



Sound Policy. Quality Care.

November 8, 2019

The Honorable Alex Azar  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue S.W.  
Washington, D.C. 20201

**RE: Executive Order (EO) entitled “Protecting and Improving Medicare for Our Nation’s Seniors”**

Dear Secretary Azar,

The Alliance of Specialty Medicine (the “Alliance”) represents more than 100,000 specialty physicians and is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. The Alliance writes to share feedback to the agency as it works toward implementing aspects of the Trump Administration’s Executive Order (EO) entitled “Protecting and Improving Medicare for Our Nation’s Seniors.”

#### **Medicare Advantage and Fee-for-Service**

Among other things, the EO directs the Secretary of the Department of Health and Human Services (HHS) to, within 180 days, submit to the President a report that identifies approaches to modify Medicare fee-for-service (FFS) payments to more closely reflect the prices paid for services in Medicare Advantage (MA) and the commercial insurance market, to encourage more robust price competition, and inject market pricing into FFS reimbursement.

At present, MA payments are generally determined through a comparison of a plan’s estimated cost (bid) and the maximum amount Medicare will pay a plan (benchmark). The benchmark is 95, 100, 107.5 or 115 percent of the FFS projected rate. Additional factors that influence MA payments include risk-adjustment, coding intensity, and quality bonuses. In turn, MA plans directly contract and negotiate reimbursement rates with healthcare providers, such as physicians. According to a recent study,<sup>1</sup> “[p]hysician reimbursement in MA was more strongly tied to [traditional Medicare (TM)] rates than commercial prices, although MA plans tended to pay physicians less than TM [emphasis added].” Another study from the Congressional Budget Office (CBO) shows average MA payments for the professional component of select physician services are at or below Medicare FFS rates.<sup>2</sup>

***We are deeply concerned with the Administration’s call to further reduce Medicare FFS rates based on reimbursements made to MA participating providers, particularly to physicians.*** First, as the aforementioned study explains, reimbursement for physicians’ services in MA are generally lower than traditional FFS. In fact, the authors went on to explain that, “[f]or a mid-level office visit with an established patient (Current Procedural Terminology [CPT] code 99213), the mean MA price was 96.9% (95% CI, 96.7%-97.2%) of TM. Across the common physician services [study authors] evaluated, mean

<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pubmed/28692718>

<sup>2</sup> <https://www.cbo.gov/system/files/115th-congress-2017-2018/presentation/52818-dp-presentation.pdf>

MA reimbursement ranged from 91.3% of TM for cataract removal in an ambulatory surgery center (CPT 66984; 95% CI, 90.7%-91.9%) to 102.3% of TM for complex evaluation and management of a patient in the emergency department (CPT 99285; 95% CI, 102.1%-102.6%).” In contrast, MA payments to hospitals are usually at or above TM rates.<sup>3</sup>

In addition, Medicare Physician Fee Schedule (MPFS) rates have not kept pace with inflation, remaining relatively flat for the last two decades. In fact, the 2019 conversion factor (\$36.0391) is lower than the rate paid in 1998 (\$36.6873). With MPFS rates at historic lows, any further reductions will set Medicare payments to physicians at unsustainable rates. Other Medicare providers, including hospitals, receive market basket updates each year. Payments to physicians should not be declining; rather, rates to physicians should at least keep pace with medical inflation given increased complexity in the health status of the Medicare population and increasing administrative and regulatory requirements imposed by the Centers for Medicare and Medicaid Services (CMS), particularly those associated with quality reporting which are not adequately funded by the associated incentives and bonuses.

Furthermore, despite a study that shows slight increases in the number of primary care physicians in MA provider networks,<sup>4</sup> the number of specialists and subspecialists continues to decline. In fact, access to some specialties is extremely low.<sup>5</sup> While several factors influence a plan’s decision to contract with physicians, reducing FFS rates to those paid by MA plans – on which MA benchmarks are currently set – will only further hinder the ability of specialists and subspecialists to find it feasible to contract with plans. We discuss additional concerns related to network adequacy in the section that follows.

Finally, the Omnibus Budget Reconciliation Act of 1989 mandated the resource-based relative value scale (RBRVS) for reforming physician payment under Medicare. The RBRVS fee schedule includes three basic elements: 1) work relative value units (wRVUs) for each medical service based on the resources associated with the physician's work (i.e., time and effort); RVUs to account for practice expenses (or PE RVUs); and RVUs that are intended to account for costs associated with professional liability insurance (or PLI RVUs); 2) a geographic adjustment to account for geographic variations in the cost of practicing medicine in different areas within the country;<sup>6</sup> and 3) a conversion factor (CF) that converts the RVUs into a payment amount for each service.<sup>7</sup> Without a change in law, it is unclear how the agency could revise Medicare FFS payments to physicians based on prices paid by MA plans.

Given the above, ***we oppose efforts to further erode Medicare FFS payments to physicians.***

### **Network Adequacy**

The EO directs the Secretary to, within one year, adjust network adequacy requirements for MA plans to account for the competitiveness of the health market in the States in which such plans operate, including whether those States maintain certificate-of-need laws or other anti-competitive restrictions, and the enhanced access to health outcomes made possible through telehealth or other innovative technologies.

Beneficiary access to specialty medical care remains hindered due to inadequate MA provider networks. As the agency notes in its network adequacy requirements, CMS expects that organizations continuously monitor their contracted networks throughout the respective contract year to ensure compliance with the current network adequacy criteria. In addition to a review of its requirements, CMS monitors

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<sup>3</sup> <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1427>

<sup>4</sup> <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05501>

<sup>5</sup> <http://files.kff.org/attachment/Report-Medicare-Advantage-How-Robust-Are-Plans-Physician-Networks>

<sup>6</sup> Each of the three components of a services’ RVU is adjusted by geographic practice cost indices (GPCIs)

<sup>7</sup> The formula used to set the annual CF is set in statute

network compliance by reviewing MA networks on a triennial basis, as well as following specific triggering events (e.g., significant provider/facility contract termination, network access complaint). However, the provider specialty types<sup>8</sup> that CMS measures against do not include a range of specialty and subspecialty physicians to which beneficiaries will likely need access for a multitude of complex health conditions. As a result, many specialists, and particularly subspecialists, are not accounted for under network adequacy reviews as they are currently conducted.

As we have shared before, a number of specialists and subspecialists struggle to join or maintain in-network status with MA plans. Since MA premiums have dropped and more MA plans have entered the market, more beneficiaries may choose to join an MA plan. However, without an adequate supply of specialists and subspecialists to diagnose, treat, and manage complex health conditions in key disease areas, these plans will not be able to deliver the promise of meaningful coverage equal to or beyond original Medicare.

As CMS adjusts network adequacy requirements for MA plans, ***we urge the agency to consider the following recommendations:***

- Update the provider specialty types to include all physician specialties and subspecialties listed in the Healthcare Provider Taxonomy Code Set.<sup>9</sup>
- Require MA plans to maintain accurate, real-time provider directories.
- Develop Quality Rating System (QRS) measures that tie adequate networks to MA quality metrics, further incentivizing plans to maintain adequate networks of specialists and subspecialists.
- Require MA plans to provide reasonable notice regarding termination of a provider's in-network status, including the cause for termination and pathways to re-enter the network.

### **Enabling Providers to Spend More Time with Patients**

The EO directs the Secretary to, within one year, propose reforms to Medicare to enable providers to spend more time with patients by:

- eliminating burdensome regulatory billing requirements, conditions of participation, supervision requirements, benefit definitions, and all other licensure requirements of the Medicare program that are more stringent than applicable Federal or State laws require and that limit professionals from practicing at the top of their profession;
- ensuring appropriate reimbursement for time spent with patients by primary and specialist health providers practicing in all types of health professions; and
- conducting a comprehensive review of regulatory policies that create disparities in reimbursement between physicians and non-physician practitioners and proposing a regulation that would ensure that items and services provided by clinicians, including physicians, physician assistants, and nurse practitioners, are appropriately reimbursed in accordance with the work performed rather than the clinician's occupation.

We appreciate that this Administration seeks to ensure appropriate reimbursement for time spent with patients by primary and specialist health providers practicing in all types of health professions. The Alliance has repeatedly emphasized the value of specialty physicians in the diagnosis, treatment, and management of complex health conditions. As we have shared previously, specialists use their deep knowledge and expertise to reach a precise medical diagnosis, present the full array of available interventions, and assist patients in determining which option is most appropriate based on their

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<sup>8</sup> See [Appendix C](#) of the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance

<sup>9</sup> <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/JSMTDL-08515MedicarProviderTypetoHCPTaxonomy.pdf>

preferences and values, as well as coordinate and manage their specialty and related care until treatment is complete and the patient is ready to return to their primary care provider. No other clinician, provider-type, or health care professional can replace the value offered by specialty physicians; specialists are an essential and needed component of the healthcare system.

However, ***we oppose Section 5 of the Executive Order that aims to expand the scope of practice of non-physician professionals such as nurse practitioners (NPs) and physician assistants (PAs) and reimburse them at the same rate as physicians.*** While NPs and PAs are a valuable part of a physician-led team, they do not have the requisite training and education to independently practice and be reimbursed as such. We also believe that the Executive Order is misguided in the belief that expanding NP and PA scope of practice will help increase access in areas that have difficulty attracting physicians. It is important to note that rigorous studies conducted by the American Medical Association have consistently shown that expanding physician assistant (PA) and nurse practitioner (NP) scope of practice does not increase access to care in underserved areas.<sup>10</sup> For these reasons, we encourage the Administration to rescind Sections 5(a) and 5(c) of the Executive Order.

### **Encouraging Innovation for Patients**

The EO directs the Secretary to, within one year, propose changes to Medicare to streamline the approval, coverage, and coding process between the U.S. Food and Drug Administration (FDA) and CMS, so that innovative products are brought to market faster, and appropriately reimbursed and widely available.

The Alliance supports concurrent review for FDA-approved therapies, a concept that is embodied in the Parallel Review program,<sup>11</sup> which was fully implemented in 2016. However, the program's emphasis on establishing National Coverage Determinations (NCDs) is a known barrier to manufacturers volunteering for the program. This may be particularly problematic if a manufacturer's product is expected to experience geographic variation in use due to its target population. Rather than focusing on national coverage, the program should simply assist manufacturers in answering key questions aimed at securing coverage and reimbursement by Medicare and private payers in their FFS and value-based payment models. ***We urge CMS and FDA to work with specialty physicians as they seek to improve the Parallel Review program.***

### **Transparency**

The EO directs the Secretary to, within one year, propose a regulation that would provide seniors with better quality care and cost data, improving their ability to make decisions about their healthcare that work best for them and to hold providers and plans accountable. Additionally, the Secretary must use Medicare claims data to give health providers additional information regarding practice patterns for services that may pose undue risks to patients and to inform health providers about practice patterns that are outliers or that are outside recommended standards of care.

In prior comments to CMS, we have urged CMS to improve transparency with respect to experience reports associated with the Quality Payment Program (QPP), including the Merit-based Incentive Payment System (MIPS), and APM engagement. Specifically, we made the following requests:

- As part of the QPP Experience Reports and/or annual notice-and-comment rulemaking for the QPP, provide detailed ***specialty-specific*** data and information on:

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<sup>10</sup> The AMA Health Workforce Mapper, 1995-2019. <https://www.ama-assn.org/about-us/health-workforce-mapper>.

<sup>11</sup> <https://www.federalregister.gov/documents/2016/10/24/2016-25659/program-for-parallel-review-of-medical-devices>

- MIPS scoring and payment adjustments (including exceptional performance);
- MIPS reporting mechanisms;
  - quality measures reported;
- group vs. individual reporting; and
- participation in each of CMS' Advanced APMs (A-APMs).

In addition, we expressed concern about the lack of detailed specialty data in the MIPS Feedback Reports. Of particular concern is feedback on the Medicare Spending per Beneficiary (MSPB) and Total Per Capita Costs (TPCC) measures used in the Cost performance category of MIPS, given it does not assist specialists in better managing key resources relative to the conditions and services where they have clinical expertise and control over treatment decisions. As such, the information does not drive any meaningful change in behavior that would allow improvements in patient care, utilization, or the clinician's performance score.

***We urge CMS to adopt the recommendations to improve QPP Experience Reports, as well as ensure feedback provided as part of the MIPS Performance Feedback Reports is meaningful, actionable, and relevant for specialty physicians.***

Furthermore, we remain concerned that publicly-reported Medicare quality and cost information may be confusing and unclear to beneficiaries and their caregivers, thus inadvertently thwarting access to medically necessary care. Even more concerning is the inappropriate, and often inaccurate, synthesis of these quality and cost data, with Medicare payment, prescribing and "Sunshine" data, to create potentially damaging narratives about Medicare providers<sup>12</sup> and prompting beneficiaries to delay care.

***We urge CMS to provide appropriate disclaimers about the data it makes available to the public, as well as to educate external entities about their use of Medicare's data, including the relationship between various data sets.***

### **Waste, Fraud, and Abuse**

The Secretary must propose changes to Medicare with an effective date of January 1, 2021, and annually thereafter, to combat fraud, waste, and abuse in Medicare. Within 180 days, the Secretary must also recommend approaches to transition toward true market-based pricing in the FFS program. According to the EO, approaches studied shall include shared savings and competitive bidding in FFS Medicare; use of MA-negotiated rates to set FFS Medicare rates; and novel approaches to information development and sharing that may enable markets to lower cost and improve quality for FFS Medicare beneficiaries.

The Alliance continues to support agency efforts to maintain the integrity of the Medicare program through implementation of laws and regulations related to fraud and abuse. CMS' recent Request for Information (RFI) describing the future of Medicare program integrity, as well as proposed rules from CMS and the Office of Inspector General (OIG) that would improve Stark and Anti-kickback rules for those providers working in value-based payment and delivery models are important steps toward reducing provider burden while still ensuring robust safeguards to the Medicare program from fraud, waste, and abuse. We look forward to continued collaboration in these and additional areas.

We also note that CMS has made significant revisions to the provider enrollment process, including new polices that would revoke or deny a physician's Medicare enrollment if CMS determines that he or she has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, or represents a threat to the health and safety of Medicare beneficiaries,

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<sup>12</sup> <https://www.policymed.com/2015/03/medicare-data-and-when-transparency-isnt-transparent.html>

among other things. While we appreciate CMS' approach that focuses on "bad actors," we are concerned that CMS' threshold for evaluation of its criteria is unclear, which may result in qualified physicians being excluded from the Medicare program inappropriately. ***We urge CMS to reconsider these policies, which may inadvertently limit access to care. At the very least, CMS should closely monitor physician enrollment as these new policies are implemented and work with the provider community to address challenges that arise.*** We also point CMS to our comments regarding CMS' recently finalized disclosure of affiliation requirements, and ***as CMS contemplates future phases of its reporting requirements, we urge CMS to pursue policies that will minimize burden for those providers and suppliers who pose low risk of fraud, waste, and abuse to the Medicare program.***

### **Reducing Obstacles to Improved Patient Care**

Within one year, the Secretary must propose regulatory changes to the Medicare program to reduce the burden on providers and eliminate regulations that create inefficiencies or undermine patient outcomes.

#### ***Utilization Management Policies***

We appreciate the Administration's intent to reduce obstacles to improved patient care. With that in mind, we urge CMS to improve overreaching utilization management policies – such as prior authorization (PA) and step-therapy – from Medicare.

As we previously shared with CMS, prior authorization is a significant and growing challenge for specialty physicians and their patients. According to a recent survey of specialty physicians, the Alliance found that:

- Nearly 90% have delayed or avoided prescribing a treatment due to the PA process;
- 95% report that this increased administrative burden has influenced their ability to practice medicine;
- 82% state that PA either always (37%) or often (45%) delays access to necessary care;
- PA causes patients to abandon treatment altogether, with 32% reporting that patients often abandon treatment and 50% reporting that patients sometimes abandon treatment;
- Nearly two-thirds report having staff who work exclusively on PA, with one-half estimating that staff spend 10-20 hours/week dedicated to fulfilling PA requests and another 13% spending 21-40 hours/week; and
- Ultimately, the majority of services are approved (71%), with one-third of physicians getting approved 90% or more of the time.

In 2018, a bipartisan group of more than 100 members of Congress weighed in on this issue, urging CMS to provide Medicare Advantage plans with direction to increase transparency, streamline PA, and minimize the impact on patients. They called on CMS to:

- Issue guidance to MA plans to dissuade the widespread use of prior authorization and to provide direction to the health plans to increase transparency, streamline prior authorization, and minimize the impact on beneficiaries;
- Ensure that prior authorization practices do not create inappropriate barriers to care for Medicare enrollees; and
- Collect data on the scope of prior authorization practices (i.e., denial, delay, and approval rates).

***We urge CMS to propose significant improvements in prior authorization consistent with the above Congressional recommendations, which are supported by the Alliance.***

In addition, we are deeply concerned with CMS' step-therapy protocols for Part B medications in Medicare Advantage. These protocols require patients to try and fail "preferred" medications before

being allowed to access the physician-prescribed medication. The goal is to control drug spending – with little regard for quality, outcomes, and other key factors. These policies have devastating health consequences for beneficiaries and ultimately lead to increased health care costs. Beneficiaries who are denied first coverage of medications recommended by their physicians can end up with poor health outcomes due to adverse health events, which can lead to costly hospitalizations and permanent disability. This is particularly true for beneficiaries with chronic diseases such as inflammatory bowel disease, rheumatoid arthritis, cancer, psoriasis, or age-related macular degeneration, who may respond differently to various medications used to treat these diseases.

In 2017, the Alliance conducted a survey of specialists, finding that:

- More than 85% have experienced an occasion during which a stable patient was asked to switch from his or her medication by the insurer even though there was no medical reason to do so.
- 70% reported that their patients were unable to follow recommended treatment plans due to out-of-pocket costs.
- Nearly 95% report needing to change a prescription to a different medication due to delay tactics from insurers related to the original prescription.
- More than half reported that it took longer than three days to get a patient the proper medication.

These policies hinder efforts to personalize healthcare for beneficiaries, and particularly in certain populations with complex health needs. ***We oppose step-therapy in Medicare and urge the agency to withdraw these policies.***

#### ***Merit-Based Incentive Payment System (MIPS)***

The Alliance appreciates recent efforts by CMS to streamline MIPS, which is the only value-based pathway for most specialists to engage in the QPP at this time. However, the program continues to impose a considerable burden on physicians due to its disjointed reporting requirements, complex eligibility and scoring methodologies, and misaligned measure sets. At the same time, the program has become increasingly irrelevant to specialists as CMS continues to scale back on specialty-focused measures. Most specialists now have few relevant participation options and are forced to report on general measures, rather than measures that can result in meaningful improvements in specialty care. Specialty physicians are required to invest resources in revising their clinical workflows and establishing administrative protocols simply to collect extraneous data that falls outside their day-to-day clinical practice. CMS' ongoing removal of specialty measures also leaves patients with little relevant performance data on which to make decisions regarding specialty care. Finally, the program produces performance feedback that is confusing, overwhelming, and unusable by most specialists, which further limits the utility of this program.

***To ensure that specialty practices can meaningfully engage in MIPS, we recommend that CMS:***

- ***Truly streamline the program so that clinicians, including specialists, can get credit across multiple categories of MIPS for a single comprehensive demonstration of a commitment to quality improvement***
- ***Re-evaluate efforts to scale back on the diversity of measures offered under MIPS while recognizing the need to retain and incentivize the use of specialty-focused measure; and***
- ***Offer more flexible and specialty-friendly participation and reporting options.***

#### ***Imaging Appropriate Use Criteria Program***

The Medicare Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging was authorized under the Protecting Access to Medicare Act of 2014 (PAMA). Under the program, physician Medicare reimbursements hinge on the consultation of AUC using a CMS qualified Clinical Decision Support

Mechanism (CDSM) and documenting the consultation on the furnishing physician's claim. Although implementation of the program has been delayed multiple times, CMS is set to launch an education and operations testing period on January 1, 2020. The Alliance supports the use of AUC for purposes of clinical decision-making. However, we do not agree with the inflexible manner in which it is mandated under this program, and we are unconvinced the program can be implemented without significant disruption to physicians, hospitals, and other health care providers. This program, when fully implemented, will impose significant costs and administrative burdens on physician practices. The requirement to use federally qualified CDSMs will force physicians to abandon long-standing and often more relevant methods of AUC consultation. It also will require specialty societies and physician practices to divert resources from QPP outreach and education, just as physicians are struggling with QPP participation.

Much has changed in health care since this program was first authorized in 2014. Physicians must comply with the value-focused requirements of the QPP, and Medicare payment and delivery model participants are assuming more downside risk. In this rapidly evolving landscape, this separate, standalone AUC Program adds yet another administrative layer that brings questionable value to our healthcare system.

CMS has admitted that it faces serious operational challenges related to this program and that solutions are limited due to the requirements of the law. CMS officials have even questioned the benefits of this program, noting that "information on benefits overall is limited."<sup>13</sup>

***The Alliance requests that CMS continue voluntary participation in the AUC Program until it can adequately address technical and workflow challenges with its implementation and any overlap with efforts to promote more appropriate care through the QPP. The Alliance further requests that the Administration work with Congress to achieve necessary legislative changes to allow for the harmonization of the QPP and AUC Program to alleviate the additional burdens caused by these duplicate and overlapping programs.***

### **Maximizing Freedom for Medicare Patients and Providers**

Within 180 days, the Secretary, with the Social Security Commissioner, must revise current rules to preserve Social Security benefits for seniors who choose not to receive benefits under Medicare Part A and propose other improvements to Medicare enrollment processes for beneficiaries. Within one year, the Secretary must also identify and remove unnecessary barriers to private contracts that allow Medicare beneficiaries to obtain the care of their choice and facilitate the development of market-driven prices.

***We are eager to collaborate with CMS as it works to remove barriers that limit the ability of beneficiaries to privately contract with physicians.*** As you know, current law requires Medicare beneficiaries to pay out-of-pocket if they choose to see a physician that does not accept Medicare and Medicare will not cover any portion of the charges incurred. Further, physicians who choose to provide covered services to Medicare beneficiaries under private contracts must "opt-out" of the Medicare program for two years. Medicare will not pay the physician for any covered services provided to Medicare beneficiaries during that time. Medicare beneficiaries – tax-paying Americans who have paid into the program for years – should not be prevented from using their Medicare benefits if they choose to see a physician that does not accept Medicare. These discriminatory policies are inappropriate and impede Medicare beneficiaries' freedom of choice.

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<sup>13</sup> Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019

As noted above, Medicare reimbursements to physicians continue to decline and the amount of regulatory burden increases with each regulation. As a result, we anticipate more and more physicians will reconsider their participation in Medicare. Ultimately, beneficiary access to high-quality care will be compromised – particularly in some areas of specialty care. The Alliance has supported legislative efforts to allow private contracting, which would restore confidence in the Medicare program by ensuring beneficiary access to any physician they choose to see, regardless of the physician’s participation status.

***We urge CMS to issue a Request for Information (RFI) that would inform proposals aimed at removing barriers to private contracting.***

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Thank you for considering these important issues to specialty physicians. We look forward to working with you as you carry out rulemaking and other regulatory activities related to the EO.

Sincerely,

American Association of Neurological Surgeons  
American College of Osteopathic Surgeons  
American College of Mohs Surgery  
American Gastroenterological Association  
American Society for Dermatologic Surgery Association  
American Society of Cataract and Refractive Surgery  
American Society of Plastic Surgeons  
American Society of Retina Specialists  
American Urological Association  
Coalition of State Rheumatology Organizations  
Congress of Neurological Surgeons  
North American Spine Society  
Society for Cardiovascular Angiography and Interventions