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Hearing on Utilization Management:
Barriers to Care and Burdens on Small Medical Practice
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Testimony
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Chairwoman Velazquez, Ranking Member Chabot, and members of the Committee, thank you for the opportunity to testify before the House Committee on Small Business. I offer this testimony on behalf of the American Society of Anesthesiologists (ASA) and my colleagues who are pain medicine specialists. We are all too familiar with the burdens of prior authorization and the toll it takes on our patients.

I am a physician, board certified in both anesthesiology and pain medicine, currently practicing at Northwestern Memorial Hospital which is part of Northwestern University Feinberg School of Medicine in Chicago. In my clinical practice that spans 19 years, I treat patients suffering from chronic pain and cancer related pain. In my daily practice, I am frequently told by patients and their families that I am the last hope.

As an anesthesiologist with a clinical focus on diagnosis, treatment and rehabilitation of patients with debilitating chronic pain and cancer-related pain conditions, I want to impress upon the Committee the current health care environment in which I practice. Indeed, there are dual crises that confront our healthcare system, an important context for today's discussion.

First, the opioid epidemic, a crisis we've grown accustomed to hearing about in the media. Here, we are finally making measurable progress. Through outreach and education in the medical community, opioid prescribing habits have changed, and the number of opioid prescriptions is down[1]. The number of overdose deaths involving prescription opioids has started to decline.[2] Fearing addiction, patients and providers are seeking all non-opioid treatments, and opt for opioid therapy when no other viable treatment option exists.

Second, is the crisis of chronic pain. The statistics on the prevalence of chronic pain conditions in the U.S. are staggering. In 2011, the National Academy of Medicine (then, known as the Institute of Medicine) reported that over 100 million Americans suffer from chronic pain.[3] More recently, the CDC released population-based estimates that show the incidence of chronic pain among U.S. adults ranges from 11% to 40%.[4]

To illustrate the complicated interaction of these dual crises and the predicament many pain specialists like me encounter daily, I'd like to tell you about a patient of mine, whom I will call Betsy, for the sake of this discussion. Betsy was on long-term opioid therapy for nearly 10 years for chronic back pain but under my care, she was able to successfully taper off all opioids so we could implement a non-opioid, evidence based treatment for back pain that has decades of safety and efficacy data available in the peer reviewed literature. Although I can ultimately call her case a "success", success did not come easily to Betsy, her family, nor me. It was only after several treatment denials from her health insurer, months of delays in

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[1] There was 22 percent decrease in opioid prescriptions nationally between 2013 and 2017; reported by AMA. Accessed 9/3/19: https://www.ama-assn.org/press-center/ama-statements/ama-sees-progress-declining-opioid-prescriptions

[2] Provisional opioid-involved overdose deaths suggest slight declines from 2017 to 2018, contrasting with sharp increases during 2014–2017 driven by fentanyl overdose deaths; reported in CDC MMWR. Accessed 9/3/19: https://www.cdc.gov/mmwr/volumes/68/wr/mm6834a2.htm?s_cid=mm6834a2_w

[3] Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research; Accessed 9/3/19: http://www.nationalacademies.org/hmd/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx

[4] Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults, United States, 2016; MMRW, September 14, 2018; Accessed 9/3/19: https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm

care, and being forced to go back on opioids to control her pain during these delays, that we were able to improve her pain, her function and her quality of life.

Betsy is a 38-year-old woman who came to me with chronic back and leg pain for over 10 years. She had been a primary school educator until she had a lifting injury that resulted in severe back pain, for which she underwent spinal fusion surgery, which left her with debilitating pain, and little physical or social function. She was married, had two children with special needs that she was unable to care for independently, leaving much of the responsibility of child rearing to her husband, who was a small business owner with long work hours trying to keep the business running. By the time Betsy and her husband came to my office for consultation, she was depressed, she was unable to sleep through the night due to pain and she was dependent on opioids. Tearfully that day in my office, she pleaded, "Is there anything you can do for me?"

After speaking with her, getting her medical history, examining her and reviewing her spine imaging, I knew Betsy would be an ideal candidate for a non-opioid treatment called spinal cord stimulation (SCS). SCS is a treatment in which we surgically place small electrode wires into the spinal canal adjacent to the spinal cord and deliver imperceptible electrical currents into the spinal cord to block pain signals from reaching the brain. This treatment was first developed in the late 1960s but has obviously advanced with the technological advances we have seen in medicine in the past decade. Multiple clinical studies have shown strong efficacy of this treatment in patients with back pain like Betsy, and SCS is a lifelong successful treatment in well selected patients. It has been shown to decrease pain, improve physical and psychological function, and decrease the need for opioids for pain control.

As with any patient, to ensure SCS would be beneficial to her, I asked Betsy to taper her opioid use by at least 50% before we would proceed with treatment. High doses of opioids can cloud the effects of SCS. We created a tapering schedule for Betsy so she would decrease the dose every few days until we reached our target dose. Not only did she taper, but she actually discontinued all opioids after her consultation with me, showing her strong motivation to get pain relief and change her life for the better.

As is typical with SCS, I first implanted a temporary SCS system for a 10-day trial, which her health insurance provider approved. To measure whether a patient should receive a permanently implanted SCS, the patient must achieve at least a 50% reduction in pain during their trial.

When Betsy returned to my office at the end of her trial in order for me to assess her progress and remove the temporary system, her improvement was nothing less than astounding. She was a completely different person. Her face was bright, she moved around the office without grimacing in pain, and she even laughed. Her husband told me they were able to go for walks in the evenings around the neighborhood, something they hadn't done together in years. She was able to get on the floor of her family room and play with her kids. For the first time in yeas she was able to sleep for 7 hours without interruption because her pain relief was so profound. She quantified a 75% reduction in pain during this trial period, with improved physical function and she was excited to get the permanent system implanted, which I told her would be a couple of weeks. Indeed, in all manners our expectations with the trail were exceeded.

Per standard practice, I submitted the required forms and letters of medical necessity to her insurer to obtain prior authorization and approval to implant the permanent SCS system. The insurer denied the request on the basis that the treatment was not "medically efficacious." I then appealed the denial. The appeal process took several months. As part of the appeal, I had to connect with another physician reviewer, appointed by Betsy's insurer, for what is called a "peer-to-peer" review. Betsy's fate was then in that individual's hands, not mine.

The concept behind the peer-to-peer review is to assign another physician to objectively review the medical necessity of a proposed treatment, be it a medication, a device, or a surgery, and discuss the case with the appealing physician, to glean more context or nuanced information that is not necessarily clear in the medical records and forms that are provided to insurers when prior authorization for treatment is requested. Unfortunately, "peer to peer" is often a misnomer, as the physician reviewer is usually not a

similarly trained or experienced specialist in the field. In fact, I have had cases wherein a general pediatrician reviewed the medical necessity for a similar case. He did not practice pain medicine, he did not have patients in his practice who had a pain condition that required SCS, and he had never seen nor performed the SCS procedure. He didn't even treat adults, let alone chronic pain. You can imagine how frustrating this interaction can be for a physician trying to establish that your patient's treatment is medically necessary and to effectively advocate for your patient's care.

In this case the appeals process took 8½ months. Feeling hopeless and experiencing her intolerable levels of pain again after the temporary SCS system was removed, we had to place Betsy back on opioid therapy to give her some element of pain relief. We lost whatever gains and progress she had already made. Betsy and her family lost hope all over again, even though we had a proven treatment that was effective for her.

Finally, after an appeal to the medical director of her insurance company, the treatment was approved, despite an unnecessary 8 ½ month delay. She has done extremely well post operatively, remains off opioids for her back pain, is driving a car again, taking care of her kids, and is returning to the workforce.

Though this may seem like an extreme case, I can tell you it is not uncommon.

Her eventual outcome is the reason I became a physician: to help patients live their best lives. But what would have happened had the patient and I not kept on appealing and fighting? I am confident she would still be the completely disabled and opioid dependent mother of two with a poor quality of life—the same person I met when she first came to my office for an evaluation.

I know that I did the right thing for Betsy. In our current practice environment, physicians don't have the time to fight this fight for every patient. These cases take valuable time away from providing care for other patients in need of pain relief. Because of this broken system, more and more physician time and resources are allocated to fighting insurers instead of caring for patients. It's a system built to fail, and to fail all of us.

ASA Recommendations

<u>Remove barriers to comprehensive, multimodal, multidisciplinary pain care</u>

Administrative barriers, such as paperwork, phone calls and the need for specific staff dedicated to prior authorization take time away from patients that deserve comprehensive, individualized care. Barriers or delays in care result from policies imposed by payers, pharmacy benefit or behavioral health management companies even when there are evidence-based, non-opioid treatment options that are available and appropriate.

1. **ASA supports increased research and access to evidence-based treatments as part of a multimodal pain care plan. To further efforts to address the opioid crisis, this should include:**

    - **Medication**: non-opioid pain relievers, anticonvulsants, antidepressants, musculoskeletal agents, anxiolytics as well as opioid analgesics when appropriate.
    - **Restorative therapies**: physical therapy, occupational therapy, physiotherapy, therapeutic exercise, osteopathic manipulative therapy (OMT), and other modalities such as massage and therapeutic ultrasound.
    - **Interventional procedures**: neuromodulation, radio frequency nerve ablation, peripheral nerve stimulation, central and peripheral nerve ablation, spine surgery and steroid injections, and other emerging interventional therapies.

The health care system, including physicians and patients, are inundated with new laws and regulations, guidelines and policies from payers, PBMs and national organizations, which are often contradictory. **ASA cautions against policies that negatively impact patient care and access to appropriate**

treatments, including one-size fits all prescribing limits or thresholds. ASA urges physicians to make informed prescribing decisions, tailored to the individual patient, in order to reduce opioid related harm. In some cases, a physician may find, after weighing risks versus benefits, that a patient might benefit from opioids prescribed beyond a certain threshold dose recommended by a federal agency, health insurance company, pharmacy chain, pharmacy benefit manager (PBM) or other advisory or regulatory body.

2. **ASA supports a regulatory review of formulary and benefit design by payers and PBMs to ensure that patients have affordable, timely access to evidence-based non-opioid alternatives, pharmacologic and non-pharmacologic.** ASA urges policymakers work closely with physicians to ensure appropriate clinical input. This will help ensure more uniform and comprehensive coverage and access. **ASA recommends:**

    - Payers and others are fully transparent when making care decisions and patients and providers have all relevant, necessary information.
    - Unanticipated changes to a formulary or a coverage restriction can only be made if appropriate notifications are given in a timely manner and coverage remains for the rest of that year.

3. **ASA supports transparency in care decisions and policies to ensure timely and uninterrupted care for patients.** Physicians and other health care providers want to ensure they provide the most appropriate care for patients. However, these treatments are not always affordable or accessible to patients. **ASA recommends:**

    - If a patient is stabilized on a particular treatment or protocol, the health plan or other payer should permit ongoing care to continue while additional authorizations are obtained in order to prevent negative health impacts on patients.
    - Payers and others provide clinically relevant information that providers can observe to ensure their patients get the treatments they need.
    - Cost alone, without medical justification, should never be the basis of policy decisions.

4. **ASA supports a peer-to-peer policy for prior authorization if a physician in the same field or specialty is assigned to the physician working to obtain approval. ASA recommends:**

    - Timely scheduling and flexibility for the peer-to-peer review.
    - Prompt decision-making to enable the patient to access or schedule the care.
    - Prior authorization approvals remain valid and coverage should be guaranteed for a sufficient period of time to allow patients to access the necessary care.

<u>Remove prior authorization, and other inappropriate burdens or barriers that delay or deny care for FDA-approved medications used as part of medication assisted treatment (MAT) for opioid use disorder</u>

I do not claim to be an addiction specialist, but I have seen first-hand in my practice, the patients that suffer from opioid dependence and experience undesirable side effects. I've assisted those patients with reducing their opioids so that they can successfully taper to a lower dose or eliminate them completely from their pain care regimen. It's no easy feat. However, I have seen patients who were suffering from opioid use disorder (OUD) and I've had to refer them to an addiction expert to get the help they need. At Northwestern, we do not have an addiction services team but when patients present with OUD, we want to assist them with the transition to another provider to ensure they seek treatment.

Recognizing that there is an opioid crisis facing this country, ASA supports measures to ensure patients receive the addiction treatment they need. Evidence-based treatment for OUD should be covered by payers and affordable and accessible to patients.

1. **ASA urges all payers—commercial insurers, self-insured plans, Medicare, Medicaid—as well as PBMs to end prior authorization and other unnecessary utilization management protocols for the treatment of OUD.**

- There is clear evidence in support of MAT as a proven medical model to support recovery, save lives, reduce crime and improve quality of life.

2. **MAT must be available on the lowest cost-sharing tier to promote affordability as well as prompt availability. Multiple payers in states (e.g. Maryland, New York, Pennsylvania) already have taken these steps—now it is time for all payers to support increased access to MAT.**

- Timely care is especially important for patients facing addiction. When an individual is ready to seek help, it is essential that their care is not delayed or denied.

Conclusion

First and foremost, we need to address prior authorization because it is bad for patient care. Delays and denials only contribute to further suffering for chronic pain patients.

Practicing at Northwestern, I am fortunate that prior authorization burdens do not financially bankrupt us. However, I recognize that it can be very costly. In one year, my practice dedicated over $80,000 in resources for prior authorizations. If the same costs and circumstances were incurred in a small group medical practice, it could be financially devastating to have overhead costs rise so high.

For these reasons, I'm appreciative that the Committee is looking critically at this issue and looking for ways to not only help patients and providers, but to ensure that small businesses like medical practices are not harmed by prior authorization burdens.

Thank you for your time and consideration. It was an honor to testify before the Committee. Please do not hesitate to reach out to me or the ASA to discuss any of these recommendations further.