June 21, 2021

To: Suchitra Iyer, Ph.D.
   Task Order Officer
   Center for Evidence and Practice Improvement
   Agency for Healthcare Research and Quality

Re: Integrated Pain Management Programs, Draft Report

Cc: David Meyers, M.D., Acting Director, AHRQ
    Arlene S. Bierman, M.D., M.S., Director, Center for Evidence and Practice Improvement, AHRQ
    Christine Chang, M.D., M.P.H., Acting Director, Evidence-based Practice Center Program, Center for Evidence and Practice Improvement, AHRQ
    Mark Helfand, M.D., M.P.H., Director, Scientific Resource Center, Effective Health Care Program, AHRQ
    Shari Ling, MD, Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services
    Representative Jackie Walorski (R) – Indiana

Dear Dr. Iyer and Respected Reviewers at the Agency for Healthcare Research and Quality:

We, the undersigned members of the Alliance to Advance Comprehensive Integrative Pain Management, are writing to you in response to the Integrated Pain Management Programs Systematic Review draft report that was published for stakeholder review on May 21, 2021.

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 value-based, person-centered model of integrative 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 Systematic Review.

AACIPM is incredibly grateful for the efforts of the Agency for Healthcare Research and Quality (AHRQ) in designing and conducting this systematic review of comprehensive and integrated pain management programs. An integral part of the Dr. Todd Graham Pain Management Study, this review from AHRQ will substantially influence the design of Medicare benefits, impacting access to evidence-based modalities for the treatment of pain, including non-opioid pain management treatments. However, the findings of AHRQ will impact payment design and healthcare delivery far beyond the Medicare program. In the Federal health improvement and healthcare delivery sector, AHRQ and Medicare decisions will have ripple effects, heavily influencing access to care for those covered by Medicaid, Tricare,1 and the Department of Veterans Affairs. Beyond the federal healthcare system, AHRQ reviews impact the large commercial sector and the myriad of self-funded companies and institutions also providing healthcare coverage. AHRQ’s findings are heavily relied upon as trusted

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1 Tricare, the health insurance for active-duty military dependents and retirees, is required to cover what Medicare covers. This population is mostly under age 65 and is known to have a high rate of chronic pain and poor access to non-pharmacological pain care, as Tricare does not cover acupuncture, massage therapy, or chiropractic for military dependents, though this population does seek out these evidence-based services to help them manage their chronic pain (https://www.nccih.nih.gov/health/complementary-health-practices-for-us-military-veterans-and-families).
systematic reviews that impact standard of care, as they are often cited by hundreds of peer-reviewed journal articles and by national guidelines.\(^2\) When looking at the potential impact on patient care, the influence of AHRQ’s work cannot be understated.

To this end, AACIPM commends the authors for conducting this review, which we know has been a challenging undertaking given the complexity of the field of study. When read very carefully across its 80 pages, this review highlights the shortcomings of older pain management programs along with highlighting the challenges of RCT-based research efforts in fully and accurately assessing the current state of clinical practice and evidence-informed possibilities for the millions of people with chronic pain. That said, this review’s “Main Points” and “Conclusions” sections do not fully integrate these shortcomings, instead implying a generalization of findings that are based on limited and often low-quality evidence.

AACIPM is respectfully asking for consideration of modifications that will more accurately reflect the review’s findings in order to clarify the breadth and nuance of this review for its audiences.

For clarity, you will find our full set of recommendations regarding language changes immediately below (#1), followed by three supporting issues for your consideration:

1. **Recommendations: Amending the “Main Points” and Abstract Conclusion to More Accurately Reflect the Systematic Review’s Findings**

2. **The Impact of AHRQ Reviews on Access to Safe and Effective Pain Management, Including the Weight of Definitions, Language, and Non-Medicare Studies**


4. **The Importance of Properly Ranking Quality of Evidence and Ensuring Equity to Provide Appropriate Context for Findings**

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1. **Recommendations: Amending the “Main Points” and Abstract Conclusion to More Accurately Reflect the Systematic Review’s Findings**

With respect to the large-scale influence that AHRQ systematic reviews have when determining plan design and coverage decisions, it is imperative that the “Main Points” of this systematic review are impeccably accurate and not subject to misinterpretation. Furthermore, as emphasized in the forthcoming sections of this letter, the evidence underlying this review is sparse and not of high quality, making it even more imperative that any highlighted findings be explicit in their wording, so as not to inappropriately affect payment design and service delivery based on inadequate evidence.

As we noted in our letter to AHRQ in December 2020, and as acknowledged in this review on Page 1 (“There is not a standardized set of terms or program definitions for pain management programs”), Comprehensive Pain Management Programs (CPMPs) and Integrated Pain Management Programs (IPMPs) are not industry-standard terms.\(^3\) As a result, these terms are likely to be misconstrued by readers to apply to all pain programs that

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\(^2\) AHRQ’s *Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review* (2018) has been cited by at least 102 academic journal articles since its release, and the 2020 update has already been cited at least another 33 times. The 2018 version was cited by the *American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee* (2019), which itself has been cited by another 452 articles since its release.

\(^3\) As AACIPM noted in our December 2020 letter to AHRQ, IPMPs and CPMPs are not standard industry terms, and the three components (pharmacotherapy, psychological, and physical reconditioning) 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...
provide comprehensive integrative pain management. The risk of misapplication by payers and other stakeholders is exacerbated by the Main Points as they are currently written, as they do not maintain consistent use of the IPMP/CPMP terminology, but rather use “integrated pain management programs,” “comprehensive pain management programs,” and “comprehensive programs” seemingly interchangeably.

**Recommendations:**

To best reflect the most important takeaways from this systematic review, we recommend amending the “Conclusions” section of the Structured Abstract, found on Page V, to read:

- **Conclusions.** The improvements in function and pain for CPMPs and IPMPs were consistent with those reported for other therapies for pain, including opioids for chronic pain, nonpharmacologic treatments, and surgery. Further, IPMPs and CPMPs may provide small to moderate improvements in function and small improvements in pain in patients with chronic pain compared with usual care. Evidence regarding harm was limited but generally minor. To the extent that programs are tailored to patients’ needs, our findings are potentially applicable to the Medicare population.

To avoid misapplication of this review to programs that were not evaluated by the review, and to clearly acknowledge the paucity of evidence, we recommend amending the first three Main Points, found in the Evidence Summary on Page ES-1, to read as follows:

- **Primary Care Based Integrated Pain Management Programs (IPMPs)** improved both pain and function in patients with chronic pain at some, but not all, time frames compared with usual care. The evidence that met the selection criteria for these programs as defined for this review was limited in number and/or included low-quality evidence.
- **Specialty Care Based Comprehensive Pain Management Programs (CPMPs)** improved function at multiple time points and improved pain immediately after the program as compared with usual care.
- **CPMPs** improved function and pain compared with medications alone at multiple time points.

Regarding the current fourth bullet, it is unclear whether “Beneficial effects were usually considered small to moderate” applies to IPMPs, CPMPs, or both. Further, it is unclear what level of evidence this is based upon and if these benefits exist in the short-term, medium-term, or long-term. This bullet should be significantly clarified or deleted.

We believe that the fourth bullet should be replaced entirely, instead highlighting a finding from the “Implications and Conclusions” section:

- The improvements in function and pain found for CPMPs and IPMPs were consistent with those reported for other therapies for pain, including opioids for chronic pain, nonpharmacologic treatments, and surgery.

In the fifth bullet, “Comprehensive programs” should be replaced with CPMP to maintain clarity.

The sixth bullet should be deleted entirely. This systematic review did not request comparative data on CPMPs versus psychological supports alone, so this bullet is out of place and inappropriate as one of the review’s Main Points. In fact, it is our understanding that all single modality studies were rejected by the exclusion standards 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 CPMP, 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 integrated pain care.
set forth by AHRQ, so it is unclear why this bullet point is present, as no other single modalities were analyzed, compared, or highlighted in this way.

The seventh bullet is of vital importance, but it is unclear why AHRQ chose to highlight the limited evidence in only this bullet point. If AHRQ intends to point out the limited evidence regarding potential harm (particularly when a major draw of non-pharmacological treatments for pain is their lower risk of harm versus opioids), AHRQ should similarly point out the limited evidence regarding the potential benefits in the previous bullet points.

We recommend amending the seventh and final bullet point to read:

- Reported harms in CPMP programs were generally minor and no intervention-specific adverse events were reported related to IPMPs. The evidence that met the selection criteria for this review was limited in number.

2. The Impact of AHRQ Reviews on Access to Safe and Effective Pain Management, Including the Weight of Definitions, Language, and Non-Medicare Studies

Last year, AACIPM responded to AHRQ’s proposed research protocol for this systematic review to express a number of concerns on behalf of 56 individual experts in the field of pain management, as well as 13 national organizations, collectively representing millions of patients across the nation. Those concerns related to a number of specific issues, including the definitions of integrated and comprehensive pain management programs being used for purposes of this review and the population scope of the review. We further expressed concern with the study design and outcome measures, as we believe that the inclusion and exclusion standards are likely to result in the omission of vital scientific data and information that would be significant in determining the narrative of integrative pain and clinical outcomes.

It is important for us to note that we support fully the use of non-Medicare studies to be considered for Medicare patients, as they include relevant and vital medical information. As we had noted in the past, while included research should be applicable to a Medicare population, data that are not considered exclusively relevant to a Medicare population should not be excluded, as there are very few studies and programs specific to only this population. Ultimately, AHRQ seems to have heeded our (and the larger community’s) advice, as it eventually found that of the 57 randomized controlled trials that fell within their narrow inclusion standards, not a single trial specifically enrolled Medicare beneficiaries. Whether AHRQ took our advice or independently concluded that it would need to extrapolate potentially-applicable data from studies not specific to Medicare beneficiaries, we are grateful to AHRQ for broadening its inclusion standards in this way.

We also appreciate seeing one of our key concerns about the lack of industry-standard terms acknowledged by AHRQ on Page 1 of the draft report, which states, “There is not a standardized set of terms or program definitions for pain management programs” and again on Page 61, which states, “Across the general models as operationalized for this review, there is substantial variation in how programs and their components are delivered, thus, specification of common models or mechanisms is elusive. The models described in this review likely do not fully capture the diversity of programs potentially available in clinical practice.” However, despite this acknowledgement, the “Main Points” section of the review presents these programs as if they are common and standardized models of care, making sweeping statements about the quality of said programs. Such statements run the risk of tainting the reputation of successful comprehensive and integrative programs across the nation that did not fall into AHRQ’s arbitrarily-defined CPMP and IPMP buckets for purposes of this review.

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and thus were unable to prove their value. **In the “recommendations” portion of this letter, above, you will find our suggestion that these terms be clarified as “Primary Care Based Integrated Pain Management Programs (IPMPs)” and “Specialty Care Based Comprehensive Pain Management Programs (CPMPs)”**.

Because of the far-reaching effects of AHRQ’s esteemed systematic reviews on patients in nearly every health system across the country, it is imperative that the language chosen to communicate findings within these reviews is exceedingly clear. After a thorough review of the proposed draft report, AACIPM is concerned that the findings of the review, which were largely based on limited and/or low-quality evidence, and which excluded all but randomized controlled trials (RCTs), are not accurate outcomes reflecting of the field of comprehensive integrative pain management.\(^5\) Further, we are concerned that the “Main Points” section, as it is currently written, does not accurately reflect the content of the draft report and will thus be misconstrued and misapplied by those who will make payment design and service delivery choices based upon the findings of this report. This of course would result in devastating reimbursement actions that would likely adversely impact millions of people’s quality of life, activities of daily living, and ability to function and work.


As we noted in our previous comments to AHRQ, 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 previously recommended that AHRQ accept high quality studies of this design within the review criteria along with RCTs; however, only RCTs were considered for purposes of this systematic review. In limiting the evidence in this way, AHRQ was only able to capture 57 total RCTs for purposes of this systematic review. Even worse, only eight of those RCTs evaluated IPMPs.

We are deeply concerned that AHRQ plans to release a “systematic review” that makes sweeping statements about CPMPs and IPMPs—statements that will greatly affect access to care—based on so few evidentiary resources. While it seems that AHRQ has attempted to clarify that these programs, as defined by AHRQ, are not representative of the diversity and reality of available pain programs, the takeaway by most audiences will not likely reflect any such nuance. Rather, all comprehensive and integrated pain management programs will be lumped into these findings, despite the fact that many of those programs didn’t even meet the arbitrary inclusion and exclusion parameters and therefore were not evaluated by AHRQ. Specifically egregious would be making any statement about “integrated pain management programs”, a term with limits defined only by AHRQ that only resulted in eight total RCTs. Any and all statements made about IPMPs should be accompanied by a clarification regarding the severe lack of evidence the finding is based upon—particularly if made in the “Main Points” portion of the review (see our recommendations, above).

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What’s more, sole reliance upon RCTs for this particular systematic review is misguided due to their well-recognized shortcomings in the field of comprehensive and integrated pain management. RCTs were largely developed for, and applied to, single drug agent or surgical interventions. Simply put, one can easily randomize a trial when a drug may be given to one group of patients, other patients receive a placebo, and researchers are able to observe the differences in that single change in treatment. However, in the context of complementary and integrative health and medicine modalities, RCTs are often impractical because the context, practitioner, and sequencing of modalities all play important roles in treatment. In fact, an important shortcoming of the studies cited within the systematic review was the failure to examine the sequencing of complementary and integrative modalities in the course of chronic pain development for a given patient, and the timing of their use with other more conventional pain management modalities, such as surgery, implanted devices, and catheter-infused agents. Sequencing and timing of treatments has been shown to be an important part of successful pain management, and this does not lend itself to RCT studies. Therefore, it is imperative to analyze pragmatic trials, comparative effectiveness studies, healthcare utilization data, and cost analyses when making effectiveness determinations in this area of healthcare.

Of the studies that did meet the inclusion parameters for this systematic review, most were older, often hospital-based programs with significant resources to dedicate to conducting RCTs, but this simply does not reflect the reality of the way that most comprehensive and integrative pain management is delivered, which significantly hampered AHRQ’s pool of evidence.

A number of recent studies, many based in the United States, have reported extensively on the efficacy of programs this report would consider to meet the criteria for a Comprehensive Pain Management Program and included well-designed comparative effectiveness, longitudinal observational, and pragmatic trials from tertiary, community, and hospital-based outpatient programs. A number of these studies, including a recent observational cohort study from the VA Health System, importantly include short-term and long-term data related to improved functional outcomes; significant reductions, and many times, elimination of opioids; improved psychosocial function; and sustained improvements in quality of life. Unfortunately, much of this robust and recent literature was not included given this report’s reliance on RCTs.

Further, there are many impressive and well-documented comprehensive and/or integrated pain management programs around the country that, because of the limited inclusion and exclusion standards, were unable to be analyzed for purposes of this review. In one example, the Duke Margolis Center for Health Policy and Duke Orthopaedic Surgery have written case studies on numerous pain programs that are comprehensive, integrated and integrative but do not have published RCT studies from their programs. One such case study is about the West Virginia University Center for Integrative Pain Management, the largest health system in an Appalachian state whose top leadership responded quickly to assist in developing solutions to the state’s growing opioid crisis. Another example comes from the Comprehensive Pain Program at University of Vermont Medical Center, which is an important example of a provider/payor partnership with Blue Cross Blue

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8 See Appendix A.

9 AACIPM is currently building a repository of these person-centered clinical examples for acute and chronic pain that are currently not captured in reviews such as this one. This will provide preliminary evidence for these programs and opportunities for more rigorous evaluation.

Shield of Vermont. As defined by this review, both programs would qualify as CPMPs, as they have embedded or easy access to multidisciplinary providers and are not based in primary care. Each program includes the minimum components required for this review and more (medication management, behavioral health, exercise management, care coordination), adding that one third of the patients in the West Virginia program are on Medicare or Medicaid.

Additional data on the effectiveness of comprehensive and integrated pain management can be found through your federal partners, as many agencies have analyzed this type of care delivery in recent years. The U.S. Department of Health and Human Services Pain Management Best Practices Inter-Agency Task Force was established via Congressional mandate and the FACA 1971 and tasked its members with proposing updates to best practices and issuing recommendations that addressed gaps or inconsistencies for managing chronic and acute pain, ultimately issuing a final report that strongly supports a comprehensive and integrative approach to pain management.\textsuperscript{11} The report specifically notes that importance of including complementary and integrative health as a pillar of a multidisciplinary approach to acute and chronic pain treatment and then emphasizes the need to have access to it via telehealth, improved reimbursement, public and provider education. The HHS report also stresses the importance of individualization of care in integrative pain management with treatment modalities selected from a broad range of treatment approaches outlined in the report. This stands in contrast to the AHRQ review’s focus on programs with only three modes of treatment – medication, physical activity and psychological support.

Further, NCCIH, along with the Departments of Defense and Veterans Affairs, have been studying the effectiveness of comprehensive integrative pain management in the context of their care platforms in active-duty military, dependents, and veteran populations living with chronic pain. Initial publications and reports by QUERI are available showing marked beneficial effects of this type of care.\textsuperscript{12,13,14} The heterogeneity of the population included in this body of evidence makes it relevant to this review, and its exclusion does a disservice to the entire pain management community, from government and private payers to health care providers, and ultimately to the patients who receive evidence-based care.

4. The Importance of Properly Ranking Quality of Evidence and Ensuring Equity to Provide Appropriate Context for Findings

By AHRQ’s own admission, the strength of evidence underlying this systematic review is weak. Only 57 total RCTs were included within the review, and fewer than 10 RCTs laid the basis for all statements made in regard to the effectiveness of IPMPs. This poor sample size resulted in four of the eight statements in the “Results” portion of the abstract being based on low strength of evidence, with the other half faring only slightly better with moderate evidence. Further, the “Strengths and Limitations” section acknowledges that, “It was not possible to fully capture the diversity of programs potentially available in clinical practice in this review. This is in

\textsuperscript{12} The VA Whole Health website provides current presentations and publications on Veterans Whole Health, and is a reference that provides a comprehensive source of all results on individual and combined CIH/M modalities within the VA Whole Health transformation: https://www.va.gov/WHOLEHEALTH/professional-resources/clinician-tools/Evidence-Based-Research.asp
\textsuperscript{13} Elwy AR, Taylor SL, Zhao S, McGowan M, Plumb DN, Westfield W, Gaj L, Yan WG, Bokhour BG. Participating in complementary and integrative health approaches is associated with Veterans’ patient reported outcomes over time. Medical Care. 2020; 58 (9, Suppl 2): S75-S77.
\textsuperscript{14} Elwy AR, Taylor SL. Progress of VA complementary and integrative health research along the QUERI implementation roadmap. Medical Care. 2020; 58 (9, Suppl 2): S125-S132.
part due to the wide variety of programs available clinically, many of which may not be evaluated in the peer-reviewed literature.”

We would also add that people in underserved communities are not represented in the study samples selected for this review and the criteria developed for the review itself did not account for underserved/diverse populations. Chronic pain has been associated with poor health with evidence of particularly high prevalence in patients with healthcare disparities.\textsuperscript{15,16} Previous research indicates that residency in low-income neighborhoods correlates with higher cost users of the health care system, especially with regard to chronic pain.\textsuperscript{17,18} Furthermore, how this chronic pain is managed often differs between income groups, as lower income patients are more likely to take prescription pain medications and less likely to use exercise to alleviate chronic pain.\textsuperscript{19} This emphasizes another reason the results are not generalizable, and further context is encouraged.

While we appreciate the admission by AHRQ that the evidence is weak, and that AHRQ was unable to capture the diversity of comprehensive and integrated pain management programs, we are deeply concerned that this nuance will not be understood by many audiences without further clarification by AHRQ. To avoid misapplication of this review to programs that were not evaluated by the review, and to clearly acknowledge the paucity of evidence, we recommend amending the “Main Points” and “Conclusions”, with specific suggestions found in the “Recommendations” section of this letter, above.

Strong statements based upon weak evidence have an unfortunate history of negatively impacting people living with pain in recent years, with the CDC Guideline for Prescribing Opioids for Chronic Pain (2016) being a prime example.\textsuperscript{20} Despite many public comments warning the CDC of the potential misapplication of their proposed guideline, itself based on weak or very weak evidence, the finalized guideline made a number of impactful recommendations based upon low quality evidence. While they attempted to clarify within their guideline that practitioners should ultimately base decisions on each individual’s unique needs, reiterating that recommendations are not binding one-sized-fits-all rules, the reality was that legislatures across the nation immediately began to adopt the CDC’s recommendations—based on weak evidence—as binding law.

Three years after its initial release, the CDC recognized the chaos and harm it inadvertently created with its guideline and released a statement advising against the misapplication of their guideline and offering further clarifications.\textsuperscript{21} A year later, CDC established a new Opioid Workgroup and plans to complete updates to their guideline by the end of 2021, because, “Despite the best intentions [sic], they have seen barriers and challenges in implementing the guideline’s strategies. Unfortunately, some policies and practices derived from the guideline have been inconsistent with and often go beyond its recommendations.”\textsuperscript{22} It is our hope that AHRQ will not add to the body of confusing and low-quality evidence, but rather, will set a new standard for basing

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\item \textsuperscript{17} Grol-Prokopczyk H (2017) Sociodemographic disparities in chronic pain, based on 12-year longitudinal data. Pain 158:313-322.
\item \textsuperscript{20} https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf
\item \textsuperscript{21} https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html
\item \textsuperscript{22} https://www.cdc.gov/injury/pdfs/bsc/BSNCIIPC_Minute_7-22_2020_Certified_Combined_PC.pdf
\end{itemize}
findings upon high-quality evidence, or, at the very least, being explicitly clear when making a statement based upon low quality evidence.

The Alliance to Advance Comprehensive Integrative Pain Management (AACIPM) and its collaborators sincerely thank you for the work you have invested in this systematic review of comprehensive and integrated pain management programs. AACIPM remains an ally in support of AHRQ efforts, aiming to ensure the result of the time and funds invested in this systematic review produce a result that will benefit the greatest number of American citizens.

Thank you for considering our recommendations.

Individual Signatories (Alphabetically)

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Academy of Integrative Health & Medicine

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American Holistic Nurses Association


