September 6, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

The Alliance to Advance Comprehensive Integrative Pain Management (AACIPM) is respectfully submitting comments on CMS-1770-P, related to the proposed 2023 Physician Fee Schedule and other changes to Part B payment policies (the "PFS"). We will specifically be responding to Section 33, Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1 and GYYY2).

AACIPM is a multi-stakeholder collaborative comprised of more than 75 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 CMS' proposed PFS for CY 2023, and we are grateful for the opportunity to provide CMS with information to aid in improving coding design to improve the availability of safe, evidence-based, and cost-effective treatments to people living with pain.

AACIPM is grateful to CMS for its recognition that adequate treatment of pain is a significant public health challenge and for the significant effort that has been invested in developing GYYY1 and GYYY2. We fully support CMS' effort to (1) encourage the adoption of high-quality integrative pain care while minimizing reliance on higher risk, low value care that is often more costly, (2) collect accurate data on the number of people requiring treatment for chronic pain and the types of services they require, and (3) promote health equity. We are deeply supportive of CMS' goal to improve the care experience for individuals with pain, expand access to evidence-based treatments for pain, and increase coordination between primary and specialty care through payment episodes, incentives, and payment models. While we will be offering a number of comments and recommendations within this letter, it is our hope that these comments be taken in the spirit of collaboration and partnership with which they are intended.

In our comments, we will answer a number of questions posed by CMS in the PFS, as well as offer recommendations, related to:

1. Need for Clarification regarding Required Services
2. Need for Clarification regarding In-Person vs. Remote Visits
3. Disallowing Same-Day Billing will Exacerbate Health Equity Concerns
4. Valuing CPM Codes Below Standard Follow-up Codes will Disincentivize Use
5. Validated Pain Assessment Scales are Steeped in Bias
6. Proposed "Bundles" Do Not Align with Traditional Bundles

Need for Clarification regarding Required Services

Our stakeholders are concerned that GYYY1 currently seems to indicate that all listed services must be completed in order for the provider to bill for the code.

As it is drafted, GYYY1 links all of the listed services with an "and" clause as opposed to an "and/or" clause. Thus, it is our understanding that, in order to be reimbursed for the code, a provider would have to provide all of the following services, in a single encounter: diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development implementation revision and maintenance of a person-centered care plan; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community-based care), as appropriate.

It is possible that the "as appropriate" is intended to indicate that all services do not need to be provided in order to bill for the code, but the language offered by CMS is not sufficient to make that clear. Our working understanding is that "as appropriate" is currently linked to the need to coordinate with relevant practitioners furnishing care, making this coordinative service, perhaps, the **only** optional provision. However, our concern is that many of the listed services either (1) will not be indicated for a particular patient who otherwise does require CPM, such as a patient who does not require medication management, or (2) won't be feasible to combine in a single encounter, or (3) won't be available in all offices or locales, making the codes inaccessible in all but the most advanced and established CPM programs (many practitioners are not set up to have coordination with behavioral health, or haven't been trained in health literacy, for example).

Not all CPM patients will require every service listed in GYYY1, and not all geographic locations will have access to offices which provide every service. However, treatment plans and/or CPM programs can be highly effective without using *every* component of comprehensive pain care, and these patients are no less deserving of health coverage for their CPM care than those patients who require every service and/or live in urban areas.

AACIPM recommends that CMS:

1. Clarify GYYY1 so that it is clear that clinicians are not responsible for providing every listed service, allowing for flexibility in individual treatment plans based on the patient's needs and the geographically available services. (This could be done by adding "as appropriate" after all optional clauses, such as medication management, coordination with community-based care, and coordination with behavioral health treatment).

Need for Clarification regarding In-Person vs. Remote Visits

Our alliance is concerned with an unclear provision in GYYY1 that seemingly requires an "initial" face-to-face visit of at least 30 minutes *each month*. We do not object to one required initial face-to-face visit at the onset of CPM treatment; however, our stakeholders agree that requiring an in-person visit *monthly* is unnecessary, overburdensome, and would exacerbate healthcare disparities.

Given CMS' explanation for restricting access to GYYY1 until after an initial face-to-face appointment ("We believe it would be unlikely the practitioner is prepared to address the complex pain needs of a new patient on the same day he or she is seen for a general visit"), we believe that the unclear monthly requirement in GYYY1 is a drafting error rather than intentional, and we are hopeful that CMS will agree.

While the draft is certainly subject to interpretation, our current understanding is this—

CMS' intention seems to be:
Month one: Initial face-to-face appointment --> GYYY1 --> GYYY2 (as needed)
Month two: GYYY1 --> GYYY2 (as needed)

But currently, GYYY1 seems to be requiring:
Month one: Initial face-to-face appointment --> GYYY1 --> GYYY2 (as needed)
Month two: Initial face-to-face appointment --> GYYY1 --> GYYY2 (as needed)

The clinicians in our alliance all agree that, while an initial in-person visit is preferable (though telehealth *can* successfully be used for initial appointments), in-person visits are <u>not</u> necessary for the pain care coordination that is covered by GYYY1 and GYYY2. Telehealth should be an option for these appointments, as geographic factors (rural, underserved) and life circumstance (childcare, transportation) can make repeated in-person appointments inaccessible, thus exacerbating health equity and disparities concerns (an issue at the forefront of CMS' forward thinking, as evidenced by the current Request for Information related to health equity, CMS-4203-NC). Our stakeholders have informed us that their patients with chronic pain have expressed interest in integrative care services, but that these patients are often in too much pain to travel to the clinic and have often inquired about the availability of receiving integrative care services via Zoom.

AACIPM recommends that CMS:

2. Clarify and/or redraft GYYY1 so it is clear that only the initial CPM visit is required to be in-person, and that follow-up CPM visits may be delivered in-person or remotely, whether or not they occur within the same month.
3. Add equivalent codes to GYYY1 and GYYY2 to the Telehealth Services list.

Disallowing Same-Day Billing will Exacerbate Health Equity Concerns

Many stakeholders in our alliance have expressed great concern at CMS' proposed intention to disallow use of GYYY1 and GYYY2 if care is furnished on the same day as a general visit, such as an evaluation/management or procedural visit where the person is being seen for some other illness or condition. We believe this would be a grave mistake that would significantly hamper the delivery of truly integrative pain care, as well as exacerbate disparities at a time when CMS is actively working to promote health equity.

People living with chronic pain conditions have a significantly greater likelihood than the general public of having at least one or more comorbidities that are being treated alongside their pain, and often these health concerns are, in fact, addressed by one singular practitioner on the same day. What's more, a patient receiving optimal integrative pain care should be able to count on their practitioner to take into account the entirety of their health history—their Whole Person, in terms frequently used by the federal government—when managing their pain condition. This becomes particularly important when considering the type of care coordination contemplated by GYYY1 and GYYY2 which include care coordination with other clinicians and the responsibility to teach health literacy—pain conditions exist alongside other conditions, not in isolation from them, and must often be treated concurrently to achieve optimal results.

Further, requiring all patients receiving CPM services to come into the office for care *on a different day* than they come in for their other health services will significantly reduce the number of people who are willing or

able to receive this type of care. There are many people living with chronic pain who are elderly, disabled, homeless, lack reliable or affordable transportation, cannot take time off work, and/or are unable to secure alternate childcare (among other things). While these patients may be able to make it in for one in-person appointment each month, if necessary, it is highly unlikely that most of these patients would be able to come to a second in-person appointment each month. Mandating repeated in-person visits will be arduous for disabled beneficiaries in communities poorly-served by public transportation, a reality that characterizes many smaller cities, suburbs, and rural locales.

Our stakeholders that provide comprehensive pain management in their clinics—particularly those in primary care—have assured us that they do, in fact, offer comprehensive pain management services on the same day as offering other services to the patient, such as blood pressure or diabetes management, cancer screening, or follow-up on mental health concerns. They have expressed serious concerns that use of these codes would make delivery of CPM unavailable to many of their lower-income patients who would not be able to attend both a general appointment and a separate CPM appointment.

We strongly advise CMS to reconsider its current stance on this issue if its goal is to (1) encourage the adoption of high-quality integrative pain care in place of higher risk, low value care that is often more costly, (2) collect accurate data on the number of people requiring treatment for chronic pain and the types of services they require, and (3) promote health equity. We believe that disallowing use of GYYY1 and GYYY2 on the same day that a patient is being seen for a general visit or for another illness or condition would significantly hamper these goals.

AACIPM recommends that CMS:

4. Allow providers to bill for GYYY1 (and GYYY2, as appropriate) on the same day that a patient is being seen for a general visit or for another illness or condition.

Valuing CPM Codes Below Standard Follow-up Codes will Disincentivize Use

Despite what we know are the best of intentions on the part of CMS, our alliance is concerned that the currently proposed Relative Value Unit (RVU) valuation of GYYY1 and GYYY2 will actually *disincentivize* practitioners from using these codes. However, we are grateful to CMS for asking for feedback on the proposed valuation, and we are hopeful that CMS will understand our concerns.

CMS currently proposes valuing codes GYYY1 and GYYY2 based on a crosswalk to the principal care management codes 99424 and 99425, respectively. To our understanding, this would mean a valuation of $83.40 for GYYY1 and a valuation of $30.11 for GYYY2. However, this proposed valuation is significantly below that of a current 99214 for a 30 minute follow-up clinical visit, which is presently reimbursed at $129 per visit by Medicare.

We are gravely concerned that the currently proposed valuation will inhibit use of the new CPM codes. At present, the proposed reimbursement levels do not make use of the codes financially tenable. For providers who already offer CPM services, these new codes would either (1) go unused, as they pay less than a standard 99214, or (2) result in significantly less payment, causing these clinics to reconsider the number of pain patients they are willing to take on. For those providers who are currently wary of taking on patients with pain, the valuation for these codes would actually *disincentivize* them from treating patients with pain, as the codes pay *less* than standard 99xxx codes, yet require *more* work from the provider. Of even greater concern, if use of

these codes became *required* for patients receiving CPM services (i.e. use of a 99xxx code for pain was deemed fraudulent), we anticipate that many clinicians would cease serving people living with complex pain conditions altogether, as the valuation is too low and the required services are extraordinarily laborious as compared to standard visits.

Below are some real-life narratives from physicians working in this space, describing this issue:

Steven Stanos, DO, Certified in Physical Medicine and Rehabilitation and Pain Medicine, Past President of the American Academy of Pain Medicine:

> Our self-management program at Swedish Pain Services provides coordinated physical, occupational, and behavioral health therapies to patients 2-3 days per week in group and individual sessions, usually 4-6 weeks in duration. These types of structured functional restoration programs require significant time and coordination of services which include checking and managing authorizations for therapy, coordinating clinical scheduling, program planning, and orientation time usually shared by a patient care representative and nurse manager or educator.
>
> The proposed care coordination codes would not support or incentivize this type of work, especially given its limitations to one time per month. Our team (physical and occupational therapy, behavioral health specialist, pain medicine specialist, and nurse educator) meets weekly to review each individual's progress in treatment in a team conference format. During these meetings, there is a patient-centered documentation of patient progress and adjustments in therapy are made. The current 15-minute team conference time and available code (99367) is billable but not reimbursable under CMS rules. The current proposed codes would also not be applicable to this important and necessary care coordination team conference work. Expanding the CPM services codes to include coverage for this type of interdisciplinary management could help to incentivize this care provided in pain management centers and patient medical homes.
>
> At the provider level, much of the coordination of care and components mentioned in the proposed bundle include many activities a pain management physician provides and documents during a scheduled new person or established patient visit. With time-based coding, providers are able to document time-related to the care of the patient on that day of services, including coordination of services, reviewing records, providing face to face care, adjusting treatment plans, and coordinating any additional referrals to other providers many times fulfilling time-based cut offs for 99214 (at least 30 min) and 99215 (at least 40 min). Current proposed codes would be reimbursed at much lower rates than the current time-based codes.

Stefan Kertesz, MD, Certified in Internal Medicine and Addiction Medicine, Member of multiple task forces and teams related to opioid safety:

> CPM includes diagnostic and clinical assessment, treatment planning, managing pain care crises, changing plans for care and (incidentally) coordination of services. It's every month, sometimes. To me that's what I do on Friday mornings. I see these patients who are in my primary care clinic but have challenging pain and social crises. We are discussing life crises, pain related function, return to work, medication, opioid safety, and I'm also trying to figure out whether they did or did not get to the physiatrist, or the psychologist. It's uniquely challenging because it's so far from the cookie cutter of standard primary care. And it's emotionally exhausting. Often the patients are telling me their pain is horrible, and I'm often caught between competing pressures in regard to my opioid prescriptions.

> It's emotionally laborious. Excellent survey data shows that lots of doctors do not wish to enter primary care right now because they do not want to deal with pain or opioids. The cognitive and emotional work, particularly where opioids are involved, is emotionally and intellectually and logistically arduous, far harder than following up on an abnormal screening test or discussing the next modification to an insulin regimen.

These narratives encapsulate the experiences of other clinicians who provide comprehensive and integrative pain services. These clinicians strongly believe in the effectiveness of CPM, but providing this care needs to be financially feasible for the providers if we truly want to (1) encourage the adoption of high-quality integrative pain care while minimizing reliance on higher risk, low value care that is often more costly, and (2) collect accurate data on the number of people requiring treatment for chronic pain and the types of services they require.

If CMS wishes to support the use of CPM services, valuation must be *at least* comparable to a 99213 or 99214. However, to truly *incentivize* adoption and utilization of CPM services, CMS should consider applying a 30-50% modifier (more reimbursement) to a 99213 or 99214 for the additional intellectual labor and time involved in providing and coordinating all of the services listed in GYYY1. Until CPM services are reimbursed on par with other commonly used services (such as procedural interventions), it is unlikely that CPM will be able to grow to sufficiently meet the demand for these services.

AACIPM recommends that CMS:

5. Crosswalk the valuation of GYYY1 and GYYY2 to 99214 (rather than 99424 and 99425) and consider adding a modifier that would compensate providers for the additional labor involved in providing CPM.

Validated Pain Assessment Scales are Steeped in Bias

We oppose the proposed requirement that a provider must use a validated pain assessment scales in order to access GYYY1 and GYYY2. There are several reasons behind this stance, including concerns with pain bias, proprietary systems, and established positive outcomes in whole person, value-based pain care from the use of patient health assessment tools beyond “validated pain scales”. These issues, when considered together, create a clear case for the need to avoid requirements for health care providers to use pain scales that have not achieved widespread support across affected stakeholders.

Although originally validated, many subjective pain scales have subsequently been shown through well documented research to result in pain bias.[1,2,3] This bias is most often against women, the elderly, and certain ethnic groups. Unfortunately, once a scale is originally validated and released, these pain scales are not removed from use even after their pain bias is well documented. These subjective pain scales are a health equity problem, and the health equity issue would only be perpetuated by CMS if these subjective pain scales were codified into coding requirements.

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[1] Karcioglu O, Topacoglu H, Dikme O, et al. A Systematic review of the pain scales in adults: Which to use? American Journal of Emergency Medicine. 2018. Available at: https://doi.org/10.1016/j.ajem.2018.01.008

[2] Morley S. Bias and reliability in pain ratings. Pain. 2016. Available at: https://doi.org/10.1097/j.pain.0000000000000448

[3] Hoffman KM, Trawalter S, Axt JR, etc. al. Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. Proceedings of the National Academy of Sciences. 2016. Available at: https://doi.org/10.1073/pnas.1516047113

Further, it is important that a combination of data measurements and instruments for health-related outcomes be considered in determining a "successful" outcome from the perspectives of the patient, payer, and provider. Patients seek clinically meaningful outcomes which cannot always be measured accurately through pain scales (particularly when bias is present), but more often have to do with how they are able to meaningfully engage with their life activities. Payers and providers involved with integrative pain management are looking for value-based quality care and meaningful functional clinical improvement. The use of widely validated measurements is important, but we must not overlook the current meaningful push towards Whole Person health (i.e., Net Promoter Score, Global Perceived Effect, Visual Analog Scale, Short Form Survey, tracking non-traditional well-being such as BMI, longitudinal claims, etc.). Apart from simply measuring pain changes on a scale, there are also numerous payer and provider utilization and outcome measurements that can readily be measured to assess efficacy and cost-effectiveness, such as hospitalizations, ER and urgent care visits, specialist utilization and pain related procedures, prescription claims per year, longitudinal claims reports, and primary care visits.

Finally, there is significant disagreement over the use of proprietary pain scales. Both frustrating and also understandable, this barrier has, thus far, prevented a wide adoption of any single pain scale across the country. The topic of convening stakeholders to find consensus and then promote use of a common use pain scale has been discussed many times over the years. However, despite a strong interest in the concept across stakeholders, it has never moved forward—in large part due to the proprietary nature of many of the scales.

Our stakeholders unanimously agree that, while we empathize with the desire for uniform measurement tools, accurate and unbiased subjective pain measurement tools simply do not yet exist. Therefore, we suggest that a combination of subjective and objective pain scales be used alongside quality of life and functional measures. Further, we suggest that CMS either establish a stakeholder workgroup or issue a Request for Information (RFI) related to validated pain assessment tools prior to requiring their use to access GYYY1 and GYYY2.

AACIPM recommends that CMS:

6. Replace "administration of a validated pain rating scale or tool" with "documentation of pain based on subjective and objective pain measures, including function and quality of life."
7. Establish a Stakeholder Work Group, or issue an RFI, to further investigate subjective and objective pain measurement tools.

Proposed "Bundles" Do Not Align with Traditional Bundles

The members of our alliance have expressed concern and confusion over the use of the term "bundle" to describe GYYY1 and GYYY2.

In most cases, use of the term "bundle" indicates that the payment will be connected to outcomes measures, with the billing provider able to utilize a number of different health services and providers to create a truly individualized treatment plan. The billing provider is being paid to achieve an outcome, and to achieve that outcome they select the treatments and other providers that are best suited for the patient and will achieve the best return on investment (ROI). This approach encourages providers to be very careful about which services they select for each patient, as there is one set "bundled" payment with which the billing provider will, in turn, pay any other involved providers. Put simply, bundles are payments for episodes of care that have a specific duration, set of services, and have risk attached to them in the form of outcomes desirable to patients, payers, and providers.

In contrast, GYYY1 and GYYY2 are far more equivalent to chronic care management codes and/or health and behavior management codes. In the proposed codes, it appears the intent is to support ongoing and continuous management and coordination of care of a chronic condition and appears to be an iteration of the evolving care management codes. These codes are important in and of themselves to support the transformation of our health system from an acute "sick care" system to a whole person health and wellness support system.

The establishment of these CPM codes is an important step forward in chronic care management, and we are supportive of their implementation. However, we are concerned that labeling them as "bundles" runs the risk of confusing both health care providers and private insurers who understand "bundle" to mean something entirely different. Further, while we do support the currently proposed CPM codes, we also believe that true "bundles" (as we described above) are an extremely valuable tool in the management of chronic pain, and we are hesitant to apply that label to the currently proposed codes lest it be claimed in the future that we "already have CPM bundles" down the road. Bundling services for pain care is a fast-growing and highly-promising form of pain care, and we would hate to see CMS miss the opportunity to explore this type of bundling in the future due to having erroneously labeled the CPM codes as "bundles."

AACIPM recommends that CMS:

8. Remove any mention of "bundles" or "bundling" from the proposed CPM codes to eliminate confusion with traditional bundles that are based on outcome measures.

AACIPM and its collaborators sincerely thank CMS for the steps it is taking to improve care for Americans living with chronic pain conditions. We are truly grateful for the obvious effort that has gone into the proposed 2023 Physician Fee Schedule, and we remain a committed ally in helping CMS to hone their proposal to best meet the goals of encouraging the adoption of high-quality integrative pain care, collecting accurate data on the number of people requiring treatment for chronic pain and the types of services they require, and promoting health equity.

We offer these comments to CMS in the spirit of collaboration, and we sincerely thank you for considering our recommendations.

Final Recommendations

1. Clarify GYYY1 so that it is clear that clinicians are not responsible for providing every listed service, allowing for flexibility in individual treatment plans based on the patient's needs and the geographically available services. (This could be done by adding "as appropriate" after all optional clauses, such as medication management, coordination with community-based care, and coordination with behavioral health treatment).
2. Clarify and/or redraft GYYY1 so it is clear that only the initial CPM visit is required to be in-person, and that follow-up CPM visits may be delivered in-person or remotely, whether or not they occur within the same month.
3. Add equivalent codes to GYYY1 and GYYY2 to the Telehealth Services list.
4. Allow providers to bill for GYYY1 (and GYYY2, as appropriate) on the same day that a patient is being seen for a general visit or for another illness or condition.
5. Crosswalk the valuation of GYYY1 and GYYY2 to 99214 (rather than 99424 and 99425) and consider adding a modifier that would compensate providers for the additional labor involved in providing CPM.

6. Replace “administration of a validated pain rating scale or tool” with “documentation of pain based on subjective and objective pain measures, including function and quality of life.”
7. Establish a Stakeholder Work Group, or issue an RFI, to further investigate subjective and objective pain measurement tools.
8. Remove any mention of “bundles” or “bundling” from the proposed CPM codes to eliminate confusion with traditional bundles that are based on outcome measures.

Individual Signatories (Alphabetically)

Katie Bennett, JD, Law and Ethics Columnist, Practical Pain Management

Amy Goldstein, MSW, Director, Alliance to Advance Comprehensive Integrative Pain Management

Joanna Katzman, MD, MSPH, Professor, Comprehensive Pain Treatment & Center Director, University of New Mexico

Megan Kingsley Gale, MSAOM, Director, The Hospital Handbook Project for Acupuncturists and Their Hospital Sponsors

Martha Lawrence, CEO and Co-Founder, Accendowave

Josh Plavin, MD, MPH, MBA, Vice President and Chief Medical Officer, Blue Cross® and Blue Shield® Vermont

Jon Porter MD, Comprehensive Pain Program, University of Vermont Medical Center

Ravi Prasad, PhD, Clinical Professor, Director of Behavioral Health, University of California, Davis School of Medicine, Department of Anesthesiology and Pain Medicine

Adam Seidner, MD, MPH, Chief Medical Officer, The Hartford

Steven Stanos, DO, Executive Medical Director, Rehabilitation and Performance Medicine, Providence Swedish Health System

Cindy Steinberg, Director of Policy and Advocacy, U.S. Pain Foundation

Robert Twillman, PhD, Pain Management Psychologist, Clinical Associate Professor of Psychiatry (Volunteer Faculty), University of Kansas School of Medicine

Richard M. Vaglienti, MD, MBA, Associate Professor of Anesthesiology, Behavioral Medicine and Psychiatry & Neuroscience, Director of WVU Center for Integrative Pain Management

Organizational Signatories (Alphabetically)

Academy of Integrative Health and Medicine

Accendowave

AcuCongress

Alliance to Advance Comprehensive Integrative Pain Management

American Academy of Pain Medicine

Fulcrum Health

National Patient Advocate Foundation

The Ehlers Danlos Society

The Pain Community

US Pain Foundation