

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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FREDERICK A. BOOP, MD
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June 17, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Subject: Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and FY 2017 Rates Proposed Rule; New Technology Add-on Status for Responsive Neurostimulator System (RNS)

Dear Mr. Slavitt,

On behalf of more than 4,000 practicing neurosurgeons in the United States, the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) appreciate the opportunity to comment on an important item in the above referenced CMS hospital inpatient prospective payment system proposed rule.

The AANS and CNS disagree with the CMS decision not to provide a third year of new technology add-on payment for the responsive neurostimulator (RNS) system. The technology represents a substantial clinical improvement for patients who are medically refractive or not candidates for surgery. We presented these views at the Food and Drug Administration's (FDA) Neurological Devices Advisory Panel on February 22, 2013, and in our comments on the IPPS proposed rule for the last two years. A significant number of epilepsy patients — possibly over a third of these individuals — will not find adequate relief from medications. While traditional surgery may help some of these patients, surgery is not always the best option. This is particularly true for individuals with intractable epilepsy where surgery may help less than ten percent of these patients, leaving a significant portion of patients with either medically or surgically untreatable epilepsy. For these patients, RNS offers substantial clinical improvement.

We understand that CMS has stated that the agency will not extend the new technology add-on status because the three-year anniversary date of the entry of RNS System on the U.S. market (Nov. 14, 2016) will occur in the first half of FY 2017, and the agency typically only extends new technology add-on payments for an additional year if the three-year anniversary date of the product's entry into the U.S. market occurs in the latter half of the fiscal year. We believe, however, that CMS should make an exception for this important technology.

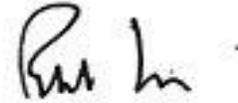
The AANS and CNS appreciate the opportunity to comment on the proposed regulation. As always, we

look forward to working with CMS to make improvements to the Medicare program. If you have any questions or need further information, please feel free to contact us.

Sincerely,



Frederick A. Boop, MD, President
American Association of Neurological Surgeons



Russell R. Lonser, President
Congress of Neurological Surgeons

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