

and 0448T. The invoices that we received from a commenter list a supply increase (SD334) from \$1500 to \$3000, which would be a supply input for both 0446T and 0448T. The invoices also list the equipment (EQ392) as having an increase in equipment minutes, but not a change in the cost of the transmitter itself. The increase in equipment minutes applies only to CPT code 0446T. The physician work remains the same for both codes, therefore there is no change to work RVUs.

In consideration of the comments and invoices received, we are finalizing changes to codes G0308, G0309, 0446T, and 0448T. G codes G0308 and G0309 will be deleted effective January 1, 2023. CPT codes 0446T and 0448T will have supply input SD334 valued at \$3,000. CPT code 0446T equipment EQ392 will have equipment minutes equal to 60 minutes * 24 hours * 30 days * 6 months / 1 out of every 5 minutes = 51,840 minutes.

(33) Chronic Pain Management and Treatment (CPM) Bundles (HCPCS G3002 and G3003, formerly GYYY1 and GYYY2, respectively)

(a) Background and Proposal

In the CY 2022 PFS proposed rule (86 FR 39104, 39179 through 39181), we solicited comments on and explored refinements to the PFS that would appropriately value chronic pain management and treatment (CPM) for the purpose of future rulemaking. In our solicitation, we described Federal efforts for more than a decade to effectively address pain management as a response to the nation's overdose crisis¹⁰, such as the National Pain Strategy¹¹ and the HHS Pain Management Best Practices Inter-Agency Task Force (PMTF) Report.¹² As we noted in our CY 2022 comment solicitation, several sections of the Support for Patients and Communities Act of 2018¹³ (SUPPORT Act) describe actions the Department of Health and Human Services has

¹⁰ <https://www.hhs.gov/overdose-prevention/>.

¹¹ https://www.iprcc.nih.gov/sites/default/files/documents/NationalPainStrategy_508C.pdf.

¹² <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>.

¹³ <https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf>.

been directed to take to improve pain care, such as section 2003, which amended Medicare’s Annual Wellness Visit¹⁴ to include a review of factors for evaluation related to pain for patients using opioid medications; section 6086, the Dr. Todd Graham Pain Management Study¹⁵; and section 6032, which required CMS to furnish a Report to Congress and develop a related Action Plan to review coverage and payment policies in Medicare and Medicaid related to the treatment of opioid use disorder and for non-opioid therapies to help manage acute and chronic pain.¹⁶ In the section 6032 Report and the Action Plan, CMS included a recommendation to explore the possibility of establishing a new bundled payment under the Medicare Physician Fee Schedule for integrated multimodal pain care that could include certain elements such as diagnosis, a person-centered plan of care, care coordination, medication management, and other aspects of pain care.

As described in Goal 3 of CMS’ 2022 Behavioral Health Strategy¹⁷ (Strategy), CMS intends to improve the care experience for individuals with acute and/or chronic pain, expand access to evidence-based treatments for acute and chronic pain, and increase coordination between primary and specialty care through payment episodes, incentives, and payment models. In late 2019, the CMS Office of Burden Reduction & Health Informatics launched the “Chronic Pain Stakeholder Engagement,” which focused on understanding access to covered treatment and services for people living with pain¹⁸. CMS recently released information gathered from interested parties through this Engagement using qualitative research methods and the human-centered design process, to uncover provider burden, and identify opportunities to improve

¹⁴ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html>.

¹⁵ <https://effectivehealthcare.ahrq.gov/products/improving-pain-management/rapid-evidence>.

¹⁶ https://www.cms.gov/sites/default/files/2022-4/SUPPORT%206032%20Action%20Plan_Final_061521_Clean.pdf.

¹⁷ <https://www.cms.gov/cms-behavioral-health-strategy>.

¹⁸ <https://www.cms.gov/About-CMS/OBRHI>.

access to covered services by illustrating the experiences of people living with, and treating, chronic pain. The intent of this project was to highlight the most prominent barriers people with pain face in accessing care, and the factors influencing clinicians that can affect people with chronic pain, the quality of their care, and their quality of life.

In the context of the Biden-Harris' Administration's commitment to equity¹⁹, and the inclusion of equity as a pillar of CMS' Strategic Vision²⁰, disparities exist in pain treatment due to bias in treatment, language barriers, cultural norms, and socioeconomic status. We are also aware that pain is a factor in suicidality and suicide, prioritized in the Surgeon General's Call to Action to Implement the National Strategy for Suicide Prevention²¹ and in HHS' work to implement "988"²², the new national dialing code for suicide and crisis assistance that was implemented nationally this year.

In coordination with all of these initiatives, we also have continued to explore refinements to the PFS that would appropriately value CPM. In the CY 2022 PFS proposed rule, we sought comment on whether we should approach CPM through a standalone code or E/M add-on coding, and about the specific activities that are involved in CPM, how we might value such a code or service, the settings where this care is provided, the types of practitioners that furnish this care, and whether the service or any components of it could or should be furnished as "incident to"²³ services under the direction of the billing practitioner by other members of the care team (86 FR 39182). We received just under 2,000 comments on this comment solicitation, including comments from provider associations, federations, and societies that represent health

¹⁹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

²⁰ <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms>.

²¹ <https://www.hhs.gov/sites/default/files/sprc-call-to-action.pdf>.

²² <https://www.samhsa.gov/find-help/988>.

²³ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0441.pdf>.

care professionals; organizations that educate, connect, and advocate for people with pain; State-based health care organizations, medical societies and associations; cancer care centers; health care companies; device manufacturers; pain care providers; and people living with pain. Almost all commenters were supportive of our efforts to carefully consider an approach to coding and payment for care for CPM. Many commenters supported the creation of separate coding and payment for CPM under the PFS. We summarized these comments, expressed appreciation for the commenters' attention to informing our approach to payment and coding for comprehensive CPM services, and thanked the commenters for their comments in the CY 2022 PFS final rule (86 FR 65129).

Generally, commenters agreed that efforts are needed to effectively support the complex needs of beneficiaries with chronic pain. Commenters emphasized that there are numerous conditions giving rise to chronic pain and that people presenting with chronic pain respond variably to various treatment modalities, and often require longer office visit times, and longer follow-up coordinating care with social workers and case managers, mental and behavioral health support, communications with emergency department physicians and nurses, and numerous medication adjustments. One commenter stated that beneficiaries with complex chronic pain conditions may require a lot of time for correct dosing of medications and counseling, and that such time is not captured effectively using existing E/M codes. This commenter also believed that separate coding and payment for chronic pain management could help with better understanding of the treatment of chronic pain than when the service is reported with existing visit codes and would allow for valuation based on the resources involved in furnishing these specific services to people with chronic pain, enhancing the likelihood of appropriate payment, especially for non-face-to-face time involved with the service.

A few commenters expressed preference for using existing E/M codes and the creation of codes to be used in conjunction with E/M codes. One commenter suggested that CMS either clarify or modify existing codes so they can support services for patients with chronic pain or significant acute pain, as well as beneficiaries with a chronic disease and a behavioral health condition, stating that using the existing codes would avoid any concerns about overpayment for patients with both a chronic disease and pain, while also making it more feasible for small practices to employ care management staff and provide customized care management services for all the patients who need them.

One commenter who was agreeable with various approaches to payment suggested that the guidelines for Cognitive Assessment and Care Plan Services code 99483 include “chronic pain syndromes” in the “assessment of factors that could be contributing to cognitive impairment” and that these codes could be reported by physicians who consult with a pain specialist about their patient’s pain. This commenter also suggested that Transitional Care Management could also potentially include pain management following inpatient care to help prevent acute pain from progressing to chronic pain. Other commenters also likened CPM services to chronic care management services. We believe that chronic care management codes, which, except for Principal Care Management, specify that the chronic condition being managed is expected to last at least one year or until death, would not properly describe the condition of many beneficiaries with chronic pain, which could potentially improve with treatment and intervention, or recur after improvement. For example, the 11th revision of the World Health Organization’s International Classification of Diseases and Related Health Problems define chronic pain as persistent or recurring pain lasting longer than 3 months.²⁴

²⁴ <https://icd.who.int/en>.

Commenters included feedback about other specific activities involved in the management of patients with chronic pain in addition to those we specified in the comment solicitation. Commenters also identified codes that CMS might examine as models for payment, either as stand-alone timed codes or monthly bundles. Commenters suggested which practitioners should be able to bill such CPM codes, which practitioners should be able to furnish CPM services incident to the services of a physician or other practitioner, and expressed views on adding CPM services to the Medicare Telehealth Services List and obtaining beneficiary consent for CPM services.

We agree with commenters who believe that E/M codes may not reflect all the services and resources required to furnish comprehensive, chronic pain management to beneficiaries living with pain. While we agree in principle that it might be appropriate to establish bundled all-inclusive coding with monthly payment for a broader set of CPM services, we do not have data at the present time on the full scope of services and resource inputs involved in care for patients with chronic pain to support development of a proposed monthly bundled all-inclusive rate. We do believe that E/M codes do not appropriately reflect the time and other potential resources involved in furnishing comprehensive CPM for beneficiaries with chronic pain. Beginning in the CY 2014 PFS final rule (78 FR 74414 through 74427), we recognized that the resources involved in furnishing comprehensive care to patients with multiple chronic conditions are greater than those required to support care in a typical E/M service. In response, we finalized a separately payable HCPCS code G0316 (*Chronic Care Management (CCM) services furnished to patients with multiple (2 or more) chronic conditions expected to last at least 12 months, or until the death of the patient; 20 minutes or more per in 30 days of chronic care management services provided by clinical staff and directed by a physician or other qualified health care practitioner*).

The following year, in the CY 2015 PFS final rule (79 FR 67715 through 67730), we refined aspects of the existing CCM policies and adopted separate payment for CCM services under CPT code 99490 (*Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; Comprehensive care plan established, implemented, revised, or monitored*). In the CY 2017 PFS final rule (81 FR 80244), we adopted CPT codes 99487 (*Complex chronic care management (CCCM) services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) and 99489 (*CCCM services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*). Then, in the CY 2019 PFS final rule (83 FR 59577), we adopted a new CPT code, 99491 (*CCM services, provided personally by a physician or other*

qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored), to describe at least 30 minutes of CCM services performed personally by a physician or NPP. In the CY 2020 PFS final rule (84 FR 62690), we established payment for an add-on code to CPT code 99490 by creating HCPCS code G2058 (CCM services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month). We also created two new HCPCS G codes, G2064 and G2065 (84 FR 62692 through 62694), representing comprehensive services for a single high-risk disease (that is, principal care management). In the CY 2021 PFS final rule (85 FR 84639), we finalized a RUC-recommended replacement code for HCPCS code G2058 with the identical descriptor, CPT code 99439, and assigned the same valuation as for G2058. For CY 2022, the RUC resurveyed the CCM code family, including CCCM and Principal Care Management (PCM), and added five new CPT codes: 99437 (CCM services each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)), 99424 (PCM services for a single high-risk disease first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month), 99425 (PCM services for a single high risk disease each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)), 99426 (PCM, for a single high-risk disease first 30 minutes of clinical staff time directed by physician or other

qualified health care professional, per calendar month), and 99427 (PCM services, for a single high-risk disease each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)).

The CCM/CCCM/PCM code family now includes five sets of codes, each set with a base code and an add-on code. The sets vary by the degree of complexity of care (that is, CCM, CCCM, or PCM), who directly performs the services (that is, clinical staff, or the physician or NPP), and the time spent furnishing the services. The RUC-recommended values for work RVUs and direct PE inputs for these codes in CY 2022 were derived from a recent RUC specialty society survey. We proposed to accept the RUC-recommended values, considered public comments, and finalized the proposed values for the 10 CCM/CCCM/PCM codes.

In consideration of the supportive comments we received last year in response to our comment solicitation, clinical expertise within CMS, and internal input from CMS staff and from our HHS operating division partners, we proposed to create separate coding and payment for CPM services beginning January 1, 2023. We recognize that there is currently no existing CPT code that specifically describes the work of the clinician who performs comprehensive, holistic CPM. We also believe the resources involved in furnishing CPM services to beneficiaries with chronic pain are not appropriately recognized under current coding and payment mechanisms. As noted above, we do not believe that E/M codes and values appropriately reflect time involved in furnishing CPM for beneficiaries with chronic pain. CMS has authority under section 1848 of the Act to establish codes that describe services furnished by clinicians and suppliers that bill for physicians' services, and to establish payment amounts for those services that reflect the relative value of the resources involved in furnishing them. We also expect that creating separate coding

and payment for CPM will help facilitate the development of data regarding the prevalence and impact of chronic pain in the Medicare population, where conditions including osteoarthritis, cancer, and other similar conditions that cause pain over extended periods of time are common²⁵. Such information can assist us in identifying potential coding and valuation refinements to ensure appropriate payment for these services. We also believe that the comprehensive care management involved in CPM services may potentially prevent or reduce the need for acute services, such as those due to falls²⁶ and emergency department care²⁷ associated with chronic pain – for example, sickle cell disease or migraine pain - and also have the potential to reduce the need for treatment for concurrent behavioral health disorders, including substance use disorders. There is some evidence that addressing chronic pain early in its course may result in averting the development of “high-impact” chronic pain²⁸ in some individuals; these people report more severe pain, more difficulty with self-care, and higher health care use than others with chronic pain.

There are various definitions for chronic pain from, for example, the Centers for Disease Control and Prevention²⁹ and the National Institutes of Health³⁰, and in the Institute of Medicine’s (IOM) “Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research”³¹, and in the World Health Organization International Classification of Disease Edition 11, – most define chronic pain consistently, with some variation, as pain that persists longer than 3 months. The CDC, for example, has defined chronic pain within its 2016 opioid prescribing Guideline as “pain that typically lasts >3 months or past the time of normal

²⁵ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.

²⁶ <https://www.cdc.gov/falls/facts.html>.

²⁷ <https://effectivehealthcare.ahrq.gov/products/improving-pain-management/rapid-evidence>.

²⁸ <https://www.sciencedirect.com/science/article/pii/S1526590018303584?via%3Dihub>.

²⁹ <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>.

³⁰ <https://www.nccih.nih.gov/research/research-results/prevalence-and-profile-of-high-impact-chronic-pain>.

³¹ <https://www.ncbi.nlm.nih.gov/books/NBK92525/#ch1.s3>.

tissue healing, and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause.” For clarity and operational use, we proposed to define chronic pain as “persistent or recurrent pain lasting longer than 3 months.” We welcomed comments from the public regarding whether this was an appropriate definition of chronic pain, or whether we should consider some other interval or description to define chronic pain. We were also interested in hearing from commenters about how the chronic nature of the person’s pain should be documented in the medical record.

We posited a monthly payment approach may also be more financially straightforward from the standpoint of beneficiaries receiving treatment for chronic pain, particularly with respect to applicable coinsurance, which is generally 20 percent of the payment amount, after the annual Part B deductible amount is met³².

Beginning for CY 2023, we proposed to create two HCPCS G-codes to describe monthly CPM services. The codes and descriptors for the proposed G-codes are:

- HCPCS code G3002: *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/or 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, e.g. physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a*

³² <https://www.medicare.gov/what-medicare-covers/what-part-b-covers>.

physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.)

- HCPCS code G3003: *Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month. (List separately in addition to code for G3002. When using G3003, 15 minutes must be met or exceeded.)*

We were interested in hearing from commenters regarding our proposed inclusion of “administration of a validated pain assessment rating scale or tool,” as an element of the proposed CPM services, and including it within the descriptor of the proposed HCPCS code G3002. We also solicited comment on whether a repository or list of such tools would be helpful to practitioners delivering CPM services.

We proposed to include, as an element of the CPM codes, the development of and/or revisions to a person-centered care plan that included goals, clinical needs, and desired outcomes, as outlined above and maintained by the practitioner furnishing CPM services.

We proposed to include health literacy counseling as an element of the CPM codes, because we believe it will enable beneficiaries with chronic pain to make well-informed decisions about their care, increases pain knowledge, and strengthens self-management skills. Health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.³³ Adequate health literacy may improve the person’s capability to take responsibility for their health, including pain-related health issues such as adherence to treatment regimens and

³³ <https://health.gov/healthypeople/priority-areas/health-literacy-healthy-people-2030#:~:text=Health%20literacy%20is%20a%20central,well-being%20of%20all.%E2%80%9D>

medication administration, and have a positive influence on health outcomes, and health disparities. CMS' Network of Quality Improvement and Innovation Contractors have used health literacy counseling to improve health counseling³⁴, and health literacy counseling has been used to treat arthritis.³⁵ We noted in the proposed rule that we were 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.

For HCPCS code G3002, we proposed to include an initial face-to-face visit of at least 30 minutes, provided by a physician or other qualified health professional, to a beneficiary who has chronic pain, as defined above, or is being diagnosed with chronic pain that has lasted more than 3 months at the time of the initial visit. After consultation with our medical officers, we believe the management of a new patient with chronic pain would involve an initial face-to-face visit of at least 30 minutes due to the complexity involved with the initial assessment. We believe follow-up or subsequent visits could be non-face to face. HCPCS code G3003 describes an additional 15 minutes of CPM and treatment by a physician or other qualified health care professional, per calendar month (listed separately in addition to G3002). We solicited comment on the appropriateness of the proposed 30-minute duration per calendar month for G3002, and also on the proposed duration and frequency for G3003. We also solicited comment on whether we should consider specifying a longer duration of time for G3002 (for example, one hour - or 45 minutes). Similarly, we solicited comment on whether we should consider specifying a longer duration of time for G3003 (for example, 20-minute increments). We also welcomed comment

³⁴ <https://qi.ipro.org/health-equity/health-literacy/>.

³⁵ <https://www.ahrq.gov/health-literacy/improve/precautions/1stedition/tool3.html>.

on our proposal to permit billing of CPM services for beneficiaries who have already been diagnosed with chronic pain, and for people who are being diagnosed with chronic pain during the visit.

We welcomed 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 also considered whether to add the CPM codes to the Medicare Telehealth Services List, based on our review of any information provided through the public comments and our analysis of how these new services may be appropriately furnished to Medicare beneficiaries. We also requested comment regarding whether there are components of the proposed CPM services that do not necessarily require face-to-face interaction with the billing practitioner, such as care that could be provided by auxiliary staff incident to the billing practitioner's services. For any components that could be furnished incident to the services of the billing practitioner, we requested comment on whether these could be appropriately furnished under the general supervision of the billing physician or non-physician practitioner (NPP), for example, administration of a pain rating scale or tool, or elements of care coordination, as we have provided for certain care management services.

We believe that most CPM services would be billed by primary care practitioners who are focused on long-term management of their patients with chronic pain. As calls for improved pain management have increased in recent years, this has resulted in better education and training of primary care practitioners and heightened awareness of the need for pain care nationally. We believe the codes we proposed for CPM services will create appropriate payment for physicians and other practitioners (beyond primary care practitioners) that reflects the time and resources involved in attending comprehensively to the needs of beneficiaries with chronic

pain. As the IOM “Blueprint” report noted, even people who need consultation with a pain specialist should benefit from the sustained involvement of a primary care practitioner who is able to help coordinate care across the full spectrum of health care providers, as such coordination “helps prevent people from seeking relief from multiple providers and treatment approaches that may leave them frustrated and angry and worse off both physically and mentally, and from falling into a downward spiral of disability, withdrawal, and hopelessness.”³⁶ The Blueprint stated that this type of fragmentation hinders the development of a strong, mutually trusting relationship with a single health professional who takes responsibility, and that this established relationship is one of the keys to successful pain treatment. We anticipated that if these proposed codes are finalized, primary care practitioners will employ a variety of person-centered pain management strategies, such as those suggested in the PMTF Report and illustrated in CMS’ CPM graphic³⁷ including medications, therapies, exercise, behavioral health approaches, complementary and integrative health, and community-based care based on the complexity, goals, and characteristics of each person they serve with chronic pain and according to the person-centered plan of care. It is also important to note that, in many parts of the country, people have access only to their primary care practitioner for chronic pain care.³⁸ We understand, however, the need or desire that some individuals with chronic pain have to be seen on an ongoing basis for CPM by a pain specialist who has received special training and/or certification to meet the needs of the most complex and challenging patients with chronic pain.

Therefore, we proposed to permit billing by another practitioner after HCPCS code G3002 has already been billed in the same calendar month by a different practitioner. In these

³⁶ <https://www.ncbi.nlm.nih.gov/books/NBK91497/>.

³⁷ <https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf>.

³⁸ <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>.

situations, we anticipate that there could be occasional instances where care of an individual with chronic pain is transferred to a pain specialist or other specialist during the same month they received the CPM services from a primary care practitioner, for ongoing care. In these or other situations (such as when the beneficiary elects to choose a different physician or practitioner to furnish CPM services), we would anticipate G3002 and potentially G3003 could be billed by another practitioner during the same month, for the same beneficiary. We believe that it would be unlikely for G3002 to be billed more than twice per month under such circumstances and proposed placing a limit on the number of times the code could be billed per beneficiary per calendar month, at a maximum of twice per calendar month. We solicited comment on our proposal to permit billing by another practitioner after the G3002 has already been billed in the same month by a different practitioner, and on the number of times the code could be appropriately billed per month, per beneficiary.

We proposed to require that the beneficiary's verbal consent to receive CPM services at the initiating visit be documented in the beneficiary's medical record, as not all Medicare beneficiaries with chronic pain eligible to receive these separately billable CPM services may understand or want to receive these services, and the beneficiary should be aware that they are receiving them. 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. Practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of similar care management services, such as CCM services, and we solicited comment on how best to effectively educate both practitioners and beneficiaries with chronic pain about the existence of, and the benefits and value of, the proposed CPM services. We solicited comment regarding

whether the initiating visit is the appropriate time for billing practitioners to obtain beneficiary verbal consent, if consent should be given at each visit, and also if beneficiary consent should be sought by the practitioners with whom CPM billing practitioners coordinate other Medicare services under the CPM plan of care, or even more broadly.

We believe there might be some potential for duplicative payment for services allocated to the same patient concurrent with certain other Medicare care management services, such as CCM or behavioral health integration (BHI) services; however, we believe the proposed CPM codes have features that would mitigate such circumstances, such as the elements of the service that specifically address the beneficiary's pain – for example, the administration of a validated pain rating scale or tool. We welcomed comments regarding what, if any, Medicare services we should consider that could not be billed by the same practitioner for the same patient concurrent with any other Medicare services, to avoid duplication of payment, and help limit financial burden to the Medicare beneficiary with chronic pain. We noted that we would expect to refine these codes as needed through future rulemaking as we receive more information how the codes are being used, and how they are implemented in practice.

To the extent that components of the proposed CPM codes are also components of other care management services, we reiterate our policy against double-counting time and require that the time used in reporting CPM services may not represent time spent in any other reported service. We proposed that the CPM codes could be billed in the same month as a care management service, such as CCM, or BHI. We believe there are circumstances in which it is reasonable and necessary to provide both services in a given month, based on the needs of the Medicare beneficiary with chronic pain, for example, when the beneficiary has both chronic pain, and a mental disorder(s), or multiple chronic conditions. We also proposed that the CPM

codes would be able to be billed for the same Medicare patient in the same month as another bundled service such as HCPCS Codes G2086-G2088, which describe bundled payments under the PFS for opioid use disorders. We noted that patient consent would need to be obtained for both of the bundled services such as, for example, CPM and BHI, and all other requirements to report CPM and to report the other service or services would need to be met. We invite comments on these billing proposals and their appropriateness in the context of CPM.

Finally, we questioned commenters whether we should consider creating additional coding and payment to address acute pain. We are interested in information regarding a definition for acute pain, standalone or E/M coding, the specific activities that could be furnished, how we might value and price such a code or service, the settings where care should be provided, the types of practitioners that should furnish acute pain care, if the service or any components should be furnished as “incident to” services under the direction of the billing practitioner or by other members of the care team, and other information that might help us in proposing such a code or codes.

(b) Valuation of Chronic Pain Management Services

Consistent with the valuation methodology for other services under the PFS, proposed HCPCS codes G3002 and G3003 would be valued based on what we believe to be a typical case, and we understand that, based on variability in patient needs, some patients will require more resources, and some fewer. The proposed CPM codes would separately pay for a specified set of CPM elements furnished during a month, including the administration of validated rating scales, establishment and review of a person-centered care plan that includes goals, clinical needs, and desired outcomes, and other elements as described in the proposed code descriptors. To value CPM, we compared the proposed services to codes that involve care management. In doing so,

we concluded that the CPM services were similar in work (time and intensity) to that of PCM in that both the PCM codes and proposed CPM codes reflect services that have similar complexities, possible comorbidities, require cognitive time on the part of the practitioner, and may involve coordination of care across multiple practitioners.

For HCPCS code G3002, we developed proposed inputs using a crosswalk to CPT code 99424 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month.*), which is assigned a work RVU of 1.45. Additionally, for G3002 we proposed to use a crosswalk to the direct PE inputs associated with CPT code 99424. We believe that the work and PE described by this crosswalk code is analogous to the services described in G3002, because G3002 includes similar *care plan, medication management, unusually complex clinical management; care coordination between relevant practitioners furnishing care; and time for care provided personally by a physician or other qualified health care professional*, as described in CPT code 99424.

We proposed to value G3003 at a work RVU of 0.50, using a crosswalk to CPT code 99425 (*each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*) (*List separately in addition to code for G3002*), which is

assigned a work RVU of 1.00. However, the required minimum number of minutes described in G3003 is half of the number of minutes in CPT code 99425. For HCPCS code G3003, we proposed to use a crosswalk to half of the direct PE inputs associated with CPT code 99425. We believe that the work and PE described by this crosswalk code is analogous to the services described in G3003, because G3003 includes similar activities as described in CPT code 99425.

We proposed that G3002 can only be billed when the full 30 minutes of service time has been met or exceeded. Additionally, we proposed that the add-on code (G3003) can only be billed when the full 15 minutes of service time is met or exceeded.

Our proposed valuation of CPM services includes services that are personally performed by a physician (or other appropriate billing practitioner, such as a nurse practitioner (NP) or physician assistant (PA)) described by certain E/M visit codes that apply to a new patient in various settings. Accordingly, we proposed that G3002/G3003 must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same date of service as CPT codes 99202– 99215 (*Office/outpatient visits new*), since these codes reflect face-to-face services furnished by the physician or other billing practitioner for related, separately billable services that are being furnished to a patient the practitioner has not previously seen. 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, or a visit where the person is being seen for some other illness or condition. We do not believe that the services included in G3002/G3003 would significantly overlap with CCM services; Transitional Care Management (TCM) services; or BHI services, which have various clinical purposes separate from CPM. We do believe there is likely overlap in the Medicare beneficiary population eligible to receive CCM, TCM, BHI, and the proposed CPM services, but we believe there are distinctions in the

nature and extent of the assessments, care coordination, medication management, and care planning for CPM to allow concurrent billing for services that are medically reasonable and necessary, and that it is particularly important to allow for the provision of needed services, including behavioral health services, to beneficiaries with chronic pain. We solicited comment on whether we have appropriately identified the codes Medicare should not pay if furnished during the same day as the proposed CPM codes, and if there are circumstances where multiple care planning codes could be furnished without overlap or other situations, such as where the practitioner is seeing a new patient.

We noted that the proposed CPM codes would be limited to beneficiaries in office or other outpatient or domiciliary settings. We will consider for future rulemaking separately identifying and paying for CPM services furnished to beneficiaries in any appropriate setting of care, in recognition of the prevalence and burden of pain across all settings of care, and the associated time and service complexity to provide care for chronic pain. We appreciate comments on other settings where CPM services could be provided.

(c) Request for Comment

We believe there could be circumstances in which a beneficiary receiving CPM services needs referrals or recommendations, based on a clinician's assessment, for services or interventions that are not included as elements of the CPM services, such as for community-based care or physical and occupational therapy. We welcomed comments on the care coordination that may occur between relevant practitioners furnishing services, such as complementary and integrative care, and on the community-based care element included in the descriptors for proposed G3002 and G3003.

We also asked commenters to weigh in on how documentation of the performance of the elements of CPM services might best be addressed in medical recordkeeping. We solicited general comment on whether there are any elements of CPM services outlined in this proposal that the public and interested parties believe are not typically furnished in connection with comprehensive chronic pain management, or any proposed elements of the CPM services that should be removed or altered. We solicited comment on whether there are elements of CPM services that we have not identified and should be added to the code descriptors.

Additionally, we solicited comment on which, if any, CPM elements could be furnished as “incident to” services, and whether to add G3002 and G3003 to the list of services for which we allow general supervision as described in our regulation at § 410.26(b)(5). We welcomed comments from the public for future rulemaking regarding what elements of the CPM services could be furnished under general supervision, or direct supervision. For example, facilitation and coordination of any necessary behavioral health treatment, chronic pain related crisis care, and ongoing communication and care coordination between relevant practitioners furnishing care might be appropriate activities to be considered under general supervision.

The proposed CPM codes may involve arrangements where the physician or other health professional might work in collaboration with other health care providers or members of a care team, such as a psychologist, dental practitioner, or social worker, where these individuals might furnish certain elements of the service bundle under the direction of the physician or qualified health practitioner, such as assessments, person-centered care planning, referrals to community-based care, and other activities, as appropriate. We requested comments on if, and how, we should structure the proposed CPM code and payment for these services to account for these types of arrangements that could include team-based care.

We received over 150 unique comments on our proposal from national health care organizations including provider associations, federations, and societies that represent health care professionals; organizations that educate, connect, and advocate for people with pain; State-based health care organizations, medical societies and associations; cancer care centers; health care companies; hospice and palliative care organizations; device manufacturers; pain care providers; and people living with pain and their caregivers. Almost all commenters were supportive of our proposal. We also received several comments mainly from psychologists or psychology associations, requesting we adopt additional coding without medication management in the code descriptor, as medication management in most states is outside the scope of a psychologist's license. The following is a summary of the comments we received and our responses.

Comment: Commenters living with chronic pain and their caregivers shared poignant stories about the importance of the proposed codes. One person observed that in recent years, since the release of the Centers for Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids, for people taking opioid medications or for those who were forced to stop taking medications, the relationship between providers and patients has become fraught, tense, and stigmatizing, even risky for physicians and for all these reasons, many clinicians have refused to treat chronic pain patients or have terminated chronic pain patients from their practices, with growing numbers of pain patients unable to find anyone to treat them, even if they do not use opioid medications. The spouse of a person living with chronic pain told of repeated trips to a local hospital seeking emergency treatment that worsened, instead of improved, her care, in part because the couple believed clinicians at the hospital were fearful of prescribing opioids and did not have access to, or ignored, the recommendations of the patient's longtime

clinicians, who included several pain specialists. A beneficiary who lives with chronic pain stated that she hoped the change in codes would motivate clinicians to focus more attention on people with pain, as after many years of seeing provider inexperience first-hand, along with the accompanying administrative demands and paperwork pain care demands, she believed having a special billing code will be a “giant step” forward for people with pain, potentially allowing more people like her with painful conditions to continue to contribute to society, including through employment. A person living with chronic pain stated he liked what he saw in the code proposal because he hoped it would open the doors to more doctors who would provide pain care, including appropriate medication management, because he thinks doctors are still fearful of Federal and State prescribing guidelines. Another person living with pain stated the CPM services are “so needed by people like me.”

One commenter noted that they would expect that the amount of pain care required and the cost to Medicare to be large and increasing, especially given the aging American population and the prevalence of age-associated chronic pain conditions in Medicare like arthritis, cancer, and diabetic neuropathy; the same commenter stated that 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, and that a standalone code will signal to physicians that, when patients have complaints of pain, it is critical to take them seriously. Conversely, another commenter was not supportive of the new codes as they believe that physicians will continue to bill evaluation and management (E/M) codes to avoid adding to their administrative burden.

One commenter requested that we “pause” implementation of the codes, further engage with interested parties, and make additional clarifications within the code to address valuation, descriptors, and guidance. Another commenter noted that they do not support including the CPM

codes in the applicable list used for accountable care organizations beneficiary assignment, citing that managing chronic pain does not routinely follow the overall health of the patient, and is typically managed by clinicians with specific skills beyond primary care. One commenter questioned if a single bundled code was adequate to address the breadth of conditions that patients may experience, as well as the variety of treatment and management approaches. One commenter urged us to consider that for some people, a visit with a practitioner might focus not just on pain management, but also whole-person care. The same commenter noted that, although they appreciated our efforts to simplify billing requirements for the CCM codes, uptake appears to be low in part due to administrative burden, and they expressed concerns that similar challenges would apply to the CPM codes, which could entail documentation of services rendered in an E/M service. The commenter asked us if we could determine a pathway to make billing more streamlined, perhaps through billing using the G89.xx ICD-10 series. A commenter thanked us for improving access to pain care, including through prevention and treatment for substance use disorders (SUD). A different commentator congratulated us on, through creation of the codes, helping to prevent some individuals from developing SUD. One commenter noted the codes would prompt more practitioners to welcome Medicare beneficiaries with chronic pain into their practices, and encourage practitioners already treating Medicare beneficiaries who have pain to spend the time to help them manage their condition within a trusting, supportive, and ongoing care partnership.

Response: We thank all the commenters who expressed enthusiastic support of the proposed new HCPCS codes for CPM services, and we appreciate the attention to informing our approach in shaping this policy that we believe will provide improved access to holistic and comprehensive pain management for people with Medicare. A few commenters disagreed with

our proposal. One commenter stated that our proposal is not substantially different than existing codes, while another questioned whether one code was sufficient to address the breadth of conditions patients experiencing chronic pain face. We do not agree that there is an existing code that specifically describes the work of the clinician in performing the specific tasks described in the code descriptor for HCPCS code G3002. We anticipate that the CPM codes will be used to address the full range of chronic pain conditions that impact Medicare patients. We look forward to gaining more knowledge through data, and clinician and beneficiary experience as use of the CPM codes becomes more frequent.

Comment: We received a few comments regarding our proposal to define chronic pain as “persistent or recurrent pain lasting longer than 3 months.” Most commenters agreed with our proposed definition. We received several suggestions related to the specification of 3 months duration, including one month, 90 days, and the addition of “expected to last longer” to our definition. A few others suggested we broaden the definition generally, to ensure that patients with cancer, neuropathic pain, psychogenic pain, and headaches would also benefit from this proposal to create HCPCS codes that describe CPM services, while another commenter congratulated us on using language that it noted was inclusive of all types of pain treatment. One commenter asked us to integrate acute pain and biopsychosocial factors into our definition, and stated that risk indicators of pain are apparent early, potentially limiting robust interventions for the prevention of chronic pain. One commenter opined that our definition of chronic pain was overly broad and did not address the many types of conditions that pain patients may experience. A commenter who agreed with our definition noted that in the International Classification of Disease, 11th edition (ICD-11)³⁹, chronic pain has its own diagnosis, independent of an

³⁹ <https://icd.who.int/en>.

underlying disease or condition. Still, another commenter, who also agreed with our definition, noted there are ICD-10 diagnostic codes for chronic pain, the G89.xx series. Another commenter agreed that the proposed definition is largely in line with their understanding, adding more context to include, “persistent or recurrent pain without a serious progression or exacerbation of an underlying pathologic condition and without tolerability over time.” Another commenter stated that at a high level, they believe the metric of “time” is not the dispositive component to define a chronic pain diagnosis, but the definition should instead take into account a complex series of associated factors like amount of suffering or hindrance of function, and that not all recurrent pain should be considered chronic pain; instead chronic pain as a diagnosis should be utilized for an individual who does not understand how to manage or live their life with their current, recurring, episodic symptoms.

Response: We appreciate all the commenters’ suggestions and observations. As we described in the proposed rule, we reviewed definitions from the Centers for Disease Control and Prevention, the National Institutes of Health, the World Health Organization⁴⁰, and in the Institute of Medicine’s “Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.” For operational ease and consistency with the proposed rule and various sources, we are finalizing as proposed the definition of chronic pain as “persistent or recurrent pain lasting longer than 3 months.”

Comment: One commenter recommended we focus on improving care for all pain, such as acute pain, as well as pain related to cancer, sickle cell disease, and for people in palliative care, with another commenter also agreeing that additional codes could focus on people with palliative and cancer pain. This commenter noted that increased support for comprehensive acute

⁴⁰ <https://painconcern.org.uk/new-classification-for-chronic-pain/#:~:text=Chronic%20primary%20pain%20is%20defined,explained%20by%20another%20chronic%20condition.>

pain management could also reduce the number of patients who progress from acute to chronic pain. This sentiment was echoed by other commenters, who suggested an additional pain code for acute care that would incorporate massage therapy and other complementary and integrative services for both in-patient and outpatient visits, as is seen in some large health systems. Several other commenters generally supported the inclusion or addition of acute pain management in this or other codes. One commenter suggested that after we gain experience with the use of the codes for chronic pain, we consider their application to acute pain management. A few commenters did not support additional coding and payment for acute pain management, as they believed these circumstances are adequately handled via existing E/M coding and payment.

Response: As we mentioned in the proposed rule, we understand there is some evidence that addressing chronic pain early in its course, such as when the person is experiencing acute pain, may result in averting the development of “high-impact” chronic pain in some individuals and that these people report more severe pain, more difficulty with self-care, and higher health care use than others with chronic pain. We considered, in the development of this code, whether or not to include acute pain, and elected not to include it in the CPM services descriptor. We will continue to consider how best to approach management of acute pain through coding and payment.

In our proposal, we required an initial face-to-face visit of at least 30 minutes provided by a physician or other qualified health professional with the first 30 minutes personally provided by the physician or other qualified health professional, per calendar month for HCPCS code G3002. We noted that HCPCS codes GYYY1 and GYYY2 were placeholder codes and that the final code number will be HCPCS code G3002 and G3003, respectively. We proposed, for HCPCS code G3003, an additional fifteen minutes of CPM services by a physician or other

qualified health professional, per calendar month, and we proposed limiting the application of HCPCS code G3003 to up to three units of an additional 15 minutes of CPM services, per calendar month (listed separately in addition to proposed HCPCS code G3002). We sought comment on both the proposed duration of 30 minutes for HCPCS code G3002, and the duration and the limit on HCPCS code G3003.

Comment: Most commenters agreed that our proposal for 30 minutes for HCPCS code G3002 was reasonable and adequate for the treatment and management of the first visit for a person with chronic pain and that fifteen-minute intervals for subsequent time-based intervals is adequate.

One commenter expressed a concern that neither code allowed for adequate time, and that the codes should allow for at least an hour for the first visit and 45 minutes for subsequent visits, especially to allow for the intensity of clinical time that would be likely needed to diagnose and treat a new patient. The same commenter urged us, because the myriad of situations that could apply based on the complexity of treating pain overall in the Medicare population, to consider additional flexibilities in the duration of time for the codes based on each person with pain's situation. Another commenter noted that the time required to coordinate with other specialists, referrals, therapies, and trial different treatments is "considerable" to create and modify an individual treatment plan for each patient. Another commenter suggested that twice a month billing for proposed HCPCS code G3002 is insufficient for completion of the list of requirements, and recommended that four visits per month be allowed to ensure that the element list is completed. A separate commenter echoed this sentiment, suggesting there be no limitation on the number of times per month this code can be billed, citing the multitude of providers seen by some patients. Another commenter recommended we consider extending the length of visits

from 45 minutes (30 minutes for proposed HCPCS code G3002, 15 minutes for proposed G3003) to 60 minutes to account for the complexity of pain care. A commenter noted that 30 minutes was too high a threshold for appointments beyond the initial visit, and recommended that subsequent visits only have a limit of 15 minutes after which billing is allowed. One commenter stated that we should not put any limits on the number of times proposed HCPCS code G3003 can be billed each month. A commenter requested that the frequency and duration of permitted CPM visits be flexible enough to account for the variety of practice types - from primary care to specialized clinics offering intensive and integrated chronic pain management services, and this commenter also noted that patients have different intensities of need, with some requiring longer appointments, or at greater frequency, while some have lower needs, stating that 30 minute and 15 minute durations of HCPCS codes G3002 and G3003 respectively, as well as the frequency, may be too limited to adequately account for the challenging demands of chronic pain management. Another commenter stated that 30 minutes seems reasonable but flexibility is important as chronic pain conditions vary and sometimes more than 30 minutes may be needed, especially for a first visit. Another commenter requested clarification related to the frequency of allowed billing for CPM codes, as some services such as comprehensive palliative care require a wide range of care.

Response: We appreciate the commenters' overall support of our proposal to set the duration of HCPCS code G3002 at 30 minutes, to accommodate both the specified elements of the monthly bundle, and the complex needs of the person with chronic pain, and we are finalizing HCPCS code G3002 for 30 minutes duration. We agree with the commenters who observed that additional flexibilities are needed to account for the numerous situations that could apply to each person with pain's clinical situation, and the factors that might go into the

clinician's determination regarding how much time is appropriate to spend treating a person with chronic pain, and also how many and what type of clinicians might need to also furnish care during a particular month. Although we expect that in most instances the person with chronic pain would see one clinician on a regular basis who is performing a lead role in managing that individual's pain, we can also foresee limited circumstances where a beneficiary may need to have their care transferred to a pain specialist, or other specialist in the same month, and the pain specialist or other specialist may also bill HCPCS code G3002 for the same beneficiary, in the same month. There may also be situations where the person with chronic pain needs to see two different clinicians managing their pain on a regular basis, for example, a cancer specialist and a rheumatologist, with both billing the CPM code(s). We would not expect many beneficiaries living with chronic pain would typically be seeing more than one or two physicians or qualified health professionals in a month who might be performing HCPCS code G3002; in part, because of the burden of care described by chronic pain patients and their caregivers, and also because beneficiaries incur cost-sharing expenses for these services and other care they receive—typically 20 percent of the Medicare payment amount after the annual Medicare Part B deductible amount is met.

Based on the comments, especially those that encouraged us to increase billing flexibilities to account for the unique needs of each person with chronic pain, we have reconsidered the proposed limit on billing G3003 to three times per month, and are finalizing in this rule flexibility to bill the second code, for each additional 15 minutes of care, an unlimited number of times, as medically necessary, per month, after HCPCS code G3002 has been billed. We will be monitoring use of the codes going forward to understand more about how they are being used.

Comment: One commenter asked if our proposal required the physician to meet with the patient each month or only once in the initial month of the service, as the commenter noted that monthly visits with the physician are not likely to be necessary for some people receiving ongoing chronic pain management. Another commenter stated that a monthly visit may be onerous for cancer patients who are already receiving time-intensive care. A commenter pointed out that it could take year or more of regular visits to develop, coordinate, and revise a treatment plan optimal in managing the patient's chronic pain; the same commenter stated that a patient might drop back to bi-monthly, quarterly, bi-annually, and annual visits so long as pain is being effectively managed. Another commenter requested clarification regarding if all the elements in the descriptor would be required each month.

Response: We agree with the commenters who noted that each person with chronic pain may not need to receive the monthly bundle every month; rather, using a person-centered approach, one which optimizes care according to individual circumstances and preferences, requires variability in how often services are appropriately rendered. Therefore, the CPM services for the HCPCS code G3002 may not be rendered more than once per month by each individual practitioner billing the code for each beneficiary, but could be rendered less than twelve times per year, depending on the specific needs of the person with chronic pain.

Comment: Some commenters requested clarification on our proposal that the first time HCPCS code G3002 is billed that initial visit must be in person, or if subsequent monthly visits must be "face-to-face," or in person. Several commenters recommended that we not make in-person first time visits an absolute requirement, so as to accommodate for mobility difficulties for people living a long-distance from the physician's office. Other commenters recommended that "face-to-face" components be available via both video and telecommunication technology to

support access. Several commenters stated that we needed to clarify that the code required that only the very first visit be in-person, and that follow-up visits could be delivered in-person, or by telehealth. A different commenter's concern was that HCPCS code G3002 seemingly requires an "initial" face-to-face visit of at least 30 minutes, and while the commenter did not object to one required initial face-to-face visit at the onset of CPM treatment, they thought that CMS potentially requiring an in-person visit monthly is unnecessary, overburdensome, and would exacerbate health care disparities. One commenter noted an initial visit with the patient could be supported by telehealth. Another commenter noted that patients should be seen in the office for the initial visit, at least until they are regulated on their pain medicines. An additional commenter requested clarification as to whether a practitioner could bill these codes both for patients that have an established history of chronic pain, and those that are being diagnosed as having chronic pain for the first time.

Response: We thank the commenters for their comments, but we are finalizing the requirement that the first time HCPCS code G3002 is billed, the physician or qualified health practitioner must see the beneficiary in-person, where both individuals are in a clinical setting such as a primary care practitioner's office or other applicable setting. We believe that an in-person visit at the onset of care will benefit both the clinician's accuracy in administering the elements of the HCPCS code G3002 bundle of services, and help at the beginning of care to foster a successful therapeutic relationship between the clinician and the person with chronic pain. One commenter told us doctor-patient relationships in pain management have become so "fraught, mistrustful, and corrosive" that they have led to a crisis, as illustrated by CMS' own Journey Map of the Chronic Pain Experience⁴¹, which, in their view, accurately demonstrates the

⁴¹ <https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf>.

current “dysfunctional and damaging state” of pain care. These reports support our decision to require that the physician or other qualified health professional meet with the beneficiary in person for the first time. We acknowledge that for some people living with chronic pain who may live far from the clinician’s office, or who have issues with transportation, or whose pain is exacerbated by activity, even getting to a clinician in-person for a first visit may be challenging. We are not requiring that each subsequent visit, whether these be monthly or at some other periodicity be held in-person, but rather leaving that determination to the discretion and preference of the clinician and the beneficiary as they are best positioned to together determine how to develop and maintain the care partnership to effectively manage pain.

Comment: A commenter stated that while patients earlier in their journey managing chronic pain may have care primarily coordinated by a primary care practitioner, others progressing to high-impact chronic pain may have their care mainly coordinated via a pain management specialist; this commenter suggested we allow the codes to be billed at a maximum twice per month to account for the difference in specialty primarily managing a patient’s care. This commenter also suggested we add pain management specialists to the list of examples of care that a patient might need (for example, physical and occupational therapy, etc.).

Response: We agree with the commenter that it is possible that a beneficiary living with chronic pain might need to see more than one clinician type who is enabled to bill for the CPM services – as the commenter noted, one likely scenario might be a person who sees a primary care practitioner, and a pain specialist (for the purposes of this rule, we are not defining “pain specialist”). As described in the proposed rule, we believe it is unlikely that most beneficiaries with pain would want, or need to, see more than a few physicians or other qualified health professionals in the same month to manage their pain, and administer the elements of the CPM

services for various reasons, including the reasons commenters who urged us to add the CPM services to the telehealth list have flagged. We also believe that the beneficiary would likely object to, or could even be confused by, having large numbers of clinicians managing their chronic pain. Although we are not restricting the numbers of clinicians who can bill HCPCS code G3002, we will be monitoring its use going forward to better understand more about the types of practitioners and patients using the CPM codes and services.

Comment: A few commenters requested clarification as to whether the person being seen for the first time with proposed HCPCS code G3002 had to have already been diagnosed with a chronic pain diagnosis, or a condition that causes chronic pain. One commenter stated we should include both people who both meet the definition of chronic pain on the first visit, and also people who have adequate medication documentation or concerns that would likely attest they have met the definition of chronic pain, to create an equitable care environment.

Response: We are clarifying that the beneficiary, at the first visit, need not have an established history or diagnosis of chronic pain, or be diagnosed with a condition that causes or involves chronic pain; rather, it is the clinician's responsibility to establish, confirm, or reject a chronic pain and/or pain-related diagnosis when the beneficiary first presents for care and the clinician is using HCPCS code G3002.

Comment: Several commenters questioned if clinicians are required to furnish all appropriate elements of the code bundle in each encounter for HCPCS code G3002, including medication management. One commenter stated that we should allow clinicians flexibility for any of the services listed, in any order and over any time period to best manage the person's pain condition(s) and that should allow for omission of certain ones when they are not appropriate or not desired by the patient (for example, medication management, behavioral counseling).

Another commenter stated that its stakeholders were concerned that HCPCS code G3002 seems to indicate that all listed services must be completed to bill for the code.

Response: We are clarifying that clinicians will be required to furnish all appropriate elements of the code bundle, but also clarifying that we do not expect that all elements of the code bundle will be appropriate for every patient. Therefore, we can confirm that if medication management is appropriate for a specific patient, then a clinician who bills HCPCS code G3002 will be required to furnish medication management to that patient. As described later in this preamble, we will be finalizing the descriptor of HCPCS code G3002 as follows, with the two modifications shown in italics: 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/or* 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, for example, physical therapy and occupational therapy, *complementary and integrative approaches*, and community-based care, as appropriate. We believe that the services enumerated as examples accurately summarize the components of some elements of key care for people with Medicare living with pain.

Comment: Many commenters requested that we remove medication management from the code descriptors. One commenter stated it appreciated medication management being included in the code descriptor and that careful evaluation of all medications, including use of American Geriatrics Society Beers Criteria®, should be included as part of the CPM service,

urging us to keep the element of medication management in the descriptor finalized for this code.

Response: We continue to believe that medication management is an essential element of pain care, and we are not removing it from the code descriptors for HCPCS codes G3002 and G3003. A 2022 Congressional Budget Office publication⁴² indicated nationwide per capita use of prescription drugs has increased in recent years, as has Medicare Part D enrollee use, from an average of 48 prescriptions per year in 2009 to 54 prescriptions per year in 2018. In addition, between 2017-2018, nearly 58 percent of U.S. adults used a dietary supplement⁴³ in the past 30 days, and the percentage of adults using these supplements increases with age⁴⁴; nutritional supplements are used by some people for the treatment of pain⁴⁵. Although we are not explicitly defining medication management for the purposes of HCPCS codes G3002 and G3003, we believe that medication management would customarily include, as part of this element, a review of prescription drugs, over-the-counter medications, supplements, natural treatments, and/or any other substances the person with chronic pain might be using for any purpose. Medicare's Annual Wellness Visit requires the clinician to collect and document use or exposure to "medications and supplements, including calcium and vitamins⁴⁶." Common prescription medications used for pain include acetaminophen, non-steroidal anti-inflammatory drugs, anticonvulsants, antidepressants, musculoskeletal agents, antianxiety medications, and opioids. Americans also use dietary supplements for a range of purposes, including the treatment of pain^{47,48}. Some individuals with pain may also be using substances such as cannabis and other

⁴²<https://www.cbo.gov/publication/57772#:~:text=Use%20of%20prescription%20drugs%20among,year%E2%80%942013%20percent%20increase>.

⁴³ <https://ods.od.nih.gov/factsheets/list-all/>.

⁴⁴ https://www.cdc.gov/nchs/products/databriefs/db399.htm#section_3.

⁴⁵ <https://www.nccih.nih.gov/health/providers/digest/nutritional-approaches-for-musculoskeletal-pain-and-inflammation>.

⁴⁶ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html>.

⁴⁷ <https://ods.od.nih.gov/>.

⁴⁸ <https://www.fda.gov/food/dietary-supplements>.

plant-based treatments for pain⁴⁹⁵⁰. Bearing this information in mind, we believe medication management by the eligible physician or qualified health professional would be an applicable element of the HCPCS code G3002 for most beneficiaries with chronic pain.

Comment: One commenter stated that massage therapy, therapeutic exercise programs, and complementary and integrative services (like acupuncture, tai chi, yoga, and mindfulness meditation) should be referenced in the code, even if currently not covered by Medicare, and that clinicians should be allowed to bill for the range of treatments listed in the HHS PMTF Report, even though the Medicare program may not pay for those services. One commenter noted that care coordination could include not just complementary and integrative care, but also prescribing of durable medical equipment. One commenter stated we should try to remove barriers to more “alternative” therapies.

Response: The PMTF Report recommends a range of treatments and therapies that could be used for successful pain management including medications, restorative therapies (for example, therapeutic exercise, massage therapy), interventional procedures (for example, nerve blocks, joint injections), behavioral health approaches (for example, cognitive behavioral therapy), and complementary and integrative health approaches. The latter include, as described in the Report, acupuncture, massage and manipulative therapies, mindfulness-based stress reduction, yoga, tai chi, and spirituality. HHS’s 2010 National Pain Strategy⁵¹ (NPS) also mentions complementary and integrative care, focusing mostly on access difficulties for patients with chronic pain, including insurance coverage. Since the NPS was published, Medicare has finalized a coverage decision to cover acupuncture for chronic low back pain⁵². NIH’s National

⁴⁹ <https://www.cdc.gov/marijuana/health-effects/chronic-pain.html>.

⁵⁰ <https://effectivehealthcare.ahrq.gov/products/plant-based-chronic-pain-treatment/living-review>.

⁵¹ https://www.iprcc.nih.gov/sites/default/files/documents/NationalPainStrategy_508C.pdf.

⁵² <https://www.cms.gov/medicare-coverage-database/view/nacal-decision-memo.aspx?proposed=N&NCAId=295>.

Center for Complementary and Integrative Health continues to evaluate various approaches⁵³, as is the cross-cutting NIH HEAL Initiative⁵⁴. The HHS Agency for Healthcare Research and Quality has also performed some work in this area⁵⁵.

First, we are clarifying that we are not requiring in the code descriptor that a clinician refer a beneficiary to services; that determination should be made between the clinician and the beneficiary. We understand that clinicians customarily refer beneficiaries, including those who have chronic pain, to a range of treatments based on their individual circumstances, and according to the person-centered plan of care.

Second, based on the commenter's suggestion and on our proposal within the CY 2023 PFS proposed rule, where we solicited comment regarding interest in chronic pain management services and specifically mentioned specialty care coordination such as complementary and integrative pain care; recent coverage in Medicare for acupuncture for chronic low back pain⁵⁶; and evidence that may point to efficacy for some individuals with chronic pain using complementary and integrative approaches, we have elected to revise the code descriptor for HCPCS code G3003 by adding "complementary and integrative approaches" to the code descriptor as examples of approaches that a clinician could take in coordinating pain care across a range of treatments and therapies for a beneficiary. However, we are not requiring that a clinician make a referral to such care, nor are we requiring that the clinician only refer Medicare beneficiaries to services currently covered by Medicare. We are finalizing the addition of "*complementary and integrative approaches*" to the descriptor for HCPCS code G3003. In context, the addition will read as follows: "...any necessary chronic pain related crisis care; and

⁵³ <https://www.nccih.nih.gov/health/providers/digest/mind-and-body-approaches-for-chronic-pain-science>.

⁵⁴ <https://heal.nih.gov/funding/awarded>.

⁵⁵ <https://www.ahrq.gov/topics/complementary-and-alternative-medicine.html>.

⁵⁶ <https://www.medicare.gov/coverage/acupuncture>.

ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, complementary and integrative approaches, and community-based care, as appropriate.”

Comment: Several commenters supported the requirement for the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes by the practitioner furnishing CPM services. A commenter asked that we recognize the role nurses play in person-centered planning. One commenter supported this element of the CPM services, and stated that person-centered care planning is not only key for people living with chronic pain, but also for others living with serious illness, and that the person-centered care plan and specifically these elements in the CPM service should become required for people with serious illness. One commenter expressed concern that current billing codes compensate providers the same regardless of the severity of the beneficiary’s condition or time spent with the provider.

Response: We are correcting the code descriptor to more clearly indicate that we do not expect the clinician to develop, implement, revise, and maintain the person-centered care plan, that is, performing each of these activities each time HCPCS codes G3002 or G3003 is billed; rather, the status of the person-centered plan may vary based upon the individual circumstances of the beneficiary with chronic pain. Thus, we are finalizing a revision to the HCPCS code G3002 descriptor to clarify this element as “the development, implementation, revision, *and/or* maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes”. We do not agree, based on the revisions to proposed concurrent billing policies and revisions in the descriptors that we are finalizing for HCPCS codes G3002 and G3003, as described above and below, that there will be insufficient flexibility to address the

severity or breadth of needs that a Medicare beneficiary living with chronic pain might have. We believe that both the “and/or” edit that we are finalizing as part of the code descriptor, and the additional flexibilities for payment, discussed below, are sufficient to address the unique needs of each beneficiary with chronic pain.

Comment: Several commenters opined on the inclusion of pain and health literacy counseling, which we included as a proposed element of the HCPCS code G3002 descriptor, 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 them⁵⁷. One commenter recommended we instead use the term “self-care management,” and noted that this term is more broadly inclusive of health literacy counseling. Another commenter stressed the important role nurses have in ensuring patients are fully informed by educating and advocating on behalf of patients as they navigate the care continuum. Another commenter stressed that the receipt of integrative pain care would involve the practitioner taking into account the “whole person” in managing pain, especially important in light of the importance of care coordination coupled with the goals of health literacy. (We note that we recently emphasized the importance of health literacy in our 2022-2032 CMS Framework for Health Equity⁵⁸.) The Framework’s fourth priority is to “advance language access, health literacy, and the provision of culturally-tailored services,” and states that “Medicare-enrolled individuals with low health literacy experience increased hospital admissions and visits to emergency departments, as well as higher medical costs and lower access to care.” Another commenter stated that in their experience, health literacy counseling is most efficiently done through networks of chronic pain support groups led

⁵⁷ <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/health-literacy>.

⁵⁸ <https://www.cms.gov/files/document/cms-framework-health-equity.pdf>.

by specially trained individuals who have received training and education by pain leaders, and that it is a fundamental and essential component in learning to cope with chronic pain, which is devastating and challenging. The commenter further observed that we could improve health outcomes by providing funding to non-profit groups that specialize in chronic pain management to help grow these type of educational and skill-based support groups. Another commenter supported this requirement, adding that this should be able to be provided via telehealth to reduce barriers to entry. A commenter noted that health literacy, especially with medication adherence, is valuable to people with chronic pain using multiple medications, as often these patients lack a comprehensive understanding of all their medications, which can deter adherence; if they had better resources to help them understand them, adherence would increase.

Response: We agree that pain and health literacy counseling is an important element of care for people with chronic pain and appreciate the commenters' suggestions about how it can contribute to improved health outcomes. We thank the commenters, and we are finalizing pain and health literacy counseling as an element of the HCPCS code G3002 descriptor, as proposed. As we gain experience with the CPM codes we may consider additional options to increase the availability of pain and health literacy counseling for Medicare beneficiaries.

Comment: Many commenters opined on our proposal to include administration of a validated pain assessment rating scale or tool as an element of code descriptor of HCPCS code G3002. Several commenters noted that pain subjectivity can make pain management a difficult task, and that the use of validated pain assessment tools can illuminate and inform a fuller picture of the person's condition, as well as the person's care plan. One commenter stated that pain scales can be beneficial, but they need to be tailored to each person, and that function and quality of life are also important elements to monitor. The same commenter recommended the use of the

National Quality Forum’s patient-reported measure, Patients’ Experience of Receiving Desired Help for Pain to achieve this. Another commenter stated something similar, indicating that we should explore ways to address the inconsistencies in pain measurement due to influences like geography and cultural norms. Among the many comments related to bias in pain assessment, one commenter urged us to consider the biases of assessment tools when proposing a validated pain scale. One commenter vehemently opposed the inclusion of a validated pain assessment scale citing concerns with pain bias, proprietary systems, and established outcomes beyond such scales, which they noted together create a case to avoid requirements for providers to use scales that have not received widespread support. The commenter also expressed concerns with pain bias that has developed over time in pain scales, especially for women, older adults, and ethnic groups, where the scales were not removed from use even after bias was documented, potentially worsening health equity issues. This commenter continued, stating that there is disagreement over the use of pain scales and that no single scale has been adopted as a common scale, in part because of proprietary issues. A different commenter agreed with the assessments of bias in traditionally marginalized populations, offering that objective pain scales and objective benchmarked pain data be used. This commenter defined benchmarked objective pain data including a pain database on adults, a database on women and pain, an orthopedic pain database, or an older adult pain database.

Additionally, we received comments related to the “well-documented bias against historically-disadvantaged groups” in pain assessment, and suggestions that the best tools for chronic pain also focus on pain interference, impact on function, activities of daily living, emotional and psychological health, and the patient’s perception of their own quality of life. Regarding specific tools, one commenter agreed with administration of a validated pain

assessment rating scale or tool, and stated that we should not limit the acceptable tools; rather we should enable practitioners to select the most appropriate tool for staff to administer as part of the person-centered CPM care plan, and that a reference repository or list of potential tools would be helpful. The same commenter asked that we not be prescriptive in requiring a particular scale or tool. Another commenter recommended the consideration of the use of outcome and quality-of-life measures as opposed to reductionistic tools that only measure one aspect of pain. A different commenter supported our proposal to use a validated tool, suggesting the PROMIS-8A, but urging us to make a list of validated tools available, and also avoid requiring use of a specific tool. Another commenter expressed concern about unintended consequences of using a pain rating scale or tool for validation and suggested the addition of a measurement that uses objective measures. A commenter noted that a pain scale is a reliable and valid way to understand the extent of how pain is impacting the person, but should not be the sole measure to show improvement. Further, a commenter recommended we undertake more inquiry before mandating the use of any specific tool or registry and assemble a stakeholder group, issue a Request for Information, or use some other means to conduct a landscape analysis of validated tools. One commenter noted that the use of a validated pain assessment tool should be excluded and be available as a separate add-on code. This commenter also noted that such a step would incentivize a multidimensional assessment of physical, social, and emotional functioning.

Response: We recognize that periodic assessment of the experience of pain is an essential element of pain care in the immediate sense and over time, as chronic pain may be enduring as a symptom of disease or a long-term disease in and of itself. We also note that no prescribed set nor single pain assessment measure will be required in the administration of HCPCS code G3002 or G3003, because no particular tool or tool set can assess the complex

nature of the experience of pain across all individuals, nor appropriately guide its treatment. We regularly collaborate with other HHS operating divisions including working with the National Institutes of Health (NIH) on the NIH HEAL[®] Initiative (Helping to End Addiction Long-term), which includes more than 30 large scale pain and substance use disorder programs. The NIH HEAL Initiative and the NIH Pain Consortium pain research agendas engage nearly all NIH Institutes, Centers, and Offices. The ambitious and crosscutting nature of the NIH HEAL Initiative[®] and trans-agency interactions of the NIH Pain Consortium require engagement from experts across disciplines and sectors and with other HHS operating divisions including CMS. Much of this NIH research effort focuses on preclinical, translational and clinical research aimed to improve pain management⁵⁹. We have been working with NIH to create and disseminate an accessible, curated, and dynamic set of Pain Assessment resources for clinicians seeking instruments to assess their patients' pain and pain-related symptoms (such as sleep disruption, loss of function, and behavioral health). The resources are carefully selected as validated and meaningful tools to inform clinicians and patients in shared decision making as to the most effective pain management plan for each person. Recognizing that while many tools are validated in certain populations, they may need refinement to address cultural sensitivities in populations with health disparities. We will leverage efforts of the NIH HEAL Initiative to continue to include appropriately updated tools for these populations as they evolve. We are finalizing the inclusion of administration of a validated pain rating scale or tool in the HCPCS code G3002 descriptor. We will continue to consider opinions and feedback from clinicians and people with pain as to the use of The Pain Assessment Resource and more generally, validated screening tools, and collaborate with our NIH operating division partners to leverage their work

⁵⁹ <https://heal.nih.gov/about>.

in this area and ensure that the Pain Assessment Resource is comprehensive, inclusive across disciplines, and up to date over time. A link to the resource is available at

<https://www.painconsortium.nih.gov/resource-library/resources-pain-assessment>.

Comment: We received numerous comments on components of the proposed CPM services that do not necessarily require a “face-to-face” or in-person visit with the practitioner, such as care that could be provided by auxiliary staff “incident to” the services of the physician or other qualified health care practitioner. A few commenters requested clarification on which specific aspects of the code could be furnished without face-to-face care. We also received many comments requesting a general supervision requirement, rather than a direct supervision requirement, with commenters citing provider shortages as barriers to care. Another commenter suggested that the initial visit would not have to be face-to-face so long as an in-person visit occurred shortly after the CPM initiation, and prior to the prescribing of controlled substance medications for pain. One commenter stated that other clinical staff in the practice should be able to follow up and interact with patients. Another commenter stated that relevant components that could be non-face-to-face could include questions about medication and improvements related to medication, social determinants of health, or history of substance use disorders, or crime, as well as coordination of any necessary behavioral health treatment, and pain and health literacy counseling. A commenter stated that most components of the proposed CPM services do not require face-to-face interaction with the billing practitioner such as overall treatment management, medication management, pain and health literacy counseling, and care management which can be provided by clinical staff incident-to a billing practitioner under general supervision, and that these providers’ ability to furnish care has proved to increase access to medically necessary care, and helped relieve some of the burden for billing practitioners while

still ensuring patients are receiving high-quality care. A commenter noted that registered nurse care managers could provide CPM services as incident to services, under the general supervision of a physician or other qualified health professional. Another commenter stated that the definition provided of “provided by a physician or other qualified health care professional” was limiting, and suggested that we use, “clinical staff time directed by a physician or other qualified health care professional.” Another commenter requested that CMS consider creating separate billing codes to reflect time spent by physicians and clinical staff as is done in the chronic care management (CCM) code.

Response: We agree with the commenters and believe that certain elements of the proposed bundle, such as care planning or care coordination with other health care professionals, would not likely require face-to-face care. These might include activities such as telephone calls, medical records review, and coordination and information exchange with other health care providers. We are also not requiring that subsequent visits for which a physician or other qualified health professional bills HCPCS code G3002 or G3003 be for services that were provided to a beneficiary face-to-face. However, the initial visit for HCPCS code G3002 must be a face-to-face visit.

Comment: A few commenters applauded our efforts to support team-based care for Medicare beneficiaries with chronic pain. One commenter stated that chronic pain management may involve arrangements with psychologists as part of team-based care. Another commenter stated that since there is no disease-modifying or curative therapy for chronic pain, best managing chronic pain requires multi-modal interventions and coordination across a patient’s care team, and coordinating care with other practitioners and providers such as integrative medicine, physical therapists, psychiatry, and hospital programs.

Response: We agree with the commenters about team-based care, which leads to better outcomes for beneficiaries, and better experience for staff, and improves all aspects of care delivery. Team-based care positively effects the person’s care experience, such as office visit cycle time, care access, preventive screening, self-management, goal setting and action planning, and medication management. Team-based care also improves process and workflows, helping to ensure staff are working at the top of their capabilities, and sharing in accountability.⁶⁰

Comment: A few commenters requested that the structure of the CPM codes include payment for the time interdisciplinary providers spend in consultation with one another. Additionally, this commenter noted concern that requesting coordination with “relevant providers” was not specific enough, and would not require inclusion of the range of services available to treat chronic pain. One commenter stated that we should ensure that reimbursement is revenue neutral, to continue to encourage practitioners to treat chronic pain.

Response: We are not requiring in the code elements that the clinician billing CPM codes coordinate and communicate with other relevant practitioners, as these actions would vary based on the beneficiary with chronic pain’s circumstances. Nor is the list of services we have used as examples meant to be inclusive of every type of care a person with chronic pain could require in the course of individualized treatment for chronic pain. We do expect that communication and care coordination between providers of all types would be of benefit to the beneficiary with pain and we leave the extent of that communication and coordination to the discretion of the physician or qualified health professional billing the CPM codes, as appropriate.

Comment: Several commenters requested that we recognize CPM services for all practitioners who may bill E/M visits, including oncologists. One commenter noted we had

⁶⁰ <https://innovation.cms.gov/files/x/tcpi-changepkgmod-nextsteps.pdf>.

stated the new codes can be billed by a “physician or other qualified health care professional” and agreed 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; the commenter asked us to clarify what types of practitioners can bill for proposed HCPCS code G3002 and G3003. A commenter noted that we stated our anticipation that the CPM codes would most frequently be billed by primary care providers. This commenter specified that cancer specialists also spend considerable time managing acute and chronic pain, with this sentiment being echoed by providers of palliative and hospice care, as well as nurse anesthetists, all concerned and asking for clarification regarding whether they “counted” as approved providers. A commenter requested more support and increased access for innovative alternative treatment to opioids (ALTO) programs, which have been shown in a few states to reduce opioid prescriptions in emergency department settings. One commenter stated that, if we identify specialties expected to furnish the CPM services, geriatrics should be included. Two commenters recommended that Rural Health Centers and Federally Qualified Health Centers be allowed separate payment for these codes. One commenter requested that the code be inclusive of the broad range of providers that treat pain, as each patient should be able to access the provider best suited to primarily manage their pain. A commenter stated that, while we stated we believe primary care providers might most often use the codes, cancer specialists spend considerable time managing both acute and chronic pain associated with cancer, and we should explicitly state that CPM services can be billed by any clinician with E/M services in their scope, including oncologists and pain management specialists. Two commenters stated we should make rehabilitation therapists eligible to bill the code, and, if they are part of the care team, they should

share in the reimbursement proportionally among practitioners rendering care. One commenter asked that we include marriage and family therapists as providers who can render CPM services. A commenter recommended HCPCS code G3002 be billable by other Medicare providers like doctors of chiropractic. Another commenter encouraged us to include massage therapists under Medicare Part C in coding and billing changes to capture services that are provided as part of complementary and integrative pain care.

Response: We appreciate the commenters' thoughts about the broad range of provider types that might furnish care that effectively addresses the many aspects of chronic pain, and note that we are not limiting the types of physician specialties, or the types of qualified health professionals, who can furnish CPM services, as long as they can furnish all of the service elements of HCPCS code G3002, including prescribing medication as needed, within their scope of practice in the State in which the services are furnished.

Comment: Several commenters urged us to consider the contributions of interdisciplinary teams including physical and occupational therapists, social workers, massage therapists, pharmacists, and athletic trainers when creating rules for incident to billing. Two commenters requested that CMS use the term, "clinical staff" as is used in other codes to ensure inclusion of different provider types. One commenter noted that members of the interdisciplinary team are needed to provide person-centered, holistic pain management and that incident to billing will support team-based care, and that we should consider separate billing for physician time versus other clinical staff time; another commenter also made this request. A different commenter noted that limitations on "incident to" billing has been limiting for the creation of collaborative, interdisciplinary teams. A commenter asked us to address "incident to" with greater clarity, to explain if the CPM services could be provided in a domiciliary or home setting, which is not the

same as a provider's office or clinic, including under general supervision. One commenter noted that component activities of CPM services can be appropriately provided as "incident to" physician services, as well as by hospital staff under the Medicare Part B outpatient benefits. The commenter further stated that since staff who implement CPM care plan services are either office or facility-based, payment for the services should be recognized under both the PFS and the Outpatient Hospital Prospective Payment System. One commenter stated that clinicians such as social workers, pharmacists, and chaplains could be very helpful to address aspects of chronic pain through incident to billing. Another commenter recommended CMS focus on a simpler way to capture and reimburse for CPM services. For example, CMS might explore whether E/M codes billed with an ICD-10 diagnosis code for chronic pain from the G89.xx series, in which a person-centered plan of care for pain is documented, could be eligible for monthly billing of a G3003-type code (for example, each 15 minutes of CPM care plan services implementing an individualized CPM plan inclusive of staff monitoring patient's adherence and response to the plan, coordinating services and communicating with other practitioners and providers). This G3003-type code would acknowledge and pay for the component activities of CPM care plan services that are appropriately provided "incident to" physician services by practitioner-employed office staff or by hospital staff under the outpatient hospital benefits.

Response: We note that this rule generally addresses payment for physicians' services under the PFS. Comments regarding other payment systems not addressed in the proposed rule are outside the scope of this rulemaking. The billing practitioner should report the place of service for the location where they would ordinarily provide face-to-face chronic pain management services to the beneficiary. We thank commenters for their feedback and may consider further development of the CPM codes to recognize components that could be furnished

by auxiliary personnel incident to the services of the billing practitioner, and components that could be primarily performed by clinical staff, in the future. We note that auxiliary personnel is defined at § 410.26(a)(1) as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid, and all other Federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. We did not propose to change this definition of auxiliary personnel in the proposed rule, and therefore, the comments asking CMS to modify the definition of auxiliary services are outside the scope of this rulemaking. Additionally, we note that all requirements for services furnished incident to a physician's (or practitioner's) professional services listed at § 410.26 continue to apply. We will keep the commenters' concerns in mind when considering any further development of the CPM codes in the future.

Comment: Many commenters asked us to clarify if the proposed CPM services would be available for billing/reporting in conjunction with remote patient monitoring (CPT code 99091), remote physiologic monitoring (CPT codes 99453, 99454, 9457, 99458), or remote therapeutic monitoring (CPT codes 98975, 98976, 98977, 98980, 98981 and as proposed GRTM1/2/3/4 codes. One commenter also requested clarification surrounding what virtual presence/remote supervision is permitted, who can order these services, what documentation is required, and whether billing is permitted for individual services in addition to the management components of CPM. A commenter noted that patients with chronic pain may also benefit from remote therapy

monitoring to monitor their pain levels, medication adherence, and response to prescribed therapy regimens.

Response: HCPCS codes G3002 and G3003, and the services describing remote patient monitoring, remote physiologic monitoring, and remote therapeutic monitoring, are distinct types of services, although there may be some overlap in eligible patient populations. There may be some circumstances where it is reasonable and necessary to provide both services in a given month. Thus, HCPCS codes G3002 and G3003, could be billed for the same patient in the same month as the Remote Physiologic Monitoring (RPM) or Remote Therapeutic Monitoring (RTM) services. All applicable requirements for the individual codes must be met, per the elements of each individual code, for both types of remote monitoring and CPM services. Additionally, the time and effort cannot be counted more than once when billing CPM codes concurrently with RPM or RTM. Billing practitioners should remember that cost sharing applies to each service independently. If all requirements to report each service are met, without time or effort being counted more than once, then CPM and RPM or RTM may be billed.

Comment: Several commenters stated they were concerned about low payment, and other payment issues related to the proposed CPM codes, which we had valued in our proposal based on our conclusion that the CPM services were similar in work (time and intensity) to that of Principal Care Management (PCM) service. One commenter observed that in order for physicians to be willing to treat chronic pain patients, especially primary care physicians, we need to make physician payments for the new CPM codes higher than primary care and PCM visits to avoid lower payment for CPM than for a standard follow-up clinical visit for primary care (CPT code 99214 for 30 min clinical visit). The commenter was very concerned that unless we considered raising these rates before the new CPM codes go into effect, physicians will not

use them to accomplish the intended improvements in pain care that Medicare patients so desperately need, and that the use of other codes not specific to pain will impair our ability to accurately track data regarding chronic pain, and care outcomes, in the Medicare program.

Another commenter had similar concerns, recommending that the valuation of the new codes be on par with current office and outpatient E/M codes. A different commenter noted that it had significant concerns with our proposal to disallow use of the codes on the same day as a

“general” visit like an E/M visit where the person is being seen for a separate illness or condition, and that this would be a grave mistake that would hamper the delivery of truly integrative pain care. This commenter also added that this move would exacerbate disparities at a time when CMS is working to promote health equity, urging us to allow same day E/M billing.

Another commenter requested clarification regarding the interaction with other service codes to ensure that this code enhances rather than inhibits physician encounters. A different commenter stated that people living with chronic pain are likely to have at least one or more comorbidities that are being treated along with their pain, and often these health concerns are, in fact, addressed by one singular practitioner on the same day. The same commenter noted that requiring people to be seen on different days that they come for other health care services will significantly reduce numbers of people with pain who are willing, or able, to receive CPM services, including people who are older adults, disabled, homeless, lack reliable/affordable transportation, cannot take time off work, and/or are unable to secure child care – among other issues. The commenter stated mandating repeated in-person visits would be arduous for disabled people already poorly served by public transportation, a problem that characterizes many smaller cities, suburbs, and rural communities. Another commenter stated that our proposed code valuation will prohibit use of the codes or make them go unused, as they pay less than CPT code 99214, or result in less payment,

causing providers to reconsider the number of pain patients they care for. Additionally, the commenter expressed fears that for providers already wary of rendering care to people with chronic pain, the valuation of the codes would further disincentivize them from treating these patients, not only paying less, but requiring more work. The commenter described a “worst case” scenario where if the codes became “required” for people receiving CPM services (for example, use of a 99xxx code was deemed fraudulent) it anticipated that many clinicians would cease seeing patients with chronic pain because of the low valuation, and required services that appear “extraordinarily laborious.” This commenter included several real life scenarios from clinicians working at the front lines of pain; stating that if we really wish to support the use of CPM, the valuation should be *at least* (emphasis added) comparable to CPT code 99213 or 99214, but *to truly incentivize* (emphasis added) adoption and utilization of CPM services, we should consider significantly increased reimbursement to allow CPM services to grow sufficiently to meet anticipated demand. A different commenter noted primary care providers will be disinclined to prescribe opioids due to this payment rule. The commenter expressed concern that these patients will then have to find pain management clinics, which are not present in all communities. A commenter stated a similar opinion, discussing that primary care providers are afraid of prescribing opioids and that patients are suffering as a result. Another commenter noted that they would like the code to differentiate between a patient who is now meeting the threshold for chronic pain from those patients with a previous diagnosis of chronic pain, who is simply seeing a new provider. This commenter noted that a person is an expert in their own condition, and sharing all of that information with a new provider is often very time-consuming, whereas someone with new chronic pain may not have as much information to share. This commenter recommended “substantial” time for both scenarios. One commenter requested clarity on the

interaction between the E/M and CPM codes to avoid any inadvertent misuse by providers, and recommended that CMS consider creating a modifier to attach to the CPM codes to prevent double payments. Another commenter was concerned that the proposed CPM codes could lead to an underutilization of important non-opioid pain management options because providers are not clear on the rules around the use of these codes. One commenter opined that there should not be any concurrent billing restrictions imposed on CPM services, which would force patients to pick between certain services and care. Another commenter noted that the current valuation and payment are disproportionate to the work required of HCPCS code G3002, and noted that this code more closely aligns with what is included in a level 4 or 5 E/M service. A different commenter echoed previous statements regarding concern that the valuation of HCPCS codes G3002 (formerly GYYY1) and G3003 (formerly GYYY2) and RVUs will create disincentives to care for patients with chronic pain. The commenter suggested separating HCPCS code G3002 into two codes: one code for face-to-face that is valued higher than a standard E/M visit, and a second for coordination undertaken by the physician or other qualified healthcare professional outside of face-to-face care (similar to CCM and PCM codes). Another commenter suggested two add-on codes for HCPCS code G3003 because these patients can be complex, and may require intense coordination. An additional commenter suggested adding a GYYY3 and GYYY4 code. HCPCS code G3002 (formerly GYYY1) would remain and HCPCS code G3003 (formerly GYYY2) would be half the resource inputs of G3002. GYYY3 would be a new code for subsequent visits after the initial visit with a 15-minute threshold instead of a 30-minute threshold, and GYYY4 would be another new code for administration of the validated pain measurement as an add-on for HCPCS codes G3002 or G3003. One commenter stated that the code should be treated as an E/M and fall into the category as a visit, billed in FFS clinics and

related to RHCs and FQHCs paid for as per the current methodology. The commentator suggested using a payment “crosswalk” of 99213 and 99214 tied to proposed HCPCS codes G3002 and G3003, including a modifier of 30-40 percent to compensate providers adequately for the labor involved in CPM services. One commenter stated that it believed clinicians billing for CPM services would face substantial decreases in work RVUs generated relative to current reimbursement compared to outpatient E/M codes and is unclear on how both codes could be billed. Another commenter stated that they believed the reimbursement proposed is inappropriately low, and urged us to adjust the proposed RVUs of 1.45 for HCPCS code G3002 and 0.5 for HCPCS code G3003 in the final rule. This commenter noted the work intended in this code will require significant time investment by physicians, qualified health professionals, and clinical staff. The same commenter noted HCPCS code G3002 should be crosswalked with CPT code 99414 at 1.92 work RVUs and HCPCS code G3003 be crosswalked with CPT code 99212 at 0.7 work RVUs. Another commenter stated we are undervaluing HCPCS code G3002 by crosswalking it to CPT code 99424, which has 1.45 RVUs. A similar 30-minute new patient office visit (CPT code 99203) is valued at 1.6 RVUs. This commenter also stated that an established patient visit (CPT code 99214) is valued at 1.92 RVUs. This commenter recommended CPT codes 99495 and 99496 for better crosswalks. Another commenter requested clarification on whether it is permissible for the same practitioner to bill a service like interventional pain management during the same month the clinician bills for the CPM services. Another commenter noted that E/M codes 99214 and 99213 already allow for time-based, face to face encounters with providers, have similar or greater work RVUs, and less limitations and requirements as compared to those specified in the code descriptors for G3002 and G3003. This commenter recommends increasing the time allotment to 45 and 20 minutes for HCPCS codes

G3002 and G3003, respectfully. The same commenter also expressed concern that providers would be less likely to utilize the CPM codes in favor of those they are already using and allowing for an increase in time allotment would correct this issue, according to this commenter.

Response: It is not our intent to either underpay, or create incentives for clinicians to use other codes that would constrain the use of the new codes. However, in the absence of experience with these new codes, we must base our projections reasonably on our experience with existing codes that we believe bear some relationship to the new proposed codes, such as the PCM code. Therefore, in light of the crosswalk to CPT codes 99424 and 99425, we are finalizing as proposed the work RVUs of 1.45 for HCPCS code G3002 and 0.5 for HCPCS code G3003. We will monitor use of the CPM codes to better determine if the payment rates and billing flexibilities are appropriate. In the proposed rule, we outlined our concerns about duplicate, or overlap billing in situations where the eligible clinician might bill certain E/M codes on the same day the CPM service(s) are rendered. Based on the commenters' concerns, we have reconsidered our approach to billing CPM services. We believe that, due to the complexities of pain treatment, there could be beneficiaries seeing a clinician for the first time, or in a subsequent visit, who could also need to be seen by the clinician for the CPM service(s) on the same day, or for a subsequent visit. The code sets for E/M services are organized into various categories and levels; the more complex the visit, the higher level of the code the clinician would bill within the appropriate category. Clinicians must make certain that the codes selected are appropriate for the services furnished, and that they fulfill the requirements to bill an E/M service⁶¹. Many Medicare beneficiaries have multiple chronic conditions⁶², and many of

⁶¹ <https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/eval-mgmt-serv-guide-icn006764.pdf>.

⁶² https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Chartbook_Charts.

these conditions could involve chronic pain. We believe it is reasonable to assume that in many instances, the clinician could be spending time with the Medicare patient discussing health and wellness related to a variety of conditions that person may be experiencing, or expect to experience, and that interaction might not have a focus on the chronic pain aspects of the person's care. Additionally, if the person with pain has made the effort – which could be considerable, as commenters have noted, to get to an appointment with a clinician, it makes sense from a burden standpoint – allowing for the burden on both the clinician, and the person with Medicare, to permit billing for both the E/M service, and the CPM service(s) on the same day. Therefore, if all requirements to report each service are met, without time or effort being counted more than once, then both E/M and CPM may be billed on the same day.

Comment: Two commenters requested that we revisit existing guidance and regulations to allow pharmacies to bill Medicare for opioid-based compounded drugs. Another commenter urged CMS to reconsider the issue of reimbursement for medication used in intrathecal pumps. One of these commenters also requested that the compounded medications delivered to the physician's office for insertion into an implanted pump be reimbursed as an incident-to drug or Durable Medical Equipment, depending on the billing entity.

Response: We appreciate the commenters' thoughts about compounded drugs and reimbursement for medication used in intrathecal pumps; however, these comments are out of the scope of our proposals for CPM services.

Comment: Many commenters asked us to add CPM services to the Medicare Telehealth Services List. One commenter asked that we enable the CPM codes, in addition to being rendered through telehealth, to be furnished through audio-only technology. We address these comments in section II.D.1.c. of this final rule, Other Services Proposed for Addition to the

Medicare Telehealth Services List.

Comment: One commenter suggested we include screening services in the CPM bundle to identify, reduce, and prevent hazardous or harmful alcohol and drug use, which the commenter characterized as common in people with SUD in residential treatment settings living with chronic pain. An additional commenter echoed the request for screening to identify, reduce, and prevent hazardous or harmful alcohol and drug use generally. This commenter also encouraged the inclusion of ordering of tests and Durable Medical Equipment, as well as consultations with other providers and communication with pharmacies be included. One commenter suggested the inclusion of nutrition screening and nutrition therapy in the code descriptions, as people with chronic pain often have complex dietetic and nutritional needs. Another provider group recommended that the term “prognosis” be added to the “diagnosis” in the bundle description as an option.

Response: As outlined in the proposed rule and in the CPM code descriptors, we expect clinicians to facilitate and coordinate any necessary behavioral health treatment, and other relevant care associated with HCPCS codes G3002 and G3003, such as complementary and integrative approaches and/or community-based care. This includes, as described in the CMS Behavioral Health Strategy,⁶³ multiple elements including access to prevention and treatment services for SUD, mental health services, crisis intervention and pain care to enable care that is well-coordinated and effectively integrated. Under the Strategy, we have defined behavioral health as “encompassing a beneficiary’s whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental disorders and substance use disorders.” “Whole-person care” is defined as “the whole of a beneficiary’s needs including

⁶³ [cms.gov/cms-behavioral-health-strategy](https://www.cms.gov/cms-behavioral-health-strategy).

physical health, behavioral health, long-term services and supports (home and community-based services, and institutional care), and health-related social needs.”

Comment: One commenter suggested we ensure that the proposed CPM codes are reimbursable in the beneficiary’s home, and all other settings where primary care, mental health care, and SUD care can occur. Another commenter recommended inclusion of residential treatment facilities, long term care facilities, and homes as settings in which billing can occur.

Response: We appreciate the commenter’s suggestion that we ensure that the proposed CPM codes are payable for services delivered in the beneficiary’s home, and all other settings where primary care, mental health care, and SUD care can occur. We note that CPM is priced in both facility and non-facility settings, and we are not limiting the place of service for CPM, other than as discussed above (the initial visit must be in-person). The billing practitioner should report the place of service for the location where they would ordinarily provide face-to-face chronic pain management services to the beneficiary

Comment: Several commenters stated that the elements of the proposed CPM codes favor prescriptions by medical providers, instead of prioritizing non-pharmacological strategies for pain management, including those developed by psychologists, that may be safe and effective for many patients. One commenter further stated that the creation of additional bundled codes that do not include medication management will allow for greater flexibility in treatment and allow psychologists to provide pain management services and practice to the top of their license when participating in team-based comprehensive chronic pain treatment. Another commenter suggested that physical and occupational therapists should be able to bill the codes, stating that these practitioners’ practice integrates an understanding of a patient’s or client’s prescription and non-prescription regimen with consideration of its impact on health, function, movement, and

disability, and that it is within the physical therapist's professional scope of practice to administer and store medication to facilitate outcomes of physical therapist patient and client management. The same commenter asked that we require, in the code descriptor, that physicians and other non-physician practitioners must refer appropriate chronic pain patients to physical and/or occupational therapy prior to being reimbursed for the codes. A few commenters requested that CMS create a code for providers who do not bill for E/M codes. One commenter stated that physical therapists and psychologists are not qualified to perform all the necessary services we have outlined, such as thorough pain assessments and diagnoses, medication management, crisis care, etc. and suggested we establish a path whereby non-physician professionals can bill a chronic pain code for services that are part of an overall treatment plan. Two commenters suggested that education be provided to physician providers to increase the consultation of physical and occupational therapists, also stating that physical therapists are significantly underutilized in community and rural settings.

Response: We acknowledge and support the important work of psychologists and occupational and physical therapists in the care of people with Medicare, including beneficiaries with chronic pain. We believe that this code describes a distinct PFS service that is reasonable and necessary in the diagnosis and treatment of the person with chronic pain, and that medication management, as described in the preamble text above, is a key element of such care and of the proposed HCPCS code G3002; therefore, we are including it as a code element.

We understand that cognitive behavior therapy (CBT), as one example, is a common treatment provided by psychologists, including to people with chronic pain⁶⁴⁶⁵⁶⁶. Medicare

⁶⁴<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁶⁵ https://www.va.gov/painmanagement/docs/cbt-cp_therapist_manual.pdf.

⁶⁶ <https://www.nih.gov/news-events/nih-research-matters/meditation-cognitive-behavioral-therapy-ease-low-back-pain>.

covers psychotherapy, as well as other services that support mental health and wellness⁶⁷.

Chronic pain can be linked, in some people, to mental health conditions, such as anxiety and depression⁶⁸. Psychotherapy is billed with Current Procedural Terminology (CPT) codes⁶⁹ that reflect the amount of time spent with the patient, and family may or may not be present during these therapy sessions. To bill these CPT codes, the psychotherapist must provide a mental health diagnosis using an International Classification of Diseases (ICD) code and/or Diagnostic and Statistical Manual (DSM) code.

While clinical psychologists (CPs) do not have prescription authority in all States and are therefore, not authorized to bill the Medicare program for any of the CPT codes that include medication management components, there are CPT codes that CPs can bill for treating Medicare patients who are diagnosed with chronic pain. Hence, the Health and Behavior Assessment and Intervention (HBAI) range of CPT codes are intended to be used for psychological assessment and treatment, when the primary diagnosis is a medical condition, such as chronic pain.

This family of codes was revised in 2020, when a new set of codes to describe these HBAI treatment services went into effect⁷⁰. Health behavior assessment under these HBAI services is conducted through health-focused clinical interviews, behavioral observation and clinical decision-making and includes evaluation of the person's responses to disease, illness or injury, outlook, coping strategies, motivation and adherence to medical treatment. Health behavior interventions under these HBAI services are provided individually, to a group (two or more patients), and/or to the family, with or without the patient present, and include promotion

⁶⁷ <https://www.cms.gov/files/document/mln1986542-medicare-mental-health.pdf>.

⁶⁸ <https://health.gov/healthypeople/objectives-and-data/browse-objectives/chronic-pain>.

⁶⁹ <https://www.ama-assn.org/practice-management/cpt>.

⁷⁰ <https://www.apaservices.org/practice/reimbursement/health-codes/health-behavior>.

of functional improvement, minimization of psychological and/or psychosocial barriers to recovery, and management of and improved coping with medical conditions. The HBAI codes apply to services that address psychological, behavioral, emotional, cognitive, and interpersonal factors in the treatment/management of people diagnosed with physical health issues. Use of HBAI codes requires a physical health diagnosis (ICD-10) to be the primary diagnosis. The HBAI codes capture services related to physical health, such as adherence to medical treatment, symptom management, health-promoting behaviors, health-related risky behaviors, and adjustment to physical illness. The HBAI codes and the Psychotherapy codes cannot be billed contemporaneously. We believe HBAI codes are well-suited to the provision of CBT, as appropriate, to people with chronic pain when the person does not have a concurrent mental disorder.

For HCPCS codes G3002 and G3003, we are finalizing the codes for use by physicians and other qualified health professionals. However, we will consider if there is a benefit to modifying these codes and/or creating new codes that can potentially support broader chronic pain management by other practitioner types, including those who may not be prescribers in the scope of practice in the State in which they practice and are an important part of the care team for beneficiaries with chronic pain, in future rulemaking, such as clinical psychologists, or doctors of chiropractic. We do not agree that clinicians should be required to make referrals to occupational and physical therapists; although, as we stated in the proposed rule, and in the code descriptor, we do expect that there will be “ongoing communication and care coordination between relevant practitioners furnishing care, for example physical therapy and occupational therapy...as appropriate.”

Comment: Several commenters opined on our proposal to require verbal consent at the

initiating visit, or at the initiating visit and subsequent visits, to help make sure that people with Medicare living with chronic pain want the services, are aware they may need them, and that they also receive an explanation of any cost sharing that may apply in their particular situation. All commenters were supportive of our proposal. One commenter stated that, although it supported requiring consent, it noted that consent should be obtained at the third visit, so patients could be given an opportunity to work with the physician a few times, but at the first visit the physician should still be required to educate patients regarding CPM services, explain their frequency/purpose/value, and any cost-sharing that may apply, so patients can better understand the model which is different according to the commenter from the disjointed, fragmented, solitary struggle for effective pain care that the vast majority of pain patients presently experience, and that in this manner, patients would have an opportunity to understand CPM services better. The commenter also stated consent should be discussed, including any costs with family/unpaid caregivers. The same commenter stated we need not require consent at each visit, and suggested that we should support practitioners referred by the CPM billing practitioner to also seek the patient's consent, to emphasize in part that they are working as a team. A different commenter stated that in implementing the new codes, we should establish requirements similar to CCM services, for example, requiring that providers document that all components of the service are met and that informed consent, inclusive of cost-sharing, has been obtained. Another commenter urged us to allow consent to be obtained and documented by members of the care team in addition to the physician/qualified health profession. One commenter believes that verbal consent should be obtained upon enrollment (at the first visit) and not at every visit, which would create inefficiencies. The spouse of a person living with longtime chronic pain observed that "patient consent, consultation should always be a part of primary care as patients are typically

ignored, especially in pain management.” A commenter stated that consent, for some people with dementia or other cognitive health issues, might have to be obtained through a legal representative outside of the face to face initiating visit.

Response: We are appreciative of the comments regarding consent, as we believe the person with chronic pain should be educated regarding what the CPM services are, how often they may be generally expected to receive the services at this initial visit, and receive an explanation of any cost sharing that may apply in their particular situation; this is an important element of person-centered care and self-determination. We disagree with the commenter who suggested we obtain verbal consent after the first visit. Similar to how the Medicare Chronic Care Management service is administered, we believe the physician or qualified health care practitioner should get the person’s consent for services before the practitioner bills for them. This helps to ensure that beneficiaries are engaged and are aware of their treatment and cost sharing responsibilities, and helps prevent duplicate billing. If the beneficiary does not provide consent or if other conditions for payment are not met, the practitioner cannot bill Medicare. As outlined in this preamble, referrals may be made to providers who are not rendering a Medicare covered service(s), or who may not be enrolled in Medicare, such as acupuncturists, massage therapists, psychiatrists, dietitians, dentists, and providers of community-based services, which could include companies that make environmental modifications, adult day health programs, direct support workers, and others, and we do not believe that requiring consent from providers who are not billing for the CPM codes is necessary or practicable. We agree that providers should document in the record that the beneficiary has given consent for the services, although we are not requiring that the clinician document that “each element” of the code has been delivered, since that would vary based upon the person’s needs. We are thankful for the

commenter who noted that consent, for some beneficiaries, may have to be obtained from a legally responsible person, such as for people with chronic pain who have dementia, an intellectual or developmental disability, or any other type of cognitive disorder; those arrangements vary under State law.

Comment: One commenter recommended that we focus and support continued communication and care coordination for the CPM services, which it stated has been a long-time struggle for chronic pain care, but an essential element, especially in underserved communities.

Response: We agree that care coordination and communication between all clinicians and other providers furnishing care to beneficiaries living with chronic pain is an essential element, including for people with pain living in underserved communities.

Comment: A few commenters stated that payers and providers should look at quality care and meaningful improvements in function and quality of life (beyond use of a validated pain rating scale or tool). One commenter stressed the importance of utilization and outcome measures that can assess efficacy and cost-effectiveness such as hospitalizations, emergency department and urgent care visits, specialist utilization and procedures, number of prescription medications, and other health care data. Another appreciated our interest in growing the available data related to the prevalence and impact of chronic pain in the Medicare population, and requested that once we collect data, this data be deidentified and made available to the public to assist interested parties in the development and refinement of programs. Another commenter requested that we provide a mechanism for quality outcomes measurement based on the provided service to shed light on pain experienced by the Medicare population, what works best, and what provides improved health outcomes, in part to reduce the need for specialty care and hospitalization. One commenter noted the importance of medication adherence, and data

regarding medication adherence specific to chronic pain, including to avoid unnecessary hospitalizations, adverse events, and deaths.

Response: We agree with the commenters that quality and data collection are foundational components to delivering value as part of the overall care journey, and help ensure optimal care and best outcomes for people of all ages and backgrounds, and across service delivery systems/settings, and payer types, as described in our CMS National Quality Strategy⁷¹. We are aware that there are scant measures that examine chronic pain and medication adherence for chronic pain, and trust that government and interested parties will continue to explore options in measure development, testing, and endorsement to improve measurement in chronic pain care. However, because we did not make any proposals regarding the link between quality and CPM codes, these comments are out of the scope of our proposed rule.

Comment: Several commenters wanted to ensure that use of the CPM codes would not limit or interfere with the beneficiary's access to other medical or pharmacy benefits.

Response: We appreciate the comment and can confirm that its use will not interfere with other medically necessary Medicare benefits.

Comment: Many commenters requested more specifics related to the administrative requirements and potential burdens the use of the CPM codes would place on providers. Commenters urged CMS to work to ensure the documentation requirements not be overly burdensome. This was echoed by a commenter with chronic pain who noted that physicians seem “overwhelmed with today's paperwork and administrative demands.”

Response: In 2020, we established our Office of Burden Reduction and Health Informatics⁷², to unify our efforts to reduce regulatory and administrative burden, and advance

⁷¹ <https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>.

⁷² <https://www.cms.gov/About-CMS/OBRHI>.

interoperability and national standards. We are continuing to engage beneficiaries and the clinical community to better understand their experiences, form solutions, and infuse CMS with a customer-focused mindset. We will be interested to get feedback from clinicians about burden, once the CPM codes are implemented in practice.

Comment: A few commenters recommended CMS reduce potentially prohibitive payment methods, including prior authorization and cost sharing to improve access to chronic pain management. These commenters also suggested increasing access for non-opioid methods of pain management, such as physical therapy and behavioral health care. Another commenter also requested further clarification of cost sharing requirements, as many people with chronic pain have disabilities, with concern about limited access to pain management.

Response: The various interventions described in the PMTF Report's pain management "Toolbox" attest that individualized care consists of diagnostic evaluation that results in an integrative, person-centered care plan that includes all necessary treatment options, that we hope clinicians will consider when they treat Medicare beneficiaries with chronic pain. Regarding cost-sharing, as described above, standard Part B cost-sharing will apply to the CPM services. In some instances, people who are low income or disabled and are dually eligible Medicare and Medicaid beneficiaries, for example, will have different cost-sharing from beneficiaries who are enrolled in Medicare, only. We emphasize that the CPM codes do not require prior authorization.

Comment: One commenter expressed concern and confusion over our use of the word "bundle" in the proposed rule, which they interpreted as payment that contemplated paying other involved providers in an episode of care environment. The commenter further stated that payment-based "bundling" is already a fast-growing and promising form of pain care that should be correctly labeled.

Response: We apologize for any confusion by our use of the word “bundle.” The proposed CPM codes are not bundles as the commenter contemplates, but rather codes similar to the CCM codes, or the code for Cognitive Assessment and Care Planning Services, 99483, that denote the elements of the code itself. By “bundle,” we were just referring to all of the elements contained within the CPM code descriptors.

Comment: One commenter stated that caregivers and trusted family members are also part of the team providing support to people with chronic pain, and recommended including these individuals in the CPM services, which it noted is especially important for people who have communication or cognitive issues. Another commenter stated that caregiver participation for these individuals is especially important as they are often directly affected by the person’s pain and can help in making its perception better, or worse.

Response: We agree that the role of caregivers is of critical importance across Medicare as caregivers provide a broad range of mostly unpaid assistance with diverse health-related activities provided by a friend, family member, partner, or neighbor to a care recipient. The caregiver has a significant personal relationship with the care recipient, and care may be episodic, daily, occasional, or of short or long duration. Caregivers assist in basic personal care activities such as eating and bathing; household management activities, such as shopping and meal preparation; and other activities, such as managing medications, attending medical encounters, and coordinating financial and other activities, such as handling insurance and paying bills. Caregivers may also be involved in managing complex health care and assistive technology activities at home and in navigating care transitions between settings of care. We are pointing out that Medicare makes payment for CPT code 96161 (*Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the*

patient, with scoring and documentation, per standardized instrument). However, as noted in the descriptors for HCPCS codes G3002 and G3003, CPM services must be furnished by a physician or other qualified health practitioner.

Comment: One commenter stated that in implementing the CPM services, it is important for CMS to take a balanced approach between administrative burden and program integrity, and that use of the codes should be considered along with potential risk of “bad actors” to inappropriately use them. The same commenter indicated that we should prevent multiple group practices from concurrently billing for this service for the same patient during the same time period as this would eliminate duplicative services and payment. A different commenter echoed that sentiment, concerned with “doctor shopping,” leading to billing denials and driving up provider costs. Another commenter viewed this problem differently, discussing that some patients will travel for answers, or based on the availability of chronic pain providers in their areas, may need to see their primary care provider first, then may see other providers. This commenter was concerned that providers would not specifically know when this code was billed by previous providers, risking rejection even after services were provided. This commenter recommended eliminating the limits on monthly billing.

Response: As with implementation of any new billing code, we will be monitoring its use going forward, not just for data and other purposes, but also for program integrity reasons. For HCPCS code G3002 and G3003, we would not generally expect multiple group practices to be concurrently billing for a service that is to be rendered once per month, per practitioner, per beneficiary. As noted previously, we will be gathering data on the clinicians billing for and patients receiving the services described by these CPM codes, and we may consider making changes to these codes in future rulemaking, if necessary.

Comment: One commenter asked us to consider whether or not our proposal to create new codes for CPM is the best course, or if we should reconsider and expand the CCM codes. Another commenter elaborated on issues with the CCM codes, stating these are confusing to clinicians, involve administrative and documentation burden, which discourages uptake, and that it hopes this scenario will not develop with the CPM codes.

Response: We appreciate the comments about CCM vs. CPM; we did consider differences in the CCM codes, which we explained in the proposed rule, and believe the best course is to finalize the CPM codes and monitor their use in practice.

Comment: One commenter stated that evidence shows that many people with chronic pain, especially people from communities of color, have low trust in the health care system, based on previous discrimination and follow up. Another commenter stated that it is very important we improve pain management for members of racial and ethnic minorities, given both the rising rates of drug overdose deaths among these populations and disparities in the identification and effective management of pain.

Response: As we outlined in the proposed rule, we are aware of disparities in chronic pain care and seek to address these disparities in part through finalization of the CPM codes.

Comment: A commenter asked that we consider a “MedLearn” article or Educational Transmittal to help providers understand more about the CPM services including who can bill, documentation, potential restrictions with other codes, etc. Several other commenters suggested provider communication such as a Medicare Learning Network article or similar blog post to summarize comments and the final rule. Another commenter suggested that we convene all essential stakeholders in public meetings, organized by the Agency, to hear stakeholder input about the best way to move forward to encourage rather than limit non-opioid pain management.

Response: We appreciate these suggestions from the commenters and are considering how best we can educate providers about use of the new codes, working with our HHS operating division partners.

Comment: A few commenters stated that CPM services should be able to be billed concurrently with CCM, Behavioral Health Integration, or Primary Care Management. Another commenter noted that CPM services might disincentivize the provision of CPM services to the most complex patients in part because neurologists routinely bill certain codes for safety purposes, and the CPM proposal, which prohibited same day billing of certain other codes, would impair care.

Response: We thank the commenters for sharing their feedback. As noted in the CY 2023 PFS proposed rule, we believe there are distinctions in the nature and extent of the assessments, care coordination, medication management, and care planning for CPM to allow concurrent billing for services that are medically reasonable and necessary, and that it is particularly important to allow for the provision of needed services, including behavioral health services to beneficiaries with chronic pain. Therefore, if all requirements to report each service are met then CPM may be billed in the same month as CCM, TCM, and BHI services. We reiterate that the time spent in providing CPM services may not represent time spent in providing any other reported service.

Comment: A commenter questioned how the CPM codes relate to the proposal in the CY 2023 OPPTS proposed rule that would add the Facet Joint Interventions service category to the prior authorization list. This commenter noted that it seems incongruous for CMS to be encouraging chronic pain management with this CPM code while discouraging it in another.

Response: We thank the commenter for the comment; however, the discussion of the

new prior authorization proposal in the CY 2023 OPPS proposed rule is beyond the scope of this CY 2023 PFS rule.

To further assist clinicians and interested parties in understanding more about how we anticipate the CPM services might be used, members of our clinical team have prepared the following scenarios to illustrate how the codes might be used in practice.

- **Scenario 1:** An individual clinician sees a new patient who is seeking to establish care (for example, a general internist sees a patient who is new to her practice and has a history of chronic pain). The internist/clinician would need to review the patient's history, including current and prior medications and treatments tried, and perform an examination to ascertain the source of the patient's symptoms as well as an initial functional assessment and develop a care management plan as part of the visit).

++ This scenario would also likely involve some aspect of medication management, may include referrals to behavioral health clinicians, substance use disorder, and/or pain management specialists, and would most certainly involve scheduling a follow-up appointment with the internist, which could occur in 1-2 weeks or in several months (or somewhere in between) depending on the needs of the patient.

++ While other clinicians are involved either through referrals or to support other elements of the CPM services, it is expected that generally only one or two clinicians would bill HCPCS code G3002/G3003, asserting that they are providing the CPM services.

- **Scenario 2:** An individual clinician sees an established patient who is well known and has a stable care plan and on maintenance medications (that is, a family physician sees a patient for routine care to update the care management plan and perform a functional assessment to ensure that the treatment plan is still supporting the patient's goals of care).

++ As we stated above, it would be unusual for no medications or supplements to be involved in the majority of cases of the management of chronic pain. This may or may not mean the patient is on a chronic opioid or other medication, and medication management is an almost universal component of chronic pain management care – even for very stable patients.

++ Medication management does not only involve management of medications that the patient is currently taking, but the ability to recognize when a new medication or over the counter treatment should be considered as an adjunct to other treatment, to discuss that recommendation in the context of shared decision-making and to initiate the pharmacotherapeutic plan of care.

++ Coordination of care (be it the person's behavioral health treatment or pain management care in general) is critical, and we mention in the proposed rule language that coordination is expected "as an element of the CPM codes, the development of and/or revisions to a person-centered care plan that includes goals, clinical needs, and desired outcomes, as outlined above and maintained by the practitioner furnishing CPM services." However, not all psychologists are trained or authorized to coordinate such care as a primary care clinician is trained, as we have explained.

- **Scenario 3:** An individual clinician provides care to a patient with multiple chronic conditions (for example, a family physician sees a patient with a history of chronic low back pain, obesity, diabetes, and chronic renal insufficiency and routinely must manage multiple concerns at the same visit).

++ This clinician would likely perform routine functional assessments of this patient, medication management, ongoing clinical assessments of their diabetes and kidney function, and discussion of what their options are when it comes to managing their pain in the context of these

other conditions. As such, without knowing the history of this patient's conditions, their current medications, past treatments that have been successful or failures, the clinician cannot properly manage this patient's chronic pain (for example. changes in medication must be made in the context of this patients' kidney function). Additionally, the clinician may wish to offer the patient non-pharmacologic options for the treatment of their chronic low back pain, which may include referrals to chiropractic, acupuncture, physical therapy, massage, cognitive behavioral therapy or other integrative or complementary/integrative treatments, all of which would be reasonable discussions to take place in the context of billing HCPCS codes G3002 and G3003, as appropriate.

- **Scenario 4:** One individual clinician transfers care of a patient to another individual clinician in the course of the month (for example, a family physician refers to a pain management specialist who then takes over the pain care aspects of a patient with chronic pain).

++ This situation could necessitate two different practitioners billing HCPCS code G3002 during that first month; the lead clinician could change to someone else on an infrequent and limited basis,

In summary, we are finalizing code descriptors for HCPCS codes G3002 and G3003, with two modifications to HCPCS code G3002 shown in italics, below.

HCPCS code G3002 (*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/or 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, e.g. physical therapy and occupational therapy, complementary and integrative approaches, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.)

HCPCS code G3003 (Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month. (List separately in addition to code for G3002. When using G3003, 15 minutes must be met or exceeded.))

In response to public comments, we are finalizing our proposed policies pertaining to HCPCS codes G3002 and G3003, with a few modifications, as follows:

- We are defining chronic pain as persistent or recurrent pain lasting longer than 3 months, as proposed;
- We are requiring that the first time HCPCS code G3002 is billed, the physician or qualified health practitioner must see the beneficiary in-person. Both individuals must be in a clinical setting such as a primary care practitioner's office or other applicable setting, as proposed;
- A physician or other qualified health practitioner may bill HCPCS code G3003, for each additional 15 minutes of care, an unlimited number of times, as medically necessary, per month, after HCPCS code G3002 has been billed, as revised;
- A work RVU of 1.45 for HCPCS code G3002 and a work RVU of 0.5 for HCPCS code G3003, as proposed;

- That any of the CPM in-person components included in HCPCS codes G3002 and G3003 may be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries, as revised;
- That HCPCS codes G3002 and G3003 may be furnished and billed by physicians and other qualified health professionals, as proposed; and
- That both E/M and CPM may be billed on the same day if all requirements to report each service are met, and time spent providing CPM services does not represent time spent for providing any other reported service, as proposed.

In response to comments expressing lack of clarity about certain proposed policies pertaining to HCPCS codes G3002 and G3003, we are clarifying in this final rule that:

- The beneficiary, at the first visit, need not have an established history or diagnosis of chronic pain, or be diagnosed with a condition that causes or involves chronic pain; but that rather, it is the clinician's responsibility to establish, confirm, or reject a chronic pain and/or pain-related diagnosis when the beneficiary first presents for care and the clinician first reports HCPCS code G3002;
- That clinicians will be required to furnish all appropriate elements of the code bundle, but that we do not expect that all elements of the code bundle will be appropriate for every patient;
- That we are not requiring in the code descriptor that a clinician refer a beneficiary to other services; that determination should be made between the clinician and the beneficiary; and finally
- That CPM services would be available for billing/reporting in conjunction with remote patient monitoring, remote physiologic monitoring, or remote therapeutic monitoring if all

requirements to report each service are met, and time spent providing CPM services does not represent time spent for any other furnished and billed service.

(34) Revisions to the “Incident to” Physicians’ Services Regulation for Behavioral Health Services

In the CY 2014 PFS final rule with comment period (78 FR 74425 through 74427), we created an exception to our “incident to” regulation at § 410.26(b)(5) under which “incident to” services generally must be furnished under direct supervision. Specifically, we finalized a policy to require general, rather than direct, supervision when chronic care management services are furnished incident to the billing physician’s or NPP’s services outside of the practice’s normal business hours by clinical staff. In the CY 2017 PFS final rule (81 FR 80255), we finalized a revision to our regulation under § 410.26(b)(5) to require a general, rather than direct, level of supervision for designated care management services, and established that we would designate care management services through notice and comment rulemaking.

We understand that circumstances related to the PHE for COVID-19 have likely contributed to an increase in the demand for behavioral health services while also exacerbating existing barriers to beneficiaries’ access to needed behavioral health services. For example, the American Psychological Association (APA) conducted a survey in 2020 and a follow-up survey in 2021 to better understand the impact of the COVID-19 pandemic on mental health treatment and the work of practicing psychologists. In the 2021 follow-up survey, many psychologists reported increases in the demand for treatment of anxiety and depression. They reported the greatest increases in treating anxiety disorders (84 percent, up from 74 percent), depressive disorders (72 percent, up from 60 percent), and trauma- and stress-related disorders (62 percent,