

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, *Executive Director*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org



American
Association of
Neurological
Surgeons



Congress of
Neurological
Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS

REGINA SHUPAK, *CEO*
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@cns.org

President
CHRISTOPHER I. SHAFFREY, MD
Durham, North Carolina

President
STEVEN N KALKANIS, MD
Detroit, Michigan

December 16, 2019

The Honorable Diana DeGette
US House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
US House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Submitted electronically via cures2@mail.house.gov

SUBJECT: Comments on Request for Feedback on Cures 2.0 Legislation

Dear Reps. DeGette and Upton:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate the opportunity to provide our comments on legislation to follow up on the 21st Century Cures Act, P.L. 114-255. We commend you for your efforts to build upon the excellent foundation established in the 21st Century Cures Act and look forward to working with you as you craft important provisions of Cures 2.0.

Support for the Use of Registry Data

Although the 21st Century Cures Act did include a mandate for a breakthrough medical device process to help bring important innovation to patients, the final law did not include specific language to clarify that valid scientific evidence may include registry data. The neurosurgery-led NeuroPoint Alliance (NPA) has worked closely with the FDA and other societies on several important initiatives to explore “real world” data sources and alternatives to costly and time-consuming randomized controlled trials. As you move forward with Cures 2.0 and consider more timely and innovative ways to assess clinical efficacy and safety, we urge you to continue to formulate language to strengthen the use of registry data to help bring potentially life-saving medical products to patients more quickly and affordably. In addition to the use of registry data to speed innovation and device approval, registry expertise is useful for post-market surveillance.

We are eager to share our registry experience, including the multispecialty projects such as the American Spine Registry (a collaborative project with the American Academy of Orthopaedic Surgeons) and an initiative with the Society of NeuroInterventional Surgery to establish a single registry for neurovascular surgical procedures. In the case of the neurovascular registry, we are working with the FDA to use the data to evaluate thrombectomy devices for the treatment of stroke.

The AANS and the CNS remain convinced that these registries are precisely the kind of collaborative efforts that will lead to better care, and ultimately outcomes, for our patients. We, therefore, applaud your dedication to foster a regulatory environment that supports and encourages the use of real-world data and encourage Cures 2.0 to include more explicit language to support registry data for device approval and post-market surveillance.

Reimbursement for Innovative Treatment

The AANS and the CNS appreciate your invitation to examine how reforming Medicare coding, coverage and payment could better support patients’ access to innovative therapies, and we are eager to work with

you to identify improvements in current Medicare policies to foster innovation. Neurosurgeons are at the cutting-edge of advances in treating diseases and disorders of the brain and spine, including stroke, back pain, Parkinson's disease, brain tumors and more. For example, neurosurgeons have developed evidence-based and effective therapies to reduce the dependence of chronic pain patients on opioid medications. Unfortunately, Medicare, Medicaid and many private insurers often deny the use of these treatments, including spinal cord stimulation, peripheral nerve stimulation, deep brain stimulation, peripheral neurectomy, cordotomy and others despite substantial high-quality peer-reviewed evidence supporting their efficacy in reducing chronic pain and patients' dependence on opioid medications.

We look forward to working with you to develop effective coverage and reimbursement policies to bring these and other important treatments to patients. In addition, the AANS and the CNS have been actively working to find a legislative solution to reduce the burdens of prior authorization, which often unnecessarily delay access to medically necessary therapies. Provisions such as those included in H.R. 3107, the Improving Patients' Timely Access to Care Act, will help bring necessary transparency and oversight to the prior authorization process.

Local Coverage Determination Process

The 21st Century Cures Act made significant changes in the Medicare Administrative Contractor (MAC) local coverage determination process (LCD). Neurosurgery has recently had first-hand experience with this process through a multi-jurisdictional carrier advisory committee (CAC) and numerous LCDs produced for Percutaneous Vertebral Augmentation. The final LCDs produced by several of the MACs were significantly inconsistent with the evidence provided in the CAC meeting and in response to the draft LCDs. Now that several LCDs have been produced under the new procedures, we encourage you to review these and take appropriate steps to refine the LCD process further to ensure that it is being implemented as Congress intended to ensure that innovative therapies are available to patients in an efficient manner.

Open Payments and Sharing of Valid Scientific Information

We continue to support legislative language that exempts the sharing of peer-reviewed journals, journal reprints, journal supplements and medical textbooks that help educate physicians and contribute to continuing medical education.

Conclusion

The AANS and the CNS appreciate the opportunity to work with you as you craft the Cures 2.0 legislation, and we stand ready to provide expertise and support in this effort.

Sincerely,



Christopher I. Shaffrey, MD, President
American Association of Neurological Surgeons



Steven N. Kalkanis, MD, President
Congress of Neurological Surgeons

Staff Contact:

Katie O. Orrico, Director
AANS/CNS Washington Office
25 Massachusetts Avenue, NW, Suite 610
Washington, DC 20001
Direct: 202-446-2024
Fax: 202-628-5264
Email: korrigo@neurosurgery.org