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February 11, 2019

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
200 Independence Avenue, S.W., Room 736E,
Attn: Alicia Richmond Scott, Task Force Designated Federal Officer
Washington, DC 20201

RE: Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. Docket Number: HHS-OS-2018-0027

On behalf of the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP), 50 state societies and the Puerto Rico Society of Interventional Pain Physicians, the Society of Interventional Pain Management Surgery (SIPMS), and the entire membership of ASIPP and SIPMS, we would like to congratulate the Department of Health and Human Services (HHS) Task Force headed by Vanila Singh, MD, a pain physician, and express our appreciation for the multiple recommendations you have provided regarding acute and chronic pain management. Your recommendations address various treatment modalities with and without medications, and include, interventional procedures, behavioral health therapies, and complimentary and integrative approaches to health; focusing on improving access to pain care that avoids stigma. The recommendations also focus on education, training, risk assessment and evaluation incorporating a multitude of special populations and conditions.

Your document is extensive and discusses all of the different facets of the pain management speciality including patients, patient groups, providers, and payers. The document brings to light numerous gaps and provides multiple recommendations in almost all areas. Consequently, it is crucial that Congress and HHS take the lead in implementing these recommendations and improving them through regulations rather than guidelines. CMS, the largest insurer in the United States, with Medicare and Medicaid, the Veterans Administration, and other governmental payers must exert their influence over other payer communities educating them on the importance of the treatment of pain and providing access to these services.

In the past, ASIPP has lead on the issue of the opioid epidemic. ASIPP has brought the issues of medication access and methods to curb opioid abuse to the attention of Congressional policy makers and the medical profession. ASIPP successfully sponsored the National All Schedules Prescription Electronic Reporting (NASPER) Act which resulted in prescription drug monitoring programs (PDMPs) in each and every state providing access to physicians (funded by Harold Rogers' PDMP program). It was ASIPP that brought these issues into light by tirelessly working to obtain PDMPs in each state through their state societies and advocacy programs. ASIPP continues to maintain an appropriate distance from the opioid industry regarding funding and contributions. Additionally, ASIPP has published multiple guidelines. ASIPP has also testified in congressional hearings on numerous occasions.

SECTION 2.1 - APPROACHES TO PAIN MANAGEMENT

Gap 1: This appropriately shows current inconsistencies and the fragmentation of pain care which are obviously limiting to best practices.

> **Recommendation 1a:** The authors of this document quote a collaborative stepped model of pain care as adopted by the Veterans Administration (VA) and Department of Defense Health Systems.
>
> Overall, these are available for only a few patients. Further, there is no uniformity in application even in VA systems. Some of the systems are so disjointed, it is not even appropriate to follow the model of pain care here except to use it as the template.

SECTION 2.2 - MEDICATION

Gap 1: This appropriately shows the lack of supporting and substantive literature for a multitude of recommendations made, similar to opioids. Further, there is a lack of collaboration and specific guidance for specialty group and setting. As an example, the Centers for Disease Control and Prevention (CDC) guidelines basically excludes all interventional techniques. It appears that they were meant for only family practitioners, but were converted to be applicable to all physicians including the specialty of interventional pain management and pain medicine.

> **Recommendation 1a, 1b, 1c, 1d:** All the recommendations are appropriate. There has been significant abuse on the part of insurers by not providing coverage for many of the functions. The uniform development of mandates requiring implementation by all payers will be appropriate.

Further, present guidelines are too cumbersome, specifically the ones modified from CDC by state medical boards, e.g. recommending too many patient visits, too much testing. These problems need to be addressed.

Gap 2: This is the most crucial gap in which education lacks. A majority of patients receive a prescription in the early phase, as well as after acute pain, without risk stratification or explanation about the numerous harms patients might incur including dependency and addiction .

As we have testified on multiple occasions, education is of prime importance. This should include the following:
1. Mandatory physician education for prescribers of any amount of opioids or benzodiazepines.
2. Mandatory patient education associated with the first prescription of any amount of opioid.
3. An aggressive public education campaign.
4. A public education campaign focusing on the adverse consequences of opioid abuse in general with emphasis on the adverse consequences in combination with benzodiazepines.

Recommendation 2a-2e: These recommendations are appropriate and CMS should enforce these recommendations.

Gap 3: Chronic pain is often ineffectively managed with a tremendous bias against interventional techniques, opioids, and any expensive treatment.

Gap 4: This is a crucial gap in which buprenorphine treatment for chronic pain is often ignored, or not approved, even by governmental organizations such as Medicare and Medicaid. This discourages physicians from providing this effective treatment.

Recommendation 4a: This is appropriate and must be mandated.

Recommendation 4b: This is an appropriate recommendation. Currently state boards (and others) have limited buprenorphine treatment to opioid dependency. Many states have limited buprenorphine dosage. These limitations on buprenorphine treatment must be removed.

Gap 5: Agree with this gap.

Recommendations 5a-5e: We have recommended public education above. This education should also include safe storage.

SECTION 2.2.1.2 - SCREENING AND MONITORING
Gap 1: This gap describes comprehensive screening and risk assessment of the patients.

Recommendation 1a: This recommendation is appropriate, but has the potential for abuse. Urine toxicology screening should be reasonably reimbursed, unlike in the past where reimbursement was haphazard. Urine drug testing should be considered a vital aspect of risk assessment and stratification.

Recommendation 1b: Rather than keeping patients on long term opioid therapy (with or without appropriate monitoring) which typically leads them to dependency, patients should be referred to interventional pain management services as soon as possible so that multimodal approaches can be applied. The chances of maintaining them on low dose opioids is extremely high with improved function and reduced disability and pain, even though complete elimination may not be feasible.

SECTION 2.2.2 - OVERDOSE PREVENTION AND EDUCATION AND NALOXONE
Gap 1: This is an appropriate gap with multiple insurers refusing to reimburse for Naloxone.

Recommendation 1a-1c: These are appropriate recommendations and must be implemented.

SECTION 2.4 - INTERVENTIONAL PROCEDURES
This document fairly includes interventional procedures.

Gap 1: Appropriate description of the gap.

Recommendation 1a-1c: Recommendations must be implemented using an appropriate certification process such as certification from the American Board of Interventional Pain Physicians (ABIPP). ABIPP's examination process tests physicians on their diagnostic skills, , treatment planning, and their understanding of various modalities. In addition, ABIPP requires a "hands-on" practical examination testing the competency of physicians in their performance of interventional techniques. ABIPP also examines physician knowledge in controlled substance management.

Gap 2: This should start with Medicare providers. Traditional fee-for-service Medicare starting with Noridian has provided discriminatory policies, benefiting a certain group of physicians. These inequitable polices have become standards for refusal of care across the nation by other Medicare Administrative Contractors (MACs). Unfortunately this bias spreads to all other Medicare Advantage plans which will not approve any treatments without local coverage determinations (LCDs). These partisan policies are also utilized by private insurers.

CMS's interpretation of the Cures Act and LCD's is even more concerning. We have advocated for higher transparency of the Cures Act. Instead, CMS has made a decision basically to remove the Carrier Advisory Committees (CACs) and their membership.

Because Congress expresses sincere concern about the CMS interpretation on this issue, the Secretary of Health and Human Services, and the CMS Administrator must take this issue seriously and provide appropriate information reverting to the previously held CAC while adding transparency rather than remove it. (Please see letter sent to Seema Verma)

Gap 3: This describes inadequate training for physicians and provision of the care by nonphysicians.

> **Recommendation 3a-3c:** These recommendations provide appropriate guidance. CMS should recognize ABIPP specifically. Beyond providing didactic knowledge, ABIPP extensively trains physicians in controlled substances management; documentation, billing, coding, and compliance. Through ABIPP physicians receive, extensive training in interventional techniques and using cadavers, are examined on their ability to perform the most commonly used techniques.
>
> Congress has discussed the issues related to the recognition of ABIPP and has made recommendations in the past without much success.

SECTION 2.5.1 - ACCESS TO PSYCHOLOGICAL INTERVENTIONS
Gap 1: This gap appropriately recommends various deficiencies and difficulties in obtaining psychological interventions. Insurers have the luxury of recommending these and at the same time have the financial benefits of denying such care.

> **Recommendation 1a-1c:** These recommendations are appropriate and should be implemented.

We are hoping that these comments will assist in removing the stigmata of chronic pain and in giving physicians the tools to provide appropriate pain care while improving treatment access, quality, and cost effectiveness into the future.

ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States.

SIPMS is a not-for-profit professional organization founded in 2005, with membership involving surgical centers focusing on interventional pain management, dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic pain. There are approximately 500 surgery centers across the nation approved by Medicare providing an overwhelming majority of interventional pain management services.

If you have any questions, please feel free to contact us.

Thank you,

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