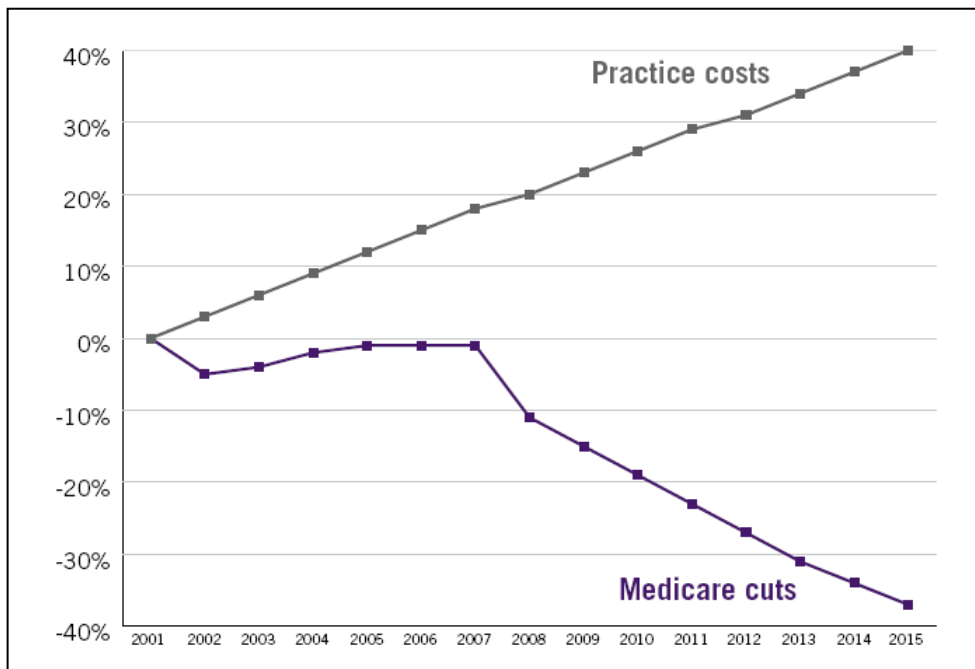


## CODING AND REIMBUSREMENT

**Medicare Physician Payment Update/Sustainable Growth Rate (SGR) Formula.** As a reminder, since 2002, Congress has had to take legislative action each year to avoid automatic, formulaic driven Medicare physician payment cuts under the Sustainable Growth Rate (SGR) formula. Payments will be cut by nearly 40% from 2008 to 2015 unless Congress acts. On January 1, 2008, all physicians face a 9.9% Medicare fee reduction unless Congress intervenes yet again. In addition, the July 12, 2007 Medicare Physician Fee Schedule indicates cuts for Neurosurgeons will total approximately 12% (an additional 1% each for already mandated changes to the practice expense methodology and the five year review of work values).



**In Summary -- 2008 Neurosurgery Payments (under current law):**

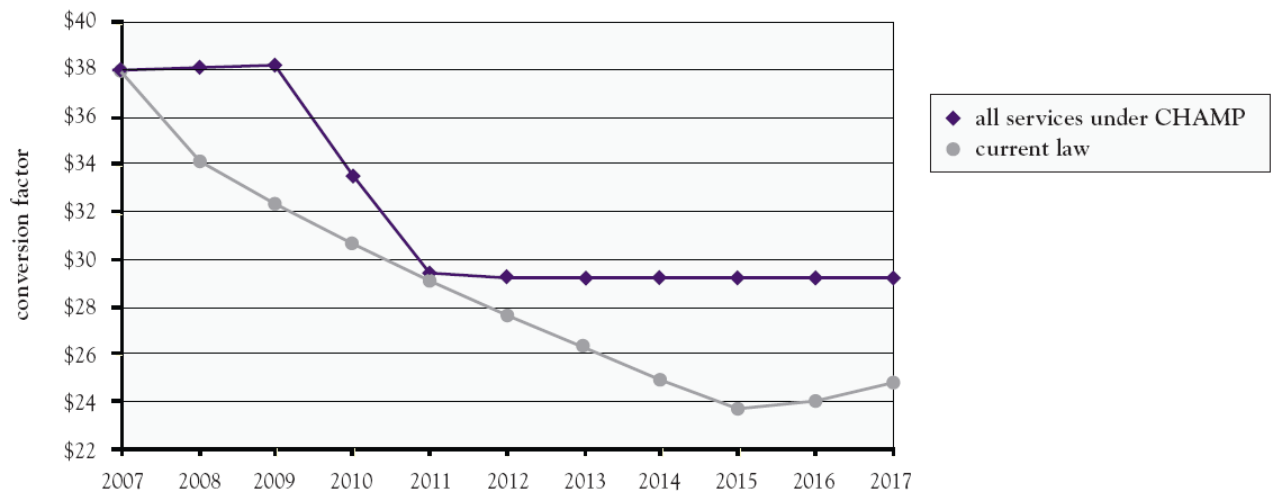
- 5 year review of work RVUs - 1.0%
  - Practice expenses - 1.0%
  - SGR cuts - 9.9%
- TOTAL: -11.9% in 2008**

- **Medicare Payment Advisory Commission (MedPAC) March Report on SGR.** The Deficit Reduction Act passed in February 2006 mandated that the Medicare Payment Advisory Commission (MedPAC) submit a report to Congress in March 2007 exploring alternatives to the SGR for assessing volume growth and updating physician’s Medicare payments which was released on March 1. The report placed an emphasis on efficiency and quality in the Medicare program as well as discussing alternatives to the current payment system. The report also made strong statements regarding the need for Medicare to increase the accuracy of payments, the need for more bundling of payments, and the need to create new payment policies that reward providers for efficiency, quality and coordination of care. Finally, the report laid out two pathways for altering the physician payment program. Because the MedPAC report did not offer Congress any preferred recommendation, and because many of the options they proposed were non-starters for cost or political reasons on Capitol Hill, the report essentially died (for now).

**ACTION TAKEN:** Following review and discussion by a working group of Washington Committee members and staff (Drs. Kusske, Boop, Wehby and Ms. Shoaf), a statement of recommendations was developed that was subsequently ratified by the Washington Committee to be used as guide to evaluating future legislative and regulatory proposals.

- **CBO Report on Physician Spending.** The Congressional Budget Office (CBO) issued a report on June 7, 2007 titled *Factors Underlying the Growth in Medicare's Spending for Physicians' Services*. The study analyzed a set of claims from 1997 to 2005 and found that (after adjusting for inflation and the number of beneficiaries enrolled in Medicare) spending on physician services grew 39.4%. The growth was not attributable to payment rates, but to the volume and intensity of services. After determining that quantity changes, and not payment rates, were responsible for spending growth, CBO identified factors driving the change in volume and found that behavioral changes (increasing volume to compensate for decreasing payment rates) did contribute. However, CBO did state that most of the increase is attributable to the underlying trend of increased volume rather than the "behavioral response" which only accounted for 1.4% of the 39.4% growth. Changing treatment modalities and prevalence of disease account for 38.8% of the growth with unexplained factors accounting for -.7%. The report does not address defensive medicine but we certainly believe some of this is reflected in the changing treatment modalities. However, a recent study in Health Affairs entitled, *Malpractice Liability Costs and the Practice of Medicine In the Medicare Program* did acknowledge the impact of lawsuits, particularly for imaging services, on geographic variation in spending for physician services.
- **Administrative Changes to the SGR.** Organized medicine continued to urge the administration to take actions to reduce the negative impact of the SGR formula on physician payment including applying the \$1.35 billion fund set aside last year in the Tax Reform and Health Care Act (TRHCA) for "payment or quality activities" to be applied against the 9.9% physician payment cut for 2008. Other actions we urged were taking Part B drugs administered in a physician's office out of the SGR formula, recognizing national Medicare coverage decisions in the formula, and that CMS reduce its productivity adjustment for physicians. While the administration did not act on these recommendations, the House passed legislation (CHAMP Act) described below does mandate many of these changes.
- **Congressional Action.**
  - **ACS Separate Conversion Factor Proposal.** We also have continued to work with the ACS and other surgical societies as well as the American Osteopathic Association (AOA) to pursue changes to the SGR structure including creating separate categories of expenditure targets. On June 28, 2007, Representative Pete Sessions (R-TX) introduced H.R. 3038, a bill largely based on the ACS proposal. In addition, the idea of reverting to separate expenditure targets/conversion factors for various Medicare services was also part of the House passed Medicare legislation (CHAMP Act) described below.
  - **House Passes Legislation (CHAMP Act of 2007) Preventing 9.9% Cut and Reforming Physician Payment System.** On August 2, 2007, by a vote of 225 to 204, the U. S. House of Representatives passed H.R. 3162, the Children's Health and Medicare Protection (CHAMP) Act of 2007. The bill would reauthorize and increase funding for the State Children's Health Insurance Program (SCHIP) and contains Medicare provisions, which would mitigate the 2008 and 2009 physician payment cuts and begin to stabilize physician payment rates in the future by repealing the flawed sustainable growth rate (SGR) formula.

## Medicare Physician Payment Update under CHAMP



The CHAMP legislation, which spends over \$20 billion on physician payment-related provisions, replaces the total 15 percent physician payment cut in 2008 and 2009 with a .5 percent increase in both 2007 and 2008. Further, the bill repeals the flawed sustainable growth rate (SGR) formula. In addition, there would be annual spending targets that would be re-set each year, unlike the SGR where the physician “debt” not paid off in any given year accumulates into the future years making the cost of stabilizing physician payments prohibitively expensive from a federal budgeting standpoint. Finally, under the new system, drugs furnished incident to a physician service are removed from the expenditure target in 2010. Including drug expenditures in the annual physician growth target has exacerbated the formula driven payment cuts, and the AANS and CNS have long advocated for this change as Part B drugs are not actually physician services.

Neurosurgery Payments	In 2008 under Current Law	In 2008 under CHAMP Act	In 2009 under Current Law	In 2009 under CHAMP Act
SGR cuts	-9.9%	.5%	-5.0%*	.5%
Practice Expense Cuts	-1.0%	-1.0%	-1.0%*	-1.0%
RVU cuts	-1.0%	-1.0%	-1.0%*	
<b>Total</b>	<b>-11.9%</b>	<b>-1.5%</b>	<b>-7.0%*</b>	<b>-.5%*</b>

As advocated by AANS and CNS, there will no longer be one global target that applies to all physicians. Instead, there will be a system based on six separate service specific expenditure targets, including major surgery (10 and 90 day global services), primary and preventive care, other E&M services, imaging, minor procedures and anesthesia. Major surgery is a relatively low growth area as compared to evaluation and management and other services and thus this system should generally be more beneficial to surgeons than the current SGR system. There are other provisions of the legislation less favorable to neurosurgery, and we are working to mitigate those provisions as we move forward. However, this legislation represents a step in the right direction that has failed to materialize in recent years.

The other provisions of the bill – good and not so good -- include:

- Repeals the Physician Quality Reporting Initiative (PQRI) and applying the \$1.35 billion savings from this repeal to the physician payment update fix
- A two year extension of geographic work index floors to avoid cuts in rural areas.
- Repeals the Medicare Modernization Act's "trigger provision" that implements a process for automatic Medicare provider cuts when general revenue expenditure thresholds are exceeded.
- Creates a new CMS educational program aimed at utilization that provides physicians with information on how their practice patterns relate to their region and the nation.
- Makes changes to the RUC in 2009 that give CMS more tools to analyze recommendations coming out of the RUC, including the creation of an expert panel of clinical/economic experts not directly affected by RUC recommendations to improve the accuracy of RVUs. It also gives the Secretary authority to make recommendations on consolidating coding for procedures performed together, to make recommendations on increased use of bundling, to reduce work RVUs for excess volume growth (defined as over 10% increase from previous year) and to adjust for efficiency gains for new procedures. Some of this already exists under HHS administrative authority.
- Expands the primary care "medical home" demonstration.
- Creates a framework and initial funding for comparative effectiveness studies.
- Gives more authority for developing quality measures to the national quality forum (NQF).
- Includes new imaging accreditation criteria.
- Prohibits self referral to specialty hospitals and includes strict requirements for existing physician-owned specialty hospitals.
- Reduces or eliminates payments for "never events."

In an effort to help secure the necessary 218 votes for passage, a group of specialty societies, including neurosurgery, contributed to a radio advertisement campaign. Each group contributed \$10,000. This multi-specialty effort (which included the anesthesiologists, ophthalmologists, cataract surgeons, American College of Surgeons, thoracic surgeons, dentists, and osteopaths) ran radio ads in about 10 Congressional districts. The script read as follows:

*What if there were programs that provided needed health care to kids, and older Americans?*

*Linking our doctors and dentists to the patients they serve?*

*You'd think convincing Congress to continue them would be a "no-brainer", right?*

*Think again.*

*These programs do exist – and they are on the chopping block.*

*Right now, Congress is considering legislation to renew and improve medical and dental health insurance programs for kids – and prevent funding cuts for doctors who treat Medicare patients.*

*But greedy special interests – Big Tobacco and HMO's – are standing in the way, trying to gut these programs.*

*Tell Congress that meeting the basic health care needs of our children and seniors matters to you – and should be a priority for them.*

*Call Congressman \_\_\_\_\_ at (insert DC office phone number).*

*Tell him/her to vote for the CHAMP Act – to renew the Children's Health Insurance Program and stop Medicare cuts.*

*Now that's a no-brainer.*

*Paid for by Doctors Who Put Patients First.*

**ACTION TAKEN:** In addition to the radio ads, the AANS and CNS sent letters to Congress providing our general endorsement of the CHAMP act. We will continue to work to make improvements to this bill as it goes through the legislative process.

- ***Outlook Unclear due to Senate and Administration.*** During July in the Senate, the Democratic leadership opted to only pass legislation reauthorizing and strengthening the SCHIP program, without including any Medicare provisions. This is partially a result of the fact that penetration of Medicare Advantage plans in rural areas causes concern for powerful Senate Finance committee members who represent rural areas. The SCHIP bill passed in the Senate provides \$35 billion for children's health insurance as opposed to the \$50 billion in the CHAMP bill, and is financed only by a tobacco tax.

In late September, the House and Senate reached a deal to vote on the Senate version of the SCHIP bill and leave Medicare issues on the table to be dealt with later. Senate Finance Committee Chairman, Max Baucus (D-MT), has stated that he is working on a Medicare bill that will address the physician fee cut, but no details are yet available. The president has threatened to veto both the House and Senate SCHIP bills. At this point, it is unlikely there will be a final resolution to this issue before November or December.

### **CPT Coding Issues**

- **Jeffery Cozzens, MD, appointed to CPT Editorial Panel.** On June 28, 2007, Michael Beebe, Director of the AMA Division of CPT, announced that the AMA Board of Trustees had appointed Jeffrey Cozzens, MD, to the CPT Editorial Panel. Samuel Hassenbusch, MD will finish his second term as an AMA CPT Editorial Panel member in October 2007. The competition to fill Dr. Hassenbusch's position on the CPT was fierce and many societies nominated individuals for the seat, including the American College of Surgeons and the North American Spine Society. This was a group victory with many individuals deserving a lot of credit for helping make this happen. Washington office staff was able to get many specialty societies to write letters on behalf of Dr. Cozzens. Individual neurosurgeons contacted members of the AMA Board of Trustees urging support of Dr. Cozzens. In the end, however, the leadership and vocal support of Peter Carmel, MD, a member of the AMA Board of Trustees and, more importantly, the nominating committee, was the key to securing Dr. Cozzens' appointment. Dr. Cozzens' term will commence at the end of the next CPT meeting to be held in Philadelphia October 11 through 13, 2007. Dr. Hassenbusch has agreed to serve as AANS CPT Advisor until another advisor can be found to take Dr. Cozzens' place.
- **June 2007 CPT Panel Meeting.** The CPT Panel met June 7 through June 10, 2007. Attending for AANS and CNS were Jeffery Cozzens, MD, Patrick Jacob, MD, and Washington Office staff. In addition, Joseph Cheng, MD, a new AANS/CNS Coding and Reimbursement Committee Member attended to observe. AANS and CNS did not present code change proposals at the meeting. However, several issues of interest to neurosurgeons are pending before CPT:
  - ***Modifier for Reporting to Quality Improvement Database.*** At the February 2007 CPT Editorial Panel Meeting, Jeffrey Cozzens, MD, presented a CPT Code Change Proposal to create a new modifier for use when a procedure is entered into a Quality Improvement Database. The proposed wording for the modifier is:
    - **-XX Data From Procedure Entered Into Quality Improvement Database -- When data from a procedure, other than E/M service, is entered into a quality improvement database approved by a national specialty society or board, use modifier 1X.**

The proposed modifier is primarily intended to identify when outcomes have been recorded for a particular procedure. The proposal is especially important in light of provisions in the Tax Relief and Health Care Act of 2006, PL 109-432, which includes a program for data reporting beginning in 2008 in which physicians may report to a data registry such as the Society of Thoracic Surgeons outcomes data base. The CPT Editorial Panel postponed action on the proposal and referred the issue to the AMA Performance Measures Advisory Group (PMAG), which considered the issue at its June 27, 2007 meeting in Chicago. Dr. Cozzens attended the meeting and reported that the PMAG did not see the modifier as a “measure” and has referred the issue back to the CPT Panel for possible consideration as a Category III code.

- ***Stereotactic Radiosurgery CPT Assistant Article.*** At the June 2007 CPT meeting, the CPT Assistant Editorial Board met to review several articles, included a Q and A article on coding for CPT Code 61793. On Friday, June 8, Tracy Gordy, MD, CPT Panel Chairman, presented the Executive Committee report. The report included a statement that the CPT Assistant Editorial Board was unable to resolve questions about CPT Code 61793. Specifically, the board supported coding of CPT 61793 only once per course of treatment but referred the matter to the Executive Committee for consideration. The CPT Editorial Panel passed the executive committee report without opportunity for response or clarification. The article in question stemmed from a request from AMA staff to Dr. Cozzens on September 12, 2006, asking that he clarify the use of the term “session” in a January 2006 CPT Assistant article. Dr. Cozzens circulated a draft to the AANS/CNS SRS Task Force leaders for comment and worked with CPT Assistant staff to incorporate revisions. Language allowing the coding of CPT Code 61793 for up to five lesions per session was retained in every draft version reviewed until the CPT Assistant Editorial Board meeting on June 7.

**ACTION TAKEN: On July 3, 2007, AANS and CNS Presidents sent a letter to Dr. Gordy asking that the CPT Assistant Q and A not be published unless the wording was changed back to allow coding of 61793 for multiple lesions in a single session, up to five lesions. In response to the letter to Dr. Gordy, CPT staff has said that the CPT Assistant article will not be published without opportunity for further review by the AANS and CNS and the issue has been referred back to the CPT Panel for consideration at its meeting in October 2007.**

- **New SRS CPT Codes.** Following an analysis of an initial survey to evaluate the practice patterns of neurosurgeons performing SRS, Jeffery Cozzens, MD, developed a draft coding proposal for a set of new codes for SRS. Dr. Cozzens discussed the codes with the AANS/CNS Joint Stereotactic and Functional Section and the Tumor Section. A “test” RUC-style survey is currently being conducted. Following a review of the test survey results, a final decision will be made about whether to submit the CPT Code Change Proposal by November 7, 2007, the deadline for the February 2008 CPT Editorial Panel Meeting.
- **Category I CPT Codes for Cervical Spinal Discs.** Following the FDA approval of the Medtronic Prestige Cervical Disc on July 16, 2007, the Coding and Reimbursement Committee began developing a CPT Code Change Proposal to convert the current Category III Cervical Disc Codes to Category I codes. Patrick Jacob, MD, is writing the codes to be submitted for the November 7, 2007 deadline to be presented at the February 2008 CPT Editorial Panel Meeting.

## **RUC Issues**

- **Multispecialty Practice Expense Survey.** On June 20, 2007, AMA RUC staff contacted AANS/CNS Washington Office staff to say that the representatives of the Gallop organization

conducting the AMA led multispecialty practice expense survey were impressed that the neurosurgeons they contacted to complete the survey were aware of the survey and knowledgeable about the purpose of the project. Washington Office staff published information about the survey in 3 of the regular AANS E-blasts and one e-blast dedicated to just the issue of the survey. In addition, the issue was written up in the *Bulletin* and NERVES sent notices to their members. The multispecialty survey will replace the old AMA SMS Survey and is financed by contributions from participating specialties, including the AANS and CNS. Gallop is currently conducting telephone interviews of and will continue to do so until December 2007. The complete analysis of the survey data is expected to be completed by January 2008.

## **Medicare Coverage Issues**

- **Clinical Trial Coverage Policy.** On April 10, 2007, CMS issued a draft National Coverage Decision (NCD) proposing revisions to the Medicare National Clinical Trial Policy, which it plans to rename the Medicare National Clinical Research Policy. CMS had indicated in earlier versions of the clinical trial NCD that they might provide a special coverage path for Humanitarian Use Devices (HUDs), devices approved under the FDA Humanitarian Device Exemption (HDE) approval process. However, in the April 10, 2007 memorandum, CMS stated that consideration of HUDs would be under the regular NCD process, requiring a level of evidence development which may be difficult for these “orphan” devices. On May 10, 2007, AANS and CNS sent a letter to CMS asking that the agency examine the possibility of creating a special path for coverage of HUDs in clinical trials that takes into consideration the fact that HUDs involve a very small number of patients and, therefore, clinical trials for these devices present some unique considerations. On July 9, 2007, CMS issued a final NCD for the Clinical Research Policy in which it essentially maintained the current policy issued in 2000 and stated that it would immediately issue a new reconsideration of the policy.

As promised, on July 19, 2007, CMS issued a new draft Clinical Research Policy. The reconsideration clarifies policy for Medicare coverage in research studies and proposes a mechanism by which study sponsors or principal investigators can certify that a study has met Medicare standards for coverage. The “self-certification” provision is one that CMS has considered since releasing the original Clinical Trial Policy in 2000 but never implemented. In order to certify a study, CMS would require that the trial be registered at ClinicalTrials.gov and that letter be sent stating the following:

- Name of the research study
- ClinicalTrials.gov registry number (“NCT” followed by eight numbers)
- Study start date
- A point of contact with telephone number for questions if the letter is not complete.
- Discussion as to how the study meets each of the standards in this policy.

CMS has scheduled a “town hall meeting” entitled “The Effect of Coverage and Payment on Clinical Research Study Participation and Retention” at its Baltimore headquarters on September 20, 2007 to further discuss the issue of Medicare Coverage and Clinical Research with interested stakeholders. Washington Office Staff will attend the meeting.

**ACTION TAKEN: On August 18, 2007, following review by the Coding and Reimbursement Committee and selected neurosurgeon clinical research experts, comments were submitted on behalf of AANS and CNS commending CMS for clarifying the standards for Medicare payment for services provided in clinical research. In addition, we urged CMS to reconsider including devices approved under the FDA**

## Humanitarian Device Exemption (HDE) process as part of the current Clinical Research Policy NCD.

- **Lumbar Artificial Disc Replacement (LADR)—First Reconsideration.** On May 25, 2007, CMS issued a draft NCD following the FDA approval of the ProDisc lumbar artificial disc. Basically, CMS proposed to uphold its decision made regarding the DePuy Charite Disc, for which it issued a national non-coverage policy for Medicare patients over the age of 60. On August 14, 2007, CMS issued a final NCD policy on the ProDisc, which is manufactured by Synthes Spine Corporation. As expected, CMS upheld its non-coverage of the artificial lumbar disc in the over age 60 Medicare population. CMS has stated that they will review the policy whenever a new artificial spinal disc is approved by the FDA. The decision is posted on the web at <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=197>
- **Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting--3rd Reconsideration.** On April 30, 2007, CMS issued a National Coverage Decision stating that, with the exception of clarifications regarding the use of embolic protection devices and the facility certification and recertification process, the agency would not implement changes in covered indications for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting that were outlined in the proposed decision memorandum issued in February 2007. The expansion in coverage had been requested by Guidant Endovascular Solutions, which has since become part of Abbott Neurovascular Laboratories.

In the April 30 decision memorandum, CMS also said that they were removing the requirement that a surgical consultation be required to determine if the patient was at high risk for carotid endarterectomy (CEA). CMS stated, “we believe that a surgeon qualified to perform CEA would be the most appropriate physician to determine whether a patient had an anatomical high risk criteria for CEA. CMS has determined with this final decision that requiring a surgeon credentialed to perform CEA to determine whether patients are at high risk for CEA was overly restrictive. We have removed this language from the final decision but would like to stress the importance of ensuring appropriate patient selection. As evident from the public comments discussed in the previous section, this issue has created a serious “turf” war between various physicians who treat carotid artery disease. Regardless of physicians’ personal feelings for their colleagues, treatment decisions still must be made in the best interest of the patient. CMS encourages physicians of different specialties to work together to determine the best course of treatment for patients with carotid artery disease. Only by evaluating all possible treatment options can beneficiaries receive optimal care. We continue to strongly encourage consultation with a surgeon qualified to perform CEA and consideration of establishing a multidisciplinary team including a surgeon qualified to perform CEA to the evaluation of patients prior to performing carotid PTA and stenting as in the SAPPHIRE trial.”

- **CAS Stakeholders Meeting.** CMS Coverage staff hosted a “CAS stakeholders meeting” on Thursday June 21, 2007. The purpose of this meeting was to discuss the CAS national coverage determination (NCD) released on April 30, 2007 and the additional evidence CMS considers necessary in order to expand coverage of CAS. Charles Prestigiacomo, MD, attended on behalf of AANS and CNS along with AANS/CNS Washington Office staff. Cardiology groups and industry support the expansion of coverage to include those patients who are at “high risk” for CAE because of anatomical or general health risks. Neurologists attending supported waiting for the outcome of continuing clinical trials before expanding coverage. At the conclusion of the meeting, CMS staff stated that they were not sure about the next step but were interested in hearing from stakeholders regarding the state of evidence to support expanded coverage for a smaller subset of patients than was included in the recently rejected request by Abbott.

➤ **Industry Proposal for Expanded PTA CAS coverage.** Following the April 30 rejection by CMS of the request from Abbott corporation and others to expand CAS coverage, AANS and CNS have been contacted by Boston Scientific Corporation (BSC) regarding a more limited proposal for expansion of Medicare coverage for CAS in patients who are at high risk for surgery due to anatomical risk factors. BSC is considering requesting that CMS provide coverage outside of clinical trials and post-market studies for symptomatic patients with stenosis 50%-69% and asymptomatic patients with stenosis  $\geq 80\%$  who are at high risk for carotid endarterectomy (CEA) due to the presence of the anatomical risk factors such as prior radiation therapy to the neck, previous ablative neck surgery (e.g., radical neck dissection), or other anatomical issues. BSC and other industry stakeholders raised the issue at the CMS hosted CAS Stakeholders meeting on June 21, 2007. A representative for Abbott Corporation contacted the Washington office on August 31, 2007, to share additional information on evidence for expanding coverage for CAS. Industry representatives would prefer that the request for expanded coverage come from physician specialty societies, as they feel CMS would be more receptive to such a request.

- **Medicare Coverage for Intracranial Stenting and Angioplasty.** On August 14, 2007, Boston Scientific Corporation requested that CMS reopen the national non-coverage decision for intracranial stenting and angioplasty, which was approved by FDA under the Humanitarian Device Exemption policy, but for which CMS issued a national non-coverage decision on November 6, 2006. On August 24, 2007, CMS accepted the Boston Scientific request and formally reopened the non-coverage NCD for intracranial stenting and angioplasty. CMS has opened a 30 day comment period for the proposal, which ends on September 23, 2007. The policy can be viewed at: <https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=214>

**ACTION TAKEN: The AANS and CNS submitted comments once again urging Medicare coverage of this procedure under the “Coverage with Evidence Development” process.**

- **Wisconsin Physician Services (WPS) SRS Local Coverage Decision.** On July 13, 2007, Wisconsin Physician Services, Medicare Carriers for Wisconsin, Minnesota, Illinois, and Michigan, announced a Local Coverage Decision (LCD) for Stereotactic Radiosurgery. Unlike the policy issued by the Medicare carrier Noridian that limited billing of CPT Code 61793 to once per course of treatment, the WPS Policy would permit CPT Code 61793 to be coded for multiple lesions treated in a single session. Specifically the WPS NCD language states, “Code 61793 *Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator), one or more sessions* is valued for a single metastatic lesion. There is significantly more physician work involved for radiosurgical planning and treatment when more than one lesion is treated during a single operative session. This code may then be reported more than once i.e. it may be reported twice if the patient is being treated for two lesions, one on the right side and one on the left etc. Append the subsequent code with the modifier '59', distinct procedural service.” Jeffrey Cozzens, MD, a member of the Carrier Medical Advisory Committee for WPS, had several contacts with WPS during the development of the policy and stressed to the WPS carrier medical director and staff the appropriate coding for CPT Code 61793.

### **Miscellaneous Medicare Physician Payment Issues**

- **Medicare Hospital Inpatient Prospective Payment System (IPPS)** On May 3, 2007, CMS published a Notice of Proposed Rulemaking (NPRM) in the Federal Register detailing policies that CMS was considering for the Medicare Hospital IPPS for 2008, several of which are of interest to neurosurgery. The NPRM included a proposal to implement a severity adjusted Diagnosis-related Group (DRG) system in FY 2008. This change had been proposed for FY 2007 but was withdrawn in response to objections that implementing the severity adjustment would be too

disruptive, as CMS also began shifting from a charge-base to a cost-based DRG system in FY 2007.

FY 2008 proposed DRG changes of interest to neurosurgery included reassignment to higher DRGs for certain implantable neurostimulators, intracranial stents, spinal fusion cases with a principal diagnosis of tuberculosis or osteomyelitis or fusion of nine or more vertebrae, and spinal disc devices. The only request from industry for a new technology add-on payment for FY 2008 was from Boston Scientific Corporation who requested it for the Wingspan intracranial stent system. In the NPRM, CMS states that they are uncertain if they can make a judgment about whether the clinical effectiveness requirement for an add-on payment is met because the device was approved by FDA under a Humanitarian Device Exemption (HDE), leading CMS to possibly consider the device experimental. CMS is asked for public comment on this issue. In addition to the issues above, CMS proposed not to pay for six hospital-acquired conditions: catheter associated urinary tract infections, pressure ulcers, staph infections, objects accidentally left in the body during surgery, air embolisms, and blood incompatibility; not to count medical residents sick and vacation time for Indirect Graduate Medical Education purposes; and not to pay for devices that are provided free to the hospital by manufacturers.

On June 12, 2007, AANS and CNS sent a letter to CMS stating that the CMS analysis for reassignment of several neurosurgical devices to higher paying DRGs seemed reasonable and expressing concern that the CMS proposal not to pay for certain "hospital-acquired" conditions be very carefully considered, as Medicare patients often have many co-morbidities and non-payment for any infections developed in the hospital setting may be inappropriate. On August 1, 2007, CMS issued the Final Rule for the 2008 Medicare Hospital IPPS. Most of its proposals, including its intention not to pay for the hospital-acquired conditions listed above, were maintained in the final rule.

- **Final Rule for 2008 ASC Payment Policy and Proposed Rule for Hospital Outpatient Policy.** On July 16, 2007, CMS published a final rule establishing the policies for the revised payment system for Ambulatory Surgical Centers (ASCs). On the same day, CMS also published a proposed rule combining recommendations for the calendar year (CY) 2008 payment update to the Medicare Hospital Outpatient Prospective Payment System (HOPPS) and to the CY 2008 ASC conversion factor and payment rates. The Medicare Modernization Act (MMA) of 2003 required CMS to revise the ASC payment system by January 1, 2008. In August 2006, CMS issued a proposed rule suggesting that the ASC payment system be based on the HOPPS system. In November 2006, the General Accountability Office (GAO) issued a report entitled, *Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient System*, which supported the CMS recommendation. In the future, the ASC and HOPPS annual Payment Policy rules will be combined. Comments on the HOPPS proposed rule are due on September 14 by 5pm. Washington office staff is in the process of reviewing the proposed rule and drafting comments.
- **National Provider Identifier Data Dissemination.** On May 30, 2007, CMS published a notice in the Federal Register, outlining the process for dissemination of information on National Provider Identifier (NPI) numbers to interested parties who would require their use in business transactions with Medicare. Following the publication of the notice, the AMA and other groups become concerned that CMS had not clearly informed providers at the time they applied for their NPI numbers that some information in their NPI profiles was optional. In addition, providers may not have realized that some of the information they provided would be made available to the public. As a result, CMS delayed the scheduled date several times for making NPI information available. Ultimately, CMS gave providers until August 31, 2007, to review their NPI file and to make any permitted changes, and changed the date for release of data to September 4, 2007.

## QUALITY IMPROVEMENT

### Medicare Physician Quality Reporting Initiative (PQRI)

- **Regulatory Initiatives.** Medicare's new voluntary reporting program, the Physician Quality Reporting Initiative (PQRI), began on July 1, 2007. The PQRI is the first CMS national program to link the reporting of performance data to physician payment.

**ACTION TAKEN:** Leading up to the PQRI's start date, AANS and the CNS educated its members about participating in the PQRI through its various publications, including several e-blasts and a June AANS *Bulletin* article. Links to important information were also posted on the AANS website. In these publications, organized neurosurgery encouraged neurosurgeons to carefully evaluate whether the benefits of participation outweigh the administrative costs and complexity of preparing their practices for the program. Rachel Groman has also responded to a handful of member inquiry's regarding the program.

- ***PQRI in 2008.*** In July's Medicare Fee Schedule notice of proposed rulemaking (NPRM), CMS confirmed that the 2007 PQRI will be renewed in January 2008 for at least a year. In the proposed rule, CMS indicates that it will use the \$1.35 billion set aside under Tax Relief and Health Care Act (TRHCA) for quality improvement bonuses (and not to minimize cuts to the physician fee schedule). Bonuses will be somewhere in the range of 1.5 to 2 percent of allowed charges for participating professionals, but can not be determined until participation rates are known. CMS proposes to select measures from seven broad categories for inclusion in the 2008 PQRI, provided that the measures are either endorsed by the National Quality Forum (NQF) or adopted by the AQA. These categories include existing measures from the AQA Starter Set, other measures from the NQF Ambulatory measure set, and new quality measures currently being developed with input from the AMA's Physician Consortium for Performance Improvement (physician measures), the Pennsylvania Quality Improvement Organization (QIO) (non-physician and structural measures), and the American Podiatric Medical Association. The rule also proposes to retain the 2007 PQRI measures to the extent that they have been NQF endorsed.

The proposed rule also included language outlining CMS's plan to test different models by which providers could submit existing process measures to CMS via registries or electronic databases. As a result of conversations with CMS officials throughout the last six months, AANS and CNS were under the impression that CMS would reward physicians for submitting prospective data to registries that have the capability to compare outcomes on regional and national levels. We were greatly disappointed by the registry language included in the proposed rule, since it does not recognize the value of outcomes data and instead continues to reward the reporting of insignificant process measures.

**ACTION TAKEN:** The AANS and CNS submitted comprehensive comments to CMS urging the agency to use the \$1.35 billion fund to prevent the Medicare payment cut rather than applying it to PQRI bonus payments. In addition, we outlined our concerns about the measure development process and our disappointment with the data registry reporting proposal.

- ***MOC and the PQRI.*** Several ABMS Boards, including internal medicine, ophthalmology, and general surgery, have expressed interested in having Maintenance of Certification reporting programs qualify for PQRI bonus payments. While the general concept is good, these Boards are suggesting that the MOC programs should be reviewed and endorsed by the National

Quality Forum (NQF) to qualify for PQRI bonus payments. The AANS, CNS and ABNS have serious concerns with elements of the proposal.

**ACTION TAKEN:** The AANS and CNS will write a letter to the ABNS requesting that the Board write a letter to the ABMS to: (1) Laud them for approaching the Centers for Medicare and Medicaid Services (CMS) about having physician participation in MOC as meeting the requirements of the Physician Quality Reporting Initiative (PQRI) program; (2) Object to having any aspect of the MOC process go through the National Quality Forum (NQF); (3) Ensure that the ABMS does not adopt a one-size-fits-all MOC/quality reporting system to satisfy the PQRI requirements. Rather each individual Board should develop systems that best meet the needs of the individual specialties (e.g., ABNS to implement outcomes system, rather than one based on process measures) and then the ABMS can “certify” to CMS that the participating Boards meet the PQRI requirements.; and (4) Evaluate/investigate the various legal implications, including potential discoverability of individual data and Medicare fraud and abuse penalties.

#### ▪ Legislative Initiatives

- ***Voluntary Medicare Quality Reporting Act of 2007, S. 1519 and H.R. 2749.*** On May 24, 2007, at the request of the AANS, CNS and other members of the Alliance of Specialty Medicine, the Voluntary Medicare Quality Reporting Act of 2007, S. 1519, was introduced by Senators Ben Cardin (D-MD) and Arlen Specter (R-PA). The bill would make much needed improvements to Medicare’s physician quality reporting program, which was enacted as part of the Tax Relief and Health Care Act of 2006 (TRHCA). To help ensure a more reasonable quality reporting program, S. 1519 includes the following provisions:
  - Requires CMS to conduct a review of the 2007 PQRI program and report its findings on a number of specific issues to Congress before next summer;
  - Delays implementation of any new reporting program until January 2010 and clarifies that quality reporting should be voluntary;
  - Sets forth a detailed process by which quality measures must be developed, which ensures that the AMA Physician Consortium for Performance Improvement (PCPI) is the focal point for all measure development and that CMS will be prohibited from using any measures not developed through this process;
  - Encourages demonstration projects to test and evaluate clinical outcomes data registries.

On June 15, 2007, virtually the same bill, H.R. 2749 was introduced in the House of Representatives by Representatives Bart Gordon (D-TN) and John Shadegg (R-AZ).

- ***Legislation.*** As stated above, the House CHAMP legislation repeals the \$1.35 billion funding for the quality reporting program if enacted. In the Senate, Finance Committee Chairman Baucus favors expanding the quality reporting program. This sets up a situation where a compromise will likely be needed in the conference committee. The AANS and CNS helped develop legislation, the Voluntary Medicare Quality Reporting Act, S. 1519, that could become the basis of such a compromise. This legislation clarifies that the program is voluntary and sets certain parameters to ensure that quality measure development is implemented in a fair and scientifically valid manner.

**Comparative Effectiveness Research.** Lately, there has been increasing interest in Congress about comparative effectiveness research – funding research to investigate which treatments (procedures, drugs and devices) work best. MedPAC, the Agency for Healthcare Research and Quality (AHRQ), and CBO have all endorsed such research, in principle. The proposals center around a comparative effectiveness board that would serve as a national policymaking body setting priorities for research

and endorsing methodologies for conducting such research. The health plans believe the research should ultimately be used for Medicare reimbursement and coverage decisions. However, MedPAC and former CMS Administrator Gail Wilensky have opposed tying this research to Medicare coverage and reimbursement, preferring to make the information available to providers, insurers and consumers and allowing the market to react as it will.

- **Legislation.** Both Blue Cross Blue Shield Association (BCBSA) and America's Health Insurance Plans (AHIP) have released proposals on comparative effectiveness research and on May 7<sup>th</sup>, Representative Tom Allen (D-ME) and Jo Ann Emerson (R-MO) introduced H.R. 2184, "the Enhanced Health Care Value for All Act." This bill would finance new comparative effectiveness research through AHRQ and establish a national Comparative Effectiveness Advisory Board to prioritize research and facilitate the comparative effectiveness agenda. The bill provides \$3 billion over five years, but does not allow the results of research to be used for reimbursement and coverage decisions. The bill also includes clinical advisory panels for each priority area and other provisions for transparency and stakeholder input. Senator Hillary Clinton (D-NY) is working on a bill on this topic, and Ways and Means Health Subcommittee Chair Pete Stark (D-CA) has indicated he may address the issue later this year or next year. At the Ways and Means Health Subcommittee hearing on this topic in June, there was broad bipartisan support for the concept. However, some Members of Congress expressed concern about access to technologies and felt it was critical that the research take different subsets of patient populations and their differing reactions to drugs and procedures into account. On a somewhat related note, on May 24, Senator Sheldon Whitehouse (D-RI) introduced S. 1471 that would encourage the voluntary development of best practices by states and to provide for differential payment rates under Medicare and Medicaid favoring treatment provided consistent with qualifying best practices.
- **Congressional Budget Office (CBO).** While CBO encouraged Congress to move in the direction of comparative effectiveness research in order to generate long term savings for the Medicare program, CBO indicated that they would not score savings for comparative effectiveness provisions. The rationale for that is that those savings were at least a decade away (because the research would need to be conducted and the findings incorporated into practice) from being realized, and thus the savings would be outside of the budget window under which CBO develops their scores for legislation. CBO also strongly encouraged Congress to use comparative effectiveness research for Medicare reimbursement and coverage decisions.
- **Medicare Payment Advisory Commission (MedPAC).** On June 15, MedPAC released a report entitled, *Promoting Greater Efficiency in Medicare*. In Chapter 2 of this report, MedPAC recommended that Congress charge an independent entity to sponsor credible research on the comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers. According to MedPAC, the entity should be independent and have a secure and sufficient source of funding; produce objective information and operate under a transparent process; seek input on agenda items from patients, providers and payers; reexamine comparative effectiveness of interventions over time; disseminate information to providers, patients, and federal and private health plans; and have no role in making or recommending coverage or payment decisions for payers.

**Quality Improvement Workgroup Activities.** QIW members and staff remain busy trying to represent neurosurgery in the multiple forums focusing on quality improvement.

**ACTION TAKEN: The QIW membership recently underwent an evaluation to ensure broad representation and committee members' active involvement in the various quality improvement coalitions/workgroups (e.g., AQA, NQF, PCPI, etc.). New members with specific expertise and/or interest were added to the group and existing members were given new assignments. The QIW recently formed a Registry Reporting Workgroup. The**

**QIW also continues to work to ensure coordination between the QIW and Joint Guidelines Committee. Current members of the QIW and their respective assignments, if any, include:**

Robert Harbaugh, MD	<ul style="list-style-type: none"> <li>▪ QIW Chair</li> <li>▪ Spine Outcomes Pilot</li> <li>▪ SQA Representative</li> </ul>	Michael Kaiser, MD	PCPI Alternate Rep
Daniel Resnick, MD	<ul style="list-style-type: none"> <li>▪ QIW Vice-Chair</li> <li>▪ Spine Outcomes Pilot</li> <li>▪ PCPI Representative</li> </ul>	John Kuskke, MD	<ul style="list-style-type: none"> <li>▪ Health Policy Liaison</li> <li>▪ NQF Alternate Rep</li> </ul>
David Adelson, MD	Guidelines Committee Co-Chair	David McKalip, MD	
Hunt Bajer, MD	ABNS Liaison	Mark McLaughlin, MD	
Gary Bloomgarden, MD	<ul style="list-style-type: none"> <li>▪ SQA Representative</li> <li>▪ AQA Representative</li> </ul>	Robert Rosenwasser, MD	
Aaron Cohen-Gadol, MD		Gail Rosseau, MD	NQF Representative
John Cowan, MD	NSQIP Liaison	Michael Rutigliano, MD	
Larry Chin, MD		Craig Van der Veer, MD	
Jeffrey Cozzens, MD	CPT Liaison	Monica Wehby, MD	
Fernando Diaz, MD		Philip Weinstein, MD	Senior Society Liaison
Elana Farace	Spine Outcome Pilot	Richard Wohns, MD	
Bob Heary, MD			

**Quality Improvement Organizations.** Since June 2007, the following meetings of various quality improvement organizations have taken place:

- **AMA Physician Consortium for Performance Improvement (PCPI).** This physician-led group that develops evidence-based measures held one full meeting on June 1, 2007. Dan Resnick (with the support of Katie Orrico and Rachel Groman) continues to represent neurosurgery on the PCPI and Michael Kaiser was recently assigned as an alternate representative. This physician-led group has approved 184 evidence-based quality measures to date through on-line voting and three in-person meetings annually. A description of these measures is available online (<http://www.ama-assn.org/ama/pub/category/4837.html>).

- **Reviewing the PCPI charge.** The PCPI is currently trying to determine the best way to manage the large number of requests for measure development/review. These numerous requests are a result of the quality bonuses offered for successfully reporting measures under the Medicare Physician Quality Reporting Initiative (PQRI). At its June meeting, the PCPI presented a draft document titled, “Guidance for Requesting Consortium Review and Approval of Measures Developed Independently by Consortium Voting Members,” which proposes a way to deal with increased demands.

**ACTION TAKEN: The AANS and CNS submitted comments on the PCPI’s draft proposal to allow for review of independently developed measures. AANS/CNS made a few suggestions, but generally supported the proposal since it did not seem to weaken the PCPI’s strongest feature-- the ability to guarantee multi-stakeholder input. The PCPI is now incorporating collected comments into a final document.**

- **Spinal Stenosis Workgroup.** The newly formed Spinal Stenosis workgroup, co-lead by neurosurgery (Dan Resnick and Michael Kaiser) met throughout the summer to develop quality measures on lumbar spinal stenosis based on the North American Spine Society’s LSS guidelines.

**ACTION TAKEN: The PCPI Spinal Stenosis workgroup has developed 6 measures intended for quality improvement purposes, and one measure intended for accountability purposes. The measures are on the NCQA website for public comment until September 25, 2007 at: <http://web.ncqa.org/Default.aspx?tabid=542>.**

- **National Quality Forum (NQF).** In August, the NQF accepted neurosurgery's application for membership. Since we used the 501(c)(6) account, we are paying a lower dues of \$5,250 (rather than \$15,000 per year, which would have been required if we used the 501(c)(3) budget). Gail Rousseau will be the primary representative to the NQF and John Kusske will be the alternate.
  - **Assessing Value Across Episodes.** Dr. Joseph Alexander was recently asked to participate on an NQF project titled, "Establishing Priorities, Goals and a Measurement Framework for Assessing Value Across Episodes of Care." Dr. Alexander will be part of a Low Back Pain Workgroup, which will assess the current state of efficiency in low back pain care, including availability of measures and data, and will establish national performance goals (measurable targets for low back pain) over the next three to five years. Another workgroup will be looking at Acute Myocardial Infarction (AMI). A meeting of this workgroup was held on August 29.
- **Surgical Quality Alliance (SQA).** This group, which acts alongside the AQA to ensure the unique perspective of surgeons is preserved in quality conversations, met in person in late May prior to the AQA meeting. The group's focus is now on registry reporting collaboration among surgical specialties, ensuring a due process and a defined voting structure at the AQA, and coordinating meetings with federal officials, payers and plans. Bob Harbaugh and Gary Bloomgarden (with staff support from Rachel Groman) continue to represent neurosurgery within the SQA.
  - **NQF Nomination.** In June, the AANS and CNS supported the SQA's nomination of Bill Rich, MD to Chair of the Health Professional Council of the National Quality Forum (NQF), which is the newly formed council representing physicians. Dr. Rich is currently the Medical Director for Health Policy for the American Academy of Ophthalmology (AAO).
  - **SQA Data Registry Workgroup.** Bob Harbaugh, Elana Farace, and John Cowan, staffed by Rachel Groman, participate on this workgroup, which continues to evaluate which outcomes reporting models are most effective and which can be easily adapted across the surgical spectrum. AANS and CNS continue to pursue their own data registry activities in addition to participating on this workgroup. The group held multiple calls over the summer and an in-person meeting in August, at which the group evaluated the feasibility of a collaborative surgical outcomes registry. Ms. Groman presented information on possible funding models and opportunities.
- **Ambulatory Care Quality Alliance (AQA).** This multi-stakeholder group, lead by health plans and primary care physicians, continues to approve measures that are ready for implementation and to develop principles on issues related to data aggregation, reporting, and harmonization of measures. Gary Bloomgarden represents the AANS and CNS at the AQA and is staffed by Rachel Groman. The AQA is still working to finalize its governance and voting structure, which is non-existent and a significant source of concern for neurosurgery and others. The AQA is also trying to manage an overload of measure review requests as a result of the 2007 and 2008 Physician Quality Reporting Initiative. The AQA has decided to prioritize review of measures specifically indicated by CMS for the 2008 PQRI.

**Neurosurgery Quality Projects.** Members of the QIW are involved in the following activities:

- **AANS Lumbar Spine Surgery Outcomes Pilot:** In an effort to determine the feasibility of creating an outcomes data registry system for a cross-section of neurosurgical procedures, the QIW is currently conducting a pilot outcomes study focusing on lumbar spinal stenosis.

**ACTION TAKEN:** The lumbar spinal stenosis pilot project will continue throughout the remainder of 2007, at which time currently budgeted funds will end. The AANS and CNS will then evaluate whether or not this approach is viable for future expansion.

- **Establishing a Comprehensive Neurosurgery Clinical Data Reporting System.** Building on the lumbar spine surgery outcomes pilot, the AANS, CNS and ABNS are in the early stages of putting together a plan to create a single system that will accomplish reporting requirements for residents, MOC and pay-for-performance/quality programs.

**ACTION TAKEN:** (1) The American Board of Neurological Surgery (ABNS) recently gave the QIW permission to use the ABNS procedure specific modules developed for MOC for the QIW's proposed pay-for-performance registry. (2) AANS and CNS leaders, Bob Harbaugh and Hunt Batjer, will meet to discuss and develop a strategic plan for pursuing the development of a single entity for reporting clinical/outcomes data to be used by candidates for certification, maintenance of certification, pay for performance, comparative effectiveness, etc. Among the questions to be addressed include: whether to use the NeuroKnowledge LLC to serve as this entity, the audit process, finances, governance, relationship between the NeuroKnowledge LLS and the ABNS LLC, physician participation, etc. (3) QIW members and staff will meet with third party payors (CMS, United HealthCare, BCBS, others) to discuss the value of outcomes registries and to seek possible funding/support.

## GUIDELINES

**Joint Guidelines Committee April Meeting.** The JGC has been busy working on various projects this summer.

- **Metastatic Brain Tumor Multidisciplinary Evidence-Based Clinical Practice Parameter Guideline Initiative.** In April, the JGC selected a proposal submitted by McMaster EPC in response to the AANS/CNS RFP for services related to the development of multidisciplinary evidence based clinical practice parameter guidelines on metastatic brain tumors. The Joint Tumor Section, which has already developed and trained the project's multidisciplinary writing group of about 25 contributors, voted to endorse this project and to contribute up to \$50,000. The AANS also voted to contribute up to \$50,000, while the CNS voted to spend up to \$150,000. The final contract is currently being negotiated between the parties and is expected to be finalized by the end of August. The JGC and staff are prepared for the 12-month project to begin as soon as the contract is signed. On August 29, 2007, a call was held to make introductions and bring Joint Tumor Section and McMaster staff up to speed on the contract and next steps.
- **Newly-Diagnosed GBM Initiative.** This initiative was started in 2002. The committee was asked by the Joint Tumor Section to review and make a recommendation on this five chapter draft document. Following a comprehensive review, the JGC sent a letter to the Tumor Section in May 2006, summarizing the JGC's concerns. In general, the JGC offered positive feedback. In August, the Tumor Section responded to the JGC's comments. The JGC is now re-evaluating the revised document, but anticipates a favorable decision.
- **Society of Interventional Radiology reports: "Reporting Terminology for Angioplasty and Stent-Assisted Angioplasty for Intracranial Cerebral Atherosclerosis, Radiographic Features for Use in Clinical Reporting" and "Reporting Standards for Endovascular Repair of Saccular Intracranial Cerebral Aneurysms."** Earlier in the year, Drs. Bederson, Lavine, and Rasmussen were selected to participate on a review committee for these two SIR reports. These CV Section representatives, along with Dr. Phil Meyer, referred these documents to the JGC for review. In August, the JGC held a conference call to review the two documents and is currently drafting a letter to the CV Section outlining its comments.
- **Spine Clinical Guideline Collaborative Project -- Diagnosis and Management of Lumbar Radiculopathy.** At its December 2006 meeting, the Washington Committee voted in favor of the AANS and CNS participating in the first NASS-sponsored collaborative spine clinical guidelines project, which will focus on Diagnosis and Management of Lumbar Radiculopathy. The estimated direct cost per society is \$3,150.00, plus travel and staff time. Other groups that may participate include: NASS, AAOS, American Society of Spine Radiology, American Academy of Pain Medicine, American College of Rheumatology, American Academy of Physical Medicine & Rehabilitation, and the American Pain Society. AANS and CNS have requested that NASS modify the Terms and Agreement in a way that limits our financial obligation. NASS is currently working to resolve this and other requests for changes to the agreement. The following individuals have agreed to represent neurosurgery on this project: Paul Matz, Tim Ryken, Dan Resnick, Michael Kaiser, and Robert Heary. Each has been asked to complete the NASS Evidence-Based Medicine (EBM) Training Module prior to the start of the project. The group will soon meet to identify clinical questions and discuss work group formations.
- **Brain Trauma Foundation's Third Edition of the *Guidelines for the Management of Severe Traumatic Brain Injury*.** In December 2006, the JGC submitted comments on the Brain Trauma Foundation's Third Edition of the *Guidelines for the Management of Severe Traumatic Brain Injury*. The authors responded promptly by making revisions based on the JGC's concerns. After

considering the authors' responses, the AANS/CNS decided to endorse the guidelines. When the Third Edition of the *Guidelines for the Management of Severe Traumatic Brain Injury* guidelines are published, the JGC will post an abstract of the final guidelines and a summary of the guideline review process on the JGC webpage.

- **Carotid stent registry** (with ACCF): In February 2007, AANS and CNS officially partnered with the American College of Cardiology Foundation to operate the new carotid stent and carotid endarterectomy data registry. Neurosurgery has appointed the following members to each committee: Nick Hopkins (Steering Committee); Elad Levy (Research and Publications Committee); and Peter Rasmussen (Registry and Clinical Oversight Committee). In March, the group participated in a stakeholder's meeting with the FDA.
- **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. Robert Rosenwasser is representing the AANS and CNS and is impressed with the effort, thus far.
- **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 March. Robert Rosenwasser is representing the AANS and CNS and is impressed with the effort, thus far

## **EMERGENCY MEDICAL SERVICES**

**American College of Surgeons/Acute Care Surgeon.** At its February meeting, the ACS Board of Regents adopted the following statement:

### ***Statement on Emergency Surgical Care***

*The American College of Surgeons believes that it is the responsibility of all surgeons, regardless of their practice, to participate in their local system of emergency surgical care in order to provide for the health of the public. Emergency surgical care should be provided by surgeons who have completed an accredited residency, are board certified or are in the certification process, and possess the appropriate knowledge, experience, and skills for the delivery of emergency surgical care. This care should be patient-centered, humane, responsive, and readily accessible to all.*

*We recognize that general surgeons with the proper training, knowledge, experience, and skills can provide optimal treatment for many surgical emergencies. Other available medical and surgical specialists should be consulted to enhance care when appropriate. Credentialing criteria for emergency surgical practice should be developed at the local level based on the surgeon's qualifications, experience, and the community need. The treating surgeons should be responsible for providing coordination and continuity of surgical care.*

*We believe that this level of coordinated, skilled, optimal care can be delivered only if healthcare organizations commit the necessary resources and support, and appropriate reimbursement is provided by insurers and other responsible agencies.*

Following the objections of the AANS and CNS, and several other surgical societies, in July, the College put forth a revised statement and solicited input and comments.

**ACTION TAKEN:** The AANS and CNS sent the ACS a letter with our suggested corrections (see below). The Board of Regents will consider this matter at its October meeting.

### ***Draft NEW***

### ***Statement on Emergency Surgical Care***

*The American College of Surgeons believes ~~that it is the responsibility of surgeons to~~ should work in concert with their hospitals and communities to provide appropriate and timely emergency surgical care. This care should be patient-centered, humane, responsive, and readily accessible to all. The treating surgeon should be responsible to provide coordination and continuity of surgical care.*

*We recognize that surgeons with the proper training, knowledge, experience, and skills are best qualified to deliver optimal treatment for surgical emergencies. Emergency surgical care should be provided by surgeons who have completed an accredited residency, are board certified or are in the certification process, and possess the appropriate knowledge, experience, and skills for the delivery of emergency surgical care. ~~Other available medical and surgical specialists should be consulted to enhance care when appropriate. Credentialing criteria for emergency surgical care should be developed at the local level based on national standards or those of state medical boards in conjunction with the individual surgeon's qualifications and experience.~~*

*We believe that ~~this level of~~ coordinated, skilled, and optimal care can only be delivered: only (1) with the cooperation of hospitals, which must commit the necessary resources and support in a regionalized system of emergency care; (2) if ~~, and with~~ insurers and other responsible agencies, ~~which must~~ provide appropriate reimbursement for emergency care; and(3) where there are demonstrated improvements in the medical liability system.*

## Legislation

- **Regionalization Demonstration Programs.** In July, Senator Barack Obama (D-IL) introduced S. 1873, the "Improving Emergency Medical Care and Response Act of 2007". A similar bill of the same name, H.R. 3173, was introduced in the House by Henry Waxman (D-CA). The legislation would authorize the creation of a 5 year demonstration program at \$12 million each year to test regionalization of EMS. The bill primarily addresses pre-hospital coordination, but also requires establishment of a mechanism in each demonstration project to ensure that patients are directed to the right in-patient facility initially, and transferred if needed, in a timely fashion. Special medical care facilities must be categorized or designated consistent with State laws and regulations and integrated with protocols for transport and destination throughout the region. While this demonstration project does not specifically address solutions to the problem of on-call coverage by specialty physicians, such as providing incentives to hospitals to organize regionally for emergency care conditions, it is certainly a step in the right direction.

**ACTION TAKEN: The AANS and CNS, along with the American College of Surgeons and other in the Trauma Coalition, send letters to Senator Obama and Rep. Waxman endorsing this legislation.**

- **Trauma System Legislation.** In April, the Congress passed, and the president signed into law, the "Trauma Care Systems Planning and Development Act". This program was not funded last year. The purpose of the legislation is to provide matching grants to states and localities for the purposes of developing and implementing trauma systems. The AANS and CNS continue to work with the American College of Surgeons and the Coalition for American Trauma Care (Alex Valadka was recently appointed to their Board of Directors) to seek funding for this legislation in FY 08. We are asking for \$12 million to be allocated. The Congress has not yet finalized the appropriations for FY 2008, but at this time no funds have been provided for this program.
- **Stark Legislation.** Representative Pete Stark (D-CA) is considering drafting legislation to address the problems with on-call physician availability. Rep. Stark, who is chairman of the House Ways and Means Health Subcommittee, believes it is the moral obligation for physicians to take emergency call.

**ACTION TAKEN: Alex Valadka and Katie Orrico participated in a half-day meeting with Chairman Stark's staff and members of the Coalition for American Trauma Care in June to discuss various legislative approaches, including regionalization, to address the on-call shortage problems. No legislation has been introduced.**

- **Emergency Medical Services for Children (EMSC) program.** The House Appropriations Subcommittee on Labor, Health and Human Services once again rejected the President's request to eliminate the Emergency Medical Services for Children (EMSC) program and restored its funding at a level of \$19.8 million. The Congress has not yet finalized the appropriations for FY 2008, but funding for this program looks promising. In addition, legislation to reauthorize the bill, H.R. 2464 and S. 60, the Wakefield Act, has been introduced, but no action has yet to be taken.

**ACTION TAKEN: The AANS and CNS are working with the American Academy of Pediatrics and others to seek passage of the Wakefield act and full funding for the program.**

- **Traumatic Brain Injury.** There are a number of bills focusing on increased funding for traumatic brain injury, particularly through Department of Defense appropriations. One effort, spearheaded by Rep. John Murtha (D-PA) and Senator Kay Bailey Hutchinson (R-TX), and supported by the

AANS and CNS, would provide funding for a National Trauma Institute, which would be a collaborative research grant program between the Department of Defense and private sector. In March, the AANS and CNS sent Rep.

**EMTALA.** John Kusske continues to serve on the EMTALA Technical Advisory Group (TAG), which is making some progress in further clarifying the rules required for on-call physicians. Dr. Kusske, the chairman of the TAG's On-call Subcommittee, has done an excellent job in preventing the hospitals from implementing more onerous EMTALA burdens (e.g., the hospitals attempted to make on-call coverage mandatory as a condition of Medicare participation for physicians). The first set of TAG recommendations, relating to specialty hospitals, were included in the FY 2007 Hospital Inpatient Prospective Payment regulations. The TAG is scheduled to sunset this fall.

**ACTION TAKEN:** Katie Orrico met with Rep. John Shadegg (R-AZ), the original author of the legislation creating the TAG and he has agreed to introduce a bill extending the TAG's charter by an additional 6 months to give it more time to complete its activities and write its final report.

## **MEDICAL LIABILITY REFORM**

**Doctors for Medical Liability Reform.** In 2007, DMLR's key objectives include:

- To advance medical liability reform as a key issue in the public debate, through press briefings, policy conferences, candidate information materials, 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.

DMLR continues to send regular emails to its grassroots network, as well as monthly newsletters, which can be accessed at: [www.protectpatientsnow.org](http://www.protectpatientsnow.org).

- **Presidential Candidate Forum.** DMLR is currently planning, along with several other organizations, a presidential candidate health care forum, for late 2007. Medical liability reform will be one aspect of health care reform discussed at the forum.
- **DMLR Membership.** Unfortunately, given the fact that medical liability reform has faded from the spotlight, several of the original members of DMLR are no longer paying dues to support the organization. The remaining dues paying organizations include: American Association of Neurological Surgeons, Congress of Neurological Surgeons, American Association of Orthopaedic Surgeons, American College of Surgeons and the American College of Cardiology. Other groups that are still involved to a limited extent, although they are paying no dues, include the American Society of Plastic Surgeons, American College of Emergency Physicians and The Society of Thoracic Surgeons. At the end of the year, DMLR will reassess the viability of the organization.

**Report on Medical Liability Achievements.** Although federal legislation has not passed, and many states still do not have effective medical liability reforms in place, there is some evidence to suggest that the public relations and grassroots lobbying/education activities are having a positive effect. Premiums are generally stable for the moment (with the notable exception of New York, which just saw double-digit increases), medical liability insurance carriers are reporting very favorable loss ratios (i.e., they are paying out less than they are receiving in premiums) for the first time in years, and anecdotal reports suggest that juries have become much more informed and reluctant to award the "jackpot" verdicts of the past. Nevertheless, interest among physicians in keeping this reform movement alive is waning, perhaps in part because most doctors are not necessarily aware of these successful outcomes.

**ACTION TAKEN:** The AANS and CNS has requested that the Health Coalition on Liability and Access (HCLA) prepare a report outlining the various medical liability reform successes. HCLA, whose Vice-Chair is Katie Orrico, has agreed, and will complete this report later this fall. Upon completion, the report will be widely disseminated to the media, HCLA members and others to encourage the continuation of efforts to seek reform.

### **Federal Legislation**

- **Medical Care Access Protection Act.** On January 10, 2007, Senator John Ensign (R-NV) introduced a medical liability reform bill, S. 243, the Medical Care Access Protection Act (MCAP). This legislation is modeled after the Texas reform legislation and includes the following provisions: (1) a \$250,000 cap on non-economic damages against physicians; (2) a 3-year statute of

limitations for filing a lawsuit; (3) limits on attorneys' fees to 40% of the first \$50,000, 33.3% of the next \$50,000, 25% of the next \$500,000 and 15% of any amount exceeding \$600,000; (4) standards for expert witnesses; (5) elimination of joint and several liability; and (6) fine for attorneys who file frivolous lawsuits. The bill currently has 15 co-sponsors. On the same day, Senator Judd Gregg (R-NH) S. 244, the Healthy Mothers and Healthy Babies Access to Care Act, applies the same reform provisions as S. 243 for obstetrics and gynecology services only. This legislation has 12 co-sponsors. The AANS and CNS have endorsed both bills.

- **Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2007.** On June 6, 2007, Rep. Phil Gingrey, MD (R-GA) introduced H.R. 2580, the HEALTH Act. The bill is identical to the HEALTH Act that has passed the House of Representatives over the past several years, and is patterned after California's MICRA, including a \$250,000 cap on noneconomic damages. The legislation currently has 70 co-sponsors. The AANS and CNS, along with numerous other organizations, endorsed this legislation.
- **Comprehensive HealthCARE Act of 2007.** Introduced on June 7, 2007 by Rep. Tom Price, MD (R-GA), this "kitchen sink" healthcare legislation also incorporates the provisions of the HEALTH Act. The bill has no cosponsors and was endorsed by the AANS and CNS.
- **Congressman Bart Gordon Initiative.** Rep. Bart Gordon (D-TN) continues to encourage democrats, including leadership, to address the medical liability issue and support reform legislation. To that end, he is working with the AANS and CNS and other interested organizations to draft bi-partisan legislation. He would like to see a dual/multiple track approach to legislation: one bill (the "caps" bill), modeled after Texas or even California (but that only applies to providers, and does not project drug companies and HMOs) and perhaps several other "incremental" bills that would look at aspects of successful state initiatives (e.g., pretrial screening, catastrophic compensation fund, ways to prevent frivolous lawsuits, etc.) or other things we think would be worthwhile to pursue give the current political realities of passing a comprehensive bill in this Congress. The AANS and CNS will continue to work with the Health Coalition on Liability and Access (HCLA) and Rep. Gordon's office to develop this legislation.
- **Health Courts.** With the U.S. House of Representatives and Senate now in control of the Democrats, comprehensive tort reform that includes caps on non-economic damages at the federal level is dead. The issue itself, however, is not completely off the table and there is still some interest (both democrats and republicans) for looking at alternative legislation that would authorize demonstration projects on different systems. One idea that continues to be put forward is the creation of specialized health courts. Common Good has been an aggressive proponent of this system.
  - **AMA Health Court Principles.** In recognition of this movement, the AMA Board of Trustees recently adopted "Health Court Principles". A key difference between the AMA principles and the Common Good approach is that the AMA continues to call for negligence as the standard by which "malpractice" is measured and the Common Good applies essentially a no-fault approach. The AANS and CNS have endorsed the AMA Health Court principles.
  - **Fair and Reliable Medical Justice Act.** On May 24, 2007, S. 1481 and H.R. 2497, the Fair and Reliable Medical Justice Act was introduced in the Senate by Senators Max Baucus (D-MT) and Mike Enzi (R-WY) and in the House by Jim Cooper (D-TN) and Mac Thornberry (R-TX). The legislation would support state demonstration projects to test and evaluate alternative medical liability systems, including health courts. The Senate bill has 2 cosponsors and the House bill has 3 cosponsors. The AANS and CNS have endorsed these bills.

## **DRUGS AND DEVICES**

**Orthopaedic Panel Meeting.** On July 17, 2007, the FDA Orthopaedic Devices Panel met to discuss and make recommendations regarding the Bryan Total Cervical Disc manufactured by Medtronic Sofamor Danek, Inc. Paul McCormick, MD, and Stephen Haines, MD were voting members of the panel (Dr. McCormick is a permanent voting member of the Orthopaedic Panel and Dr. Haines was sworn in as a voting member for the meeting). In addition, Stephen Papadopoulos, MD, and Richard Fessler, MD were at the meeting as Medtronic physician consultants. Richard Toselli, MD, was at the meeting for DePuy.

The panel voted 7 to 1 in favor of recommending approval of the Medtronic Sofamor Danek Bryan Cervical Disc with seven conditions including limits on claims of superiority, requirements for surgeon training and patient education, further nephrotoxicity studies, and post approval studies to be carried out for ten years. The negative vote was from Sanjiv Haidu, MD, Ph.D, an orthopaedic surgeon specializing in materials science and engineering. He was concerned that polyurethane material used in the device would not withstand the likely number of years the typical patient would have left to live.

**FDA Approved Medtronic Prestige Cervical Disc.** On July 16, 2007, the FDA approved the Medtronic Prestige Cervical Disc. The device had been presented to the FDA Panel on Orthopaedic Devices on September 19, 2006. At that meeting, Charles Branch, MD, gave a statement on behalf of AANS and CNS requesting that the FDA give serious and favorable consideration to cervical disc arthroplasty technology.

**Reclassification of Intervertebral Body Fusion Devices.** On June 12, 2007, the FDA published a final rule on the Reclassification of Intervertebral Body Fusion Devices and issued a Guidance Document on the subject. In the final rule, FDA announced its plan to reclassify devices that contain bone grafting material from Class III (PMA) to Class II (Special Controls) and retain those that contain therapeutic biologic such as bone morphogenetic protein in class III. The AANS and CNS had sent a letter regarding the proposed rule published on February 9, 2007, stating that the devices should be down-classed but BMP should stay in Class III. In other words, AANS and CNS recommended separating the material in the cage from the cage itself for purposes of classification. In the June 12, 2007 *Federal Register* notice on the final rule, FDA responded to AANS and CNS comments by saying the following:

“Two comments suggested that FDA classify all intervertebral body fusion devices into class II regardless of the grafting material the devices contain and regardless of whether grafting materials composed of therapeutic biologics remain class III. FDA disagrees with this comment. The intervertebral body fusion device and the grafting material it contains do not act independently in the body, thus the mitigation measures described in the special controls guidance are insufficient to provide reasonable assurance of safety and effectiveness for an intervertebral body fusion device when it contains a therapeutic biologic grafting material.”

**FDA Reauthorization Legislation.** On June 21, 2007, the House Energy and Commerce Committee approved FDA reform legislation. The committee voted to combine nine FDA bills, including legislation to reauthorize the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA). Included in the bill is a provision which would limit the number of waivers for conflicts of interest to one per panel meeting. In full committee and in subcommittee consideration of the bills, Rep. Michael Burgess (R-TX) proposed an amendment to remove the cap on waivers of conflicts of interest. The committee voted to report the bill without amendments to the conflicts of interest provisions but with the promise from committee leadership that a compromise on the issue would be worked out. The House passed its bill on July 11, 2007. The Senate approved its version of a drugs and devices bill, S. 1082, on May 9, 2007. The Senate

language on conflicts of interest does not limit the number of waivers allowed. Washington Office worked with the Alliance of Specialty Medicine Subcommittee on Drugs and Devices to fight limits on conflicts of interest waivers.

**ACTION TAKEN: On July 23, 2007, the AANS and CNS signed on to a letter from the Alliance of Specialty Medicine to the leaders of the House/Senate Conference Committee on FDA reform legislation. The letter urges the conferees to adopt the less restrictive Senate language on the conflict of interest issue.**

In mid-September, the House and Senate passed a final version of H.R. 3580, the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee and Modernization Act (MDUFA) and the Pediatric Medical Device Safety and Improvement Act, clearing the measure for the president's signature. The bill includes strict conflict of interest disclosure requirements for those individuals serving on FDA advisory panels. Unfortunately, the final bill also includes restrictions on the number of waivers that the FDA grants for those individuals who have conflicts.

In early August, the House also passed the Agricultural Appropriations Bill (HR 3161) which included a provision that would require FDA to eliminate all conflicts of interest on advisory committees. Senate leaders have said they intend to fight the provision but increased Congressional action is expected to put pressure on FDA to finalize a pending Conflict of Interest policy for which the public comment period ended on May 21, 2007.

## MISCELLANEOUS

### Health Information Technology

- **Legislative Activity in the U.S. Senate.** The Senate was the first to act on HIT in the 110<sup>th</sup> Congress by passing S. 1693, the “Wired for Health Care Quality Act of 2007” out of the Health, Education, Labor and Pensions (HELP) committee on June 26, 2007. This bill would provide some assistance to physicians in the form of grants for purchasing HIT and also includes measures to standardize and make interoperable electronic medical records. The bill allocates \$278 million in matching grants for physicians providing services to underserved communities and practices that demonstrate financial need. The bill is jointly sponsored by Senators Ted Kennedy (D-MA), Mike Enzi (R-WY), Hillary Clinton (D-NY) and Orrin Hatch (R-UT) and is expected the bill will pass the full Senate this fall.

Unfortunately, the bill contains a worrisome section on quality measures. The AANS, CNS and other groups in the Alliance of Specialty Medicine have sent letters to the sponsors raising our concerns. Essentially, we cautioned against the creation of dual quality reporting systems (one for Medicare and another for Public Health Service Act programs), but stressed that any quality reporting program should comport with the process outlined in the Alliance bill, S. 1519, the “Medicare Voluntary Quality Reporting Program” and also contain the protections in that bill that ensure the appropriate development of quality measures by the physician organizations themselves.

- **Legislative Activity in the House of Representatives.** In the House of Representatives, the committees of jurisdiction have been slow to move on the HIT issue, though several bills have been introduced by various members of Congress. The bill that the Energy and Commerce Committee will most likely act on has not yet been introduced, but the sponsors will be Anna Eshoo (D-CA) and Mike Rogers (R-MI). At this point, it is not clear how closely this bill will be aligned with the Senate bill and the House may actually wait until next year to address the issue of health information technology.

Chairman Bart Gordon (D-TN) of the House Science Committee was one of the members of the House who introduced HIT legislation. His bill, H.R. 2406, would authorize the National Institute of Standards and Technology (NIST) to enhance efforts to integrate healthcare information enterprises in the United States, and by increasing interoperability, promote widespread adoption of effective HIT. Mr. Gordon has been a champion on many issues for us this year and we signed a letter from the Alliance thanking him for this legislation.

- **ICD-10 System for Diagnosis Codes.** The AANS and CNS continue to be very involved in a coalition with Blue Cross Blue Shield and other physician organizations, including the AMA, to ensure that ICD-10 is not implemented too quickly and without an adequate opportunity to educate physicians regarding these major changes (where ICD-9 has approximately 20,000 codes, ICD-10 has almost 200,000). We continue to express concerns, as does the American College of Physicians (ACP), that the proposed ICD-10 system is needlessly complex and perhaps should be re-evaluated. However, those arguments are being strongly rebutted by the hospitals and device manufacturers who want to move very quickly to ICD-10. At this point, we continue to express our concerns about the system as a whole, but advocate for a reasonable timeline for these changes (somewhere in the neighborhood of 2012/2013). We recently signed a coalition letter to HHS Secretary Leavitt on this topic.

There are two pieces of good news on this front: 1) The Senate HIT bill did not include a provision to force CMS to move more quickly to ICD-10 and 2) the proposed ICD-10 rule that was expected

this spring has been delayed due to technical difficulties some of the contractors are having in developing the rule.

**Antitrust Relief for Physicians.** Over the past several years there has been a continued consolidation of the health insurance market. According to a 2005 AMA-commissioned study, "Competition in Health Insurance: A Comprehensive Study of U.S. Markets," in many parts of the country, health insurance markets are now dominated by a few companies that have significant power over the market place. Health plans also benefit from a special exemption from the antitrust laws, so they are in a position to engage in anti-competitive practices that are detrimental to patient care. At the same time, the antitrust laws prevent individual physicians from joining together (subject to a few exceptions), creating an imbalance in the market place. As a result of this imbalance, health plans are forcing unreasonable, restrictive, and "take-it-or-leave-it" contracts upon physicians. Organized medicine therefore came together to seek legislation that would enable physicians and other health care professionals to effectively negotiate with health plans without fear of violating antitrust laws.

The AANS and CNS are leading an effort, along with the American Medical Association, to work with Congress, the Department of Justice and Federal Trade Commission to amend the DOJ/FTC "Statements of Antitrust Enforcement Policy in Health Care" to, among other things:

1. Relax the current financial and clinical integration requirements so independent physicians can qualify for antitrust "safety zones" when jointly negotiating with health plans; and
2. Adopt new policy statements regarding market concentration to prompt more aggressive enforcement against health plan mergers such things as all-products clauses, most-favored-nation clauses, and delayed payment policies

If the Department of Justice and Federal Trade Commission do not change their "Statements of Antitrust Enforcement Policy in Health Care" to reflect the above, we will seek the introduction and passage of legislation mandating the adoption of these new policies.

**Kitchen-Sink Health Care Reform.** On June 7, 2007, Representative Tom Price, MD (R-GA) introduced H.R. 2626, the Comprehensive HealthCARE Act of 2007. The bill, which the AANS and CNS endorsed, is very broad and contains the following provisions:

- Tax incentives for expanding health insurance coverage
- Reforms antitrust laws to enhance physician bargaining power with health plans
- Allows purchase of health insurance across state lines
- MICRA style tort reform
- Tax credits for health information technology
- Liability protections for physicians in emergency rooms
- Tax deductions for uncompensated care in the emergency room
- Establishes a HIPAA advisory group to review HIPAA implementation issues
- Substitutes MEI (medical inflation) for the SGR for physician payment updates
- Removes limitations on balance billing if beneficiaries are notified
- Repeals the two year moratorium on physicians engaging in private contracts
- Strengthens the EMTALA TAG
- Creates a loan deferment program for medical school graduates
- Requires HHS to report to Congress a proposal for a formalized process to develop performance-based quality measures for Medicare services in concert and agreement with the physician consortium and only allows HHS to utilize measures agreed to by each specialty group

**Biomedical Research.** Through the Brain Attack Coalition, the National Coalition for Heart and Stroke Research, the National Heart, Lung, and Blood Institute (NHLBI) Constituency Group, and the Coalition for the Advancement of Medical Research, the AANS and CNS continue to work to support adequate biomedical research funding. Rachel Groman represents neurosurgery on these coalitions.

- **Health and Human Services Appropriations.** Health-related appropriations continue to face an uphill battle in an attempt to recover from Fiscal Year 2006 (FY06), when the Labor, Health and Human Services and Education (L-HHS-Ed) appropriations bill was cut by \$1.6 billion. Congress worked to restore some of those cuts in the FY07 Joint Resolution, but many programs still remain far below their FY05 level, and others lost all funding. The President's FY08 budget request continues or deepens cuts for most of the programs in the Departments of Labor, HHS, and Education. Although the House passed all 12 of its appropriations bills by the August recess, the Senate still has 11 to go (including HHS) and little time to complete them before the end of the FY 2007 fiscal year. A vote on a continuing resolution to fund agency operations beyond September 30th is expected and the prospect of a year-end omnibus bill looms ever larger as the President continues to threaten to veto any appropriations bill that exceed his budget request.

**ACTION TAKEN: Throughout the spring and summer, AANS and CNS signed various letters encouraging Congress to support an increase in the health and human services appropriation and to override an anticipated Presidential veto.**

- **Embryonic Stem Cell Research.** On June 7, the House joined the Senate in passing legislation to provide federal funding for embryonic stem cell research, marking the second time in less than a year that Congress sent a bill to the President to increase the number of embryonic stem cell lines eligible for federally funded research. On June 20, however, the President vetoed the legislation. On the same day, the President issued an executive order that would enact the second provision of S. 5, which directs the NIH to study alternative ways of procuring stem cells that have the same qualities as embryonic cells, but do not destroy an embryo. The Senate may hold a vote to override the veto between the Labor Day and Columbus Day recess.
- **Brain Attack Coalition.** Drs. Sander Connelly and Rocco Armonda represent the AANS and CNS on the Brain Attack Coalition (BAC), which is a group of professional, voluntary, and governmental agencies that work on issues related to stroke care. Dr. Rocco Armonda and Rachel Groman attended a June meeting of the group, at which the following projects were discussed: Revision of the Classification of Cerebrovascular Diseases III; Revision of Primary Stroke Centers Paper; and Guidelines for the Prehospital Management of Traumatic Brain Injury.

**Value of Neurosurgeons to Hospitals.** The Washington Committee is exploring a new project aimed at establishing the value of neurosurgeons to hospitals so as to help neurosurgeons develop partnerships and joint ventures with hospitals, which may help improve the delivery of patient care, improve relationships between neurosurgeons and their hospitals and help increase/maintain reimbursement. A working group, which has held several conference calls to date, has been assigned to this project, and includes Drs. Doug Kondziolka, John Kusske, Gary Bloomgarden, Greg Przybylski, Mark Linskey and Jim Bean. A number of thoughts/concepts have evolved from the initial discussions:

- This project should be focused on the issue of hospital revenue as a source of supplemental neurosurgery income. The purpose in documenting the value of a neurosurgeon to a hospital is to improve negotiating opportunity for either revenue sharing (call pay, directorship compensation, salary supplementation, or other form of legal revenue transfer) or service line development (stroke/endovascular, stereotactic radiosurgery, DBS, minimally invasive spinal surgery, etc.).
- What neurosurgeons want and need to know is what services are most successful, what the range of generated revenue is (knowing there will be variation from place to place), how successful

negotiations are done, what are examples of successful service lines ("focused factories") from others' practical experience, how to do it with or without a hospital, advantages and disadvantages of hospital joint ventures, how to decipher Byzantine and deluding hospital cost accounting, proforma examples of service line start-up and different opportunities for "gainsharing", and numerous other details of justifying and entering new business/practice arrangements.

- A consultant may be an expensive way to get information with limited usefulness. It may (or may not) provide answers to the initial question, "What hospital revenue is generated directly or indirectly by a neurosurgeon?" It won't necessarily help neurosurgeons in practice without a practical plan for devising a better business design or service line, negotiating a joint venture, and operating an unfamiliar business. Much of this information should be available from our own members, those who have thought this through already and established their own new arrangements. See for example the Neurosurgeon as CEO course regularly offered by the AANS. Jim Ausman, MD has some excellent presentations along these lines.
- Rather than spend money on a report that gathers dust and benefits only the consultant, we should generate money by teaching neurosurgeons interested in new business ventures through the experience of those who have done it. If we want to gather data, we should select a core few who have already done so and use their experience, and publish it in our socioeconomic publications.
- On the other hand, most neurosurgeons lack even a basic source of hospital cost/revenue information. For example, in 2005 the Health Care Advisory Board published a report entitled "Future of Neurosciences: Strategic Forecast and Investment Blueprint". While this may not be precisely the kind of report/information that we need, many neurosurgeons may simply desire this kind of information, while others would be interested in a more robust program that addresses their individual practice/business model needs. A menu of options may be a good way to go.

**ACTION TAKEN: The Value of a Neurosurgeon Project workgroup will further develop this project, including: (1) Disseminating basic information about hospitals' neurosurgical service line costs/revenues; (2) Continue to put on the Neurosurgeon as a CEO; (3) Identifying a consultant(s) that the AANS/CNS can recommend to individual neurosurgeons to help negotiate hospital/neurosurgeon joint ventures; and (4) Require the consultant(s), as part of any arrangement, to collect and share its hospital cost/revenue data with the AANS and CNS.**

**CSNS April Resolutions.** The Washington Committee acted on a number of resolutions that came from the CSNS during its April meeting as follows:

- **RESOLUTION VI.** Collective Bargaining; Antitrust Immunity

**Action:** Adopted Amended Substitute Resolution

**BE IT RESOLVED,** that our council of state neurosurgical societies, support the AANS, the CNS and the Washington Committee in their efforts to actively campaign for passage by the United States Congress of the Health Care Antitrust Improvements Act of 2007 and/or any similar future legislation, that will legalize collective bargaining by groups of physicians for payment of services by third party carriers without the threat of violating antitrust laws;

**BE IT FURTHER RESOLVED,** that the AANS and CNS Delegations to the House of Delegates of the AMA actively campaign for the AMA to support passage of the **Health Care Antitrust Improvements Act of 2007** by the United States Congress.

**AANS/CNS ACTION TAKEN: The AANS/CNS submitted Resolution 225 "Antitrust Relief for Physicians" to the AMA House of Delegates at its June meeting. It is already AMA**

**policy to support health care antitrust improvements and the House of Delegates reaffirmed this policy at the June meeting. In addition, the Washington Office staff is actively participating in an AMA-Specialty Society Antitrust Workgroup, which is seeking modification of antitrust regulations and passage of antitrust legislation, if necessary. Finally, the AANS and CNS recently voted to endorse Rep. Tom Price's (R-GA) legislation, H.R. 2626, the Comprehensive HealthCARE Act of 2007. This bill includes a section that reforms antitrust laws to enhance physician bargaining power with health plans.**

▪ **RESOLUTION VII.** Ending AMA Support for PFP and Public Reporting Programs

**Action:** Combined with Resolution X

**BE IT RESOLVED**, that our AMA finds that Pay-For-Performance and Public Reporting Programs pose more risks to patients than benefits and calls for an immediate cessation of such programs by private and public Third Party Payers; and

**BE IT FURTHER RESOLVED**, that our AMA Chair and Board of Trustees advise the Secretary of Health and Human Services and the Ambulatory Care Quality Alliance (AQA) that the AMA will no longer participate in the creation, development or implementation of the Secretary's "Transparency Initiative" or other Pay-For-Performance Programs; and

**BE IT FURTHER RESOLVED**, that our AMA Board of Trustees (a) mount a properly resourced public relations and media campaign by November, 2007, to educate Americans on the risks and benefits of the Pay-For-Performance and Public Reporting Programs and other elements of the DHHS "Health Care Transparency Initiative" being promoted by Medicare and Private Insurance Companies and (b) present a progress report at each of the HOD meetings over the next 3 years, as called for in I-05 (Sub. Res. 902 "Protecting Patients Rights").

▪ **RESOLUTION X.** Ending AANS and CNS Support for PFP and Public Reporting Programs

**Action:** Adopted Amended Resolution

**BE IT RESOLVED**, that our CSNS finds that Pay-For-Performance and Public Reporting Programs pose more risks to patients than benefits and calls for an immediate cessation of such programs by private and public Third Party Payers; and

**BE IT FURTHER RESOLVED**, that CSNS ask that the AANS and CNS sponsor a resolution at the June 07 AMA Meeting. This resolution would provide for education of AMA Members regarding the risks and liabilities of the Pay-For-Performance and Public Reporting Programs and other elements of the DHHS "Health Care Transparency Initiative" being promoted by Medicare and Private Insurance Companies; and

**BE IT FURTHER RESOLVED**, that the CSNS also work with component state societies to accomplish the same mission.

**AANS/CNS ACTION TAKEN:** The AANS/CNS submitted Resolution 226 "AMA Member Education on Pay-for-Performance and Public Reporting Programs" to the AMA House of Delegates at its June meeting. It is already AMA policy to launch such an education program, and this policy was reaffirmed at the June meeting. The House of Delegates also considered numerous other resolutions on various topics related to pay-for-performance. Following extensive discussion and debate, the AMA adopted a comprehensive policy addressing many of the issues raised by the CSNS. The final comprehensive report of these issues is available on the AMA website at: <http://www.ama-assn.org/ama1/pub/upload/mm/467/combannotateda07.pdf>

- **RESOLUTION XI.** Risks and liabilities of Physician Quality Reporting Initiative

**Action:** Adopted Amended Resolution

**BE IT RESOLVED**, that our CSNS issue a letter through component state societies advising neurosurgeons that participation in the Physician Quality Reporting Program (PQRI) in its current form may not be in the best interest of their patients or their practice and that CSNS asks the AANS and CNS issue a similar letter to its members.

**AANS/CNS ACTION TAKEN:** In June, the Washington Office sent an e-blast to all U.S. neurosurgeons outlining the details of the PQRI program and the pros and cons of participation. In addition, Washington Office staff wrote an article that was published in the Summer AANS *Bulletin*.

- **RESOLUTION XII.** Outcome Studies

**Action:** Request that the Washington Committee Report on the Status of the Pilot Outcome Study

**BE IT RESOLVED**, the CSNS asks the AANS and the CNS to develop an outcomes registry for voluntary use by the board eligible and board certified neurosurgeons with the goal of gathering data on individual practice patterns and outcomes. Data from such a registry shall not be submitted to the government for public reporting and shall be entirely private for the surgeon's own use unless he or she otherwise consents. The CSNS continues to support efforts by organized neurosurgery and academic neurosurgery to evaluate the efficacy of neurosurgical management using all funding streams available.

**AANS/CNS ACTION TAKEN:** A small workgroup of representatives from the AANS, CNS, ABNS, Washington Committee and Quality Improvement Workgroup are developing a comprehensive plan for developing a mechanism to collect clinical practice and outcomes data to satisfy both Maintenance of Certification requirements as well as various government and third party payer quality reporting programs. The Washington Committee is working with other medical organizations to help ensure that such information remains confidential and not subject to public reporting.

- **RESOLUTION XV.** A Simplified Solution to Digital Imaging Distribution

**Recommendation:** Adopted

**BE IT RESOLVED**, that the CSNS request the AANS and CNS work with imaging manufacturers via the AMA to seek that all CD's with radiographic imaging have freely accessible DICOMM image sets placed on them so that the physician can use a DICOMM reader of their own choice, should they find the "included" image presentation software inadequate.

**AANS/CNS ACTION TAKEN:** The AANS and CNS continue to participate on a workgroup convened by the AMA to address various problems associated with radiographic imaging. At the June AMA House of Delegates Meeting, the AMA Board Issued Report 30 "Development of Standards for MRI Equipment and Interpretation to Improve Patient Safety". The report was adopted by the House of Delegates and the AMA will convene further stakeholder meetings between physicians (including neurosurgery) and manufacturers with the goal of developing appropriate standards.