September 6, 2022

*Submitted to the Federal Register*

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

**Attn: Docket No. CMS-1770-P**

Dear CMS representatives:

We thank you for the opportunity to provide feedback on CMS-1770-P, in regard to the proposed rule on the 2023 Physician Fee Schedule and other changes to Part B payment policies, 87 Fed. Reg. 45860 (July 29, 2022). Our comments focus solely on Section 33, Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1 and GYYY2), 87 Fed. Reg. 45932-45938.

The **National Pain Advocacy Center (NPAC)** is a 501(c)(3) nonprofit alliance of clinicians, scientists, public health experts, and people with lived experience of pain or addiction, working together to advance the health and human rights of people with pain. We take no pharmaceutical or industry funding and are currently funded by grants from Open Societies Foundation, the Ford Foundation, and individual donations.

We applaud the Center for Medicare and Medicaid Services (CMS) for its explicit recognition of the scope, consequence, and complexity of pain as a public health problem, and for its effort to address the burden borne by the individuals and families most deeply affected by it. We fully endorse CMS’ goal to improve the care experience for individuals with acute and chronic pain, expand access to evidence-based treatments, and increase coordination between primary and specialty care through payment episodes, incentives and payment models. As an organization that takes an equity and rights-based approach to pain, we strongly value and endorse the inclusion of healthy equity as a central pillar of CMS’ Strategic Vision.

It is in support of these critically important goals that we offer the following comments on:

1. *Clarification of Proposed Services.*
2. *Valuation of Proposed Bundles.*
3. *Billing for Same-Day Services.*
4. *Service Delivery – In-Person vs. Remote Care.*
5. *Inclusion of Validated Pain Scales and a Pain Scale Registry.*
6. *Frequency and Duration of Proposed Services.*

We address each, in turn, below.

1. *Clarification of Proposed Services.*

We endorse the type of care that CMS seeks to promote in GYYY1, which is well summarized at 87 Fed. Reg. 45934-45935:

 Chronic pain management and treatment, monthly bundle including, 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 that includes strengths, goals, clinical needs and desired outcomes; 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…., as appropriate.’ 87 Fed. Reg. 45934-45935

To be successful, however, the service payments must be applied with flexibility—they must be sufficiently nimble to permit coverage of individualized care across a variety of chronic pain needs, for patients at different stages of disease and care, and in a manner recognizing that access to some listed services varies.

Currently, there is ambiguity in the drafting that could be read rigidly to require that *all* itemized services must be provided in *every* initial monthly visit to support billing under the code. We recognize that the term “as appropriate” appears at the end of the itemized list, but the draft is sufficiently unclear to give rise to concern. (“As appropriate” could be interpreted as modifying only the last clause (related to coordination with physical and occupational therapy and community-based care) in a list in which services are connected by “and” not “and/or”).

We urge CMS not to require every itemized service in every initial monthly visit. Different services are likely to be needed for different patients at different times; rarely will everything listed arise in a single visit. Although diagnosis can be ongoing, for example, it is likely to be a focus early in care with a patient who is relatively new to chronic pain. An interpretation that requires every listed service to be performed at each initial monthly visit would burden patients and providers alike, moving away from a focus on patient-centered care toward onerous documentation requirements. As such, it would have the opposite impact of CMS’ intention—disincentivizing, rather than creating incentives for, the treatment of patients with chronic pain.

Moreover, given the disparate regional availability of services such as behavioral health care or literacy counseling, requiring such services for use of the CPM code would exacerbate existing health inequities related to access to care, flying in the face of CMS’ cornerstone focus on health equity. Encouraging use and coverage of services that traditionally have been limited in availability or coverage is critical, but a practice shift takes time. At this early stage of coverage for CPM, CMS must recognize that a consistent infrastructure for and coverage of interdisciplinary pain care remains lacking.

We thus urge CMS to clarify that the list describing billing code GYYYI, at 87 Fed. Reg. 45934-45935, is descriptive of the type of care covered by the code, but that not all services are required to be completed in a single encounter in order to bill using GYYY1. In addition, a final rule should enumerate precisely what CMS considers appropriate documentation for application of this code. We have heard concerns that the documentation requirements for CCM and PCM are sufficiently burdensome to cause some providers not to use those codes, so we urge CMS not to create overly demanding documentation requirements if CPM care is to be encouraged.

1. *Valuation of Proposed Bundles.*

We are most concerned that the method of valuation of GYYY1 and GYYY2 and proposed Relative Value Units (RVUs) will create disincentives, rather than incentives, to care for people with chronic pain.

The level of service described in GYYY1, as quoted in A., requires lengthy and sustained face-to-face office visits that are more demanding intellectually, logistically, emotionally, and in regard to time of both professionals and staff than the standard, level four E/M visit, 99214. Any plan to incentivize the delivery of chronic pain management must recognize it as care of high complexity that merits a higher or additional valuation.

Moreover, CMS’ proposed model for valuation is not an appropriate analogue for the type of services listed in the CPM code, and, for that reason, it is unlikely to draw interest from clinicians in primary care or other specialties, or their employers.

As we understand it, CMS based valuation on its current coding of Chronic Care Management (CCM) and, specifically, Principle Care Management (PCM). But the analogous codes related to services provided “personally” by “a physician or otherwise qualified health professional” in these contexts describe coordination that does not typically involve face-to-face visits.[[1]](#footnote-1) Perhaps for this reason, they are valued by CMS at a rate lower than that for a level four E/M visit involving patient care. Compare 99491 (Chronic Care Management by physician 1st 30 minutes) at a work RVU of 1.50 and 99424 (Principle Care Management by Physician 1st 30 minutes) at 1.45 with 99214 (level four E/M visit at 1.92).

By contrast, CMS' declaration of the types of work needed under GYYY1 requires in-person (or possibly telehealth) care by a professional who is making examinations and decisions, hearing complaints, identifying and managing crises, and—*in addition to all of that*—performing service and care coordination.

Thus, while the *patient populations* in CCM and PCM may well be roughly analogous to those in CPM, the *types of services itemized* in the description of GYYY1 are not. Rather, GYYY1 appears to be an amalgam of two types of services—a sort of super code that combines an E/M visit (hence the requirement for in-person care) with the type of coordination of care provided “personally” but not typically face-to-face that is seen in codes for CCM and PCM.

A preferred system might separate distinct types of services required for CPM into two codes:

* One code for face-to-face care that is valued higher than the standard E/M visit, due to the higher complexity of managing patients with chronic pain; and
* One code for coordination undertaken personally by a physician or other qualified healthcare professional outside of face-to-face care (and analogous to codes for CCM and PCM).

Dividing these services into two codes would acknowledge that, while some coordination of care will happen when a patient is present, most will likely occur outside a scheduled visit. In addition, we would urge CMS to adopt a third code to reflect coordination by staff working under the supervision of a physician or other qualified healthcare professional (one analogous to codes for CCM and PCM).

At a minimum, adjustments in valuation for GYYY1 codes are necessary in order to effectuate CMS’ stated goal to compensate or provide incentives for CPM. CMS has stated in its proposed rule that the CPM codes are targeted chiefly at primary care providers. Our advisors who practice primary care have indicated that they and many of their colleagues often find the management of patients with long-term pain more challenging than managing the care of patients with “conventional” chronic disease challenges such as diabetes or hypertension.

Studies have similar findings. One study suggests that primary care professionals find chronic pain management especially challenging because it can intersect with mental health, substance use, and difficult social conditions; the same study indicates that those who provide chronic pain management often show signs of burnout.[[2]](#footnote-2) Other studies show that primary care providers are increasingly disinclined to treat patients with chronic pain who use opioids to manage their pain, leaving a subgroup of vulnerable patients that the healthcare system put on these medications at risk: 40-50% of primary care doctors will refuse to take on a new patient currently taking opioid to manage pain,[[3]](#footnote-3) and 81% are reluctant to treat such patients.[[4]](#footnote-4)

In sum, as GYYY1 is currently proposed, there is little incentive for primary care organizations to allot time or rooms to the care for this vulnerable patient population, when doing so provides less compensation than a standard 99214 visit. At best, primary care providers may continue to bill using time-based codes like 99214, ignoring the CPM code; at worst, the CPM code may create confusion and disincentives to care.

1. *Billing for Same-Day Services.*

As currently drafted, the limitation suggesting that GYYY1/GYYY2 cannot be billed on the same day of service as CPT codes 99202-99215 is unclear, because of the phrase, “services are being furnished to a patient the practitioner has not previously seen.” 78 Fed. Reg. 45937. Both GYYY1/GYYY2 appear to refer to treatment of new as well as continuing patients, and the CPT codes listed, which include 99214, similarly reference both new and established patients.

If CMS intends that chronic pain management cannot be performed on the same day as evaluation, management, or treatment of other care complaints, we are concerned that such a limitation fails to reflect the reality of chronic pain expression and threatens to exacerbate existing health disparities and inequities.

Many people with chronic pain have co-morbid conditions; their pain is merely one part of their overall health spectrum. We appreciate CMS’ recognition that pain treatment poses special challenges and its intent in proposing CPM coding to allow for time and compensation to address those unique challenges. Nevertheless, siloing treatment of a patient’s pain from treatment for other, perhaps related conditions, by requiring patients to report on multiple days, is impracticable, out of synch with the call for integrated, coordinated, whole-person, patient-centered care, and burdensome.

Many people living with chronic pain are individuals with disabilities who already face heightened barriers to access to transportation, making trips into a provider’s office challenging. For many patients, pain itself limits mobility; a patient’s pain is often exacerbated by having to report to an office in-person. Requiring visits on multiple days will only intensify these problems. People who have difficulty getting time off from work or arranging for childcare, people who are elderly, people who are unhoused, people living in rural areas where services are sparce, and many others stand to be disparately burdened by such a requirement, which will only exaggerate existing health disparities.

1. *Delivery of Services – In-Person vs. Telehealth.*

In a related issue, the type of care envisioned by “in-person” visits can, in most cases, be provided using telehealth and other telecommunications systems. We strongly urge CMS to afford sufficient flexibility in its application of the CPM code to allow for use of telemedicine and other forms of remote healthcare.

Certainly, there are times when a patient will benefit from an in-person examination, especially for an initial, new patient evaluation. In addition, we understand that, once the public health emergency ends and the extension to avoid a care cliff also ends, the current exceptions to the Ryan Haight Act that allow for prescribing of controlled substances using telemedicine without an initial in-person examination will no longer apply.

Nevertheless, most chronic pain management can be conducted through telemedicine. Therefore, CMS’ proposal to require an initial visit to be conducted *in-person every month* is not necessary; it is burdensome and threatens to exacerbate health disparities and inequities.

As highlighted in the previous section, people living with pain experience a variety of barriers to care that specifically impede their ability to participate in care in-person, barriers that can be ameliorated by use of remote care services. Expanded access to telehealth during the pandemic proved invaluable for people who don’t live near their providers, or who have chronic conditions like pain that make in-person visits challenging, or those who experience significant transportation barriers, or whose work or childcare obligations made juggling such appointments infeasible. The vast uptick in use of telehealth services across-the-board during the public health emergency, with Medicare beneficiaries using 88 times more telehealth services than before the pandemic, attests to the utility of remote services in encouraging health care use.[[5]](#footnote-5)

Even as expansion of telehealth stands to improve access to services for many historically-disadvantaged groups, a digital divide remains: not everyone has access to broadband, a home computer, or the digital literacy to utilize video telehealth services. It is important not to entrench existing inequities stemming from poverty, geographic location, itineracy, or age, while expanding access to remote services. Special privacy considerations may also arise when appointments take place at home, such as situations involving domestic violence or where children may overhear delicate medical information. Some services may still need to be provided remotely using audio-only care, and some in-person.

The best way forward is for CMS to build sufficient flexibility into its coding for CPM to enable greater use of telemedicine and remote care, while understanding that in-person visits will at times be needed. Chronic Pain Management stands to improve the health of people with chronic pain, but only if those services are utilized.

1. *Inclusion of Validated Pain Scales and a Pain Scale Registry.*

In response to a fundamental gap it identified, one of the National Pain Strategy (NPS)’s goals was to develop standardized, consistent, and comprehensive tools for pain assessment. Unfortunately, like much of the NPS, that goal has not yet been put into action, which means that the gap remains. Just because a tool has been validated does not mean that it is optimal, especially when applied to chronic pain. Historically, use of the Numerical Rating Scale in chronic pain proved problematic. Not all assessment tools are created equal, and even commonly used, validated measurement tools can perpetuate well-documented bias against historically-disadvantaged groups in pain assessment.[[6]](#footnote-6)

The best tools for chronic pain assessment typically involve not merely measures of pain intensity but of pain interference, its impact on function, activities of daily living, emotional and psychological health, and on a patient’s perception of their quality of life. Both objective and subjective measures, and the use of tools that are health literate for the patient being examined, are important in ensuring patient-centered care. Before mandating use of any “validated” pain scale or creating a registry of such scales, we urge CMS to undertake further inquiry, either by assembling a stakeholder group, issuing a Request for Information (RFI), or by some other means, to conduct a landscape analysis of validated tools as applied to chronic pain.

1. *Frequency and Duration of Proposed Services.*

The frequency and duration of permitted CPM visits must be sufficiently flexible to account for a variety of practice types—which range from primary care to specialized clinics offering intensive and integrated chronic pain management services. CPM codes must also accommodate different intensities of patient need: some patients may require appointments of longer duration or at greater frequencies; some will have lower intensity needs; and many will have higher needs at some points in their care than at others.

Our professional experts generally consider the durations (of 30 and 15 minutes, respectively) as well as the proposed frequency of visits to be too limited to adequately account for the demands of chronic pain management.

Some appointments for chronic pain management will need to be longer than 30 minutes. In addition to 30 minutes being inadequate for patients with significant needs, too short a time frame for appointments could also lead to over-diagnosis if clinicians do not have sufficient time to make a proper evaluation. Similarly, a 15 minute visit is likely to be adequate only for very basic care like refilling a prescription. One way to accommodate variability in time frames needed might be to permit GYYY1 and GYYY2 to be billed on the same billing day, thereby allowing providers to structure appointments of longer duration (30 minutes plus another 15, if those durations remain) as well as shorter appointments, where appropriate.

Arbitrary limits on the frequency of visits per month is also potentially problematic. Most patients will not require multiple visits in a month, but those in an intensive chronic pain management program, or those undergoing opioid tapering, for example, are likely to.

We urge CMS to allow maximum flexibility, while at the same time ensuring that beneficiaries are informed and protected when it comes to the cost of care. Obtaining consent for services extends the time required for patient visits, yet it essential that patients be fully informed of their potential out-of-pocket costs and the possible benefits of care focused on chronic pain management. Sufficient time must be added to whatever duration CMS determines for this process. So long as adequate protections for consent are in place, we recommend that CMS not place arbitrary limits on the duration or frequency of permitted visits.

Finally, we wish to reiterate our earlier point that CMS should carefully reconsider the interplay of its proposed CPM codes with current time-based codes for E/M visits and the values assigned to each.

In closing, we sincerely thank you for your efforts to recognize the importance of ensuring quality care for the tens of millions of Americans living with chronic pain. We also thank you for your consideration of our comments.

Sincerely,

Kate M. Nicholson

Kate M. Nicholson

1. *See* CMS Machine Learning Network, MLN909188, March 2022; <https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf>; *see also*, National Association of Community Health Centers, Tips for Reimbursement (for CCM and PCM) <https://www.nachc.org/wp-content/uploads/2020/04/Payment-Reimb.-Tips_CCM-April-2021.pdf> (CCM and PCM services are typically provided outside of face-to-face visits). [↑](#footnote-ref-1)
2. Webster F, Rice K, Katz J, Bhattacharyya O, Dale C, Upshur R, An ethnography of chronic pain management in primary care: The social organization of physicians’ work in the midst of the opioid crisis (2019). PLoS ONE 14(5): e0215148. <https://doi.org/10.1371/journal.pone.0215148>. (Treating chronic pain is “challenging at best, and at worst frustrating and overwhelming. In many instances, [the providers’] narratives suggested experiences of depersonalization, loss of job satisfaction and emotional exhaustion in relation to providing care for these patients, key dimensions of burnout). [↑](#footnote-ref-2)
3. Lagisetty, P, Macleod, C, Thomas, J Slat, S, Kehne, A, Heisler, M, Bohnert, A,Bohnert, K, Assessing reasons for decreased primary care access for individuals on prescribed opioids: an audit study. PAIN: May 2021 - Volume 162 - Issue 5 - p 1379-1386 doi: 10.1097/j.pain.0000000000002145 and Lagisetty P, Healy N, Garpestad C, Jannausch M, Tipirneni R, Bohnert A, Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. *JAMA Netw Open.* 2019;2(7):e196928. doi:10.1001/jamanetworkopen.2019.6928. *See also* Gavin, K. University of Michigan Health Lab Blog, Pain Patients Who Take Opioids Can’t Get in the Door at Half of Primary Care Clinics, January 25, 2021

<https://labblog.uofmhealth.org/industry-dx/pain-patients-who-take-opioids-cant-get-door-at-half-of-primary-care-clinics>. [↑](#footnote-ref-3)
4. Quest Diagnostics, Center for Addiction, Health Trends: Drug Misuse in America 2019, Physician Perspectives and Diagnostic Insights on the Evolving Drug Crisis, <https://mma.prnewswire.com/media/1011170/Quest_Diagnostics___Health_Trends_Report.pdf?p=original> [↑](#footnote-ref-4)
5. #  Report, Department of Health and Human Services, Office of Inspector General Telehealth Was Critical for Providing Services to Medicare Beneficiaries During the First Year of the COVID-19 Pandemic, OEI-2-20-00520, March 15, 2022. <https://oig.hhs.gov/oei/reports/OEI-02-20-00520.asp>

 [↑](#footnote-ref-5)
6. *See*, *e.g.,* Hoffman K, Trawalter S, Axt J, et. 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. <https://doi.org/10.1073/pnas.1516047113> [↑](#footnote-ref-6)