December 21, 2020

To: Jenae J. Benns, Agency for Healthcare Research and Quality

RE: Todd Graham Study: Integrated Pain Management Programs Research Protocol

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We are grateful for the efforts of the Agency for Healthcare Research and Quality (AHRQ) in designing this systematic review. An integral part of the Dr. Todd Graham Pain Management Study, this review will aid in the design of Medicare benefits so that whole person pain management is optimized by providing access to evidence-based modalities, including non-opioid pain management treatments. These efforts should also avoid financial incentives to use opioids instead of non-opioid treatments. The members of our coalition have been working on the complex issues related to comprehensive integrative pain management for many years. More than two dozen leaders who are engaged in comprehensive pain care as payers, providers, researchers, and patients, discussed this research initiative and share important concerns about a few critical elements of the AHRQ proposal. Thank you for considering input of this diverse group of experts.

The Alliance to Advance Comprehensive Integrative Pain Management (AACIPM) is a multi-stakeholder collaborative, comprised of non-profit organizations representing people living with pain, public and private insurers, patient and caregiver advocates, researchers, purchasers of healthcare, policy experts, and 37 professional trade organizations representing the full spectrum of healthcare providers. These diverse experts are united in a shared interest to advance access to a person-centered model of pain care focused on maximizing function and wellness that includes biomedical, psychosocial, complementary and integrative health, and spiritual care. It is with this unique perspective that the undersigned members of AACIPM respectfully offer the following comments in response to AHRQ's Integrated Pain Management Programs Research Protocol.

In discussion with our collaborators, several themes have emerged. We will enumerate those themes and briefly present our feedback related to each and a possible solution to further advance the work of AHRQ and the research directed in the Todd Graham study.

Timing & Deadlines – AHRQ released this review protocol and request for relevant information during the week of Thanksgiving with a deadline of less than 30 days after it was first released to the public. Further complicating matters, many relevant stakeholders who have information helpful to AHRQ are health care providers who are currently dealing with a widespread surge of COVID-19, including recent vaccination roll-out.

Additionally, many of these stakeholders are engaged in ongoing and/or innovative telehealth for pain management during the pandemic and receiving information on these cutting-edge issues is imperative if we are to get a true picture of the pain management landscape in 2020. We have heard

from numerous stakeholders who would like to respond but will be unable to do so in the short timeframe provided.

> **Recommendation 1:** To ensure the highest quality information is made available for this review, we request that AHRQ extend the deadline into middle of 1Q2021 or allow for a second round of responses before the evidence is reviewed.

Definition of Integrated and Comprehensive Pain Management Programs – Within the inclusion standards for this review, AHRQ defines which types of pain programs will be included within the study by defining Integrated Pain Management Programs (IPMPs) and Comprehensive Pain Management Programs (CPMPs). The inclusion standards require that included programs have, at a minimum: (1) a pharmacotherapy component, (2) a psychological component, and (3) a physical reconditioning component.

IPMPs and CPMPs are not standard industry terms, and the components proposed in the AHRQ definitions are not industry-standard components. While it may be considered advisable to have all three components in each of these program types, the reality of the healthcare industry is that most programs will have only two of the three components, and patients may be referred outside of the system to access the third component.

Many of our collaborators are concerned that IPMPs and CPMPs, as currently defined, do not reflect the reality of Pain Management that most patients are receiving, even in cases where we would say the patient is receiving some form of comprehensive integrative pain care. Further, as they are currently written, the terms exclude a substantial population of patients that access comprehensive, integrative pain management through a self-organized approach because more cohesive care is not available within their healthcare system. While almost all current clinical pain management guidelines recommend first-line use of evidence-based non-pharmacological treatments, a practical reality is the lack of integration into primary care for numerous reasons. Further, many of these treatments are not commonly covered by health plans, or if covered, the utilization is often poor. This creates a disincentive for programs to offer these services—which is exactly what this review is attempting to address. We fear that in leaving out comprehensive integrative pain management programs that fall short of the current IPMP/CPMP standards, the research will fail to encapsulate the full spectrum of practical issues faced in Pain Management, which could further perpetuate the problems that we are working to remedy.

We are concerned that the current inclusion standards will prevent highly relevant data related to comprehensive integrative pain management, which is delivered in various modes and organized structures, from being included in the review.

> **Recommendation 2:** We suggest that AHRQ request definitional clarification from the key constituencies by accepting written proposals and/or empaneling an Advisory Work Group or hearing for the AHRQ research team to hear recommendations from a comprehensive cross-section of patients and stakeholders in the medical and complementary Pain Management disciplines. We recommend broadening these definitions so that additional programs may be considered, and a more comprehensive evaluation of Pain Management be reviewed.

Recommendation 3: We recommended that the AHRQ research team look to the HHS Interagency Pain Management Task Force report for definitions and support for the research and organization of comprehensive integrative pain management components.

Population Scope – After carefully reviewing the inclusion and exclusion standards, we have a number of concerns regarding the populations which will and will not be considered by this review.

Recommendation 4: Medicare Beneficiaries – While we agree that included research should be *applicable* to a Medicare population, we strongly caution against excluding data which is not considered "*exclusively"* relevant to a Medicare population, as very few studies and programs will be specific to only this population. For example, the NCCIH has funded joint studies by the NIH-DoD-VA Pain Management Collaboratory on the use of non-opioid pain management in military and military beneficiary populations. Additionally, including studies involving state Medicaid data should be considered given the growing development of these programs, which is outlined in the recently published National Governors Association report "*Expanding Access to Non-Opioid Management of Chronic Pain*." Because there is significant overlap between the Medicare beneficiary population and the population covered by these studies, they should be considered as relevant to the purpose of this review. Therefore, we recommend extrapolating the appropriate and relevant data pertinent to Medicare beneficiaries from broader studies/programs.

Recommendation 5: Palliative Care – The exclusion list includes "palliative care" alongside "end-of-life care" and "terminally ill (e.g., hospice) patients", to which we must strongly object. While we understand excluding those who are receiving end-of-life care, it must be noted that palliative care programs are not synonymous with end-of-life/hospice care. Unlike hospice care, which begins after treatment of the disease has stopped and it is clear the patient will not survive the illness, palliative care can begin at diagnosis of a life-altering condition and often goes on for many years or until the patient recovers. Patients are not required to be at end-of-life to avail themselves of palliative care services, and in many communities, palliative care services are the only form of comprehensive integrative pain care available. We recommend that relevant information about these palliative programs is highly relevant to the AHRQ's review and should not be excluded.

Recommendation 6: Pediatric and Military Populations – It is unclear whether these patients are to be included, and if so, to what extent. The exclusion list related to CPMPs and IPMPs excludes "Programs in very young and non-disabled populations (e.g., military populations)". We recommend that AHRQ clarify the following: Are "young" populations *and* "non-disabled" populations being excluded, or are "young and non-disabled" populations being excluded? In other words, would young disabled populations who qualify for Medicare be included (as we would recommend), or are all young populations being excluded? Further, does "military populations" refer to active-duty servicemembers, or does it refer to young, non-disabled family members of those serving in the military? We recommend that AHRQ clarify this language to better enable stakeholder responses.

Study Design and Outcome Measures – AACIPM identified concerns that the inclusion/exclusion standards for outcome measures will result in the omission of vital information. While measurements in pain, function, and opioid use are all important measures, there are many other outcomes that are important in a patient-centered approach to comprehensive integrative pain management. Many patients, regardless of treatment, will continue to live a life with a certain amount of pain. Thus, in comprehensive programs, success is often measured as progress toward a patient's goal of improved quality of life, such as being able to return to work, being able to resume a favorite hobby, or improving overall sleep quality. In fact, there has been a strong push in recent years to utilize outcome measures *other than* the traditional pain and function. Further, excluding standard measurement methods will exclude data from progressive patient-centered comprehensive integrative pain management programs.

> **Recommendation 7:** We recommend expanding the outcome measures that will be included, as excluding valid and appropriately collected data currently defined by AHRQ as "non-validated instruments for outcomes", is inconsistent with current evidence-based best practice standards.
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> **Recommendation 8**: There is strong agreement among Pain Management stakeholders that inclusion of data from pragmatic trials, comparative effectiveness studies, healthcare utilization data, and cost analyses is critically important and highly relevant for addressing the question this review was commissioned to answer. We recommend that AHRQ accept high quality studies of this design within the review criteria along with randomized controlled trials.

The Alliance to Advance Comprehensive Integrative Pain Management (AACIPM) and its collaborators remain 'at-the-ready' in service to and support of the AHRQ efforts to ensure the result of the time and funds invested produce a result that can benefit the greatest number of American citizens. Thank you for considering our recommendations.

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Academic Collaborative for Integrative Health

Academy of Integrative Health and Medicine

Alliance to Advance Comprehensive Integrative Pain Management

American Academy of Pain Medicine

American Chronic Pain Association

American Occupational Therapy Association, Inc.

Center to Advance Palliative Care

American Massage Therapy Association

Integrative, Complementary, and Traditional Health Practices Section of the American Public Health Association

Integrative Health Policy Consortium

Integrative Medicine for the Underserved

International Association of Yoga Therapists

US Pain Foundation

The Pain Community