



Washington Update April 2018







Washington Committee Meeting Executive Summary

Progress Report on the AANS/CNS Legislative and Regulatory Agenda

The AANS and CNS are making steady forward progress on our legislative agenda. Positive outcomes to date include:

- Legislation expanding funding for the Children's Health Insurance Program (CHIP) for ten years was signed into law.
- Bills for additional Medicare graduate medical education funding have been introduced.
- Congress repealed the Independent Payment Advisory Board (IPAB).
- The House passed comprehensive medical liability reform legislation, and multiple other medical liability reform bills have been introduced.
- Legislation suspending the medical device tax for an additional two years was signed into law.
- Improvements to Medicare's Quality Payment Program to reduce the reporting burden and minimize penalties have been made.
- Massive changes to global surgery codes will not likely be forthcoming in 2019.

Washington Office Relocation

Effective Feb. 1, 2018, the AANS and CNS took possession of a new office suite. Located in the building that also houses the American Medical Association, the office is across the street from the American College of Surgeons, is a short three block walk from the Senate side of the Capitol Complex, and is a modern building. The new address is:

25 Massachusetts Avenue, NW, Suite 610 Washington, DC 20001

Health Reform Update

Congressional Activities

The tax bill (H.R. 1) repealed the individual mandate to purchase insurance, and while not exactly living up to the Obamacare repeal and replace mantra, eliminated the individual mandate does strike a significant blow to a major structural element of the Affordable Care Act (ACA). On Jan. 22, 2018, Congress passed H.R. 195, as amended, a continuing resolution (CR) to fund the federal government through Feb. 8. Included in this bill was a provision renewing the Children's Health Insurance Program (CHIP) — which provides coverage to 9 million children in families who earn too much qualify for Medicaid but cannot afford private insurance — for six years. The Bipartisan Budget Act (H.R. 1892), which was signed into law on Feb. 9, extended coverage for a total of 10 years. Included in the Jan. 22, 2018 CR was a provision further suspending the medical device excise tax through 2019. Finally, after more than eight years of lobbying, the AANS and CNS successfully advocated for the repeal of the Independent Payment Advisory Board, which was included in H.R. 1892.

Regulatory Activities

Approximately 8.8 million people selected or were automatically re-enrolled in plans using the HealthCare.gov platform during the 2018 open enrollment period. An additional 2.8 million enrolled through state exchanges. While some analysts had projected a shortfall of millions due to reduced federal outreach and a shortened sign-up period, a late surge brought the 2018 total in line with previous years. Premiums continue to rise, as to out-of-pocket costs. The nation is bracing for double-digit increases in 2019.

Public Opinion Remains Split

Public opinion over ObamaCare has been split throughout its inception. The most recent Kaiser Family Foundation tracking poll from March 2018 conducted by the Kaiser Family Foundation, shows that adults now have more favorable (50%) rather than unfavorable (43%) opinion of the ACA.

Regulatory Relief Update

Picking up on the efforts of Dr. Price, following his resignation, CMS Administrator Seema Verma launched the "Patients Over Paperwork Initiative," a crosscutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. The AANS and CNS are focusing on a handful of topics for regulatory relief including:

- MACRA's Quality Payment Program
- AUC for advanced diagnostic imaging
- Electronic health records
- Global surgery code data collection
- Prior authorization
- FDA-related topics, such as off-label use, approval of devices and streamlining paperwork requirements for FDA volunteer experts

Representatives from the AANS and CNS have had multiple meetings with high-level HHS officials. Most recently, as part of this effort, on March 15, 2018, the House Ways and Means Committee Covered a "Red Tape Relief Roundtable" to discuss ways in which Congress and/or the Centers for Medicare & Medicaid Services can provide regulatory relief for physicians. Washington Office staff represented the Alliance of Specialty Medicine at the meeting, which highlighted a wide-variety topics, include those mentioned above.

MACRA Update

In November, CMS released the MACRA program requirements for 2018.

Key changes for 2018 include:

- Clinicians who bill Medicare \$90,000 or less in 2018 (and increase from \$30,000 in 2017) or who
 provide care for 200 or fewer patients in 2018 (an increase from 100 patients in 2017) are exempt
 from MIPS.
- Resource/use cost category will be worth 10% of the MIPS score (the weight was zero in 2017).
- Increased the data completeness threshold from 50% to 60%.
- Expanded the quality reporting performance period to an entire year, rather than for a minimum of 90-days.
- Approved 21 additional new clinical improvement activities, including allowing credit for CME.
- Adopted an advancing care information (EHR) hardship exception for clinicians in small practices.
- Allows groups of 10 or fewer clinicians to form "virtual groups" for purposes of participating in MIPS.

According to a recent AMA survey, 75 percent of physicians say that are not ready for MACRA changes. In an effort to minimize MIPS-related penalties, the AANS and CNS have been advocating for Congress to make some technical changes to MACRA. This effort was successful, and following months of sustained advocacy by the AANS, CNS and others in organized medicine, the Bipartisan Budget Act (<u>H.R. 1892</u>), was signed into law on Feb. 9. The law includes the following technical amendments:

- Allows CMS to reweight the cost performance category to not less than 10 percent for the second, third, fourth, and fifth years of the Merit-based Payment System (MIPS). Under current law, beginning next year, the cost category would have counted for 30 percent of a clinicians MIPS score.
- Eliminates improvement scoring for the cost performance category for the second, third, fourth and fifth years of MIPS.

- Provides CMS flexibility in setting the performance threshold for years two through five to ensure a
 gradual and incremental transition to the performance threshold set at the mean or median for the
 sixth year.
- Medicare Part B drug costs are excluded from Merit-based Payment System MIPS payment adjustments.

Washington Office staff are also serving on the AMA MIPS workgroup, which has developed further proposals to streamline the program and make it more meaningful and less burdensome to clinicians. Finally, the AANS and CNS, working with our colleagues in the Alliance of Specialty Medicine, opposed a new proposal by the Medicare Payment Advisory Commission (MedPAC) to replace MIPS with an entirely new quality payment system — the Voluntary Value Program. Under this program, physicians would be assessed by population-based measures that do not generally apply to specialty physicians, leaving specialists with annual pay cuts for non-compliance. Congress has expressed zero interest in following the MedPAC recommendation.

Coding and Reimbursement Update

Medicare Fee Schedule

Beginning on July 1, 2017, CMS required certain neurosurgeons in nine states — Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon and Rhode Island — to report the number of post-operative visits that they provide related to a variety of common neurosurgical procedures using CPT code 99024. Many neurosurgeons appear to be submitting data, but it is not possible to assess its accuracy at this time. CMS has also contracted with RAND to conduct a national survey on global surgery services. Last fall, in the Surgical Coalition letter, the AANS and CNS raised significant concerns about the survey, not the least of which is that it is too long and any data collected will be flawed and from too small a sample. RAND made some changes and is currently piloting the survey. Following a meeting in March with CMS, it appears that the agency has received quite a bit of data from the claims-based effort, but the data have not yet been analyzed. The lack of progress on the data collection front means that it seems highly unlikely that CMS will make wholesale changes to the global surgery codes for 2019.

CPT Issues

After sustained advocacy by the AANS and CNS, on Feb. 8, 2018, the CPT Assistant Editorial Board agreed to rescind a Frequency Asked Question (FAQ) published in October 2016 that inaccurately supported a National Correct Coding Initiative (NCCI) edit for Medicare prohibiting the reporting of CPT codes 63047 and 22633 if performed at the same interspace. The FAQ inaccurately supports a National Correct Coding Initiative (NCCI) edit for Medicare prohibiting the reporting of CPT codes 63047 and 22633 if performed at the same interspace.

After many years of service, **Pat Jacob**, MD, will be rotating off of the CPT Editorial panel in the spring of 2018. Unfortunately, the AMA board did not select **Joe Cheng** as his replacement.

RUC Issues

Efforts improve the accuracy of malpractice premium data for purpose of valuing the malpractice (MP) RVUs in the Medicare Physician Fee Schedule are underway. CMS postponed updating MP values due to the advocacy of the AANS, CNS and others who all raised concerns about the accuracy of the data. The RUC will send a letter to CMS on March 30 further elaborating our complaints about the MP values. At the April RUC meeting, the AANS and CNS, along with other spine societies, will present survey data for revaluation of CPT code 27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device, and CPT code 22310 Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing.

After many years of service, **Greg Przybylski**, MD is retiring from his seat on the RUC. Neurosurgery's new RUC representative will be **Ed Vates**, MD.

Coverage Issues

The AANS/CNS Coverage Rapid Response Team (RRT) continues help neurosurgeons address coverage issues as they arise nationally and in their states. Recent coverage activity includes:

- Anthem deep brain, Cortical and Cerebellar stimulation
- Anthem payment for E/M codes reported with modifier -25
- Washington State HTA review of single level laminectomy
- Aetna refusal to pay for MIR-guided neurosurgical laser ablation (LITT)
- Aetna limits on spinal cages
- Ohio Bureau of Workers Compensation policy on lumbar fusion
- Blue Cross/Blue Shield policy on interspinous and interlaminar stabilization/distraction devices

Other Medicare Issues

On Jan. 24, 2018, by a <u>vote of 55 to 43</u>, Alex Azar was confirmed as the new Secretary of the Department of Health and Human Services. A lawyer, and former president of Lilly USA, Secretary Azar is no stranger to government, having worked as HHS general counsel and deputy secretary under President George W. Bush. He also cleared for Supreme Court Justice, Antonin Scalia. He has enunciated four key priorities for the department:

- 1. Soaring drug prices
- 2. Affordability
- 3. Shift to value
- 4. Opioids

The AANS and CNS recently joined the Alliance of Specialty Medicine in sending a letter to Secretary Azar, requesting an opportunity to meet with him to discuss health policy topics of concern.

In other Medicare news, the AANS and CNS nominated **Jeffrey W. Cozzens**, MD, **Ahmen M. Raslan**, MD, **Clemens M. Schirmer**, MD and **G. Edward Vates**, MD to serve on the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). In addition, the AANS and CNS, along with others in organized medicine, were successful in defeating propose legislation that would have extended the so-called misvalued codes beyond 2020. Under this policy, CMS is directed to identify codes totaling 1.0 percent of physician expenditures as misvalued, and the failure to do so requires across-the-board cuts to all physicians. Finally, CMS is soliciting feedback from stakeholders on potential changes to the E/M documentation guidelines.

MedPAC

Efforts to increase primary care payments at the expense of surgical payments continue, and on Jan. 10, the AANS and CNS joined the Surgical Coalition in sending a letter to MedPAC challenging the commission's proposals to increase primary care's Medicare payments at the expense of surgical/specialist payments. As a result of this advocacy, MedPAC has postponed making any recommendations to Congress on this issue, although the topic may resurface in the commission's June report.

Quality Improvement Update

2018 Medicare Physician Fee Schedule Final Rule

CMS adopted many of the neurosurgery's recommendations to better align the legacy physician quality programs with the new Quality Payment Program (QPP) requirements, including reducing the number of measures from nine to six and limiting the maximum Value Modifier (VM) adjustment to -1 percent rather than -2 percent. Additionally, CMS delayed the appropriate use criteria for advanced diagnostic imaging program until 2020, rather than 2019, and the initial year will begin with education and operations testing.

Medicare Access and CHIP Reauthorization Act (MACRA)

CMS continues to develop episode-based cost measures, and the AANS and CNS were represented on two committees working on this project. The initial cost measures will include one area of interest to neurosurgery: Intracranial Hemorrhage or Cerebral Infarction. The goal is to incorporate these measures into the Merit-based Incentive Payment System (MIPS) as early as 2019. For Wave 2 of the project, the following neurosurgeons were appointed to the advisory committees:

- Peripheral Vascular Disease Management: Clemens Schirmer, MD; Kimon Bekelis, MD; and Jay Nathan. MD
- Musculoskeletal Disease Management Spine: Anand Rughani, MD; Jay Nathan, MD; and Mo Bydon, MD
- Neuropsychiatric Disease Management: Clemens Schirmer, MD, and Anand Rughani, MD_

Physician Value-Based Payment Modifier

In January 2018 CMS released the 2018 VM results. A mere 20,000 physicians received bonuses ranging from 6.6% to 19.9%. Three-quarters of physicians subject to the VM had neither a positive or negative payment adjustment. The remaining physicians received penalties of 1% to 2%.

CMS Meaningful Measures Initiative

CMS Administrator, **Seema Verma**, announced a new initiative aimed at streamlining quality measures, reducing regulatory burden and promoting innovation. The Measures Under Consideration (MUC) list for 2019 only contains 32 measures, down from 97. Measures relevant to neurosurgery include:

- Average change in functional status following lumbar spine fusion surgery
- Average change in functional status following lumbar discectomy laminotomy surgery
- Average change in leg pain following lumbar spine fusion surgery
- Optimal Vascular Care
- Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication
- Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication
- Intracranial Hemorrhage or Cerebral Infarction

Public Reporting and Transparency

Currently, Physician Compare only includes performance data on physicians for PQRS quality measures that prove to be:

- Valid, reliable, and accurate
- Deemed statistically comparable
- Meet a minimum sample size of 20 patients
- · Are not first year measures; and
- All measure data are also subject to a 30-day preview period before being posted.

Since not all measures have been deemed appropriate for posting on Physician Compare profile pages, many physicians will find a simple check mark on their profile page indicating that he/she "Successfully reported Medicare quality program performance information" and/or "Used electronic health records."

Clinical Registry Policies and Activities.

Neurosurgery's NeuroPoint Alliance (NPA) and its Quality Outcomes Database (QOD) was recently approved as a federally recognized Qualified Clinical Data Registry (QCDR). After a frustrating process, CMS approved 16 measures focusing on spine surgery for 2018. As members of the Physician Clinical Registry Coalition (PCRC), neurosurgery has been working with CMS to improve the QCDR self-nomination and measure review process, and for the agency to address issues related to data blocking. To this end, we will participate in a high-level meeting with staff from the HHS Office of Inspector General and Office of the National Coordinator.

Alternative Payment Models (APMs)

In November 2017, the AANS and CNS submitted comments to CMS suggesting improvements for the Center for Medicare and Medicaid Innovation (CMMI) and its process of developing APMs. The AANS and CNS also joined an effort in support of the Medicare Care Coordination Improvement Act, which would modernize the "Stark" self-referral law, which currently prohibits or inhibits certain payment arrangements. Following advocacy by the AANS, CNS and others, CMS finalized its decision to cancel the new mandatory bundled payment models for cardiac and orthopaedic care. While not opposed to bundled payment arrangements, neurosurgery is opposed to mandating these APMs. To this end, on the voluntary bundled payment arrangement front, in January 2018, CMS announced a new program — The Bundled Payments for Care Improvement-Advanced Model. This new program includes 32 clinical-care episodes in both the inpatient and outpatient settings. Those relevant to neurosurgery include:

- Back & neck except spinal fusion (inpatient and outpatient)
- Cervical spinal fusion
- Combined anterior posterior spinal fusion
- Spinal fusion (non-cervical)
- Stroke (not sure which codes are included here yet)

Finally, the AANS and CNS are working with Blue Cross Blue Shield of America (BCBSA) to update their Blue Distinction Spine program. **John K. Ratliff**, MD; **John J. Knightly**, MD; **Ralph F. Reeder**, MD; and **Mohamed Bydon**, MD, have volunteered to work with BCBSA on this project.

Health Information Technology

The Office of the National Coordinator for Information Technology (ONC) is working to address issues related to interoperability and data sharing, which remains a challenge and unsolved problem much to the ongoing consternation of physicians. As mentioned above, AANS/CNS staff will be meeting with ONC on this topic.

Appropriate Use Criteria (AUC) for Advanced Imaging Services

As mentioned above, CMS further delayed implementation until 2020 of the "Protecting Access to Medicare Act" (PAMA) requirements that ordering physicians consult AUCs before rendering physicians can provide advanced diagnostic imaging services. The AANS and CNS have made eliminating this requirement a top priority, engaging with HHS, CMS and the House Ways and Means Committee to better align this program with MIPS. To this end, neurosurgery has drafted legislative language that we hope will be adopted by Congress before the program goes into effect.

Quality Improvement Organizations

The AANS and CNS dropped membership in the Physician Consortium for Performance Improvement (PCPI) for 2018, but remain involved with the National Quality Forum (NQF), Surgical Quality Alliance (SQA) and the Partnership to Improve Patient Care (PIPC)

Guidelines Update

Administrative Issues

To better distinguish between the CNS Guidelines Committee, whose function is creating guidelines, and the AANS/CNS Joint Guidelines Committee, whose function is reviewing guidelines, the JGC has changed its name to the Joint Guidelines Review Committee (JGRC). In addition, The JGRC is in the process of updating its governance documents. The document will include JGRC operations, rules and processes. In addition, updated COI and endorsement language will be incorporated. Finally, effective Dec. 1, 2017, the CNS and AANS contracted with a new outside consultant — Kirsten Aquino — to serve as the administrator for the JGRC.

Guidelines Projects

Recent guidelines projects include:

- AHA/ASA Guidelines for Acute Ischemic Stroke
- Disorders of Consciousness
- Thoraco-Lumbar Trauma
- Spinal Cord Injury (SCI) and Degenerative Cervical Myelopathy (DCM)
- Use of Intraoperative Monitoring in Spinal Surgery
- Deep Brain Stimulation for Parkinson's
- Pediatric Mild TBI
- Vestibular Schwannoma Guideline
- Metastatic Brain Tumor update

The Committee is also exploring the feasibility to establish a collaborative arrangement with the North American Spine Society and the American Academy of Neurology, and is negotiating an agreement with the Neurocritical Care Society on a guidelines project related to Medical Management of Cerebral Edema. Finally, we have an ongoing relationship with the American College of Radiology for the development of appropriate use criteria for diagnostic imaging.

Drugs and Devices Update

Physician Industry Relations

On Jan.17, 2018, the Centers for Medicare and Medicaid Services (CMS) updated the Open Payments dataset to reflect changes to the data that took place since the last publication on June 30, 2017.

Congressional Activity

On Jan. 22, 2018, Congress passed <u>H.R. 195</u>, as amended, a continuing resolution to fund the federal government through Feb. 8, 2018. The legislation, which was signed into law by President Trump, included a suspension of the medical device excise tax through 2019. Several Congressional committees continue to hold hearings on the opioid crisis, including the Senate Health, Education, Labor and Pensions (HELP) Committee, as well as the House Energy and Commerce and Ways and Means Committees. The AANS and CNS have written several letter to Congress outlining our suggestions related to opioids, and objecting to strict prescribing limits (e.g., maximum of 3 or 7 days) without any exceptions for post-surgical acute pain management. Finally, the House Energy and Commerce Committee also recently held a hearing on how drug and device companies can share information regarding an investigational use of a drug or device.

Food and Drug Administration

The AANS and CNS have been very active on the FDA front, including:

- On Feb. 5, 2018, submitted a letter urging regulatory relief for off-label use, burdensome conflict of interest paperwork for neurosurgeon volunteers, and other topics. We joined the Alliance of Specialty Medicine in sending another letter.
- On Dec.12, 2017, the FDA Orthopaedic and Rehabilitation Devices Advisory Panel met to discuss, make recommendations and vote on information regarding the premarket approval application (PMA) for the Barricaid annular closure device manufactured by Intrinsic Therapeutics. Three neurosurgeons served on the FDA panel: Bong-Soo Kim, MD; Eli M. Baron, MD; and Marjorie C. Wang, MD.
- The FDA held a public hearing on Jan. 30, 2018, titled, Opioid Policy Steering Committee:
 Prescribing Intervention Exploring a Strategy for Implementation. Robert F. Heary, MD made a
 presentation on behalf of organized neurosurgery.
- On March, 1, 2018, the FDA Neurological Devices Advisory Panel will meet to review the evaluation
 of clinical study data to support the safety and effectiveness of intracranial aneurysm treatment
 devices. Attending on behalf of the AANS and CNS and the AANS/CNS Section on
 Cerebrovascular Neurosurgery will be Kevin M. Cockroft, MD; Robert E. Harbaugh, MD; J

- Mocco, MD, MS; Clemens M. Schirmer, MD; Adnan H. Siddiqui, MD, PhD; Babu G. Welch, MD; and Gregory J. Zipfel, MD.
- The AANS and CNS submitted a letter to the FDA in response to the agency's notice requesting stakeholder feedback regarding regulatory burdens. In our letter we discussed off-label regulations, simplification for IDE projects and reducing the paperwork burdens for FDA panel participants.
- The Association for Testing and Materials (ASTM) continues work on its draft ASTM standard for neurosurgical head holder devices Yakov Gologorsky, MD, as the representative from neurosurgery to the ASTM, participated in numerous meetings and conference calls with FDA staff and industry representatives to provide input for the development of the draft standard. Neurosurgeon Bennett Blumenkopf, MD, FDA medical officer, has helped lead the effort for the FDA.

Neurosurgical Training and Education Update

Thus far in the 115th Congress, a handful of bills related to graduate medical education (GME) have been introduced, including bills to increase funding for GME residency training slots — H.R. 2267/S. 1301, the Resident Physician Shortage Reduction Act — and a bill (H.R. 2373) to effectively eliminate the single accreditation system and require at least one additional accreditor for osteopathic programs. Washington Office staff are working with the ACGME, AAMC and others to derail the osteopathic legislation. These advocacy efforts thwarted an attempt by Sen. Toomey to get language included in the omnibus spending bill that would have required CMS to evaluate the impact of the ACGME and AOA agreement to determine whether a second accreditor is necessary. Once again the American College of Surgeons (ACS) as invited representatives from organized neurosurgery to attend the Third Annual ACS Summit on Surgical Training in May. We have requested an opportunity to discuss the ACS Position Statement on GME at this meeting.

Medical Liability Reform Update

Federal Legislation

Multiple bills have been introduced in the House and Senate, including:

- Sports Medicine Licensure Clarity Act (H.R. 302)
- Protecting Access to Care Act (H.R. 1215)
- Health Care Safety Net Enhancement Act (S. 527/H.R. 548)
- Saving Lives, Saving Costs Act (H.R. 1565)
- Good Samaritan Health Professionals Act (S. 781/H.R. 1876)

In June 2017, the House passed H.R. 1215, and most recently, the House Energy and Commerce Committee passed H.R. 1876 out of committee where it now awaits floor action.

State Activities

The **Pennsylvania Neurosurgical Society** has joined the AMA an the Pennsylvania Medical Association and others in an amicus brief challenging position taken by the plaintiff in the case *Mitchell v. Shikora et al.*, who contends that evidence concerning the known risks and complications of a surgical procedure are irrelevant as to the question of negligence. Following the Superior Court's decision in favor of Ms. Mitchell, the defendants appealed to the Pennsylvania Supreme Court. Court will consider the defendant's appeal only in regard to one issue: Whether the Superior Court's holding directly conflicts with the Pennsylvania Supreme Court's holdings in Brady v. Urbas, which permits evidence of general risks and complications in a medical liability claim? Amici support allowing general risks and complications evidence in medical negligence cases. Legislation is pending in **Kentucky** that would limit attorney fees, provide physicians with protections when they apologize to patients, and require affidavits of merit to ensure only legitimate malpractices move forward. In **Missouri**, legislation is pending to establish a three-year statute of limitations. Finally, a **North Dakota** judge recently struck down the state's \$500,000 limit on non-economic damages, finding that it violated equal protection guaranteed by the North Dakota constitution by arbitrarily reducing damages for people who suffer the most severe injuries.

Miscellaneous

The AMA just released the 2018 edition of "Medical Liability Reform – Now!" This publication includes background on the problems with the current system, proven solutions to improve the liability climate and a discussion of innovative reforms that could complement traditional MLR provisions. This comprehensive medical liability reform (MLR) compendium is accessible electronically at www.ama-assn.org/medical-liability-reform-now. The AMA also released three new research reports from its Health Policy department:

- Medical Liability Claim Frequency Among U.S. Physicians
- Professional Liability Insurance Indemnity Payments, Expenses and Claim Disposition, 2006-2015.
- Medical Professional Liability Insurance Premiums: An Overview of the Market from 2008 to 2017.

Emergency Neurosurgical Services Update

Congressional Activities

Working with other organizations interested in trauma and emergency care (Trauma Coalition), the AANS and CNS continue to advocate for legislation to fund and support programs aimed at improving emergency and trauma care services, including:

- Health Care Safety Net Enhancement Act (S. 527/H.R. 548)
- Good Samaritan Health Professionals Act (<u>S. 781/H.R. 1876</u>)
- Concussion Awareness and Education Act (H.R. 2360)

The Pandemic and All Hazards Preparedness Act (PAHPA), first created in 2006 to improve the nation's response to public health and medical emergencies, is up for reauthorization in 2018. Efforts to include the Good Samaritan Act within the PAHPA bill are underway, as well as additional monies for funding regionalize trauma systems. Additionally, the Military Injury Surgical Systems Integrated Operationally Nationwide (MISSION) to Achieve Zero Preventable Deaths Act (H.R. 880/S. 1022), which would assist U.S. military health care providers in maintaining a state of readiness by embedding military trauma teams and providers in civilian trauma centers, is passed the House on Feb. 26 and is pending action in the Senate. Finally, the recent omnibus spending bill included additional money for trauma-related activities including:

\$1.45 billion for Public Health Preparedness and Response programs;
\$6.75 million for Traumatic Brain Injury; and
\$9 million for Injury Control Research Centers

Regulatory Activities

A neurosurgeon member, **Michael Brisman**, MD, has requested that the AANS and CNS advocate that for emergency services provided by out-of-network providers HHS regulations should be changed to say that: "the insurance plan must pay the physician charge up to the 80th percentile of charges for that code and that geographic region based on the FAIRHEALTH database." Washington Office staff have had conversation with several medical societies, including the AMA, to work on this proposal. In addition, a resolution is pending before the Council of State Neurosurgical Societies (CSNS) on this topic.

Biomedical Research Update

Congress passed an omnibus spending bill in March, providing a total of \$78 billion for programs within the Department of Health and Human Services. Programmatic funding in the bill included:

- \$37 billion for the National Institutes of Health (NIH), an increase of \$3 billion above FY 2017 of which \$400 million (+\$140 million) was allocated to Brain Research through Application of Innovative Neurotechnologies (BRAIN) initiative; and
- \$334 million for the **Agency for Healthcare Research and Quality (AHRQ)**, which is \$10 million above the fiscal year 2017 enacted level.

On January 11, as part of the National Coalition for Heart Disease and Stroke, AANS/CNS staff met with several NIH personnel, including Walter Koroshetz, M.D., Director of the NIH National Institute of Neurological Disorders and Stroke (NINDS), to receive an update on the current research funding programs currently under way at NINDS.

Communications and PR Update

Communications Activities

Throughout the months of March (and part of April), Neurosurgery Blog is a spine-focus awareness campaign. To maximize attention on spine related issues, we planned our efforts around the 2018 Annual Meeting of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves. We will highlight these issues through: patient stories, epidemiology, economics, value, innovation and advocacy. In October and November, Neurosurgery Blog also hosted a regulatory relief awareness campaign. During this initiative, we shined a laser spotlight on a single issue, Physician Regulatory Relief: Breaking the Red Tape to Improve Patient Care. Through these and other efforts, Neurosurgery Blog: More Than Just Brain Surgery, has continued to ramp up its reporting efforts to include multiple guest blog posts from key thought leaders and members of the neurosurgical community this year. As of March 23, we have disseminated 333 blog posts on topics including regulatory relief, opioids, spine, and health reform in general. In an effort to continue building our online presence, Neurosurgery Blog recently unveiled an Instagram page.

In addition to the social media efforts, the DC office continues to implement traditional media/ communication efforts including Op Eds, letters to the editor, radio "tours" and desk side briefings with reporters. Since 2012, we have generated 168 traditional media hits reaching a circulation/audience of 13.6 million. Examples include:

- OpEd published in The Hill by Robert E. Heary, MD, titled "Efforts to Curb Opioid Misuse Must Preserve Patient Access to Medically-Necessary Opioids" Modern Healthcare article titled, "Docs worry CMS measures ping them for costs out of their control" (Rachel Groman quoted)
- Politico, piece titled, "Physicians wary of Medicare payments under Azar." (Katie Orrico quoted)
- Inside Health Policy piece titled, "House Passes Legislation to Repeal Independent Payment Advisory Board." (Ann Stroink, MD quoted)

We also issued press releases on the following topics:

	FDA Public Hearing on Opioid Use
	Neurosurgery 2018 Legislative and Regulatory Agenda
	MedPAC Proposal to Rebalance" Physician Fees
	House Passage of IPAB Repeal Legislation
•	MedPAC's Proposal to Eliminate MIPS
	Bipartisan Health Care Efforts
	Ways and Means Passage of IPAB Repeal Legislation

Accomplishments

We continue to expand our social media reach. In 2017, we had more than 170 million Twitter "touches" and nearly 10 million Facebook touches. We have nearly 100,000 regular Twitter followers, significantly dwarfing other medical groups that are bigger than us including the American College of Surgeons and American Academy of Orthopaedic Surgeons. With regard to our blog, to date, Neurosurgery Blog has accumulated over 133,171 page views from 75,656 users. Finally, our DC e-newsletter continues to have a consistent open rate, with about one-third of our members reading this publication.

AMA Update

The AMA House of Delegates (HOD) held its Interim meeting from Nov. 10-14, 2017 in Honolulu, HI. Our Delegation for the I-17 HOD Meeting included:

☐ Ann R. Stroink, MD, CNS Delegate, Delegation Chair

 Kenneth S. Blumenfeld, MD, AANS Delegate Maya Babu, MD, AANS Alternate Delegate/Resident & Fellow Section Delegate Krystal L. Tomei, MD, CNS Alternate Delegate/Young Physicians Section Delegate
Neurosurgery's delegates continue to take leadership roles at the AMA. Dr. Stroink is a member of Reference Committee F (which oversees AMA governance issues) for two years; Dr. Blumenfeld served on Reference Committee B (legislation); and Dr. Tomei is in her first year as an elected member of the AMA's Council on Medical Education (CME).
Resolutions of interest to neurosurgery included:
 Physician assistant independent practice (<i>AANS/CNS sponsored resolution</i>); Merit-Based Incentive Payment System/MACRA On-Call and Emergency Services Pay; Consultation Codes and Private Payers; Neuropathic Pain as a Disease; and Maintenance of certification fees.
The next meeting of the AMA will be held in June in Chicago, II.

Questions or Comments about this report should be directed to:

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2018 Legislative and Regulatory Agenda

The AANS and CNS released their <u>legislative and regulatory agenda</u>, which includes health policy action items that neurosurgeons plan to advance with Congress and the Trump Administration. Organized neurosurgery will be pursuing the following priorities:

- □ Improving the health care delivery system, including maintaining existing insurance market reforms and advancing solutions that will lower costs and expand choice. Additionally, to ensure that our nation's children have continuous health insurance coverage, Congress should reauthorize the Children's Health Insurance Program (CHIP).
- □ Supporting quality resident training and education by increasing the number of Medicarefunded residency positions and preserving the ability of surgeons to maximize education and training opportunities within the profession's current regulatory structures.
- □ Abolishing the Independent Payment Advisory Board (IPAB) because Medicare payment decisions in the hands of an unelected, unaccountable governmental body with minimal congressional oversight will negatively affect timely access to quality neurosurgical care for our nation's senior citizens and those with disabilities.
- ☐ Alleviating the medical liability crisis with the adoption of proven reforms that are in place in California and Texas.
- ☐ Continuing progress with medical innovation through the repeal of the medical device tax and by implementing the 21st Century Cures Act.
- ☐ Restructuring Medicare's quality improvement programs by streamlining the new Meritbased Incentive Payment System (MIPS), adopting specialty-specific quality measures and alternative payment models (APMs) and ensuring electronic health record (EHR) interoperability.
- □ Championing fair reimbursement and preserving timely access to care by maintaining a viable fee-for-service option in Medicare and by empowering patients and physicians to privately contract fee arrangements. Additionally, Medicare must maintain the 10- and 90-day global surgery payment package and minimize the burden of the global surgery code data collection initiative.
- Modernizing Medicare to a defined contribution system, to enhance beneficiary choice and ensure the viability of the program into the future.

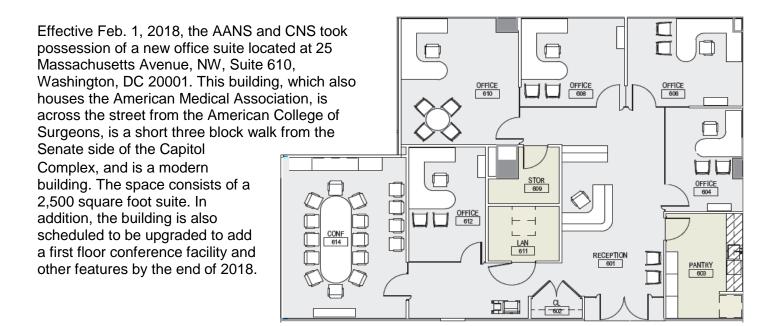
A Snapshot of Progress

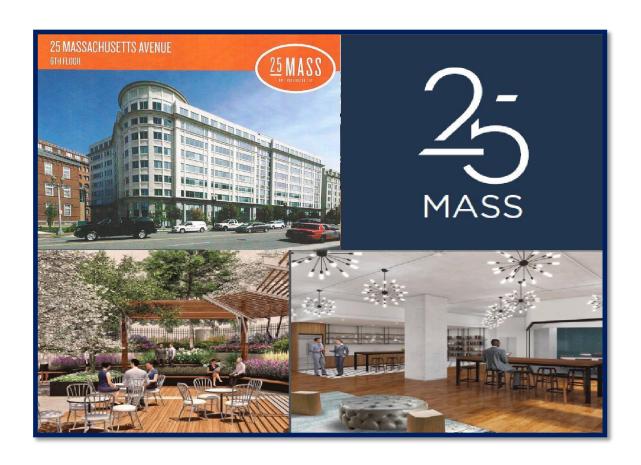
A quick summary is provides the current snapshot of the AANS/CNS Legislative and Regulatory Agenda and the progress made:

AGENDA ITEM	STATUS	
	American Health Care Act (H.R. 1628) passed the House on 5/5/17	
	 Continuing funding resolution (<u>H.R. 195</u>) reauthorized Children's Health Insurance Program (CHIP) for six years. Signed into law on 1/22/18 	_
Improve the Health Care Delivery System	 Bipartisan Budget Act (H.R. 1892) included an additional four years of CHIP funding. Signed into law on 2/9/18 	TOPPESS
	 Tax bill (H.R. 1) repealed the individual mandate to purchase health insurance. Signed into law on 12/22/17 	Billian Control
	 Continuing funding resolution (<u>H.R. 195</u>) suspended the Cadillac tax for an additional two years to 2022. Signed into law on 1/22/18 	
Support Quality Resident	Resident physician Shortage Reduction Act (<u>S. 1301</u>), <i>introduced</i> in the Senate, has 7 cosponsors	2
Training and Education	 Resident Physician Shortage Reduction Act (<u>H.R. 2267</u>), <i>introduced</i> in the House, has 78 cosponsors 	modi S
Abolish the Independent Payment Advisory Board (IPAB)	Bipartisan Budget Act (<u>H.R. 1892</u>) repealed the IPAB. <i>Signed into law</i> on 2/9/18	1
	Sports Medicine Licensure Clarity Act (<u>H.R. 302</u>) <i>passed</i> the House on 1/9/17	
	 Protecting Access to Care Act (<u>H.R. 1215</u>) passed the House on 6/28/17 	
	 Health Care Safety Net Enhancement Act (<u>S. 527</u>) introduced in the Senate, has 7 cosponsors 	
Alleviate the Medical Liability Crisis	 Health Care Safety Net Enhancement Act (<u>H.R. 548</u>) introduced in the House, has 61 cosponsors 	65
Choic	Saving Lives, Saving Costs Act (<u>H.R. 1565</u>) <i>introduced</i> in the House, has 33 cosponsors	20.Gi 3
	 Good Samaritan Health Professionals Act (<u>S. 781</u>) introduced in the Senate, has 6 cosponsors 	
	 Good Samaritan Health Professionals Act (<u>H.R. 1876</u>) introduced in the House, has 41 sponsors; passed House Energy and Commerce on 2/14/18 	
Continue Progress with Medical Innovations	 Continuing funding resolution (<u>H.R. 195</u>) suspended medical device excise tax for two years. Signed into law on 1/22/18 	1
	2018 MACRA-Quality Payment Program Final Rule provides greater flexibility, reduces complexity and minimizes potential penalties	
Restructure Medicare Quality Improvement	2018 Medicare Physician Fee Schedule Final Rule reduces PQRS reporting burden and minimizes penalties	_
Programs	 Bipartisan Budget Act (<u>H.R. 1892</u>) included additional flexibility to minimize penalties for years 2021-23 and eliminate the requirement that EHR standards become more stringent over time, while also maintaining EHR hardship exemptions. <i>Signed into law</i> on 1/22/18 	

AGENDA ITEM	STATUS	
Champion Fair Reimbursement	While CMS is moving forward with its global surgery data collection project, requiring neurosurgeons in Fla., Ky., La., Nev., N.J., N.D., Ohio, Ore. and R.I. to report data on post-op visits during the 10- and 90-day global period of certain procedures using CPT code 99024, it is not likely that any wholesale changes in global surgery fees will be forthcoming in 2019.	anogn SS
Modernize Medicare to a Defined Contribution System	House Speaker Ryan has indicated his desire to continue the conversation on how to improve the Medicare program	

Washington Office Relocation







Suite 610 Entrance
(The logos on the door are for illustrative purposes only and will be added at a later date)



Reception Area and 3 of 5 Offices



Director's Office



Conference Room





Kitchen



Copier and Work Space



Health Care Reform Update

Congressional Activities

With comprehensive health care reform off the table, Congress is focusing on bits and pieces.

Tax Bill

The tax bill had just a handful of provisions related to health care. On the consumer side, individuals will be able to deduce medical expenses for expenses exceeding 7.5% of adjusted gross income (2017 & 2018) and 10% beginning in 2019. The new law also eliminated the individual mandate to buy insurance staring in 2019. While not exactly living up to the Obamacare repeal and replace mantra, eliminated the individual mandate does strike a significant blow to a major structural element of the Affordable Care Act (ACA).

Children's Health Insurance Program

On Jan. 22, 2018, Congress passed <u>H.R. 195</u>, as amended, a continuing resolution to fund the federal government through Feb. 8. Included in this bill was a provision renewing the Children's Health Insurance Program (CHIP) — which provides coverage to 9 million children in families who earn too much qualify for Medicaid but cannot afford private insurance — for six years.

Medical Device Tax Repeal

The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on Dec. 18, 2015, included a two year moratorium on the medical device excise tax, enacted as part of the Affordable Care Act (ACA). As a result, the medical device excise tax did not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on Jan. 1, 2016, and ending on Dec. 31, 2017. Included in the Jan. 22, 2018 continuing resolution was a provision further suspending the medical device excise tax through 2019.

IPAB Repeal

The Independent Payment Advisory Board (IPAB) was created by the ACA and is a board of 15 unelected and largely unaccountable government bureaucrats whose primary purpose is to cut Medicare spending. Repealing the IPAB has been a top legislative priority of the AANS and CNS since its inception. After more than seven years of effort, Congress repealed the IPAB as part of the Bipartisan Budget Act (H.R. 1892) repealed the IPAB. President Trump signed the bill into law on Feb. 9, 2018.

Regulatory Activities

2018 Health Insurance Exchanges Insurer Availability

In the months leading up to the 2018 open enrollment period, there was widespread concern that the administration's lack of commitment to implementing the ACA, including ending federal funding for cost-sharing subsidies, would lead many insurers to exit the marketplaces. Some insurers, including large publicly traded companies like <u>Aetna</u> and <u>Humana</u>, did announce in early spring 2017 that they would leave some states or markets. However, every county ultimately retained at least one insurer, and <u>nearly half</u> of marketplace enrollees can choose among three or more insurers in 2018. Overall, insurer participation in the state-based marketplaces was more stable than in the federally facilitated marketplace.

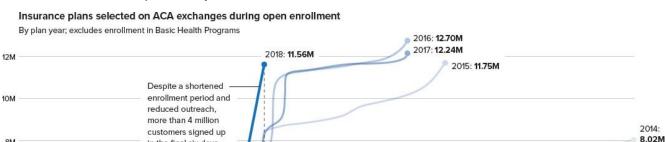
2018 ObamaCare Exchange Enrollment

8M

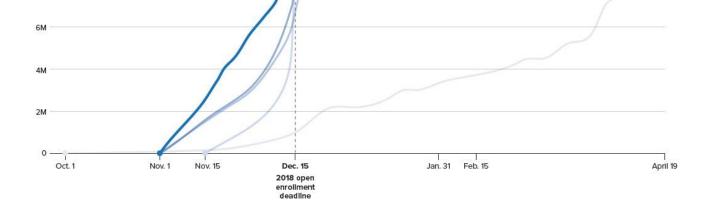
Approximately 8.8 million people selected or were automatically re-enrolled in plans using the HealthCare.gov platform during the 2018 open enrollment period.

State	Enrollment	State	Enrollment	State	Enrollment
Alaska	18,313	Louisiana	109,855	Ohio	230,127
Alabama	170,211	Maine	75,809	Oklahoma	140,184
Arkansas	68,100	Michigan	293,940	Oregon	156,105
Arizona	165,758	Missouri	243,382	Pennsylvania	389,081
Delaware	24,500	Mississippi	83,649	South Carolina	215,983
Florida	1,715,227	Montana	47,699	South Dakota	29,652
Georgia	480,912	North Carolina	519,803	Tennessee	228,646
Hawaii	19,799	North Dakota	22,486	Texas	1,126,838
lowa	53,217	Nebraska	88,213	Utah	194,118
Illinois	334,979	New Hampshire	49,573	Virginia	400,015
Indiana	166,711	New Jersey	274,782	Wisconsin	225,435
Kansas	98,238	New Mexico	49,792	West Virginia	27,409
Kentucky	89,569	Nevada	91,003	Wyoming	24,529

An additional 2.8 million enrolled through state exchanges. While some analysts had projected a shortfall of millions due to reduced federal outreach and a shortened sign-up period, a late surge brought the 2018 total in line with previous years.



in the final six days.



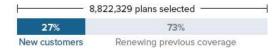
New Customers Continued to Flock to Healthcare.gov

Because federal outreach was sharply reduced — President Donald Trump's administration reduced funding for advertising by 90 percent, to just \$10 million — some advocates feared that Healthcare.gov would fail to attract newer customers.

Ultimately, new customers enrolled at a similar rate: 27 percent of sign-ups were new customers this year, compared to 32 percent in the previous year. In the final week alone, more than 1 million new customers signed up.

While the final enrollment tally exceeded expectations, there were still some indications that reduced federal outreach may have had an effect. Web traffic to the Healthcare.gov website was down by 34 percent compared to last year's open enrollment period, and the volume of calls to the Healthcare.gov call center was down by nearly 50 percent.

Enrollment using Healthcare.gov (39 states)

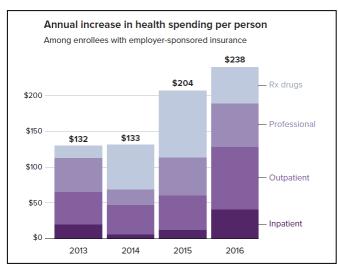


Volume of calls to Healthcare.gov call center



Health Care Costs Continue to Rise

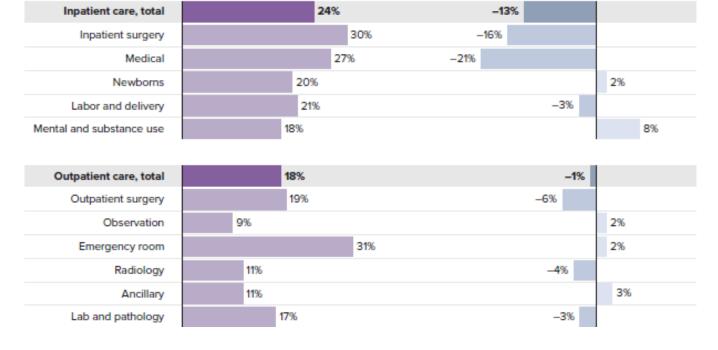
Using claims data from four major insurers, a new report by the Health Care Cost Institute says that increasing health care prices have driven Americans' health care spending to its highest level ever. Utilization of care — how often patients access services or purchase drugs — decreased overall. On average, enrollees with employer-sponsored insurance spent \$5,407 on health care in 2016, an annual increase of 4.6 percent. Of that total, about \$848 on average was spent out-of-pocket. Prescription drugs have accounted for a large portion of recent spending increases. Since 2012, the average price of brand-name drugs has increased by 110 percent, according to the report.

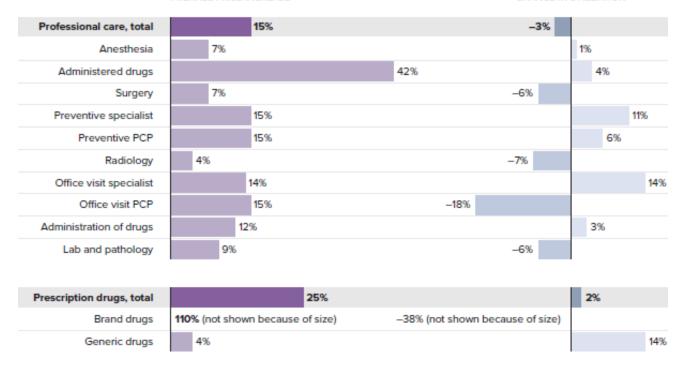


Below are charts depicting changes in health care prices and utilization, 2012-16, among enrollees with employer-sponsored insurance. Subcategories are ordered by total amount spent — highest to lowest.

AVERAGE PRICE INCREASE

CHANGE IN UTILIZATION



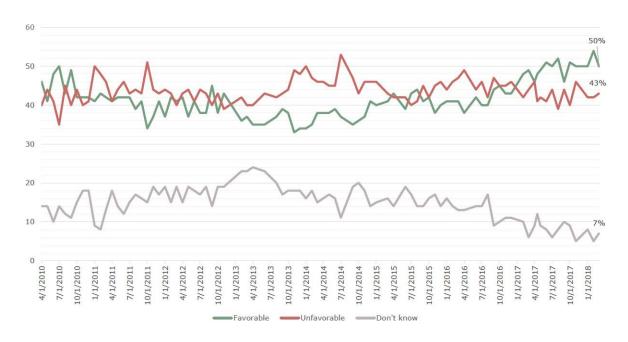


ACA Resources

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

Public Opinion Remains Split

Public opinion over ObamaCare has been split throughout its inception. The most recent Kaiser Family Foundation <u>tracking poll</u> from March conducted by the Kaiser Family Foundation, shows that adults now have more *favorable* (50%) rather than unfavorable (43%) opinion of the ACA.





Physician Regulatory Relief Update

HHS Physician Regulatory Relief Initiative

Patients over Paperwork Initiative

Picking up on the efforts of Dr. Price, following his resignation, CMS Administrator Seema Verma

launched the "Patients Over Paperwork Initiative," a crosscutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. This work is in accordance with the agency's strategic goals:

- 1. Empower patients and clinicians to make decisions about their health care.
- 2. Usher in a new era of state flexibility and local leadership.
- 3. Support innovative approaches to improve quality, accessibility, and affordability.
- 4. Improve the CMS customer experience.

Click here to learn more about Patients over Paperwork



The following chart depicts the progress we are making on key issues:

Issue	Status
Medicare legacy quality (PQRS, EHR/meaningful use, value – based payment modifier) program penalties	 CMS retroactively modifies 2016 PQRS, MU, and VBM policies to align with MIPS; changes will reduce penalties for physicians in 2018
Quality Payment Program (QPP) proposed rule	 Makes 2018 another transitional year Triples low-volume threshold exemption to \$90,000 or 200 Medicare beneficiaries Initiates virtual groups Helps small practices with exemption from EHR reporting and additional bonus points Postpones mandate for physicians to upgrade to 2015 edition certified EHRs Does not increase requirements for number of quality measures or data completeness Keeps cost category's weight lower than 30% (10% for 2018)



Issue	Status
Appropriate Use Criteria (AUC) for advanced diagnostic imaging	 CMS delays program until 2020 (original start date was Jan. 1, 2017) 2020 will be an educational and operations testing year during which Medicare claims will continue to be paid even if they do not correctly include required AUC consultation information.
Electronic Health Records	 Vendors must communicate to physicians the fees associated with EHR functions Law passed preventing vendors from data blocking Law passed requiring reduction of EHR burdens EHRs must now include enhanced interoperability technology and support for apps Physicians can now register complaints with an EHR product directly to the federal government for action
Medical Unique Identifier	CMS scrapped plans to require the unique identifier on administrative claims forms
Medicare audit reform	MACs begin to use targeted modeling for audits

House Ways and Means Committee Effort

As previously reported, the House Ways and Means Committee launched a "Medicare Red Tape Relief Project" last summary. The AANS and CNS

submitted comments on the following three priority topics:

Medicare Appropriate Use Criteria (AUC) for Imaging (Priority Issue #1)
 Medicare Global Surgery Data Collection (Priority Issue #2)

Medicare Access and CHIP Reauthorization
Act of 2015 (MACRA) Improvements (Priority Issue #3)

MEDICARE RED TAPE
RELIEF PROJECT

Encouraging doctors, hospitals, nurses, and other health care providers to tell us exactly what's working and what's not.

Taking action to cut through the red tape and improve patient care.

We also joined the Alliance of Specialty Medicine in submitting comments on the following topics:

Two-midnight rule;
Narrow networks;
Program integrity initiatives;
Virtual groups under MIPS;
Drug compounding;
MACRA transition policies;
Appropriate Use Criteria for Advanced Imaging;
Adjusting MIPS for Part B drug costs;
Prior authorization; and
Use of Certified EHR Technology

The committee received hundreds of submissions, and finally, on March 15, 2018, the House Ways and Means Committee convened a "Red Tape Relief Roundtable" to discuss ways in which Congress and/or the Centers for Medicare & Medicaid Services can provide regulatory relief for physicians. Washington Office staff, represented the Alliance of Specialty Medicine at the meeting. We gave testimony on the four topics: (1) prior authorization; (2) mandatory consultation with appropriate use criteria before

ordering diagnostic imaging; (3) narrow networks; and (4) Medicare audit programs and the local coverage determination process.

Members of Congress Attending

Peter Roskam (R-III.) Chair, Health Subcommittee Eric Paulsen (R-Minn.)
Pat Meehan (R-Penn.)
Tom Reed (R-N.Y.)
Mike Kelly (R-Penn.)
Lynn Jenkins (R-Kan.)
Adrian Smith (R-Neb.)

Tom Rice (R-S.C.)
Diane Black (R-Tenn.)

Also, while not at the discussion table, Ways and Means Committee chair, Kevin Brady (R-Texas), was in the Committee room for a little bit.

Invited Organizations

Alliance of Specialty Medicine
American Academy of Family Physicians
American College of Cardiology
American College of Emergency Physicians
American College of Physicians
American College of Surgeons
American Medical Association
American Medical Group Association
Medical Group Management Association
National Association of ACOs

Topics Discussed

A wide-variety of topics were discussed. Those most often mentioned were complaints about **prior authorization**, the need to harmonize and minimize the **reporting burdens of the Merit-based Incentive Payment System** (MIPS), and the redundancy of the program mandating the consultation of **appropriate use criteria** before physicians can order advanced diagnostic imaging. The complete list of topics follows:

П	Accelerate adoption of Advanced Alternative Payment Models (A-APMs)
	Reduce paperwork and rules related to the prescribing of diabetes testing strips
	Harmonization reporting under MIPS
	Improve and simplify MIPS scoring and allow credit across multiple MIPS categories (e.g., if you
	are reporting through a registry, you should get credit for quality, EHR and improvement categories)
•	Reduce MIPS reporting requirements—fewer measures, consistent reporting period across MIPS
	categories for 90-days
•	Require EHR systems to be interoperable and simply require physicians to "attest" to using EHR to satisfy MIPS/meaningful use requirements
	Eliminate routine use of prior authorization and other utilization management tools
	Adopt electronic prior authorization for medications and all other medical services
	Require CMS to implement uniform guidance for prior authorization
	Allow access to medical records for patients with substance abuse to better address opioid epidemic
	Eliminate separate appropriate use criteria program and incorporate AUC into MIPS

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Due to votes, the roundtable was cut short and there was no opportunity for the planned question and answer session. However, Chairman Roskam pledged to convene Part II to reconvene the groups for additional engagement. In addition, the Alliance of Specialty Medicine will be meeting with Chairman Roskam next week for an additional hour-long session on regulatory relief.				
e nd				
After the release of the principles, American's Health Insurance Plans (AHIP) and Blue Cross Blue Shield Association (BCBSA) requested meetings with the AMA to discuss the principles. Follow-up discussions led to the creation of a small workgroup of representatives from the AMA, AHIP, BCBSA, American Hospital Association (AHA), American Pharmacists Association (APhA), and Medical Group Management Association (MGMA). The goal of this activity was to reach agreement on actions to meaningfully improve prior authorization programs.				
ion				

While there are many remaining concerns on this issue this is an important initial step toward right-sizing prior authorization programs.

Click here to access the "Consensus Statement on Improving the Prior Authorization Process."

Regulatory Relief Coalition

The physician Regulatory Relief Coalition, of which the AANS and CNS are members, has also been pressing for prior authorization reform. The initial focus of the coalition's efforts has been prior authorization in Medicare Advantage plans. The coalition commissioned a legal memo to help frame the issues for discussion with CMS. On Nov. 28, 2017, the group met with CMS Deputy Administrator, **Demetrios Kouzoukas**. In preparation for this meeting, Washington Office staff worked with NERVES to obtain some examples where prior authorization in Medicare has been a problem. Mr. Kouzoukas listened carefully to our concerns and we followed-up with additional information. In addition, the coalition is again meeting with CMS staff on Feb. 5. We hope to encourage CMS to issue some uniform guidance/standards for Medicare Advantage plans to follow so as to minimize the frequency and burden of prior authorization.

Food and Drug Administration

On Feb. 5, 2018, the AANS and CNS submitted comments to the Food and Drug Administration in response to the agency's request for suggestions on how to reduce regulatory burden. In our comments we urged the FDA to:

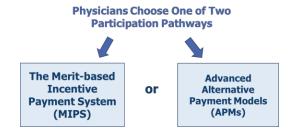
Revise its 2014 guidance on off-label promotion to preserve access to truthful scientific
information from manufacturers;
Simplify the rules for investigator-sponsored Investigational Device Exemption (IDE) submissions
Simplify and streamline the paperwork requirements for physician reviewers/experts; and
Expand the use of physician-led clinical data registries.



Medicare Access and CHIP Reauthorization Act (MACRA) Update

Background

In November 2017, CMS released the <u>final rule</u> implementing the second year (2018) of the Medicare <u>Quality Payment Program</u> (QPP). Mandated by the Medicare Access and CHIP Reauthorization Act (MACRA), the QPP provides a new framework for rewarding the delivery of quality patient care through two pathways: the <u>Merit-based Incentive Payment System</u> (MIPS) or through <u>Advanced Alternative Payment Models</u> (Advanced APMs).



The second year of the QPP will largely serve as another transition period. Many physicians and other health professionals who bill Medicare won't have to participate in 2018 and hardly any are projected to receive a penalty that will affect their payment in 2020. A fact sheet regarding the 2018 QPP final rule is available here and a summary provided below. Click here for a more detailed summary prepared by Hart Health Strategies. CMS continues to post new guidance documents and other informational resources to the QPP Resources Library. Clinicians are encouraged to regularly check the QPP Resources Library for updates.

In the rule, CMS estimates that physicians who perform well under MIPS are set to receive a mere 0.9% bonus in 2018 equaling to \$618 million. At the same time, the Medical Group Management Association (MGMA) found that the total administrative costs for physicians and physician practices is about \$300 billion per year and that one-half of surveyed practices are spending \$40,000 or more to comply with just the quality reporting programs.

Merit-based Incentive Payment System (MIPS)

Eligible Clinicians

In general, clinicians eligible to participate in the 2018 QPP include physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists. There are three **exemptions** for 2018:

П	Clinicians who are new to the Medicare program in 2018;
	Clinicians who bill Medicare \$90,000 or less in 2018 (and increase from \$30,000 in 2017) or who
	provide care for 200 or fewer patients in 2018 (an increase from 100 patients in 2017);
	Clinicians who are determined to be Qualifying Participants (QP) in an Advanced APM in 2018.
	, , ,

General 2018 Participation Estimates

CMS estimates that only 37% of clinicians who bill Medicare will be included in MIPS in 2018, largely as a result of its decision to triple the low-volume threshold for the second year of the program.

The vast majority (97%) of MIPS eligible clinicians are anticipated to receive positive or neutral
MIPS payment adjustments for the 2020 MIPS payment year, with only 2.9% receiving negative
MIPS payment adjustments.
In 2020, based on 2018 performance, about 95% of MIPS eligible neurosurgeons are expected to
receive a neutral or positive adjustment in 2020 based on 2018 performance, about 70% are
expected to be eligible for exceptional performance bonus money authorized under MACRA, and
about 5% are expected to receive a negative adjustment.

CMS has not yet updated its online MIPS Participation Status Tool with data regarding 2018 eligibility. The tool will eventually allow clinicians to enter their NPI and to find out whether they are included or exempt from MIPS in 2018. It also provides information about any special status designations (e.g. small or rural practice). These designations typically do not exempt clinicians from the entire program, but might provide special reporting and scoring accommodations for select performance categories.

Eligible clinicians who choose not to participate in MIPS in 2018 will receive the maximum penalty in 2020, which is 5%. When the program is fully implemented in 2022, maximum penalties will increase to 9%, which is less than the penalties that would have been applied under legacy programs in 2019 and beyond.

Performance Categories

Physicians opting to participate in MIPS will be scored based on their performance in four categories:

П	Qua	ality
	Q G	anty,

□ Resource Use/Cost;

 Advancing Care Information (ACI) — formerly known as meaningful use of electronic health records); and

☐ Clinical Practice Improvement Activities (IA)

A single MIPS composite performance score will factor in performance in these four weighted performance categories on a 0-100 point scale. For the 2018 program/2020 payment year, the category weights are as follows:

Performance Category	2019 Payment Year	2020 Payment Year	2021 Payment Year and beyond
Quality	60%	50%	?%
\$ Resource Use/Cost	0%	10%	?%
Advancing Care Information (EHR)	25%	25%	25%
Clinical Practice Improvement Activities	15%	15%	15%

In some instances, CMS may reweight these categories in certain limited circumstances where physicians do not have the opportunity to meet the requirements of a particular category.

For 2018, CMS also finalized a higher overall MIPS performance threshold of 15 points (versus 3 points, which is the minimum number of points needed in 2017 to avoid a penalty in 2019). There are multiple ways in which a clinician can meet the 15 point threshold, such as submitting the maximum number of improvement activities OR full participation in the quality category (see requirements below). However, unlike in 2017, clinicians can no longer avoid a penalty by simply reporting a single measure or single Improvement Activity. CMS also maintains its performance threshold for exceptional performance at 70 points.

Data Requirements

eme largery mamamed data requirements for zero.	CMS large	ly maintained	data requirement	s for 2018:
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- □ **Quality.** The following changes in the quality category were made:
 - For 2018, CMS maintains that to qualify for the maximum quality performance score, clinicians must report on six quality measures, or one specialty-specific or subspecialtyspecific measure set. Reported measures must include one outcomes or high priority measure.
 - CMS <u>increased</u> the data completeness threshold from 50% to 60% for 2018. This means that when reporting a measure, a clinician or group must report a selected measure for at least 60% of all patients to which the measure applies (this threshold applies only to Medicare patients for claims-based reporting, but to all-payer patients for all other reporting mechanisms, such as registry and EHR).
 - CMS also <u>expanded</u> the quality performance period for 2018, requiring clinicians to report on measures for the entire calendar year, rather than for a minimum of 90 days.
 - CMS also modified its quality measure scoring policy for 2018. A clinician will continue to get at least three points for a quality measure, except in the case that he/she does not meet the 60% data completeness threshold. In that case, the clinician will get one point on the measure (unless he/she is part of a small practice, in which case he/she would still receive three points on the measure). The clinician can get more than three points (up to 10 points) based on performance for each quality measure if all three of the following are true: the clinician meets the data completeness threshold, the clinician reports on at least 20 patients, and CMS is able to calculate a measure benchmark.
 - Bonus points will continue to be available for those who report additional outcomes and high priority measures, and those who rely on end-to-end electronic reporting to submit measures (e.g., using certified HIT to capture and electronically provide to a registry clinical data for the measures).
 - For the first time in 2018, CMS will incorporate both achievement and year-to-year improvement in a clinician's quality score. Improvement points will be available almost like bonus points in that they are capped and cannot result in a lower overall score.
 - For the 2019 performance year, CMS will allow clinicians to combine measures reported across different reporting mechanisms (currently, CMS will score measures reported via claims and registry separately and use the higher of the two scores). CMS clarified that when this new policy begins, it will validate the availability and applicability of other quality measures only with respect to the data submission mechanisms that are used. For example, if a clinician submits via claims, CMS would only validate against claims measures and not evaluate whether there were potentially other applicable measures available via registries.

Improvement Activities (IAs)	 Few changes 	were made	e to the clinication	al improvement	activities
category:					

- For 2018, eligible clinicians must continue to attest to having completed up to four mediumweighted or two high-weighted clinical practice improvement activities, as in 2017. Smaller practices must only attest to up to two activities to receive the maximum score in this category.
- CMS approved 21 new activities, bringing the total inventory to over 100 available activities (new activities are listed <u>here</u> and include completion of CME).
- The Improvement Activity performance period will remain 90-days for 2018.
- Advancing Care Information (ACI or meaningful use of EHRs). The following policies for EHR use will include:
 - This category will continue to be composed of a base score (based simply on the reporting of specific measures), a performance score, and bonus points.
 - While clinicians may use either 2014 or 2015 Edition CEHRT for 2018, those who adopt 2015 Edition are eligible for additional bonus points.
 - Eligible clinicians will continue to be required to report on four to five EHR use-related measures (depending on which edition CEHRT is used). However, CMS finalized exclusions to the measures associated with the Health Information Exchange and Electronic Prescribing objectives required for the base score, which will apply retrospectively beginning with the 2017 performance period.
 - At the request of many specialty societies, CMS also finalized that a MIPS eligible clinician may earn 10 percentage points (rather than 5) in the performance score for reporting to any single public health agency or clinical data registry for purposes of the Public Health and Clinical Data Registry Reporting Objective, regardless of whether an immunization registry is available to the clinician. CMS also finalized that a MIPS eligible clinician would not receive credit under both the performance score and bonus score for reporting to the same agency or registry.
 - CMS also expanded the definition of hospital-based clinicians for 2018 to include those with 75% or more of professional services in the following sites of service: inpatient hospital (POS 21), on-campus outpatient hospital (POS 22), off-campus outpatient hospital (POS 19), or emergency room (POS 23) setting. Those who meet this definition are exempt from the ACI category in 2018, but may voluntarily choose to submit data for credit.
 - CMS also finalized a separate ACI exemption for those who furnish 75% or more of their covered professional services in ambulatory surgical centers or ASCs (POS 24). However, this policy applies retrospectively, starting in 2017.
 - CMS finalized an ACI Significant Hardship Exception for MIPS eligible clinicians in small practices.
 - The ACI performance period will remain 90 days for 2018.
- □ **Cost**. Finally, with regard to cost/resource use, CMS adopted the following policies for 2018:
 - Much to the surprise of organized medicine, CMS decided to weigh this category at 10% (rather than 0% as original proposed) for 2018 in order to ease the transition to 2019, when CMS is required to weigh the category at 30 percent. Unfortunately, the category will consist of the Medicare Spending Per Beneficiary (MSPB) measure and Total Per Capita Cost (TPCC) measures used under the Value-Based Payment Modifier (VM) and being calculated based on claims for confidential feedback under MIPS in 2017:
 - MSPB measure: evaluates Part A and B costs spanning an episode defined as three days prior and 30 days after an inpatient hospitalization. Beneficiaries are attributed

- to the clinician that provided the plurality of all Part B services during the inpatient hospitalization, including day of admission.
- TPCC measure, evaluates all Medicare Part A and B costs associated with any beneficiary over a year. This measure continues to rely on a 2-step attribution methodology triggered by the clinician that provides the plurality of primary care services (although CMS made some modifications to the primary care services definition so that it now includes transitional care management (TCM) codes (CPT codes 99495 and 99496) and the chronic care management (CCM) code (CPT code 99490)).
- Clinicians will only be scored on these measures if they are attributed a sufficient number of patients. For the TPCC measure that is 20 patients, which is the same as under the VM. For the MSPB, its 35 patients, which is a significant drop from under the VM, when it was 125 patients. As a result, more physicians could be held accountable for this measure.
- Another notable difference between the VM and MIPS cost measures is that CMS will evaluate clinicians at the individual whereas the VM only relied on group analyses. As such, if a clinician opts to participate in MIPS as an individual, he/she might not have a sufficient number of cases attributed under these measures. However, if he/she is part of a TIN that opts to participate at the group level, the group could meet the case minimum since CMS will add up all patients attributed to each individual member of the group.
- If a clinician is not attributed a sufficient number of patients under both of these measures, the weight of the cost category will be redistributed to the quality category. If CMS is able to score a clinician on only one of these measures, then his/her performance on that single measure will make up the entire cost category score.
- CMS is also working with CMS and Acumen to develop more granular episode-based cost measures that CMS is hoping to add to the cost category of MIPS as early as 2019. See Quality Update for more information on this effort.

Other Policies

Virtual Groups. 2018 will be the first year that clinicians in TINs with less than 10 eligible clinicians can come together to form a virtual group for purposes of participating in MIPS. Virtual groups will essentially be treated as a regular group under MIPS. There are no restrictions in terms of the overall size of the virtual group nor any restrictions regarding its makeup, such as geographic location of practices or mix of specialties. However, CMS sets forth specific criteria related to the formal written agreements that must exist between the members of the group and the election process, which must occur before Dec. 31, 2017 for purposes of the 2018 performance year.
Facility-Based Measurement . CMS decided to delay implementation of facility-based measurement until the 2019 performance period. Under this policy, clinicians will be able to opt to have their MIPS quality and cost categories scored based on the performance of the facility in which they most often practice. CMS had originally intended to tie this to Hospital Value-Based Purchasing Program performance, but decided to further evaluate this decision over the next year.
Complex Patient Bonus. CMS finalized a complex patient bonus based on medical complexity, as measured through Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients with dual eligible status. This bonus will be subject to a 5-point cap.

Submitting MIPS Data

Under MIPS, physicians will continue to have multiple methods for providing data to CMS, whether participating as individuals or as groups.

For physicians submitting data as an <u>individual</u>, payment adjustments will be based on individual performances. An individual is defined as a single National Provider Identifier (NPI) tied to a single Tax Identification Number. These physicians will send individual data for each of the MIPS categories through the routine Medicare claims process, a certified electronic health record, registry or a qualified clinical data registry.

If physicians submit with a **group**, the group will get one payment adjustment based on the group's performance. A group is defined as a set of clinicians (identified by their NPIs) sharing a common Tax Identification Number, no matter the specialty or practice site. Group-level data for each of the MIPS categories will be sent to CMS through the CMS web interface or a third-party data-submission service such as a certified electronic health record, registry, or a qualified clinical data registry.

Performance Category	Individual Reporting Data Submission Mechanisms			
Quality	ClaimsQCDRQualified registryEHR	 QCDR Qualified registry EHR CMS Web Interface (groups of 25+) CMS-approved survey vendor for CAHPS for MIPS (must be reported w/ another data submission mechanism) Administrative claims (for all-cause hospital readmission measure – no submission required) 		
\$ Resource Use/Cost	 Administrative claims (no submission required) 	Administrative claims (no submission required)		
Advancing Care Information (EHR)	AttestationQCDRQualified registryEHR	 Attestation QCDR Qualified registry EHR CMS Web-based Portal (expected in early 2018) 		
Clinical Practice Improvement Activities	 Attestation Qualified Clinical Data Registry Qualified registry Electronic Health Record 	 Attestation Qualified Clinical Data Registry Qualified registry Electronic Health Record CMS Web-based Portal (expected in early 2018) 		

In January 2018, CMS launched a new QPP Data Submission Portal that clinicians and 3rd party vendors, such as Qualified Clinical Data Registries (QCDRs), can use to submit select data to CMS for 2017 and to track their performance in certain categories of MIPS. The data submission deadline for the 2017 performance year is March 31, 2017. Additional information about the portal, including a fact sheet and instructional videos, is available here.

CMS expects to make more detailed performance feedback available to clinicians through the QPP portal in mid-July 2018.

MIPS Score and Payment Adjustment

MIPS is budget neutral, similar to the VM. The downward adjustment is capped each year and a scaling factor applied to ensure upward adjustments equal downward adjustments. Unlike the VM, clinicians with a final score at or above a set composite performance threshold (which was increased to 15 points for 2018, as described earlier) will receive a zero or positive MIPS adjustment factor on a linear sliding scale such that a MIPS adjustment factor of zero percent is assigned for a final score at the threshold and an adjustment factor of the applicable percent is assigned for a final score of 100.1

There is also additional funding set aside for each of the years 2019 through 2024 for clinicians with exceptional performance. As mentioned earlier, CMS set the *additional* performance threshold for the 2018 performance year at 70 points. Thus, clinicians with final composite MIPS score above 70 points are eligible for the exceptional bonus. These clinicians receive a MIPS upward adjustment, plus an additional payment adjustment factor for exceptional performance (capped at 10%).

Automatic Extreme and Uncontrollable Circumstances Policy

The 2018 QPP final rule also included an Automatic Extreme and Uncontrollable Circumstances policy for the 2017 MIPS performance period to account for recent hurricanes and other disasters that occurred in 2017. Clinicians in the geographic areas impacted by these disasters will be automatically protected from penalties under MIPS and won't have to file any request to receive this special treatment since CMS will determine if clinician is in an impacted area based on the practice location address listed in PECOS. Note that this policy only applies to individuals and not groups. An individual will avoid the penalty if they do not submit any data or submit data on only one performance category for 2017. If the individual submits data on two or more performance categories, then the clinician will be scored on their data submissions under the normal policies of MIPS.

CMS Study on Burdens Associated with Quality Reporting

For 2018, CMS also will increase the sample size of a study to examine the challenges and costs of reporting quality measures. This study will help CMS learn "the root causes of clinicians' performance-measure data-collection and data-submission burdens and challenges that hinders accurate and timely quality-measurement activities."

MACRA Quality Measure Development Funding

In March 2018, CMS announced that it will award up to \$30 million in grant funding (with a \$6 million award ceiling) to clinical specialty societies, clinical professional organizations and independent research organizations to develop quality measures. MACRA authorizes \$15 million for each of fiscal years 2015 through 2019, to fund quality measure development and related activities. The funding will be used for developing, improving, updating or expanding quality measures for use in the QPP. CMS will prioritize the development of outcomes measures, such as patient-reported outcomes and functional status measures, as well as measures of appropriate use of services, such as measures of overuse Applications are due May 2, 2018, and awarded projects expected to begin in early August 2018. The AANS and CNS have decided that new measure development for purposes of the QPP is not a priority at this time given the newness of the program and its evolving rules. As such, it will not be applying for this funding at this time.

Advanced Alternative Payment Models

Providers who receive a substantial portion of their reimbursement or see a substantial number of patients under what CMS designates as an "Advanced APM" are exempt from MIPS. These "Qualifying

¹ Under the VM, a clinician is determined to be either a low or high performer based on whether their quality or cost scores are one standard deviation below/above the national mean. As such, only outliers are directly impacted and everyone else is considered "average" and receives no payment adjustment.

Participants" (QP) are eligible for a 5% bonus payment in 2020 and, later, an accruing reimbursement differential from their non-Advanced APM colleagues.

One of the key criteria by which an APM is determined to be "Advanced" is that the participating provider must bear more than nominal risk under the reimbursement model. In the final rule, CMS maintains as a standard for 2018 a potential downside of 8% of all Medicare reimbursements or 3% of the expected expenditures for which the provider is responsible under the APM itself.

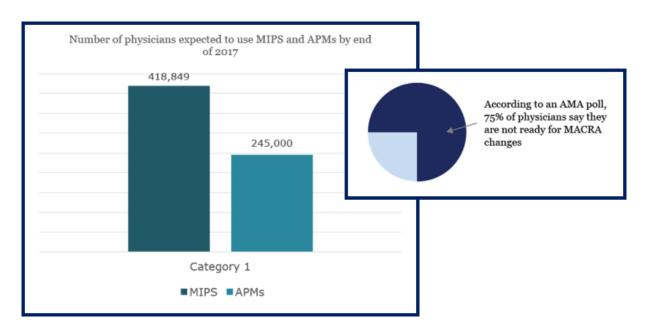
To minimize reporting burden, CMS also maintains for 2018 special policies that would give clinicians credit under MIPS when they participate in certain APMs that hold participants accountable for cost and quality, but do not meet the threshold to be considered a QP. These are referred to as MIPS APMs and participants in MIPS APMs receive special MIPS scoring under the "APM scoring standard." Most Advanced APMs are also MIPS APMs, so that if an eligible clinician participating in the Advanced APM does not meet the threshold to become a QP for a year, the eligible clinician will be subject to MIPS, but will receive special scoring accommodations that recognize quality improvement efforts already being performed through the APM and minimize duplication of effort. For example, participation in a MIPS-qualifying APM will automatically give a clinician full credit under the clinical practice improvement activities (IA) performance category.

Additional information about the requirements for this track is available here and discussed below. In February 2018, CMS released a list of APMs that it has determined to be MIPS APMs or Advanced APMs. CMS also has a QP Lookup Tool that clinicians can use to determine whether they qualify for QP status and are thus exempt from MIPS. As of March 2018, this tool still pertains only to 2017 status.

CMS estimates that between 185,000 and 250,000 eligible clinicians will become QPs in 2018. These QPs will be exempt from MIPS in 2018, and qualify for a lump sum incentive payment based on five percent of their Part B allowable charges for covered professional services.

Physician Readiness

It's been two years since MACRA was passed, and around 75% of physicians say they are not equipped for the changes coming. A key reason some are struggling to prepare for implementing MACRA's QPP is that EHR vendors have not been ready to make the changes. For others, the issue isn't whether their vendor is ready, it's if they can afford one in the first place.



AANS/CNS Advocacy

AANS/CNS Comments

In January 2018, the AANS and CNS submitted <u>comments</u> to CMS on its 2018 QPP Final Rule. The letter thanked CMS for extending many transition year policies to year 2 of the program, but voiced concern about ongoing, unnecessary complexity; the need for enhanced transparency; and related concerns specific to the QCDR measure approval process. The AANS and CNS also helped prepare and signed on to comment letters submitted by the <u>Alliance of Specialty Medicine</u> and the <u>Physician Clinical Registry Coalition</u> (PCRC). The PCRC letter focused more exclusively on polices and suggestions that would impact the use of registries under MIPS.

Legislative Corrections

The AANS and CNS also have been working with the AMA and the Alliance to develop a set of legislative changes to MACRA to present to members of Congress and their staff. While CMS has offered proposals that address many implementation concerns, there are other ongoing issues that cannot be addressed through regulatory action alone. Although there is little Congressional interest in re-opening MACRA, the plan is to frame these changes as necessary to allow MACRA to succeed, and for legislators to get ahead of the problem.

The <u>Bipartisan Budget Act of 2018</u>, enacted in early February 2018, responded directly to our concerns by adding much-needed flexibility to MIPS. The AANS and CNS supported the following changes included in the bill:

Elimination of MIPS payment adjustment impact on Part B drugs
More gradual increase of threshold for avoiding a MIPS payment penalty
Slower transition to counting cost measures in MIPS total score

Additional details regarding these changes are available in this <u>summary</u>.

In November, a group of Senators long critical of Medicare's EHR meaningful use policies, led by Sen. **John Thune** (R-S.D.), and including Sen. **Bill Cassidy**, MD (R-La.), also reintroduced legislation (<u>S. 2059</u>), that would roll back meaningful use requirements in several ways. The bill would create a permanent 90-day reporting period for the MIPS ACI category, remove its all-or-nothing scoring approach to scoring, and expand hardship exemptions. One section of the legislation eliminates part of the 2009 HITECH Act that requires the HHS secretary to create "more stringent measures of meaningful use" over time. A companion to that section (<u>H.R. 3120</u>) cleared the House Energy and Commerce Committee earlier this fall.

AMA-Specialty Society MIPS Workgroup

Washington Office staff continue to participate on an AMA MIPS workgroup, which was created at the direction of the AMA MACRA Task Force, of which the AANS and CNS are members. The purpose is to have an ongoing collaboration between the AMA, national specialty and state medical societies to provide input to CMS regarding the implementation of MACRA's MIPS and APM payment programs. Earlier in the year, the workgroup provided CMS with suggested regulatory changes that could improve the QPP. The AANS and CNS were pleased to see most of its priorities reflected in the 2018 proposed and final rules. More recently, the AMA MIPS workgroup has been working to develop proposals to streamline the program and make it more meaningful and less burdensome to clinicians. The overall strategy focuses on increasing opportunities for clinicians to get credit across multiple categories for a single set of actions; applying all extra/special status points at the composite score level rather than at the individual measure or performance category level to keep things simpler; eliminating the use of percentages and shifting to a more concrete point system; and adopting minimum threshold "reporting" requirements/points, with the option of earning more based on performance/achievement.

The ideas have been shared with CMS. Hopefully the agency will incorporate our suggested modifications in the 2019 proposed rule, which will be released in June or July.

MedPAC Recommendations

Despite reservations from several of its members, the Medicare Payment Advisory Commission (MedPAC) in January 2018 agreed to call on Congress to kill MIPS and replace it with a sweeping new plan that would base payment adjustments on large-scale application of population measures, such as potentially preventable admissions and emergency room visits. These recommendations were formalized in a report released in March 2018.

Due in part to heightened concern from several commissioners, the official recommendation is relatively general and would require further development if Congress unexpectedly adopts it. However, the basic concept remains unchanged, which is to replace the 300 or so MIPS condition-oriented quality measures with eight or nine claims-calculated measures that would be applied uniformly to physician groups or health systems that are large enough to make this concept statistically viable. Those that did not find and sign up with a group on their own would have the option of participating in regional groups established by the CMS. To induce movement into this so-called Voluntary Value Program (VVP), the Commission had tentatively agreed to include a mandatory withhold from Medicare payments. Physicians who did not move into a VVP-type plan would forfeit the withhold. Those who did participate in the VVP would receive positive or negative payment adjustments based on how their performance on population-based measures compared with that of other groups. Whether a withhold would be required and exactly how big it might be are uncertain.

MedPAC staff had laid out an "illustrative" plan using a 2% withhold. In earlier meetings, a number of commissioners had argued that 2% was too small. At the January meeting, several commissioners expressed concerns with a withhold, however, and some wondered if a withhold could be avoided altogether by co-opting the \$500 million authorized for "exceptional" performers in MIPS. Exactly how big the VVP groups would need to be is also unclear. MedPAC staff has argued that they could be created by physician independent practice associations, county medical societies, hospital medical staffs or virtual groups. The intent, as expressed by several commissioners, is to force physicians to turn quality and efficiency improvement into "a team sport" and to create a system where beneficiaries would essentially be choosing between health systems rather than individual physicians.

MedPAC staff and commissioners argue that MIPS is too complex and administratively burdensome, relies too much on process measures that must be reported by physicians, has too many of these measures, and will reward or punish physicians based on very small differences in performance. They are also concerned that the possibility of very large MIPS bonuses will deter physicians from moving into Advanced APMs, which they believe provide more incentives for cost-effective care.

Kate Goodrich, MD, chief medical officer and director of the CMS Center for Clinical Standards and Quality, said MedPAC's draft recommendations are "intriguing." However, she said the recommendations from the Medicare Payment Advisory Commission would "certainly require a complete legislative change."

Leading up to this decision, the Alliance of Specialty Medicine sent a <u>letter</u> to MedPAC, voicing sharp criticism for its forthcoming recommendations to eliminate MIPS in favor of a new Voluntary Value Program (VVP) and push physicians into APMs. The letter noted that APMs are not available for the vast majority of specialists and that population-based measures are ill-suited for specialty medical care. It also noted that members of the Alliance have made significant investments in developing specialty-focused quality measures and establishing qualified clinical data registries to deepen their understanding of complex medical conditions and improve the value of care they deliver to all patients, including Medicare beneficiaries. It reminded MedPAC that concerns with the MIPS program are being addressed by the Medicare agency and Congress, in conjunction with medical community. The AANS and CNS

issued a <u>press release</u> to bring attention to this letter, which resulted in several health care/Congressional trade press articles covering the story.

The Alliance also met with MedPAC Commissioner **David Nerenz**, PhD, who is the Director of the Center for Health Policy and Health Services Research at the Henry Ford Health System in Detroit, as well as Director of Outcomes Research at the Henry Ford Neuroscience Institute and Vice Chair for Research in the Department of Neurosurgery at Henry Ford Hospital. Dr. Nerenz, an ally of neurosurgery and the Alliance, also has very serious concerns about the VVP, including the fact that MedPAC has not yet talked about the necessary work that would go into making this type of group level analysis function. "Good performance doesn't just fall out of the sky, you have to do things. And just putting people together and saying they're a group doesn't accomplish that, so I think there's got to be a lot more attention to that," Nerenz said. There are also costs to getting such a group to function well, he added. Nerenz said he didn't see evidence that beneficiaries would benefit from the VVP measures, and questions why all types of physicians should be subject to the same measures. "[Other Commissioners] used the word voluntary but I don't think it's very voluntary if there's a financial penalty for non-participation," Nerenz said. He added that if MedPAC really wanted the program to be voluntary, perhaps the withhold should be removed. Dr. Nerenz pledged to represent the concerns of specialty medicine as this proposal continues to be considered by MedPAC.

OIG Report on QPP Progress

In December 2017, HHS' Office of the Inspector General released a <u>report</u> that concluded that CMS has made mixed progress implementing the QPP in its first year of operation. The agency has done well building the program's information technology infrastructure, but lags on outreach and education to providers and fraud prevention the report say. The agency is partly relying on contractors to spread the word about the new payment scheme, but the contractors' performance varies, the report said.

The OIG in its 2016 report said the CMS faced challenges in developing information technology systems. It warned that activities must be ramped up quickly to support clinicians' participation. But the latest report was more upbeat. The OIG said the agency had come a long way. The IT system seems to be ready to accept the quality data collected by doctors in 2017 that will be used to adjust their payments in 2019, the report said.

The OIG report was less sanguine about the CMS's fraud fighting efforts for the program. CMS needs to develop and implement a comprehensive program integrity plan, the report said. "This is particularly important to ensure the accuracy of clinician-submitted data and to prevent improper QPP payment adjustments," it said.



Coding and Reimbursement Update

Administrative Issues

The Coding and Reimbursement Committee leadership is as follows:

CRC Leaders
Joseph S. Cheng, MD, Chair
G. Edward Vates, MD, Vice-chair RUC
Henry H. Woo, MD, Vice-chair CPT
Luis Tumialan, MD, Vice-chair Coverage

Medicare Fee Schedule

Global Surgical Services

Beginning on July 1, 2017, a new Centers for Medicare & Medicaid Services (CMS) policy required certain neurosurgeons in their states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon and Rhode Island) to report the number of post-operative visits that they provide related to particular neurosurgical procedures using CPT code 99024. This reporting requirement applies to any group of 10 or more practitioners (including physicians and non-physicians) for all visits (in-hospital and outpatient) during the 10- and 90-day global period. Previously no billing during the global period was required, and many neurosurgeons may not routinely track their visits for patients after surgery.

The AANS and CNS have prepared a <u>guide</u> for neurosurgeons in the nine states. Included in the document is a list of codes for which reporting is required and the number of visits "built-in" for the typical patient, information which is publicly available on the CMS website, to help neurosurgeons better understand the issue. In addition, CMS has released <u>slides</u> containing information on how to comply with the new data reporting requirement, along with an updated list of frequently asked questions and answers. More information available on the CMS website <u>here</u>. On Jan. 1, 2018, CMS issued an updated list of codes for reporting, due to changes in some CPT codes, however these codes are not typically reported by neurosurgeons. The <u>2018 list of codes</u> is the same as 2017 except CPT codes 15732, 34802, and 34825 are deleted and CPT Codes CPT codes 30140, 36470, and 36471 have a 0-day global period, therefore, reporting is not needed.

• Neurosurgery Voices Concerns about RAND Global Surgical Services Survey. On Oct. 27, 2017, the AANS and CNS joined 16 other surgical specialty societies and the American Society of Anesthesiologists in a letter to RAND expressing serious concerns about a proposed survey of global surgical services that RAND plans to send to approximately 10,000 physicians that bill 10- and 90-day global surgery codes. The letter provided a detailed review of the survey flaws and urges RAND to revise the document "to capture relevant information about postoperative visits using a format that is clear, straightforward, and logical. The survey should be directly related to capturing data on postoperative visits and should impose the least possible burden on the physicians in the survey sample."

On Jan. 8, 2018, RAND responded to the letter and they made some additional changes to reflect the surgical societies' recommendations and will conduct a pilot before the full survey launch, which may

lead to additional opportunities for comments and revisions. However, it is clear that they still anticipate that this survey will require a significant time commitment to complete; thus ongoing concerns about the reliability of any data collected remain an issue.

Meeting with CMS. In early March, Washington Office staff met with CMS for a status report on the project. CMS noted that the agency has received quite a bit of data from the 99024 claims-based effort, but at this time the data have not been analyzed. In addition, the RAND survey is still in the pilot phase, with 500 surveys sent into the field. Based on the results of this survey, RAND may make additional changes, or if not, they will use this data and add to it with additional survey responses (they plan to send out approximately 10,000 surveys). It is clear from this conversation that CMS is not in the position to recommend any changes to the global surgery codes for 2019. The statute states:

For years beginning with 2019, the Secretary shall use the information reported under subparagraph (B)(i) as *appropriate* and other available data for the purpose of improving the accuracy of valuation of surgical services under the physician fee schedule under this section.

If the data don't exist then it was not be "appropriate" to make any changes to the values in 2019. Furthermore, CMS is authorized to reassess the value of the information collected every four years. However, the agency has the authority to pull the plug on this initiative if it believes adequate data exists to appropriately value global surgery codes. Given the change of direction in the Trump Administration, it is entirely possible that the global surgery data initiative could simply fade away.

The AANS and CNS will remain vigilant to ensure the accuracy of global surgery codes.

CPT Issues

Short summaries of each CPT Editorial Panel meetings are available on the AMA CPT <u>public website</u>. Below are highlights of current proposals of interest to neurosurgeons:

February 2018 CPT Meeting

Neurosurgery did not present codes at the February 2018 CPT Meeting, however, a significant issue of interest to neurosurgery was discussed:

- Follow up on CPT Assistant FAQ Error. On Feb. 8, 2018, the *CPT Assistant* Editorial Board agreed to rescind a Frequency Asked Question (FAQ) published in October 2016 that inaccurately supported a National Correct Coding Initiative (NCCI) edit for Medicare prohibiting the reporting of CPT codes 63047 and 22633 if performed at the same interspace. On Jan. 3, 2018, the AANS and CNS joined the International Society for the Advancement of Spine Surgery (ISASS), North American Spine Society (NASS), and American Academy of Orthopaedic Surgeon (AAOS) in sending a strongly worded letter asking the AMA CPT Editorial Panel to direct the *CPT Assistant* Editorial Board to correct the erroneous FAQ. Neurosurgery drafted the letter and the other spine society groups agreed to support neurosurgery in the effort to correct the FAQ, which has caused significant difficulty. Previously, on Feb. 8, 2017, the CPT Assistant Editorial Board had reviewed the issue and decided not correct the error and, as a result, private payors began to follow Medicare in establishing similar edits. Efforts to have the edit reversed was a top priority and John K. Ratliff, MD, took the lead on this issue. AMA CPT staff have stated that the correction will appear in the May 2018 issue of the *CPT Assistant*.
- AANS and CNS Nomination of Joseph S. Cheng, MD for CPT Editorial Panel Vacancy. On Dec. 6, 2017, the AMA sent a letter notifying Joseph S. Cheng, MD that he had not been selected for a seat on the AMA CPT Editorial Panel. The AANS and CNS had nominated Dr. Cheng on Sept. 11, 2017. R. Patrick Jacob, MD, is completing a 4 years term that was renewable for a second four years. However, Dr. Jacob decided to step down following stellar service on the panel since 2014 and his last meeting was in February 2018. The CPT Editorial Panel is comprised of 17

members. Of these, 11 are physicians nominated by the national medical specialty societies and approved by the AMA Board of Trustees. One physician is nominated from each of the following: the Blue Cross and Blue Shield Association, America's Health Insurance Plans, the American Hospital Association, and the Centers for Medicare & Medicaid Services. The remaining two seats on the CPT Editorial Panel are reserved for members of the CPT Health Care Professionals Advisory Committee (co-chair and one member-at-large). Dr. Jacob has been replaced by **Dan Nagle**, MD, an orthopedic surgeon who previously served on the RUC.

RUC Issues

January 2018 RUC Meeting

Neurosurgery did not present codes at the January 2018 RUC meeting but below are several items of interest:

- RUC RAW Meeting. Included in the codes reviewed by the RUC Relative Value Assessment Workgroup (RAW) at this meeting was CPT Code 64590 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling under its "originally surveyed by one specialty but currently performed by another" screen. The RAW referred the code to CPT to revise the descriptor to indicate that the code is used for urological conditions. Neurosurgery's reporting of this code is under 1.4% but, as with all the neurostimulator services, we will be vigilant to make sure that any proposed changes do not have an impact on neurosurgery.
- □ PLI Workgroup. The RUC Professional Liability (PLI) Workgroup held a discussion with staff from CMS and Acumen, the contractor responsible for collecting and analyzing PLI data for the Medicare Physician Fee Schedule (MPFS). The AANS and CNS, along with the RUC, ACS and other surgical groups, had expressed concerns regarding a number of PLI issues in the 2018 MPFS proposed rule resulting in a planned decrease in payment for neurosurgery. Following objections, CMS held off on the changes in the final rule, halting the decrease for FY 2018. The PLI workgroup raised several points to CMS and Acumen including the need to continue to strive to obtain premium data for all specialties in all 50 states, concerns that professional liability costs are not adequately captured by the current methodology and objections to the overstatement of PLI for non-MD specialties, now accounting for over 20% of Medicare billing. The RUC will send a letter to CMS on March 30, 2018, restating the aforementioned issues and urging the agency to address the concerns.
- Gregory J. Przybylski, MD has decided to step down as our RUC member after the April 2018 meeting. Dr. Przybylski has served on the RUC for nearly 18 years. He has graciously agreed to continue to assist in a transition to new leadership for our RUC team and to provide guidance and education to new participants. **G. Edward Vates**, MD who currently serves as our RUC alternate will take over as our RUC member.

April 2018 RUC Meeting

On April, 27, 2018, **Alexander M. Mason**, MD, will join RUC advisors from the American Academy of Orthopaedic Surgeons (AAOS), International Society for the Advancement of Spine Surgery (ISASS) and North American Spine Society (NASS) to present survey data for re-valuation of CPT code 27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device, and CPT code 22310 Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing.

Coverage Issues

The AANS/CNS Coverage Rapid Response Team (RRT) continues help neurosurgeons address coverage issues as they arise nationally and in their states. To this end, the RRT is using Policy Reporter software, which provides coverage policy updates from state and national payors — typically sending

over 120 coverage policy update documents each month. Since June 2017, Neurosurgery residents **William Jeong**, MD and **Nicolas W Villelli**, MD, under the tutelage of CSNS fellow **Owoicho Adogwa**, MD, have been tracking the Policy Reporter documents and producing monthly summaries of the policies. In addition to other coverage activities, **Joseph S. Cheng**, MD, is piloting a new service with Drs. Jeong, Villelli, and Adogwa using the Policy Reporter coverage updates. They will field questions from Section Chairs, Quadrant Chairs, and State Society leaders about policies for specific procedures in individual states. For example, upon request they would be able to look up and summarize available coverage policies for a particular procedure in a state if the procedure is one for which the AANS and CNS have contracted to receive updates. Requests may be made through Cathy Hill in the AANS/CNS Washington Office.

Below are some highlights of recent coverage activity:

Anthem (formerly WellPoint) Coverage Activity

- Anthem Deep Brain, Cortical, and Cerebellar Stimulation. On March 9, 2017, Anthem staff informed the AANS/CNS Washington Office staff that they had reviewed their current coverage policy for deep brain, cortical, and cerebellar stimulation and would not be making changes at this time. Initially, the AANS and CNS submitted a completed questionnaire on the subject from the CRC and AANS/CNS Stereotactic and Functional Section organized by Jason M. Schwalb, MD, FAANS, which recommended a number of changes to the policy. Included in the comments was an objection to the Anthem policy to limit coverage only to FDA approved indications and a failure to accurately report current literature in support for DBS for secondary dystonia. Subsequently, Dr. Schwalb developed an updated questionnaire strengthening and reiterating the AANS and CNS support for increased coverage which was reviewed by the RRT and Section leaders. The document was shared with the American Epilepsy Society for review. On Nov. 20, 2017, the AANS and CNS submitted the updated form to Anthem. The Epilepsy Society has reached out to Anthem as well to share similar comments. On Jan. 23, 2018, Anthem acknowledged receipt of the updated information from the AANS and CNS and stated that it would be considered when the issue was next reviewed in the second half of 2018.
- □ Anthem Payment for E/M Codes Reported with Modifier 25. On Feb. 23, 2018, Anthem sent a letter to the AMA stating that they would not proceed with a policy to reduce payments for E/M services reported with CPT modifier 25 that had been set to take effect on March 1, 2018. On March 2, 2018, the AMA and Anthem issued a joint statement announcing plans for future collaboration on a number of issues of concern to physicians including retrospective denial of payment for emergency room visits and restrictions on advanced imaging in hospital outpatient facilities. The announcement came after months of protests from the AMA and other specialty societies. In September 2017, Anthem had said they would reduce payment for visits reported with modifier 25 by 50%. On Nov. 20, 2017, the AMA sent a letter to Anthem requesting that the company halt plans to implement the policy and a face-to-face meeting was held between AMA leaders and senior Anthem officials. On Dec. 22, 2018, Anthem informed the AMA that it still planned to reduce payments for E/M services billed with CPT modifier 25, but that payments will be reduced by 25% instead of 50%, as originally planned. After continued objections, Anthem has agreed not to implement a reduction for E/M services billed with modifier 25. More information is available here.

Washington State Health Technology Assessment (HTA) Program

• Washington State HTA Review of Single Level Laminectomy. On March 21, 2018, neurosurgery took the lead in sending a letter from the AANS, CNS, the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, Washington State Association of Neurological Surgeons (WSANS), International Society for the Advancement of Spine Surgery, North American Spine Society (NASS) and the American Academy of Orthopaedic Surgeons (AAOS) to the Washington State HTA program regarding a draft evidence report prepared by RTI International — Evidence based Practice Center. On Nov. 27, 2017, the AANS and CNS draft a letter and statement from to the same groups in

response to a list of key questions for the evidence review of surgery for symptomatic lumbar radiculopathy. That letter and statement provided literature supporting the fact that surgery in patients with symptomatic lumbar radiculopathy secondary to disc herniation or stenosis represents a cost-effective treatment and compares very favorably with other accepted medical and surgical interventions The HCA HTA Health Technology Clinical Committee will meet on May 18, 2018 to consider the technology assessment and vote on whether to continue coverage for the procedure. More information is available <a href="https://example.com/here/bea/health/new/medical-new/me

On March 23, 2018, the Washington State HCA released its <u>list</u> of technologies for review in the next year. On the list are several technologies of interest to neurosurgery included sacroiliac joint fusion, facet neurotomy and Optune/Novocure. The deadline for comments is April 23, 2018 and the RRT will review the technologies in coordination with WSANS and draft a response.

Aetna

- CNN story on AETNA's Refusal to Pay for MRI-guided neurosurgical laser ablation (LITT). In December 2017, CNN aired a story about the refusal of AETNA to pay for MRI-guided neurosurgical laser ablation or interstitial thermotherapy (LITT) for a 15 year old girl and other patients because it considered the procedure experimental and investigational for the treatment of epilepsy. The article quotes a cost of \$300 thousand for the treatment. The story prompted a robust discussion of AANS/CNS Coding and Reimbursement Committee (CRC) and the Section on Stereotactic and Functional Neurosurgeon leaders. Although there was support for the procedure in appropriately selected patients, many leader felt the cost quoted was greater than is typically paid for the treatment. In addition, the article stated that thousands of the procedures had been performed and some felt that was an overstatement. Consideration for a new Category III Tracking CPT code for LITT treatment has been explored by the CRC for several years but the decision has been made to wait until there is enough clinical literature to request a Cat. I CPT Code.
- Spinal Cages. Section on DSPN RRT members have reviewed concerns raised by Kurt Eichholz, MD and others regarding Aetna's limitations on the selection of interbody devices for lumbar fusions. A similar issue was successfully addressed in the past when Aetna disallowed the use of CPT code 22851 in the cervical spine, before that code was deleted from CPT. Stephen Reintjes, MD and Section on DSPN RRT members produced a draft response on March 14, 2018 for review by Section leadership that examines the evidence in available literature on expandable cages and notes that the FDA approval for the devices does not restrict them to L5/S1 as Aetna has proposed.

Ohio Workers' Comp

The Ohio Bureau of Workers Compensation issued a <u>rule</u> effective Jan. 1, 2018, that requires injured workers to undergo at least 60 days of "conservative" care, while avoiding opioids if possible, before they pursue lumbar fusion surgery. The Ohio policy goes further that other states that have restricted lumbar fusion surgery by embedding an opioid warning specifically into its surgical restriction. More information is available <u>here</u>.

Blue Cross/Blue Shield Association Evidence Street

On March 23, 2018 the AANS and CNS received a request from the Blue Cross/Blue Shield Association Evidence Street program for feedback on Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers). The issue has been referred to the AANS/CNS Joint Section on DSPN.

North American Spine Society

On March 10, 2018, the AANS and CNS Joint Section on DSPN sent a <u>statement</u> to NASS in response to their draft coverage policy on lumbar interspinous device without fusion and decompression. NASS issued its <u>draft</u> policy on Feb. 9, 2018. Section leaders were generally in agreement with the NASS

proposal but recommended that the title of the proposal be changed for clarification and differed with NASS on some of the indications for use.

Other Medicare Issues

HHS Secretary Confirmed

On Jan. 24, 2018, the Senate confirmed, in a 55-43 vote, Alex Azar to be the Secretary of Health and Human Services (HHS). Six Democrats joined in supporting the nomination, Sens. Tom Carper (D-Del.); Chris Coons (D-Del); Joe Donnelly (D-Ind.); Heidi Heitkamp (D-N.D.); Doug Jones (D-Ala.) and Joe Manchin (D-W.Va.). Sen. Rand Paul (R-Ky.) was the only Republican to oppose the nomination. Mr. Azar was formerly president of Eli Lilly USA and previously served as HHS general counsel under President George W. Bush.

Alex Azar is confirmed as President Trump's second secretary health and human Services



Biography
Previous position: President of Lilly USA, LLC
Assumed position: 2012
Date of birth: June 17, 1967
Home: Johnstown, Pennsylvania
Education: B.A., Dartmouth University; J.D. Yale University
Family: Married (Jennifer), 2 children
Political party: Republican

Professional experience

- As the secretary of health and human services, Azar will be a key player in implementing Trump's drug pricing control agenda in an industry he just left
- Previously, Azar clerked under Supreme Court Justice Antonin Scalia and worked for two years on the Clinton Whitewater investigation
- Under President W. Bush, Azar worked as HHS general counsel from 2001-2005, and then as the deputy secretary from
- Azar joined Eli Lilly and Company as the senior vice president of corporate affairs and communications from 2007-2009, and then served as President of Lilly USA, LLC from 2012-January 2017

MEDCAC Nominations

On Nov. 27, 2017, the AANS and CNS sent a letter to CMS nominating **Jeffrey W. Cozzens**, MD; **Ahmen M. Raslan**, MD; **Clemens M. Schirmer**, MD and **G. Edward Vates**, MD to serve on the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). On Nov. 3, 2017 CMS issued a <u>notice</u> requesting nominations. MEDCAC is a list of 100 appointed individuals — 94 at-large standing members (mostly MDs, PhDs, and other experts in evidence based medicine and 6 patient advocates) and 6 industry representatives. Currently neurosurgery has one representative — **Joseph S. Cheng**, MD on the list. CMS calls on MEDCAC members when it is considering National Coverage Determinations. Some members are never called to serve during their tenure and rarely are members called more than one or two times. CMS may also ask members to review documents from time to time.

Misvalued Code Cuts Averted

Due to strong lobbying efforts, the AANS and CNS, along with others in organized medicine, were successful in defeating proposed legislation that would extend the so-called misvalued codes beyond 2020. Under this policy, CMS is directed to identify codes totaling 1.0 percent of physician expenditures that are misvalued. If this target is met, a budget-neutral adjustment is made such that the money remains within the Medicare physician fee schedule. If the target is not met, then all physicians receive a cut, and in each of the past three years, the target has not been met, and physicians received corresponding cuts. The payment reductions related to misvalued codes are in addition to the annual 2.0% sequestration cut.

The AANS and CNS led the efforts and worked with colleagues in the Alliance of Specialty Medicine and Surgical Coalition to write Congress to oppose these cuts on Nov. 30, 2017, Dec. 6, 2017, and Dec. 11, 2017. This advocacy has also resulted in a letter from the GOP Doctors' Caucus to House leaders. Although, elimination of the policy was not included in the 2018 appropriations legislation, the AANS and CNS will continue to lead efforts to oppose the cuts.

Unfortunately, physicians did not emerge from the various budget deals unscathed. While the misvalued code provisions was not included in the Bipartisan Budget Act (<u>H.R. 1892</u>), Congress reduce the Physician Fee Schedule conversion factor for 2019 from 0.5 percent to 0.25 percent.

CMS Briefing Call on Evaluation and Management (E/M) Documentation Guidelines

CMS staff held a call on March 21, 2018, to obtain feedback from stakeholders on six questions regarding efforts to update Evaluation and Management (E/M) Documentation Guidelines to bring them more in line with current (post EHR) practice and reduce the paperwork burden on physicians and other providers. Slides from the call and more information are available on the CMS website by clicking here. CMS will include its draft proposal for E/M documentation changes in the Calendar Year (CY) 2019 Medicare Physician Fee Schedule (MPFS) proposed rule to be released on or about July 1, 2018 and they urged the callers to be sure to review and submit their E/M concerns during the comment period.

CMS Provider Compliance Focus Group Meeting

On Jan. 19, 2018, CMS Center for Program Integrity Provider Compliance Group (PCG) hosted a meeting for provider and physician groups giving an overview of the numerous audit, compliance, and probe and educate programs at CMS. CMS staff plans to host the meeting quarterly to provide a forum for physician and provider groups to bring their questions and issues regarding the programs to CMS staff. Items discussed included review activities conducted by the Recovery Audit Contractors (RACs), Medicare Administrative Contractors (MACs) and CMS programs such as comparative billing reports (see below).

CMS Opioid Prescribing Comparative Billing Reports (CBRs)

CMS currently utilizes a contractor to send out "educational" reports on individual clinician billing patterns on certain topics, called Comparative Billing Reports (CBRs). Most recently, CMS has issued one on *Opioid Prescribing*. The analysis is based on Medicare Part D claims data (using the Integrated Data Repository) and relies on the "Prescribing NPI." The reports are only sent to those that are deemed to be "outliers" on certain metrics. The comparisons were done at both the <u>specialty level</u> and the <u>national level</u> (regardless of specialty). This report relies on the following metrics:

Percentage of beneficiaries prescribed opioids above 90 Morphine Equivalent Dose (MED) for 3 months
Average number of days prescribed per beneficiary
Average charges per beneficiary for prescribed opioids
Percentage of beneficiaries prescribed opioids by four providers or more

The reports are intended to be only educational, and the report notes that it does not change any current Medicare policy. More information about the Comparative Billing Report (CBR) program is here. Information about the Opioid Prescribing CBR, including a sample report, is here. An educational webinar is available here.

New Medicare Cards Provider Resources

Starting in April 2018, CMS will begin mailing new Medicare cards to all people with Medicare on a rolling basis, based on geographic location and other factors. To help physicians prepare for the transition to the Medicare Beneficiary Identifier (MBI) on Medicare cards, CMS has posted educational information. Beginning in October 2018, through the <u>transition period</u>, when providers submit a claim using a patient's valid and active Health Insurance Claim Number (HICN), CMS will return both the HICN and the MBI on every <u>remittance advice</u>. Here are examples of different remittance advices:

ery	remittance advice. Here are examples of different remittance advices:
	Medicare Remit Easy Print (Medicare Part B providers and suppliers)
	PC Print for Institutions
	Standard Paper Remits: FISS (Medicare Part A/Institutions), MCS (Medicare Part
	B/Professionals), VMS (Durable Medicare Equipment)

More information is available on the Medicare Card <u>provider</u> webpage.

CMS Request for Nominations to the Advisory Panel on Hospital Outpatient Payment

On Jan. 26, 2018, CMS issued a <u>notice</u> of the agency's acceptance for nominations to the Advisory Panel on Hospital Outpatient Payment. The panel has one meeting a year in August. More information on the panel is available <u>here</u>. The nominees must be full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPPS. The agency will accept nominations on a continuous basis. The notice has been referred to the AANS/CNS Coding and Reimbursement Committee for consideration.

MedPAC

MedPAC Issue Briefs and Transcripts

The <u>Medicare Payment Advisory Commission</u> (MedPAC) is an independent panel established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise Congress on issues affecting the administration of the Medicare program. The Commission meets monthly in public from September to April to review and make recommendations on Medicare payment updates and other policy. MedPAC issues briefs, presentations and meeting transcripts are available here.

MedPAC March 2018 Report

On Jan. 10, 2018, the AANS and CNS helped draft a Surgical Coalition <u>letter</u> to MedPAC challenging the commission's proposals to increase primary care's Medicare payments at the expense of surgical/specialist payments. The letter vigorously disputes many of MedPAC's claims about primary care services and includes thorough documentation to refute erroneous assertions by MedPAC.

On March 15, 2018, MedPAC released its annual March report on Medicare Payment Policy. A press release is available here and a fact sheet is available here. For Calendar Year (CY) 2019 for physicians, MedPAC recommends a payment update in keeping with current law. In addition, the commission formalized its recommendation that the Congress eliminate the Merit-based Incentive Payment System (MIPS). Finally, the report did not include any recommendations related to primary care payments in this report.

Advocacy on this issues continues, particularly in light of the fact that MedPAC may include information and recommendations on this topic in its June 2018 report.

Other Issues

ACS Releases 2018 Update to the Physicians as Assistants at Surgery Report

The American College of Surgeons (ACS), in collaboration with the AANS, CNS and 13 other national specialty surgical organizations, has recently published the eighth edition of *Physicians as Assistants at Surgery Report*, a study first undertaken in 1994. The 2018 report reflects the most recent clinical practices and provides guidance on how often an operation might typically require a physician to assist at surgery. Using codes from the 2018 CPT book, the AANS and CNS Coding and Reimbursement Committee reviewed new and revised codes since 2016 and other codes of interest and indicated whether the operation requires a physician as an assistant: (1) almost always; (2) almost never; or (3) some of the time. The 2018 report adds 93 codes for all specialties that were approved by the CPT Editorial Panel since the last report was issued in 2016. In addition, the 2018 report updates 384 revised codes and deletes 48 codes that are no longer in CPT.

Quality Improvement Update

Agency for Healthcare Research and Quality



Administrative Issues

The Neurosurgery Quality Council (NQC) leadership is as follows:

NQC Leaders
Paul L. Penar, MD, Chair
John K. Ratliff, MD, Immediate Past-Chair
John J. Knightly, MD, Vice-chair, Performance Measurement
Anthony L. Asher, MD, Vice-chair Data Collection and Performance Improvement
Ralph Reeder, MD, Vice-chair, Payment and Delivery Models
Jeffrey M. Sorenson MD, Vice-chair, Health Information Technology

2018 Medicare Physician Fee Schedule (MPFS) Final Rule

Earlier in the year, the AANS and CNS had submitted a comment letter on the 2018 MPFS proposed rule that voiced support for CMS's efforts to minimize the impact of legacy program payment penalties, which is something organized medicine strongly urged the new Administration to do earlier in the year. The letter requested that CMS consider strengthening these proposals so that they align even more closely with 2017 MIPS transition year policies, where a clinician can avoid a penalty by reporting on a single measure for a single patient. The comment letter also raised concerns about the implementation of the Patient Relationship Code reporting requirement and the AUC Program. In November, CMS released its 2018 MPFS final rule, which includes multiple quality provisions highlighted below. Click here for a detailed summary of the 2018 MPFS final rule prepared by Hart Health Strategies. Overall, neurosurgery was pleased that CMS took its comments into consideration when finalizing these policies.

Legacy Physician Quality Reporting Programs

CMS finalized its decision to:

Modify 2016 PQRS reporting requirements from nine to six measures, with no cross-cutting measure requirement, for purposes of determining the 2018 payment adjustment. QCDR participants also are not required to report an outcome or high priority measure.
Limit the maximum adjustment under the 2018 VM, based on failure to satisfy the revised 2016 PQRS requirements, to -2 percent for all eligible professionals (EPs) rather than -4 percent (smaller practices would be subject to a -1 percent adjustment, rather than -2 percent).
For groups who do satisfy the revised 2016 PQRS requirements, they would be held harmless from any downward performance-based adjustments under the 2018 VM and can only receive neutral or upward performance-based adjustments. Because the VM is budget neutral, this

means that CMS also had to reduce the extent of upward performance-based adjustments for the 2018 VM so these won't be as high as expected (see section below on *Value Modifier Results*).

Patient Relationship Codes/Categories

MACRA directed CMS to not only develop more granular episode groups, but also patient relationship categories and codes to better describe a clinician's relationship and role over a patient's care. The goal here is to help clarify the clinician's responsibility over the patient so that CMS can more accurately attribute costs to clinicians under MIPS. In the 2018 MPFS final rule, CMS finalized that physicians and other applicable practitioners can voluntarily report applicable HCPCS modifiers on Medicare claims starting on Jan. 1, 2018. In other words, the use and selection of these modifiers would not be a condition of payment. The modifiers reflect five different relationships that a clinician may have with a patient, which are described in more detail in this CMS Operational List:

- 1) Continuous/broad services;
- 2) Continuous/focused services:
- 3) Episodic/broad services:
- 4) Episodic/focused services; or
- 5) You provide care only as ordered by another clinician.

CMS recognizes concerns that these are broad and potentially vague, but was aiming to minimize clinician reporting burden. CMS also acknowledges that these categories might not apply to all specialties, but intends to use the test year to examine trends and further refine the categories if necessary. The AANS and CNS commented on previous iterations of this list, supporting efforts to ensure more accurate and effective resource use measurement, but highlighting several fundamental challenges that remain unaddressed.

For additional information on related work in this area, see the section on *Episode Based Cost Measures*.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

This program will begin with an educational and operations testing year in 2020, rather than 2019. This means that starting Jan. 1, 2020, ordering clinicians would be required to start consulting AUCs through qualified clinical decision support mechanisms and furnishing clinicians would be required to report information about the AUC consultation on their claims. However, during this testing year, CMS will pay claims for advanced diagnostic imaging services regardless of whether they correctly contain information on the required AUC consultation. This allows both clinicians and the agency to prepare for this new program. CMS also opted not to finalize specific policies related to how professionals will be expected to report AUC consultation data to CMS in 2020. Instead, CMS will continue to work with stakeholders to explore the use of more standardized, less burdensome mechanisms for reporting these data via Medicare claims. For additional information, see section below on *Appropriate Use Criteria for Advanced Imaging Services*.

Medicare Access and CHIP Reauthorization Act (MACRA)

NOTE: See separate MACRA Update for information on the Quality Payment Program (QPP).

Episode Based Cost Measures

As mandated under MACRA, CMS is working on a multi-pronged strategy to more accurately measure resource use among physicians. This includes the development of more granular episode-based cost measures and the development of more accurate ways to attribute patients to providers and to evaluate the status of a patient at the time of care. Working through its contractor Acumen, and building off of previous work done in this space, CMS convened its first wave of clinical subcommittees in 2017 to assist with the development of episode-based cost measures for potential use under MIPS. This first

phase of work included seven Clinical Subcommittees composed of 147 members affiliated with 98 professional societies. Two committees were relevant to neurosurgery:

- Peripheral Vascular Disease Management Subcommittee, which includes Clemens M. Schirmer, MD, and Henry H. Woo, MD. Although "Procedure for Carotid Stenosis" was identified as a priority for this subcommittee, the committee instead chose to focus on: Dialysis Access and Lower Extremity Peripheral Vascular Disease.
- Neuropsychiatric Disease Management Subcommittee, which includes Clemens M. Schirmer, MD, and identified the following topics as priorities: Intracranial Hemorrhage or Cerebral Infarction, Acute Ischemic Stroke with Use of Thrombolytic Agent, and Seizures.

Over the late spring and summer, these subcommittees produced eight draft cost measures, only one of which — Intracranial Hemorrhage or Cerebral Infarction — is directly related to neurosurgery. In September 2017, CMS distributed confidential data reports to group practices and solo practitioners who were attributed at least 10 patients under any of the measures. Reports provided TIN and TIN-NPI level payment-standardized, risk adjusted cost measure scores based on Medicare claims data for the following measures. Mock feedback reports and other methodology documents were also distributed to the general public for their review and feedback. The AANS/CNS Washington Office worked with the Cerebrovascular Section to alert members to these reports and the opportunity to provide more general feedback. In mid-November, the AANS and CNS submitted more general feedback to CMS on ways to improve the measures and overall format of the reports.

In December, the subcommittees reconvened to revise the measures based on public input. During that time, draft versions of these measures were submitted to the Measures Application Partnership (MAP), with the goal of having them proposed for inclusion in MIPS as early as 2019. In mid-January 2018, CMS released the final specifications of these measures. In its final recommendations to HHS, the MAP offered "conditional support" for the Intracranial Hemorrhage or Cerebral Infarction cost measure, recognizing the importance of the measure, but expressing concern with the clinical cohort definition as it captures the cost of two related conditions with different treatment plans. MAP also discussed the need to ensure that this measure appropriately handles transfers for tertiary medical centers that may receive transfer patients with more severe presentation that may not be reflected in administrative claims data, and to consider the appropriateness of the risk adjustment model for both clinical and social risk factors.

The <u>Operational List of Care Episode and Patient Condition Codes</u> presents the operational list of the final eight episode-based cost measures and their corresponding episode group trigger codes and was released along with a <u>backgrounder</u>.

While current subcommittees have focused on Procedural Episodes Groups and Acute Inpatient Medical Condition Episode Groups, future subcommittees will focus on Chronic Condition Episode Groups. In March 2018, Acumen solicited nominees for Wave 2 of this project. The AANS/CNS nominated the following individuals to the listed subcommittees:

- ☐ Clemens Schirmer, MD: Peripheral Vascular Disease (Carotid Stenosis); Neuropsychiatric Disease
- Anand Rughani, MD: Neuropsychiatric Disease Management; Musculoskeletal Disease Management

 – Spine subcommittee
- **Jay Nathan, MD:** Musculoskeletal Disease Management Spine; Peripheral Vascular Disease Management (Carotid Stenosis)
- ☐ **Kimon Bekelis, MD:** Peripheral Vascular Disease (Carotid Stenosis)

Legacy Medicare Physician Quality Reporting Programs

MACRA sunsets legacy physician quality reporting programs and their penalty structure starting with the 2019 payment year, but maintains many of these programs' features and measures in a newly

consolidated program known as the Merit-Based Incentive Payment System (MIPS). 2018 represents the last year of penalties under the following legacy programs:

Program	Reporting Year	Payment Year	Medicare Payment at Risk
PQRS	2016	2018	-2.0%
Value Modifier	2016	2018	Up to -4.0% (note recent CMS proposal change to reduce this to -2.0%)
EHR Incentive Program	2016	2018	-3.0%
TOTAL			Up to 9%

As noted earlier, the 2018 MPFS final rule includes multiple provisions that provide additional relief from these program requirements and penalties.

PQRS Feedback Reports

We expect CMS to release the 2016 PQRS Experience Report, summarizing trends in reporting by specialty, in the spring or summer of 2018. The most current summary of trends is available in the 2015 PQRS Experience Report, which summarizes the historical reporting experience of eligible professionals and group practices in the PQRS through program year 2015.

Physician Value-Based Payment Modifier

2018 Value Modifier Results

In January 2018, CMS released the 2018 Value Modifier (VM) national results and payment adjustment factor. In its final year, the VM will reward 20,481 physicians and other clinicians with bonus payments ranging from 6.6% to 19.9%. Three-quarters of those who were subject to the VM had neither a positive or negative adjustment. The remaining one-fourth received penalties of 1% to 2% because they did not meet minimum quality standards. Adjustments in 2018 are based on 2016 performance and are the last that will be made before the VM is replaced by MIPS cost and quality measures.

As noted earlier, due to pressure from the medical community, CMS halved the size of previously-promulgated penalties under the VM related to non-successful PQRS reporting and held any practice that met the PQRS reporting requirements harmless from performance-based penalties that would otherwise have been imposed. This reduced the penalty assessment by \$22 million and about 7% of practices escaped penalties as a result. Some 53 practices received a maximum bonus of 19.9% because they were both low cost and high quality and were among those with the highest percentage of high-complexity patients. Another 4,485 practices received a 13.2% bonus and 11,692 received a 6.6% bonus.

The 2018 <u>Value Modifier results</u> and the <u>payment adjustment factor</u> are available on the <u>2016 QRUR and 2018 Value Modifier</u> webpage.

CMS Meaningful Measures Initiative

In late October, CMS Administrator **Seema Verma** announced CMS' new <u>Meaningful Measures Initiative</u>, which aims to streamline quality measures, reduce regulatory burden, and promote innovation. According to a CMS, Meaningful Measures will involve only assessing those core issues that are most vital to providing high-quality care and improving patient outcomes. The agency aims to focus on outcome-based measures going forward, as opposed to trying to micromanage processes. The initiative

aligns with the <u>Patients Over Paperwork Initiative</u>, also announced in late October. According to CMS, Patients Over Paperwork is a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience.

In December, CMS posted its Measures Under Consideration (MUC) list for 2019, which contains only 32 quality measures spanning numerous Medicare programs and settings. This represents a drastic reduction from the 97 measures it listed a year ago. The agency focused on selecting measures that focus on clearly defined, meaningful measure priority areas that safeguard public health and improve patient outcomes, while minimizing burden. According to CMS, approximately 40% of measures on the MUC list are outcome measures, including patient-reported outcome measures. Also, on the list were the eight episode-based cost measures, recently subject to field testing and described earlier, as well as other measures relevant to neurosurgery, listed below.

While the AANS/CNS abstained from voting on these measures, it voiced concern that the MN Community Measures specify improvement in ODI specifically and recommended that the wording be changed to "improvement on a validated pain or disability patient reported outcome measure" to provide clinicians with more flexibility. The AANS/CNS also supported the MAP's concern that the episode-based cost measure focused on intracranial hemorrhage and cerebral infarction relies on an opaque method of risk adjusting these two different populations.

The MAP's final recommendations for 2019 are available <u>here</u>. Measures relevant to neurosurgery are listed below:

#	Title	Progra m	Developer	Final MAP Recommendation
MUC17- 168	Average change in functional status following lumbar spine fusion surgery	MIPS	MN Community Measurement	Support For Rulemaking
MUC17- 170	Average change in functional status following lumbar discectomy laminotomy surgery	MIPS	MN Community Measurement	Conditional Support for Rulemaking
MUC17- 177	Average change in leg pain following lumbar spine fusion surgery	MIPS	MN Community Measurement	Conditional Support for Rulemaking
MUC17- 194	Optimal Vascular Care	MIPS	MN Community Measurement	Support For Rulemaking
MUC17- 234	Ischemic Vascular Disease Use of Aspirin or Anti- platelet Medication	MIPS	MN Community Measurement	Conditional Support for Rulemaking
MUC17- 363	Intracranial Hemorrhage or Cerebral Infarction	MIPS	CMS	Conditional Support for Rulemaking

Public Reporting and Transparency

Physician Compare

Physician Compare, authorized under the Affordable Care Act of 2010, is a public reporting initiative intended to provide an additional incentive for physicians to improve their performance. The website started off as simply providing the public with basic demographic data on physicians, including specialty, board certification, group practice and hospital affiliation, and a simple indicator of whether or not they participated in the PQRS. But starting in 2014, CMS began providing the public with quality measure performance data for select physician groups and ACOs and as of late 2016, CMS now provides performance data on all physicians, where applicable. CMS has certain criteria for what performance data it will post. It only reports on measures that prove to be:

Valid, reliable, and accurate
Deemed statistically comparable
Meet a minimum sample size of 20 patients
Are not first year measures; and
All measure data are also subject to a 30-day preview period before being posted.

Currently, Physician Compare only includes PQRS quality measure data and not cost measures calculated under the VM. Performance data posted on a physician profile page must not only meet the criteria listed above, but also must have been found to resonate with users through CMS consumer testing, which is why the number of measures posted on profile pages is smaller than the number found in the downloadable database.

As the next step in CMS's phased approach to public reporting, starting in December 2017 CMS began publicly reporting certain 2016 performance information on Physician Compare. Data are available for public reporting on public-facing profile pages and/or via the Physician Compare Downloadable Database available on data.medicare.gov. Because of the different primary audiences, CMS publicly reports information differently in the Downloadable Database than on profile pages. The primary audience for profile pages is patients and caregivers. On the profile pages, groups may have the following measures reported: a subset of 2016 PQRS measures reported as performance-based star ratings (none of which are directly relevant to neurosurgery); Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS summary survey measures; and/or non-PQRS Qualified Clinical Data Registry (QCDR) measures. The 2016 QCDR measures, available for both groups and individual clinicians, and 2016 CAHPS for PQRS measures available for only groups, are being reported as a percent – not as star ratings – on the relevant profile pages.

Since not all measures have been deemed appropriate for posting on Physician Compare profile pages, many physicians will find a simple check mark on their profile page indicating that he/she "Successfully reported Medicare quality program performance information" and/or "Used electronic health records." However, more specific, raw performance data are accessible to the public via the Downloadable
Database. The database is mainly intended as a resource for clinicians and group representatives, as well as third-party data users. Groups may have 2016 PQRS measures, CAHPS for PQRS summary survey measures, and/or non-PQRS QCDR measures included in the Downloadable Database. Individual clinicians may have 2016 PQRS and non-PQRS QCDR measures, as well as 2015 utilization data reported in the Downloadable Database. The final 2016 data will be available for download in late spring or early summer of 2018 once the informal review process has been completed. At this time, the most current general information (updated every two weeks) and performance information for 2015 is available for download.

In addition to the measures being reported for groups and individual clinicians, 2016 data for the Shared Savings Program, Pioneer, and Next Generation Accountable Care Organizations (ACOs) are now also publicly reported on Physician Compare. ACO measures are reported as percent performance rates. Physician Compare also now includes information about group ACO affiliation. If a group is part of an ACO, there will be a link to that ACO's Physician Compare profile page from the group profile page. Finally, as mandated under MACRA, CMS also includes utilization data in the Physician Compare downloadable database.

For more information about Physician Compare methodologies, including information about the new star ratings, visit the CMS Physician Compare Initiative page.

Clinical Registry Policies and Activities

NeuroPoint Alliance

2017 marked the fifth anniversary of NeuroPoint Alliance's (NPA) major registry initiative, the <u>Quality</u> <u>Outcomes Database</u> (QOD). Within this brief period, the NPA has witnessed the growth of QOD from a

small database with a single project domain and three participating neurosurgical centers to the largest spine registry and one of the largest cross-specialty clinical registries in North America.



As of November 2017, the QOD data are as follows:

Registry	Lumbar	Cervical	Deformity	CV
# Contracted Sites	103	73	55	20
# Participating Sites	87	73	55	20
# Surgeons	662	493	203	85
# Patients	50,383	20,881	1,397	3,021
# Hospitals	190	144	80	22

Follow-Up	Lumbar	Cervical	Deformity	cv
Baseline Accrual	38,018	15,602	1,093	2,803
3-Month	72.6%	74.1%	72.8%	80.3%*
12-Month	63.7%	62.2%	65.1%	*

^{*} CV is 30-day outcomes

NPA's most recent endeavor, the QOD Tumor registry, is expected to launch in the near future. In addition, the NPA welcomed the first health system, Intermountain Healthcare in Salt Lake City, to the family of participating centers. Finally, NPA leaders and Washington Office staff continue to work to position the NPA as a one-stop portal for purposes of MOC, PQRS and future quality reporting under MIPS.

PQRS/MIPS Qualified Clinical Data Registry (QCDR)

The QOD, neurosurgery's federally approved Qualified Clinical Data Registry (QCDR) for MIPS reporting, had 38 surgeons report across 7 practice groups for 2017 had 38 surgeons report across 7 practice groups for 2017.

More recently, the QOD was approved as a federally recognized Qualified Clinical Data Registry (QCDR) for 2018, which represents the third year the QOD has been awarded this status. Once again, NPA staff fought hard late in the year to defend QOD measures in response to CMS efforts to retire, consolidate, harmonize, or otherwise modify QCDR measures. Through these communications with CMS, the NPA team successfully demonstrated why some of the agency's decisions were arbitrary and not clinically thoughtful. Ultimately, CMS approved 16 measures focusing on spine surgery for 2018. Nevertheless, navigating the QCDR self-nomination and measure vetting process this year was especially painful for neurosurgery and practically every other specialty society applicant. Despite multiple efforts to alert CMS to our concerns (see section on *Physician Clinical Registry Coalition*), the process remains disorganized and relies on impractical timelines and arbitrary decision-making that lacks transparency.

The complete list and measure specifications for QCDRs approved for use under MIPS in 2018 is available for download here. In addition to neurosurgery's QCDR (QOD) and AAPM&R's QCDR, there are two other spine-focused QCDRs that are NOT professional-society led. One is the SpineTRACK, run by NuVasive. The other is The Spine Institute for Quality Conservative Care: QCDR For Individuals (SPINE IQ), administered by Premier, Inc.

Physician Clinical Registry Coalition (PCRC)

Neurosurgery continues to be an active participant in the PCRC, which includes over 20 physician organizations that have clinical data registries and aims to address common regulatory and legislative issues. The coalition recently launched a new website. Recent activities include:

- In November 2017, submitted a <u>letter</u> to CMS regarding concerns with the commercial use of QCDR/MIPS measures and licensing.
 In January 2018, the PCRC submitted a <u>comment letter</u> on the 2018 QPP final rule.
- The PCRC sent a letter to the HHS Office of the Inspector General (OIG) and the Office of the National Coordinator (ONC) for HIT regarding concerns about data blocking and is currently trying to schedule a meeting.
- In March 2018, the PCRC had an encouraging follow-up meeting with CMS to discuss serious, unresolved concerns about the QCDR self-nomination and measure review process, some of which are outlined in this <u>letter</u> sent to CMS in July 2017. CMS acknowledged the PCRC's concerns and seemed committed to improving the process and working more closely with speiclaty societies going forward.

Value-Based Payment Reform

In various speeches throughout early 2018, HHS Secretary **Alex Azar** noted his commitment to value-based transformation as a top priority for the Department and outlined a 4-point plan to accelerate movement toward a value-based system, including:

- 1. Moving ownership and control of EHRs from providers to patients;
- 2. Providing payers and providers with incentives to be more transparent about healthcare costs;
- 3. Using Medicare and Medicaid to drive industry change; and
- 4. Reducing regulatory burden.

Calling the results of previous efforts to drive innovation such as efforts around affordable care organizations "lackluster," the Secretary promised "bold measures that will fundamentally reorient how Medicare and Medicaid pay for care" and "create a true competitive playing field where value is rewarded handsomely." He also expressed interest in revisiting requirements for Accountable Care Organizations

(ACOs), reducing quality reporting burden, and considering the effects of models on provider consolidation.

Alternative Payment Models

Medicare Care Coordination Improvement Act of 2017

In November, the AANS and CNS <u>signed on to a letter</u> of support for the Medicare Care Coordination Improvement Act of 2017 (<u>S. 2051</u>), which would improve care coordination for patients, improve health outcomes and restrain costs by allowing physicians to participate and succeed in APMs. The bill would modernize the "Stark" self-referral law that was enacted nearly 30 years ago and pose barriers to care coordination. The Stark Law prohibits payment arrangements that consider the volume or value of referrals or other business generated by the parties. These prohibitions stifle care delivery innovation by inhibiting practices from incentivizing their physicians to deliver patient care more effectively and efficiently because the practices cannot use resources from designated health services in rewarding or penalizing adherence to clinical guidelines and treatment pathways.

In January 2018, CMS Administrator Verma acknowledged during a webcast with the American Hospital Association that change to the Stark law, which has been in place since 1990, is becoming necessary as Medicare transitions from a fee-for-service payment model to a value-based payment methodology.

Bundled Payment for Care Initiative (BPCI) Advanced

interested in participating have until March 12 to apply.

In January 2018, CMS announced a new voluntary bundled-payment model that will be considered an advanced alternative payment model under MACRA. The <u>Bundled Payments for Care Improvement-Advanced Model</u> includes 32 clinical-care episodes that providers can choose from, 29 of which are in the inpatient setting and three in the outpatient setting. The 32 types of clinical episodes in BPCI Advanced add outpatient episodes to the inpatient episodes that were offered in the Innovation Center's previous bundled payment model (the BPCI).

In BPCI Advanced, participants will be expected to redesign care delivery to keep Medicare expenditures within a defined budget while maintaining or improving performance on specific quality measures. Seven quality measures have been selected for the BPCI-Advanced Model, including the all-cause hospital readmission measure and advance care plan measure. Participants will need to bear financial risk, have payments under the model tied to quality performance, and are required to use Certified Electronic Health Record Technology (CEHRT). By meeting these requirements, the model qualifies as an Advanced APM under the QPP, which means that participants could qualify for a 5% lump sum bonus under the QPP and avoid MIPS. This represents the first Advanced APM to be introduced by the Trump administration.

Under the model, clinician payment will be based on quality performance during a 90-day episode of care. Participants must select at least one of the 32 clinical episodes to apply to the model. Some of the inpatient clinical episode include:

'	1
	Back & neck except spinal fusion
	Cervical spinal fusion
	Combined anterior posterior spinal fusion
	Spinal fusion (non-cervical)
	Stroke (not sure which codes are included here yet)
Of the	3 outpatient clinical episodes, the following is included:
	Back & Neck except Spinal Fusion
The fi	rst cohort will begin Oct. 1. The model performance period will run through Dec. 31, 2023. Those

John K. Ratliff, MD, continues to serve on a Technical Expert Panel (TEP) to provide clinical input into evaluation and potential refinement of current <u>Bundled Payment for Care Initiative (BPCI)</u> bundles that focus on non-cervical spinal fusion (non-Cervical). It is still unclear whether/how this work will transition to this new initiative.

Physician-Focused Payment Model Technical Advisory Committee (PTAC)

The <u>Physician-Focused Payment Model Technical Advisory Committee (PTAC)</u> was established under MACRA to review physician-focused payment model (PFPM) proposals, and if appropriate, provide comments and recommendations to HHS. The panel has 11 members appointed by the Comptroller General of the United States. The HHS is not obligated to adopt any models recommended by PTAC.

In December 2016, American College of Surgeons (ACS) submitted its proposed "ACS-Brandeis Advanced Alternative Payment Model (APM)" to the PTAC. In June 2017, PTAC recommended the ACS-Brandeis model for limited scale testing and HHS Secretary Price subsequently requested changes to the model before it could be tested. While organized neurosurgery supports the concept of the ACS-Brandeis model, it continues to have concerns about providing unqualified support due to the lack of detail regarding the way it would approach spine surgery. Neurosurgery has made some progress illustrating to Brandeis consultants the danger of heterogeneous bundles and the need for smaller sets of better defined procedures that could be incorporated into APMs, however, the proposal does not yet include a level of detail that would allow the AANS/CNS to understand exactly how this would work for neurosurgery and its specific episodes.

In September, the Chairman of the PTAC submitted a letter to former HHS Secretary Price that identifies "several opportunities for improvement that PTAC alone cannot fully address." PTAC shared that submitters of PFPMs would benefit from individualized technical assistance in payment model design. PTAC suggested offering public workshops to provide submitters' access to experts in payment model design, which could also be helpful by triaging good ideas from submitters. Specifically, PTAC could identify those that warrant a payment model versus those that would benefit from other intervention, such as a new code or change in payment amount. PTAC also requested that a mechanism be established for applicants to obtain analyses of Medicare claims data to be incorporated within their proposals. Finally, PTAC discussed thoughts on data sharing capabilities of HIT; limited-scale testing of innovative payment models; and, barriers to innovation in current payment systems.

In November, the House Energy and Commerce Subcommittee on Health held a hearing titled <u>Medicare Access and CHIP Reauthorization Act of 2015: Examining Physician Efforts to Prepare for Medicare Payment Reforms</u>. In their testimony, the Chair and Vice-Chair of PTAC noted that although MACRA requires a move to APMs, providers continue to face major barriers to transitioning because of information blocking, the lack of interoperability and other factors limiting access to data.

In December, the PTAC met again to review proposals. Many models were either not recommended or found to be inapplicable to the Medicare population. The next PTAC meeting is scheduled for March 26-28, 2018.

BCBSA Blue Distinction Program

The AANS and CNS nominated participants include **John K. Ratliff**, MD; **John J. Knightly**, MD; **Ralph F. Reeder**, MD; and **Mohamed Bydon**, MD. They will assist Blue Cross Blue Shield of America (BCBSA) with a retooling their Spine Blue Distinction Program. BCBSA is looking to convene a technical expert panel to update the Spine Program in two main ways:

- 1. In an effort to compare apples to apples and focus on a more homogenous population, they originally opted to focus on cervical and lumber spondylolisthesis, but 300+ sites couldn't meet the criteria, so they are trying to tweak the inclusion criteria and identify better measures.
- 2. They're also looking at possibly adding ASCs and specialty hospitals to the designation process.

On a call in October, they noted that of the 2,700 sites that were invited to join the Spine, Knee, and Hip Program, 887 sites responded to the Spine portion/asked for the Spine designation. A big challenge is that there's not really any risk-adjusted data out there, unlike hip/knee for which CMS already has an adjusted quality measure that allows them to standardize everyone. Washington office staff reminded them about our registry as a resource for refining inclusion criteria, helping to identify better measures, and possibly being a future element of the designation. BCBSA is aware of our registry, but is interested in learning more and requested a webinar that demonstrates its capabilities and data points. They noted that a challenge will be the fact that decisions about entering data are made at the physician level while the BCBSA designation program is a facility level designation. Nevertheless, they are willing to discuss this further and would like to schedule a webinar in the near future, which is in the works.

In December the NQC and NPA leadership held a webinar with BCBSA staff to demonstrate the QOD and discuss its potential use under the Distinction Program. In February 2018, BCBSA held its second spine expert panel to discuss *Cost Evaluation* measures for its Blue Distinction Centers for Spine Surgery Spine designation.

Health Information Technology

The 21st Century Cures Act, which was signed into law under the Obama Administration in December 2016, authorizes the HHS OIG to investigate any claims of information blocking by HIT vendors and mandates open application programming interfaces (APIs). Section 4003 of the Cures Act defines "interoperability" as having the following characteristics:

- Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
- Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
- Does not constitute information blocking

The Cures Act defines "information blocking" as a practice that "interferes with, prevents, or materially discourages access, exchange, or use of electronic health information." Both vendors and health care providers must refrain from information blocking or be subject to civil monetary penalties that can be as high as \$1 million per violation.

As a result of this legislation, the ONC is shifting its focus from adoption of HIT to interoperability and data sharing. It is currently working on a rule to address data blocking, which is expected by mid-2018.

In January 2018, ONC also issued a draft <u>Trusted Exchange Framework</u>, as required under the Cures Act. The framework seeks to solve a challenging problem posed in the aftermath of Obama administration-era HIT policy, which is how to build on the first flawed efforts to encourage interoperability. The HITECH Act built up regional and state health information exchanges, and new private networks are growing. But obtaining data from outside one's network remains a heavy lift.

The intent of the trusted exchange framework is to build "a single on-ramp to interoperability." The draft describes principles for the technical processes of network-to-network exchange, including charges (which it states should not exceed the costs for retrieving and sending the data), privacy and security, and data standards. Networks that agree to abide by those principles would be able to connect more economically, without having to negotiate agreements between each other, which should encourage greater data sharing. The operations of network-to-network exchange would be coordinated and administered by a private entity, with a funding opportunity announcement to be made in the spring. Despite this movement forward, critics say the framework does not go far enough and that it is only useful if the underlying technology works, which is still a question. Also, the process is focused on health information exchanges, which represent only a portion of the health-care system. ONC is soliciting comments on the draft until Feb. 18. It hopes to have the exchange framework ready to go by the end of the year.

Also in early 2018, CMS announced MyHealthEData, a new initiative aimed at empowering patients "by giving them control of their healthcare data, and allowing it to follow them through their healthcare journey." CMS also announced the launch of Medicare's Blue Button 2.0, allowing a patient to access and share their healthcare information, previous prescriptions, treatments, and procedures with a new doctor, which can lead to less duplication in testing and provide continuity of care. Finally, CMS announced that it intends to overhaul its EHR Incentive Programs to refocus the programs on interoperability and to reduce the time and cost required of providers to comply with the programs' requirements. Chairman of the House Energy and Commerce Health Subcommittee Michael Burgess, MD (R-Texas) applauded the announcement, saying that it builds on the committee's work in the Medicare and CHIP Reauthorization Act of 2015 (MACRA) and the 21st Century Cures Act.

On the legislative side, in late September, the Senate Health, Education, Labor and Pensions Committee held a hearing on 21st Century Cures Act Implementation and Interoperability, where it was noted that physicians spend two hours of work on EHRs and desk work for every one hour spent with a patient. Sen. **Lamar Alexander** (R-Tenn.), chair of the committee, said that while regulations are important and have their place, they can sometimes inhibit innovation in the private sector.

As noted in the MACRA update, the EHR Regulatory Relief Act (<u>S. 2059</u>) would roll back meaningful use requirements in several ways. The bill would create a permanent 90-day reporting period for the MIPS ACI category, remove its all-or-nothing scoring approach to scoring, and expand hardship exemptions. One section of the legislation eliminates part of the 2009 HITECH Act that requires the HHS secretary to create "more stringent measures of meaningful use" over time. A companion to that section (<u>H.R. 3120</u>) cleared the House Energy and Commerce Committee earlier this fall.

However, one significant obstacle to interoperability is a proposed cut to the ONC's budget. The Trump administration's budget request for fiscal year 2018 proposed cutting the ONC's funding from \$60 million to \$38 million

Appropriate Use Criteria for Advanced Imaging Services

The "Protecting Access to Medicare Act of 2014 (PAMA)" (P.L. 113-93) established an appropriate use criteria (AUC) program for advanced diagnostic imaging services provided to Medicare beneficiaries. Per the statute, beginning Jan. 1, 2017, physicians and other health care professionals who order advanced diagnostic imaging tests (i.e., diagnostic MRI, CT, and nuclear medicine, but not X-ray, fluoroscopy or ultrasound) must consult with AUC using a qualified decision support (CDS) mechanism. Professionals who furnish these tests must document the ordering professional's consultation of AUC to be paid for the service. The law also directs CMS to require prior authorization beginning in 2020 for ordering outlier professionals related to specific clinical priority areas. The program only applies to outpatient settings such as physician offices, hospital outpatient departments, and ambulatory surgical centers, but not inpatient settings.

AUC under this program may only be developed by qualified provider-led entities. The initial list of qualified entities and qualified CDS mechanisms is available here. CMS also previously finalized the clinical priority areas that will be subject to pre-authorization requirements starting in 2020 if an ordering professional is found to be an outlier on adherence to AUC. These include: Headache and Low Back Pain. CMS also established exceptions for ordering professionals for whom consultation with AUC could pose a significant hardship.

As noted earlier, the <u>2018 MPFS final rule</u> delayed the program for another year so that physicians will not be required to start reporting AUC consultations until 2020 (rather than 2019, as proposed). 2019 will remain an educational and testing year.

In March 2018, CMS released a an <u>article titled</u>, "Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging — Voluntary Participation and Reporting Period — Claims Processing Requirements — HCPCS Modifier QQ." The article discusses the appropriate HCPCS modifier QQ that may be

reported on the same claim line as the CPT code for an advanced diagnostic imaging service that is furnished in an applicable setting and paid for under an applicable payment system. The new coding guidance refers to a voluntary reporting period, which begins July 1, 2018, that will allow practices to test their systems and become familiar with the operation of the program. During both the voluntary reporting and testing year, CMS will pay claims for advanced diagnostic imaging services regardless of whether they correctly contain information on the required AUC consultation.

More information about the Imaging AUC Program is available here.

Effort to Delay AUC Implementation

In addition to opposing the implementation of this program through rulemaking, the AANS/CNS, through a coalition of specialty societies, is currently supporting a legislative effort to further delay implementation of the mandatory AUC consultation for a few years due to the following concerns:

	The AUC Program was enacted prior to MACRA and might now be unnecessary. The law is financially advantageous to CDS developers at the expense of clinicians who order advance diagnostic imaging tests.
•	Not all applicable AUC will be available for consultation by the ordering professional because CDS vendors can "pick and choose" among qualified AUC so long as the CDS incorporate AUC that comprise the entire clinical scope of all priority clinical areas.
	There are already multiple significant demands being placed on claims forms as a result of MACRA and other initiatives.
	The program may ultimately be costlier to administer than the potential for savings, and lacks a patient outcomes or quality component.

In late December, members of the coalition, including the AANS and CNS, worked to develop proposed legislation to eliminate the AUC program. Representing the Alliance of Specialty Medicine at a House Ways and Means Committee roundtable, **Katie Orrico** urged the Committee to adopt legislation to fold the AUC program into Medicare's Quality Payment Program. Additional efforts to eliminate this redundant program will continue.

Quality Improvement Organizations

Physician Consortium for Performance Improvement (PCPI)

Due to its waning role in the quality measurement landscape and its aimless effort to focus on broader activities outside of measure development, the AANS and CNS decided not to renew its membership in the PCPI for 2018.

National Quality Forum (NQF)

Organized neurosurgery continues to monitor its return on investment related to NQF membership. While CMS is not required to use NQF-endorsed measures under MIPS, it continues to view NQF-endorsed measures in high regards and has even indicated interest in applying some/all of the NQF's criteria to non-NQF measures. Still, as CMS attempts to close existing measurement gaps, there is a clear shift away from NQF measures. In fact, about 50% of current MIPS measures are not NQF endorsed. Furthermore, there is frustration with the NQF review process, which is resource and time intensive, and often driven by politics rather than science.

• **Ketan R. Bulsara**, MD, FAANS, represents the AANS on the NQF's Neurology Panel, which recently voted on a set of stroke measures. In June, neurosurgery voted in support of measures evaluated by this group, per Dr. Bulsara's recommendation.

	John K. Ratliff, MD, FAANS, serves on the NQF Cost and Efficiency Standing Committee which is reviewing cost and resource use maintenance measures. As of September 2017, he was appointed to a new 3-year term.
	John J. Knightly , MD, FAANS, serves on the NQF Physician Advisory Panel, which was assembled to advise the NQF on measurement science. This panel will be an ongoing committee of the NQF, and neurosurgery has a two-year term.
	ee earlier discussion about CMS' 2019 MUC List, which is currently under consideration by the Measures Application Partnership (MAP)
Surgio	cal Quality Alliance (SQA)
met in discus measu	Penar, MD, FAANS, continues to serve as the AANS/CNS representative to the SQA. The SQA November, where it met with CMS to clarify specific policies and concerns related to MIPS, and sed ongoing gaps in surgical measures, concerns about CMS' efforts to harmonize QCDR ires, surgical APMs, and concerns about the ongoing lack of interoperability and EHR data ag. It will next meet in late April 2018.
Misce	llaneous Quality Projects/Appointments
Some	additional recent appointments and work include:
•	John K. Ratliff, MD, continues to serve as a Clinical Working Group (CWG) contributor to the CMS public domain episode grouper project. They have used this feedback to adjust episode content and continue to inform the development of new clinical episodes of care for cost measurement, including the Clinical Subcommittees convened by Acumen. As discussed earlier, Brandeis and Acumen (the project's contractors) continue to engage him in feedback on clinical content and other logical aspects of the grouper.
•	In late summer 2017, Erica F. Bisson , MD, FAANS, was nominated to a Technical Expert Panel related to a project titled "CMS Quality Measure Development Plan: Supporting the Transition to the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)." The intent of this TEP is to proactively engage stakeholders (e.g., frontline clinicians, patients/caregivers, and professional societies), to provide expertise, and to contribute direction and thoughtful input related to future clinician quality measure development to support the QPP.
	In August, Mo Bydon , MD; Paul Penar , MD, FAANS; and Scott Simon , MD, FAANS were nominated serve on MIPS Inpatient Outcomes Measures TEP, which will focus on hospital quality and will likely include one outcome measure assessing a range of hospitalized patients and one measure based on an elective procedure.
	The AAOS also recently convened an informal TEP to review why previous attempts at developing bundled spine payments by CMS have failed. Dr. Ratliff represents neurosurgery on the TEP, which will focus on non-cervical spinal fusion procedures for CMS. The intent here is to conduct a root cause analysis of why previous efforts were unsuccessful; there is no concrete deliverable.



GUIDELINES Update

Administrative Issues

New Committee Name

To better distinguish between the CNS Guidelines Committee, whose function is creating guidelines, and the AANS/CNS Joint Guidelines Committee, whose function is reviewing guidelines, the JGC has changed its name to the Joint Guidelines Review Committee (JGRC).

Updating the JGRC Governance Documents

The JGRC is in the process of updating its governance documents. The document will include JGRC operations, rules and processes. In addition, updated COI and endorsement language will be incorporated.

Leadership

The AANS/CNS Joint Guidelines Review Committee leadership includes:

JGRC Leaders
Sepideh Amin-Hanjani, MD, Chair
Kevin Cockroft, MD, Immediate Past-Chair
Steven Kalkanis, MD, Vice-Chair
John O'Toole, MD, Vice-Chair
Patricia Raksin, MD, Vice-Chair

The JGRC adopted a more standardized process for making JGRC appointments and ensuring active participation from each of the AANS/CNS subspecialty sections, as well as from the CSNS, the Young Neurosurgeons, the CNS Guidelines Committee, and the Coding and Reimbursement Committee. Each section/entity is allotted 1-9 appointees based on the size of their membership and guideline productivity. Each term is three years in length, and may be renewed at the direction of the nominating organization.

New members are expected to complete an evidence-based medicine methodology training prior to participating in a guideline review on behalf of the JGRC. A handful of new members attended the EBM Practical Course held in association with the 2015 CNS Annual Meeting. The CNS again offered this training at the 2017 CNS annual meeting in Boston. This training was recorded and has been made available for members to complete online following the in-person meeting.

Over the last year, the AANS and CNS approved revised endorsement wording to better reflect the nature of JGRC and subspecialty section reviews. The JGRC is also working to finalize a COI form that members of the committee would sign for each specific guideline review. The CNS also continues to update its website dedicated to organized neurosurgery's guideline efforts, with includes inks to JGRC activities. The site is available at: https://www.cns.org/guidelines.

Transitioning Staff Support of the JGRC

Effective Dec. 1, 2017, the CNS and AANS contracted with a new outside consultant — **Kirsten Aquino** — to serve as the administrator for the JGRC. No stranger to the medical specialty community, Kirsten

also does work for the American Urological Association (since 2000). Before that, she worked at Johns Hopkins University School of Medicine and at the University of Maryland, Baltimore. Kirsten holds a Master's in Experimental Psychology from Towson University, and a BS in Psychology from Frostburg State University.

Guidelines Projects

Cerebrovascular

- AHA Projects. There are several AHA guidelines and scientific statements of interest to neurosurgery that recently have been, or soon will be, updated. These include:
 - Guidelines for Acute Ischemic Stroke: AANS/CNS endorsed on Jan. 2, 2018.
 - Scientific Rationale for Inclusion and Exclusion Criteria for Intravenous Thrombolysis: AANS/CNS endorsed, published December 2015.
 - 2015 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients with Acute Ischemic Stroke Regarding Endovascular Treatment. AANS/CNS endorsed, published June 2015.
 - Guidelines for the Management of Spontaneous Intracerebral Hemorrhage: JGRC reviewed in summer/fall 2014; endorsed by AANS/CNS, published May 2015.
 - Guidelines for Management of Unruptured Intracranial Aneurysms: endorsed by the AANS/CNS published in June 2015.
 - Guidelines for the Prevention of Stroke in Patients with Ischemic or Transient Ischemic Attack: Endorsed by AANS/CNS, published in May 2014
 - Guidelines for the Primary Prevention of Stroke: Endorsed by AANS/CNS, published October 2014

Other projects reviewed and affirmed by the CV section with parent organization approval:

- Treatment and Outcome of Hemorrhagic Transformation After Intravenous Alteplase in Acute Ischemic Stroke affirmed by the AANS/CNS CV section, published November 2017.
- Management of Brain Arteriovenous Malformations affirmed by the AANS/CNS CV section, published June 2017.

*Note: New AHA guidelines commissioned after September 2015 will include evidence tables.

- Neurocritical Care Society. The AANS and CNS formed a collaborative guidelines relationship with the NCS where neurosurgery prospectively identifies guideline projects of interest for review and potential endorsement, and look to have a formal AANS/CNS designee on the writing group. Two AANS/CNS liaisons to the NCS's guidelines committee (Stav Tjoumakaris, MD, FAANS and Michael C. Huang, MD, FAANS) are expected to keep the JGRC apprised of NCS activities. In return, the JGRC has allowed the NCS to appoint a liaison to the JGRC for similar informational purposes. Current NCS projects include:
 - Multimodality monitoring in Neuro ICU: Consensus statement, which the Trauma Section determined in September 2014 that it would not endorse due to incomplete documentation provided by authors and other methodological issues
 - Large Hemispheric Infarction: In October, the AANS/CNS endorsed the educational content of this scientific statement, which was published in March 2015
 - Devastating Brain Injury: JGRC submitted a letter declining endorsement due to methodological issues in early July 2014; Trauma Section also declined to review due to methodological issues
 - Anticoagulation Reversal: Reviewed by the JGRC in early fall 2015; JGRC/AANS/CNS affirmed the educational content of this document in January.

- Deep Vein Thrombosis: Reviewed by the JGRC in early fall 2015; authors made no changes in response so JGRC/AANS/CNS could not endorse or offer any other supportive statement.
- Insertion and Management of External Ventricular Drains: Reviewed by Trauma and CV sections.
- Medical Management of Cerebral Edema Guideline: Working to finalize an MOU between the AANS/CNS and the Neurocritical Care Society. Work will begin once the MOU is signed, and Gregory Hawryluk, MD, will serve as the Trauma Section's representative on the writing group.

American Academy of Neurology

- Idiopathic Normal Pressure Hydrocephalus: Reviewed by JGRC in February 2015; in June, the AANS and CNS responded to the authors requesting inclusion of a statement that the AANS and CNS affirm educational content of this document.
- The AAN has reached out to the AANS and CNS to discuss developing a more collaborative working relationship, similar to the arrangement that the CV Section has with the AHA/ASA.
- Disorders of Consciousness: Document was submitted for review and comments were provided to AAN in 2017. It has been revised and is now out for final review for potential endorsement by the Neurotrauma and Critical Care Section, due by April 11, 2018.

☐ Society of Interventional Radiology (SIR)

 Multisociety Consensus Quality Improvement Revised Consensus Statement for Endovascular Therapy of Acute Ischemic Stroke Guidelines: June 2015, the AANS appointed Sean Lavine, MD and the CNS appointed Alex Khalessi, MD to serve on the writing team to update this document. CV section recommends endorsement.

Pain

Occipital Nerve Stimulation for Treatment of Medically Refractory Occipital Neuralgia: Revised by
the JGRC, endorsed by the AANS/CNS, and published in <i>Neurosurgery</i> in September 2015
Section is now working on an Ablative Neurosurgery for Cancer Pain document.

Pediatrics

Pediatric Hydrocephalus: Reviewed by JGRC; endorsed by AANS/CNS in February 2014; sent
to Child Neurology Society for endorsement in June 2015.
Plagiocephaly: Pediatric Section guideline reviewed by the JGRC in January 2016; approved by
the JGRC and endorsed by the AANS/CNS in June 2016
Myelomeningocele (Spine Bifida): guideline is ready for JGRC review and reviewers are being
recruited.

Spine/Peripheral Nerve

almost ready for JGRC review.

review comments to authors in early July. The authors responded and the JGRC, after review,
has submitted a letter to the Presidents of AANS/CNS recommending Endorsement of the
document.
Use of Electrophysiological Monitoring for Surgery of Spinal Column and Cord: Endorsed by the
AANS/CNS in June 2017, per a recommendation from the JGRC.
Guidelines for the Surgical Management of Cervical Degenerative Disease: Update in progress.
Metastatic Spinal Tumor: Under development, in collaboration with Tumor Section. Document is

☐ Thoraco-Lumbar Trauma: Developed in collaboration with Trauma Section. JGRC submitted

•	Diagnosis and Treatment of Low Back Pain: NASS project currently under development, O'Toole representing Spine Section. In June 2016, AOSpine and CSRS requested that JGRC review two guidelines on Spinal Cord Injury (SCI) and Degenerative Cervical Myelopathy (DCM). Following a review by the JGRC, the AANS/CNS affirmed the educational benefit of the DCM guideline and declined endorsement of the SCI guideline due to methodological concerns. Subsequently, after publication, it was discovered that the guidelines gave the appearance of AANS/CNS endorsement and did not appropriately convey our non-endorsement. Michael Fehlings , MD, agreed to get the document corrected. In January 2016, AAOS requested review of its carpal tunnel "guidelines." In May, the Peripheral Nerve Task Force affirmed the educational content of what is truly a consensus statement. Use of Intraoperative Monitoring in Spinal Surgery (Beverly Walters , MD, and Mark Hadley , MD) recently: reviewed by JGRC, and AANS/CNS endorsed; published November 2017 in <i>Neurosurgery</i> .
Stered	otactic/Functional
•	Deep Brain Stimulation for Parkinson's: reviewed by JGRC and recommended for endorsement after revision; endorsed by AANS/CNS October 2017. Deep Brain Stimulation for Patients with Obsessive Compulsive Disorder: Reviewed by JGRC in spring 2014; endorsed by AANS/CNS in June 2014 and subsequently published in Neurosurgery. Epilepsy – in development with representation from Pediatrics Section.
Traum	na en la companya de
•	Rekindling of section's relationship with BTF. BTF TBI guidelines efforts will be taken over by CNS Guidelines Committee. Trauma and CV Section representatives reviewed the NCS' Consensus Statement on Insertion and Management of External Ventricular Drains in November. The NCS responded with modifications in January. Ongoing review of the BTF's Updated TBI Algorithm. Brain Trauma Foundation Severe Traumatic Brain Injury: 4th Edition provided to JGRC for review in March 2015; multiple revisions provided since; ultimately supported by the JGRC and endorsed by the AANS/CNS in April 2016. Pediatric Mild TBI: Ongoing CDC project led by Shelly Timmons , MD. The guidelines will soon be published in <i>JAMA Pediatrics</i> and Dr. Timmons will be heading up a writing group to publish (hopefully in <i>Journal of Neurosurgery</i>) the neurosurgical perspective. Thoraco-Lumbar Trauma (see Spine Section)
Tumo	r
•	Guideline on Radiation Therapy for Glioblastoma (ASTRO): JGRC submitted response in September 2015; declined to endorse as an EBM guideline. Low-Grade Glioma: Reviewed by JGRC in fall 2014; endorsed by AANS/CNS in February 2015. Non-Functioning Pituitary Adenoma Guideline: JGRC reviewed in September 2015, supported by JGRC and endorsed by AANS/CNS in June 2016. Metastatic Spinal Tumor (see Spine Section) Vestibular Schwannoma Guideline: endorsed by the AANS/CNS in June 2017, per the JGRC's recommendation. Metastatic Brain Tumor update: JGRC comments submitted to authors in September. The authors made revisions and the JGRC is reviewing the document again. Newly Diagnosed GBM update: under development

Cross-Sectional Projects		
	Appropriateness Criteria for Diagnostic Imaging . Neurosurgery recently updated its representatives to this initiative, which is particularly important now that in 2020 Medicare will require physicians to consult appropriate use criteria prior to ordering advanced imaging.	



Drugs and Devices Update

Administrative Issues

The Drugs and Devices Committee leaders are as follows:

Drugs and Devices Leaders

Robert F. Heary, MD, Chair

William C. Welch, MD, Vice-Chair

Physician Industry Relations

Open Payment Data "Refresh"

On Jan.17, 2018, the Centers for Medicare and Medicaid Services (CMS) updated the Open Payments dataset to reflect changes to the data that took place since the last publication on June 30, 2017. The updated dataset is now available for viewing here. CMS updates the Open Payments data at least once annually to include updates from disputes and other corrections made since the initial publication of the data.

The "refreshed" Open Payments Data Set includes:

Record Updates: Changes to non-disputed records that were made on or before November 15, 2017.
Disputed Records: Dispute resolutions completed on or before December 31, 2017, are
displayed with the updated information. Records with active disputes that remained unresolved as
of December 31, 2017 are displayed as disputed.
Record Deletions: Records deleted before December 31, 2017, were removed from the Open
Payments database. Records deleted after December 31, 2017, remained in the database but will
be removed during the next data publication in June 2018.

CMS will open a 45 day period for teaching hospitals and physicians to review their 2017 data and dispute errors on or about April 1-May 15, 2018. More information about the Open Payments Program timeline is available here.

Congressional Activity

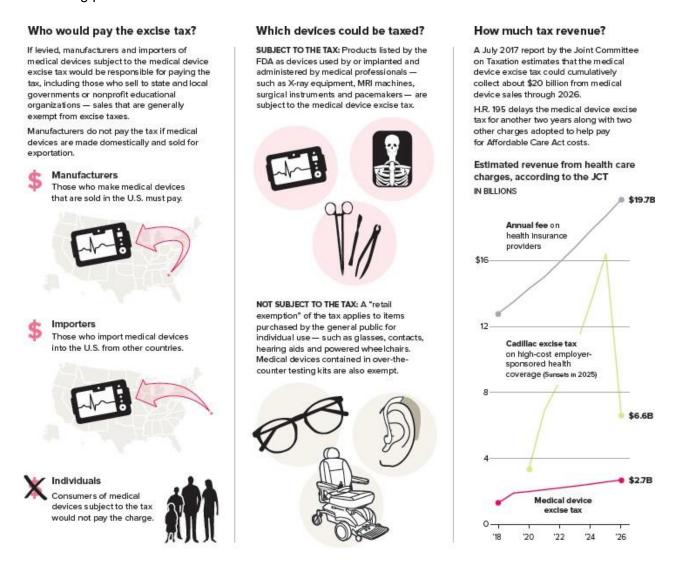
Extension of Moratorium on Medical Device Excise Tax

On Jan. 22, 2018, Congress passed <u>H.R. 195</u>, as amended, a continuing resolution to fund the federal government through Feb. 8, 2018. The legislation, which was signed into law by President Trump, included a suspension of the medical device excise tax through 2019. Repeal of the tax is a priority item on the AANS/CNS 2018 Legislative and Regulatory Agenda. The medical device excise tax is a 2.3 percent tax imposed on manufacturers and importers on the sales of certain medical devices. Excise taxes are paid on sales of a specific good and are often included in the price of a product. Most excise taxes are fixed, per-unit taxes. The medical device excise tax is an "ad valorem" excise tax — a fixed percentage rate based on the value of the product. Businesses making and selling medical devices in

the United States or importing them into the states from foreign manufacturers or foreign operations of U.S. firms would be subject to the tax. Medical devices made in the U.S. and exported abroad would be exempt from the tax.

Medical device-makers have opposed the tax, citing that it could affect research and development funding of products, and may pass the cost on to consumers by increasing medical device prices. Also at issue — how much revenue the tax could generate considering complications related to regulation compliance and administration of the charge. In July 2017, the Joint Committee on Taxation reported that about \$20 billion in lost tax revenue could occur over the next 10 years if the medical device excise tax is repealed.

The following provides a visual overview of the tax:



Opioids

• Senate HELP Committee Hearing on the Opioid Crisis. On Jan. 9, 2018, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing entitled *The Opioid Crisis: An Examination of How We Got Here and How We Move Forward*. The sole witness was Sam Quinones, author of "Dreamland: The True Tale of America's Opiate Epidemic." A copy of Mr. Quinones' statement is here.

The tenor of the hearing was bipartisan, courteous and heartbreaking, as many senators on the committee described the scope of the epidemic in their states and the impact on addicts and their families and communities. Mr. Quinones' book uses the town of Portsmouth, Ohio as an example of the erosion of a vital community with a large swimming pool called Dreamland built in the 1920s that was the center of recreation and a symbol of the town's dedication to the common good. Portsmouth is now devastated by addiction and Mr. Quinones' contention is that loss of community cohesion has contributed to the epidemic and strengthening of communities is essential to addressing the problem. Mr. Quinones complemented the Senators on the passage of the 21st Century Cures Act (P.L. 114-255) and the Comprehensive Addiction and Recovery Act (P.L. 114-198), but said more must be done. He recommended an effort on the scale of the Marshall Plan or the space program. To view the hearing and see more information, click here. House Ways and Means Oversight Subcommittee Hearing on CMS and the Opioid Crisis. On Jan. 17, 2018, the House Ways and Means Oversight Subcommittee held a hearing entitled The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse. Witnesses included Gary L. Cantrell, Deputy Inspector General for Investigations, HHS Office of the Inspector General, Elizabeth H. Curda, Director, Health Care, Government Accountability Office (GAO) and Kimberly Brandt, CMS Principal Deputy Administrator for Operations. Neurosurgery Letter to Senate Finance Leaders on Opioid Issues. On Feb. 16, 2018, the AANS and CNS sent a letter drafted by leaders of the AANS/CNS Joint Sections on Pain and Disorders of the Spine and Peripheral Nerves (DSPN) to Sens. Orrin G. Hatch (R-Utah), Chairman, and Ron Wyden, (D-Ore.) Ranking Member, of the Senate Committee on Finance, responding their request for feedback on policies to address opioid and substance use disorders. □ AANS/CNS Letter to Congress on CARA 2.0 Act of 2018. On Feb. 28, 2018, the AANS and CNS sent a letter to Sens. Rob Portman (R-Ohio); Sheldon Whitehouse (D-R.I.); Shelley Moore Capito (R-W.Va.); Amy Klobuchar (D-Minn.); Dan Sullivan (R-Alaska); Maggie Hassan (D-N.H.); Bill Cassidy (R-La.) and Maria Cantwell (D-Wash.) regarding S. 2456, the Comprehensive Addiction and Recovery Act (CARA). Among other things, the letter recommends that the Senators consider adopting language similar to that included in H.R. 4482, the Opioid Abuse Deterrence, Research and Recovery Act, which was introduced by Reps. Mark Meadows (R-N.C.) and Jim Renacci (R-Ohio). It allows physicians to prescribe opioids for immediate, post-operative pain relief, and to prescribe opioids in excess of an initial 7-day supply if the practitioner documents the reason in the patient record. On March 20, 2018, the AANS and CNS sent a similar letter to Reps. Marsha Blackburn (R-Tenn.), Tim Ryan (D-Ohio), Tom MacArthur (R-N.J.) and Ann McLane Kuster (D-N.H.), who introduced CARA 2.0 (H.R. 5311) in the House. Alliance Letter in Response to House Ways and Means Committee Opioid Questions. On March 15, 2018, the AANS and CNS joined the Alliance of Specialty Medicine in sending a letter to the Leaders of Ways and Means Committee and its Subcommittee on Health in response to a request for feedback regarding recommendations to address the opioid crisis. The American Medical Association (AMA) also sent a letter. Opioid Provisions of 2018 Consolidated Appropriations Act. On March 23, 2018, the President

House Energy and Commerce Health Subcommittee Action on Information for Investigational Use

signed <u>H.R.1625</u>, the Consolidated Appropriations Act of 2018, allocating \$1.3 trillion in discretionary funding among all 12 annual appropriations bills. The new law allows nearly \$4 billion in resources for prevention, treatment, and law enforcement to combat the opioid crisis, including \$1 billion for

On Jan. 17, 2018, the House Energy and Commerce Health Subcommittee voted 18 to 14 to pass the Pharmaceutical Information Exchange (PIE) Act (H.R. 2026) on to the full committee. The legislation,

grants to states to fund programs to fight the opioid epidemic.

introduced by Rep. Brett Guthrie (R-Ky.), would clarify how drug and device companies can share information as it relates to an investigational use of a drug or device. Republican sub-committee members argued that the bill would help ensure faster access to new treatments and cures, but many Democrats on the subcommittee expressed concerns about the legislation's potential to compromise patient safety.

Right to Try

On March 21, 2018, the House passed the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act (<u>H.R. 5247</u>), on a largely party-line vote of 267-149. The legislation would permit individuals with terminal diseases to access experimental therapies. This was the second time the legislation had been brought to the House floor for a vote, after House Republicans previously were unable to obtain the required two-thirds majority to pass the bill under suspension of the rules. The legislation has been referred to a conference committee. The Senate passed its version of the bill, <u>S. 204</u>, on Aug. 3, 2017. On March 23, 2018, Sen. **Ron Johnson** (R-Wis.) unsuccessfully attempted to pass H.R. 5247 under suspension of the rules.

Alliance Biosimilar Letter

On March 23, 2018, the AANS and CNS joined the Alliance of Specialty Medicine in a letter to Jim Justice, Governor of West Virginia regarding legislation, <u>H.B. 4524</u>, on biosimilar products that would allow for timely notification of substitutions for biosimilar medication and permit prescribers to indicate "dispense as written," when a substitute is deemed not appropriate.

Food and Drug Administration Activities

FDA Safety Warning for MRA

On March 12, 2018, the FDA issued a safety <u>notice</u> due to the potential for increased image artifact associated with Magnetic Resonance Angiography (MRA) imaging for patient follow-up of certain post neurovascular embolization coil procedures. The agency has received reports indicating that when MRA is performed on patients implanted with neurovascular embolization coils containing 304V stainless steel (either as part of the coil implant itself, or left behind as part of the detachment process), the images may contain larger than expected MR artifact, or image voids when compared to other metals. In these cases, the reduced quality of the MRA image from increased artifact can result in inaccurate clinical diagnoses (e.g., occlusion status) and subsequent inappropriate medical decisions. FDA asks physicians to report adverse events or side effects related to the use of medical products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report

FDA Safety Warning for Neuroblate

On March 22, 2018, the FDA issued a Class I recall <u>notice</u> due to the potential for unintended heating and patient injury with use of the Monteris Medical NeuroBlate probe, which is part of the NeuroBlate System. A Class I recall is issued when the agency believes use of the device may cause serious injuries or death. Monteris issued three product advisories between October and December 2017, which were part of the Class I recall; however, the FDA has concerns that the information provided by Monteris has not sufficiently mitigated the risk of unintended probe tip heating.

FDA Pediatric Medical Device Development Meeting

The FDA has announced a public meeting entitled "Pediatric Medical Device Development" to be held on Aug. 13 and 14, 2018. The purpose of the meeting is to identify strategies to enhance the medical device development and innovation for devices that serve the unique needs of pediatric populations. Topics for discussion will include ways to improve research infrastructure and research networks to facilitate clinical studies of pediatric devices, extrapolation, use of post-market registries and data to increase pediatric medical device labeling, assistance to medical device manufacturers in developing

devices for pediatric populations, and identifying barriers to pediatric device development and incentives to address such barriers. The notice was referred to the AANS/CNS Section on Pediatric Neurosurgery. **Samuel R. Browd**, MD, PhD, has agreed to attend and **Joseph R. Madsen**, MD may attend as well. Drs. Browd and Madsen serve as Pediatric Section liaisons to the AANS/CNS Drugs and Devices Committee. More information on the meeting can be found <a href="https://example.com/here-new-material-

FDA Clears First Blood Test for TBI

On Feb. 14, 2018, the FDA cleared the first blood test to evaluate mild traumatic brain injury (mTBI) in adults. The Banyan Brain Trauma Indicator (Banyan Biomarkers Inc) is designed to help physicians determine the need for computed tomography (CT) in patients suspected of having mTBI and help prevent unnecessary neuroimaging and associated radiation exposure to patients. More information is available here.

Neurosurgery Responds to FDA Call for Regulatory Reform Feedback

On Feb. 5, 2018, the AANS and CNS sent a <u>letter</u> to the FDA in response to the agency's <u>notice</u> requesting stakeholder feedback regarding regulatory burdens for programs under its broad purview.

Items addressed in the neurosurgery letter include:

	Off-label regulation.
	Simplification for Investigator-sponsored IDE Projects.
•	Burdensome conflict of interest paperwork for panel participationboth for increasing the agency's ability to issue waivers for conflicts and for simplifying paperwork for volunteers who
	have worked with the agency in the past. (The FDA has recently lost the participation of at least 3 neurosurgeons with long volunteer advisory panel service because of the requirement to
	resubmit burdensome paperwork, most of which had already been provided in the past).
	Use of real world registry data, highlighting our NeuroPoint Alliance.

Alliance of Specialty Medicine Letter to FDA on Regulatory Relief

In addition to our own letter, the AANS and CNS joined the Alliance of Specialty Medicine in drafting a <u>letter</u> to FDA Commissioner **Scott Gottlieb**, MD in response to the call for comment on regulations. The Alliance letter includes comments on off-label use and compounding pharmacy regulations.

FDA Orthopaedic Panel Review of Annular Closure Device

On Dec.12, 2017, the FDA Orthopaedic and Rehabilitation Devices Advisory Panel met to discuss, make recommendations and vote on information regarding the premarket approval application (PMA) for the Barricaid annular closure device manufactured by Intrinsic Therapeutics. The device is intended to be implanted following a limited discectomy, to prevent reherniation and the recurrence of pain or dysfunction. The AANS/CNS Drugs and Devices Committee and Spine Section leaders reviewed the notice and felt that a formal statement was not warranted. Three neurosurgeons served on the FDA panel: **Bong-Soo Kim**, MD, **Eli M. Baron**, MD, and **Marjorie C. Wang**, MD. **Matthew J. McGirt**, MD was also at the meeting, presenting data on behalf of the manufacturer. The presentation material is available here. A copy of the notice for the meeting is here.

The panel	took	three	votes:
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On the question of whether the device was safe, the panel voted 5 yes and 9 no.
On the question of is the device effective, the panel voted 12 yes, 1 no, and 1 abstention.
On the question of do the benefits outweigh the risks, the panel voted 5 yes, 8 no, and 1 abstention.

Advisory panels make recommendations that FDA staff take into consideration but do not have to follow. They will use the vote and the discussion to inform their ultimate decision about the PMA.

FDA Hearing on Opioid Prescribing

The FDA held a public hearing on Jan. 30, 2018, titled, *Opioid Policy Steering Committee: Prescribing Intervention*— Exploring a Strategy for Implementation--to seek public comment on how the agency can better address opioid issues, including improving education for providers, using the FDA Risk Management Authorities (REMS) to help make sure the dispensing of opioid medication more closely matches clinical needs and assuring that the risk of abuse is considered in the review process of opioid products. **Robert F. Heary**, MD made a presentation on behalf of organized neurosurgery and a written statement from the AANS, CNS, and AANS/CNS Joint Sections on DSPN and Pain was submitted for the official record of the meeting. **Janet Woodcock**, MD, Director of the FDA Center for Drug Evaluation and Research (CDER) was complementary of Dr. Heary's presentation and FDA staff followed up regarding data cited by Dr. Heary for an upcoming article. More information, including a recorded webcast, is available here.

FDA Neurological Devices Advisory Panel Meeting on Aneurysm Treatment

On March, 1, 2018, the FDA Neurological Devices Advisory Panel met to review the evaluation of clinical study data to support the safety and effectiveness of intracranial aneurysm treatment devices and factors that can affect clinical outcomes such as aneurysm morphology, size, and location in the neurovasculature. In addition, the FDA asked the committee for its expert opinion on the scientific and clinical considerations relating to the clinical trial design that may be relevant to the determination of safety and effectiveness for these devices. A copy of the notice for the meeting is available here.

Attending on behalf of the AANS and CNS and the AANS/CNS Section on Cerebrovascular Neurosurgery were Kevin M. Cockroft, MD; Robert E. Harbaugh, MD; J Mocco, MD, MS; Clemens M. Schirmer, MD; Adnan H. Siddiqui, MD, PhD; and Babu G. Welch, MD. Neurosurgeons serving on the panel included Julie G. Pilitis, MD, PhD; Kadir Erkmen, MD; William W. Ashley, MD, PhD and Gregory Thompson, MD. Christopher M. Loftus, MD, was at the meeting in his role as Chief Medical Officer for the FDA Division of Neurological Devices. Meeting materials, including the AANS/CNS/SVIN/SNIS slide presentation and statement are available here.

FDA Policy Priorities

In January 2018, FDA Commissioner **Scott Gottlieb**, MD, released the agency's <u>Strategic Policy Roadmap for 2018</u>, which focuses on the opioid crisis, nicotine addition, generic competition, and aiding consumer healthcare decision-making. The roadmap outlines four priority areas: reducing the nation's burden of addiction (both nicotine and opioid); promoting generic drug competition and other industry innovation; empowering consumers to make better healthcare decisions and expanding opportunities to use nutrition to combat chronic disease, often through digital health technology; and strengthening FDA's scientific workforce and its tools for efficient risk-management.

ASTM Neurosurgical Head Holder Standard

The Association for Testing and Materials (ASTM) and FDA staff continue work on draft ASTM standard for neurosurgical head holder devices. Yakov Gologorsky, MD, as the representative from neurosurgery to the ASTM, has participated in numerous meetings and conference calls with FDA staff and industry representatives to provide input for the development of the draft standard. The most recent call was held on March 13, 2018. The draft standard was presented for initial consideration at the ASTM meeting on Nov. 15, 2017. Neurosurgeon **Bennett Blumenkopf**, MD, FDA medical officer, has helped lead the effort for the FDA. Dr. Gologorsky and AANS/CNS Washington Office staff attended the ASTM meeting by conference call. ASTM's medical device and implant standards are instrumental in specifying and evaluating the design and performance requirements for biomedical materials, tools, and equipment. Standards are created through a voluntary consensus process and are used by industry and

the FDA to help establish best practices for assessing devices for proper quality and workmanship. A list of current ASTM medical device and implant standards is available here.

FDA Compounding Guidance

On March 7, 2018, the FDA held a conference call briefing to discuss a recently released draft guidance document setting forth the agency's policy for evaluating drug compounding facilities. On March 23, 2018, FDA Commissioner **Scott Gottlieb**, MD issued a <u>statement</u> on the agency's plans for improved oversight of drug compounding facilities.

Other issues

More on the Opioid Crisis

- Presidents Statement. On March 19, 2018, the President issued a <u>statement</u> titled *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand.*
- White House Issues Summary of 2017 Opioid Crisis Action. Recently, the White House issued a comprehensive summary of its actions to combat the opioid crisis in the year 2017. Included are funds awarded by the Department of Health and Human Services (HHS), research at the National Institutes of Health (NIH), and enforcement action by the Department of Justice (DOJ). The White House has also formally responded to recommendations from the President's Opioids Commission on how to fight the misuse and abuse of prescription painkillers, largely endorsing the Commission's 56 recommendations. The Office of National Drug Control Policy (ONDCP) stated that it will maintain the opioid crisis as a top priority and continue to focus on both preventing new addictions and supporting those suffering from addiction through recovery.
- White House Council of Economic Advisors Report on the Cost of the Opioid Crisis. On Nov. 20, 2017, the White House Council of Economic Advisors (CEA) released a report titled The Underestimated Cost of the Opioid Crisis. The CEA estimates the cost of the opioid crisis at \$504 billion. The higher figure is a result of CEA's inclusion of the "value of a statistical life," which places a cost on the intangible value of life itself, beyond the concrete estimates of lost earnings included other reports. The number of overdose deaths have doubled during the past decade; the total number of life-years lost in 2016 due to opioid overdoses reached 1.84 million years in 2016. The CEA calls for a better understanding of the economic causes contributing to the crisis. The White House also said that it plans to offer a follow-up analysis of recent actions aimed at solving the crisis.
- Medicare Part D Opioid Policy. On March 5, 2018, AANS and CNS sent a letter to CMS regarding opioid prescribing provisions of the *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter.* The letter, drafted by **Christopher J. Winfree**, MD and the leaders of the AANS/CNS Joint Section on Pain, expresses concern about the CMS proposed policy to restrict multiple prescribers from providing opioid prescriptions for a single patient and highlights the situation in which a chronic pain patient undergoing a major surgical procedure may appropriately be prescribed opioid medication by both the operating surgeon and the physician managing the chronic pain. In addition, the letter addresses the imposition of a 90 morphine milligram equivalent (MME) limit for opioid prescribing. Again, for a chronic pain patient this limit may not be appropriate during the acute postoperative period.

GAO Report on Least Burdensome Approach for Device Evaluation

On Jan. 16, 2018, the Government Accountability Office (GAO) released a <u>report</u> titled *FDA Medical Device Reviews: Evaluation is Needed to Assure Requests for Additional Information Follow a Least Burdensome Approach, (GAO-18-1400). The GAO was asked to provide information on FDA's implementation of the least burdensome requirements in its medical device review process. This report (1) describes FDA's requests for additional information and sponsor disagreements, (2) describes its*

least burdensome training efforts, and (3) describes FDA actions to improve its requests for additional information and examines the extent to which it has evaluated its implementation of the least burdensome requirements. GAO reviewed FDA documents and guidance and interviewed agency officials and leaders from four relevant medical device manufacturing associations. GAO recommended that FDA develop and use performance metrics to evaluate the implementation of the least burdensome requirements. The Department of Health and Human Services agreed with GAO's recommendation.



Neurosurgical Education and Training

Legislative Activities

GME Bills Introduced

Thus far in the 115th Congress, a handful of bills related to graduate medical education (GME) have been introduced.

- Resident Physician Shortage Reduction Act (<u>H.R. 2267/S. 1301</u>). Introduced in the House on May 1, 2017, by Reps. Joe Crowley (D-Pa.) and Ryan Costello (R-Pa.), and in the Senate on June 7, 2017, by Sens. Bill Nelson (D-Fla.), Dean Heller (R-Nev.) and Chuck Schumer (D-N.Y), this bill would provide funding for 3,000 more residency slots, per year for next years for a total of 15,000 new slots. The House bill has 78 cosponsors and the Senate bill has seven. Efforts to garner additional cosponsors continue. Earlier this year, the AANS and CNS sent letters supporting the House and Senate bills to the cosponsors and members of the House Ways and Means and Energy and Commerce Committees, and Senate Finance Committee.
- Accreditation of osteopathic residency training programs (<u>H.R. 2373</u>). On May 4, 2017, Reps. **Mike Kelly** (R-Pa.) and **Vern Buchanan** (R-Fla.) introduced legislation to require the Department of Health and Human Services to certify at least two graduate medical education accreditation bodies, including at least one entity that accredits osteopathic residency training programs. The bill also removes any specific mention of the Accreditation Council for Graduate Medical Education (ACGME) in Medicare law, among other things.

In July, the AANS and CNS <u>sent a letter</u> to the authors of the bill, expressing our serious concerns with the legislation. AANS/CNS Washington Office staff are working with various stakeholders, including the ACGME, Association of American Medical Colleges, and the American Osteopathic Association, to educate members of Congress about the single accreditation process and the importance of uniform standards in residency training.

Meanwhile, efforts are underway to revise the bill, due to the fact that in its current form it is not acceptable to Sen. Toomey. In addition, Sen. Toomey and proponents of the bill launched an effort to get report language to accompany the omnibus spending bill that is worrisome to many in the medical community. The language:

Graduate Medical Education Accreditation – The Committee is concerned with challenges posed by the merger of the Accreditation Council for Graduate Medical Education and the American Osteopathic Association particularly for medical schools and hospitals who utilize the osteopathic community residency training model. The Committee requests that the Center for Medicare and Medicaid Services (CMS) issue a Request for Information to assess the merger's impact on medical residency programs and whether there is a need for a second accreditor.

Organized neurosurgery's major concern was that CMS has not, and should not, be in the business of micromanaging the GME accreditation process. This would be a very slippery slope to have the government interceding in matters that belong in the hands of the medical profession. The Toomey language (and the Kelly/Buchanan bills) would put CMS directly in the middle of this process. Beyond the appropriations language, we are very worried that if two accreditation bodies are

mandated by CMS, then there will be two different (and likely unequal) standards for training physicians. The public will be unable to discern which is which, and quality of care may suffer.

Fortunately, after concerted advocacy efforts, we were able to block this effort and the language was not included in the final spending package. We will now regroup and continue to prevent this bill, or similar language, from moving forward. In the end analysis, generally speaking, issues related to GME are on the back-burner pending the release of the next Government Accountability Office (GAO) sometime this spring. It is possible, however, that "reforms" to indirect medical education (IME) payments to hospitals could surface and House Ways and Means Committee chair, **Kevin Brady** (R-Texas), has suggested that he may revive his previous IME bill.

American College of Surgeons' GME Reform Proposal

On Feb. 1, 2017, the American College of Surgeons released a <u>Policy and Position Paper on GME Reform</u>. The document lays out some principles and then goes on to delineate a series of proposed GME reforms. On May 22, organized neurosurgery — the AANS, ABNS, CNS and SNS — sent a letter to ACS executive director, **David B. Hoyt**, MD, FACS, outlining our view about the proposal and the process by which it was developed. Subsequently, representatives from neurosurgery met with **Patrick V. Bailey**, MD, FACS, and Dr. Hoyt, at the July 27 meeting of the One Neurosurgery Summit. Dr. Hoyt agreed to focus the May 2018 residency training summit meeting on this topic. Prior to this meeting, we will submit our detailed edits to the ACS paper.

Miscellaneous

ACS Summit on Surgical Training

Once again the American College of Surgeons (ACS) as invited representatives from organized neurosurgery to attend the Third Annual ACS Summit on Surgical Training. The Summit will commence on Wednesday, May 23, 2018, and conclude on Thursday, May 24, 2018. The pertinent details are included below:

This meeting brings together representatives from the Boards, Professional Associations, Program Director Organizations, and Review Committees of each surgical specialty. Many training needs are similar across various surgical specialties and exchange of ideas with definition of concrete solutions to address various challenges should serve everyone well across the House of Surgery. This year, the ACS plans to build upon the discussions from last year that focused on assessment of cognitive skills, technical skills, soft skills, and residency programs, and focus on development of autonomy and independence in residency training.

Shelly Timmons, MD, PhD, will be communicating with Dr. Hoyt to ensure that the meeting also focuses on the development of a revised GME position statement that reflects the views of the various surgical organizations.

The following individuals will be attending the meeting:					
□ Shelly D. Timmons, MD, PhD (AANS)					
☐ H. Hunt Batjer, MD (AANS/ACGME)					
☐ Clemens M. Schirmer, MD (CNS)					
□ Daniel L. Barrow, MD (SNS)					



Medical Liability Reform Update

Health Coalition on Liability and Access

The Health Coalition on Liability and Access (HCLA), of which **Katie Orrico** is Vice Chair and **Alison Dye** is co-chair of its Communications Committee, continues its efforts to keep the topic of medical liability reform active in Congress and among the public. A wide variety of information can be found on HCLA's website www.hcla.org.

Federal Legislation

Several medical liability reform bills have been introduced in the 115th Congress:

House

- H.R. 302, Sports Medicine Licensure Clarity Act. The bill passed the House by voice vote on Jan.
 9, 2017 and is now pending before the Senate. The legislation provides protections for certain sports medicine professionals who provide certain medical services in a secondary State.
- ☐ H.R. 548, the Health Care Safety Net Enhancement Act. Pending action, the bill has 61 cosponsors. The legislation provides liability protections to physicians providing EMTALA-mandated services.
- H.R. 1215, the Protecting Access to Care Act. Comprehensive medical liability reform, modeled after California's MICRA, including at \$250,000 cap on noneconomic damages. On June 28, by a vote of 218 to 210, passed the bill, as amended. The AANS and CNS endorsed the bill. Additionally, the AANS and CNS joined the Alliance of Specialty Medicine and the Health Coalition on Liability and Access (HCLA) in supporting this legislation.

Key provisions of the bill include:

- Encouraging speedy resolution of claims. The statute of limitations is three years after the injury or one year after the claimant discovers the injury, whichever occurs first. For a minor, the statute of limitations is three years after the injury, except for a minor under six years old, for whom it is three years after the injury, one year after discovery of the injury, or the minor's eighth birthday, whichever occurs later. These limitations are tolled under certain circumstances.
- Compensating patient injury. Noneconomic damages are limited to \$250,000. Juries
 may not be informed of this limitation. Parties are liable for the amount of damages
 directly proportional to their responsibility. These provisions do not preempt state laws that
 specify a particular monetary amount of damages.
- Maximizing patient recovery. Courts must supervise the payment of damages and may restrict attorney contingency fees. The bill sets limits — on a sliding scale — on contingency fees.
- Future damages. The bill provides for periodic payment of future damage awards.
- Product liability. A health care provider who prescribes or dispenses pursuant to a
 prescription a medical product approved by the Food and Drug Administration, may
 not be named as a party to a product liability lawsuit or a class action lawsuit regarding
 the medical product.

 State Flexibility. Protects the rights of states that have already enacted comprehensive medical liability reforms or do so in the future.

In addition, the bill was amended to include provisions defining who qualifies as an expert witness; requirements for an affidavit of merit prior to bringing a lawsuit; allowing a physician to apologize to a patient for an unintended outcome without having the apology count against them in the court of law; and requiring a 90-day cooling off period before lawsuits can be filed to facilitate voluntary settlements. Note that the latter four provisions included in this amendment are also included in H.R. 1704, the Accessible Care by Curbing Excessive lawSuitS (ACCESS) Act; thus in effect, the House passed the ACCESS Act. Organized neurosurgery endorsed this bill. The AANS and CNS also joined HCLA and the Alliance in supporting the ACCESS Act.

Efforts are now underway in the Senate, where passage is more of a challenge. Senate rules in effect require 60 votes to pass this or a similar bill. Given the partisan divide, and because not all Republicans support federal medical liability reform legislation, reform may remain elusive. The AANS and CNS will nevertheless continue our efforts to gain passage.

- H.R.1565, the Saving Lives, Saving Costs Act. The bill would provide liability protections to
 physicians who follow their specialty society's clinical practice guidelines. The bill has 33
 cosponsors.
- H.R. 1704, the Accessible Care by Curbing Excessive lawSuitS (ACCESS) Act. Comprehensive
 medical liability reform, modeled after California's MICRA, including at \$250,000 cap on
 noneconomic damages. The bill also includes provisions related to expert witnesses, pretrial
 screening and protections for apologies. The bill has three cosponsors. See above on H.R. 1215.
- ☐ H.R. 1876, the Good Samaritan Health Professionals Act. The bill would limit the liability of health care professionals who volunteer to provide health care services in response to a disaster. The bill has 41 cosponsors and recently was passed out of the Energy and Commerce Health Subcommittee. The full committee is expected to take up the measure in mid-February.

Senate

- S. 527, the Health Care Safety Net Enhancement Act. Pending action, the bill has seven cosponsors. The legislation provides liability protections to physicians providing EMTALA-mandated services. The bill has five cosponsors.
- S. 781, Good Samaritan Health Professionals Act. The bill would limit the liability of health care professionals who volunteer to provide health care services in response to a disaster. The bill has six cosponsors.

State Activities

AMA active in supporting state liability challenges

The American Medical Association continues to work against attempts at the state level to roll back liability reforms proven to reduce medical lawsuit abuse.

Even as federal liability reform awaits consideration by the Senate, the AMA Litigation Center is providing support to legal challenges in Maryland, Michigan, Wisconsin and Kentucky.

In Maryland and Michigan, the Litigation Center is actively pushing back against "artful pleading" maneuvers that look for ways around the medical liability review process and open up new avenues for meritless lawsuits.

The Litigation Center is also fighting to defend the constitutionality of Wisconsin's reasonable limits on non-economic damages, as well as challenges to Kentucky's recently enacted medical liability review courts.

The Litigation Center will continue to play an active role amid efforts to pass strong state liability laws, in the absence of comprehensive reform at the federal level.

To read more about the AMA Litigation Center's activities in 2017, click here

Sweeping changes to liability system would bring benefits to Kentucky

Initiating legislation that would bring benefits and improvements to Kentucky's liability climate, members of the State Senate brought forward a bill with the state's patients in mind. With provisions that limit the fees of personal injury attorneys in favor of deserving patients, give physicians the ability to make statements of sympathy, and require affidavits of merit to ensure only legitimate claims move forward, the bill passed a committee vote and moves forward for consideration. This legislative effort follows the passage of medical review panel legislation in 2017, with panels of experts able to review claims and fulfill the affidavit of merit requirement when patients are found to be victims of negligence. To read more about the latest liability reform legislation in Kentucky, click here.

Pa. Supreme Court to Hear Case with Implications for Medical Liability Evidence

The Pennsylvania Supreme Court has agreed to hear a case that could affect what evidence physicians may present in defense of medical liability claims.

In *Mitchell v. Shikora et al.*, the plaintiff, Lanette Mitchell, contends that evidence concerning the known risks and complications of a surgical procedure are irrelevant as to the question of negligence. The case stems from injuries Ms. Mitchell suffered while undergoing a hysterectomy. Despite Ms. Mitchell's objections, evidence of the risks and complications associated with hysterectomies was presented at trial. Ms. Mitchell claims this evidence was unfairly prejudicial and should have been excluded as irrelevant.

Case Background. In May 2012, Dr. Evan Shikora performed a hysterectomy on Ms. Mitchell at Magee Women's Hospital of UPMC. During the procedure, Dr. Shikora severed Ms. Mitchell's bowel.

Ms. Mitchell subsequently filed a medical liability action against Dr. Shikora, Magee, and Dr. Shikora's practice group. By failing to identify her bowel prior to cutting it, Ms. Mitchell claimed Dr. Shikora had breached his duty of care. Dr. Shikora countered that Ms. Mitchell's injury was a complication of injury, not an indication that negligence occurred.

The case proceeded to a jury trial. During the trial, Ms. Mitchell sought to exclude all consent-related evidence and all evidence pertaining to the known risk/complications of hysterectomies. Since Ms. Mitchell did not raise any consent-related claims in her suit, the trial court excluded all evidence regarding Ms. Mitchell's consent to undergo a hysterectomy. The trial court, however, allowed evidence regarding the known risks and complications of hysterectomies to be presented to the jury.

Following a jury verdict in favor of the defendants, Ms. Mitchell filed a motion seeking a new trial excluding the risk/complications evidence. The trial court denied Ms. Mitchell's motion.

Ms. Mitchell subsequently appealed to the Pennsylvania Superior Court. Ms. Mitchell claimed that the trial court had erred in allowing the defendants to present evidence on the risks and complications of a surgical procedure in a medical liability case that asserted only physician negligence and not any consent-related claims. Evidence of a procedure's known risks, Ms. Mitchell argued, is irrelevant as to the question of negligence. Ms. Mitchell also argued that the risk/complications evidence misled the jury by inferring that her injuries were the result of surgical complication and not medical negligence.

The Superior Court reversed the judgment of the trial court and ruled that the risks and complications evidence was irrelevant to the issue of whether Dr. Shikora's treatment of Ms. Mitchell met the applicable standard of care. This evidence, the Superior Court held, was inadmissible and a new trial without admission of risks and complications evidence is required.

In rendering this decision, the Superior Court relied heavily on the Pennsylvania Supreme Court's recent holding in the case of *Brady v. Urbas*. In Brady, the Pennsylvania Supreme Court held that evidence that a patient affirmatively consented to treatment after being informed of the risks of that treatments is generally irrelevant to a medical liability suit. Such evidence, however, may be admitted under limited circumstances if it is relevant to establishing an applicable standard of care. In a trial on a medical liability suit where only negligence is asserted and not lack of informed consent, the Brady decision holds, evidence that a patient agreed to go forward with a procedure in spite of the risks of which they were informed is irrelevant and should be excluded.

Applying the *Brady* rationale to the circumstances of Ms. Mitchell's case, the Superior Court reasoned that although evidence of a surgical procedure's risks and complications may be introduced to establish the relevant standard of care, determination of whether such evidence should be admissible is to be conducted on a case-by-case basis. The evidence in the Mitchell case, the Superior Court opined, was irrelevant in determining whether Dr. Shikora acted within the applicable standard of care. The Superior Court further reasoned that the fact that one of the risks and complications of a hysterectomy was the injury suffered by Ms. Mitchell does not make it more or less likely that Dr. Shikora was not negligent.

Additionally, the Superior Court also theorized that risks and complications evidence could be misleading and confusing to the jury. Noting that this evidence was central to Dr. Shikora's defense, the Superior Court opined that risks and complications evidence could lead jurors to believe the plaintiff's injuries were simply the result of surgical complication and lose sight of the ultimate issue of whether the defendant's actions confirmed to the governing standard of care.

Which Issues Will the Pennsylvania Supreme Court Consider? Following the Superior Court's decision in favor of Ms. Mitchell, the defendants appealed to the Pennsylvania Supreme Court. The Supreme Court granted the defendant's appeal and agreed to hear the case. However, the Supreme Court will consider the defendant's appeal only in regard to one issue:

Whether the Superior Court's holding directly conflicts with the Pennsylvania Supreme Court's holdings in *Brady v. Urbas*, which permits evidence of general risks and complications in a medical liability claim?

The defendants maintain that the Superior Court's holding misapplies the Supreme Court's decision in *Brady v. Urbas*. In agreeing to hear the Mitchell case, it is expected that the Supreme Court will provide further guidelines on how the holding of *Brady* should be applied.

PAMED Next Steps. On Jan. 8, 2018, the Pennsylvania Medical Society — with support from the American Medical Association (AMA) — filed an amicus brief in support of allowing general risks and complications evidence in medical negligence cases. The Pennsylvania Neurosurgical Society also supported this brief.

Show me liability reform

A recent push for liability reform in Missouri could show patients how a reduction in medical lawsuit abuse can improve access to care across the states. Building on Governor Greitens' emphasis on the need for changes to the state's liability system, a new bill would bring an efficient resolution to those with legitimate claims. The latest bill, introduced by State Senator Dan Hegeman, allows physicians to address claims promptly by redefining the statute of limitations to three years. The shorter statute of limitations gives physicians peace of mind that any claims of negligence are addressed quickly, and deserving patients benefit from a system that better separates meritless lawsuits from rightful claims for

damages. To read more about Missouri's efforts to further reform their liability system for patients and physicians, click here.

North Dakota liability ruling leaves patients in the cold

Striking down the state's limits on non-economic damages, a North Dakota court became the latest to rule in favor of personal injury attorneys and against patients, absent comprehensive and cohesive federal liability laws.

Reasonable limits of \$500,000 in non-economic damages have been in place in North Dakota since 1995.

Ruling on behalf of the South Central Judicial District, Judge Cynthia Feland overturned the limits based on her interpretation that it violated equal protection guaranteed by the North Dakota constitution by arbitrarily reducing damages for people who suffer the most severe injuries. The ruling is expected to be appealed.

North Dakota becomes just the latest state to see judicial activists overturn an effective tort reform as federal medical liability reform awaits consideration by the US Senate.

To read more about the effect of the ruling in North Dakota, click here.

Miscellaneous

Year-end report sheds light on "Judicial Hellholes"

The American Tort Reform Association (ATRA) end-of-year "Judicial Hellholes" report offers a public glimpse at the most unfriendly jurisdictions for those defending themselves against civil litigation, including medical liability lawsuits.

At the top of the list this year was Florida, where once-strong medical liability reforms have been continuously rolled back at the expense of patients seeking affordable and accessible care.

"This year, thanks to a state high court majority's barely contained contempt for the policy-making authority of the legislative and executive branches of government, and a notoriously aggressive and sometimes lawless plaintiffs' bar, Florida earns the ignominious #1 ranking among eight Judicial Hellholes..." said American Tort Reform Association president Tiger Joyce.

Also high on the list was St. Louis, where "antiquated rules have made it a favorite of personal-injury lawyers shopping for big-money verdicts" resulting in \$300 million in awards since 2015. However, recent changes in state government, including a governor in support of changes to the liability system, do hold promise for much-needed reform in the coming year.

To read more about ATRA's "Judicial Hellholes" executive summary and report on the where physicians and defendants fare the worst when it comes to liability lawsuits <u>click here</u>.

AMA Releases 2018 edition of "Medical Liability Reform - Now!"

"Medical Liability Reform – Now!" includes background on the problems with the current system, proven solutions to improve the liability climate and a discussion of innovative reforms that could complement traditional MLR provisions. This comprehensive medical liability reform (MLR) compendium is accessible electronically at www.ama-assn.org/medical-liability-reform-now.

The AMA also released three new research reports from its Health Policy department. These reports examine:

	Medical Liability	Claim Frequency	Among U.S.	. Physicians.	Highlights in	this report include:
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- Getting sued is not an uncommon event for physicians. More than a third of physicians
 (34%) have had a claim filed against them at some point in their careers.
- Because older physicians have been in practice for a longer time and thus have had more exposure, the probability of getting sued increases with age. Nearly half (49.2%) of physicians age 55 and over have been sued, compared to 8.2% of physicians under age 40.
- There is wide variation in the frequency of liability claims between specialties. General surgeons and obstetricians/gynecologists have the highest risk of being sued, more than 3½ to 4 times greater than pediatricians and psychiatrists, who have the lowest risk.
- Before they reach the age of 55, more than 50% of general surgeons and obstetricians/gynecologists have already been sued.

<u>Click here</u> for the report.

- Professional Liability Insurance Indemnity Payments, Expenses and Claim Disposition, 2006-2015. Key findings include:
 - The average expense incurred on medical liability claims that closed in 2015 was \$54,165
 a substantial increase of 64.5% since 2006.
 - In 2015, 68.2% of all closed claims were dropped, dismissed, or withdrawn; however, they
 are not cost-free. Each of these claims costs an average of \$30,475 to defend, accounting
 for more than one-third (38.4%) of total expenses incurred.
 - Only 7% of claims are decided by a trial verdict, and the vast majority (87.5 percent) were won by the defendants.
 - In about 25% of claims, an indemnity payment was paid to the claimant. The average indemnity payment was \$365,503 for claims that closed in 2015 a notable increase of 11.5% from two years prior.

Click here for the report.

- Medical Professional Liability Insurance Premiums: An Overview of the Market from 2008 to 2017. Highlights in the report include:
 - Despite increasing stability in liability premiums, the prospects for the near future are less than certain. Since 2015, more premiums increased than decreased, reversing the trend of the earlier part of the study period. In 2017, 13.4% of premiums were higher than those for 2016. Since 2010, 12 to 17% of premiums have increased from the previous year.
 - The share of premiums that decreased from one year to the next has been falling since 2008, particularly in the last three years. Only 12. 4% of premiums decreased in 2017.
 This is substantially down from its peak in 2008, when almost 43% of premiums fell below their 2007 levels.
 - Physicians continue to face high costs of insuring themselves against medical liability claims. There is wide geographic variation in premiums. In some areas of New York, premiums for obstetricians/gynecologists reached \$214,999 in 2017

 — while premiums for obstetricians/gynecologists in some areas of California were \$49,804.

Click here for the report.



Emergency Neurosurgical Services Update

Legislative Activities

Working with other organizations interested in trauma and emergency care (Trauma Coalition), the AANS and CNS continue to advocate for legislation to fund and support programs aimed at improving emergency and trauma care services. The Trauma Coalition is working with the 115th Congress and is currently strategizing on how to advance these vital pieces of legislation.

- ☐ H.R. 548, the **Health Care Safety Net Enhancement Act**, was reintroduced by Reps. **Charlie** Dent (R-Pa.) and Pete Sessions (R-Texas) on Jan. 13, 2017 and has 61 co-sponsors. Senate companion legislation, S. 527, was reintroduced by Sen. Roy Blunt (R-Mo.) and has seven cosponsors. This legislation provides for EMTALA-related liability protections.
- ☐ H.R. 1876/S. 781, the **Good Samaritan Health Professionals Act**, was reintroduced by Reps. Marsha Blackburn (R-Tenn.) and David Scott (D-Ga.) on April 2 and Sens. Bill Cassidy, MD (R-La.) and Angus King (I-Maine) on March 30. The bills have 41 and five co-sponsors respectively. This legislation provides liability protections for health professionals who volunteer their service during a federal declared disaster. Latest update: The House Energy & Commerce Committee passed the bill on Feb. 14, 2018. It has been placed on the House calendar where it awaits action. The Coalition has also been working to have this bill included in the Pandemic and All Hazards Preparedness Reauthorization Act.
- ☐ H.R. 2360, the Concussion Awareness and Education Act, was reintroduced by Rep. Joyce Beatty (D-Ohio) on May 4, 2017. This legislation has secured 33 co-sponsors and would provide for systemic research, treatment, prevention, awareness, and dissemination of information with respect to sports-related and other concussions.

MISSION Zero Legislation Passes House

Introduced last year by Reps. Michael Burgess, MD (R-Texas), Gene Green (D-Texas), Kathy Castor (D-Fla.), and Richard Hudson (R-N.C.), H.R. 880, the Military Injury Surgical Systems Integrated Operationally Nationwide (MISSION) to Achieve Zero Preventable Deaths Act, would assist U.S. military health care providers in maintaining a state of readiness by embedding military trauma teams and providers in civilian trauma centers. The bill was passed on the House floor on February 26, 2018.

Additionally, the Trauma Coalition worked with Sens. Johnny Isakson (R-Ga.) and Tammy Duckworth (D-III.) to introduce the Senate companion bill, S. 1022, on May 3, 2017 and the bill currently has eight co-sponsors.

Pandemic and All Hazards Preparedness Act (PAPHA) Reauthorization Act

Reps. Susan Brooks (R-IND.) and Anna Eshoo (D-Calif.) and Sens. Richard Burr (R-N.C.) and Bob Casey (D-Penn.) are the House and Senate lead sponsors of the Pandemic and All Hazards Preparedness Act (PAPHA) Reauthorization Act. The Coalition has been working with these offices. in a incl

parediress Act (I Al IIA) Readificitzation Act. The Coalition has been working with these offices
ddition to Senate Health, Education, Labor, and Pensions (HELP) Committee staff, on language to
ude:
□ The Good Samaritan Health Professionals Act

☐ The MISSION Zero Act

Grant funding for the regionalization of all emergency and trauma care systems
Permanent creation of the Emergency Care Coordination Center (ECCC) in the office of the
Assistant Secretary of Preparedness and Response (ASPR).

PAHPA expires this year and is considered a must-pass piece of legislation. It is expected to make it to the Senate and House floors by late April. The lead Senate sponsor, Sen. Bill Cassidy, MD (R-La.) has identified the S. 781, the Good Samaritan Health Professionals Act as his number one priority for inclusion in the PAHPA reauthorization bill.

FY 2018 Appropriations Legislation

After passing several continuing resolutions (CR) and one brief government shutdown, House and Senate negotiators finally passed the FY 2018 Omnibus Appropriations bill in March.

For the <u>Department of Health and Human Services</u>, the Omnibus bill would provide total funding of \$78 billion for HHS in budget authority, an increase of \$10 billion above the FY 2017 enacted level.

<u>Included</u> in the bill, the Centers for Disease Control and Prevention (CDC) would receive an extra \$1 billion for a total of \$8.3 billion, compared to its FY 2017 appropriation paving the way for several funding increases across injury center programs. This includes:

□ \$	\$1.45 billion for Public Health Preparedness and Response programs, an increase of \$45 million
□ \$	66.75 million for Traumatic Brain Injury (TBI)
□ \$	\$2 million for elderly falls (a new line item)
□ \$	\$23 million for National Violent Death Reporting System
□ \$	69 million for Injury Control Research Centers.

National Defense Authorization Act for Fiscal Year 2018

The National Defense Authorization Act (NDAA) for FY 2018 was passed by the House and Senate and is now Public Law (PL) 115-91.

AANS-CNS Participates in TCAA Fly-In

On Tuesday, March 13 staff from the AANS-CNS Washington office, along with other Trauma Coalition members, participated in the Trauma Center Association of America (TCAA) Fly-in where over 30 TCAA members and partners went to Capitol Hill to urge Senate support for the Military Injury Surgical Systems Integrated Operationally Nationwide (MISSION) to Achieve Zero Preventable Deaths Act of 2017 (S. 1022).

Coalition members met with over 20 Senate offices regarding the MISSION Zero Act and overall received positive feedback. The Coalition is pushing for additional co-sponsors and ultimately hopes to have the bill included in the Pandemic and All Hazards Preparedness Reauthorization Act (PAHPA), which as previously mentioned, is expected to make it to the Senate and House floors by late April.



Biomedical Research Update

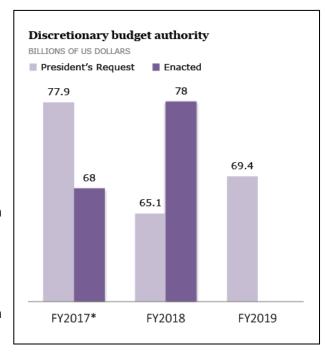
Legislative Activities

FY 2018 Appropriations

After passing several continuing resolutions (CR) and one brief government shutdown, House and Senate negotiators finally passed the FY 2018 Omnibus Appropriations bill in March.

For the <u>Department of Health and Human Services</u>, the Omnibus bill would provide total funding of \$78 billion for HHS in budget authority, an increase of \$10 billion above the FY 2017 enacted level, <u>including</u>:

- \$37 billion for the **National Institutes of Health (NIH)**, an increase of \$3 billion above FY 2017, providing:
 - \$1.8 billion (+\$414 million) for Alzheimer's disease research
 - \$400 million (+\$140 million) for the Brain
 Research through Application of Innovative
 Neurotechnologies (BRAIN) initiative
- a total of \$8.3 billion for the Centers for Disease Control and Prevention (CDC) – an increase of \$1.1 billion above the FY 2017;
- □ \$5 billion in funding for the **Substance Abuse and Mental Health Administration (SAMHSA)** at \$5 billion, or \$1.3 billion more than FY 2017, including \$1.7 billion to address opioid and heroin abuse, an increase of \$1.5 billion above last year;
- □ \$7 billion for the Health Resources and Services
 Administration (HRSA), an increase of \$550 million
 above FY 2017, which also includes an increase of
 \$15 million for a total \$315 million for the
 Children's Hospital Graduate Medical Education;
 and
- □ \$334 million for the Agency for Healthcare Research and Quality (AHRQ), which is \$10 million above the fiscal year 2017 enacted level.



As mentioned above, opioid activities will get \$500 million targeting research on addiction as well as development of alternatives to opioids for treatment of pain and for new addiction treatments. Additionally, \$500 million more is slated for the CDC's prevention and surveillance activities. An additional \$130 million is slated to address opioid addiction in rural areas and \$94 million would help FDA expand its efforts to crack down on shipments of synthetic opioids at international mail facilities. The proposal also includes a \$1.3 billion increase for the Substance Abuse and Mental Health Administration — with the lion's share pegged for substance abuse treatment programs. The boost in opioid-related funding comes as House and Senate lawmakers work on a spate of new policy proposals to address the crisis

Communications and Public Relations Update



Administrative Issues

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

(CPR	Lead	ders

Deborah L. Benzil, MD, Chair

Clemens M. Schirmer, MD, Vice-chair

Committee members include:

Richard Anderson, MD (Pediatric Section)

Anthony L. Asher, MD (NeuroPoint Alliance)

Maya A. Babu, MD

Kimon Bekelis, MD (CSNS Young Neurosurgeons Section)

Randy S. Bell, MD (Committee of Military Neurosurgeons)

Mary Cloninger (NERVES)

Sanjay S. Dhall, MD (Spine Section)

Rimal H. Dossani, MD (WC AMA Fellow)

Bharat Guthikonda, MD (CSNS)

Sepideh Amin-Hanjani, MD (Society of Neurological Surgeons)

Randy L. Jensen, MD (Journal of Neurosurgery)

Benjamin Kennedy, MD (Pediatric Section)

Kristopher Kimmell, MD (AANS Neurosurgeon)

Elad I. Levy, MD (CNS Quarterly)

Alon Y. Mogilner, MD (Pain)

Carrie R. Muh, MD (NeurosurgeryPAC)

Staff Liaison:

Alison Dye, Sr. Manager for Communications

Brian V. Nahed, MD (Tumor Section & Neurosurgery)

David O. Okonkwo, MD (Trauma Section)

Paul Park, MD (NQC)

Ann M. Parr, MD (WINS)

Brian T. Ragel, MD (CNS)

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Daniel Refai, MD (Coding and Reimbursement)

Michael P. Steinmetz, MD (Spine Section)

Brian R. Subach, MD (AANS)

Ashwin Viswanathan, MD (Pain Section)

William C. Welch, MD (Drugs and Devices)

Jon T. Willie, MD (Stereotactic and Functional Section)

Christopher J. Winfree, MD (Guidelines Committee)

Brett E. Youngerman, MD (WC AMA Fellow)

Gabriel Zada, MD (Young Neurosurgeons Committee)

Ex-Officio:

Ann R. Stroink, MD (WC, Chair) Alex B. Valadka, MD (AANS President) Ashwini D. Sharan, MD (CNS President)

Communication Activities

AANS/CNS Communications and Public Relations Committee Meets in Boston

At the 2017 CNS October Annual Meeting in Boston the CPR hosted a <u>productive meeting</u> which highlighted recent efforts of the committee. The discussion included details about our pain, regulatory relief and spine awareness campaigns, expanding our social media efforts, increasing our blog subscribers and continuing to grow Neurosurgery Blog's reporting efforts. The committee also highlighted that a new editorial board position has been added to help coordinate blog copy from the sections and other AANS and CNS committees. **Ann M. Parr**, MD, FAANS has been chosen for this

position and she will be reaching out to the various groups to help solicit content. To this end, if you are willing to author a section or committee blog post, please email Dr. Parr at annmparr@hotmail.com.

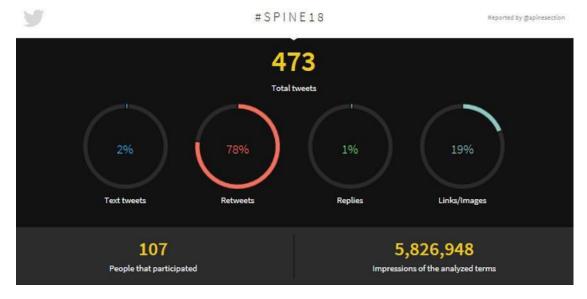
**Reurosurgery Blog's Spine-Focus Month Underway!

Throughout the months of March (and part of April), Neurosurgery Blog is hosting a spine-focus awareness campaign. To maximize attention on spine related issues, we planned our efforts around the 2018 Annual Meeting of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves. Our goal is to shed important light on spine facts, innovation and the role of spine interventions. Misinformation regarding spine care in the U.S. is a major hindrance to understanding the important issues surrounding the care of patients with spinal conditions. We will highlight these issues through: patient stories, epidemiology, economics, value, innovation and advocacy. We have posted the following blogs so far, with numerous others on the way thanks to our many contributors.

- □ Spine Facts, Innovation and Improved Patient Outcomes: Neurosurgery Leading the Way;
- ☐ Faces of Neurosurgery: Dr. Matt McGirt Runs Marathon with Formerly Paralyzed Patient;
- AANS/CNS Spotlight Exceptional Speakers at the 2018 Spine Summit;
- What Neurosurgeons are Learning from the Quality Outcomes Database Spine; and
- ☐ Help Prevent Spinal Cord Injury: ThinkFirst.

Additionally, as part of our spine-focus campaign, we coordinated with Spine Section leaders to develop a social media plan to implement during Spine Summit 2018. Some highlights from the #Spine18 effort include:

- □ 473 #Spine18 tweets were disseminated by 107 twitter users;
- ☐ The #Spine18 hashtag made 5,826,948 impressions during the meeting;
- @SpineSection added 50+ followers, including the following accounts: UF Neurosurgery, UMich Neurosciences, Neurosurgery at Northwestern, OHSU Brain Institute, UMich Neurosurgery, Columbia Neurosurgery, UNC Neurosurgery, Duke Spine, The Spine Hospital (Columbia) and various neurosurgeons/residents.



Neurosurgery Blog Hosted Regulatory Relief Campaign

Neurosurgery Blog recently hosted a <u>regulatory relief awareness campaign</u>. During this initiative, we shined a laser spotlight on a single issue, Physician Regulatory Relief: Breaking the Red Tape to Improve Patient Care. Our goal is not just to identify and relate burdensome regulations, but to offer real solutions that will address the issues and problems that prompted the mandates. Neurosurgery Blog and other communications outlets focused on regulatory relief topics, with multiple guest blog posts. A

plethora of pieces — on such topics as electronic medical records (EMR), prior authorization, FDA approval, Appropriate Use Criteria (AUC) — were authored by the neurosurgical community, including:
 Physician Regulatory Relief: Breaking the Red Tape to Improve Patient Care; Faces of Neurosurgery: Dr. Ann Stroink, a Tireless Advocate; Cross Post – Bipartisan Payment System Improvements Mean More Physician Participation and Better Patient Care; EHR Interconnectivity Challenges Continue to Impact Patient Care; Cost Post – Impact of Insurance Precertification on Neurosurgery Practice and Health Care Delivery; King Arthur or Don Quixote: What Kind of Knight are EHR Systems?; Unnecessary Regulatory Burden: Appropriate Use Criteria for Advanced Diagnostic Imaging; MIPS, Cost Measures and Innovation from a Neurosurgical Perspective The FDA and Regulation – Neurosurgery Partners with FDA for Patient Safety, Innovation and Regulatory Reform; Cross Post – Super Macranomics; A Better, Kinder, More Effective MOC Product; and Atlas Shrugged Retold.
We invite all neurosurgeons to continue the conversation using the #RegRelief hashtag so we can grow awareness through social media. In the meantime, if you have not already done so, we also encourage you to subscribe to Neurosurgery Blog to stay informed on this and other important topics facing neurosurgery. Just click here to enter your email address, confirm your subscription and away you go!
Neurosurgery Blog Continues to Expand Neurosurgery's Message
Neurosurgery Blog: More Than Just Brain Surgery, has seen a significant expansion of its social media outreach. For AANS/CNS members, that means access to an effective echo chamber, linking and promoting section websites, sharing neurosurgery news including speeches and op-eds to a growing audience of health care media and policy influencers. Neurosurgery Blog is disseminated not only to all neurosurgeons, but also to influencers in the media, on Capitol Hill, in various health policy circles, and the general public at large. We also use the blog as the centerpiece of our other social media activities by promoting blog posts via our Twitter, Facebook , Instagram , LinkedIn , <a href="YouTube Channel, Tumbler and Google+ . Overall, these media platforms have amassed a subscription audience of Over 135,000 individuals!
Neurosurgery Blog has also continued to ramp up its reporting efforts to include multiple guest blog posts from key thought leaders and members of the neurosurgical community this year. As of March 23, we have discominated 333 blog posts on topics including regulatory relief, epipide, spine, and health reform
have disseminated 333 blog posts on topics including regulatory relief, opioids, spine, and health reform in general. Since our last report, the following new blog posts have been published:

Opioids

Cross Post – Efforts to Curb Opioid Misuse Must Preserve Patient Access to Medically-necessary

 Vital Signs: Physicians Keep the Economy Healthy Cross Post – Anniversary of Konrad Reuland Tragedy Reminds Us of the Toll of Brain Aneurysms MIPS, Cost Measures and Innovation from a Neurosurgical Perspective Cross Post – When Are Neurosurgeons Too Old to Perform Surgery? Unnecessary Regulatory Burden: Appropriate Use Criteria for Advanced Diagnostic Imaging King Arthur or Don Quixote: What Kind of Knight are EHR Systems? Cost Post – Impact of Insurance Precertification on Neurosurgery Practice and Health Care Delivery EHR Interconnectivity Challenges Continue to Impact Patient Care Cross Post – Bipartisan Payment System Improvements Mean More Physician Participation and Better Patient Care Faces of Neurosurgery: Dr. Ann Stroink, a Tireless Advocate Physician Regulatory Relief: Breaking the Red Tape to Improve Patient Care 						
We invite you to visit the blog and subscribe to it, as platforms, so that you can keep your pulse on the macapital and help promote our digital efforts.						
Traditional Media Outreach						
 Neurosurgery's DC Office Continues to Imple aforementioned new media efforts, the DC office media/communication efforts including Op Eds, le briefings with reporters. As such, we have been a American Medical News AMA Wire Becker's ASC Review Becker's Spine Review British Medical Journal Bureau of National Affairs (BNA) California Healthline Diane Rehm Show Forbes The Hill Health Data Management Health Leaders Media iHealthBeat Inside Health Policy Inside CMS McKinight's Long Term Care 	continues to implement traditional					
 Medical Marketing & Media MedPage Today Medscape medwire News 	 The Wall Street Journal WSJ Pharmalot Blog The Washington Post Yahoo News 					

Since December 2012, the Washington Office has generated 168 traditional media hits reaching a circulation/audience of 13.6 million. To this end, organized neurosurgery continues to work to promote our health policy positions to the media. Most recently, on Feb. 6, *The Hill* published an opinion piece featuring neurosurgery's own Robert F. Heary, MD, FAANS, professor of neurological surgery at the Rutgers New Jersey Medical School, and chair of the AANS/CNS Committee on Drugs and Devices. The article, "Efforts to Curb Opioid Misuse Must Preserve Patient Access to Medically-

necessary Opioids," addresses several key points related to opioid misuse and offers a few recommendations to help tackle the opioid crisis. On Feb. 1, *Modern Healthcare* published an article titled, "Docs worry CMS measures ping them for costs out of their control." Rachel Groman, quality policy consultant for the AANS and CNS, was quoted in the piece citing, "Multiple challenges remain, including how to appropriately attribute costs to an individual physician in the context of team-based care, how to properly adjust for factors that physicians have little control over, and how to ensure measure data are presented in a way that is meaningful and actionable to physicians." On Jan. 25, *Politico*, issued a piece titled, "Physicians wary of Medicare payments under Azar." Katie O. Orrico, director of the AANS/CNS Washington Office, was quoted in the piece and highlighted neurosurgery's concerns on how Alex Azar, new HHS Secretary, will handle MACRA implementation. Additionally, on Nov. 2, *Inside Health Policy* published a piece titled, "House Passes Legislation to Repeal Independent Payment Advisory Board." Ann R. Stroink, chair of the AANS/CNS Washington Committee, was quoted in the article citing, "Neurosurgeons recognize that we need to control the growth of health care spending, but the IPAB is simply the wrong solution for addressing these budgetary challenges."

As a reminder, for individuals who want to keep tabs on our media outreach please visit our <u>Press</u> <u>Room</u> on the website. There you will find our statements and releases, letters to the editor, and media hits.

- AANS and CNS Issues Press Releases on Several Issues. Over the past six months, the AANS/CNS Washington Office has issued a number of press releases including most recently:
 - FDA Public Hearing on Opioid Use. On Jan. 28, the DC office sent out a <u>press release</u> highlighting the participation of **Robert F. Heary**, MD, FAANS, in a FDA hearing on opioid use.
 - Neurosurgery 2018 Legislative and Regulatory Agenda. On Jan. 23, the DC office issued a release highlight the release of the AANS and CNS 2018 legislative and regulatory agenda.
 - MedPAC Proposal to "Rebalance" Physician Fees. On Jan. 12, the DC office put out a statement opposing MedPAC's proposal for "rebalancing" the Medicare physician fee schedule towards primary care services.
 - House Passage of IPAB Repeal Legislation. On Nov. 2, the DC office disseminated a
 statement applauding the U.S. House of Representatives for passing H.R. 849, the Protecting
 Seniors' Access to Medicare Act which repeals the Independent Payment Advisory Board
 (IPAB). Additionally, on Nov. 1, the DC office also sent a release joining a chorus of physician
 and dental groups calling for repeal of the Medicare board.
 - MedPAC's Proposal to Eliminate MIPS. On Oct. 25, the DC office sent out a <u>statement</u> highlighting how specialty physicians are strongly opposed MedPAC's policy option aimed at moving physicians toward Advanced Alternative Payment Models (A-APMs) by eliminating the MIPS program and replacing it with a Voluntary Value Program (VVP).
 - Bipartisan Health Care Efforts. On Oct. 24, the DC office put out a release commending Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.) and Ranking Member Patty Murray (D-Wash.) for reaching a bipartisan agreement on legislation to improve our nation's health care system.
 - Ways and Means Passage of IPAB Repeal Legislation. On Oct. 5, the DC office issued a statement applauding the U.S. House Ways and Means Committee for passing H.R. 849, the Protecting Seniors' Access to Medicare Act. Sponsored by Rep. Phil Roe, MD (R-Tenn.), and Rep. Raul Ruiz, MD (D-Calif.), this bipartisan legislation would repeal the IPAB, which is

charged with making steep cuts to the Medicare program; thus adversely affecting seniors' ability to see their trusted physicians and get the care they need when they need it.

Member Outreach

The AANS and CNS have continued to update our members by disseminating a monthly DC enewsletter to better inform them of key health policy activities happening in Washington. To date, we have we have produced fifty-one "Neurosurgeons Taking Action" newsletters, which reach a distribution list of 10,350 individuals and covered a variety of topics including gradate medial education, medical liability, MACRA, and a host of other topics of concern to organized neurosurgery. Accessing past issues is easy as they are archived directly on the AANS website. Click here for copies. The DC office also regularly submits items to AANS and CNS for website postings and continues to provide content for AANS and CNS newsletters and publications.

Coalition Efforts

• The Alliance of Specialty Medicine and Health Coalition on Liability and Access. The AANS and CNS continue to work closely with other health care organizations, including the Alliance of Specialty Medicine (Alliance), the Health Coalition on Liability and Access (HCLA) to provide assistance in promoting those organizations and/or their health policy and advocacy to the media. Past Washington Committee Chairman, Alex B. Valadka, MD, FAANS serves as the spokesperson for the Alliance. Washington Office staff member, Alison Dye, also serves as HCLA's communications chair. Working with these groups, we have been able to generate media hits in the following outlets:

	American Medical News	•	MedPage Today
•	Crain's Detroit Business	•	Morning Consult
	The Congressional Quarterly	•	Modern Healthcare Magazine
	CQ Healthbeat	•	Modern Physician
	FierceHealthcare	•	Politico Pulse
	Health Affairs	•	Roll Call
	Inside Health Policy	•	The Hill

Most recently, on Nov. 9, *The Hill* newspaper published an <u>op-ed</u> by **Alex B. Valadka**, MD, FAANS, spokesperson for the <u>Alliance of Specialty Medicine</u>, which provided an overview of critical issues concerning the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). On Oct. 25, the DC office sent out a <u>statement</u> highlighting how specialty physicians are strongly opposed MedPAC's policy option aimed at moving physicians toward Advanced Alternative Payment Models (A-APMs) by eliminating the MIPS program and replacing it with a Voluntary Value Program (VVP). The following news articles are a result of this aforementioned release:

- Specialty physicians oppose Medicare advisory council's call to scrap MIPS;
- Specialist groups oppose MedPAC recommendation to end MIPS:
- Specialty Societies to MedPAC: MIPS Should Stay Put;
- Specialist Physicians Counter Call for Eliminating MIPS.

Neurosurgery Spotlighted in Specialty Medicine On-call. In October 2017, the Alliance of
Specialty Medicine featured neurosurgery in its fall 2017 e-newsletter On-Call. The publication was
circulated to all members of Congress, select media and others. Each issue spotlights a specialty,
and this issue looks at ensuring adequate pediatric trauma care; drawing on a previous post we
featured on Neurosurgery Blog about this topic. It is yet another way in which we try to get our
advocacy messages out to policymakers, media and the general public.

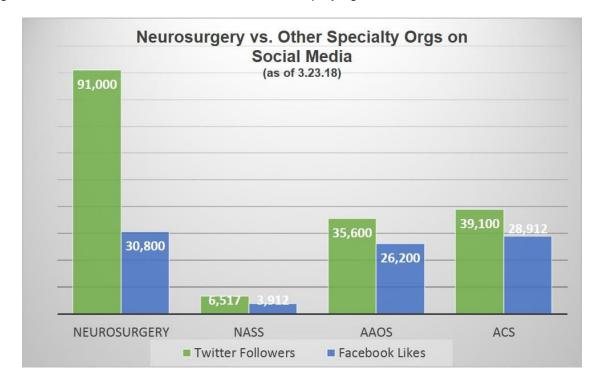
Accomplishments

Making Progress

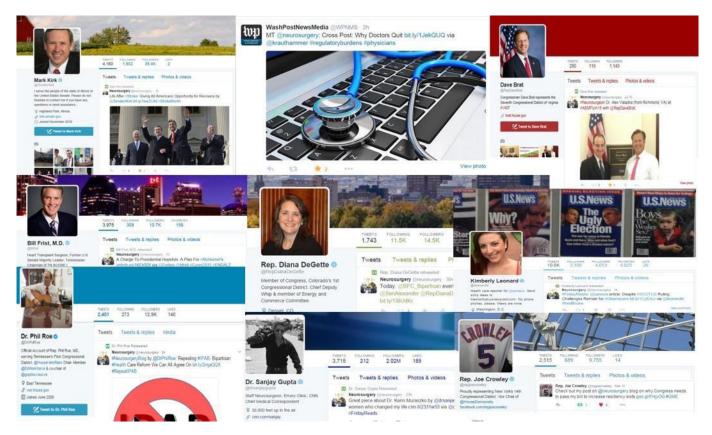
Neurosurgery continues to see a significant expansion of its digital media outreach. This highly effective online echo chamber, allows us the ability to share neurosurgery news and AANS/CNS health policy positions to a growing audience of health care media and key policy influencers in a very rapid manner. Listed below (as of Feb. 28) are some key metrics pertaining to neurosurgery's digital media efforts:

Categories	3/15/12 – 12/31/13	2014	2015	2016	2017	2018 YTD	3/15/12 - YTD
Twitter touches	7,197,265	11,375,809	89,462,400	99,405,700	170,625,900	17,145,200	467,212,274
Bitly hits	26,899	16,413	40,840	41,688	27,669	3,398	162,907
Blog hits	16,477	11,891	30,255	32,521	35,201	6,903	133,248
Facebook touches	241,037	528,582	2,635,000	4,595,136	9,513,900	1,584,800	19,098,455
LinkedIn touches	19,782	57,275	302,250	203,034	159,732	31,240	773,313
Total Digital Impressions							487,380,197

The following chart compares and contrasts neurosurgery's social media followers versus several other medical organizations. Overall, we are demonstrating consistently higher penetration on Twitter, which continues to grow. Since we have completed the task of getting Twitter up and running, we will be turning our attention to Facebook so we can level the playing field there as well.



Neurosurgery's Washington office continues to use social media platforms to expand the reach of its message by reaching key health policy influencers online. We have engaged on Twitter with individuals such as:



With regard to our blog, to date, Neurosurgery Blog has accumulated over 133,171 page views from 75,656 users. In 2018, Neurosurgery Blog has ramped up its health policy reporting efforts to include multiple topic months and guest blog posts from key thought leaders and members of the neurosurgical community.



When assessing Neurosurgery Blog's efforts as compared to other Washington, DC health blogs, we compare somewhat favorable given the small size of our specialty. Take for example the following:

Blog	Number of Blog Posts in 2016	Number of Blog Posts in 2017	Number of Blog Posts in 2018	Global Rank*
AAFP Leader Voices Blog	51	43	12	12,274
ACC In Touch	46 (last updated June 2016)	(last updated June 2016)	(last updated June 2016)	60,203
AUA	174	120	60	162,393
Neurosurgery Blog	75	51	16	486,804
HLC's Prognosis Blog	15	6	1	Not Enough Data to Rank
NASS	15	12	4	Not Enough Data to Rank

^{*}Global ranks are from Alexa on 1/31/18. Most blogs have been around a lot longer than us which can help global rankings stats.

Expanding the reach of Neurosurgery Blog will continue to be a priority going forward.

Finally, our DC e-newsletter continues to have a consistent open rate, with about one-third of our members reading this publication. The newsletter has been redesigned to improve its viewability.



AMA Update

The AMA House of Delegates (HOD) held its Interim meeting from Nov. 10-14, 2017 in Honolulu, HI.

Our Delegation for the I-17 HOD Meeting

- ☐ Ann R. Stroink, MD, CNS Delegate, Delegation Chair
- ☐ Kenneth S. Blumenfeld, MD, AANS Delegate
- Maya Babu, MD, AANS Alternate Delegate/Resident & Fellow Section Delegate
- ☐ Krystal L. Tomei, MD, CNS Alternate Delegate/Young Physicians Section Delegate



Neurosurgery Leading the Way

Once again, neurosurgery's delegates stepped-up to volunteer to serve at the AMA meeting. Dr. Stroink has been appointed to serve on Reference Committee F, which is a two-year commitment. This reference committee is tasked with oversight on AMA management, finances, its strategic plan and other operational matters. As such, she will be working closely with the AMA Board of Trustees and executive management for the next two years.

In addition, Dr. Blumenfeld volunteered to serve on Reference Committee B, which focuses on topics related to legislation.





Resolutions

The House of Delegates considered a number of resolutions on topics of interest to neurosurgery, including:

□ Physician assistant independent practice (*AANS/CNS sponsored resolution*);

	Merit-Based Incentive Payment System/MACRA
	On-Call and Emergency Services Pay;
	Consultation Codes and Private Payers;
	Neuropathic Pain as a Disease; and
П	Maintenance of certification fees

Final action on a number of reports and resolutions of interest to neurosurgery include:

Resolution 230 – Oppose Physician Assistant Independent Practice. This resolution was sponsored by the AANS, CNS and numerous other medical societies and asked that the AMA adopt policy to oppose legislation or regulation that allows physician assistant independent practice. Related to this were two other resolutions, one involving the Advanced Practice Registered Nurse Compact and another opposing licensing for individuals holding Degree of Doctor of Medical Science.

Regarding the physician assistants, the HOD adopted the following new AMA policy:

RESOLVED, That our American Medical Association adopt policy to oppose legislation or regulation that allows physician assistant independent practice. (New HOD Policy)

Resolution 237 – Implementation of Score Assessment for Cost Under MACRA MIPS. Led by a
handful of specialties, including the cardiologists, neurologists and oncologists, this resolution called
on the AMA to work with CMS to ensure sound methodologies for risk adjustment for physicians with
patient populations at risk for high resource use; and that the AMA urgently lobby the Congress and
the federal government to expedite development of an equitable, validated patient-specific risk
adjustment mechanism and not include a cost score in the Merit Based Incentive Payment System
(MIPS) until such time as it can be developed.

Because the AMA and others in organized medicine are currently actively negotiating changes to MACRA to address some of the issues raised by this resolution, the neurosurgery delegation was prepared to propose an amendment to help ensure that these current advocacy efforts were not disrupted. Ultimately, the sponsors agreed to let the reference committee's recommendations stand and the matter was **referred for decision**.

 Resolution 818 – On-Call and Emergency Services Pay. The Utah delegation introduced a resolution that the AANS and CNS fully backed, regarding emergency call pay.

The HOD adopted the following policy:

RESOLVED, That our American Medical Association amend Policy H-130.948, "On-Call Physicians," by addition to read as follows:

(d) Physicians should be provided adequate compensation for being available and providing oncall and emergency services.

The neurosurgery delegation had proposed an amendment to insert the phrase "based on fair market value" to ensure that there was definition of "adequate compensation." However, reference committee determined that leaving the language more flexibility was the preferred approach.

Resolution 819 – Consultation Codes and Private Payers. This resolution asks that the AMA proactively engage and advocate with any commercial insurance company that discontinues payment for consultation codes or that is proposing to or considering eliminating payment for such codes. The neurosurgery delegation put forward an amendment to expand this advocacy to include the Centers for Medicare & Medicaid Services (CMS), which discontinued paying for inpatient and outpatient consultation codes. The reference committee rejected this amendment and the final HOD policy was adopted:

RESOLVED, That our American Medical Association proactively engage and advocate with any commercial insurance company that discontinues payment for consultation codes or that is proposing to or considering eliminating payment for such codes, requesting that the company reconsider the policy change (Directive to Take Action); and be it further

RESOLVED, Where a reason given by an insurance company for policy change to discontinue payment of consultation codes includes purported coding errors or abuses, that our AMA request the company carry out coding education and outreach to physicians on consultation codes rather than discontinue payment for the codes, and call for release of de-identified data from the company related to purported coding issues in order to help facilitate potential education by physician societies. (Directive to Take Action)

Council on Science and Public Health Report 3 – Neuropathic Pain as a Disease. This report
considered whether neuropathic pain should be recognized as a distinct disease state. The report
concluded that evaluating neuropathic pain as a distinct disease state would be best deliberated by a
group of multi-specialty experts involved in the evaluation and treatment of pain who could more
deeply focus on the topic and consider all of its ramifications.

The HOD agreed with the report's recommendation, to wit:

That the Federation Task Force on Pain Care evaluate the relative merits of declaring neuropathic pain as a distinct disease state, and provide a recommendation to the Council on Science and Public Health. (Directive to Take Action)

The AANS and CNS have requested to have a representative from the AANS/CNS Joint Section on Pain participate on the task force.

Resolution 953 – Fees for Taking Maintenance of Certification Examination. This asks that the
AMA request reductions in maintenance of certification examination fees so as to work towards a
balanced/neutral budget of ABMS medical boards given their status as non-profit organizations. The
neurosurgery delegation pointed out that ABNS MOC fees are set to only cover costs and have
remained constant for the past decade or so.

The HOD took the following action, amending AMA Policy H-275.924, Maintenance of Certification:

- 19. The MOC process should <u>be reflective of and consistent with the cost of development and administration of the MOC components, ensure a fair fee structure, and not be cost prohibitive or present a barriers to patient care.</u>
- <u>27. That our AMA continue to work with the national medical specialty societies to advocate for the physicians of America to receive value in the services they purchase for Maintenance of Certification from their specialty boards. Value in MOC should include cost effectiveness with full financial transparency, respect for physicians' time and their patient care commitments, alignment of MOC requirements with other regulator and payer requirements, and adherence to an evidence basis for both MOC content and processes.</u>

The next meeting of the House of Delegates will be in June 2018 in Chicago, IL.

Questions or Comments about this report should be directed to:

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