MAYO CLINIC

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February16, 2018

The Honorable Orrin Hatch
Chairman
Senate Finance Committee
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Via electronic mail to: opioids@finance.senate.gov

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of Mayo Clinic, I appreciate the opportunity to offer our perspective as the Senate Finance Committee considers policy options for improving Medicare and Medicaid's response to the ongoing opioid epidemic. We see the devastating effects of this crisis in our communities every day at Mayo Clinic and applaud the work being undertaken by the Committee to address this issue. We stand ready to serve as a partner in your efforts.

Mayo Clinic has taken a multi-faceted approach to address the 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 development of clinical guidelines that minimize the risk of addiction and abuse with minimal impact on patient experience. This letter highlights our findings and how they may inform the Committee's own work to address the opioid crisis.

Mayo Clinic Opioid Stewardship Program

The Opioid Stewardship Program was launched in 2016 with a specific focus on the effective management of acute and chronic pain, development of educational tools for providers and patients and on monitoring of opioid prescribing behavior across our organization. The Program also ensures compliance with clinical practice guidelines and utilization of relevant Electronic Health record tools, workflows and dashboards. The resulting "Mayo Clinic Guidelines for Acute and Chronic Opioid Prescribing" is now available to all of Mayo's care team members and I included them as attachments to this letter. These recommendations reflect Mayo Clinic consensus based on review of existing evidence and guidelines, but are not a replacement for clinical judgment.

In order to develop updated guidelines for more appropriate opioid prescribing within our organization, we conducted extensive research on our clinicians' existing prescribing practices 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 understand 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. It 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. We also continue to educate future clinicians on responsible and appropriate opioid prescribing practices for chronic pain, illnesses and palliative care as part of their planned curriculums.

We anticipate that the standards developed under our stewardship program will result in uniform acute and chronic care prescribing practices, improved pain management for our patients, and a drastic reduction in excess opioid availability. In fact, early results from the rollout of these guidelines in three areas of high-volume surgical practice demonstrated an average 40% reduction in prescription volume with minimal patient complaints

or disruption. The goal of this work is to not only to 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.

Our stewardship experience has already led to a larger effort with 14 other major healthcare 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), Minneapolis, MN, and will yield ongoing information that can inform broader efforts to address opioid use and abuse across entire communities beyond just one organization.

Mayo Clinic Pain Rehabilitation Center

Mayo Clinic created the Pain Rehabilitation Center (PRC) in 1974 in Rochester, MN, and it 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 Clinic'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 and while the program is covered under Medicare, it is not covered by Medicaid.

Medicare and Medicaid Program Recommendations for the Committee

As the Senate Finance Committee moves forward with its effort to address the opioid epidemic that is devastating individuals, families, and communities throughout the country, Mayo Clinic offers the following recommendations to aid Medicare and Medicaid's response to this problem.

First, we believe that it is important 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. The Finance Committee 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 need to be able to respond accordingly to both circumstances.

Chronic pain, however, is generally considered pain that lasts longer than 45 days to 3 months. The pain could be the result of an underlying medical disease or condition such as cancer, Rheumatoid Arthritis or chronic back or neck problems, 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 use and utilization of opioid medications. These patients often present with more complex clinical considerations and their needs may change over time. They also may be better candidates for alternative therapies that are able to address pain over longer periods of time or offer a cumulative effect that would be negligible for patients needing just a few days or weeks of pain relief.

Second, while we agree that 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 from all 50 states and more than 140 countries. 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, utilizing all of the tolls available to policymakers to prevent and curtail opioid abuse, is the most effective means of addressing the crisis before us without compromising legitimate patient care needs.

Medications, particularly opioid medications, often have to be dose-adjusted to the individual and medical state. To give you a couple of examples, a 37 year old 80 kg male having knee surgery would not require the same amount of medication as an 85 year old 50 kg female. Similarly, absolute dose limits on opioid prescriptions, such as the 7-day limitation being considered by CMS and a number of state regulators, are not going to satisfy the pain requirement of a 27 year old trauma patient with multiple extremity and rib fractures. In essence, the emphasis of prescribing efforts should be to ensuring that 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. As proposals are considered, Mayo would encourage policy makers to take into account 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.

Third, 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 t 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 not covered by many insurers or require large co-payments or cost sharing that is prohibitively expensive for beneficiaries. Examples include therapies that fall into the dynamic physical therapy, cognitive behavioral therapy, and alternative and complementary medicine services. Interventional treatment options are restricted, but these therapies keep many patients not only off of opioids but contribute to a high functioning status.

Notably, neuromodulation and regenerative medicine are two of the fastest growing areas of medicine, and neuromodulation is an effective pain modulating therapy that is an alternative to opioid therapy for many patients. Insurance and Medicare payment for neuromodulation services needs to be improved if these therapies are going to offer value in addressing opioid abuse and addiction as well as improving patient outcomes. Likewise, regenerative medicine may, indeed, hold the "key" to managing or eliminating many forms of chronic pain, and research and implementation of regenerative medical techniques should be supported. 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 (CED) process for Medicare in areas where the public health would benefit from broader coverage of emerging therapies, such as pain treatment and management.

Fourth, the Committee should also consider pursuing opportunities for optimizing existing prescription drug monitoring programs (PDMP) at the national level. 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 fifty 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 Committee to explore 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 first focus on providers participating the Medicare and Medicaid programs by identifying partnerships with states that would apply consistent standards across that population.

Finally, 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.

Mayo Clinic believes that our mission to ensure that the needs of the patients come first, we have a responsibility to our patients and communities to prescribe opioids responsibly and to recognize and treat opioid use disorder. Our multi-faceted approach involving all three of our shields - research, practice and education – to address the opioid crisis across our own enterprise is one that could be replicated within the federal government's own efforts, emphasizing activities from the payer, research and regulatory roles shaped by Finance Committee.

I thank you for the opportunity to share our insights as the Committee considers meaningful policies and legislation to address the opioid crisis. Should you need any additional information or would like to speak with me, please contact Jennifer Mallard, Director of Federal Government Relations, at 202-621-1850 or mallard.jennifer@mayo.edu.

Sincerely,

Halena. M Gazelka, M.D.
Director of Inpatient Pain Services
Mayo Clinic

Attachments 1: Mayo Clinic Guidelines for Chronic Opioid Prescribing
Attachment 2: Mayo Clinic Guidelines for Acute Opioid Prescribing

Mayo Clinic Guidelines for Chronic Opioid Prescribing

***The following guidelines are intended to complement the Centers for Disease Control and Prevention (CDC) guidelines published in March 2016. They are not intended to be widely applicable to patients with active cancer or the skilled nursing, hospice, or palliative care setting.*

Definitions

- *Opiate: Any substance having an addiction forming or addiction sustaining liability similar to morphine or being capable of conversion into a drug having addiction forming or addiction sustaining liability.*

- *Opioid: Any chemical with agonist and antagonist with morphine-like effects both naturally occurring (e.g., codeine) and synthetic (tramadol and tapentadol).*

- *Chronic use = ≥ 45 days*

- *Morphine Milligram Equivalents (MME): An estimation of the amount of opioids a patient receives allowing for comparison across different types opioids. Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, naloxone prescribing, or other measures to reduce risk of overdose.*

Provider

- State Prescription Drug Monitoring Program (PDMP)
  - All providers of opioids should enroll with the PDMP in their state
  - The PDMP should be checked:
    - On initiation of opioid therapy
    - With each new prescription
    - Consistent with State Prescribing guidelines/laws in state of practice
  - Documentation of PDMP review is encouraged as part of the patient's medical record, and may be required by state law
  - Documentation of PDMP review is encouraged on each prescription, and may be required by state law
- Emergency department, urgent care, and other clinicians managing acute pain issues should avoid prescribing or refilling opioid medications for chronic pain

Patient Selection

- Non-pharmacologic and non-opioid treatments should be trialed first
- History and physical Exam documented in medical record:
    - Diagnosis/diagnostic testing performed
    - Other therapies trialed
        - Physical therapy
        - Interventional therapies
        - Adjuncts
    - Appropriate physical exam
    - Review of radiologic imaging, if required by state guidelines
    - Establish treatment goals: pain and function
    - Risk-benefit analysis discussion
        - Benefits on pain and function should outweigh risks
        - Document discussion of addiction, overdose, death, current alcohol use
        - Document discussion of major side effects: constipation, hypogonadism
- Consider appropriate referrals for evaluation
    - Medical or surgical specialty
    - Pain Medicine
    - Behavioral Health/Addiction Medicine
        - Consideration for Medication-assisted treatment
- Risk assessment: Provider should assess patients for risk of opioid aberrant behavior and risk of abuse
    - At initiation of opioids
    - At a minimum of yearly thereafter
    - Suggested tool: Opioid Risk Tool (ORT)
    - Consider referral to addiction medicine for high risk patients
- Depression screening: Provider should screen for depression
    - At initiation of opioids
    - At a minimum of yearly thereafter
    - Suggested tool: PHQ9
    - Consider referral to psychiatry for high risk patients
- Anxiety screening: Provider should screen for anxiety
    - At initiation of opioids
    - At a minimum of yearly thereafter
    - Suggested tool: GAD7

        - Consider non-pharmacologic options for anxiety treatment and enhancement of coping skills
    - Functional assessment: Provider should assess functional status
        - At initiation of opioids
        - At a minimum of every 3 months thereafter
        - Suggested tool: PEG
    - Opioid Therapy Agreement (Link)
        - Signed at initiation of therapy
        - Should be utilized for patients receiving
            - Chronic opioids
            - Episodic use of >90 days or when 3rd prescription is written
        - Re-signed and/or reviewed at a minimum of yearly thereafter

Dosing

- Provider should follow CDC guideline recommendations for doses, duration
    - Use immediate release in preference to extended release formulations
    - Use lowest effective dose
        - Carefully reassess benefits/risks at ≥ 50 MME/day
        - Avoid/carefully justify decision for ≥ 90 MME/day
    - Avoid concurrent prescribing of benzodiazepines, sedatives, and opioids

Monitoring

- Clinical assessment
    - Evaluate benefits and harms within 1-4 weeks of initiation or dose escalation
    - Evaluate benefits and harms of continued treatment at a minimum of every 3 months
    - Patient should be seen and reassessed at a minimum of every 3 months
    - Document in the EMR
        - Physical examination
        - Pain intensity
        - Function
        - Adherence
        - Assessment and plan for treatment of side effects:
            - Constipation
                - Daily opioid use should include a laxative
                - Avoid fiber laxatives with opioids

        - Endocrine dysfunction/hypogonadism
        - Accidents, injuries, falls
    - Consider appropriate referrals to Psychiatry, addiction med, pain medicine
- Urine Drug Testing (UDT) with *Pain Clinic Survey*
    - UDT should be performed at initiation and at a minimum of yearly thereafter
    - At any point if aberrant behavior is suspected
- Consider periodic medication counts at each visit to assess compliance
- Consider a naloxone prescription for high risk patients where opioids prescribing cannot be avoided (i.e., history of substance abuse, concomitant benzodiazepine use, history of overdose, sleep apnea, obesity, major depression)

Opioid Use disorder

- Offer appropriate referrals to addiction medicine for patients with known or suspected opioid use disorder
- Discontinuation of chronic opioid therapy should be considered for these patients

De-escalation and Discontinuation of Therapy

Dose de-escalation or discontinuation of therapy should be considered and discussed at each visit.

- Tapering - individualize based on patient factors (document link)
- Aberrant behavior - consider therapy discontinuation and appropriate referrals

Mayo Clinic Guidelines for Acute Opioid Prescribing

*****_These guidelines are intended to complement the Centers for Disease Control (CDC) guidelines, March 2016. Not intended to be widely applicable to skilled nursing facilities, active cancer, hospice, or palliative medicine patients._

Acute = 45 days of opioid use or less.

Opiate definition: Any dangerous substance having an addiction forming or addiction sustaining liability similar to morphine or being capable of conversion into a drug having such addiction forming or addiction sustaining liability.

Opioid definition: applies to all agonist and antagonist with morphine-like activity as well as to naturally occurring and synthetic opioid peptides. (this would include agents such as tramadol and tapentadol)

MME: Morphine Milligram Equivalents (MME) give a normalized way to trend the amount of opioid level calculated as estimate from the drug, formulation and route. Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.(link to opioid calculator, here)

Provider responsibility:

- State Prescription Drug Monitoring Program (PDMP)
  - All providers of opioids shall enroll with the PDMP in their state
  - The PDMP should be checked
    - On initiation of opioid therapy
    - With each new prescription
    - Consistent with State Prescribing guidelines/laws in state of practice
- When opioids are initiated post operatively with persistent pain outside the time normally expected for healing, it is the surgeon's responsibility to see the patient in follow up, which may occur in collaboration with the primary care provider (PCP).
  - If there is no indication for continuing opioid therapy, refer back to PCP to discuss other pain management options.
- Emergency department, urgent care, and other clinicians managing acute pain issues should avoid prescribing or refilling opioid medications for chronic pain

Patient Selection: ***These guidelines are most broadly applicable to patients ≥ 18 years and older and < 65 years of age who are opioid naïve (no opioids in the last 90 days)***

- Non-pharmacologic and non-opioid treatment options should be considered first
- Document in treatment record:
    - Diagnosis/Diagnostic testing performed
    - Other therapies trialed or to be trialed
        - Non-pharmacologic therapies such as Physical Therapy, Cognitive Behavioral Therapy, Biofeedback, etc. as applicable
            - Interventional therapies
            - Adjuncts such as NSAIDs, acetaminophen, antidepressants, anticonvulsants
    - Appropriate physical exam
    - Establish treatment goals: pain level and function
    - Risk/Benefit assessment discussion, as applicable
        - Benefits on pain level and function should outweigh risks
        - Risk of , addiction, overdose, death
        - Risk of side effects such as constipation, sedation, and concerns with driving with using opioids
    - Risk assessment: Providers should assess patients for risk of opioid aberrant behavior and risk of abuse, current alcohol use, and uncontrolled depression or suicidal ideation

Dosing

- Providers should follow CDC guideline recommendations for doses, duration in the setting where opioids are deemed beneficial in the Risk / Benefit evaluation.
    - Opioids, when prescribed, are part of a structured multi-modal pain management care plan.
    - Opioid prescribing is discouraged for pain without an explained cause
    - Use immediate release formulations preferentially over long-acting formulations
    - Avoid prescribing more than one opioid/opioid related medication at one time
    - Avoid concurrent prescribing of benzodiazepines, sedatives, and opioids
    - Avoid prescribing more than a 3-day supply unless circumstances clearly warrant additional therapy (i.e. medical illness, major surgery or trauma with high pain expectations not able to be managed solely with non-opioid options)
        - For most patients, limiting the entire prescription to 100 MME (morphine mg equivalents) is appropriate

- For patients requiring additional opioid therapy (e.g. medical illness or surgery with high pain expectations or severe trauma), a 7-day supply is appropriate
    - For most, limiting the entire prescription to 200 MME will suffice
    - When possible, Reassess after 7 days and prior to providing further prescriptions.
        - Reevaluate patients who experience severe acute pain that continues longer to confirm or revise the initial diagnosis and adjust management accordingly.
        - Document reason for longer duration, new prescriptions, and higher doses
- For patients chronically using opioids, the above guidelines apply, and every attempt should be made to return to their chronic dose, without escalation, as above.
    - Chronic opioid patients should return to their regular provider for management, as per the Mayo Clinic Guidelines for Chronic Opioid Prescribing (link)
- Consider prescribing naloxone for patients at high risk of overdose or respiratory depression where opioids prescribing cannot be avoided (i.e. history of substance abuse, high Opioid Risk Tool score, concomitant benzodiazepine use, history of overdose, sleep apnea, obesity, major depression).
- Consider a focused taper to off plan for patients with prior opioid usage and for patients with acute on chronic pain. Refer to tapering guidelines (link) and resources as appropriate.