CHLPI CENTER for HEALTH LAW and POLICY INNOVATION
HARVARD LAW SCHOOL

Review of Proposed Rule for CY 2024 Payment Policies under the Physician Fee Schedule

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I. Background

The Centers for Medicare & Medicaid Services (CMS) reimburses physicians for care furnished under Medicare Part B based on the Medicare Physician Fee Schedule (PFS). In other words, Medicare uses the PFS to determine reimbursement for services including the professional services of physicians and other enrolled health care providers, services covered "incident to" physicians' services, and certain diagnostic tests (i.e., diagnostic tests other than clinical laboratory tests). The PFS lists more than 10,000 unique covered service codes and their payment rates.

CMS updates the PFS on a regular basis. Payment policy changes are published annually, which process kicks off with a proposed rule to allow for public comment. For Calendar Year (CY) 2024, an unpublished version of the proposed rule was released on July 13th.[1] Written comments must be received on or before September 11, 2023, to be assured of consideration.

II. Review of the CY 2024 Proposed Rule

This analysis focuses on one specific aspect of the proposed rule: new payment policies for services addressing health-related social needs. More specifically, CMS has set forth a proposal for reimbursement of (1) Community Health Integration (CHI) Services, (2) Social Determinants of Health Risk Assessment, and (3) Principal Illness Navigation (PIN) Services.

According to CMS, the agency is "exploring ways to better identify and value practitioners' work when they incur additional time and resources helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with the practitioner's ability to execute a medically necessary plan of care. . . . Medical practice has evolved to increasingly recognize the importance of these activities, and we believe practitioners are performing them more often. However, this work is not explicitly identified in current coding, and as such, we believe it is underutilized and undervalued."

Notably, the proposals for CHI services and PIN services are very similar in terms of operational parameters and valuation. CMS explains the need for separate categories as follows: "The navigation services [patients with a serious, high-risk condition] need are

[1] The official version is slated to be published in the Federal Register on August 7, 2023.

similar to CHI services, but SDOH need(s) may be fewer or not present; and there are specific service elements that are more relevant for the subset of patients with serious illness. Accordingly, we are proposing for PIN services a parallel set of services to the proposed CHI services, but focused on patients with a serious, high-risk illness who may not necessarily have SDOH needs; and adding service elements to describe identifying or referring the patient to appropriate supportive services, providing information/resources to consider participation in clinical research/clinical trials, and inclusion of lived experience or training in the specific condition being addressed."

Please note that the analysis below is *not* exhaustive; rather, we have highlighted features that we anticipate will be of particular interest to our community partners.

Service	Proposed Codes and Valuation	Additional Information on Proposed Parameters
Community Health Integration (CHI) Services	**GXXX1** Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address SDOH need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit: (a) Person-centered assessment (b) Practitioner, home-, and community-based care coordination (c) Health education (d) Building patient self-advocacy skills (e) Health care access / health system navigation (f) Facilitating behavioral change (g) Facilitating and providing social and emotional support (h) Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals **GXXX2** Community health integration services, each additional 30 minutes per calendar month	• **Initiating visit:** CHI services could be furnished monthly, as medically necessary, following an initiating Evaluation/Management visit in which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the visit. CMS would not require an initiating E/M visit every month that CHI services are billed—only before commencing CHI services (to establish the treatment plan, specify how addressing the unmet SDOH need(s) would help accomplish that plan, and establish the CHI services as incident to the billing practitioner's service). Per CMS, "certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as CHI initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary CHI services in the subsequent month(s)." • **Billing and documentation:** The same practitioner would furnish and bill for both the CHI initiating visit and the CHI services. Time spent furnishing CHI services for purposes of billing HCPCS codes GXXX1 and/or GXXX2 would have to be documented in the patient's medical record in its relationship to the SDOH need(s) they are intended to address and the clinical problem(s) they are intended to help resolve. Per the proposed rule, "[t]he activities performed by the auxiliary personnel would be described in the medical record, just as all clinical care is documented in the medical record. We are proposing to require the SDOH need(s) to be recorded in the patient's medical record, and for data standardization, practitioners would be encouraged to record the associated ICD-10 Z-code (Z55-Z65) in the medical record and on the claim." Only one practitioner per beneficiary per calendar month could bill for CHI services to support coordination and avoid duplication / fragmentation in addressing specific SDOH. • **Service delivery:** CHI services would have to be performed by "certified or trained auxiliary personnel," which may be a CHW, incident to the professional services and under the general supervision of the billing practitioner.

Service	Proposed Codes and Valuation	Additional Information on Proposed Parameters
	Valuation for GXXX1 = Work RVU of 1.00; work time of 25 minutes **Valuation for GXXX2** = Work RVU of .70; work time of 20 minutes	○ **General supervision** means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service. ○ In States where there are no **applicable licensure or other laws or regulations** relating to individuals performing CHI services, we are proposing to require auxiliary personnel providing CHI services to be trained to provide them. **Training** must include the competencies of patient and family communication, interpersonal and relationship building, patient and family capacity-building, service coordination and system navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including of local community-based resources. ○ Regarding **scope**, CMS explains that "[s]ince Medicare payment generally is limited to items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, the focus of CHI services would need to be on addressing the particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit." ○ **Performance of services by a third party:** CMS proposes that a billing practitioner may arrange to have CHI services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the requirements and conditions for payment of CHI services are met. There must be "sufficient clinical integration between the third party and the billing practitioner."
SDOH Risk Assessment	**GXXX5** Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months. **Valuation** = Work RVU of .18; work time of 15 minutes	• **Initiating visit:** The SDOH risk assessment must be furnished by a practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. • **Billing and documentation:** The SDOH needs identified through the risk assessment must be documented in the medical record, and may be documented using Z codes Z55-Z65. • **Service delivery: Required elements** would include administration of a standardized, evidence-based SDOH risk assessment tool that has been tested and validated through research, and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties. ○ Possible **evidence-based tools** include the CMS Accountable Health Communities tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.

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<tr><th>Service</th><th>Proposed Codes and Valuation</th><th>Additional Information on Proposed Parameters</th></tr>
<tr><td></td><td></td><td>CMS is also proposing to add this code to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner (or auxiliary personnel incident to the practitioner’s services) completes the risk assessment via telehealth.</td></tr>
<tr><td>Principal Illness Navigation (PIN) Services</td><td>GXXX3 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:
(a) Person-centered assessment
(b) Identifying or referring patient (caregiver, family) to appropriate supportive services
(c) Practitioner, home-, and community-based care coordination
(d) Health education
(e) Building patient self-advocacy skills
(f) Health care access / health system navigation
(g) Facilitating behavioral change
(h) Facilitating and providing social and emotion support
(i) Leverage knowledge of the series, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals

GXXX4 Principal Illness Navigation services, additional 30 minutes per calendar month

Valuation for GXXX3 = Work RVU of 1.00; work time of 25 minutes

Valuation for GXXX4 = Work RVU of .70; work time of 20 minutes</td><td>Initiating visit: E/M visit performed by the billing practitioner who will also be furnishing the PIN services during the subsequent calendar month(s). During the visit, the billing practitioner would identify the medical necessity of PIN services and establish an appropriate treatment plan. CMS would not require an initiating E/M visit every month that PIN services are billed—only before commencing PIN services. Per CMS, “certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as PIN initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary PIN services in the subsequent month(s).”
Eligible beneficiaries: The following characteristics would have to be present: (a) one serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death; <u>and</u> (b) The condition requires development, monitoring, or revision of a disease-specific care plan, and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver.
According to CMS, “[e]xamples of a serious, high-risk condition/illness/disease include, but are not limited to, cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder.”
Billing and documentation: The PIN initiating visit would be billed separately, and would be a pre-requisite to billing for PIN services. The same practitioner would furnish and bill for both the PIN initiating visit and the PIN services. Time spent furnishing PIN services for purposes of billing HCPCS codes GXXX3-4 must be documented in the medical record in its relationship to the serious, high-risk illness. The activities performed by the auxiliary personnel, and how they are related to the treatment plan for the serious, high-risk condition, would be described in the medical record, just as all clinical care is documented in the medical record. CMSrequire identified SDOH need(s), if present, to be recorded in the medical record, and for data standardization, practitioners would be encouraged to record the associated ICD-10 Z-code in the medical record and on the claim. Only one practitioner per beneficiary per calendar month could bill for PIN services for a given serious, high-risk condition.
Service delivery: PIN services would be performed by “certified or trained auxiliary personnel” incident to the professional services and under the general supervision of the billing practitioner.</td></tr>
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Service	Proposed Codes and Valuation	Additional Information on Proposed Parameters
		○ **General supervision** means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service. ○ In States that do not have applicable **licensure, certification, or other laws or regulations**, CMS proposes to require auxiliary personnel providing PIN services to be trained to provide them. **Training** must include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity building, service coordination and systems navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including specific certification or training on the serious, high-risk condition/illness/disease addressed in the initiating visit. ○ Regarding **scope**, "[s]ince Medicare payment is limited to items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, with respect to addressing SDOH need(s), the focus of PIN services would need to be on addressing particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the serious, high-risk condition." ○ **Performance of services by a third party:** CMS proposes that a billing practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO), if all requirements and conditions for payment of PIN services are met. There must be "sufficient clinical integration between the third party and the billing practitioner."

III. Requests for Comment

The public is permitted to comment on all aspects of the proposed rule. In addition, CMS specifically requests comment on several features which are highlighted below.

CHI / PIN Services:

- To help inform whether proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, CMS is seeking comment on the typical amount of time practitioners spend per month

furnishing CHI / PIN services. CMS also asks about the typical duration of services in terms of the number of months for which practitioners furnish the services.

- CMS seeks comment as to whether it should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite initiating visit for CHI or PIN services, including, for example, an annual wellness visit that may or may not include the optional SDOH risk assessment also proposed in this rule.
- CMS seeks comment on the number of hours of training to require, as well as the training content and who should provide the training.
- CMS believes that many of the elements of CHI and PIN services would involve direct contact between the auxiliary personnel and the patient but may not necessarily be in-person and a portion might be performed via two-way audio. CMS is seeking to confirm its understanding of where and how services would typically be provided (for example, with or without direct patient contact, in-person, using audio-video, using two-way audio; and whether providers are typically local to the patient).
- CMS seeks comment regarding whether patient consent for services should be required.
- CMS seeks comment on whether States typically cover similar services under their Medicaid programs, and whether such coverage would be duplicative of the CHI / PIN service codes. CMS also seeks comment on if there are other service elements not included in the proposed CHI / PIN service codes that are part of associated care and should be included. For example, are there circumstances when clinical navigators, under the supervision of another professional, typically spend time face-to-face with patients that the PIN services codes, as currently described, may not fully account for?

SDOH Risk Assessment:

- CMS notes that appropriate follow-up is critical for mitigating the effects of the identified, unmet SDOH needs on a person's health. "An SDOH risk assessment without appropriate follow-up for identified needs would serve little purpose." CMS seeks comment on whether it should require—as a condition of payment for SDOH risk assessment—that the billing practitioner also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with CBOs to address identified SDOH needs.