Academy of Integrative Pain Management

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March 5, 2018

Demetrios Kouzoukas
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Mr. Kouzoukas:

I am writing on behalf of the Academy of Integrative Pain Management (AIPM, formerly American Academy of Pain Management) in response to the "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter." AIPM recognizes the complex challenges involved in addressing the intersection of three major public health crises—namely, ensuring adequate and appropriate treatment of pain, substance use disorders, and mental health conditions—and to that end, has been heavily involved in both national and state-level efforts to address all three public health concerns. To aid CMS in addressing these intertwined issues, AIPM offers the following comments, which we have presented in two parts: (1) Limitations on Opioids, and (2) Use of Non-Pharmacological or Non-Opioid Pain Management Interventions.

**Limitations on Opioids**

Under this proposed policy, payment would be denied for two types of prescriptions:

- Prescriptions for any beneficiary where cumulative opioid dose exceeds a calculated total dosage of 90 morphine milligram equivalents (MME) per day, subject to appeal.
- Prescriptions for durations of seven days or greater for "opioid naïve" patients, without exception or variation for any human circumstance including cancer or other diagnosis, receiving palliative or hospice care, or major geographic barriers.

**We strongly oppose these two proposals on multiple grounds.**

**The proposed policy does not align with the CDC Guideline for Prescribing Opioids for Chronic Pain.** While the proposal appears to make efforts to align with the CDC's recommendations, it unfortunately misinterprets and misapplies the guideline in ways that will harm the patients the policy intends to help. The CDC Guideline specifically applies to patients 18 and older in primary care settings. It was

never intended to apply in specialized care settings, nor was it intended to apply to cancer care, palliative care, or end-of-life care, as stated in the guideline itself. What's more, the CDC only uses 90 MME/day as a *threshold dose* at which clinicians should carefully reassess evidence of individual benefits and risks—it was *not* intended to be used as a *ceiling dose* that may not be exceeded. The guideline does not recommend that these thresholds be used as targets for non-consensual and unwarranted dose reduction for patients who are already on a stable dosage. In fact, the CDC has reiterated numerous times that these recommendations are not intended to act as hard limits, but rather, to help guide clinician decision-making as those clinicians apply their own clinical expertise to each individual patient's needs. The CDC has been emphatic that the recommendations are "voluntary, rather than prescriptive standards" and that "clinicians should consider the circumstances and unique needs of each patient when providing care." The CMS proposal would negate the CDC recommendation by completely overriding the professional decision-making ability of the clinician.

**The proposed policy will accelerate non-patient-centered, nonconsensual opioid dose reductions.** While a strong case can be made for consensual, supported opioid dose reductions for voluntary patients, no data support nonconsensual/forcible dose reductions or curtailment in otherwise stable patients. These practices have become common as prescribers react to regulations, mandates, insurers and fear for professional security (1). There is, however, anecdotal evidence of harm (emotional trauma, medical and/or psychiatric deterioration, and suicide (2-5)) that we believe the CMS proposal will accelerate.

**The proposal does not consider adverse impacts on pharmacies, providers, or patients, and it will very likely accelerate patient abandonment.** The appeal mechanism proposed by CMS calls for payers to accept a simple attestation that a higher dose is "medically necessary". The bureaucratic work to affirm these attestations entails 3- and 4-way communication between pharmacy, prior authorization management contractors (e.g. Magellan), doctors' offices, and insurers. The labor is substantial and uncompensated. Faced with countless hours of staff time spent seeking these additional authorizations, many clinicians will be forced to opt out of treating pain altogether. Worse, the CMS proposal does not provide the targeted case management for truly high-risk patients that was recommended by the Office of the Inspector General. Instead, it applies a "blunt instrument" intervention to all patients above a certain dose, regardless of their actual level of assessed risk. The CMS plan risks accelerating a chaotic pattern of churn, abandonment and medical harm to patients who receive opioids as providers flee an increasingly risk-laden and cumbersome decision matrix that does not advance patient safety.

**The proposal does not include metrics to evaluate how it affects patient health or access to care.** The plan avows no metric for success other than reducing certain measures of prescribing. However, a mere reduction in prescribing does nothing to tell us whether or not patient outcomes have improved. Yet, neither patient access to care nor patient health outcomes are mentioned. Further, while patients receiving opioids are redirected to pain specialists for opioid management, access to such specialists is extremely limited.

**The proposal ignores important exceptions that have been preserved by state statutes.** Regarding the 7-day limit, we do not disagree that shorter prescriptions, particularly for opioid naïve patients, are prudent in most situations. In fact, we have been actively supportive of similar policies across the

country. However, states that have already considered this issue have, by and large, agreed with our position that certain exceptions to this rule are necessary to ensure the policies do not cause unintended harms (6). These exceptions allow for greater than a 7-day supply when, in the clinician's professional judgment, more than a 7-day supply is needed for care related to hospice, palliative care, cancer care, chronic pain, post-surgical care, or extraordinary limitations such as extreme geographic barriers. These exceptions must be documented in the medical record. However, the CMS proposed policy would essentially render those exceptions useless.

**Use of Non-Pharmacological or Non-Opioid Pain Management Interventions**

Within this proposed policy, it is stated that, "CMS and measure developers are exploring additional measurement concepts for future work, such as functional status, and use of non-pharmacological or non-opioid pain management interventions, which will require use of non-claims data. CMS is interested in stakeholder feedback about how these "upstream" concepts can inform measurement of quality of care and […] given the importance of addressing the opioid epidemic, we will consider adding measurement or reporting burden if less burdensome options are not available."

We thank you for exploring non-pharmacological and non-opioid methods of treating pain. We recently sent a letter to the U.S. Senate Committee on Finance related to these very issues, and we would like to reiterate our suggestions related to CMS. In particular, we advocate for improved coverage of these services as a means of reducing access barriers encountered by people with pain and their clinicians, rather than just attempting to measure whether or not they are used. We recommend that CMS take the following steps:

**Reimburse Primary Care Providers and Pain Specialists for Longer Initial Visits and Frequent Follow-up Visits with Chronic Pain Patients.**

These visits should require providers to develop an individualized plan of care for each patient that includes non-pharmacological treatments in combination with or in place of pharmacological treatments. These plans should be updated at each subsequent visit including which interventions have been tried and the effect of that intervention on patient functional abilities as well as pain severity. Providers should be paid for time spent coordinating care and conferring with other therapists about the patient's progress. The proper treatment of chronic pain is complex and requires frequent monitoring and care coordination. Providers should not be penalized for providing appropriate care with respect to the cost calculation in the Merit Based Incentive System. Instead, incentives should be in place to encourage providers to provide necessary, coordinated care. When patients are being managed on opioid therapy we want to be certain that the risk of developing an OUD is minimized. This requires frequent visits to monitor compliance measures as well as functional improvement. In the long run, the cost of this additional care will more than pay for itself in reduction of emergency room visits, outpatient visits, and hospitalizations, and duplicative tests and repeated visits to specialists in the hopes of finding someone and something to help reduce patients' pain, not to mention the expense of treating OUDs that will be prevented.

**Address Additional Financial Barriers that Prevent Many Medicare and Medicaid Beneficiaries from Seeking Non-Pharmaceutical Treatments for Pain**.

The vast majority of Medicare and Medicaid beneficiaries living with chronic pain are on a fixed income or low income either due to retirement, disability, or inability to work part time (or work at all) because of their pain. Most non-pharmacological therapies that pain sufferers have reported to be beneficial are not covered by Medicare and Medicaid and the ones that are limit the number of visits or the type of treatments that can be used by practitioners. Nearly every recent effort to reduce prescriptions of opioid analgesic medications has been accompanied by a statement that urges the use of alternative treatments to treat pain. However, these treatments remain largely inaccessible due to lack of insurance coverage.

*CMS should allow a greater number of physical and occupational therapy sessions annually, and should allow patients to access physical and occupational therapy without first acquiring a referral or prior authorization.*

Physical and occupational therapies are effective at preventing and treating musculoskeletal pain syndromes, in particular, and chronic pain conditions in general. Medicare and Medicaid coverage for these therapies is inadequate in terms of the number of sessions covered, and requires that a physician serve as a gatekeeper. Physical and occupational therapists are highly-trained professionals who are capable of evaluating a patient's likelihood of benefitting from the treatments they offer. Requiring a gatekeeping appointment with a physician or a prior authorization process only drives up costs, delays a patient's access to treatment and, in some cases, may deny that patient access to an effective and cost-effective treatment that minimizes the need for opioid analgesics.

*CMS should provide full coverage of chiropractic adjustments and osteopathic manipulations and other techniques and modalities and should allow a greater number of sessions annually.*

Medicare only covers one very specific type of chiropractic manipulation for one specific type of pain syndrome – back pain. Chiropractic care, including a range of modalities (e.g., electrical stimulation) and techniques (e.g., Grasston), provides pain relief to many chronic pain sufferers. Further, chiropractic care is appropriate for many different types of musculoskeletal pain conditions and syndromes. These treatments should be fully covered by both Medicare and Medicaid.

*CMS should provide full coverage for acupuncture, massage therapy, biofeedback, yoga and tai chi.*

These integrative and complementary therapies are used successfully by many to manage chronic pain but are currently not covered by Medicare and Medicaid, outside of a few state Medicaid programs. These key treatments are recognized by the Department of Defense and the Veterans Health Administration as effective treatments for chronic pain, are included in the DoD/VHA pain management guidelines, and are covered services in DoD/VHA facilities.

*CMS should provide coverage of behavioral health services for the prevention, treatment, or management of physical health problems.*

Behavioral health care providers are well-equipped to teach patients skills and techniques in how to better manage and cope with pain including cognitive behavioral therapy, acceptance and commitment therapy, mindfulness meditation, relaxation therapy and others; however, these practitioners are often not reimbursed for their services when they use proper diagnoses and Current Procedural Terminology (CPT) codes. We urge that CMS be required to reimburse these practitioners for their services.

*CMS should provide coverage of medical devices that are FDA-approved for the treatment of chronic pain.*

There are a variety of stimulation devices such as TENS, spinal cord stimulators, low-level lasers, and others that have proven to be effective at reducing pain for certain types of chronic pain conditions. These should be covered by both Medicare and Medicaid.

**Fund Long Term (greater than 12 weeks) Research Studies Evaluating the Effectiveness of Non-Pharmaceutical Treatments for Chronic Pain.**

In order for private payers to cover the cost of non-pharmaceutical treatments, especially integrative and complementary therapies, they require valid research proving the effectiveness of these therapies for reducing pain and improving function. We lack a body of research on most of these therapies because no one will fund such research. CMS could help remove a barrier to utilization of the most promising non-pharmacological treatments for chronic pain by funding efficacy studies for a wide range of such therapies.

**Fund (through the Center for Medicare & Medicaid Innovation) Innovative Demonstration Projects using Integrated, Non-Pharmacological Treatments for Chronic Pain Care.**

A few Medicaid demonstration projects have been set up through Medicaid Waivers using non-pharmaceutical therapies for chronic pain. In most cases, these are small scale projects showing promise but need more substantial financial commitment to develop them and research their effectiveness. Example projects include:

*Colorado Medicaid Waiver for Spinal Cord Injury Pain*
Since 2012, Health First Colorado (Medicaid) has offered a waiver for persons with Spinal Cord Injury (SCI Waiver Pilot Program) that provides participants with access to massage, acupuncture, and chiropractic care. There are signs of positive trends regarding cost-saving, but additional research and larger sample sizes are required to prove effectiveness in reducing pain and costs. Personal stories from participants include describing minimal use or complete abstinence from previously used medications for pain, due to the addition these three modalities.

*Rhode Island Medicaid Pain Management Program*
Originally started as an attempt to reduce ER visits among chronic pain sufferers with severe pain flares, eligible participants were given access to massage, acupuncture and chiropractic services. To our knowledge, there is currently a study underway evaluating the program.

*Oregon Health Plan (Medicaid) Back Pain Services*
Originally started as expanded services for Medicaid recipients with muscle weakness and nerve damage the plan has been expanded to those with chronic back pain. It covers acupuncture, chiropractic and osteopathic manipulation, cognitive behavioral therapy, physical therapy and occupational therapy.

*Vermont Medicaid Acupuncture Pilot for Chronic Pain*
The Vermont Legislature set aside $200,000 for a pilot of acupuncture services for pain management.

Thank you for considering our comments. I am happy to discuss these issues with you or your staff if necessary. Please feel free to contact me by email at kduensing@aapainmanage.org, or by telephone at 209-288-2214.

Sincerely yours,

Katie Duensing, J.D.
Director of Legislative and Regulatory Affairs
Academy of Integrative Pain Management

About AIPM: The Academy of Integrative Pain Management is the premier organization for all clinicians who care for people with pain. It is the largest pain management organization in the nation and the only one that embraces, as part of its mission statement, an integrative model of care, which: is patient-centered; considers the whole person; encourages healthful lifestyle changes as part of the first line of treatment to restore wellness; is evidence-based; brings together all appropriate therapeutic approaches to reduce pain and achieve optimal health and healing; and, encourages a team approach.

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