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The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Comment on The Centers for Medicare & Medicaid Services (CMS) Proposed Rule: CY 2023 Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies (CMS-1770-P) Section 33, page 214: Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1, and GYYY2)

Dear Administrator Brooks-LaSure:

The U.S. Pain Foundation is pleased to provide comments on the CMS Proposed Rule: CY 2023 Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies (CMS-17701-P). We are commenting on Section 33 of the PFS, the Chronic Pain Treatment and Management (CPM) Bundles (HCPCS GYYY1 and GYY2).

The U.S. Pain Foundation is a national nonprofit 501(c)(3) organization for people who live with chronic pain from a myriad of diseases, conditions, and serious injuries. Our mission is to empower, educate, connect, and advocate for those living with pain, as well as their caregivers and health care providers.

The U.S. Pain Foundation enthusiastically supports CMS's decision to create separate coding and payment for chronic pain management (CPM) services beginning January 1, 2023. As we stated in our PFS comment last year, we believe a standalone code will best serve patients, clinicians and CMS. Chronic pain management is complex and there are no existing codes that account for all the tasks required to care for a patient with chronic pain. A standalone code will signal to physicians that when patients have complaints of pain that it is critical to take them seriously, conduct a thorough pain assessment, and develop a comprehensive plan of care.

Further, a standalone code would allow CMS to begin to capture the salience and prevalence of chronic pain as a primary diagnosis, as well as to better understand the types of provider activities required to effectively manage and improve the care of these patients. We would expect that the amount of care required, and consequently the cost of this care to the Medicare system, to be large and increasing given the aging American population and the prevalence of age-associated chronic pain conditions like arthritis, cancer, and diabetic neuropathy. However, without a standalone code, CMS has not been able to capture claims data on the scope of chronic pain in the Medicare population nor properly attribute and account for its costs. It could be argued that the lack of such critical data has contributed to the poor state of pain care and treatment in the U.S. It is impossible to fix a problem that you don't know you have. Without the data to better understand the problem of chronic pain in America, it is difficult to design and measure policies to ameliorate the problem.



We are pleased that CMS is taking this critically important policy step in creating separate codes for chronic pain management.

Our specific comments on Section 33 including answers to CMS questions are below.

Definition of chronic pain and allow chronic pain as a primary diagnosis

CMS has proposed to define chronic pain as “persistent or recurrent pain lasting longer than three months.” We strongly agree with this definition in terms of duration and description. Authoritative definitions of chronic pain (IASP, ICD-11, CDC) of the past five years have coalesced at longer than *three* months duration. In the International Classification of Disease, 11th edition (ICD-11)¹, chronic pain has been further classified as *chronic primary pain* which is its own diagnosis independent of an underlying disease or condition and *chronic secondary pain* where pain may, at least initially, be viewed as secondary to an underlying disease.

Furthermore, neuroscience research has now shown that once pain continues past 3 months it transitions to chronic pain and can be considered a disease itself with measurable changes in the brain, spinal cord, and peripheral nervous system that can last years or a lifetime regardless of the original etiology²³ – whether a disease such as cancer or diabetes, an injury, another condition, or an unknown etiology. Consequently, “chronic pain” **can be** a primary diagnosis.

CMS has included “diagnosis” as a service in the description of the CPM code GYYY1. We think it is important for CMS to make it clear to physicians that “chronic pain” can be a diagnosis. Many physicians still do not understand that chronic pain can become its own disease of the nervous system and brain and view persistent pain that has lasted for years as a symptom of something else. They may minimize or ignore the persistent pain and instead seek a cause while the patient continues to suffer and receive inadequate treatment. Certainly, testing to look for solvable problems that may not yet have been conducted with a patient may be appropriate. However, once all appropriate and reasonable tests have been completed and obvious treatments have been tried and yet the pain persists, CMS needs to make clear to physicians that “chronic pain” **is** a primary diagnosis for many patients and further testing is unnecessary and wasteful. There is no cure for chronic pain, at present. We still do not understand the basic neurobiological mechanism of pain in the human body. Chronic pain is a *chronic* disease that must be managed.

Lengthen Duration of visits for new HCPCS codes GYYY1 and GYYY2

We believe CMS has done an excellent job in elucidating the numerous services clinicians should perform in order to develop an individualized, multidisciplinary treatment plan considered best practice as described by the Congressionally-mandated HHS Pain Management Best Practices Interagency Task Force (PMTF). We support CMS’s view that monthly appointments are typically needed to conduct the services described by CMS. It could take a year or more to develop, coordinate, and revise a treatment plan that is optimal in managing a patient’s chronic pain.

¹ https://journals.lww.com/pain/Abstract/2019/01000/Chronic_pain_as_a_symptom_or_a_disease_the_IASP.3.aspx

² Clauw DJ, Essex MN, Pitman V, Jones KD. Reframing chronic pain as a disease, not a symptom: rationale and implications for pain management. *Postgrad Med* 2019; **131**: 185–98.

³ National Academy of Medicine (formerly the Institute of Medicine) Report: *Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research*. The National Academies Press, 2011. http://books.nap.edu/openbook.php?record_id=13172&page=1



We believe that the GYYY1 and GYYY2 codes should allow for longer duration visits with the treating physician than proposed by CMS. We recommend an hour for at least the first visit and 45 minutes for subsequent visits until a stable treatment plan has been developed. CMS has asked if the time allowed should be different for patients newly diagnosed with chronic pain as opposed to those with a long-term diagnosis of chronic pain. If a long-time chronic pain patient is seeing a new physician for the first time, there should be no difference in the time allowed. In fact, it would likely take longer to review the patient's history with pain, what treatments they have tried and failed, and what has helped them in the past. If a longtime chronic pain patient has been seeing a physician and continues with that physician when the new codes become available, the time and frequency required would depend on where the patient and physician are in progression toward an optimal treatment plan. Consequently, because accounting for the myriad of situations for such a vast population of pain patients in the Medicare system is nearly impossible, it would be best if CMS allowed for flexibility in the duration of visits with an upper bound being an hour and allowed for the physician to document the particular reason for the time required.

Once a plan is working for a patient, shorter duration visits of 30 minutes, or even 20 minutes, or less frequent visits are necessary. A patient may drop back to bi-monthly, quarterly, bi-annually, and then annually as long as his or her pain is being managed effectively.

Of course, patients' lives and medical conditions change which may necessitate changes to a treatment plan that at times, will require longer – perhaps 45 minutes again and more frequent visits to the clinician. Pain flares, relapses, and the development of new symptoms and conditions could all require major or minor changes to a treatment plan. It is well documented that many people living with chronic pain go on to develop additional comorbid pain conditions and these could require new medications and therapies. As stated earlier, there is no cure for chronic pain so once it develops, especially high-impact chronic pain, it usually lasts a lifetime, which could be decades in individuals who are afflicted early in life. This means that these conditions require active, long-term management and adaptations in treatments and lifestyle as individuals age.

Consequently, it is imperative that CMS allow clinicians the flexibility to use the new CPM codes GYYY1 and GYYY2 for any of the services listed, in any order and over any time period that the clinician deems appropriate to best manage a patient's pain condition(s). This flexibility should also allow for the omission of certain services when they are deemed inappropriate by the clinician or not desired by the patient (eg. medication or behavioral counseling) and the addition to the treatment plan of other services not described by CMS such as restorative therapies like massage therapy or therapeutic exercise programs and complementary and integrative services like acupuncture, tai chi, yoga, and mindfulness meditation even though these services may not be currently covered by CMS. This means that clinicians should be allowed to bill for time coordinating any additional services recommended by the clinician, especially all the treatments listed in the PMTF report, even though CMS may not cover these services.

Although CMS did not mention it, we assume that clinicians will be able to bill the new codes for the coordination of and communication with other specialists and services that may be included in the treatment plan such as interventional procedures, spinal cord stimulators, and other implantable medical devices and surgeries that *are* covered by CMS.

Pain and health literacy counseling is essential

We are pleased that CMS has listed pain and health literacy counseling as one of the services included in the new CPM CPT codes. We strongly agree with CMS that health literacy counseling as defined by CMS enables beneficiaries with chronic pain to make well-informed decisions about their care, increases their pain knowledge, strengthens their self-management skills and has a positive effect on health outcomes. However, health literacy counseling for pain management is rarely performed by physicians. Sadly, most physicians have very little understanding of how to effectively manage and treat chronic pain and it is well-documented that physicians graduating from American medical schools receive inadequate, if any, education in pain management in graduate medical training. A systematic review of pain medicine education at medical schools internationally conducted in 2018 found that 96% of U.S. medical schools had no compulsory, dedicated education in pain medicine.⁴ We agree with CMS that health literacy counseling is important, even essential in learning to effectively navigate the challenges that chronic pain poses to individuals' lives. However, we are concerned that if CMS includes this component in the list of services for physicians to provide, that it will not be offered to most patients or it will be inadequately conveyed. We would prefer that CMS specify that it must be offered to patients by those that specialize in teaching these skills and information.

CMS has asked whether there are components of the CPM services listed that could be provided by auxiliary staff incident to the billing practitioner. We believe that health literacy counseling as described by CMS is one of those services. In some physician practices, psychologists, clinical social workers, or nurses conduct health literacy counseling about general health maintenance such as medication and treatment plan regimens, diet, and exercise. Sometimes these providers teach health literacy around common chronic conditions like diabetes or heart disease. It is extremely rare for these providers to have an understanding of how to manage chronic pain. However, they could be taught by psychologists, clinical social workers or nurses that do specialize in pain management to effectively teach pain health literacy.

Typically, psychologists, clinical social workers, or nurses who are skilled in conducting health literacy counseling in pain management are employed by pain clinics, usually connected to hospitals although there are some in private practice. Primary care physicians who do treat the large majority of chronic pain patients could possibly send patients to these specialized professionals and coordinate their care as they would for other providers like physical therapists. However, it is clear that their numbers are inadequate to support the millions of Americans living with chronic pain.

In our experience, the most effective and efficient way to increase pain health literacy in the large population of those living with chronic pain is through networks of chronic pain support groups that are led by specially trained social workers, counselors or lay persons who themselves live with chronic pain and receive on-going leader coaching and education by very experienced, expert leaders. We have used this model with great success at the U.S. Pain Foundation establishing and training a network of leaders around the country who have helped hundreds of chronic pain patients learn important skills to use in taking an active, positive role in managing their conditions.

⁴ <https://link.springer.com/article/10.1007/s40122-018-0103-z>



Unfortunately, there is very little funding available to scale up this successful model of pain management health literacy to reach the thousands and perhaps millions of CMS beneficiaries who could benefit from such groups. The PMTF report has recommended pain management patient education programs using support group models such as the one described here. CMS has stated in the PFS, *“We are interested in hearing from commenters about how pain and health literacy counseling is or may be effectively used as a service element to help beneficiaries with chronic pain make well-informed decisions about their own care, weigh risks and benefits, make decisions, and take actions that are best for them and their health.”*

As previously stated, we believe that health literacy education and counseling is a fundamental and essential component in learning to cope with a condition as devastating and challenging as chronic pain. CMS could make great strides in advancing positive health outcomes for those suffering with chronic pain by providing funding for non-profit groups specializing in chronic pain management to establish and grow networks of educational and skill-based support groups led by trained facilitators.

Clarify which health care professionals can bill using these codes

CMS has stated that the new codes can be billed by a “physician or other qualified health care professional”. We agree that physicians, including primary care physicians, board certified pain management specialists, neurologists, anesthesiologists, board-certified headache specialists, rheumatologists, osteopaths, and other physician specialists that focus on pain conditions should be able to bill the new CPM codes. We assume by “other qualified health care professionals” that CMS means nurse practitioners specialized in pain management with independent prescription authority or physicians’ assistants specialized in pain management. We urge CMS to clearly clarify the use of this term.

Other health care professionals that commonly treat people with chronic pain include physical therapists and psychologists. However, these professionals are not qualified to perform all the necessary services CMS has outlined such as thorough pain assessments and diagnoses, medication management, crisis care, etc.

These professionals perform services that may be part of an overall pain treatment plan and we would expect the treating physician to use the new CPM codes for time spent communicating with and coordinating the services of these professionals. There does not appear to be a way for professionals such as physical and occupational therapists and psychologists, mental health counselors or clinical social workers who provide services to pain patients that are part of an overall pain management treatment plan to bill for services as part of or connected to the new CPM CPT codes. In order to capture data accurately regarding what services are used for chronic pain management and how effective these services are in helping patients with particular pain conditions better control their pain, it is important for CMS to create a way for these professionals to bill using some type of chronic pain management code. We urge CMS to establish a path whereby non-physician professionals can bill a chronic pain code for services that are part of an overall treatment plan so as to accurately capture these services in the overall cost of care and document the techniques they have used and their effectiveness for patients with specific pain conditions or types of pain.

Payment for physicians using these codes must be higher than primary care visits

As acknowledged by CMS, treating chronic pain patients can be difficult and time-consuming. In recent years, since the release of the CDC Guideline for Prescribing Opioids, for those taking opioid medications or for those



who were forced off opioid medications, the relationship between providers and patients has become fraught, tense, stigmatizing for patients and risky for physicians. For all these reasons, many physicians have refused to treat chronic pain patients or have terminated chronic pain patients from their practices.⁵ We hear weekly from patients who are unable to find physicians to treat them, even if they do not take opioid medications.

In order for physicians to be willing to treat chronic pain patients, especially primary care physicians, who because of the huge number of Americans with chronic pain must see the vast majority of these patients, CMS needs to make physician payments for the new CPM codes higher than primary care visits. As we understand it, CMS is proposing to pay physicians for the GYYY1 and GYYY2 codes at comparable rates to the Principal Care Management (PCM) codes. This would mean that the new CPM codes would pay physicians less than they get paid for a standard follow-up clinical visit for primary care (CPT code 99214 for 30 min clinical visit). If that is the case, we strongly recommend that CMS consider raising these rates before the new CPM codes go into effect or physicians will not use them, and CMS's important work on these codes will not accomplish the intended improvements in pain care that Medicare patients so desperately need and that CMS is seeking. Further, if physicians are not incentivized to use the new CPM codes as stated, they will be more likely to use the higher value, less work required codes and CMS will not be able to accurately track chronic pain usage and outcomes.

Medicare telehealth flexibilities have dramatically increased access to care and CPM codes should be added to the Medicare Telehealth Services List

In the summer of 2020, 5 months after the start of the pandemic, the U.S. Pain Foundation conducted a survey to which a total of 1,581 individuals living with chronic pain (defined for this study as persistent pain lasting 6 months or more) across all 50 states and Washington DC responded. One of the most important and surprising findings from that survey, and a silver lining to the pandemic, was that telehealth parity and flexibilities had improved patient access to pain care as compared to prior to the pandemic. Slightly more than half of respondents (50.7%) said that mobility issues – difficulty driving (70.6%), difficulty with certain positions/activities (59.4%) and difficulty being upright (40%) – had previously prevented them from accessing pain care. And, an overwhelming majority of respondents, nearly 90% (89.9%), said they would like telehealth to continue beyond COVID-19. It is a tremendous burden for patients with high impact chronic pain to physically get themselves to doctor's appointments. For many, the hardship of driving, sitting in traffic, walking distances, standing in line, sitting for long periods in doctors' waiting rooms, that people without pain and physicians rarely think about, can exacerbate and intensify chronic pain enough to cause a spike in pain levels that can last days if not weeks for some.

Consequently, we cannot emphasize enough how important access to telehealth is for this particular population of Medicare patients. In the PFS, CMS stated: *"We welcome comments regarding how best the initial visit and subsequent visits should be conducted (for example, in-person, via telehealth, or the use of a telecommunications system, and any implications for additional or different coding). We will also consider whether to add the CPM codes to the Medicare Telehealth Services List, based on our review of any information provided through the public comments..."* CMS stated that due to the complexity of an initial assessment, the first visit with a physician should be in-person and subsequent visits could be via telehealth.

⁵ <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2737896>



We agree with this assessment that an in-person first visit is preferable and that subsequent visits should be permitted via video telehealth from the patient’s home or in-person.

However, because of the significant mobility difficulties patients with chronic pain confront in physically getting to an appointment, especially if the patient lives a long distance from the physician’s office, we believe initial visits should be permitted via telehealth. We recommend that CMS not make in-person first time visits an absolute requirement.

We strongly recommend that CMS add the new CPM codes, GYYY1 and GYYY2 to the Medicare Telehealth Services List.

Patient Consent Should be Required

We agree with CMS’s proposal that the beneficiary’s verbal consent to receive CPM services be required and documented in the beneficiary’s medical record but we think it is inappropriate to require the patient’s consent on the first visit. Patients should be given an opportunity to work with the physician a few times. We believe the patient’s consent should be obtained at or by the third visit rather than the initial visit. At the initial visit, physicians should be required to educate patients regarding what CPM services are, their frequency, purpose, value, and any cost sharing that may apply depending on that beneficiary’s plan. What CMS has proposed for this model of ongoing, coordinated, integrated pain care is innovative and very different from the disjointed, fragmented, solitary struggle for effective pain care that the vast majority of pain patients now experience. We think patients should be given an opportunity to understand the model and possibly discuss it and any costs involved with family members and caretakers.

At the initial visit, the beneficiary with chronic pain should be educated regarding what the CPM services are, how often they may generally expect to receive the services, and have an explanation of any cost sharing that may apply in their particular situation. In choosing to give their consent to receive CPM services from this physician, patients need to feel comfortable entrusting their care over a long period to this individual. They should not be made to consent to receive these services from a single physician on the first visit.

We believe CMS is going about this in exactly the right way - by covering monthly visits for an extended period with the same physician in order to develop a trusting partnership in which both the patient and the physician take responsibility for developing and executing the treatment plan. Doctor-patient relations in pain management care in the U.S. in recent years have become so fraught, mistrustful, and corrosive that they have led to a crisis in pain care. One need not look further than CMS’s own recently released *Journey Map of the Chronic Pain Experience* to grasp how dysfunctional and damaging the doctor-patient relationship in pain management has become.⁶ In a recently released survey of 2,275 chronic pain patients entitled “A Chronic Pain Crisis” that U.S. Pain Foundation conducted for September Pain Awareness Month 2022, 63% of chronic pain patients said they felt stigmatized by their providers.⁷ And nearly a quarter of respondents (24%) said they “never” or “rarely” felt listened to by their providers.

⁶ <https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf>

⁷ <https://uspainfoundation.org/surveyreports/a-chronic-pain-crisis/>



CMS has asked whether consent of the patient should be given at each visit and if beneficiary consent should be sought by the practitioners with whom the CPM billing physician is coordinating the patient's care. We do not think it is necessary for patient consent to be sought at each visit. One time within the first 3 months seems reasonable. However, we do support practitioners who were referred by the CPM billing physician to seek the patient's consent. It is important and reassuring for the patient to know that their various practitioners are working as a team and coordinating their care.

We are pleased that CMS recognizes the enormous challenge that chronic pain poses to the health and well-being of CMS's beneficiaries. We thank CMS for proposing separate coding for chronic pain care and hope you will take our views into consideration as you determine how best to improve health insurance coverage and care of the vast population of Americans with chronic pain who obtain their healthcare through CMS. If you have questions about our comments, please feel free to contact me using the information listed below.

Sincerely,

A handwritten signature in black ink that reads "Cindy Steinberg". The signature is written in a cursive style with a large, stylized "C" and "S".

Cindy Steinberg
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