a number of surgical specialty societies (including the AANS and CNS), rural health organizations and other groups, the Web-based campaign addresses a range of issues including comparative effectiveness research, work force, trauma systems and resident work hours. For more information about *Operation Patient Access* go to: http://operationpatientaccess.facs.org/

• Alliance of Specialty Medicine. The Alliance of Specialty Medicine, of which the AANS and CNS are members, has also developed its own advocacy materials on Medicare issues. The Alliance is revamping its own website to use as a tool for demonstrating the importance of specialty care. Like the surgical initiative, the Alliance is also seeking repeal of the SGR and opposes increasing reimbursement for primary care at the expense of specialists' reimbursement.

Medicare Balance Billing

Representative Tom Price, MD (R-GA) has introduced legislation (H.R. 1384) that would allow physicians to balance billing for the full value of their services under Medicare and for certain non-Medicare patients. H.R. 1384 would allow physicians who elect "non-participating" status in Medicare to balance bill patients by removing the current 115 percent limiting charge on the non-participating Medicare fee schedule amount. The bill would also preempt state laws that prohibit balance billing.

Medicare Physician Fee Schedule

On December 29, 2009, AANS and CNS submitted comments to the Center for Medicare and Medicaid Services (CMS) regarding provisions in the final 2009 Medicare Physician Fee Schedule (MPFS) published on November 19, 2008. The comments focused primarily on the objections of AANS and CNS to the arbitrary reduction of reimbursement for new codes for cranial and spinal stereotactic radiosurgery (SRS) procedures. The 2009 Medicare Fee Schedule final rule is available at: http://edocket.access.gpo.gov/2008/pdf/E8-26213.pdf

In addition to submitting comments to CMS to protest the SRS cuts, Washington office staff sent out an e-blast alert to neurosurgeons urging them to submit their own comments objecting to the CMS imposed cuts in SRS reimbursement. Between 15-20 neurosurgeons (that we know of) took the time to submit comments to CMS, with copies to their Members of Congress. The AMA Relative Value Update Committee (RUC) also objected to the SRS cuts and included the AANS/CNS wording in their letter to CMS regarding the fee schedule. Washington Office staff asked the American College of Surgeons (ACS) to support the RUC-passed values and John Wilson, MD, asked the ACS RUC Member and Advisors for support. However, despite many conversations, ACS did not ultimately support the RUC-passed SRS values in their Medicare Fee Schedule letter. When new CMS leaders are in place, Washington Office staff will request a meeting to discuss the issue and will request that the codes be sent to a refinement panel for reevaluation.

CPT Coding Issues

February 2009 CPT Panel Meeting

The CPT Panel met February 5 through 8, 2009. Jeffery Cozzens, MD, attended as a CPT Editorial Panel member. Patrick Jacob, MD, AANS Advisor to CPT, Joseph Cheng, MD, CNS Advisor to CPT and Washington Office staff also attended. The following issues were addressed:

• Facet Injection Codes. AANS, CNS, and NASS joined several other societies in a code change proposal for Facet Joint Injection Codes. The procedures were identified by CMS and the RUC Five Year Review Committee on the "fastest growing procedures" list. The specialty societies felt

that the growth in volume was probably due to improper coding of other procedures such as trigger point injections. The new code set specifically requires the use of CT or Fluoroscopic Guidance in order to help clarify the difference between Facet Injection and other injection codes.

Body Radiosurgery. At the October 2008 CPT Editorial Panel meeting the American College of Surgeons (ACS), the Society of Thoracic Surgeons (STS), and the American Urological Association (AUA) presented a CPT Coding Proposal for ten new codes for Stereotactic Radiosurgery (SRS) performed in the abdomen, prostate, and thorax. AANS and CNS did not become involved except to urge the groups to coordinate their proposal with the American Society for Therapeutic Radiation and Oncology (ASTRO). ASTRO opposed creation of body SRS codes because they believe that these codes duplicate Stereotactic Body Radiotherapy (SBRT) codes used by radiation oncologists and do not represent additional necessary physician work. ASTRO submitted an alternative proposal for a code for fudicial placement by the surgeon. The panel decided to form a workgroup to consider the codes. Ken Simon, MD, CMS Medical Officer, asked that the group explore the use of the -62 co-surgeon modifier for the procedure and to determine if the procedures require two physicians or can be performed alone by one physician.

The Workgroup met by conference call on January 14, 2009. Patrick Jacob, MD, and Washington office staff participated in the call. The group decided to go forward with the fudicial placement codes and hold two additional meeting during at CPT to discuss other codes for surgeons. On February 7, 2009, the fiducial marker code was passed by the CPT Editorial Panel. However, the workgroup did not have the opportunity to discuss the codes for additional surgeon work in body SRS. ACS, AUA, and STS suggested a workgroup meeting be held with just the surgical groups and ASTRO, followed by a full workgroup conference call on April 14, and another workgroup meeting at the June 2009 CPT Editorial Panel Meeting.

As planned, a meeting of the surgical groups and ASTRO was held in Washington DC on March 22, 2009 Attending on behalf of AANS and CNS were Troy Tippett, MD, John Wilson, MD, Joseph Cheng, MD, Frederick Boop, MD, and Washington Office staff. AMA CPT staff and CMS staff were not at the meeting. The group spent four hours discussing the existence and lack of literature for SRS and SBRT, respectively; the definition of SRS and SBRT; and the possible appropriate coding options for SBRT. The group generally agreed with AANS and CNS that SRS for brain and spine was different that SBRT, because by definition, SRS always requires the presence of a neurosurgeon. Other surgeons may sometimes use SBRT to treat lesions but having a surgeon present for SBRT is not the typical case. For that reason, the possibility of a -62 "co-surgeon" type modifier just for areas of the body other than brain and spine was proposed. Dr. Tippett stated that AANS and CNS would support the -62 for SBRT only if it the codes for brain and spine SRS (for which there is incontrovertible stellar literature and which were developed with all CPT and RUC standards rigorously adhered to) were not part of the -62 scenario and only if ASTRO agreed. Based on the tenor of the meeting, it is unlikely that ASTRO would agree. STS representatives will come back to the group with a better sense of the literature, frequency, and service description for SBRT use by surgeons other than neurosurgeons.

June CPT Editorial Panel Meeting

AANS and CNS will join eight other specialty societies in presenting code change proposals for a series of transforaminal epidural injection codes, CPT Codes 64479 through 64484, to the CPT Editorial Panel at its June 2009 meeting. The codes were identified by the RUC Five Year Review Identification Workgroup as typically being performed with fluoroscopy or CT Guidance and, therefore, the RUC asked that the codes be revised and resurveyed to include the image guidance.

Dr. Cozzens Named PMAG Co-Chair

On March 6, 2009, Jeffrey Cozzens, MD, was named as a co-chair of the Performance Measures Advisory Group (PMAG). The PMAG is an advisory body to the CPT Editorial Panel and the CPT

Health Care Professionals Advisory Committee (CPT/HCPAC) responsible for reviewing CPT "Category II" codes used to report quality measures. The PMAG is comprised of performance measurement experts representing the Agency of Healthcare Research and Quality (AHRQ), the American Medical Association (AMA), the Centers for Medicare and Medicaid Services (CMS), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the National Committee for Quality Assurance (NCQA), and the Physician Consortium for Performance Improvement.

RUC Issues

January 2009 RUC Meeting

The RUC met January 29 through February 1, 2008. Attending for the AANS and CNS were Greg Przybylski, MD, John Wilson, MD, Edward Vates, MD, Alexander Mason, MD, and Washington Office Staff.

- Five Year Review Identification Workgroup. The main activity of interest at the January RUC was the Five Year Review Identification Workgroup consideration of specialty society comments submitted in response to codes identified by CMS in the 2009 Medicare Physician Fee Schedule proposed rule as "Fastest Growing Procedures." These are procedures for which the volume reported to Medicare has grown by at least 10% per year for the last three years. On December 1, 2008, AANS, CNS, AAOS, and NASS submitted joint comments on codes identified and on January 29, 2009, John Wilson, MD, defended these comments before the Five Year Review Workgroup. The workgroup agreed with all of Dr. Wilson's comments except for CPT Code 63655 Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural. The Workgroup recommended that CPT Code 63655 be included in the survey with the spinal neurostimulaor implantation codes to be presented at the April RUC meeting.
- Nerve Conduction Codes. At its January 2009 meeting the RUC valued a set of codes for nerve conduction studies. The codes were first submitted to CPT in October 2007 and referred to a workgroup. Ultimately a Category I code was approved by the CPT Editorial Panel in October 2008. The device used for the nerve conduction studies were developed by the NeuroMetrix company who had contacted several AANS and CNS leaders to urge them to support Category I codes for the procedures.
- Spinal Neurostimulator Electrode. AANS and CNS along with NASS, ASA, and several pain societies presented a code change proposal at the October 2008 CPT meeting to delete CPT Code 63660 and establish new codes, 636X1—636X4, to more distinctly define the work involved in the revision and removal of a percutaneous electrode. CPT 63660 was a code identified by the RUC Five Year Review Workgroup as having had a change of site of service and, therefore, potentially misvalued. However upon attempting to revalue the code, the pertinent specialties discovered that work involved could be better described if the code were split into several new codes. A RUC survey was conducted in March 2009 and recommended values for the codes will be presented at the April 2009 RUC meeting. As was stated above, the survey included CPT Code 63655.

RUC/CPT Joint Workgroup on Bundled Services

On February 24, 2009, AANS and CNS received a letter from CPT and RUC leaders in response to a November 5, 2008, letter from AANS, CNS, the American Academy of Orthopaedic Surgeons (AAOS) and the North American Spine Society (NASS) disagreeing with the RUC/CPT Joint Workgroup on Bundled Services request that a code be developed to bundle CPT Code 22554 Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression);cervical below C2 and 63075 Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace. The letter from CPT and RUC stated that they do not agree with the specialties and expect a CPT code change proposal to

bundle CPT Codes 22554 and 63075 to be submitted by July 15, 2009 deadline for the October 2009 CPT Editorial Panel meeting.

Multispecialty Practice Expense Survey

The joint AMA Specialty Society Physician Practice Information Survey conducted by the St. Louis research firm Dmrkynetec is completed. AANS and CNS have been active in alerting neurosurgeons that they may receive a survey and encouraging them to fill it out. Ultimately, 99% of the neurosurgeons contacted returned the survey. The AMA contracted with CMS to provide the practice expense per hour data by March 31, 2009.

New RUC Chairman

The term of current RUC Chairman, William Rich, MD, will expire in April 2009. AANS and CNS nominated Gregory Przybylski, MD, for the position, however, the AMA Board of Trustees selected Barbara Levy, MD, an obstetrician/gynecologist from Seattle, Washington. Dr. Levy has served as the Chair of the RUC Five Year Review Identification Workgroup.

Coverage Issues

Activity regarding coverage of neurosurgical procedures continues to increase with Medicare national, Medicare local, state, and private payer proposals. Below are some of the issues being tracked by the Washington Office.

Positron Emission Tomography (PET) for Solid Tumors

On April 3, 2009, CMS issued a final decision memorandum regarding FDG Positron Emission Tomography (PET) for Solid Tumors. The origin of the review was developed during an August 20, 2008, meeting of the CMS Medicare Evidence Development & Coverage Advisory Committee (MedCAC) held to discuss the scientific evidence for oncologic indications of PET for nine cancers, including brain tumors. Andrew Sloan, MD, participated in the panel. In the final decision memorandum, CMS states that they are "adopting a coverage framework that replaces the four-part diagnosis, staging, restaging and monitoring response to treatment categories with a two-part framework that differentiates FDG PET imaging used to inform the initial antitumor treatment strategy from other uses related to guiding subsequent antitumor treatment strategies after the completion of initial treatment. We are making this change for all NCDs that address coverage of FDG PET for the specific oncologic conditions addressed in this final decision memo." Specifically for PET for brain the decision would allow coverage for the initial scan but would be a "coverage with evidence development" policy for subsequent scans. More information is available on the web at: https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=218&

Carotid Artery Stenting Coverage

On March 18, 2009, CMS issued a seventh reconsideration of its coverage policy for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting. CMS is requesting public comments on coverage of the procedure for Medicare beneficiaries who are at high risk for CEA due to anatomic risk factors and have asymptomatic carotid artery stenosis \geq 80% following the release of additional industry-sponsored data. Comments are due on April 17, 2008. John Wilson, MD, and the AANS/CNS Section on Cerebrovascular Surgery leadership are reviewing the decision. In the previous several reconsiderations, AANS and CNS have suggested that the information resulting from the National Institute of Neurological Disorders and Stroke (NINDS) Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) should provide guidance regarding appropriate indications for carotid artery stenting, and recommend that coverage for this procedure not be expanded until the completion of the CREST trial and a thorough analysis of the data produced by it.

On April 4, 2009, the American Society for Neuroradiology (ASNR) circulated a draft letter to the Neurovascular Coalition recommending approval of the CAS reconsideration and the group has asked for a response by April 10, 2009.

More information is available at:

https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?from2=viewtrackingsheet.asp&id=230&

Wisconsin Physicians Services Medicare Part A Cranial Stereotactic Radiosurgery and Radiotherapy Coverage Policy

AANS President, James Bean, MD, received a letter dated January 22, 2009, from Wisconsin Physician Service (WPS) Part A Medicare Carrier requesting input on a draft policy for facility payment for "Cranial Stereotactic Radiosurgery and Radiotherapy." The issue was referred to the AANS/CNS Coding and Reimbursement Committee and reviewed by Jeff Cozzens, MD. Dr. Cozzens is on the Carrier Advisory Committee for WPS. In addition, Clarence Watridge, MD, informed the Washington Office that the policy was also sent to the American College of Surgeons and referred to the ACS Advisory Committee on Neurosurgery for comment. Dr. Cozzens has written a response that will be sent to WPS. The policy is available on the web at http://www.wpsmedicare.com/part_a/policy/rad018.pdf

Washington State Health Care Authority Health Technology Assessment Panel – Total Disc Arthroplasty

March 20, 2009, the Washington State Health Care Authority Health Technology Assessment (HTA) Clinical Committee held a conference call to discuss a number of issues, including questions surrounding the finalization of a draft proposal for coverage of Total Disc Arthroplasty (ADR) issued on December 11, 2008. On January 30, AANS and CNS joined NASS, AAOS, SRS, and SAS in sending a letter to the committee questioning requirements that "patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency" before being permitted to received a lumbar or cervical artificial discs. The language was the same as the language for the spinal fusion coverage decision but inclusion of such language for artificial spinal discs was not discussed at the October 17, 2008 public meeting. In the letter, the specialty societies expressed concern about this requirement, especially for ADR in the cervical spine and asked that requirement be removed from the coverage decision.

Several members of the AANS/CNS/NASS/AAOS/SRS/SAS coalition called into the March 30 discussion but public comment was not permitted. On the call, the HTA staff indicated that they agreed with comments submitted that if a structured, intensive multidisciplinary program for management of pain was required for the lumbar ADR, it should not be required for cervical ADR.

Washington State Health Care Authority Health Technology Assessment Panel- Procedures for Coverage Review in 2009

On December 12, 2008, the Washington State Health Care Authority published the list of procedures that it plans to review in 2009. The procedures are:

- Sleep Apnea Diagnosis and Treatment
- Calcium Scoring for Cardiac Disease
- Vagal Nerve Stimulation
- Hip Resurfacing
- Bone Growth Stimulators
- Transcutaneous Electrical Neural Stimulation (TENS)
- Glucose Monitoring

More information is available on the web at: http://www.hta.hca.wa.gov/press release/hca-administrator-selects-health-technologies.html

Wellpoint and Blue Cross/Blue Shield Tech Assessment Requests

Over the last year the Washington Office has been contacted by Wellpoint Technical Assessment for possible input on many items. These requests have been referred to the pertinent clinical sections.

In particular, Wellpoint has requested input on many spine procedures and these requests have been referred to the AANS/CNS Spine Section. Joseph Cheng, MD, Spine Section Representative to the AANS/CNS Coding and Reimbursment Committee is coordinating the response efforts. The recent requests are:

- Interspinous Distraction Devices (Spacers). NASS has decided not to comment. AAOS has developed comments and shared them with AANS and CNS for possible joint submission. On March 13, 2009, Washington Office forwarded a Spine Section response on this issue to the AANS and CNS Presidents for approval. Essentially, the Spine Section recommended expressing support for interspinous spacers as an improvement on the natural history of neurogenic claudication in appropriately selected patient. However, the section did not feel the data was sufficient to judge the devices as compared with laminectomy procedures.
- Manipulation under Anesthesia for Treatment of Chronic Spinal or Pelvic Pain. Upon initial review the Spine Section opinion is that it would not be typical for a neurosurgeon to perform these procedures and therefore input from AANS and CNS would likely not be forthcoming
- Axial Lumbar Interbody Fusion (axiaLIF). Members of the Spine Section and the Coding and Reimbursement Committee continue to discuss this issue. Dan Resnick, MD, has suggested that AANS and CNS may prefer to stay silent on this issue or, alternatively, could provide literature to Wellpoint without further comments of support or disapproval. The Coding and Reimbursement Committee will discuss this issue at its May 2009 meeting.
- Intradiscal Decompression Procedures (such as IDET). The Spine Section is in the process of discussing this issue. Initially the preference was to remain silent, as the procedure is not routinely performed by neurosurgeons, however concerns were expressed about whether remaining silent implies acceptance of the procedure.
- Percutaneous and Endoscopic Spinal Surgery. Joseph Cheng, MD, formulated a response to Wellpoint emphasizing that the draft policy statement provided by Wellpoint appears to inappropriately combine percutaneous techniques and minimally invasive spinal techniques when the endoscope is used. Dr. Cheng stated that AANS and CNS do not agree with the policy that minimally invasive endoscopic spinal surgical techniques are considered investigational and not medically necessary.

Procedures for which Wellpoint has requested input previously are:

- Percutaneous Thermal Neurolysis for Chronic Back Pain and Trigeminal Neuralgia.
 Referred to the AANS/CNS Pain Section
- Adjustable Banding as a Treatment of Plagiocephaly. This issue has been referred to the AANS/CNS Pediatric Section. Mark Proctor, MD, and Shenandoah Robinson, MD, have co-authored an article on the issue on behalf of the section for publication in the Journal of Neurosurgery. The section discussed the development of a position statement at its December 2008 meeting and will discuss the issue further in May at the AANS meeting.
- Magnetoencephalography/Magnetic Source Imaging. Referred to the AANS/CNS Section on Stereotactic and Functional Neurosurgery

- Artificial Intervertebral Disc: Lumbar Spine. Referred to the AANS/CNS Spine Section.
- Artificial Intervertebral Disc: Cervical Spine. The request was referred to the AANS/CNS Spine Section and a response was sent to Wellpoint on December 8, 2008.
- Percutaneous Vertebroplasty and Percutaneous Kyphoplasty. This issue was referred to the AANS/CNS Spine Section and Joseph Cheng, MD, who coordinated a response to Wellpoint.
- Stereotactic Radiosurgery and Stereotactic Radiotherapy. Referred to the AANS/CNS Spine Section, Section on Stereotactic and Functional Neurosurgery, and Tumor Section.

United Health Care Request for Artificial Total Disc Coverage

On March 3, UnitedHealthcare notified the AANS/CNS Washington Office that it was in the process of reviewing their coverage policy for Artificial Total Disc. The request has been referred to the Spine Section and can likely be answered with documents recently prepared for other payers.

Other Medicare Issues

Medical Home

On January 1, 2009, CMS began the Medicare Medical Home Demonstration (MMHD), a three year demonstration designed to provide "targeted, accessible, continuous and coordinated, family-centered care to high need populations (i.e. Medicare beneficiaries with prolonged or chronic illnesses that require regular medical monitoring, advising, or treatment). In December 2008, the Center for Health System Change and Mathemathica Policy Research, Inc. published an analysis of the Medical Home concept.

ICD-10 Coding

On January 15, 2009, in response to comments by AANS, CNS and other physician organizations, CMS issued a regulation that would delay by two years the compliance deadline for converting from the currently used International Classification of Diseases, Ninth Revision (ICD-9), which includes 17,000 procedure codes to the International Classification of Diseases, Tenth Revision (ICD-10), with 155,000 codes. The new implementation date is October 1, 2013.

APC Panel Nominations

On March 13, 2009, AANS and CNS sent a letter nominating Gregory Przybylski, MD, to the CMS Medicare Ambulatory Payment Classification (APC) Panel. The panel advises CMS on issue related to APC groups and relative payment weights that are components of the Medicare Hospital Outpatient Prospective Payment System (OPPS). Dr. Przybylski was asked by CMS Medical Officer Edith Hambrick, MD, JD, Chair of the panel, to apply for one of the APC panel vacancies occurring in August 2009. Dr. Przybylski currently serves on the HHS Practicing Physician Advisory Council (PPAC) but will be eligible to serve on the APC Panel, as his PPAC term expires in June 2009. More details are available at http://edocket.access.gpo.gov/2008/E8-30454.htm

February 2009 APC Panel Meeting

On February 18, 2009, Jeffrey Cozzens, MD, appeared before the APC Panel on behalf of AANS and CNS to recommend changing CPT 61885 *Brain and Cranial nerve pulse generator implantation* from its current APC 0039 to APC 0222 which includes spinal cord stimulators. The change was deemed more appropriate because the cranial neurostimulators are similar clinically and in terms of risk to the

spinal stimulators. This would result in a higher facility payment for the neurostimulators used in Vagal Nerve Stimulation (VNS) and in Deep Brain Stimulation (DBS) in the hospital outpatient setting.

Medicare Recovery Audit (RAC) Contractors

On February 6, 2009 CMS announced that the Medicare RAC program that had been put on hold for a few months due to protest by several companies that had bid for contracts and not received awards was going forward following resolution of the complaints. In October 2008, CMS had announced the award of RAC contracts, but those contract awards were protested and a stop work order was put in place.

As mandated by section 302 of the Tax Relief and Health Care Act of 2006, CMS will implement a permanent and national RAC program by January 1, 2010. The national RAC program is the outgrowth of a demonstration program that used RACs to identify Medicare overpayments and underpayments to health care providers and suppliers in California, Florida, New York, Massachusetts, South Carolina, and Arizona.

The new RACs are:

- Diversified Collection Services, Inc. (DCS) of Livermore, California, in Region A, initially working in Maine, New Hampshire, Vermont, Massachusetts, Rhode Island and New York.
- CGI Technologies and Solutions, Inc. of Fairfax, Virginia, in Region B, initially working in Michigan, Indiana and Minnesota.
- Connolly Consulting Associates, Inc. of Wilton, Connecticut, in Region C, initially working in South Carolina, Florida, Colorado and New Mexico.
- HealthDataInsights, Inc. (HDI) of Las Vegas, Nevada, in Region D, initially working in Montana, Wyoming, North Dakota, South Dakota, Utah and Arizona.

As part of the settlement of the protests, the four RACs listed above will contract with subcontractors to supplement their efforts. PRG-Schultz, Inc. will serve as a subcontractor to HDI, DCS and CGI in Regions A, B and D. Viant Payment Systems, Inc. will serve as a subcontractor to Connolly Consulting in Region C. Each subcontractor has negotiated different responsibilities in each region, including some claims review.

On February 27, 2009, AANS and CNS joined other medical specialty societies in signing a letter coordinated by AMA expressing concerns about the RAC process. In the letter, the signatories reminded CMS that problems with over and/or underpayments of Medicare claims are best resolved through physician outreach and education, asked CMS to exempt Evaluation and Management codes from RAC Audits, and recommended raising the minimum claim amount for review from \$25 to \$100 in order to reduce the burden on physicians.

More information on the RAC program is available on the CMS website at http://www.cms.hhs.gov/RAC/.

Miscellaneous Issues

AANS/CNS Reponse to ASTRO Brochure

On December 13, 2008, AANS and CNS sent a letter to Patricia Eifel, MD, Chair of the American Society for Therapeutic Radiology (ASTRO) Board of Directors, to object to several items in an ASTRO published brochure entitled "Plain Talk for Radiation Therapy Patients: Stereotactic Radiotherapy." Specifically, AANS and CNS objected to the inappropriate equating of SRS with Stereotactic Body Radiotherapy (SBRT), and the omission of any reference to the role of the

neurosurgeon in SRS. The letter emphasized that brochure is not in keeping with the agreed upon definition of SRS published by both organizations in their respective journals. On February 27, 2009, ASTRO staff notified the AANS/CNS Washington Office Director Katie Orrico that ASTRO was in the process of changing their brochure for both the web and print to reflect the correct SRS definition, as requested by AANS and CNS, The revised brochure is available on the web at: http://www.rtanswers.com/treatment/stereotactic.htm

Neurovascular Coalition

On February 18, 2009, the Neurovascular Coalition (NVC) discussed two draft documents for Stroke Intervention Training Guidelines. One draft document was developed by the Society for Neurointerventional Surgery (SNIS). This draft document was preferred by AANS, CNS, the American Academy of Neurology (AAN), and the Society of Vascular Interventional Neurology (SVIN), as those societies agree that optimal training standards for interventional stroke should be set high and should require the completion of a neuro-interventional fellowship. The second document, developed by the American Society of Neuroradiology (ASNR) and supported the Society of Interventional Radiology (SIR), allowed for an abbreviated training course. The Neurovascular Coalition, which is chaired by John Wilson, MD, includes AANS, CNS, SNIS, ASNR, AAN, and SVINS. The group was not able to reach a compromise and asked ASNR and SIR to come back with a revised document within one month.

On March 27, 2009, ASNR circulated a revision of their draft that differed from the original in that it would require additional experience in vascular and micro catheter procedures; provides more detail for education; require a written exam; require direct observation using simulators and proctored cases; and require participation in a registry with outcomes analysis. NVC members are currently reviewing the revised ASNR documents.

QUALITY IMPROVEMENT

Medicare Physician Quality Reporting Initiative (PQRI)

Reporting PQRI Participating Physicians

As required under Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS recently began to post on its web site the names of professionals who reported quality information (successfully or unsuccessfully) under the 2007 PQRI. Under this initiative, known as "Physician Compare," Medicare beneficiaries who search for a physician or other Part B provider on Medicare.gov will also find out if the provider participated in the 2007 PQRI. While the AANS, CNS and other medical specialties feel that the public posting of this information was premature and that this information is of little value to patients, we are pleased that CMS honored our request to include a disclaimer on the web site that explains that there are many reasons why a physician may not be participating in the PQRI, including that available measures may not be applicable. Neurosurgeons are encouraged to visit the CMS website to confirm whether their listing is accurate.

2008

The Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), extended the "voluntary" PQRI through 2009. For 2008, there were 45 additional reportable measures, bringing the total to 119, all of which have either been endorsed by the National Quality Forum (NQF) or adopted by the Ambulatory Quality Alliance (AQA). The bonus payment was 1.5%, with no cap, and funded through the Medicare Part B Trust Fund. Alternative reporting options were also available in 2008, including reporting of measures over a 6-month or 12-month period, reporting individual measures or groups of clinically related measures, and reporting measures through the claims system or via designated clinical data registries. In late August, CMS selected 32 self-nominated registries qualified to submit quality claims data on behalf of their participants for 2008. This list includes Outcome's TotalQuality registry, the American College of Cardiology's National Cardiac Data Registry, and the Society of Thoracic Surgery's registry. CMS plans to distribute individual feedback reports to 2008 PQRI participants by October 2009. Around that time, CMS will also publicly post the names of physicians who attempted to participate in the 2008 PQRI on its Physician Compare website.

2009

The MMSEA 2007 required CMS to use a rulemaking process to select quality measures for the 2009 PQRI and the MIPPA legislation extended the program, and 2% bonus payments, through 2010. For 2009, CMS will maintain the basic claims-based reporting option, as well as most of the alternative reporting mechanisms authorized last year, including registry reporting and the reporting of individual or group measures over either a 6- or 12-month reporting period. For registry-based reporting, CMS will continue to rely on the 32 registries selected in 2008, and will consider other registries self-nominated through January 31, 2009.

For 2009, there are 52 new quality measures, bringing the total number of measures to 153. Eighteen of the new measures will be accepted exclusively via registries due to their complex specifications, which require multiple diagnosis codes. CMS also added four new measure groups, which simplify reporting by aggregating several measures that address similar clinical conditions. The new measure groups include encounters pertaining to Perioperative Care and Back Pain. While the measures that comprise each group can be reported as a group or individually, the four Back Pain measures are only reportable as a group due to their simplicity. Physicians need only to report a single G-code to indicate he/she met all the individual process measures included in a group. Detailed specifications for both individual and group measures are available on the CMS Web site at: http://www.cms.hhs.gov/PQRI/15_MeasuresCodes.asp#TopOfPage

In 2010, CMS plans to use its Physician Compare website to publicly identify *successful* participants of the 2009 PQRI (not simply those who attempted to participate), and has stated its desire to eventually make performance information public, as well.

Neurosurgery's Reaction to PQRI Expansion

The AANS and CNS have been working with the Alliance of Specialty Medicine to voice its concern about the expansion of the PQRI, its burden on physicians, and its failure to improve quality of care. The following concerns were expressed through various sign-on letters and meetings with both Congress and CMS:

- Concern about the proliferating number of quality and efficiency measures imposed on physicians without evidence of improved health outcomes and reduced system costs;
- Concern about the lack of interim feedback reports during the course of the PQRI, which
 prevents participants from knowing whether they are successfully complying with program
 requirements; and
- Concern about CMS's proposal to move forward with public reporting before conducting a formal evaluation of the PQRI to date, before correcting the program's many technical flaws, before having a mechanism in place to risk-adjust or otherwise validate data, and before testing which public reporting formats are most accurate and user-friendly.

In the late fall of 2008, the Alliance for Specialty Medicine also asked Rep. John Dingell (D-MI), former Chair, Energy and Commerce Committee, and Rep. Frank Pallone (D-NJ), Chair, Energy and Commerce's Health Subcommittee, to hold hearings on the PQRI. As a first step, Rep. Pallone sent a letter to Kerry Weems, MD, Acting Administrator, CMS, relaying the Alliance's concerns.

Physician Pay-for-Performance

There is increasing interest in Congress and among CMS to transition quickly from the current physician pay-for-reporting (P4R) system to a pay-for-performance (P4P) system. In November 2008, CMS, as required under MIPPA, released a paper titled, "Development of a Plan to Transition to a Medicare Value-Based Purchasing Program for Physician and Other Professional Services." The paper discusses options for transitioning from physician P4R to physician P4P, with the stated goal to "improve Medicare beneficiary health outcomes and experience of care by using payment incentives and transparency to encourage higher quality, more efficient professional services." In pursuit of this goal, CMS has defined the following objectives:

- Promote evidence-based research through measurement, payment incentives, and transparency;
- Reduce fragmentation and duplication through accountability across settings, alignment of measures and incentives across settings, and better coordination for smoother transitions, and attention to episodes of care;
- Encourage effective management of chronic disease by improving early detection and prevention, focusing on preventable hospital readmissions, and emphasizing the importance of advanced care planning and appropriate end-of-life care:
- Accelerate the adoption of effective, interoperable HIT, including <u>clinical registries</u>, eprescribing, and electronic health records.

In response to CMS's transition plan, the AANS and CNS have drafted its own *Blueprint for Quality Improvement*, which outlines its own vision for meaningful quality improvement.

In early January 2009, CMS reported to the House Ways and Means Committee on the progress of its transition plan. Taking the public's feedback into consideration, CMS is now working to design various

approaches for performance-based payment that will address its stated goals and objectives for different practice arrangements. CMS will consider approaches that: 1) overlay the current physician fee schedule, such as differential fee schedule payment based on measured performance or for providing a medical home; 2) address multiple levels of accountability, including individual professionals as well as larger teams/organizations; and 3) promote more integrated care through shared savings modes and bundled payment arrangements. CMS is currently testing these approaches through various demonstration projects, including the Physician Group Practice demonstration of a shared savings model, medical home and other care coordination/disease management demonstrations, and the Acute Care Episodes demonstration of bundled payments.

Physician Resource Use

Following recommendations by MedPAC and the GAO, the MIPPA legislation included a provision that requires CMS to establish a confidential Physician Resource Use Feedback program to improve efficiency and to control costs. Under the program, which must be implemented by January 1, 2009, CMS will use Medicare claims data to provide confidential reports to physicians that measure the resources used in furnishing care to Medicare beneficiaries. In the 2009 MPFS final rule, CMS outlined current efforts to test ways to measure physician resource use (e.g., episodic versus per capita cost measurement, benchmarking, risk-adjustment, feedback report formats, etc.) in three communities across the nation. CMS will present more formal findings in the spring of 2009, but in the interim is collecting public comments on the initial phase of its implementation plan. CMS will then present a plan for the next phase of this project in the FY2010 MPFS proposed rule. Under MIPPA, the GAO is also required to conduct a study of the feedback program and make recommendations to Congress by March 2011 regarding appropriate legislation and/or administrative action. As CMS continues to provide updates on its progress, the AANS and CNS will work with other specialties to analyze and comment on the utility of this project.

Health Information Technology and E-Prescribing

HIT Provisions in Stimulus Package

Ensuring that the nation's health system moves toward an electronic system is a key component of the Administration's health care platform. In that vein, the American Recovery and Reinvestment Act (ARRA) of 2009 includes various provisions to spur adoption and use of HIT, including:

- Codifies Office of the National Coordinator for Health IT (ONCHIT) to promote the development of national interoperable HIT infrastructure and help develop electronic health record (HER) certification standards
- Establishes a HIT Policy and Standards Committee, a group of public/private stakeholders that will provide recommendations on HIT policy, standards, implementation, and certification criteria
- HHS will adopt through rule-making an initial set of standards, implementation specifications, and certification criteria for EHR adoption by December 31, 2009;
- Competitive grants to states for HIT advancement
- Creates Broadband Technology Opportunities Program to provide education and support for providers
- \$19 billion in Medicare payment incentives/penalties to spur use of EHRs
- Physicians must adopt /use in a meaningful manner certified EHRs within 5 yrs
 - ONCHIT will certify eligible EHRs that meet certain standards and provide a governmentsponsored EHR for nominal fee
 - "Meaningful use" to be defined by HHS, but will include e-Rx, information exchange standards, and reporting quality measures to CMS

- Bonus payments available over 5 yrs on a sliding scale starting in 2011, followed by penalties for non-adoption starting in 2015. Maximum incentive for early adopters is \$44,000 over 5 years. Penalty starts at -0.1% of total annual Medicare charges in 2015. The reduction phases up to -0.3% for 2017 and could be higher after that, since HHS has authority to increase the penalty up to 5% if physician uptake is low.
- Rural health professional shortage areas eligible for higher bonus
- Physicians may qualify for hardship exemption to avoid penalties (up to 5 yrs)

In late January, the Alliance of Specialty Medicine sent the House and Senate leadership a letter expressing appreciation that both stimulus packages include funding to support HIT adoption. However, we expressed concern about the ambitious timeline; the lack of federal HIT standards and certified products; new privacy regulations that have yet to be clarified; the failure to account for the ongoing cost of implementing HIT infrastructure (in December 2008, the Congressional Budget Office estimated that in addition to any initial investments, annual costs can average from \$3,000 to \$9,000 per physician); and most importantly, the use of penalties for those who fail to adopt HIT in future years given that most physicians cannot afford the upfront and ongoing costs associated with adopting HIT.

Hospital Quality Reporting

Hospital P4P

In November 2008, Senate Finance leaders Baucus (D-MT) and Grassley (R-IA) released a bipartisan discussion draft of legislation to implement a Medicare value-based purchasing (VBP) program for inpatient hospital care in 2012. The draft legislation, the Medicare Hospital Quality Improvement Act, would provide hospitals with either an increase or a decrease in their Medicare payments depending on how they perform on standard quality measures. The proposal suggests starting with an initial set of inpatient measures, including those that focus on surgical care, selected from a list of measures representing the best practices in inpatient hospital care, such as those endorsed by the National Quality Forum (NQF). The program would be phased in over the course of five years, starting in FY 2012, with full implementation beginning in FY 2016. Payment levels would gradually increase from 1.0% in FY 2012 to 2.0% by FY 2016. The proposed VBP program would be budget neutral, so any savings from reduced payments to certain hospitals would be used to increase payments to other hospitals.

Legislative action is necessary to implement any VBP policy. However, it's likely that this latest Senate Finance proposal will be folded into another large piece of healthcare legislation, such as universal healthcare or a Medicare physician payment fix, especially since the Administration's Budget Blueprint also indicated support for hospital P4P. The AANS and CNS distributed to Congress and CMS its *Blueprint for Quality Improvement*, which warns about the unintended consequences of prematurely transitioning to P4P.

Present on Admission (POA) Reporting and Non-Payment for Hospital-Acquired Conditions (HACs)

As of 2008, hospitals receive lower Medicare reimbursements if inpatients suffer from "hospital-acquired conditions" that are not documented as "present on admission," such as SSIs following spine and joint procedures. The AANS and CNS were critical of this program since it targets infections that may sometimes occur despite adherence to best practices. Furthermore, the policy's all-or-nothing approach to non-payment does not include case-mix adjustments or provide a mechanism to flag cases where an infection occurred despite adherence to evidence-based guidelines. We are also concerned that by defining what is and what is not preventable, CMS may expose providers to increased med liability risks.

In preparation for the FY 2010 rulemaking process, CMS held a listening session in December 2008 to solicit stakeholder input on expanding its inpatient HAC policy to other providers and settings (e.g., outpatient, physician practices). The AANS and CNS submitted comments outlining the flaws of the current inpatient HAC policy, the challenges associated with applying a similar policy to other provider payment systems, and the irrationality of expanding a policy that has not yet been adequately tested.

Surgical Error National Coverage Determinations

In January 2008, CMS announced three final national coverage decisions under which Medicare will not pay for the following errors resulting from surgical or other invasive procedures:

- Wrong Surgery Performed on a Patient
- Surgery Performed on the Wrong Patient
- Surgery on the Wrong Body Part

Overall, the AANS and CNS support this effort to target truly egregious errors. We had initial concerns about how intra-operative changes in the surgical plan, common in spine surgery, would be treated under this policy. However, we believe the final language is written in a way that will not adversely affect those making a good faith effort to provide high quality care. The policy places strong emphasis on the consent form, which puts more control in the hands of physician, and excludes emergent situations that preclude a provider from obtaining informed consent. Nevertheless, this is a policy we'll continue to monitor closely for unintended consequences as it is implemented.

Hospital and Outpatient Reporting Programs

Under the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program, hospitals must report 30 quality measures to qualify for a full update to their FY 2009 payment rate. For FY 2010 payment, CMS has added 13 new quality measures and will retire one existing measure. The new measures include:

- Additional Surgical Care Improvement Project (SCIP) measures related to hair removal [see section on Surgery Patient with Appropriate Hair Removal Measure] and cardiovascular surgery;
- Various AHRQ composite outcome measures: and
- Participation in a systematic database (i.e., STS's registry) for cardiac surgery.

Hospital outpatient departments must report 11 quality measures in 2009 to receive a full payment update in 2010, including four new imaging efficiency measures. Hospitals that fail to report will get dinged two percentage points in their annual Outpatient Prospective Payment System (OPPS) inflation update, as mandated under the Deficit Reduction Act of 2005. Many stakeholders, including the AANS, the CNS, and the American Hospital Association voiced major concern over the inclusion of the imaging measures, since many were not endorsed by the Hospital Quality Alliance (HQA) and two were rejected by the National Quality Forum (NQF) due to "substantial technical problems."

Surgery Patient with Appropriate Hair Removal Measure

Recent efforts at the federal level to reduce Surgical Site Infections are quickly leading to the removal of razors from the operating room. Due to the NQF's recent endorsement of a measure originally developed under the Surgical Care Improvement Project (SCIP), organizations like the Joint Commission and CMS have adopted guidelines that state that razors are "never appropriate" for surgical skin preparation. In 2008, CMS, under its inpatient hospital reporting program, will publicly report on hospital compliance with this measure and in 2009, link hospital payments to compliance with this measure. Starting in 2010, the Joint Commission will similarly seek to ban razors from the operating room through its hospital inpatient certification program. As pointed out by the Florida

Neurosurgical Society, with the assistance of the CNS Plante Public Policy Fellow, Joseph Hsieh, there is little to no literature demonstrating that adherence to this practice guideline improves SSI in neurosurgical procedures such as brain and spine surgery. The AANS and CNS are now working to reverse this policy. In February 2009, the Surgical Quality Alliance (SQA) voted to send a joint letter to CMS and The Joint Commission requesting that: 1) it only use quality measures that are based on solid evidence; and 2) when there is not reliable data to compel one practice over another, mandatory compliance with a measure is inappropriate and a surgeon's clinical autonomy should be preserved.

Establishing a Comprehensive Neurosurgery Clinical Data Reporting System

The AANS and CNS have initiated a project to create a single system that will allow practicing neurosurgeons to satisfy MOC case reporting and Medicare and other third-party payers' P4P/quality requirements. In late 2008, the NeuroPoint Alliance, LLC (NPA) was formally incorporated and continues to meet regularly to discuss the functions and scope of the registry, the structure and governance of the system, reporting relationships, data access and ownership, applications/software, and funding. The NPA has decided to contract with Outcomes Sciences, Inc., the vendor that AANS used for its earlier Lumbar Spine Outcomes Data Collection pilot, to operate the registry. The NPA is currently working with Outcomes to finalize a business plan, which will include cost estimates of setting up and maintaining a website portal and a PQRI reporting system. It will also include a proposal for any profit sharing generated by the use of the system. The NPA is also working to finalize an agreement with the ABNS to share Key Case data.

The QIW, working with the clinical subspecialty sections, will assist in developing data collection instruments (i.e., standardized measures of patient characteristics, processes and outcomes) to evaluate neurosurgery's most commonly used CPT codes, which will then be added to the data fields currently used for Neurolog and Key Case reporting. Once the registry is deployed and tested, a Research Committee also will be formed within the LLC to review various uses of the reported data.

In January 2009, the NPA made the following appointments:

- Tony Asher, President-Elect
- Paul McCormick, Treasurer
- Chris Wolfla, Secretary

Neurosurgery's leaders believe this system, which will eventually allow us to refine care processes that lead to better outcomes, will be of considerable value to neurosurgeons and payers alike, and many private payers have already expressed interest in providing incentive payments for participation in such a registry.

Private Payer Quality Recognition Initiatives

Over the last few months, the AANS and CNS have been contacted by various health plans-including Aetna, BlueCross Blue Shield, and CareFirst (the Blues plan that serves DC-MD-VA)—that have expressed interest in collaborating with neurosurgery to develop specialty-specific recognition programs. Over the last few months, Dan Resnick and Jack Knightly helped BCBS develop a program that recognizes multidisciplinary facilities that deliver high quality spine care. While the BCBS program is far from perfect and does not warrant AANS/CNS endorsement, we are pleased to have been given a seat at the table early on in the development process.

In late January, WellPoint also notified the AANS and CNS that it is interested in developing a Low Back Pain Center of Excellence-type program, which would encourage the formation of multi-stakeholder collaborations to encourage care coordination and increase quality/efficiency for managing LBP patients. While WellPoint claims flexibility in terms of protocol setting, it would require

minimum standards. It is still unclear how this program would be implemented, and we have remaining concerns about it benefiting primary care providers at the expense of surgeons' time and resources. Separately, WellPoint also proposed to work with neurosurgery to develop interactive CME to educate providers on the main tenants of quality care (e.g., adherence to EBM guidelines, use of shared decision-making tools, use of pain/functional status assessments). WellPoint recently granted the American College of Physicians a nonrestrictive grant to develop didactic, interactive, cross-specialty CME that the American Board of Internal Medicine will incorporate as a requirement of Part 4 MOC. The AANS/CNS noted that it already offers interactive CME courses and that it would be equally interested in working with WellPoint to assist with the development of an educational component that cuts across various relevant specialties.

Consumer Checkbook vs. HHS

On January 30, 2009, the US Court of Appeals for the D.C. Circuit Court reversed a federal district court's decision on Consumers' Checkbook vs. HHS Freedom of Information Act. The court's refusal to grant Consumers' Checkbook's request for physician billing records represents a momentous victory for physician privacy rights.

In 2007, a federal district court ordered CMS to release, under the Freedom of Information Act (FOIA), individually identifiable physicians' claims data to Consumer's Checkbook, a non-profit group that rates everything from plumbers to health clubs. Consumers' Checkbook planned to use the data to provide consumers with information on Medicare physicians' "quality." The 2007 decision was in conflict with a Florida district court ruling, which prohibited release of Florida Medical Association (FMA) member data due to privacy concerns.

Both the AMA and the American College of Surgeons (ACS) sent letters to HHS Secretary Leavitt urging HHS to appeal the 2007 ruling on the grounds that it posed significant privacy risks to patients and physicians and could undermine current concerted efforts to ensure meaningful, accurate health care performance data is available to patients. HHS subsequently filed an appeal, but continued to emphasize its commitment to transparency by referring to initiatives such as the Hospital Compare Web site, which offers consumers unprecedented access to Medicare data on facilities and the conditions they treat.

In May 2008, the AANS and CNS, along with 16 other medical societies, filed a "friend-of-the-court brief" in the FOIA case brought by Consumers' Checkbook. The medical societies' brief argued that disclosure of the requested information would violate the privacy rights of physicians and would harm patients and the public interest. Among other things, the brief showed that claims data alone cannot be used to assess accurately the quality of physician services or develop reliable physician rankings, which are among the purported goals behind Checkbook's request. Disclosure of the requested data would therefore mislead patients about the quality of their physicians' services and incomes from Medicare and thereby interfere with the physician-patient relationship.

In related news, another case – Alley v. HHS – has recently emerged on the same topic. The AANS and CNS also joined this amicus brief initiative. Given the outcome of the Consumer Checkbook case, we are relatively confident (although you never know) that the 11th Circuit Court of Appeals will not contradict the findings of the D.C. Circuit Court.

Comparative Effectiveness Research

The ARRA 2009 included \$1.1 billion for Comparative Effectiveness Research (CER), which is projected to result in \$6 billion in system-wide savings. This funding includes:

■ \$400 million for NIH

- \$300 million for AHRQ
- \$400 million allocated at discretion HHS for efforts that:
 - Compare clinical outcomes, effectiveness, and appropriateness of care
 - Encourage development and use of <u>clinical registries</u>, clinical data networks and other forms of electronic health data used to generate <u>outcomes data</u>
 - \$1.5 million: IOM development of recommendations on national CER priorities based on public feedback.

Leaders from the Spine Section will be submitting an NIH Challenge Grant proposal to obtain CER funds to support a clinical data registry for spine. The proposal will use the NeuroPoint Alliance as the data collection system.

The AANS/CNS will also submit written comments to the IOM that highlight the lack of high quality evidence and subsequent clinical uncertainty surrounding many neurosurgical procedures and the important role clinical outcomes registries could play in obtaining data needed to guide clinical practice. We will offer specific CER research questions related to common spinal disorders, but we will frame them in a way that does not pit one procedure against another or potentially limit treatment options for individual patients. Instead, the AANS/CNS will highlight the need for prospectively obtained clinical data to identify patient profiles that more accurately predict an outcome following a given procedure.

The legislation also creates a Federal Coordinating Council that:

- Includes 15 federal employee members appointed by president (at least 1/2 must be physicians)
- Will coordinate CER among the various government agencies, limit duplicative efforts, and encourage coordinated use of resources
- Will advise President/Congress on CER priorities and funding needs (report due June 2009)
- <u>Does not</u> have the authority to use the research for payment, coverage, or treatment decisions.

There is still debate about whether CER could be used to restrict coverage and to what extent it will include cost-of-care analyses. An earlier version of the legislation, which the AANS/CNS supported, specifically referred to the policy as comparative "clinical" research and specifically prevented cost-analyses from being included in such studies. Unfortunately, the final version of the legislation does not make those distinctions. The only language that explicitly prohibits the use of this research for coverage determinations is 1) the provision related to and limited to the Council, and 2) report language that accompanied the final bill stating that such research should not be used to mandate coverage and that research should not limit patient access to individualized treatments. While the AANS/CNS supports this report language, it represents Congressional intent, but holds no statutory force. As a result, there is lingering concern that HHS, or CMS specifically, may still have discretion over whether the research should be factored into coverage decisions.

Details regarding CER will be worked out through the rule-making process and during broader health reform discussions over the next few months. Senate Finance Chair Baucus and Budget Chair Conrad also plan to reintroduce legislation that would create a public-private CER entity financed by both the federal government and an assessment on the insurance industry. Throughout the fall and winter, the Alliance of Specialty Medicine met with Baucus' and Conrad's staff to request that they strengthen the bill's language to make it more difficult for researchers to exclude subpopulations from such research; ensure that the leadership include adequate representation by board certified clinicians who are involved in treating the disease or disorder under consideration; and that they reconsider funding the initiative with Medicare Part B funds, given the payment cuts facing physicians.

In the fall of 2008, the AANS and CNS also became a founding member of the Partnership to Improve Patient Care (PIPC), a newly formed multi-stakeholder coalition that advocates for well-designed CER. It is currently underwritten by BIO, AdvaMed and PhRMA, but the governance structure is not weighted towards the industry.

As the stimulus package was debated, the PIPC urged Congress to keep in mind that CER should:

- Enhance information about treatment options; close gap between care known to be effective and care patients receive
- Preserve patient/physician choice and support medical innovations
- Provide information on clinical value and patient health outcomes, not cost-effectiveness
- Ensure studies are valid and appropriate and reflect diversity of patient populations
- Require open and transparent processes; ensure all stakeholders have input into research priorities and design

Quality Improvement Organizations

AMA Physician Consortium for Performance Improvement (PCPI)

The AMA PCPI organizes cross-specialty work groups to develop physician-level performance measures from current evidence-based clinical guidelines. Working with the AMA's CPT panel, the PCPI also develops standardized codes to allow for the reporting of such measures. The PCPI has approved over 200 quality measures to date through on-line voting and three annual in-person meetings. CMS recently renewed for a year its contract with the PCPI, the National Committee for Quality Assurance (NCQA), and Mathematica to develop physician-level measures. Starting in 2009, Jeff Cozzens and Peter Angevine will replace Dan Resnick and Mike Kaiser as the AANS/CNS representatives to the PCPI.

The PCPI is now focusing on the following activities: testing of previously adopted measures; developing new measures of outcomes and appropriateness (including overuse); bundling of certain measures; fostering the use of clinical registries; and increasing the involvement of key stakeholders (e.g., consumers, American Board of Medical Specialties (ABMS)). The PCPI is also exploring the development of measures that assess episodes of care across care settings (rather than individual measures). In a Robert Wood Johnson Foundation-funded project titled, "Characterizing Episodes and Costs of Care," the PCPI is working with the ABMS and the NQF to define episodes of care and related cost measures for three targeted areas, one of which is low back pain [see section on NQF]. Zoher Ghogawala is representing the AANS and CNS on the newly formed Low Back Pain Cost of Care Workgroup. At the workgroup's first meeting in November, Dr. Ghogawala convinced the panel that surgery is not the real problem in dealing with the variable cost of spine care. The group has subsequently decided to develop measures that focus on the cost of treating low back pain among primary care physicians. Over the next few months there will also be a call for nominees to a Stroke Cost of Care Workgroup. AANS/CNS CV Section leaders have nominated Greg Zipfel for this activity.

National Quality Forum (NQF)

The NQF is a federally-defined voluntary consensus standards-setting organization. This multi-stakeholder group's role is to ensure that measures are scientifically sound and meaningful and to standardize performance measures used across the health care sector. NQF endorsement is viewed as the "gold standard" for health care performance measures by other stakeholders, including consumers, employers, and purchasers. Due to its legal status, the federal government is obligated to use NQF standards, where they exist, rather than creating its own. To date, the NQF has endorsed over 200 performance measures.

The NQF currently has a broad membership (over 350 members, including at least 30 medical and specialty societies) representing every sector of the health care system. Membership is organized into

eight councils, including a "Health Professionals Council." The NQF is also a member of the National Priorities Partnership (NPP), a coalition of 28 key healthcare stakeholders including the AMA's PCPI, AFL-CIO, Consumers Union and the CDC.

The NQF meets twice a year and holds monthly member conference calls, quarterly member council calls, and smaller workgroup meetings throughout the year. Gail Rousseau and John Kusske represent neurosurgery on the NQF. The QIW recently appointed Jack Knightly (Spine), Aaron Cohen-Gadol (Tumor, CV), Fernando Diaz (Spine, CV), Gary Bloomgarden (Spine), Jeff Cozzens (Tumor, Functional), Monica Wehby (Peds), and Kevin Cockroft (CV) to also assist with the increasing demands of the NQF.

- NQF Recommends Linking Performance Measurement to Health Reform. In January 2009, the NQF, in consultation with the National Priority Partnership, finalized a position paper titled, Building a Foundation for High Quality, Affordable Health Care: Linking Performance Measurement to Health Reform, which it recently sent to the new Administration and Congress. The paper calls on the federal government to build on the collaborative quality coalition work accomplished to date and to expand public investment in performance measurement and public reporting in order to improve care and lower costs. While the final paper contained many supportable elements regarding QI, the AANS/CNS felt it placed too strong of an emphasis on the role of performance measurement and public reporting, implying that these two elements are the "be all, end all" of quality improvement. As a result, the AANS/CNS decided not to sign on to this document and instead sent Congress its own Blueprint for Quality Improvement, which advises against a one-size-all approach to quality improvement [see section on Physician P4P].
- Characterizing Episodes and Costs of Care. As part of the RWJF-funded project, Characterizing Episodes and Costs of Care, [see PCPI section], the NQF recently developed a document titled, Evaluating Efficiency Across Patient-Focused Episodes of Care, which is available at: http://www.qualityforum.org/projects/ongoing/episodes/voting-materials.asp This framework for evaluating efficiency is structured to aggregate care across sites and providers, as well as over time, in order to promote shared accountability for a patient's care. It incorporates multiple measurement domains, including health outcomes, cost and resource use, and processes of care. At the end of the document, the Committee theoretically applies the framework to two chronic conditions, including acute myocardial infarction and low back pain.

The NQF addressed many of the AANS/CNS concerns regarding this paper. However, significant concerns still remain. While a commendable framework, it is hard to imagine how it can be implemented without first addressing the multitude of current barriers (e.g., the current payment system, which stands in the way of achieving many of the goals outlined in the paper. The framework also relies on a far more robust set of measures for quality and cost than currently exists. Finally, the NQF failed to take action in response to our request to clarify that consensus-based standards should only be relied on when evidence-based standards do not exist. Although this document is simply a "living" blueprint for examining models of shared accountability that will evolve over time, its failure to address critical obstacles regarding implementation is concerning. The AANS/CNS therefore abstained from supporting this document.

Surgical Quality Alliance (SQA)

The SQA acts alongside the AQA to ensure the unique perspective of surgeons is preserved in quality conversations. Gary Bloomgarden and Elana Farace represent neurosurgery on the SQA, with staff support from Rachel Groman. The group is now focusing on registry reporting collaboration among surgical specialties, developing a surgical patient experience survey, and coordinating meetings with federal officials, payers and plans.

Frustrated by current public and private performance measurement programs that rely largely on poor indicators of quality surgical care, the SQA has begun to explore the feasibility of developing a common surgical data registry that would allow for the collection of more meaningful data across surgical specialties. The hope is that the data could be combined and used for internal quality improvement purposes; standardized reporting to the government and private health plans; MOC reporting; coverage/reimbursement decisions; and general specialty-specific and cross-specialty research, including device-tracking (similar to the goals of neurosurgery's NeuroPoint Alliance (NPA), but on a much broader scale). While few details have been worked out, the group agrees that a hub and spoke model would most appropriately fit the varying needs of the different surgical specialties. Under this model, specialties with existing specialty-specific registries, such as the NPA, could maintain their own registries and simply funnel data to the collaborative surgical database as needed. Those surgical specialties who do not yet have a registry would be able to use the collaborative surgical database as their primary data collection tool.

The first real movement on this effort came in the fall of 2008, when the SQA began working with a contractor to issue a RFP to solicit feedback from vendors on possible strategies for collecting meaningful data across surgical specialties. After reviewing various proposals, the SQA decided that Outcomes Science, Inc. was the most appropriate and qualified vendor for this project (this is the same company that the NPA contracted with to build/manage the neurosurgical registry). The consulting services used to vet and select the vendor cost the SQA about \$20,000. Since the SQA is not a dues paying organization, but rather a voluntary coalition, the ACS asked surgical societies to contribute to this cost. The AANS/CNS together contributed \$1,000 in "seed money," which we felt would allow us to track this important, but somewhat overly ambitious initiative from the sidelines while we focused on the more important task of getting our own registry off the ground.

We've now reached the next phase of this project, during which Outcomes Sciences, Inc. will conduct a more in depth design study to further refine the scope of this effort, the functions of the registry, and the needs of each society. To cover the costs of this study, each surgical specialty is now being asked to contribute an additional \$6,000. Societies that contribute to this phase will be considered "charter" members of the joint surgical registry and will have input into some of the more critical (and controversial) details, such as the governance structure, ownership and use of data, and the role of the Boards. To date, 8 surgical societies have contributed funding, some of which have existing registries (American College of Surgeons, American Society of Plastic Surgeons) and some who do not (American Academy of Ophthalmology, American Academy of Otolaryngology). The American Academy of Orthopaedic Surgeons is still wavering, since it's currently trying to revamp an earlier effort to create its own Joint Procedures Registry. The Society of Thoracic Surgeons also has not yet contributed, despite its support for this effort, which is likely due to the specialty's indifference about being a "charter" member given its unparalleled experience with registries.

The Boards are also interested in this effort. The American Board of Medical Specialties (ABMS), under the leadership of Kevin Weiss, supposedly recently signed off on partnering with the surgical specialties to collect cross-specialty data. However, the ABMS' intentions are still unclear. For example, we do not know what level of involvement they envision as this collaborative relationship moves forward. In previous discussions, the ABMS seemed to indicate in that they would demand a 50% stake in the governance of the joint surgical registry. We also do not know what the ABMS intends to do with the collected data. Kevin Weiss continues to heavily advocate the ABMS' "public trust" duty when it comes to physician accountability in the quality movement, which raises red flags about his desire to make data collected through this registry widely available to the public. We also heard that ABMS intends to move forward with collecting and reporting this data with or without collaboration from the surgical specialties.

In assessing this project, the AANS and CNS will consider the following pros and cons:

Pros

- Opportunity to steer this ship and ensure the collaborative registry is in synch with neurosurgery's registry, that data goes only where we want it to go, and that the ABMS doesn't inappropriately use or prematurely release surgical data to the public. Few details have been worked out yet and becoming a "charter" member would allow us to influence some of the more controversial aspects of this project.
- Opportunity to be involved with a project that is starting to gain more attention from public and private stakeholders. The FDA, NIH, and CMS have all expressed interest in this collaborative effort, as have multiple private health plans, such as BCBS, WellPoint, and Aetna (which could mean more money for physicians who participate in the registry). Some of these groups have also expressed interest in funding some of the costs of the registry.
- Neurosurgery's involvement in this effort shouldn't affect our independent effort to collect meaningful data through our own specialty-specific registry other than at some point requiring that we standardize some mutually common surgical data points so that they can be easily aggregated across other relevant surgical specialties.
- The fact that the NPA has contracted with Outcomes Sciences, the same vendor that would manage the joint surgical registry, means that the data flow between neurosurgery's registry and the joint registry should be easier and the long-term costs lower for neurosurgery.
- Opportunity for surgery to take back the medical profession by coming together and showing meaningful dedication to quality improvement and patient care (which is especially critical at a time when there's talk of cutting payments to surgery to benefit primary care).

Cons

- Diverting resources away from our main priority, the NPA.
- The fact that the NPA could probably achieve some of the same goals, but on a smaller scale, by inviting other neurosurgically-relevant specialties to participate in our registry (e.g., other surgical and non-surgical spine care providers, such as orthopods, physiatrists, etc.).
- Concern that this initiative is overly ambitious. Will it ever get off the ground? And even if it
 does, will enough surgeons opt to participate? A registry is only as meaningful as the data
 entered.
- Will this effort disproportionately benefit those specialties that do not yet have a registry?
 Unlike neurosurgery, many of the societies that have already pledged funding don't have their own registry and are looking to the joint surgical registry to fill that role.
- Current lack of financial commitment from some key stakeholders, such as the orthopods and STS. Although this may soon change, it is nevertheless concerning, especially since there is a lot of cross-over between orthopaedic and neurosurgical procedures.

Ambulatory Care Quality Alliance (AQA)

This multi-stakeholder group, led primarily by health plans and primary care physicians, continues to evaluate whether measures are ready for implementation and develop principles on issues related to data aggregation, reporting, and harmonization of measures. The AQA does not develop measures, but instead evaluates measures to see if they are suitable for implementation. Gary Bloomgarden and Elana Farace represent neurosurgery on the AQA, with staff support from Rachel Groman. The AQA meets in-person three times a year and holds numerous conference calls in between.

As the NQF grows in size and responsibility, the AQA has begun to focus on more general issues related to quality and accountability, rather than evaluation of specific measures. These include: improving the leverage of quality measures; identifying attributes of high bar vs. low bar measures; aligning quality improvement activities and measures across disciplines of care; and identifying how board certification/MOC, state licensure, clinical registries, and outcomes data can be used for quality improvement purposes.

GUIDELINES

Administrative Issues

The committee continues to work to develop a plan to best educate neurosurgeons and members of the public about the work of the committee.

Joint Guidelines Committee Web Platform

The JGC's Technology Taskforce (Linskey, Ryken, Cockroft, Groman) has been working with the CNS' IT staff to develop a web platform that can serve as a repository for all documents related to the committee and its work. At the JGC's April 2008 meeting, CNS President David Adelson noted the CNS' willingness to initiate the development of such a website, with the assumption that the AANS would eventually create a similarly formatted website with identical links. The main functions of the JGC website would be to:

- Provide the public, third-party payers, and neurosurgery's subspecialty sections with general information related to the committee, including:
 - Committee rosters, committee staff contact information, explanation of the intent/role of the committee, JGC position statements (e.g., position statement on clinical practice guidelines, position statement on product endorsement, COI policy, etc), a list of documents previously vetted by the JGC (categorized by action taken), and a list of current projects.
- Password protected archive of the work completed by the committee, including access to original draft documents reviewed by the JGC, JGC comments, authors' response to JGC comments, decisions made by JGC/AANS/CNS, and the final version of guideline documents, if available. This site would only be available to active JGC members.
- Password protected working site for ongoing JGC work (e.g., uploading and downloading of documents currently under review and potentially, in the future, collaborative online editing of documents). This site would only be available to active JGC members.
- Serve as a portal through which members interested in joining the committee can access an Evidence-Based Medicine Methodology Training course [see Section on EMB Training].

The JGC leadership and staff are now working with CNS' IT team to estimate the cost of creating and maintaining this website and to develop a proposal to present to the CNS Project Coordination Committee (PCC).

Evidence-Based Medicine Methodology Training Course

The committee has decided to offer an online Evidence-Based Medicine Methodology Training Course for new members interested in joining the committee and current members interested in a refresher. There are about 15 individuals who are currently interested in this training, some of who have already begun to participate on the committee. The course will be offered on the new JGC website in the form of a PowerPoint presentation with audio voiceover, which Bev Walters has offered to create for a nominal fee. The 4 hour lecture will be broken up into 4 or 8 segments so that interested members can complete it at their own pace. Verification of course completion will be accomplished through self-attestation, although the JGC may consider other options in the future (e.g., CME credit).

In the interim, the North American Spine Society (NASS) has offered AANS and CNS members free access to its online EBM methodologies training course. NASS has sent those members interested in joining the JGC registration materials to access the online training.

Tim Ryken will also offer a brief refresher course for new and current members in San Diego on Saturday, May 2, 2009, from 2-3 pm, prior to the in-person JGC meeting.

Page 26 of 51

JGC EBM Position Statement

At its December 2008 meeting, the Washington Committee voted in support of the JGC's draft position statement on the varying quality of guideline and consensus statements and the appropriate use of such statements in regulatory and legislative policymaking. The position statement was subsequently endorsed by both the AANS and CNS leadership and will be posted on the JGC's website.

JGC Conflict of Interest Policy

At its December 2008 meeting, the Washington Committee offered comments on the JGC's draft Conflict of Interest (COI) Policy Statement, which discusses conflicts of interest of guideline writing group members and is based on existing AANS/CNS COI policy. Mark Linskey, with the assistance of the Co-Vice Chairs, incorporated the Washington Committee's suggestions into the document, which now states that all JGC members should complete and submit either the AANS and/or the CNS COI Disclosure Statement and Declaration forms at the time of appointment to the JGC and on an annual basis thereafter. In addition, the policy notes that all neurosurgeons and other multidisciplinary members of a JGC or AANS/CNS Joint Section-sponsored guideline initiative should complete and submit these forms at the time of initiation of such a project and on an annual basis thereafter. These disclosure forms will remain on file with the Washington Committee (i.e., a password protected JGC archive). The policy also now states that any conflicts reported by members must be stated in a guideline document. The Washington Committee approved of this policy pending legal review at its February 2009 meeting.

JGC Policy Regarding Endorsement of Products Mentioned in AANS/CNS Approved or Endorsed Guidelines

Immediately following publication of the Joint Tumor Section's Newly Diagnosed GBM Guidelines in the J Neuro Oncology, Eisai, Inc. requested if it could promote the guideline document and what it perceived to be the AANS' and CNS' endorsement of the Gliadel wafer through a series of letters to the media and treating physicians and advertisements that would appear in AANS Neurosurgeon and at Gliadel's convention booth. The materials stated that the wafer is "Now Recommended in the AANS/CNS GBM Treatment Guidelines." This request provoked the JGC, with the assistance of Mark Linskey and the Co-Vice Chairs, to develop policy on endorsement of products mentioned in AANS/CNS-approved or endorsed evidence-based clinical practice parameter guidelines. The draft policy statement stipulates that while AANS/CNS/JGC-endorsed guidelines may mention industry products, this mention should be considered within the specific strength of the guideline recommendation and within the outlined clinical circumstances, and should not be interpreted to imply that either the AANS or CNS recommends the product or implant. At its February 2009 meeting, the Washington Committee approved this policy and directed Mark Linskey to draft a letter to Gliadel expressing our displeasure in the manner in which they have used the AANS/CNS GBM Guidelines in its advertisement. This letter was recently approved with minor edits and will be sent to Gliadel shortly. [also see section on Newly Diagnosed GBM Guidelines]

Recently Completed Projects

Guidelines for the Surgical Management of Cervical Degenerative Disease

In September 2008, following the recommendations of the JGC, the AANS and CNS leadership voted to endorse the Spine Section's Cervical Degenerative Disease guideline document. Over the past few months, Paul Matz has been working to expeditiously submit the document for publication in *Journal of Neurosurgery: Spine* and the National Guideline Clearinghouse. In December, Dr. Matz was

contacted by the editor of JNS: Spine, John Jane, who noted that the guideline manuscript had undergone peer review. The two discussed how best to handle changes recommended by peer reviewers, given the AANS/CNS's endorsement of the document. Some of the suggestions were minor (e.g., editorial comments/clarifications) and would only require approval by the JGC leadership. Other suggested edits, however, were more substantive and would require a full JGC re-review of the document, as well as AANS and CNS re-approval. This situation posed an unprecedented problem for the JGC. If a peer reviewer's requested changes were not acceptable to the JGC, for example, the committee could find itself at an impasse and need to go to another journal.

In January, Mark Linskey sent Dr. Jane a detailed and convincing letter recommending that *JNS Spine* publish, alongside the guideline document, an accompanying editorial detailing the reviewers' substantive comments in lieu of making changes directly to the document, which would require rereview by the JGC and may or may not lead to a recommendation for re-endorsement by the parent organizations. Dr. Linskey clearly outlined the JGC's robust guideline review process and ultimately convinced the JNS editorial board that the JGC's own internal peer review process superseded the JNS individual peer review process in terms of methodology and recommendation concerns. Dr. Jane acknowledged that JNS peer reviewers should only make recommendations that address clarification and format issues in regards to guidelines articles/chapters already approved by the JGC. For JNS peer review conflicts or disagreements with recommendations based on the evidence provided, this should not lead to a change in recommendation, but rather, should result in an editorial by the JNS reviewer that would be responded to by the guidelines chapter writing group. The JGC greatly appreciates the *JNS: Spine* editorial board granting it this concession and views it as a major milestone for the committee. Since this issue will likely confront the committee again in the future, the JGC will place it on the agenda for its May 2009 meeting.

Newly Diagnosed GBM Guidelines

The Joint Tumor Section's Newly Diagnosed GBM Guidelines were published in the September 2008 issue of the *Journal of Neuro-Oncology* [89(3):255-362, 2008]. The publication includes 5 clinical practice parameter guidelines chapters, an introduction and methodology chapter as well as an invited overview commentary by the section guidelines committee and JGC chair outlining the promise, but also the cautions needed when comparing and interpreting guidelines. This represents the first completed and AANS/CNS-endorsed EBM clinical practice parameter guideline initiative in the history of the Joint Tumor Section. [also see section on JGC Policy Regarding Endorsement of Products Mentioned in AANS/CNS Approved or Endorsed Guidelines]

Ongoing Projects

AAOS Guidelines on the Treatment of Carpal Tunnel Syndrome

In March 2008, the JGC reviewed and responded to this draft guideline document, produced by the American Association of Orthopaedic Surgeons (AAOS). The document was written by a team of authors consisting mostly of orthopaedic and hand surgeons. Since the AAOS originally did not seek AANS/CNS endorsement of the document, neurosurgery requested that the AAOS make clear in the final document that its review does not constitute endorsement. More recently, the AAOS sent the JGC a confidential final draft of the guideline document and indicated that it would be willing to consider our endorsement, but not until the final document is approved by its Board of Directors in September. At its September 2008 meeting, the JGC reviewed the final draft of this document and decided that the AAOS responded sufficiently to its comments. Although no neurosurgeons sat on the original panel of authors, the JGC submitted thorough comments which resulted in either edits to the document or a reasonable explanation by the authors of why edits were not made. The JGC was very impressed with the AAOS's response and views it as a model for how all external review requests should be conducted. In January 2009, the AANS and CNS leadership accepted the JGC's recommendation to endorse this document.

CSNS Brain Death Guidelines

Over the past year, Cathy Mazzola and a team of CSNS volunteers have researched the need for standardized, evidence-based brain death guidelines. Aware of efforts by other specialties to develop similar guidelines, Dr. Mazzola is now working to form a multi-disciplinary group of experts to develop a single evidence-based clinical practice guideline on the Pronouncement of Brain Death in Adult and Pediatric populations. The goal is to minimize differences and discrepancies between local and state regulations, hospital policies and beliefs, which lead to confusion among clinicians.

While the JGC agrees that this is an important issue and encouraged the CSNS to pursue this effort (which would represent the first guideline project to come out of the CSNS), questions remained about the work completed to date by other specialties and whether there is sufficient evidence to develop an evidence-based guideline versus a consensus statement. The JGC volunteered the following individuals from across the neurosurgical subspecialties to assist the Dr. Mazzola's CSNS Brain Death Guideline Team with its initial development of guideline questions that it would like to see addressed and an informal review of the literature: Kulkarni (Peds), Raksin (Trauma), Levy (CV), Holloway (Stereotactic/Functional), Cockroft (CV), Maniker (Peripheral Nerve), Pilitsis (Pain), Farace. The Trauma and Peds volunteers will also reach out to their sections to recruit additional volunteers.

Throughout the late fall and winter, Dr. Mazzola worked to bring together other disciplines, including the American Academy of Pediatrics (AAP), the American College of Radiology (ACR), the American Academy of Neurology (AAN), and the Neurocritical Care Society (NCS).

During conference calls held throughout the winter, it became clear that multiple societies have been working on their own version of a brain death statement, some further along and more strongly linked to the evidence than others. There is mutual agreement that existing brain death standards lack an evidence base and mutual interest in collaborating, but at what level is still up for debate. For example, a team of neurologists is currently working to update its consensus document on Brain Death in Adults. The authors claim they are already well into their work and while they cannot yet share their document with this multi-stakeholder group, they plan to distribute the final draft for feedback. There is also an AAP-led effort to develop a Peds-focused brain death guideline document. This group is not as far along in its work as the neurology-sponsored project and welcomes multi-disciplinary support. Although the AAN and AAP are open to collaboration at varying degrees, they still seem to want to remain the lead authors of their independent projects. Dr. Mazzola continues to work to persuade the group to work together and agree to joint authorship. The JGC will continue to monitor this effort and take action relevant to the final product.

Appropriateness Criteria for Diagnostic Imaging

About three years ago, the American College of Radiology's (ACR) began to develop a comprehensive list of criteria for determining the appropriateness of imaging. The list applies to over 160 different conditions and various sub-indications, covering essentially the entire field of neurosurgery. The ACR hopes to use the criteria as the basis of a system of nationally accepted, scientifically based guidelines to assist radiologists and referring physicians in making appropriate imaging decisions for given patient clinical conditions.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) included a provision authorizing CMS to conduct a demonstration project to collect data regarding physician compliance with appropriateness criteria for advanced diagnostic imaging services. CMS has the discretion to focus the demonstration project "on services that account for a large amount of Medicare expenditures, services that have recently experienced a high rate of growth, or services for which appropriateness criteria exist." Furthermore, the legislation states that the Secretary will select the criteria "in consultation with medical specialty societies and other stakeholders."

Given the likelihood that CMS will look to the ACR Criteria for this demonstration project, the AANS and CNS volunteered neurosurgeons to assist with updating each chapter specific to neurosurgical imaging. It also outlined some general concerns, such as the fact that the criteria were drafted with little or no input from organized neurosurgery; that the criteria do not distinguish between primary care physicians and clinical subject matter specialists; that the criteria could eventually be expanded to other specialties; and that the ACR will most likely push private health plans to use the criteria as a tool for pre-certifying the ordering of imaging tests.

The ACR has acknowledged neurosurgery's concerns and the value of working with other stakeholders to improve the criteria. However, it would not, at this point in time, abandon its modified Delphi process for reaching, which the AANS/CNS feels submerges non-radiologist input, or commit to a specific number/percentage of non-radiologist involvement. Multiple neurosurgeons, appointed by AANS/CNS subspecialty section leaders, are now working to assist the ACR with its updating of each chapter.

Since the ACR currently does not have a formal process through which it solicits endorsement from non-ACR organizations and contributing consultants are listed by name and affiliated professional organization in the final document, the AANS/CNS requested that ACR add a short, generic statement to all chapters clarifying that the listed experts served as consultants and that their participation does not constitute an endorsement or approval of the document by their affiliated parent organization. The ACR agreed to add the following statement to each of the Appropriateness Criteria chapters, which the AANS/CNS Washington Committee subsequently approved in February 2009:

"The American College of Radiology seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document."

Metastatic Brain Tumor Multidisciplinary Evidence-Based Clinical Practice Parameter Guideline Initiative

In April 2007, the AANS, CNS, and Joint Tumor Section awarded a 12-month \$230,000 grant to McMaster EPC to help develop multidisciplinary evidence based clinical practice parameter guidelines on metastatic brain tumors. Throughout the winter, the Joint Tumor Section's multidisciplinary writing group of about 25 contributors, led by Steve Kalkanis, worked with McMaster to review the literature and draft guidelines that focus on eight clinical questions. Each of the final writing group drafts were submitted to Dr. Kalkanis in February 2009. Once all authors involved in the initiative offer feedback on each chapter, the final drafts will be submitted to the JGC for review. The final product is scheduled for publication in the *Journal of Neuro Oncology* in the summer of 2009 and for presentation as part of the October 2009 CNS meeting (both plenary session and IML). This project is currently on time and on budget.

American College of Cardiology Foundation Carotid Artery Revascularization and Endarterectomy (CARE) Registry

In February 2007, AANS and CNS officially partnered with the ACCF to operate this new registry. Neurosurgery appointed the following members to each CARE committee: Nick Hopkins (Steering Committee); Elad Levy (Research and Publications Committee); and Peter Rasmussen (Registry and Clinical Oversight Committee). In March 2008, Greg Thompson replaced Dr. Hopkins as the neurosurgical representative to the committee, and in September 2008, Charlie Prestigiacomo replaced Dr. Thompson. Dr. Prestigiacomo now participates on the committee's conference calls to ensure that the group stays focused on carotid artery revascularization and endarterectomy data collection and does not stray to more political issues such as using the data for coverage determinations.

In July, the Steering Committee hosted a webcast on CEA vs. CAS. The intent was to market the registry, but it quickly became clear that the purpose was to promote CAS. The AANS and CNS were not involved in the development or review of this presentation, although we were allowed to invite an unlimited number of members to participate on the call. An encore presentation of this webcast proved to be similarly biased. Following the call, Steering Committee members, including Dr. Prestigiacomo, were invited to lead a similar type webcast in March, July, or November. The invitation noted that "the webcast can be controversial (of course with committee approval), but its ultimate goal is to advertise the CARE Registry." The CV Section will work with the AANS and CNS leadership to make a decision about whether neurosurgery should take advantage of this opportunity and whether it should continue to affiliate itself with the CARE Registry.

Spine Clinical Guideline Collaborative Project -- Diagnosis and Management of Lumbar Radiculopathy

The AANS and CNS will participate in this NASS-sponsored collaborative spine clinical guidelines project if it gets off the ground. The following individuals have agreed to represent neurosurgery on this project and have completed a NASS Evidence-Based Medicine (EBM) Training Module, a requirement of participating in the project: Paul Matz, Tim Ryken, Dan Resnick, and Michael Kaiser.

Upcoming Projects

Thoraco-Lumbar Trauma Guidelines

At its September 2007, the JGC identified Thoraco-Lumbar Trauma guidelines as a future priority. The Spine Section recently approved of moving ahead with the project, although the status of the Trauma Section is unknown. Tim Ryken and Mike Kaiser will take on moving this forward through the Spine Section in collaboration with the Trauma Section.

Spine Section Metastatic Spinal Tumor Guidelines

The Tumor and Spine Sections approved funding for this proposed project in April 2008. Tim Ryken and Steve Kalkanis will keep the JGC informed of the section's progress.

Lumbar Fusion Guidelines

This document is almost 5 years old and will soon need to be updated. Dan Resnick will keep the JGC informed of the Spine Section's work.

Spinal Cord Injury

This document is even older than the Lumbar Fusion document and the Spine Section plans to update it soon. Langston Holly will keep the JGC informed.

American College of Occupational and Environmental Medicine's (ACOEM) Forearm, Wrist, and Hand Disorders Guidelines

The ACOEM is updating its *Occupational Medicine Practice Guidelines*, 2^{nd} *Edition*, chapter by chapter on a 3-year rolling process. This chapter was supposed to be available for review in August. To date, no action has been taken. Dan Resnick will continue to keep the JGC informed.

Extracranial Carotid and Vertebral Artery Disease Guidelines (with ACC)

ACC held the first meeting of this group in New Orleans in conjunction with the ACC annual meeting March 2007. Robert Rosenwasser is representing the AANS and CNS and is impressed with the effort, thus far. The multidisciplinary writing team recently requested that the AANS and CNS each

provide two volunteers for peer review of the final draft of this updated document. The JGC volunteered Kevin Cockroft and J.D. Mocco to represent the AANS and Sepideh Amin-Hanjani and Elad Levy to represent the CNS. These four members met over conference call to discuss their concerns with the document and then sent the ACC individual comments for consideration.

Clinical Data Standards for Peripheral Arterial Disease (with ACC)

ACC held the first meeting of this group in New Orleans in conjunction with the ACC annual meeting in March 2007. Robert Rosenwasser is representing the AANS and CNS and is impressed with the effort, thus far, although no drafts are yet available for JGC review.

Idiopathic Communicating Hydrocephalus

At an earlier meeting, the JGC came to a consensus that the Peds Section is desperately in need of guidelines and that it should begin by targeting this topic. The JGC will send a letter to the Section requesting a conference call with its leadership to discuss the status of this effort.

Stereotactic/Functional guideline projects

The JGC chair will talk to Ali Rezai regarding the lack of guidelines coming out of this section.

Traumatic Brain Injury

The Brain Trauma Foundation's next update will focus on pre-hospital guidelines. Surgical guidelines are also in the queue, as are an update to the pediatric TBI guidelines, which are about 3 years old.

Penetrating Head Injury

All pieces of this independently written guideline document have been written, but it's unclear how to fold it into the JGC review process since it did not go through the Trauma Section or even the Brain Trauma Foundation. Elana Farace, a member of the JGC and the PHI writing team, will request that the authors bring the document to the JGC for review.

Spinal Cord Injury

An update on this Trauma Section guideline document is long overdue. Patti Raksin will keep the JGC informed.

Pituitary Adenoma Guidelines Project

This slowly progressing project, lead by Dr. Nelson Oyesiku, has been ongoing since 2002. The authors recently completed revisions of 2 of the 6 chapters (non-functional and acromegaly). The JGC has requested that the authors submit the chapters to the JGC in piecemeal fashion upon completion. Ms. Groman will reach out to Dr. Oyesiku to remind him to send the JGC the completed chapters. The JGC will review these documents on its next conference call.

Emergency Medical Services

Regionalization of Neurosurgical Emergency Services

The AANS/CNS Emergency Neurosurgical Task Force, headed by Alex Valadka, MD, also includes: David Adelson, MD; Jim Bean, MD; Gary Bloomgarden, MD; Rich Byrne, MD; Jim Ecklund, MD; Rich Ellenbogen, MD; Bob Harbaugh, MD; John Kusske, MD; Jeff Lobosky, MD; Geoff Manley, MD; John McVicker, MD; Adnan Siddiqui, MD; Shelley Timmons, MD; and Jack Wilberger, MD.

Initial projects for the Task Force include: 1) an update to the AANS/CNS Emergency Care Survey; 2) identify and evaluate current models for regionalization, state and federal reimbursement for trauma and emergency care; 3) potential regulatory challenges; 4) technologic requirements, including electronic medical records and telemedicine; and 5) the development of federal legislation and strategy for introduction and passage next year. The task force has conducted several conference calls and continues an "ideal" emergency neurosurgical model for AANS and CNS leadership and the Washington Committee to approve for further development.

2009 Legislative Agenda

The AANS and CNS continues to work with the American College of Surgeons, American College of Emergency Physicians, Coalition of American Trauma Care, American Academy of Orthopaedic Surgeons, and the Orthopaedic Trauma Association on a emergency surgical legislative agenda that includes EMTALA-related liability protections, regionalization of emergency and trauma care, reimbursement for emergency department services, workforce and training issues, and funding for trauma care systems. The following outlines that agenda:

Regionalization of Emergency Care

- Based on recommendations from the IOM report, such legislation and would authorize multiyear grants to support demonstration programs aimed at designing, implementing, and evaluating a regionalized, accountable emergency care system. (110th Congress – H.R. 3173, Improving Emergency Medical Care and Response Act of 2007)
- Provide funding for the Health Resources and Services Administration (HRSA) Trauma-EMS Systems Program. (P.L. 110–23, Trauma Care Systems Planning and Development Act)

Reimbursement for ED Services

- Provide physicians a tax deduction equal to the amount of the Medicare fee schedule payment to alleviate the current financial burden that physicians are under to provide federally-mandated EMTALA related care; which is often not reimbursed. (H.R. 1678, Mitigating the Impact of Uncompensated Service and Time Act of 2009)
- Provide a 10 percent added bonus payment through Medicare to all physicians who provide EMTALA-related care to Medicare beneficiaries, including on-call specialists whose services are needed to stabilize the patient. (S. 468/H.R. 1188, Improving Access to Emergency Medical Services)
- Provide necessary funding to trauma centers that are at serious risk of closing due to the continual increase of uncompensated and charity care costs that these hospitals are forced to absorb. (S. 733/H.R. 936, National Trauma Center Stabilization)
- Extend the ability of critical access hospitals participating in Medicare to include stipends paid physicians providing on-call services to EDs in their cost reports. (P.L. 106-554, Section 204, Medicare, Medicaid, SCHIP Benefits Improvement and Protection Act (BIPA) of 2000) Expand this ability to all Medicare participating hospitals.

Establish statutory language for a dedicated funding source for payments to providers for uncompensated emergency health care services. This could be based on the same language in the Emergency Health Services Reimbursement Act of 2003 that allows for the reimbursement of ED services provided to undocumented aliens. (See e.g., P.L. 108-73, Medicare Modernization Act, Section 1011)

Liability Protections

- Provide liability protections under the Federal Tort Claims Act for physicians providing EMTALA-related care. (To Be Introduced by B. Gordon/C. Dent -- Health Care Safety Net Enhancement Act of 2009)
- Provide immunity or limited liability for certain medical personnel involved in the evacuation or treatment of patients during a declared state of emergency. (To Be Introduced by G. Gordon – Emergency Volunteer Health Care Professionals Protection Act of 2009)

Workforce/Training (H.R. 914, Physician Workforce and Graduate Medical Education Enhancement Act)

- Provide additional residency training positions in specialties that provide emergency and trauma care to increase the physician workforce.
- Extend medical school loan deferment to full length of residency. (H.R. 914, Physician Workforce
- Expand National Health Service Corps loan repayment/deduction programs to include general surgery and other specialties in shortage.

National Trauma Institute

Support legislation that establishes and funds a National Trauma Institute in the Department of Defense, which would advance the research of trauma related injuries. (*H.R. 3673, National Trauma Institute Act*)

Legislation

Emergency Medical Services for Children (EMSC) Program

The Wakefield Act, H.R. 479 was reintroduced in the 111th Congress in the House by Rep. Jim Matheson (D-UT). A companion bill, S. 408, was introduced by Sen. Daniel Inouye (D-HI). These bills would authorize appropriations of \$25 million for the first year, and a five percent increase for each of the following five years. H.R. 479 was passed by the U.S. House of Representatives on March 30 by a vote of 390-6. The bill now goes over to the Senate where we will now focus our efforts. Unfortunately, the Senate is not expected to act as quickly as the House. The Senate Health, Education, Labor, and Pensions (HELP) Committee appears to be totally consumed with health system reform and no agenda for EMSC has been worked out yet by the staff.

The AANS/CNS signed on to letters of support and thanks to Rep. Matheson and Sen. Inouye.

Access to Emergency Medical Services Legislation, H.R. 1188/S. 468

Introduced by Reps. Bart Gordon (D-TN) and Pete Sessions (R-TX) and Sens. Debbie Stabenow (D-MI) and Arlen Specter (R-PA), H.R. 1188 and S. 468, the Access to Emergency Medical Services Act of 2009, would establish a commission to examine factors, such as emergency department overcrowding, the availability of on-call physicians, and medical liability issues, which frequently obstructs patients from receiving quality emergency care services. The poor likelihood of reimbursement and high liability risk are broadly acknowledged as the key factors contributing to the growing shortage of specialists participating in emergency on-call panels. The bill would also provide

a 10 percent bonus payment for services provided to beneficiaries who present through the emergency department. To date H.R. 882 has garnered 63 co-sponsors and S. 468 has secured 6 co-sponsors.

The AANS/CNS sent letters to Reps. Gordon and Sessions and Sens. Stabenow and Specter in support of this legislation.

Mitigating the Impact of Uncompensated Service and Time Act of 2009

H.R. 1678 was introduced by Rep. Mary Bono-Mack (R-CA) in March. This bill would provide physicians a deduction equal to the amount of the Medicare fee schedule payment to alleviate the current financial burden that physicians are under to provide federally-mandated EMTALA related care; which is often not reimbursed. The AANS/CNS has sent a letter to Rep. Mary Bono-Mack of support and thanks for this legislation. We are also working to have companion legislation introduced in the U.S. Senate.

The AANS/CNS sent a letter to Rep. Bono-Mack in support of this legislation.

National Trauma Center Stabilization Act, H.R. 936/S. 733

H.R 936, introduced by Rep. Edolphus Towns (D-NY), would provide critical funding to trauma centers that are at serious risk of closing due to the continual increase of uncompensated and charity care costs that trauma centers are forced to absorb. A companion bill, S. 733, was recently introduced by Sen. Patty Murray (D-WA).

While the AANS/CNS has sent a letter of support for H.R. 936, we are currently reviewing the language for S. 733 which has changed significantly from the version introduced in the 110th Congress.

National Trauma Institute Research Program Act of 2008, H.R. 6010 – 110th Congress

This bill would have established a funding authorization for the National Trauma Institute Research Program at the National Trauma Institute (NTI) in San Antonio, TX. and was introduced in May 2008 by Rep. Charlie Gonzalez (D-TX). It would have authorized \$25 million in funding through the Department of Defense appropriations for grants to trauma researchers around the country. Originally, this authorization amount was \$100 million, but due to current budgetary realities was dropped to \$25 million. These funds would be used in the following areas:

- 1) Injury prevention and education
- 2) Improved prehospital and inter-hospital triage
- 3) Resuscitation
- 4) Early, effective treatment of compressible and non-compressible bleeding
- 5) Improved burn care
- 6) Head and spinal cord injury
- 7) Tissue engineering and regenerative medicine
- 8) Orthopedics
- 9) Improved intensive care unit treatment and pain management
- 10) Enhanced rehabilitation and recovery
- 11) Trauma Care Systems development
- 12) Outcomes
- 13) TBI / PTSD
- 14) Maxillofacial injury

The AANS/CNS is currently working with various organizations and coalitions to have this bill reintroduced in the 111th Congress.

Trauma-EMS Program

Despite all our efforts, the Trauma-EMS Program was not included in the final Fiscal Year (FY) 2009 legislation that was passed as part the Omnibus bill in early March.

Authorized at \$8 million for FY 2010, the AANS/CNS along with other members of the Trauma Coalition, have decided to pursue \$12 million in funding for FY 2010. Due to the lack of funding for FYs 2006, 2007, 2008, and 2009 the coalition is supporting \$12 million to provide sufficient resources to adequately re-establish the program.

In March, the AANS/CNS signed on to a Trauma Coalition letter of support to all Senate and House L-HHS-E appropriators asking for this re-established funding for the HRSA Trauma-EMS program. The AANS and CNS are also working with the offices of Sens. Pat Roberts (R-KS) and Jack Reed (D-RI) in the Senate and Reps. Michael Burgess (R-TX) and Gene Green (D-TX) to circulate sign-on letters of support for \$12 million in funding.

In addition, we are working with the Office of Management and Budget (OMB) and the Department of Health and Human Services to possibly determine a better regulatory location for the Trauma-EMS Program rather than the Health Resources and Services Administration (HRSA). To date, we have met twice with administration officials to try and further the interests of the program and hopefully promote its successes to a broader audience, thereby attracting more attention and hopefully increased future funding opportunities.

FY 2009 Labor-Health and Human Services-Education (L-HHS-E) Appropriations

Due to former President Bush's promise to veto any appropriations bill that did not adhere to the funding levels put forth in his FY 2009 budget, as expected, Congress abandoned its efforts to pass individual appropriations bills and instead passed a Continuing Resolution (CR) in September 2008. This CR and subsequent versions funded the government (including discretionary health programs such as NIH and the trauma systems program) at FY 2008 levels through March 11, 2009 when the Omnibus legislation was passed and signed by President Obama. Unfortunately, as noted above, the Trauma-EMS Program did not receive any funding in this bill.

In discretionary funds, the Omnibus Appropriations Act provides \$7.23 billion for HRSA. Included in this funding is \$9.8 million for the Traumatic Brain Injury (TBI) program, an increase of \$1.1 million from last year. The Emergency Medical Services for Children (EMSC) program received \$20 million, up from \$19.45 million last year. The Centers for Disease Control & Prevention (CDC) secured \$6.2 billion, a slight decrease from last year and the National Institutes of Health received over \$30.3 billion, a slight increase. Within the CDC funding is over \$145 for Injury Prevention and Control, a \$10 million increase from FY 2008. Included at the CDC is an additional \$6.1 million for TBI.

HEALTH SYSTEM REFORM

Obama Administration Activities

Health Care Reform Summit Meetings

The Obama Administration has been holding an ongoing series of health care reform meetings/summits. On March 25, 2009, AANS President, James Bean, was invited to attend one of these meetings.

Full details of the Administration's effort are available at: http://www.healthreform.gov/

White House Office of Health Reform Established

As promised earlier, the President signed an Executive Order establishing the White House Office of Health Reform which will be chaired by former Clinton Administration CMS Administrator Nancy-Ann DeParle. Nancy-Ann DeParle said she is optimistic health care reform legislation will clear Congress by the August congressional recess and be signed into law by President Obama by the end of 2009.

At a White House meeting on reform, Director DeParle and participants representing providers, insurers, consumers, the medical device industry, drug makers and other stakeholders discussed the rising costs of health care coverage and how it is making it difficult for small businesses to offer meaningful and affordable coverage to workers. They also discussed the workforce shortage in health care, the tax treatment of health care benefits, the need to get schools more involved in improving children's health and how living wills could help lower end-of-life treatment costs. No decisions were made during the meeting and the discussion mostly stayed clear of more controversial topics such as how to pay for reform, whether an individual mandate for coverage is needed, whether Medicare and Medicaid funding should be reduced to help pay for reform and whether a public health care plan should be created to compete with private plans. In summary, Director DeParle acknowledged that "the devil is in the details" when it comes to crafting reform legislation and getting it through Congress.

Legislative Activities

Congress is very busy holding numerous hearings on health care reform, and House and Senate leaders have set the schedule for passage of comprehensive health system reform legislation. As these conversations and meetings continue, the large, overall health system reform legislation that was initially expected in early 2009 is now expected by early summer. The chairmen of the House Committees on Ways & Means, Energy & Commerce, and Education & Labor have announced that they plan to work together to develop one bill, as opposed to three separate efforts. Chairman Waxman expects to have a bill completed by August recess. Sen. Baucus continues to work with Sen. Kennedy to develop a Senate version. He has also announced he expects to have a bill drafted by June, passed by Congress, and on the President's desk before August recess. This is a VERY ambitious schedule and will be a tall order to fill, but Congressional leaders from both sides of the Hill are claiming it is possible.

No proposals have yet to emerge, although it appears that the Senate Finance Committee's proposal will largely be based on Senator Baucus' White Paper, available at: http://finance.senate.gov/healthreform2009/home.html.

In addition, the House Ways and Means Committee is rumored to be basing its proposal on the Commonwealth Fund's plan, available at:

 $\underline{http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2009/Feb/The-Path-to-a-High-Performance-US-Health-System.aspx}$

State Children's Health Insurance Program (SCHIP)

In the first month of the 111th Congress, several bills have been introduced of health system reform, but to date only the State Children's Health Insurance Program (SCHIP) has been passed and signed into law by President Obama. The SCHIP bill provides \$32.8 billion of extra funding over the next four and a half years for the program, an amount estimated to allow coverage of an additional 4.1 million children. The program covered about 7 million in 2008. This funding expansion is provided by a 62 cents per pack cigarette tax increase.

Specialty Care Hearing

Discussions related to health care reform have largely focused on the need to improve primary care and expand services for chronic disease management and preventive care. Largely absent from the debate have been discussions about specialty care. Following a meeting with Senator Sherrod Brown (D-OH), which was attended by AANS and CNS Washington Office staff and AANS President, James Bean, the Senate HELP Committee has agreed to hold a hearing on specialty care. The AANS and CNS, working with the Alliance of Specialty Medicine, has suggested that the hearing touch on the following topics:

- Workforce shortages (now and in the future) of surgeons/specialty physicians
 - primary care is certainly important to the foundation of the health care system, however, we still need a robust specialty care workforce
 - not every disease/disorder is preventable, people will still have accidents and develop conditions that require specialty care treatment, and "it IS brain surgery!"
- Importance for patients to have direct access to and choice of the specialist without gatekeeper or too many hoops;
 - raise concerns about Medical home structure -- that this is/may be managed care in sheep's clothing
- Direct access to specialty care = quality and health care savings (as was demonstrated during the patients' bill of rights debate)
 - getting to specialty care in a timely fashion, without having patients flailing around in a
 primary care physician practice can reduce unnecessary tests and so forth because
 specialists can better assess what is necessary and what is not; also specialists more
 capable of delivering quality care for those diseases and disorders within the specific
 training and purview of the specialist
- Quality improvement programs cannot be a one-size-fits-all
 - surgeons and many specialists are focusing on outcomes and not just process of care measures;
 - improvements to be made in the PQRI program to enhance its relevance to specialty care and to better measure and lead to quality improvements;
 - need to be cautious about moving to pay for performance and rather should continue pay for reporting, which will (if done appropriately) improve quality;
 - need to provide structure for Comparative Effectiveness Research; specialties must be significantly involved in the CER and CER funds should be directed to support the infrastructure of specialty society sponsored clinical data registries for projects related CER, quality improvement, etc.
- HIT timelines for bonus and penalty structure included in the stimulus package need to be adjusted
 - EMR systems for specialty practices are lagging in their development and approval and hence specialty physicians will not be able to participate in the bonus structure and will

be subject to financial penalties through no fault of their own; problems related to eprescribing, particularly the DEA rules for narcotics, which are prescribed by many surgeons/specialists.

- Medicare SGR needs to be addressed and we cannot rob Peter (the specialist) to pay Paul (the primary care physician)
- Specialty physicians are critical to the public health; describe many prevalent medical problems and fact that specialty physicians (not just primary care physicians) take care of these patients (e.g., heart disease, back pain, arthritis, osteoporosis, cancer, obesity, stroke, head injury, emergency care, etc.)
- Potential new health care delivery paradigms demonstration projects/pilot programs to evaluate things like bundling, accountable care organizations, etc – with reality check that such delivery modes will not work for all specialties

MEDICAL LIABILITY REFORM

Doctors for Medical Liability Reform

DMLR's key objectives include:

- To advance medical liability reform as a key issue in the public debate, through press briefings, policy conferences, Congressional hearings and forums, etc.
- To maintain and expand DMLR's presence as a top resource on medical liability reform to key decision makers and opinion leaders, physicians, patients, concerned citizens and the media, through maintenance and expansion of the website, publication of press releases and op-eds, and periodic radio-tours.
- To preserve and continue to build DMLR's grassroots network by identifying, recruiting, educating, motivating and mobilizing physicians, patients, and concerned citizens to support medical liability reform, through ongoing email messages, newsletters, etc.

Keeping DMLR Alive in 2009 and Beyond

The AANS and CNS, along with the American Association of Orthopaedic Surgeons, are the current funding sources of DMLR. Because we had spent so much – time, effort and financial resources – in building DMLR, and its trademark initiative *Protect Patients Now (PPN)* – and because the medical liability reform issue could once again become a front burner issue at the federal level, organized neurosurgery contributed \$50,000 to DMLR for 2009.

DMLR is also pursuing a relationship with the Health Coalition on Liability and Access (HCLA), which is the other national coalition of which the AANS and CNS are members. Katie Orrico serves as the HCLA Vice-Chair and this group is also struggling to determine how to proceed given the overwhelmingly high odds against passage of any federal medical liability reform legislation.

Energy and Commerce Committee Hearing

On March 24, 2009, AANS President, Jim Bean, testified at a House Energy and Commerce Health Subcommittee hearing on health care reform. Representing DMLR, Dr. Bean focused his testimony on the need for medical liability reform in conjunction with any comprehensive health care reform legislation.

Federal Legislation

While we will continue to push for reform in the 111th Congress, given the fact that the Congress and the White House are now controlled by democrats, it is highly unlikely that any progress on medical liability reform will be made. Indeed, the trial lawyers have been emboldened by the strengthening of their power in Washington, DC and medicine will need to be vigilant to ensure that we do not take steps backwards.

Efforts to introduce bi-partisan, comprehensive medical liability reform legislation (patterned after MICRA or the Texas approach) continue, and Rep. Bart Gordon (D-TX) is one democrat that is interested in pursuing this issue (we have not identified a democrat in the Senate, and will not likely do so). In addition, we are pursuing the introduction of targeted liability reform efforts, such as protections for physicians providing EMTALA mandated emergency care.

Legislation for Medical Liability Protection During a Declared National Emergency

The AANS/CNS is also working with the groups mentioned above (and HCLA) to have legislation introduced in the 111th Congress that would provide liability protections for any voluntary medical

services provided by physicians, nurses and pharmacists during a declared national emergency. The "Emergency Volunteer Health Care Professionals Protection Act of 2009" will be introduced by Rep. Bart Gordon (D-TN) within the next month.

Protections for Following Guidelines

President Obama has signaled support for providing physicians protection from lawsuits if they follow practice guidelines. In addition, Senator Baucus is entering (in conjunction with his comparative effectiveness legislation) the notion that if physicians follow established practice guidelines that they should at least have an affirmative defense against a medical liability lawsuit. The AANS and CNS will pursue federal legislation on this topic.

Baucus White Paper

As reported in December, Senator Baucus's health care reform White Paper also includes a section entitled "Medical Malpractice Reform," which states:

Medical malpractice insurance premiums have risen steadily over recent decades, at times increasing an average of 15 percent a year.40 Some states have seen even more dramatic increases. Pennsylvania, for example, experienced increases ranging from 26 to 73 percent in 2003. While the Government Accountability Office has found that access to medical care is not "widely affected" by large premium increases, and malpractice costs account for less than two percent of health costs, physicians and other health care providers contend that the current legal environment leads to the practice of defensive medicine. Ordering more tests, procedures, or visits primarily to avoid liability rather than to benefit patients may contribute to unnecessary health care spending.

A serious effort at comprehensive health care reform, then, should address medical malpractice.

Reducing malpractice premiums alone would not have a substantial effect on overall health spending. CBO estimates that a 25 to 30 percent reduction in malpractice costs "would lower health care costs by only about 0.4 to 0.5 percent, and the likely effect on health insurance premiums would be comparably small." But helping patients and providers to cooperate rather than participate in time-consuming and expensive legal battles may help to shift America's health care system away from the costly practice of defensive medicine and toward the best quality care and adherence to standards of care.

The current litigation system does not do a good job of compensating victims of malpractice or of reducing the occurrence of medical malpractice. In fact, "research typically shows Americans rarely take their disputes to court. Of every one hundred Americans injured in an accident, only ten make a liability claim, and only two file a lawsuit." Yet, the large number of malpractice claims filed still overwhelms the legal system, and only 30 percent of claims filed result in payments to victims of medical malpractice. Alternatives to civil litigation need to be utilized so that administrative costs associated with litigation, which account for 60 percent of malpractice premiums, can be reduced, while simultaneously allowing credible claims to be compensated fairly and quickly.

Malpractice reform could address money and time spent on litigation, as well as improve patient and provider satisfaction with the resolution of complaints or grievances. Additionally, changes made as part of reforming the health care system would affect medical malpractice. For example, damages awarded for care necessary as a result of malpractice would be reduced because the cost of care would decrease across the board. Also, improvements in preventive care and care coordination would reduce the likelihood of risky procedures that are a source of malpractice claims.

The Fair and Reliable Medical Justice Act, introduced in the 109th Congress and again in the current Congress, includes ideas for ensuring safe and effective medical care, while working to limit malpractice insurance premiums.48 This legislation would provide grants to states to create alternatives to current tort litigation in an effort to increase access to recovery for patients with low-

dollar value claims and improve satisfaction with claims resolution for patients and provides. States would have flexibility in developing alternatives to civil litigation, with three specific models outlined in the bill: (1) the early disclosure and compensation model, (2) the administrative determination of compensation model, and (3) the health court model.

The early disclosure model offers health care providers tort liability immunity after an offer, in good faith, to pay compensation to any patient injured or harmed as a result of care. The compensation would have to include any economic loss to the patient, noneconomic damages (as determined by the state) and reasonable attorney fees. The University of Michigan Health System (UMHS) implemented this system in 2002 with astounding results. Three years after the program was established, UMHS had reduced its annual litigation costs by \$2 million and reduced the number of lawsuits, as well as the time it took to resolve the suits, by more than half. That is one of the goals of the early disclosure model. Fostering communication about medical errors and awarding appropriate compensation in a non-adversarial setting are the hallmarks of this approach.

By increasing communication about medical errors, and doing so in a non-adversarial setting, the collection of medical error data will increase, leading to improved patient safety. Data collection is essential to preventing errors by enabling providers to better understand how errors occur. "Accurate information also provides a baseline measurement for further assessment of the effectiveness of the changes made."50 Unfortunately, under the current system, data collection remains limited because of the lack of incentives. Alternatives to litigation, such as early disclosure, provide incentives to disclose medical errors, while continuing to protect the provider and improve patient safety.

The second approach, the administrative determination of compensation model, calls for the establishment of an administrative board to designate classes of avoidable injuries. Based on these classes, the board would determine the level of compensation awarded to the patient. An appeals process would also be established to review decisions made by the board.

Under the third alternative, a specialized health court would be established. The court would be presided over by judges with expertise in health care with the ability to hire outside experts. The judges' decisions regarding compensation would be binding but subject to an appeals process.

The Fair and Reliable Medical Justice Act serves as a foundation for an important element of this health reform plan. Like the legislation, the Baucus plan would call on states to take the opportunity to develop alternatives for resolving conflicts and compensating patients who are the victims of medical errors. In addition to receiving Federal assistance to establish an alternative model, states would also receive assistance to collect data about medical errors, which would help keep patients better informed and create an opportunity for providers to learn from each other. In fact, the systems developed by the Department of Defense and the Veterans Health Administration that successfully track such data could serve as models. Patients and providers should have the chance to cooperate, rather than participate in a time-consuming and expensive legal battle. This plan would help achieve that important objective.

Federal Rules Initiative

As reported in December, the AANS and CNS are working with the AMA and other medical organizations to pursue changes in the Federal Rules of Civil Procedure. The AMA launched this behind-the-scenes initiative as an additional liability reform effort to pursue while the political climate is not favorable for pushing for broader federal legislative reforms. The AMA is hopeful that pursuing targeted changes to the Federal Rules of Civil Procedure and Evidence can create a more balanced litigation environment for physicians.

One project is to attempt to modify Rule 56. Currently a significant amount of time and money is spent during the initial stages of discovery. Amending the current Rule would allow for the disposition of unsupported claims sooner rather than later; i.e., save docs/PLI insurers defense costs. Others are also in the works. We will continue this effort in 2009.

DRUGS AND DEVICES

Physician and Industry Relationships

The topic of industry-physician relationships continues to get a lot of attention – both in the media and by policymakers. The following highlights some recent activity. Although this topic was not legislated last year, we expect that Congress will pass a law requiring drug and device companies to disclose financial relationship that they have with physicians. So far most of the efforts seem to be focused on just this element and do not go beyond to regulate/prohibit industry support of CME, although that is something that we will be closely monitoring. In addition to federal activities, the states are now getting into the business of regulating in this area. Six other states and the District of Columbia have laws or regulations with regard to the conduct of pharmaceutical or medical-device manufacturers.

MedPAC

The Medicare Payment Advisory Commission (MedPAC) included recommendations for regulating physicians-industry relationships in their March 2009 report. Aspects of their recommendations include:

- Manufactures should report payments in total annual value of payments to a recipient exceeds \$100
- Should report: gifts, food, entertainment, travel honoraria, research, funding for education and conferences, consulting fees, investment interests and royalties
- Companies should report
 - Value, type, date of each payment;
 - Name, specialty, Medicare billing number (if applicable);
 - Name of related drug/device
 - Medicare billing
- Federal law should preempt state laws that collect data on same types of payments and recipients
- HHS Secretary should have authority to assess civil penalties on manufacturers

For more information go to: http://www.medpac.gov/documents/Mar09_EntireReport.pdf

ACCME

The Accreditation Council for Continuing Medical Education (ACCME) is also evaluating its policy and standards for regulating industry support of CME. Last year they called for comments on:

- Limiting Interactions between Accredited Providers and Commercial Interests over Commercial Support with Industry
- Elimination of Commercial Support of Continuing Medical Education Activities
- Additional Features of Independence in Accredited Continuing Medical Education

AANS and CNS will need to monitor this activity closely. The ACCME has also proposed significant increases in its budget to, among other things, step-up it is oversight of commercial support of CME.

Sunshine Act Reintroduced

Members of Congress, including Senator Charles Grassley (R-IA), ranking member of the Senate Committee on Finance, continue their investigations conflicts of interest with device companies. On January 22, 2009, Senators Grassley (R-IA) and Herb Kohl (D-WI) reintroduced the Physicians Payment Sunshine Act, S. 301. The bill would require all manufacturers and marketers of drugs, devices, biologicals, or medical supplies to disclose payments to physicians on a website maintained by HHS

beginning on March 31, 2011. The bill is available on the web at: http://www.grasslev.senate.gov/private/upload/12209.pdf.

Grassley Letter Regarding FDA Orthopaedics Panel Members Selection

On March 6, 2009, Senator Grasslev sent letters to acting FDA Commissioner Frank Torti and to Gerald Bisbee Jr., chairman and chief executive officer of ReGen Biologics, Sen. Grassley said that it appeared to him that FDA was going out of its way to accommodate the company and that the company had inappropriate influence in the selection of participants for the November 14, 2008 FDA Orthopaedics Panel meeting convened to consider the ReGen Biologics product "Collagen Scaffold" for knee surgery. In the letter, he asked that the FDA and the company provide copies of "all internal and external communications and other materials, including emails, memoranda, personal notes, and telephone notes, relating either directly or indirectly to ReGen and the FDA, the make-up of the Orthopaedic and Rehabilitation Devices Advisory Committee, and the development of the panel questions." Sen. Grassley's letters are available on his website at:

http://grasslev.senate.gov/news/Article.cfm?customel_dataPageID_1502=19632

Revised AdvaMed Code of Ethics

In response to recent scrutiny by policymakers, the Advanced Medical Technology Association (AdvaMed), has issued a draft revised "Code of Ethics on Interactions with Health Care Professionals" that they plan to make final on July 1, 2009. Activities prohibited by the new code include the provision of any entertainment or recreational activities (e.g., theater, sporting events, golf, etc.) for physicians or their staff, even if business or education is conducted as part of the event. This includes circumstances in which the physician serves as a consultant. Companies can longer provide branded notepads, mugs, pens or other so-called "logo" items. Companies may provide modest meals in connection with scientific, educational or business information programs but only for those who have a bona fide professional interest in the information. Meals for spouses, guests, and those not attending the program are not permitted.

The code permits medical device manufacturers to continue to provide training and education on products, including out-of-town travel when necessary; support research, educational and charitable grants; and engage health care professionals as consultants, if appropriate and subject to restrictions. A copy of the new code is available at http://www.advamed.org/MemberPortal/About/code.

HHS OIG Report on Clinical Investigators' Conflicts

On January 12, 2009, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued a report entitled The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information. The HHS OIG concluded that the Food and Drug Administration (FDA) does not adequately determine whether sponsors applications for drug and device approval have provided complete and accurate financial information for clinical investigators. The OIG recommended that FDA develop a process for improving oversight of their practices in this area. The report is available at: http://oig.hhs.gov/oei/reports/oei-05-07-00730.pdf

HHS OIG Plans to Prosecute Surgeons for Industry Conflicts

On March 4, 2009, the New York Times published an article stating that soon Federal prosecutors plan to file civil and criminal charges against a number of surgeons who the officials say demanded "profitable consulting agreements from device makers in exchange for using their products." The article quotes Lewis Morris, chief counsel to the inspector general of the Department of Health and Human Services as saying, "What we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it." The full text of the article is available at: http://query.nvtimes.com/gst/fullpage.html?res=9507E1DC163BF937A35750C0A96F9C8B63

JAMA Article on Conflict of Interest

In the March 30, 2009 issue of the Journal of the American Medical Association, a group of physicians and researchers lead by David J. Rothman, PhD, a professor at the College of Physicians and Surgeons at Columbia University in New York, called on medical associations to sharply limit the funding they receive from drug and device companies in order to limit industry's influence on how medicine is practiced. The new proposals call for medical specialty societies to refuse general budget support from industry. The recommendations, which aren't binding, would allow the groups to continue to accept industry advertising in medical journals and payments for industry-sponsored booths at doctors' conferences. A Wall Street Journal article on the issue is available at: http://online.wsj.com/article/SB123854648226076095.html

New England Journal Support of Sen. Pallone Bill on Preemption

Controversy surrounding the issue of federal law preemption of state law governing FDA approved devices continues, with device manufacturers favoring preemption and consumer groups such as Public Citizen opposing preemption. On March 19, 2009, the New England Journal of Medicine published an article by Gregory D. Curfman, MD, Stephen Morrissey, PhD, and Jeffrey M. Drazen, MD supporting legislation introduced in the house by Rep. Henry Waxman (D-CA), chair of the House Committee on Energy and Commerce, and Frank Pallone (D-NJ), chair of the Health Subcommittee entitled Medical Device Safety Act of 2009. The bill, along with a companion bill introduced by Senators Edward Kennedy (D-MA) and Patrick Leahy (D-VT), would nullify the Supreme Court's ruling issued in February 2008 in the case of Riegel v. Medtronic, Inc, which barred lawsuits in state courts involving the safety and effectiveness of certain medical devices that are FDA approved. The Court ruled that these devices are subject to Federal law which preempts state law. However, on March 4, 2009, in the case of Wyeth vs. Levine the court ruled that FDA-approved drug labeling does not preempt state tort claims, creating a seemingly disparate situation between devices and drugs in this regard.

A copy of the decision is available at http://www.supremecourtus.gov/opinions/08pdf/06-1249.pdf The legislation introduced by Senator Pallone would add language to the Medical Device Amendments to explicitly prevent federal law from preempting state lawsuits against device companies, and thereby to place medical devices and drugs on a level playing field with respect to patient lawsuits.

Food and Drug Administration Activities

FDA Scientists Claim Improprieties with PMA Process

On January 26, 2009, nine FDA scientists sent a letter to President Obama alleging improprieties in the device approval process at FDA. Specifically, the scientists stated that they had been forced to approve high-risk medical devices without proper vetting of their safety and efficacy. The same nine scientists had complained in May 2009 to FDA Commissioner Andrew C. von Eschenbach, and the agency began an internal review at that time. Dissatisfied with the pace and results of that review, the scientists wrote a letter to Congress in October 2008 asking for an investigation, and the House Committee on Energy and Commerce began considering the allegations. The New York Times article is available at http://www.nytimes.com/2009/01/28/us/28fda.html? r=1&ref=health

Acting FDA Commissioner Issues Confidentiality Memo

On March 13, 2009, acting FDA Commissioner Frank Torti issued a memo reminding FDA staff of the importance of confidentiality in dealing with trade secrets; confidential commercial info; personal privacy data; law enforcement records and privileged intra-agency and inter-agency documents, such as emails, memos and letters between FDA employees. He also reminded the staff that

consequences of a breach of confidentiality could include disciplinary sanctions, criminal liability, and potential lawsuits against the FDA for damages. The memo came in response to recent accusations of improprieties on the part of certain FDA employees. A copy of the memo is available at http://www.windhover.com/pdf/3-13-09 pm 3-52 Torti Agency-Wide Email about Confidential Information.pdf

GAO High-Risk Series Questions FDA Competency

Since 1990, the General Accountability Office (GAO) has published a biennial report on high-risk areas for mismanagement in federal government agencies. The high-risk identification is intended to "help resolve serious weaknesses in areas that involve substantial resources and provide critical services to the public." In its January 2009 report on this issue, GAO implicated FDA as an agency at risk. Regarding FDA oversight of medical products, GAO includes a section entitled "Protecting Public Health through Enhanced Oversight of Medical Products." Specifically, GAO states that "new laws, the complexity of items submitted to FDA for approval, and the globalization of the medical products industry are challenging FDA's ability to guarantee the safety and effectiveness of drugs, biologics, and medical devices. As a result, the American consumer may not be adequately protected from unsafe and ineffective medical products. FDA needs to improve the data it uses to manage the foreign drug inspection program, do more inspections of foreign establishments that manufacture drugs or medical devices, more systemically review the claims made in drug advertising and promotional material, and ensure that drug sponsors accurately report clinical trial results." The report, *High-Risk Series: An Update*, is available on the web at: http://www.gao.gov/cgi-bin/getrpt?GAO-09-271 and Highlights are available at: http://www.gao.gov/highlights/d09271high.pdf

FDA Off Label Guidance Issued

On January 13, 2009, the FDA issued a new off-label guidance notice for companies that wish to distribute published studies to promote their drugs and medical devices for indications that are not FDA approved, or "off-label use." The legal provision which previously allowed distribution of journal articles on off-label use expired in 2006. The Federal Register Notice on the new guidance is available on the web at: http://edocket.access.gpo.gov/2009/E9-452.htm and an FDA Good Guidance Practices Document is available at: http://www.fda.gov/oc/op/goodreprint.htm

Numerous medical devices that are routinely used by neurosurgeons are considered "off-label" despite having been used safely for many years and the confusion between "off-label" and "investigational" among the general public is a concern. The Washington Committee has asked the AANS/CNS Drugs and Devices Committee to write a *Position Statement on Off-label Use of Drugs, Devices, and Biologics* and the Committee is in the process of drafting the document for further review.

FDA Leadership

On March 14, 2009, President Obama officially nominated Margaret Hamburg, MD, as incoming FDA Commissioner and Joshua Sharfstein, MD, as Deputy Commissioner. Dr. Hamburg is a former New York City health commissioner and currently senior scientist at the Nuclear Threat Initiative, a non-profit organization dedicated to reducing the threat to public safety of nuclear, biological, and chemical weapons. Dr. Sharfstein is currently Health Commissioner for the City of Baltimore. Initial press reports have speculated that Ms. Hamburg will focus on food safety--and tobacco regulation should Congress transfer that issue to FDA, as some have recommended—and that Dr. Sharfstein will focus on drug and device regulation. However, subsequently Administration officials have denied that they plan a "split leadership" for the FDA.

Pediatric Drugs and Devices Meeting

On February 26, 2009, the National Institutes of Health National Institute of Child Health and Human Development hosted a meeting entitled *Consortium Meeting on Development of Pediatric Drugs and Devices: Expectations and Specifications.* The meeting was a follow up to the July 2008 interagency meeting at NIH in July 2008, at which NIH, FDA, physician specialty societies, and drug and device industry representatives made presentations regarding barriers and difficulties in the development of pediatric devices. Washington Office Staff attended the meeting. A third meeting is tentatively scheduled for May. More details are from the meeting are available at http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com_ID=282#mtg_ID_908

FDA Workshop on Biomaterials for Neurological Devices

The AANS/CNS Washington Office has been asked by FDA staff to assist with a workshop on Neurotoxicity in Biomaterials for neurological devices to be held on May 19, 2009 in Vancouver, Canada. Richard Fessler, MD, and Stephen Haines, MD, have agreed to speak at the meeting on behalf of AANS and CNS. The meeting is being held in conjunction with a meeting of the American Society for Testing and Materials (ASTM).

Unique Device Identification System Regulation

On February 27, 2009, AANS and CNS joined other specialty societies in signing a letter to the FDA in response to a January 15, 2009 *Federal Register* notice requesting comments on the Unique Device Identification (UDI) System for medical devices that the FDA has been working on for several years. Specifically, the letter, which was coordinated by the Advancing Patient Safety Coalition, suggested that the UDI be considered for all devices, be included on the individual package provided to the patient or facility using the device, coordinated with existing international standards, and be both encrypted and clearly readable to the end user.

Biosimilar Legislation

AANS and CNS joined 9 other specialty societies in sending a letter from the Alliance of Specialty Medicine to Reps. Anna Eshoo (D-CA), Jay Inslee (D-WA), and Joe Barton (R-TX) on behalf of their follow-on biologics/biosimilars bill introduced on Tuesday, March 17, 2009, that would help the development new biologics in a process somewhat analogous to the generic drug approval process. In the letter, also dated March 17, 2009, the groups urged the bill's sponsors to be vigilant in including patient protection safeguards in any legislation that goes forward to allow for a follow-on biologic or biosimilar product approval pathway in order to create great options for patients without undue risk. Specifically, the Alliance letter provided details on the unique nature of biologics and the difficulty of determining if a follow-on product is appropriate. The letter emphasizes "We have stated in the past our belief that legislation should not allow substitution or interchangeability of biosimilars for innovator products, because biosimilars can only be similar to, and are never identical to, an innovator product. They are not like generics, which are exact copies of innovator drugs. Interchanging biosimilar medications with original versions creates a complex risk-benefit assessment that can only be made appropriately by the patient's physician"

BIOMEDICAL RESEARCH

National Institutes of Health

Stimulus Package

On February 17, 2009, the President signed into law the American Recovery and Reinvestment Act of 2009, which provides \$10.4 billion for the National Institutes of Health (NIH) over 2 years, including:

- \$8.2 billion in support of scientific research priorities
- \$1 billion to support Extramural Construction, Repairs, and Alterations
- \$300 million for Shared Instrumentation and other capital equipment
- \$500 million for NIH buildings and facilities
- \$400 million for Comparative Effectiveness Research [also see QIW section on CER]

Economists estimate that the \$10 billion provided to NIH in the amendment could result in the creation of over 70,000 jobs in the health industry over the next two years. Prior to this amendment's passage, the Ad Hoc Group for Medical Research, of which the AANS and CNS are members, sent letters to Congress requesting an increase in biomedical funding.

With this funding, NIH will focus scientific activities in several areas:

- NIH will choose among recently peer reviewed, highly meritorious R01 and similar mechanisms capable of making significant advances in two years.
- NIH will also fund new R01 applications that have a reasonable expectation of making progress in two years.
- NIH will accelerate the tempo of ongoing science through targeted supplements to current grants (e.g., competitively expand the scope of current research awards or supplement an existing award with additional support for infrastructure that will be used in the two-year availability of these funds).
- NIH has also designated at least \$200 million in FYs 2009 2010 for a new initiative called the NIH Challenge Grants in Health and Science Research, to fund about 200 grants. This new program will support research on topics that address specific scientific and health research challenges in biomedical and behavioral research that will benefit from significant 2-year jumpstart funds. "Challenge Areas," defined by the NIH, focus on specific knowledge gaps, scientific opportunities, new technologies, data generation, or research methods that should have a high impact in biomedical or behavioral science and/or public health. The Washington office is working with AANS and CNS members to identify potential challenge grant funding opportunities, including the use of these funds to promote prospective outcomes reporting (i.e., the NeuroPoint Alliance) which will help neurosurgeons refine indications for specific neurosurgical procedures. [also see QIW Section on Establishing a Comprehensive Neurosurgery Clinical Data Reporting System]

Omnibus

In March 2009, the President signed into law a \$410 billion omnibus appropriations bill to fund most of the government from March 7 through September 30, 2009. Since from October 2008, the federal government was operating under a continuing resolution that funded most Cabinet departments and federal agencies at FY08 levels. The measure includes nine unapproved FY09 appropriations bills, including:

- Labor-HHS Appropriations: \$151.8 billion, about \$6 billion more than FY08 funding levels.
 - NIH: \$30.3 billion, a \$938 million or 3.2% increase (includes \$1.5 billion for NINDS)

CDC: \$6.6 billion, a \$239 million increase

- FDA: \$2 billion, or \$335 million above 08 levels

Since Congress and the White House completed a five-year doubling of the NIH budget in 2003, NIH's budget has remained flat and in 2009 was about \$29 billion, which is about 10 percent lower in real funding than what it was in 2003. The omnibus, combined with the stimulus package funding, brings NIH's budget to nearly \$40 billion over a two-year period.

President's Budget

As a member of the Ad Hoc Group for Medical Research, the AANS and CNS applauded President Obama for his vision articulated in the FY 10 budget that "Investments in science and technology foster economic growth, create millions of high-tech, high-wage jobs that allow American workers to lead the global economy, improve the quality of life for all Americans, and strengthen our national security." The budget specifically proposes over \$6 billion within NIH in support of a multi-year plan to double cancer research. These resources will be committed strategically to have the greatest impact on developing innovative diagnostics, treatments and cures for cancer. Through the Ad Hoc Group for Medical Research, the AANS and CNS also sent a letter to Congress requesting a \$7.4 billion increase over the FY09 omnibus funding level, or a 13% increase, for all the programs within the 7 major public health agencies. In a separate letter coordinated by the National Coalition for Heart and Stroke Research, the AANS and CNS requested a 7% increase (or \$32.4 billion) for the NIH over the FY09 appropriation representing a first step toward achieving the President's campaign pledge to double the NIH budget over the next 10 years. This would include 7% increases for the National Heart, Lung, and Blood Institute (NHLBI) (or \$3.2 billion) and the National Institute of Neurological Disorders and Stroke (or \$1.7 billion).

Brain Attack Coalition

In November 2008, Sander Connolly and Rocco Armonda represented the AANS and CNS at a Brain Attack Coalition (BAC) meeting. This multi-stakeholder group discussed efforts to revise its "Primary Stroke Centers" paper and its "Classification of Cerebrovascular Diseases III" paper, as well as stroke messaging.

Stem Cell Research

In March, President Obama signed an executive order to lift restrictions on embryonic stem cell research implemented by his predecessor, a move designed to increase the NIH's funding for stem cell research. The executive order revokes a policy set by the Bush administration that prohibited the use of public funds for research using embryonic stem cells created after Aug. 9, 2001. President Obama's executive order will provide scientists access to a greater number of embryonic stem cell lines—and newer, more stable lines—compared to the 21 lines available under the Bush policy. It is unclear exactly how many more lines would be available under Obama's policy. A RAND Corp. study in 2003 estimated as many as 275 lines could be available for research from discarded embryos. The International Society for Stem Cell Research science editors estimate there are more than 800 human embryonic stem cell lines cited in peer review articles, but it is unclear how many of these lines would be eligible under the NIH guidelines as part of President Obama's executive order.

MISCELLANEOUS

Institute of Medicine Work Hours Study

On December 2, 2008, the Institute of Medicine released its report entitled: "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." The report was funded the Agency for Healthcare Research and Quality (AHRQ), which was asked to investigate physician work hour issues by Rep. John Dingell (D-MI), Joe Barton (R-TX) and others on the House Energy and Commerce Committee. The IOM is expected to deliver its report by year's end.

Organized neurosurgery – including the AANS, CNS, ABNS, Senior Society and Neurosurgery RRC – worked diligently for a year to shape the report.

Key Recommendations Included in the Report

While we dodged a bullet and the IOM did not recommend further reductions on TOTAL work hours, the committee did nevertheless recommend some restrictions that may prove difficult for neurosurgery.

- Maximum shift length is 16 hours with no protected sleep; 30 hours (admitting patients for up to 16 hours, plus 5-hours protected sleep between 10:00 pm and 8:00 am)
- Maximum in-hospital on-call frequency, is every 3rd night, no averaging
- Minimum time off between shifts: 10 hours after day shift; 12 hours after night shift; 14 hours after extended period of 30 hours
- Maximum frequency of in-hospital night shifts is 4 nights, with 48 hours off after 3 or 4 nights of consecutive duty
- Mandatory time off duty is 5 days per month, 1 day per week, no averaging
- ACGME should develop criteria for granting <u>individual programs</u> (not specialties) waivers from the above scheduling parameters, but "such criteria should be formulated *only* to accommodate rare, well-documented circumstance..."
- Centers for Medicare and Medicaid Services (CMS) and JCAHO "should take an active oversight role," although the ACGME should maintain responsibility for implementing and monitoring compliance with the duty hour rules.
- ACGME should require each RRC to define and then require appropriate limits on the caseload (e.g., number of admissions and surgical cases per day) that can be assigned to a resident at a given time
- Teaching hospitals should implement and institutionalize structured handover processes, including scheduling overlap times when teams transition on and off duty.
- ACGME should convene a meeting of stakeholders and potential funders to set priorities for research and evaluation projects.

For more information about the report go to: http://www.iom.edu/CMS/3809/48553/60449.aspx

Follow-up Activities

The ACGME is now in the process of evaluating the IOM report and recommendations from key stakeholders. The AANS, CNS, SNS, ABNS and representatives from the Neurosurgery RRC are all working together to coordinate our response to the ACGME. The ACGME convened a conference on March 4-5 in Dallas, TX entitled "Promoting Good Learning and Safe, Effective Care: A Five-Year Review of the ACGME's Common Duty Hour Standards." Ralph Dacey, Hunt Batjer, Dennis Spencer, Bob Harbaugh and Katie Orrico attended. Organized neurosurgery is also finalizing a comprehensive document outlining our detailed proposal for neurosurgical resident training. This will be presented to the

ACGME and it, along with other organizations' recommendations, will be discussed at a 2-day meeting that the ACGME is sponsoring in June.

FTC Red-Flag Rule

In November 2007, the Federal Trade Commission (FTC) issued a set of regulations, known as the "Red Flags Rule," requiring that certain entities develop and implement written identity theft prevention and detection programs to protect consumers from identity theft. In response to FTC staff indications that the rule will apply to physician practices. The AANS and CNS, along with the AMA and others, are continuing our efforts to persuade the FTC that physicians are not "creditors," and therefore should not be subject to the Red Flags Rule. In the interim, the AMA has prepared a guidance document, along with sample policies, so that physicians can incorporate a simple identity theft prevention and detection program into their existing compliance and HIPAA security and privacy policies.

Go to: http://www.ama-assn.org/ama/no-index/physician-resources/red-flags-rule.shtml to access the new AMA resource, "Protect your patients, protect your practice: What you need to know about the Red Flags Rule," and a sample practice policy.

Joint Surgical Advocacy Conference

The AANS and CNS, along with over 15 surgical societies, co-sponsored the Joint Surgical Advocacy Conference on March 22-24, 2009. Over 400 surgeons from across the country came to Washington, DC for this 3-day conference. The conference began with a neurosurgery-only meeting, the Leibrock Leadership Development Conference, which was attended by nearly 40 neurosurgeons. JSAC featured topics and speakers included:

- Advocacy Training Michael Dunn
- Understanding Congress Judy Schneider from the Congressional Research Service
- Communications and Message Development Patricia Clark
- Keynote Paul Begala, CNN Policy Analyst and Commentator
- Obama Administration Quality Improvement Program Carolyn Clancy, MD, Director, Agency for Healthcare Research and Quality
- Individual Members of Congress, including:
 - Representative Roy Blunt (R-MO)
 - Representative Shelley Berkley (D-NV)
 - Senator Tom Carper (D-DE)
 - Representative John Shadegg (R-AZ)
 - Senator Ben Cardin (D-MD)
 - Representative Diana DeGette (D-CO)
 - Representative Frank Pallone (D-NJ)

NeurosurgeryPAC, along with the PACs from the American College of Surgeons, American Academy of Otolaryngology and American Society of Plastic Surgeons, held a specialty fundraiser event at a rooftop venue with a spectacular view of the U.S. Capitol building and the National Mall.

Most of the attendees spent Tuesday, the 24th on the Hill meeting with their Senators and Representatives. Key topics discussed included: reforming the Medicare physician payment system; exploring innovative Medicare payment options; improving trauma and emergency care; enhancing quality improvement initiatives; investing in healthcare research; improving surgical workforce and maintaining quality resident training; and alleviating the medical liability crisis.

2009 Legislative Agenda

The AANS and CNS have established their 2009 Legislative Agenda (see attached).