

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.

We propose the following specific codes and descriptors:

**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 social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:*

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.*

- ++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

- ++ *Facilitating patient-driven goal-setting and establishing an action plan.*

- ++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

- *Practitioner, Home-, and Community-Based Care Coordination.*

- ++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).*

- ++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

- ++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

- ++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).*

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*

- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*

- *Health care access/health system navigation*

- ++ *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*

- *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 (List separately in addition to GXXX1).*

By way of example, tailored support could be provided through CHI services to a patient experiencing homelessness with signs of potential cognitive impairment and a history of frequent ED admissions for uncontrolled diabetes. The patient's primary care practitioner (PCP) learns during a clinic visit after discharge from the ED, that the patient has been able to reliably fill their prescriptions for diabetes medication, but frequently loses the medication (or access to it) while transitioning between homeless shelters and a local friend's home. In the medical record, the PCP documents SDOH need(s) of housing insecurity and transportation insecurity contributing to medication noncompliance, resulting in inadequate insulin control and a recent ED visit for hypoglycemia. The PCP's treatment plan is daily diabetes medication, with the goal of maintaining hemoglobin A1c within appropriate levels. To accomplish the treatment plan, the PCP

orders CHI services to develop an individualized plan for daily medication adherence/access while applying for local housing assistance, and also orders a follow up visit for cognitive impairment assessment and care planning to further evaluate the potential contribution of cognitive impairment. The PCP's auxiliary personnel provide tailored support, comprised of facilitating communication between the patient, local shelters, and the friend, to help the patient identify a single location to reliably store their medication while applying for local housing assistance. The auxiliary personnel also help the patient identify a reliable means of transportation daily to that location for their medication, and show the patient how to create a daily automated phone reminder to take the diabetes medication. The auxiliary personnel document these activities (including amount of time spent) in the medical record at the PCP's office, along with periodic updates regarding the status of the patient's housing assistance application.

To help inform whether our proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, we are seeking comment on the typical amount of time practitioners spend per month furnishing CHI services to address SDOH needs that pose barriers to diagnosis and treatment of problem(s) addressed in an E/M visit. We are also seeking comment to better understand the typical duration of CHI services, in terms of the number of months for which practitioners furnish the services.

We are proposing that all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements, and authorized to perform them under applicable State laws and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide the services performed incident to the billing practitioner's professional services, including licensure, that are imposed by the State in which the services are being furnished. 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. We are proposing these competencies because they reflect professional consensus regarding appropriate core competencies for CHWs, applied to this context.<sup>9</sup> We are seeking public comment on whether it would be appropriate to specify the number of hours of required training, as well as the training content and who should provide the training.

We are proposing to require that time spent furnishing CHI services for purposes of billing HCPCS codes GXXX1–2 must 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. The 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.

Since CHI services are community-based and involve connecting the patient with local resources in their community, and are highly personalized, *e.g.*, hearing and understanding a patient's life story and culture, we believe that most of the elements of CHI services would involve direct contact between the auxiliary personnel and the patient, and that a substantial portion would be in-person but a portion might be performed via two-way audio. We are seeking to confirm our understanding of where and how these services would be typically provided (*e.g.*, in-person, audio-video, two-way audio).

We are seeking public comment, in particular, regarding whether we should require patient consent for CHI services. For care management services that could generally be performed without any direct patient contact, we require advance patient consent to receive the services as a prerequisite to furnishing and billing the services, to avoid patients receiving bills for cost sharing that they might not be expecting to receive. For example, a patient might receive chronic care management services comprised of practitioners coordinating care with each other and

reviewing or exchanging medical records between visits in ways that do not require involving the patient directly. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have statutory authority to waive cost sharing for care management or other services. Rather, cost sharing remains applicable except as specified by statute such as for certain preventive services. In recent years, we have required advance documented patient consent to receive most care management services as a condition of the practitioner billing those services, to avoid a situation where the patient is surprised to receive a bill for the associated cost sharing. These consent requirements include informing the patient about applicable cost sharing, the right to discontinue services, and, where applicable, the limitation that payment is made for the service to only one practitioner per month. We have heard from interested parties over time that requiring advance patient consent is an administrative burden and may pose a barrier to receipt of needed services. We are not proposing to require consent for CHI services, since we believe these services typically would involve direct patient contact, and largely be provided in-person. However, if we hear from public commenters that CHI services would frequently not involve direct contact with the patient, or could extend for periods of time for which the patient might not be expecting to incur cost sharing obligations (such as multiple months), we would consider requiring patient consent to receive CHI services in our final rule.

We are proposing 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 “incident to” and other requirements and conditions for payment of CHI services are met. While we are proposing to allow CHI services to be performed by auxiliary personnel under a contract with a third party, we wish to be clear, as we have in our regulations for current care management services, that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained. As we discussed in a similar context for

care management services the CY 2017 PFS final rule, if there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing the services and the billing practitioner, we do not believe CHI services, as we propose to define them, could be fully performed; and therefore, in such cases, CHI services should not be billed (see 81 FR 80249). We would expect the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner to ensure that CHI services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for CHI services to address the SDOH need(s) that limit the practitioner's ability to diagnose and treat the problem(s) addressed in the initiating visit.

As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. As described earlier, they may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve, and may have the infrastructure or systems in place to assist practitioners to provide CHI services. We understand that many CBOs provide social services and do other work that is beyond the scope of CHI services, but we believe they are well-positioned to develop relationships with practitioners for providing reasonable and necessary CHI services.

Because we are concerned about potential fragmentation that could occur in addressing specific SDOH, we are proposing that only one practitioner per beneficiary per calendar month could bill for CHI services. This would allow

<sup>9</sup> <https://chwhtraining.org/c3-project-chw-skills/>.

the patient to have a single point of contact for all their CHI services during a given month.

We are proposing that the practitioner could separately bill for other care management services during the same month as CHI services, if time and effort are not counted more than once, requirements to bill the other care management service are met, and the services are medically reasonable and necessary.

We propose that CHI services could not be billed while the patient is under a home health plan of care under Medicare Part B, since we believe there would be significant overlap between services furnished under a home health plan of care and CHI services, particularly in the home health services referred to as “medical social services,” and in comprehensive care coordination. For example, medical social services can be furnished to the patient’s family member or caregiver on a short-term basis when the home health agency (HHAs) can demonstrate that a brief intervention by a medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the patient’s medical condition or to the patient’s rate of recovery. Additionally, the home health agency (HHA) conditions of participation require that HHAs coordinate all aspects of the beneficiary’s care while under a home health plan of care, such as integrating services, whether provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines; and involvement of the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

Also, we note that when Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. Based on the specificity of the coding for our proposal, we do not expect that CHI services will neatly overlap with any other coverage for patients who are dually eligible for Medicare and Medicaid. However, we are seeking public comment regarding whether States typically cover services similar to CHI under their Medicaid programs, and whether such coverage would be duplicative of the CHI service codes. We also seek comment on whether there are other service elements not included in the proposed CHI service codes that should be included, or are important in addressing unmet

SDOH need(s) that affect the diagnosis or treatment of medical problems, where CMS should consider coding and payment in the future.

#### c. Proposed CHI Services Valuation

For HCPCS code GXXX1, we are proposing a work RVU of 1.00 based on a crosswalk to CPT code 99490 (*Chronic care management 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 that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) as we believe these values most accurately reflect the resource costs incurred when the billing practitioner furnishes CHI services. CPT code 99490 has an intraservice time of 25 minutes and the work is of similar intensity to our proposed HCPCS code GXXX1. We are, therefore, proposing a work time of 25 minutes for HCPCS code GXXX1, based on this same crosswalk to CPT code 99490. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GXXX1.

For HCPCS code GXXX2, we are proposing a crosswalk to the work RVU and direct PE inputs associated with CPT code 99439 (*Chronic care management 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 that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 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)*) as we believe these values reflect the resource costs incurred when the billing practitioner furnishes CHI services. Therefore, we are proposing a work RVU of 0.70 and a work time of 20 minutes for HCPCS code GXXX2.

#### d. Social Determinants of Health (SDOH)—Proposal To Establish a Stand-Alone G Code

##### i. Background

As previously discussed, there is increasing recognition within the health

care system of the need to take SDOH into account when providing health care services, given that it is estimated<sup>10</sup> that around 50 percent of an individual’s health is directly related to SDOH. Healthy People 2030 define the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context, which include factors like housing, food and nutrition access, and transportation needs. Many Federal agencies are also developing policies to better address the impact SDOH have on patients, in support of HHS’s Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity,<sup>11</sup> as well as the CMS Framework for Health Equity.<sup>12</sup>

##### ii. Proposed SDOH Risk Assessment Code

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients, including by recommending the assessment of SDOH through position or discussion papers,<sup>13 14 15</sup> organizational strategic plans,<sup>16</sup> and provider training modules.<sup>17</sup> Previously in this section of our proposed rule, we discuss how the practice of medicine currently includes assessment of health-related social needs or SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally

<sup>10</sup> <https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf>.

<sup>11</sup> <https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeac728ccd7/SDOH-Action-Plan-At-a-Glance.pdf>.

<sup>12</sup> <https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf>.

<sup>13</sup> <https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html>.

<sup>14</sup> <https://doi.org/10.7326/M17-2441>.

<sup>15</sup> <https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/>.

<sup>16</sup> <https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf>.

<sup>17</sup> <https://edhub.ama-assn.org/steps-forward/module/2702762>.

performed by physicians and practitioners in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. We believe the resources involved in these activities are not appropriately reflected in current coding and payment policies. As such, we are proposing to establish a code to separately identify and value a SDOH risk assessment that is furnished in conjunction with an E/M visit.

We are proposing a new stand-alone G code, GXXX5, *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*. SDOH risk assessment refers to a review of the individual's SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions. We are proposing GXXX5 to identify and value the work involved in the administering a SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. SDOH risk assessment through a standardized, evidence-based tool can more effectively and consistently identify unmet SDOH needs, and enable comparisons across populations. For example, through administration of the SDOH risk assessment for a patient presenting for diabetes management, a practitioner might discover that a patient's living situation does not permit reliable access to electricity, impacting the patient's ability to keep insulin refrigerated. The practitioner may then prescribe a type of insulin that remains stable at room temperature, or consider oral medication instead. In this example, the practitioner could furnish an SDOH risk assessment in conjunction with the E/M visit to gain a more thorough understanding of the patient's full social history and to determine whether other SDOH needs are also impacting medically necessary care.

We further propose that the SDOH risk assessment must be furnished by the 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. Required elements would include:

- Administration of a standardized, evidence-based<sup>18</sup> 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.

++ Billing practitioners may choose to assess for additional domains beyond those listed above if there are other prevalent or culturally salient social determinants in the community being treated by the practitioner.

Possible evidence-based tools include the CMS Accountable Health Communities<sup>19</sup> tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE)<sup>20</sup> tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.<sup>21</sup>

Given the multifaceted nature of unmet SDOH needs, 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. As such, CMS is seeking comment on whether we 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 community-based organizations (CBO) to address identified SDOH needs.

The SDOH needs identified through the risk assessment must be documented in the medical record, and may be documented using a set of ICD-10-CM codes known as "Z codes"<sup>22</sup> (Z55–Z65) which are used to document SDOH data to facilitate high-quality communication between providers. We are proposing GXXX5 have a duration of 5–15 minutes for the administration of an SDOH risk assessment tool, billed no more often than once every 6 months. We propose to limit the SDOH assessment service to once every six months, as we believe there are generally not significant, measurable changes to health outcomes impacted by a patient's SDOH in intervals shorter than 6 months.

#### iii. Proposed Valuation for SDOH Risk Assessment GXXX5

We propose a direct crosswalk to HCPCS code G0444 (*Screening for depression in adults, 5–15 minutes*), with a work RVU of 0.18, as we believe this service reflects the resource costs associated when the billing practitioner

performs HCPCS code GXXX5. HCPCS code G0444 has an intraservice time of 15 minutes, and the physician work is of similar intensity to our proposed HCPCS code GXXX5. Therefore, we are proposing a work time of 15 minutes for HCPCS code GXXX5 based on this same crosswalk to G0444. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GXXX5.

We believe these services would largely involve direct patient contact between the billing practitioner or billing practitioner's auxiliary personnel and the patient through in-person interactions, which could be conducted via telecommunications as appropriate. Therefore, we are proposing to add this code to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner (or their auxiliary personnel incident to the practitioner's services) completes the risk assessment in an interview format, if appropriate. We believe it is important that when furnishing this service, all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We are seeking comment on where and how these services would be typically provided, along with other aspects of the proposed SDOH assessment service.

#### e. Principal Illness Navigation (PIN) Services

##### i. Background

Experts on navigation of treatment for cancer and other high-risk, serious illnesses have demonstrated the benefits of navigation services for patients experiencing these conditions.<sup>23</sup> Experts have noted the importance of these services for all affected patients, but especially those with socioeconomic disadvantages or barriers to care. Navigation generally means the process or activity of ascertaining one's position and planning and following a route; the act of directing from one place to another; the skill or process of plotting a route and directing; the act, activity, or process of finding the way to get to a place you are traveling. In the context of healthcare, it refers to providing individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely, especially when the landscape is complex and delaying care can be deadly. It is often referred

<sup>18</sup> <https://health.gov/healthypeople/tools-action/browse-evidence-based-resources/types-evidence-based-resources>.

<sup>19</sup> <https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf>.

<sup>20</sup> <https://www.nachc.org/research-and-data/prapare/>.

<sup>21</sup> CMS-10825.

<sup>22</sup> <https://www.cms.gov/files/document/z-codes-data-highlight.pdf>.

<sup>23</sup> See for example, <https://view.ons.org/3hjHjc> and <https://www.accc-cancer.org/docs/projects/pdf/patient-navigation-guide>.

to in the context of patients diagnosed with cancer or another severe, debilitating illness, and includes identifying or referring to appropriate supportive services. It is perhaps most critical when a patient is first undergoing treatment for such conditions, due to the extensive need to access and coordinate care from a number of different specialties or service-providers for different aspects of the diagnosis or treatment, and in some cases, related social services (for example, surgery, radiation, chemotherapy for cancer; psychiatry, psychology, vocational rehabilitation for severe mental illness; psychiatry, psychology, vocational rehabilitation, rehabilitation and recovery programs for substance use disorder; infectious disease, neurology and immunology for human immunodeficiency virus (HIV)-associated neurocognitive disorders). For some conditions, patients are best able to engage with the healthcare system and access care if they have assistance from a single, dedicated individual who has “lived experience” (meaning they have personally experienced the same illness or condition the patient is facing). While we currently make separate payment under the PFS for a number of care management and other services that may include aspects of navigation services, those care management services are focused heavily on clinical aspects of care rather than social aspects, and are generally performed by auxiliary personnel who may not have lived experience or training in the specific illness being addressed. We are seeking to better understand whether there are gaps in coding for patient navigation services for treatment of serious illness, that are not already included in current care management services such as advance care planning services (CPT codes 99497–99498), chronic care management services (CPT codes 99490, 99439, 99491, 99437, 99487 and 99489), general behavioral health integration care management services (CPT code 99484), home health and hospice supervision (HCPCS codes G0181–G0182), monthly ESRD-related services (CPT codes 90951–90970), principal care management services (CPT codes 99424–99427), psychiatric collaborative care management services (CPT codes 99492–99494), and transitional care management services (CPT codes 99495–99496). See additional information on our PFS Care Management Services web page at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management>.

For CY 2024, we are proposing to better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient’s health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death. Examples of serious, high-risk diseases for which patient navigation services could be reasonable and necessary could include cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder. We are proposing new coding for Principal Illness Navigation (PIN) services. In considering the appropriate patient population, we considered the patient population eligible for principal care management service codes (CPT codes 99424 through 99427), as well as clinical definitions of “serious illness.” For example, one peer-review study defined “serious illness” as a health condition that carries a high risk of mortality and either negatively impacts a person’s daily function or quality of life, or excessively strains their caregivers.<sup>24</sup> Another study describes a serious illness as a health condition that carries a high risk of mortality and commonly affects a patient for several years.<sup>25</sup> Some measure serious illness by the amount of urgent health care use (911 calls, emergency department visits, repeated hospitalizations) and polypharmacy.<sup>26</sup> The navigation services such patients need are similar to CHI services (as discussed previously in this section), 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.

#### ii. Proposed Principal Illness Navigation (PIN) Service Definition

PIN services could be furnished following an initiating E/M visit addressing a serious high-risk condition/illness/disease, with the following characteristics:

- 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;

- 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.

Examples 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.

We propose that the PIN initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will also be furnishing the PIN services during the subsequent calendar month(s). The PIN initiating visit would be separately billed (if all requirements to do so are met), and would be a pre-requisite to billing for PIN services. We believe that 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).

The PIN initiating visit would serve as a pre-requisite to billing for PIN services, during which the billing practitioner would identify the medical necessity of PIN services and establish an appropriate treatment plan. The subsequent PIN services would be performed by auxiliary personnel incident to the professional services of the practitioner who bills the PIN initiating visit. The same practitioner would furnish and bill for both the PIN initiating visit and the PIN services, and PIN services must be furnished in accordance with the “incident to” regulation at § 410.26. We would not require an initiating E/M visit every month that PIN services are billed, but

<sup>24</sup> <https://pubmed.ncbi.nlm.nih.gov/29125784/>.

<sup>25</sup> <https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care>.

<sup>26</sup> <https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care>.