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'Managing Pain During the Opioid Crisis'
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Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to testify before you today. My name is Halena Gazelka and I am an anesthesiologist practicing at Mayo Clinic in Rochester, Minnesota. Mayo Clinic is a not-for-profit health care system dedicated to medical care, research, and education, where multiple medical experts work collaboratively to find solutions for patients with the most serious and complex illnesses. Our staff of more than 60,000 provide and support care for more than 1.3 million people from all 50 states and 140 countries. The needs of our patients span the spectrum of care – from primary care in the Mayo Clinic Health System to serious and complex conditions in our destination practice.

My specialty is in pain medicine where I have the honor of serving patients who seek pain relief therapies for acute, chronic and palliative care needs. My clinical practice and research focuses on pain medicine, palliative medicine, opioid management, acute and chronic pain management, neuromodulation, intrathecal drug delivery systems, spine care, and cancer pain management. I am an assistant professor of anesthesiology and perioperative medicine; am board certified in anesthesiology, pain medicine, and palliative medicine; and have the privilege of serving as director of Inpatient Pain Services at Mayo Clinic Rochester. I also direct Mayo's Opioid

Stewardship Program, which was established in 2016 to oversee prescribing practices across Mayo's enterprise and identify opportunities for improvement.

Recently, I have had the pleasure of serving on the Pain Management Inter-Agency Task Force overseen by the Department of Human Services. Established by the Comprehensive Addiction and Recovery Act of 2016, the Task Force was charged with developing best practices for prescribing pain medication and managing chronic and acute pain. A draft report with recommendations is currently open for public comment and will be shared with Congress later this year.

I am privileged to share my insight as both a pain medicine provider and a leader in an organization that has taken a very deliberate and thoughtful approach to guarantee the pain management needs of our patients are met while ensuring responsible prescribing practices. Mayo has taken a multi-faceted approach to address the drug abuse and opioid crisis across our own enterprise, drawing upon our expertise in integrated clinical care, research and education. Our focus includes embracing a broad range of pain treatment and management tools in our medical practice, where care delivery methods are put through scientific rigor to determine whether they improve patient care and outcomes, as well as developing clinical guidelines that minimize the risk of addiction and abuse with minimal impact on patient experience.

As a pain medicine provider, I can say without reservation that pain management is a very individualized practice of medicine. No patient is the same as another, and therefore each condition, treatment, and surgery will also have unique impact. The scope and length of pain can also vary significantly. To ensure patients continued to receive appropriate pain treatment, the

Mayo Opioid Stewardship Program uniquely looked at prescribing practices for acute and chronic pain. This coincided with the development of educational tools for providers and patients, and increased monitoring of opioid prescribing behavior across our organization. The resulting “Mayo Clinic Guidelines for Acute and Chronic Opioid Prescribing” are available to all Mayo care team members and have been shared with external colleagues as well. These recommendations reflect Mayo consensus based on review of existing evidence and guidelines, but are not a replacement for clinical judgment.

The guidelines were developed after extensive research on the existing prescribing practices of our clinicians as well as the experience of our patients. This included a number of activities aimed at better understanding practice behavior and patient experience, such as surveying thousands of patients to comprehend their prescription utilization and needs after being discharged. This combination of examining both clinician and patient behavior was a critically important component of our work as we aim to balance the need to reduce reliance on opioid medications while ensuring that patient needs for pain management are reasonably met. This dyad approach also facilitates the development of effective and relevant education tools that recognizes the current behaviors of target audiences and how to adjust them as necessary.

Early results from the standards developed under our stewardship program have shown significant results in uniform acute and chronic care prescribing practices, improved pain management for our patients, and a drastic reduction in excess opioid availability. As an example, some departments have seen a reduction in opioid prescriptions of close to 50 percent in high-volume surgical practice areas, all while maintaining a high-level of patient satisfaction with pain management. Mayo researchers continue to study the outcomes of the prescribing

practices, including continued engagement with patients, to help identify areas for improvements to optimize care. The goal of this work is to not only provide the best care to patients at Mayo Clinic, but to broadly share our work and learnings with medical experts, educators, and communities so that people can benefit from our expertise. To this effort, we continue to educate future clinicians on responsible and appropriate opioid prescribing practices for chronic pain, illnesses and palliative care as part of planned curricula.

Our stewardship experience has already led to a larger effort with 14 other major health care organizations in Minnesota, working together to improve pain management and treatments for patients, reduce risk of opioid-related morbidity, and decrease opioids available for diversion. This work is now taking place at the Institute for Clinical Systems Improvement (ICSI), in Minneapolis, Minnesota and will yield ongoing information that can inform broader efforts to address opioid use and abuse across entire communities beyond just one organization.

While great efforts are underway to standardize the prescribing of opioids, Mayo Clinic continues to promote non-opioid therapy treatments. Established in 1974 in Rochester, Minnesota, Mayo's Pain Rehabilitation Center (PRC) was one of the first pain rehabilitation programs in the world. The PRC in Rochester has helped thousands of people with chronic pain management over the past four decades, and similar centers were established in 2011 at Mayo Clinic's campus in Jacksonville, Florida, and in 2016 at Mayo's campus in Phoenix, Arizona.

The PRC is staffed with an integrated team of health care professionals trained in many areas, including pain medicine, physical therapy, occupational therapy, biofeedback and nursing. In addition to pain management, the PRC also addresses the psychological needs of all our patients

with an array of cognitive behavioral and mental health programs. A major emphasis of the program is the management of chronic pain without the use of opioids, and patients participate in a three week, full-day program that educates them on effective strategies for addressing their needs with or without prescription medications. We also operate a similar program designed for teens based upon their unique clinical and cultural needs. While we have found the PRC intervention to be a very effective means of addressing patients who cannot or should not utilize opioid therapies, the insurance coverage for this program is limited. The program is covered under Medicare, but it is not covered by Medicaid.

As Congress considers options to address the opioid epidemic that is impacting individuals, families and communities across the nation, Mayo Clinic would encourage members to not limit access to appropriate opioid treatment, increase access for patients to alternative pain management therapies, reduce the burden for providers to access prescribing data, and promote public awareness and education on the topic of pain and various treatment options. When considering these options, it is important to recognize at the outset that the needs of patients facing short-term pain, such as those recovering from a surgical procedure, are different than those of patients managing chronic pain, such as those with cancer or complex injuries. Members may want to consider different policy approaches for addressing the challenges associated with these very different populations. For the prior, opioid use as a result of surgeries, procedures or conditions require the most flexibility for physicians to manage and monitor patients. A patient recovering from removal of wisdom teeth will have different pain management needs than a patient with a major orthopedic surgery, and physicians should respond accordingly, and have the ability to do so, to both circumstances.

Chronic pain, however, is generally considered pain that lasts longer than 45 days to three months. The pain could be the result of an underlying medical disease or condition such as cancer or chronic back problem, among many other concerns. These patients can be monitored and providers can be rewarded by utilizing evidence-based care and other guidelines to ensure proper utilization of opioid medications. These patients often present with more complex clinical considerations and their needs may change as conditions evolve. They also may be better candidates for alternative non-opioid therapies that are able to address pain over longer periods of time or offer a cumulative effect that is negligible for patients needing just a few days or weeks of pain relief.

And while we strongly believe opioids should be prescribed in the smallest amounts needed, standardized prescribing guidelines and restrictions may not always meet the individual needs of all surgical and complex care patients. An individualized approach to care is a core principle of how Mayo cares for patients. As such, we believe that the most appropriate policies will encourage responsible behavior, promote the use of effective non-opioid treatments where possible and proactively address high-risk prescribing practices. This approach is the most effective means of addressing the crisis before us without compromising legitimate patient care needs.

Absolute dose limits on opioid prescriptions, such as three-day or seven-day limits already implemented in a number of states will not satisfy the pain requirement for patients equally. Medications, particularly opioid medications, often have to be dose-adjusted to the individual and medical state. For example, a 30 year old 80 kg male recovering from a tonsillectomy will have different pain management needs than a 75 old 50 kg female recovering from hip

replacement surgery. Additionally, patients appropriately using medication for non-pain treatment may also be adversely impacted by such policy changes. In essence, the emphasis of prescribing efforts should be to ensure providers are proficient in prescribing the right medication, in the right dose, for the right patient.

Our research on opioid prescribing across a number of specialties shows that there is no one correct limit for post-surgical prescribing. Several factors should be considered by the prescribing physician, such as the degree and complexity of the surgery, rehabilitation requirements, medical co-morbidities, medication interactions, and access to follow-up care (among other issues) when determining discharge prescriptions. Policies considered and implemented should recognize that no surgery—or patient—is identical to any other. As such, prescribers must have the flexibility to develop a care plan that best meets the need of his/her patient while simultaneously prescribing opioids in a responsible manner.

Additionally, the clinical community, payers, patients and regulators need to invest additional effort to develop consistent evidence-based guidelines for opioid prescribing as well as building out the evidence base for non- opioid pain treatments and therapies. While some guidelines currently exist, the wide variation in existing practice patterns demonstrates these guidelines are falling short in providing necessary information and have not been widely adopted. It is imperative that clinical standards and best practices be informed by a strong body of clinical evidence and that stakeholders feel invested in the process of developing those guidelines. These guidelines, in turn, can serve as a fair basis for measuring clinician practice and performance as part of value-based payment for services and other incentives that encourage broader adoption and utilization of practice guidelines at the facility or organization level. Existing performance

measurement initiatives, such as the Quality Payment Program, may offer natural opportunities for utilizing such guidelines effectively in the future.

To reduce the reliance on cost-effective opioid treatments, Medicare and Medicaid should develop additional coverage of and reimbursement for non-opioid pharmacotherapies and treatment regimens. There is little medical evidence in support of long-term use of opioids in treating chronic pain, and a number of alternative therapies are not covered or reimbursed in a meaningful way by the Medicare and Medicaid programs. Currently, short-acting opioids are often the least expensive option for pain suffers. But, other solutions preventing Opioid Use Disorders (OUD) such as non-opioid pharmacotherapies and other non-invasive treatments are not covered by many insurers or require large co-payments or cost sharing that is prohibitively expensive for beneficiaries. Interventional treatment options are restricted, but these therapies keep many patients not only off of opioids but contribute to a high functioning status. Understanding that Medicare and Medicaid coverage should be driven by clinical evidence demonstrating the effectiveness of treatment, there may be cases where those standards benefit from greater flexibility. For instance, Congress could direct CMS to exercise greater flexibility under the coverage with evidence development process for Medicare in areas where public health would benefit from broader coverage of emerging therapies.

Opportunities for optimizing existing prescription drug monitoring programs (PDMP) at the national level should also be strongly pursued. Most states are currently utilizing some form of a PDMP to gain greater visibility into physician prescribing and patient behavior. However, there is wide variation in how these programs operate as well as who can access and utilize the information within the program. As an organization serving patients from all 50 states and with

facilities physically located in several states, we have observed the need for greater coordination and consistency across programs. Aside from posing administrative difficulties, this inconsistency also leads to gaps in the system that diminish the ability of PDMPs to curtail inappropriate behavior and abuse.

While creating a national PDMP may be one option for reconciling these differences, we are cognizant of the challenges such a program may pose across states and are concerned that duplication of state efforts could actually complicate this issue further. As such, we encourage the exploration of opportunities to bring some element of uniformity to PDMP policies and operations without adding an additional layer of regulation on top of the existing framework. One approach for undertaking that effort may be to engage with participating Medicare and Medicaid providers in partnership with states to apply consistent standards across the programs.

Furthermore, federal policy under the Medicare and Medicaid programs should embrace integrated, multi-faceted approaches to addiction treatment, including access. Many patients continue to seek pain management, and thus opioids, in the setting of OUD. Currently, there is not enough availability of treatment programs for opioid addiction to satisfy demand and the increasing role of pain management specialists as the opioid epidemic grows is taxing many communities' available resources. Physician and other referring providers often have few or limited referral options for evaluation and/or treatment. While medically assisted therapy (MAT) for OUD has significant evidence to support its efficacy, the availability of methadone and Suboxone may be unnecessarily limited in some areas and may be financially out of reach for patients and their families with limited coverage. Further, enrolling in the DEA Suboxone program is currently administrative burdensome and significantly limits practice and patients

who may be enrolled.

While Congress reviews the various policy proposals to address this crisis, any opportunity to increase public education on the ramifications of opioid addiction, the science of pain and pain management, and non-opioid alternatives and solutions may also prove beneficial by empowering patients. A recent survey conducted as part of the Mayo Clinic National Health Checkup found that a large majority of patients would choose an alternative treatment to opioid pain relievers, but only 25 percent of those surveyed said they have spoken to their provider about alternative treatments. Mayo continues to look for opportunities to educate patients and partners on the impact of various pain management options. Additionally, we engage with local government leaders and law enforcement partners to identify opportunities for increased collaboration, and recently entered a partnership with a public broadcasting partner to develop a public awareness campaign around the opioid crisis. This epidemic will only be solved with a collective approach.

Thank you for the opportunity to join you today, and for your efforts in ensuring proper pain management amidst the opioid crisis. I would be happy to answer any questions and engage further.