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February 16, 2018

The Honorable Orrin G. Hatch, Chair
And
The Honorable Ron Wyden, Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510-6200

Re: Improving Pain Care While Reducing Opioid Use Disorder
in the Medicare and Medicaid Programs

Dear Senators Hatch and Wyden:

The American Pain Society ("APS" or "the Society") is pleased to submit these recommendations for the Committee's consideration as you review payment and related policies that promote appropriate pain care for beneficiaries served by programs under the Committee's jurisdiction.

Medicare and Medicaid have tremendously important roles to play in addressing the dual epidemics of chronic pain and opioid misuse in America. These epidemics are separately well documented but the relationship between them is often poorly understood. Concerted efforts to improve evidence-based pain management, particularly for chronic pain in the elderly and disabled populations, can contribute to a reduction in substance abuse and addiction, but will not by itself end the opioid epidemic. Similarly, efforts to prevent substance abuse and treat it effectively when it arises will not guarantee appropriate pain care for beneficiaries in need. Thus, as you consider policy changes addressed to either of these critically important public health challenges we urge your careful consideration of the implications for the other that may arise in the course of policy change.

Promoting Evidence-Based Pain Care

The American Pain Society believes that the Committee's review of the policy options should be heavily informed by work already done in the development of the National Pain Strategy ("NPS") at the Department of Health and Human Services. Recommended by the Institute of Medicine in its ground-breaking 2011 report, *Relieving Pain in America*, the NPS was prepared by HHS under the leadership of NIH and its Inter-Agency Pain Research Coordinating Committee. It was a multiyear effort involving multiple government agencies, including CMS, and recognized private sector experts from the professions, patient groups and industry. It produced a

comprehensive report which enjoys widespread support.
https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.

A major area of focus in the NPS is “Service Delivery and Payment.” (see NPS at pp. 34-40) Among its principal findings and recommendations which are highly relevant to the Committee’s review are:

- There are significant problems with insurance coverage and payment models that have encouraged fragmented single modality treatment for pain as opposed to integrated, multi-modal, interdisciplinary care. The latter has been proven more effective for many patients, particularly those with high impact chronic pain that may persist for years. As with other chronic diseases prevalent in the Medicare and Medicaid populations, these long-term chronic care patients drive costs in the system, yet there is poor reimbursement for precisely this multi-modal care that is most effective.
- Payment systems rarely cover the time and resources necessary to comprehensively assess pain at the front end of diagnosis and treatment or to follow treatment through on a long term basis in a coordinated way.
- There is inadequate coverage and payment for preventive programs and services that conform to the biopsychosocial model of care that, again, has proven effective for many seriously impacted patients.
- Low patient co-pays for pharmacological treatment, including opioids, contribute to an over-reliance on therapy that entails risk of abuse and possible addiction.
- Lack of coverage, or arbitrary limits on coverage, reduce access to services like physical therapy, cognitive behavioral therapy, and acupuncture which, for many patients, can be effective alternatives to opioids.
- Perhaps most importantly for the Committee’s purposes, the NPS recognizes that there are few “quick fixes.” Among its most important recommendations, the NPS suggests research and demonstration projects conducted through the Center for Medicare and Medicaid Innovation to test and thoroughly evaluate both care models and payment innovations. These should include “the stepped model of pain care, the biopsychosocial model, team-based care, pain self-management approaches and care planning based on comprehensive pain assessments”. (see NPS at p.36)

In sum, APS believes that the Committee should follow the path already laid out in the NPS, and not seek to implement immediate policy changes that have not yet been thoroughly evaluated, and may well have unintended consequences adverse to program beneficiaries.

PDMPs and the Sharing of Medicare and Medicaid Program Data

The Society has long supported prescription drug monitoring programs based on the NASPER legislation first enacted by Congress in 2005 and updated and reauthorized in 2016. Unfortunately, the NASPER program has never been consistently funded, and state-based PDMP efforts have suffered from lack of sufficient and sufficiently stable resources. APS suggests that the Committee consider using Medicare and Medicaid administrative funding to assist the states in maintaining and improving these programs, and particularly in making them interoperable across state lines.

The Society has supported NASPER because it is grounded in public health, patient safety and clinical improvement, not law enforcement. The states are already sufficiently challenged in realizing the full potential of PDMPs, and we think it would be a mistake, at least at the current time, for the Committee to ask them to take on a program integrity function with respect to either prescribers or patients in the Medicare and Medicaid systems.

Medicare and some state Medicaid programs are already implementing patient “lock-in” programs for identified high risk patients. Asking PDMPs to serve a similar function might duplicate these efforts, and we recommend instead that these efforts be carefully evaluated to ensure that they are meeting their objectives without interfering unreasonably with patient access and patient choice of both clinicians and pharmacies.

The Society believes strongly that Medicare and Medicaid will automatically benefit from stable well-run state PDMP programs without any additional data sharing or other coordination. To the extent that the PDMPs identify “doctor shopping” patients, irresponsible prescribers, or rogue dispensers, and take action through existing mechanisms run at the state level (i.e. Boards of Medicine and Pharmacy), all payors will realize the benefits of those actions.

The Need for a More Robust Pain Research Effort

The need for robust funding of both pain and addiction research at the National Institutes of Health has never been more apparent. While setting priorities for NIH has traditionally been the purview of other Senate committees, the Finance Committee has a unique opportunity at the current time to advance the research effort. This opportunity results from the recent referral of S. 2260, the “Opioids and STOP Pain Initiative Act,” to Senate Finance. The Society urges you and your colleagues to favorably report the bill to the full Senate without delay.

The major purpose of S.2260 is to speed the time at which safe and effective non-opioid alternatives will be a reality, giving both clinicians and patients the choices they need to rapidly reduce reliance on opioid therapy. The last Congress recognized the critical importance of expanded research when it passed the “STOP Pain Act of

2016” as Section 108 of the CARA legislation. That provision recognized the work already underway through the Interagency Pain Research Coordinating Committee (“IPRCC”) at NIH, the National Pain Strategy discussed above, and the more recently released Federal Pain Research Strategy, all of which support prioritization of pain research studies. The essential next step is for Congress to provide adequate funding.

Pain research has been woefully underfunded by virtually any measure. It has historically represented less than 2% of the NIH budget, with little if any growth in real terms in recent years. Compare this to the burden of pain as a public health problem:

- Pain costs the U.S. between \$560 and 635 Billion annually (Institute of Medicine 2011), more than heart disease and cancer combined;
- Pain is a leading cause of disability and lost productivity in the workplace;
- Pain is the leading reason patients seek medical care;
- Pain affects Americans at all stages of life, whether as a primary disease in and of itself (e.g. low back pain and migraine), or as a symptom of a wide variety of other diseases and conditions (e.g. cancer, diabetes, and heart disease).

Support for pain research funding has suffered for many reasons, principal among them being the lack of a dedicated Institute or Center at NIH. As a consequence, pain-related grants are spread across many Institutes and Centers, no one of which has pain as its highest priority. In recent years, and with strong support from the Congress, NIH has developed important infrastructure to coordinate and prioritize these separate funding streams. This includes, in addition to the IPRCC noted above, the NIH Pain Consortium and an Office of Pain Policy. These need to be supported and strengthened.

Despite these efforts, research is unlikely to “move the needle” on either pain as a public health problem, or over-reliance on opioid prescribing for pain, unless a substantial and sustained funding commitment is made. Prompt passage of S. 2260 would begin that commitment in a visible and potentially transformative way. Medicare and Medicaid would directly benefit from any future research breakthroughs that provide the beneficiaries of these programs with new and safer alternatives for effective pain care.

The American Pain Society represents thousands of health care professionals dedicated to improving pain care, research and education. Its members appreciate the opportunity to express these views, and stand ready to work with you and your colleagues to advance our common objectives.

Sincerely,

A handwritten signature in black ink, appearing to be 'EW', followed by a long horizontal line extending to the right.

Ed Michna, MD, JD, BSPHarm.
For American Pain Society