CMS Changes Expanding Coverage of Telehealth

WASHINGTON – Saturday, Nov. 30, 2013 -- Medicare beneficiaries received good news on the eve of Thanksgiving as the Centers for Medicare and Medicaid Services approved several changes expanding coverage of telehealth services starting January 2014. The new policies were established in response to proposals by the American Telemedicine Association (ATA) and several of the association's members last year. They include:

- Expanding the geographic areas where telehealth service can be provided into the fringes of metropolitan areas;
- Adding coverage for transitional care management services (CPT codes 99495 and 99496) and making explicit that coverage includes the Evaluation and Management portion of these services;
- Adding coverage for chronic care services (CPT codes 99487-99489) for patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and
- Slightly increasing the fee for originating (patient) sites to $24.63 from $24.43

"A commenter urged CMS to reconsider its decision to not include CPT codes 98969 (Online assessment and management service provided by a qualified nonphysician health care professional to an established patient, guardian, or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network) … on the list of Medicare telehealth services. The commenter noted that such services can serve as a valuable preventive benefit in the treatment and care of Medicare beneficiaries; that such services are often are unavailable to beneficiaries who reside in very rural areas; and that telehealth services should be expanded in view of the increasing number of beneficiaries and the projected physician shortage," CMS wrote.

CMS said it would not extend coverage to these types of services because, as they explained in their 2008 rulemaking document, "(1) these services are non- face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system."

Another commenter asked whether some telehealth services would be covered if they were provided in the private homes or assisted living facilities of the Medicare patient. CMS responded that they would not and again cited the law:

"Response: No, in furnishing TCM services as telehealth services, all other conditions for telehealth services still apply. In addition to geographic criteria, the statutory criteria for eligible originating sites include only certain types of locations specified in section 1834(m)(4)(C)(ii) of the Act, and those do not include private homes and assisted living facilities."

H. Medicare Telehealth Services for the Physician Fee Schedule

1. Billing and Payment for Telehealth Services

a. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional model of medical care. Examples of these services included interpretation of an x-ray, electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment that would have been made to the consultant for the service furnished. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (BIPA) (Pub. L. 106-554) added section 1834(m) to the Act, which significantly expanded Medicare telehealth services. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when delivered via a telecommunications system. We first implemented this provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified in regulations at §410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under §410.78(a)(3), an interactive telecommunications system is defined as, "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system." An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous "store-and-forward" technology when the originating site is a federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at §410.78(a)(1), store-and-forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site. Under the BIPA, originating sites were limited under section 1834(m)(3)(C) of the Act to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, CAH, a rural health clinic (RHC), a federally qualified health center (FQHC) and a hospital (as defined in section 1861(e) of the Act). More recently, section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) (MIPPA) expanded the list of telehealth originating sites to include a hospital-based renal dialysis center, a skilled nursing facility (SNF), and a community mental health center (CMHC). To serve as a telehealth originating site, the Act requires that a site must also be located in an area designated as a rural HPSA, in a county that is not in a MSA, or must be an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be with a telepresenter at the originating site.

b. Current Telehealth Billing and Payment Policies

As noted previously, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in a qualifying originating site. An originating site is defined as one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system. The originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner;
- Hospitals;
- CAHs;
- RHCs;
- FQHCs;
- Hospital-Based or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites);
- SNFs;
- CMHCs.

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations;
- Follow-up inpatient consultations;
- Office or other outpatient visits;
- Individual psychotherapy;
- Pharmacologic management;
- Psychiatric diagnostic interview examination;
- End-stage renal disease (ESRD) related services;
- Individual and group medical nutrition therapy (MNT);
- Neurobehavioral status exam;
- Individual and group health and behavior assessment and intervention (HBAI);
- Subsequent hospital care;
- Subsequent nursing facility care;

- Individual and group kidney disease education (KDE);
- Individual and group diabetes self-management training (DSMT);
- Smoking cessation services;
- Alcohol and/or substance abuse and brief intervention services;
- Screening and behavioral counseling interventions in primary care to reduce alcohol misuse;
- Screening for depression in adults;
- Screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs;
- Intensive behavioral therapy for cardiovascular disease; and
- Behavioral counseling for obesity.

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under state law to furnish the service via a telecommunications system:

- Physician;
- Physician assistant (PA);
- Nurse practitioner (NP);
- Clinical nurse specialist (CNS);
- Nurse-midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian or nutrition professional.

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service,

appended with the –GT (via interactive audio and video telecommunications system) or –GQ (via asynchronous telecommunications system) modifier. By reporting the –GT or –GQ modifier with a covered telehealth procedure code, the distant site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site certifies that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As previously described, certain professional services that are commonly furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology are

considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the –GT or –GQ modifier appended).

c. Geographic Criteria for Originating Site Eligibility

Section 1834(m)(4)(C)(i)(I) – (III) of the Act specifies three criteria for the location of eligible telehealth originating sites. One of these is for entities participating in federal telemedicine demonstration projects as of December 31, 2000, and the other two are geographic. One of the geographic criteria is that the site is located in a county that is not in an MSA and the other is that the site is located in an area that is designated as a rural HPSA under section 332(a)(1)(A) of the Public Health Service Act (PHSA) (42 U.S.C. 254e(a)(1)(A)). Section 332(a)(1)(A) of the PHSA provides for the designation of various types of HPSAs, but does not provide for "rural" HPSAs. In the absence of guidance in the PHSA, CMS has in the past interpreted the term "rural" under section 1834(m)(4)(C)(i)(I) to mean an area that is not located in an MSA. As such, the current geographic criteria for telehealth originating sites limits eligible sites to those that are not in an MSA.

To determine rural designations with more precision for other purposes, HHS and CMS have sometimes used methods that do not rely solely on MSA designations. For example, the Office of Rural Health Policy (ORHP) uses the Rural Urban Commuting Areas (RUCAs) to determine rural areas within MSAs. RUCAs are a census tract-based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions in combination with work commuting information to characterize all of the nation's census tracts regarding their rural and urban status and relationships. They were developed under a collaborative project between ORHP, the U.S. Department of Agriculture's Economic Research Service (ERS), and the WWAMI Rural Health Research Center (RHRC). A more comprehensive description is available at the USDA ERS website at: www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/documentation.aspx#.UcsKfZwzZKE. The RUCA classification scheme contains 10 primary and 30 secondary codes. The primary code numbers (1 through

10) refer to the primary, or single largest, commuting share. Census tracts with RUCA codes of 4 through 10 refer to areas with a primary commuting share outside of a metropolitan area. In addition to counties that are not in an MSA, ORHP considers some census tracts in MSA counties to be rural. Specifically, census tracts with RUCA codes 4 through 10 are considered to be rural, as well as census tracts with RUCA codes 2 and 3 that are also at least 400 square miles and have a population density of less than 35 people per square mile.

We proposed to modify our regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by ORHP stating that by defining "rural" to include geographic areas located in rural census tracts within MSAs we would allow for the appropriate inclusion of additional HPSAs as areas for telehealth originating sites. We also noted that by adopting the more precise definition of "rural" for this purpose we would expand access to health care services for Medicare beneficiaries located in rural areas.

We also proposed to change our policy so that geographic eligibility for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies. Absent this proposed change, the status of a geographic area's eligibility for telehealth originating site payment is effective at the same time as the effective date for changes in designations that are made outside of CMS. This proposed change would reduce the likelihood that mid-year changes to geographic designations would result in sudden disruptions to beneficiaries' access to services, unexpected changes in eligibility for established telehealth originating sites, and avoid the operational difficulties associated with administering mid-year Medicare telehealth payment changes. We proposed to establish geographic eligibility for Medicare telehealth originating sites for each calendar year based upon the status of the area as of December 31st of the prior calendar year.

Accordingly, we proposed to revise our regulations at §410.78(b)(4) to conform with both of these proposed policies.

The following is a summary of the comments we received regarding our proposed changes regarding geographic eligibility for serving as a Medicare telehealth originating site.

Comment: Commenters supported our proposal to modify the geographic criteria for originating site eligibility to define rural HPSAs as those located in rural census tracts, as determined by ORHP. In addition, commenters supported our proposal to establish and maintain geographic eligibility on an annual basis. Commenters noted that these modifications will:

- Expand access to health care services for Medicare beneficiaries by allowing some rural areas within MSAs to be eligible for Medicare telehealth services.
- Provide greater clarity and consistency for those involved in telehealth.
- Allow for better continuity of care in rural areas by avoiding sudden disruptions to beneficiaries' access to telehealth services.
- Restore eligibility for some counties that were affected by the updated MSAs based on the 2010 census.

Response: We appreciate the broad support for revising the geographic criteria for originating site eligibility and for establishing and maintaining geographic eligibility for an originating site on an annual basis. We are finalizing our CY 2014 proposals (1) to define rural HPSAs as those located in rural census tracts as determined by ORHP, and (2) to establish and maintain geographic eligibility for an originating site on an annual basis. Consistent with these proposals, we are also revising our regulations at §410.78(b)(4) to conform to these policies.

Comment: Commenters expressed concern that our proposed definition of a rural HPSA does not conform to the definition of a rural HPSA used for rural health clinic qualification, that is, a federally designated shortage area or a non-urbanized area, as defined by the U.S. Census Bureau. As a result, existing RHCs may be excluded from providing telehealth services to Medicare beneficiaries. To avoid this discrepancy, the commenters requested further expansion of the geographic criteria for originating site eligibility to include both non-urbanized areas, as defined by the U.S. Census Bureau, and those rural HPSAs located in rural census tracts, as determined by ORHP. A commenter also recommended that CMS work with the Health Resources and Services Administration (HRSA) to update all data with 2010 census information.

Other commenters recommended expansion of the geographic criteria for originating site to urban and suburban areas. A commenter recommended including sites that are located in (1) areas other than rural HPSAs and (2) counties that are included in MSAs. The commenter noted that beneficiaries in both urban and rural areas face significant barriers in accessing care, including access to certain specialists, such as gerontologists, and access to transportation.

A commenter noted that urban and suburban areas do not have appropriate access to acute stroke care, noting that 77 percent of U.S. counties did not have a hospital with neurological services. As a result of these and other barriers, only a small fraction of patients receive the treatment recommended by the latest scientific guidelines for acute stroke. The commenter concluded that our policy of limiting payment for telehealth services to those originating in rural areas has hampered the development of sufficient stroke consultation coverage and recommend eliminating the rural originating site requirement. Another commenter made similar points concerning cancer patients living in small urban areas without access to complex subspecialty care. A commenter proposed using RUCAs to determine eligible originating sites, to ensure greater access to telemedicine services.

Response: Telehealth originating sites are defined in section 1834(m)(4)(C) of the Act. Only a site that meets one of these requirements can qualify as an originating site:

(1) Located in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

(2) Located in a county that is not included in a Metropolitan Statistical Area; or

(3) From an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

Although RHCs are among the types of locations that are statutorily authorized to serve as originating sites for telehealth services, they also must meet the geographic requirements specified in the statute in order to serve as a telehealth originating site. While most RHCs would meet at least one of the geographic requirements to serve as a telehealth originating site, the separate statutory provisions that

establish geographic requirements for telehealth originating sites and for RHCs are sufficiently different that they do not necessarily overlap. We do not have the authority to waive the geographic telehealth requirements for those RHCs that do not meet any of the requirements to serve as an originating site.

Accordingly, we are not modifying our proposal to expand the scope of telehealth originating sites to include all RHCs, and we are finalizing our proposed regulation without change. We agree with the commenter that the data that are used to determine which areas are rural should be updated to reflect the 2010 census information.

Comment: Several commenters expressed that the complexity involved in determining geographic eligibility to serve as an originating site to provide telehealth services may deter providers from offering telehealth services. Commenters indicated that due to recent changes in the 2010 census there have been numerous changes in all rural designations. Commenters noted that RUCAs are a census tract-based classification scheme and there is no single source to determine one's census tract. Commenters recommended that CMS provide an online tool to allow beneficiaries and providers to determine what specific geographic areas are eligible as telehealth originating sites. One commenter suggested simplifying the process in future years by considering using postal ZIP codes or ZIP+4.

Response: We share the commenters' concern that expanding the geographic definition of "rural" to include more telehealth originating sites has increased the complexity in determining the eligibility of a particular location to serve as an originating site. We are working with HRSA to develop a website tool to provide assistance to potential originating sites to determine their eligibility. As it becomes available, we will post further information about this on the CMS website at www.cms.gov/teleheath/.

Comment: A commenter expressed concern about the annual changes in coverage within census tracts that may occur under the proposal. The commenter recommended that CMS use its authority under the statute to avoid annual on/off/on/off coverage to reduce constant fluctuations in coverage of telehealth services. The commenter concluded that once covered for telehealth services, a beneficiary should not lose coverage because of accidental circumstances of geographic location and administrative designation.

Response: This regulation addresses which providers can qualify to be an originating site to furnish telehealth services. Beneficiaries do not have to meet specialized criteria for telehealth services. Beneficiaries who are covered under Medicare Part B can receive services on the list of Medicare telehealth services from providers that meet the criteria to serve as an originating site (and other criteria to furnish telehealth services). We recognize that beneficiaries may experience disruptions in service or challenges in accessing services when a provider that has been an originating site is not eligible in a future year. As discussed above, we believe our proposed policy mitigates the disruptions caused by mid-year changes in geographic status and expands the scope of providers eligible to serve as telehealth originating sites. However, as noted above, we believe it is necessary to use updated information regarding whether a site meets the statutory criteria for originating site eligibility. We do not believe we have authority to continue treating a site as a telehealth originating site if it ceases to meet the statutory criteria. Thus, we are finalizing the regulations regarding originating sites, as proposed to define rural HPSAs as those located in rural census tracts as determined by ORHP and to establish and maintain geographic eligibility for an originating site on an annual basis.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. We assign any request to make additions to the list of telehealth services to one of two categories. In the November 28, 2011 **Federal Register** (76 FR 73102), we finalized revisions to criteria that we use to review requests in the second category. The two categories are:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if

necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: individual and group HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA to examine the vascular access site); individual and group MNT; neurobehavioral status exam; initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and SNFs; subsequent hospital care (with the limitation of one telehealth visit every 3 days); subsequent nursing facility care (with the limitation of one telehealth visit every 30 days); individual and group KDE; and individual and group DSMT (with a minimum of 1 hour of in-person instruction to ensure effective injection training), smoking cessation services; alcohol and/or substance abuse and brief intervention services; screening and behavioral counseling interventions in primary care to reduce alcohol misuse; screening for depression in adults; screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs; intensive behavioral therapy for cardiovascular disease; and behavioral counseling for obesity.

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2013 will be considered for the CY 2015 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS website at www.cms.gov/telehealth/.

3. Submitted Requests and Other Additions to the List of Telehealth Services for CY 2014

We received a request in CY 2012 to add online assessment and E/M services as Medicare telehealth services effective for CY 2014. The following presents a discussion of this request, and our proposals for additions to the CY 2014 telehealth list.

a. Submitted Requests

The American Telemedicine Association (ATA) submitted a request to add CPT codes 98969 (Online assessment and management service provided by a qualified nonphysician health care professional to an established patient, guardian, or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network) and 99444 (Online evaluation and management service provided by a physician to an established patient, guardian, or health care provider not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network) to the list of Medicare telehealth services.

As we explained in the CY 2008 PFS final rule with comment period (72 FR 66371), we assigned a status indicator of ''N'' (Non-covered service) to these services because: (1) these services are non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT codes 98969 and 99444 are currently noncovered, there would be no Medicare payment if these services were furnished without the use of a telecommunications system. Since these codes are noncovered services for which no payment may be made under Medicare, we did not propose to add online evaluation and management services to the list of Medicare Telehealth Services for CY 2014.

b. Other Additions

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list with respect to the roles of, and

interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 proposed rule (76 FR 42826), we believe that the category 1 criteria not only streamline our review process for publically requested services that fall into this category, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

For CY 2013, CMS finalized a payment policy for new CPT code 99495 (Transitional care management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge) and CPT code 99496 (Transitional care management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of high complexity during the service period face-to-face visit, within 7 calendar days of discharge). These services are for a patient whose medical and/or psychosocial problems require moderate or high complexity medical decision making during transitions in care from an inpatient hospital setting (including acute hospital, rehabilitation hospital, long-term acute care hospital), partial hospitalization, observation status in a hospital, or skilled nursing facility/nursing facility, to the patient's community setting (home, domiciliary, rest home, or assisted living). Transitional care management is comprised of one face-to-face visit within the specified time frames following a discharge, in combination with non-face-to-face services that may be performed by the physician or other qualified health care professional and/or licensed clinical staff under his or her direction.

We believe that the interactions between the furnishing practitioner and the beneficiary described by the required face-to-face visit component of the transitional care management (TCM) services are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under category 1. Specifically, we believe that the required face-to-face visit component of TCM services is similar to the office/outpatient evaluation and management visits described by CPT codes 99201-99205 and 99211-99215. We note that like certain other non-face-to-face PFS services, the other

components of the TCM service are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, we do not need to consider whether the non-face-to-face aspects of the TCM service are similar to other telehealth services. Were these components of the TCM services separately billable, they would not need to be on the telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology. Therefore, we proposed to add CPT codes 99495 and 99496 to the list of telehealth services for CY 2014 on a category 1 basis. Consistent with this proposal, we revised our regulations at §410.78(b) and §414.65(a)(1) to include TCM services as Medicare telehealth services.

4. Telehealth Frequency Limitations

The ATA asked that we remove the telehealth frequency limitation for subsequent nursing facility services reported by CPT codes 99307 through 99310. Subsequent nursing facility services were added to the list of Medicare telehealth services in the CY 2011 PFS final rule (75 FR 73317 through 73318), with a limitation of one telehealth subsequent nursing facility care service every 30 days. In the CY 2011 PFS final rule (75 FR 73615) we noted that, as specified in our regulation at §410.78(e)(2), the federally mandated periodic SNF visits required under §483.40(c) could not be furnished through telehealth.

The ATA requested that the frequency limitation be removed due to "recent federal telecommunications policy changes" and newly available information from recent studies. Specifically, the ATA pointed to the Federal Communications Commission (FCC) pilot funding of a program to facilitate the creation of a nationwide broadband network dedicated to health care, connecting public and private non-profit health care providers in rural and urban locations, and a series of studies that demonstrated the value to patients of telehealth technology.

In considering this request, we began with the analysis contained in the CY 2011 proposed rule (75 FR 73318), when we proposed to add SNF subsequent care, to the list of Medicare telehealth services. We discussed our complementary commitments to ensuring that SNF residents, given their potential clinical acuity, continue to receive in-person visits as appropriate to manage their complex care and to make sure that Medicare pays only for medically reasonable and necessary care. To meet these

commitments, we believed it was appropriate to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

We then reviewed the publicly available information regarding both the FCC pilot program and the ATA-referenced studies in light of the previously stated commitments to assess whether these developments warrant a change in 30-day frequency limitation policy. Based on our review of the FCC demonstration project and the studies referenced in the request, we found no information regarding the relative clinical benefits of SNF subsequent care when furnished via telehealth more frequently than once every 30 days. We did note that the FCC information reflected an aim to improve access to medical specialists in urban areas for rural health care providers, and that medical specialists in urban areas can continue to use the inpatient telehealth consultation HCPCS G-codes (specifically G0406, G0407, G0408, G0425, G0426, or G0427) when reporting medically reasonable and necessary consultations furnished to SNF residents via telehealth without any frequency limitation.

We also reviewed the studies referenced by the ATA to assess whether they provided evidence that more frequent telehealth visits would appropriately serve this particular population given the potential medical acuity and complexity of patient needs. We did not find any such evidence in the studies. Three of the studies identified by the ATA were not directly relevant to SNF subsequent care services. One of these focused on using telehealth technology to treat patients with pressure ulcers after spinal cord injuries. The second focused on the usefulness of telehealth technology for patients receiving home health care services. A third study addressed the use of interactive communication technology to facilitate the coordination of care between hospital and SNF personnel on the day of hospital discharge. The ATA also mentioned a peer-reviewed presentation delivered at its annual meeting related to SNF patient care, suggesting that the presentation demonstrated that telehealth visits are better for SNF patients than in-person visits to emergency departments or, in some cases, visits to physician offices. Although we did not have access to the full presentation it does not appear to address subsequent nursing facility services, so we do not believe this is directly relevant to the clinical benefit of SNF subsequent care furnished via telehealth. More importantly, none of these studies addresses the concerns we have

expressed about the possibility that nursing facility subsequent care visits furnished too frequently through telehealth rather than in-person could compromise care for this potentially acute and complex patient population.

We remain committed to ensuring that SNF inpatients receive appropriate in-person visits and that Medicare pays only for medically reasonable and necessary care. We are not persuaded by the information submitted by the ATA that it would be beneficial or advisable to remove the frequency limitation we established for SNF subsequent care when furnished via telehealth. Because we want to ensure that nursing facility patients with complex medical conditions have appropriately frequent, medically reasonable and necessary encounters with their admitting practitioner, we continue to believe that it is appropriate for some subsequent nursing facility care services to be furnished through telehealth. At the same time, because of the potential acuity and complexity of SNF inpatients, we remain committed to ensuring that these patients continue to receive in-person, hands-on visits as appropriate to manage their care. Therefore, we did not propose any changes to the limitations regarding SNF subsequent care services furnished via telehealth for CY 2014.

The following is summary of the comments we received regarding adding services to the list of Medicare telehealth services.

Comment: All commenters expressed support for our proposals to add transitional care management (CPT codes 99495 and 99496) to the list of Medicare telehealth services for CY 2014. A commenter suggested that CMS allow the required E/M visit component of the two CPT codes to be delivered via telehealth.

Response: We appreciate the support for the proposed additions to the list of Medicare telehealth services. In response to the commenter asking that the required E/M visit component be allowed to be furnished via telehealth, adding TCM CPT codes 99495 and 99496 to the list of Medicare telehealth services allows the E/M portion of these services to be furnished via telehealth. After consideration of the public comments received, we are finalizing our CY 2014 proposal to add TCM CPT codes 99495 and 99496 to the list of telehealth services for CY 2014 on a category 1 basis.

Comment: Another commenter recommended that the originating site be required to conduct a physical examination of a patient's mental and physical condition following a care transaction, and transmit the results to the consulting physician before or during the telehealth session, as a condition for coverage of transitional care management services provided via telehealth.

Response: Concerning the conduct of a physical examination, nothing would preclude such an in person, face-to-face examination from occurring at the originating site; and the TCM codes describe communication between practitioners, when appropriate. We are not adopting this recommendation as we do not believe there is a reason to treat these new additions to the list of telehealth services differently than services already on the list.

Comment: A commenter asked whether providing transitional care management via telehealth applies to services furnished in private homes and assisted living facilities.

Response: No, in furnishing TCM services as telehealth services, all other conditions for telehealth services still apply. In addition to geographic criteria, the statutory criteria for eligible originating sites include only certain types of locations specified in section 1834(m)(4)(C)(ii) of the Act, and those do not include private homes and assisted living facilities.

Comment: A commenter supported our decision not to remove the telehealth frequency limitation for subsequent nursing facility services reported by CPT codes 99307 through 99310. The commenter noted that telehealth occupational therapy services are just beginning to be provided and evaluated, and indicated that it is important to ensure that care for the acute and complex patients found in SNFs is not compromised, regardless of the mode used to provide services.

Another commenter disagreed with our determination that there is no relative clinical benefit from allowing SNF services to be provided via telehealth more than once every 30 days. The commenter indicated that CMS recently issued Survey and Certification Memo 13-35-NH, which put additional emphasis on the survey process for managing behavioral or psychological symptoms of dementia and limiting the use of antipsychotic medications in SNFs. The commenter concluded that having this medical/behavioral evaluation performed by the primary care provider or a psychiatrist using telehealth

could help reduce the need to transfer the patient to the emergency department, which could possibly exacerbate dementia symptoms.

A commenter stated that the frequency limitation can result in additional unnecessary transports for office or emergency department visits, additional opportunities for patient injury, and significant transportation costs especially for the immobile and disabled patient. In light of the evolving mobile health technologies, robotics, and miniaturization of telecommunications tools and medical devices, as well as the increasing complexity and co-morbidities of SNF patients, the commenter recommended setting the limit at one visit per 10 days.

A commenter suggested that subsequent nursing facility care services furnished through telehealth should not be limited to one service every 30 days, as long as the federally mandated SNF visits are conducted on an in-person basis.

Response: We appreciate the comment in support of maintaining the 30-day limit. Commenters opposed to the 30-day limit offered no clinically persuasive evidence to support their positions. Survey and Certification Memo 13-35-NH addresses dementia care in nursing homes and unnecessary drug use. The memo does not address telehealth services, and does not represent clinical evidence supporting removal of the telehealth frequency limitation for subsequent nursing facility services. Therefore, we are maintaining the 30-day frequency limitation for subsequent nursing facility services due to the absence of evidence regarding the relative clinical benefits of SNF subsequent care when furnished via telehealth more frequently than once every 30 days, and to ensure that SNF patients continue to receive in-person, hands-on visits as appropriate to manage their care.

Comment: A commenter urged CMS to reconsider its decision to not include CPT codes 98969 (Online assessment and management service provided by a qualified nonphysician health care professional to an established patient, guardian, or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network) and 99444 (Online evaluation and management service provided by a physician to an established patient, guardian, or health care provider not originating from a related E/M

service provided within the previous 7 days, using the Internet or similar electronic communications network) on the list of Medicare telehealth services. The commenter noted that such services can serve as a valuable preventive benefit in the treatment and care of Medicare beneficiaries; that such services are often are unavailable to beneficiaries who reside in very rural areas; and that telehealth services should be expanded in view of the increasing number of beneficiaries and the projected physician shortage.

Response: As noted previously, we did not propose to add the subject codes to the list of telehealth services because they are noncovered services for which no payment may be made under Medicare. Accordingly we are finalizing our proposal.

In summary, after consideration of the comments we received we are finalizing the changes to our regulation at §410.78 to add "transitional care management" to the list of services in paragraph (b) as proposed.

We remind all interested stakeholders that we are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2015, these requests must be submitted and received by December 31, 2013, or the close of the comment period for this final rule with comment period. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS website at www.cms.gov/telehealth/.

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through December 31 2002, at $20.00. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2014 is 0.8 percent. Therefore, for CY 2014, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is

80 percent of the lesser of the actual charge or $24.63. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 46.

TABLE 46: The Medicare Telehealth Originating Site Facility Fee and MEI Increase by the Applicable Time Period

Facility Fee	MEI Increase	Period
$20.00	N/A	10/01/2001 – 12/31/2002
$20.60	3.0%	01/01/2003 – 12/31/2003
$21.20	2.9%	01/01/2004 – 12/31/2004
$21.86	3.1%	01/01/2005 – 12/31/2005
$22.47	2.8%	01/01/2006 – 12/31/2006
$22.94	2.1%	01/01/2007 – 12/31/2007
$23.35	1.8%	01/01/2008 – 12/31/2008
$23.72	1.6%	01/01/2009 – 12/31/2009
$24.00	1.2%	01/01/2010 – 12/31/2010
$24.10	0.4%	01/01/2011 – 12/31/2011
$24.24	0.6%	01/01/2012 – 12/31/2012
$24.43	0.8%	01/01/2013 – 12/31/2013
$24.63	0.8%	01/01/2014 – 12/31/2014

K. Chronic Care Management (CCM) Services

As we discussed in the CY 2013 PFS final rule with comment period, we are committed to supporting primary care and we have increasingly recognized care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth (77 FR 68978). Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule" which appeared in the November 2, 2011 **Federal Register** (76 FR 67802)).

- The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Center for Medicare and Medicaid Innovation's (Innovation Center's) website at innovations.cms.gov/initiatives/ACO/Pioneer/index.html).

- The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's website at innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html).

- The Primary Care Incentive Payment (PCIP) Program (described on the CMS website at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf).

- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available (described on the CMS website at www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf).

- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS website at www.cms.gov/Medicare/Demonstration-

Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf and the Innovation Center's website at innovations.cms.gov/initiatives/FQHCs/index.html).

- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's website at innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In addition, HHS leads a broad initiative focused on optimizing health and quality of life for individuals with multiple chronic conditions. HHS' Strategic Framework on Multiple Chronic Conditions outlines specific objectives and strategies for HHS and private sector partners centered on strengthening the health care and public health systems; empowering the individual to use self-care management; equipping care providers with tools, information, and other interventions; and supporting targeted research about individuals with multiple chronic conditions and effective interventions. Further information on this initiative can be found on the HHS website at http://www.hhs.gov/ash/initiatives/mcc/index.html.

In coordination with all of these initiatives, we also have continued to explore potential refinements to the PFS that would appropriately value care management within Medicare's statutory structure for fee-for-service physician payment and quality reporting. For example, in the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community (77 FR 68978 through 68993). We view potential refinements to the PFS such as these as part of a broader strategy that relies on input and information gathered from the initiatives described above, research and demonstrations from other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and from the public at large.

1. Patient Eligibility for Separately Payable Non-Face-to-Face Chronic Care Management Services

Under current PFS policy, the payment for non-face-to-face care management services is bundled into the payment for face-to-face E/M visits because care management is a component of those E/M services. The pre- and post-encounter non-face-to-face care management work is included in calculating the total work for the typical E/M services, and the total work for the typical service is used to develop RVUs for the E/M services. In the CY 2012 PFS proposed rule, we highlighted some of the E/M services that include substantial care management work. Specifically, we noted that the vignettes that describe a typical service for mid-level office/outpatient services (CPT codes 99203 and 99213) include furnishing care management, communication, and other necessary care management related to the office visit in the post-service work (76 FR 42917).

However, the physician community continues to tell us that the care management included in many of the E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work involved for certain categories of beneficiaries. In addition, there has been substantial growth in medical practices that are organized as medical homes and devote significant resources to care management as one of the keys to improve the quality and coordination of health care services. Practitioners in these medical homes have also indicated that the care management included in many of the E/M services does not adequately describe the typical non-face-to-face care management work that they furnish to patients.

Because the current E/M office/outpatient visit CPT codes were designed to support all office visits and reflect an overall orientation toward episodic treatment, we agree that these E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. For example, we currently pay physicians separately for the non face-to-face care plan oversight services furnished to beneficiaries under the care of home health agencies or hospices and we currently pay separately for care management services furnished to beneficiaries transitioning from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community.

Similar to these situations, we believe that the resources required to furnish chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions are not adequately reflected in the existing E/M codes. Therefore, for CY 2015, we proposed to establish a separate payment under the PFS for chronic care management services furnished to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

We also stated our intent to develop standards for furnishing chronic care management services to ensure that the physicians and practitioners who bill for these services have the capability to provide them.

Comment: The vast majority of commenters overwhelmingly supported the broad policy of paying separately for non-face-to-face chronic care management services, but submitted comments on many specific aspects of our proposal.

Response: We appreciate the widespread support expressed by commenters for our proposed policy. We address the more specific comments below in this section.

Comment: Some commenters supported our proposed patient eligibility for chronic care management services, at least for the initial implementation of separate payment for the services. Typical of these comments was this statement by one commenter:

> "CMS should initially offer these services to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline."

We also received comments indicating that the patient eligibility should be broadened, for example, to allow eligibility for patients with one condition or for all patients in a practice that meets the practice standards we establish.

On the other hand, some commenters believed that the eligible patient population should be narrowed. Many of these commenters indicated that the benefits of chronic care management are likely to increase with thethe patient's acuity and risk. Many commenters indicated that the criteria described in

the prefatory language for the complex chronic care coordination CPT codes 99487-99489 describes a narrower and more appropriate patient population. The CPT criteria for CY 2014 currently state:

> "Patients who require complex chronic care coordination services may be identified by practice-specific or other published algorithms that recognize multiple illnesses, multiple medication use, inability to perform activities of daily living, requirement for a caregiver, and/or repeat admissions or emergency department visits. Typical adult patients take or receive three or more prescription medications and may also be receiving other types of therapeutic interventions (eg, physical therapy, occupational therapy) and have two or more chronic continuous or episodic health conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Typical pediatric patients receive three or more therapeutic interventions (eg, medications, nutritional support, respiratory therapy) and have two or more chronic continuous or episodic health conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Because of the complex nature of their diseases and morbidities, these patients commonly require the coordination of a number of specialties and services. In some cases, due to inability to perform IADL/ADL and/or cognitive impairment the patient is unable to adhere to the treatment plan without substantial assistance from a caregiver. For example, patients may have medical and psychiatric behavioral co-morbidities (eg, dementia and chronic obstructive pulmonary disease or substance abuse and diabetes) that complicate their care. Social support requirements or access to care difficulties may cause a need for these services. Medical, functional, and/or psychosocial problems that require medical decision making of moderate or high complexity and extensive clinical staff support are required."

MedPAC and other some commenters did not recommend specific alternative patient eligibility criteria, but stated that CMS should develop such criteria to better target the beneficiaries requiring significant management. One commenter recommended that the eligible patient population be narrowed to patients with four or more chronic conditions.

Response: As we stated in the proposed rule, we believe that the resources required tofurnish chronic care management services to beneficiaries with two or more chronic conditions are not adequately reflected in the existing E/M codes. Furnishing care management to beneficiaries with multiple chronic conditions requires multidisciplinary care modalities that involve: regular physician development and/or revision of care plans; subsequent reports of patient status; review of laboratory and other studies; communication with other health professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustment of medical therapy.

Our proposal was also supported by an analysis of Medicare claims for patients with selected multiple chronic conditions (see http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf). This analysis indicated that patients with these selected multiple chronic conditions are at increased risk for hospitalizations, use of post-acute care services, and emergency department visits. We continue to believe these findings would hold in general for patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. (We note that we did not propose to limit the eligible chronic conditions to those contained in our Medicare data analysis.) We continue to believe that successful efforts to improve chronic care management for these patients could improve the quality of care while simultaneously decreasing costs (for example, through reductions in hospitalizations, use of post-acute care services, and emergency department visits.) Therefore, we agree with the commenters who supported our proposed patient eligibility criteria.

While we also agree with the commenters who stated that the benefits from chronic care management are likely to increase the greater the acuity and risk to the patient, we disagree that the benefits and higher resource requirements for furnishing the service are limited to those even higher risk patients within the population of patients with two or more chronic conditions. Therefore, we disagree that the eligible patient population should be narrowed.

We also disagree with commenters who indicated that we should immediately expand the eligible patient population, for example, to include some patients with a single chronic condition or all the patients in a practice that meets future standards. It is not clear at this time that the resources required to provide typical chronic care management to these patients are not reflected adequately in the existing E/M codes. However, as we indicated in the proposed rule, we have over time recognized certain categories of beneficiaries for whom we allow separate payment for care management. We have not indicated that we have exhaustively identified all such categories of beneficiaries. We will continue to carefully consider whether there are categories of patients for whom the resources required to provide chronic care

management services are not adequately reflected in the existing E/M codes. We may consider changes to the patient eligibility in future rulemaking.

In summary, we are finalizing without modification our proposed patient eligibility for chronic care management services to be patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

We note that although we are finalizing our proposed eligibility criteria, since we agree with commenters that the benefits from chronic care management are likely to increase with the greater the acuity and risk to the patient, we expect that physicians and other practitioners will particularly focus on higher acuity and higher risk patients (for example, patients with four or more chronic conditions as suggested by one commenter) when furnishing chronic care management services to eligible patients.

Comment: Many commenters found our use of the term "complex" to describe these services to be confusing in light of the number of Medicare beneficiaries within a practice potentially meeting our proposed eligibility criteria, and suggested that the word could be interpreted to significantly narrow the appropriate patient population eligible for chronic care management services.

Response: We regret any confusion generated by our proposed use of the term "complex" to describe the chronic care management services that are not adequately reflected in the existing E/M codes. Although the provision of these services is complex relative to the care management reflected in the existing E/M codes, we understand the confusion on the part of commenters regarding the number of patients within a practice that are potentially eligible for the service versus those that would be considered "complex." Therefore, to reduce potential confusion, we will revise the code description for these services to describe "chronic care management" services rather than complex chronic care management services. We note that we have revised references throughout this preamble to remove the word "complex" from the description of these services.

2. Scope of Chronic Care Management Services

We proposed that the scope of chronic care management services includes:

- The provision of 24-hour- a-day, 7-day- a-week access to address a patient's acute chronic care needs. To accomplish these tasks, we would expect that the patient would be provided with a means to make timely contact with health care providers in the practice to address urgent chronic care needs regardless of the time of day or day of the week. Members of the chronic care team who are involved in the after-hours care of a patient must have access to the patient's full electronic medical record even when the office is closed so they can continue to participate in care decisions with the patient.

- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.

- Care management for chronic conditions including systematic assessment of patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications. In consultation with the patient and other key practitioners treating the patient, the practitioner furnishing chronic care management services should create a patient-centered plan of care document to assure that care is provided in a way that is congruent with patient choices and values. A plan of care is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues. It typically includes, but is not limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision, of the care plan. The provider should seek to reflect a full list of problems, medications and medication allergies in the electronic health record to inform the care plan, care coordination and ongoing clinical care.

- Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and

skilled nursing facilities. The practice must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way so as to reduce the need for repeat visits to emergency departments and re-admissions to hospitals and skilled nursing facilities.

● Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in practice's medical record system.

● Enhanced opportunities for a patient to communicate with the provider regarding their care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

Comment: Some commenters supported our proposed scope of services, indicating that the requirements are consistent with what is expected in a primary care medical home. Other commenters, while generally supportive of the proposed scope of services, provided comments on specific aspects of the proposed scope.

Response: We agree with the commenters who supported our proposed scope of services and agree that the requirements are consistent with what is expected in a primary care medical home. We summarize and respond to comments on specific aspects of the proposed scope below.

Comment: Some commenters indicated that while they agreed with the goal of having members of the chronic care team who are involved in the after-hours care of a patient having access to the patient's full EHR, that this was not currently possible for too many physicians who would otherwise be able to provide this service. Some commenters indicated that many practices will be using EHR systems that qualify for Meaningful Use Stage 2, but that do not support 24/7 remote access. Some commenters suggested that the 24/7 EHR access requirement be changed to require that members of the chronic care team have access to timely EHR information (that is, through the EHR or other formats.)

Response: Given that the comments on our proposed policy to require 24/7 access to the EHR were generally part of broader comments on the role of EHRs in the standards that must be met in order to furnish chronic care management services, we intend to address this issue in future rulemaking to establish the standards. Summaries of these broader comments can be found below in the standards section.

Comment: Some commenters stated that it was not feasible in many practices for a patient's personal practitioner or another clinical team member to be available on a 24/7 basis for every patient. Other commenters recommended gradually phasing in this requirement over time.

Response: The evolving medical literature on chronic care management and patient centered medical homes emphasizes the central importance of members of the care team being available 24/7 to address a patient's acute chronic care needs. Moreover, we believe the 24/7 availability of the care team is an important factor contributing to higher resource costs for these services that are not currently reflected in E/M services. Therefore, we disagree with commenters who requested that we relax or phase in the 24/7 requirement.

Comment: Some commenters requested that we clarify the scope of services with respect to caregivers for patients with chronic care needs. Some of these commenters recommended that we require providers to address the needs of caregivers, especially caregivers who are Medicare beneficiaries, since caregivers are at elevated risk of health issues from emotional and physical stresses.

Response: As with transitional care management (77 FR 68989), communication that is within the scope of services for chronic care management includes communication with the patient and caregiver. We also agree with commenters that caregivers who are Medicare beneficiaries, as with any Medicare beneficiary, should be provided with needed high quality, efficient care congruent with the patient's choices and values. We note, however, that we do not have the statutory authority to extend Medicare benefits to individuals who are not eligible for those benefits.

Comment: While the majority of commenters expressed support for our proposal to require a patient-centered plan of care, some commenters believed that this requirement was not necessary in all

cases. These commenters suggested that the requirement be changed to require a plan of care document as needed.

Response: We disagree with these comments. As we indicated in the propose rule, we believe that patients with multiple chronic conditions are at increased risk for hospitalizations, use of post-acute care services, and emergency department visits. Given this increased risk, we believe that a patient-centered plan of care document is a critical tool to help ensure appropriate care management for these patients. In the absence of such of document, we believe there would be significantly greater potential for gaps in care coordination. In addition, we received many comments supporting active involvement of the patient and caregiver in chronic care management. We believe our requirement that a written or electronic copy of the patient-centered plan of care document be provided to the patient facilitates this involvement.

Comment: Some commenters expressed concern regarding our proposal to include enhanced opportunities for a patient to communicate with the provider regarding their care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods. They indicated that many patients and/or caregivers may not be capable of using this type of communication, even if the practice is equipped to provide it.

Response: We disagree with these comments. Recognizing the growing use of, and patient and caregiver interest in, asynchronous communication through secure email, text and other modalities to support access to health care, we believe that it is reasonable for beneficiaries and their caregivers who would receive non-face-to-face chronic care management services to be able to communicate with the practice not only by telephone but through asynchronous communication modalities. We note that although the expectation is for the practice to provide these communication options, there is no requirement that the practice ensure that every patient and caregiver makes use of these options.

Comment: Some commenters requested that we explicitly require the chronic care management practitioner to consider various specific services or disease specific services when furnishing the scope of chronic care management services.

Response: In our proposed scope of services, we stated that, "A plan of care is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues (emphasis added)." Since the plan of care, as we described it, is to be comprehensive, we do not believe it is necessary for the scope of services to exhaustively list specific possible services that the chronic care management practitioner should consider when furnishing the scope of chronic care management services.

In summary, we are finalizing the following as the scope of chronic care management services.

- The provision of 24-hour- a-day, 7-day- a-week access to address a patient's acute chronic care needs. To accomplish these tasks, we would expect that the patient and caregiver would be provided with a means to make timely contact with health care providers in the practice to address the patient's urgent chronic care needs regardless of the time of day or day of the week.

- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.

- Care management for chronic conditions including systematic assessment of patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications. In consultation with the patient, caregiver, and other key practitioners treating the patient, the practitioner furnishing chronic care management services should create a patient-centered plan of care document to assure that care is provided in a way that is congruent with patient choices and values. A plan of care is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues. It typically includes, but is not limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable,

revision, of the care plan. The provider should seek to reflect a full list of problems, medications and medication allergies in the electronic health record to inform the care plan, care coordination and ongoing clinical care.

- Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. The practice must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way so as to reduce the need for repeat visits to emergency departments and re-admissions to hospitals and skilled nursing facilities.

- Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in practice's medical record system.

- Enhanced opportunities for a patient and caregiver to communicate with the provider regarding the patient's care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

We also note that we continue to assess the potential impact of the scope of our chronic care management policy on our current programs and demonstrations designed to improve payment for, and encourage long-term investment in, care management services. Likewise, to assure that there are not duplicate payments for delivery of care management services, we continue to consider whether such payments are appropriate for providers participating in other programs and demonstrations.

3. Standards for Furnishing Chronic Care Management Services

Not all physicians and nonphysician practitioners who wish to furnish chronic care management services currently have the capability to fully furnish the scope of these services without making additional investments in technology, staff training, and the development and maintenance of systems and

processes to furnish the services. We stated in the proposed rule that we intended to establish standards that would be necessary to furnish high quality, comprehensive and safe chronic care management services. We also stated that one of the primary reasons for our 2015 implementation date was to provide sufficient time to develop and obtain public input on the standards. Since we continue to believe that practice standards are one of the most critical components of our chronic care management policy. We are developing the standards in 2014 and will implement them in 2015. They will be established through notice and comment rulemaking for CY 2015 PFS.

In the proposed rule (78 FR 43338-43339), we solicited public comments for suggestions regarding standards for furnishing chronic care management. Although we solicited comments, we did not propose to adopt any specific standards and are, therefore, not finalizing a policy relating to this issue in this final rule with comment period.

Below are our responses to public comments received. As stated above, the public comments received for these potential standards for chronic care management are beyond the scope of the proposed rule, and therefore, the adoption of any such standards would be addressed through separate notice-and-comment rulemaking.

Comment: Some commenters were in favor of establishing standards for furnishing chronic care management services, generally supporting CMS's acknowledgement of the critical importance of managing care for these Medicare beneficiaries with chronic conditions. Commenters also believe that care coordination is an integral part of improving patient care.

Many commenters expressed concerns and did not support establishing standards for furnishing chronic care management services as we discussed in the proposed rule (78 FR 43338-43339). Some commenters stated the standards we suggested were too aggressive, needed clarification and/or refinement, and were overly burdensome citing that adoption should be delayed, perhaps for years or indefinitely. Commenters suggested that practice capabilities as outlined could exclude many physicians from furnishing these services, despite the physicians being specially trained in chronic care management and having demonstrated the ability to furnish significant quality of care. Many commenters suggested

that CMS partner (through an advisory group, workgroups, etc.) with interested stakeholders, obtain public input, and work with the CMS Innovation Center to continue developing and refining more reasonable potential future standards for furnishing chronic care management in order to ensure that the physicians who bill for these services have the capabilities to furnish them. Some commenters suggested integration of chronic care management standards with the State laws governing the practice of medicine. Commenters also urged CMS not to impose requirements that would preclude specialists from furnishing these critical services.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

As discussed in the proposed rule, potential standards (78 FR 43338-43339) could include the following:

- The practice must be using a certified Electronic Health Record (EHR) for beneficiary care that meets the most recent HHS regulatory standard for meaningful use. The EHR must be integrated into the practice to support access to care, care coordination, care management, and communication.

Comment: Commenters generally supported the value of EHRs in regard to the capabilities to enhance the quality of care for chronic care management. Commenters requested that CMS clarify the following issues if CMS were to move forward with meaningful use as a standard for chronic care management: how a provider new to Medicare or new to a practice would be treated, and how a provider would be treated who formerly met meaningful use but failed to do so in a subsequent year (specifically, whether the practice would be required to repay the chronic care management payment, and whether the practice would have to stop providing these services to beneficiaries in the future). Other commenters noted that while EHRs may facilitate documentation, they are being replaced by "cloud-based" data repositories for beneficiary medical records and social media is being used for communication solutions.

Many commenters did not support requiring the practice to use a certified EHR, some questioning whether an EHR is really essential to providing these services. These commenters discouraged CMS from including meaningful use as a standard for chronic care management, noting that it is premature to

link these services to meaningful use, and that requiring meaningful use as a standard should be delayed until the meaningful use policy has been stabilized and more practices have achieved it. Commenters generally expressed concern regarding linking the provision of chronic care management to meaningful use as practices would have to delay furnishing care management for a full year until they have met meaningful use, denying their patients the benefit of those services. Commenters urged CMS not to require a specific stage of meaningful use certification. Commenters urged elimination of this requirement noting it interfered with the physician's prerogatives and practice; and suggesting that it has nothing to do with how effectively a physician manages patients with chronic conditions. Some commenters suggested that the notion that there should be immediate online access to every patient's complete EHR is unrealistic for many practices (that is, internet access issues, 24/7 availability of the full EHR, on-call health professional being from a different practice and not having access, etc.), particularly those who would most benefit from the potential chronic care management reimbursement. Commenters also noted EHR interoperability is not yet attainable by the vast majority of physicians across the country. Many commenters suggested CMS consider flexibility (that is, a phased-in approach) in requiring EHRs to avoid excluding otherwise qualified practices in areas of need. Some commenters noted that phasing in EHR requirements would aid those smaller practices, or rural areas, that do not currently utilize EHRs and thus would not be able to be reimbursed for furnishing beneficiaries with chronic care management services. Other commenters expressed concern that this requirement could pose a problem for small practices (that is, economically depressed, medically underserved, etc.) for which the expense of obtaining and implementing EHR systems could be prohibitive despite the fact they could meet the remainder of the requirements for chronic care management. Commenters raised concerns that language in the preamble suggests that all practitioners participating in the care of a beneficiary receiving chronic care management services would need to be able to share information related to the care plan electronically, and that it would be very difficult to meet this requirement as not all practices have access to electronic means of communication.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

- The practice must employ one or more advanced practice registered nurses or physicians assistants whose written job descriptions indicate that their job roles include and are appropriately scaled to meet the needs for beneficiaries receiving services in the practice who require chronic care management services furnished by the practice.

Comment: Some commenters supported the requirement to employ non-physician professionals, and encouraged CMS to expand this list to include registered nurses, pharmacists (particularly hematology/oncology clinical specialist pharmacists), social workers, Emergency Department physicians, "caregivers" (that is, those that help with Alzheimer's disease and dementia patients), "direct-care worker," and other specialists such as hematologists, cardiologists, and nephrologists. Some commenters sought clarification regarding whether advanced practice nurse practitioners and physician assistants would have to be available 24/7, and what type of chronic care management services they must furnish.

Many commenters, however, were not in support of the requirement that advanced practice nurses or physician assistants must be employed by the medical practice. Commenters urged elimination of this requirement noting that it interfered with the physician's prerogatives; indicating that this staffing requirement would have little, if anything, to do with how effectively a physician manages patients with chronic conditions, and suggesting that it could be considered cost prohibitive. Some commenters urged CMS to relax this requirement and recognize that these services could be effectively performed by appropriately trained, licensed, and, when applicable, credentialed clinical staff. Commenters recommended that CMS not prescribe the hiring decisions for practices to be eligible to furnish chronic care management services. Commenters suggested that the agency instead should provide greater flexibility for practices to demonstrate that they have the structural capabilities, personnel, and systems to coordinate care effectively, through their own engagement with patients, as well as by having other qualified health care professionals available, either within the practice itself or through external arrangements to furnish chronic care management services.

Some commenters suggested that, under certain circumstances independently contracted (but not necessarily employed) personnel could participate in furnishing these services under the general supervision of a physician or non-physician practitioner, and sought clarification on whether "employ" could include "contract" personnel. Other commenters requested that the standards recognize that nurses can perform this work under the direction and supervision of physicians, especially since many practices employ registered nurses who are well qualified to provide care coordination. Some commenters believed that this requirement was particularly ill-advised and inappropriate, and strongly disagreed that employment of this level of staff should be a consideration in furnishing these services. Other commenters noted that this requirement would deter small and rural practices from offering chronic care management services. Commenters supported care teams/team-based care, but indicated that a practice should have the discretion to hire and develop those care teams, and not be required specifically to hire advanced practice nurse practitioners or physician assistants. Some commenters suggested that a "care manager" concept could be used, which could be a registered nurse, social worker, advanced practice nurse or physician assistant who has received training to perform the service. Commenters also suggested that CMS revise the requirement regarding who must employ the care manager to also allow the practice, or physician organization on the practice's behalf, to be the employer.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

- The practice must be able to demonstrate the use of written protocols by staff participating in the furnishing of services that describe: (1) the methods and expected "norms" for furnishing each component of chronic care management services furnished by the practice; (2) the strategies for systematically furnishing health risk assessments to identify all beneficiaries eligible and who may be willing to participate in the chronic care management services; (3) the procedures for informing eligible beneficiaries about chronic care management services and obtaining their consent; (4) the steps for monitoring the medical, functional and social needs of all beneficiaries receiving chronic care management services; (5) system based approaches to ensure timely furnishing of all recommended

preventive care services to beneficiaries; (6) guidelines for communicating common and anticipated clinical and non-clinical issues to beneficiaries; (7) care plans for beneficiaries post-discharge from an emergency department or other institutional health care setting, to assist beneficiaries with follow up visits with clinical and other suppliers or providers, and in managing any changes in their medications; (8) a systematic approach to communicate and electronically exchange clinical information with and coordinate care among all service providers involved in the ongoing care of a beneficiary receiving chronic care management services; (9) a systematic approach for linking the practice and a beneficiary receiving chronic care management services with long-term services and supports including home and community-based services; (10) a systematic approach to the care management of vulnerable beneficiary populations such as racial and ethnic minorities and people with disabilities; and (11) patient education to assist the beneficiary to self-manage a chronic condition that is considered at least one of his/her chronic conditions. These protocols must be reviewed and updated as is appropriate based on the best available clinical information at least annually.

Comment: Some commenters expressed support for the outlined written protocols. A few commenters suggested that CMS develop educational materials to be made available to patients so they better understand these services. Commenters suggested the 11th written protocol be revised (to be more interactive) to read "provide written protocols that describe collaborative problem solving/decision making that supports the patient in self-managing their chronic health conditions." Other commenters believe that physicians and other providers who care for chronically ill patients can be better supported with evidence-based guidelines, specialty expertise, and information systems; such as, providers encouraging patients (through partnerships with community organizations, etc.) to participate in medical systems like peer support groups, exercise programs, nurse educators, or dieticians.

Commenters urged CMS to revise this requirement to provide more flexibility for practices to demonstrate they have their own protocols to ensure that patients with chronic diseases have timely access to physicians and other team members within a realistic timeframe (that is, practices could be required to demonstrate that their patients have access the same or next day by phone, email,

telemedicine, or in person). Other commenters suggested CMS give more consideration to therapy services, medication management, discharge planning, care coordination, and caregiver education. Commenters also asked CMS to clarify that the practice reporting these chronic care management services does not have to perform all care management itself, and that other practices or healthcare professionals can perform some services in coordination with the reporting practice. Commenters conveyed individuals with Alzheimer's and dementias may not be able to participate in the development of a care plan in the same capacity as individuals who are not cognitively impaired. Some commenters requested CMS go a step further in noting the importance of coordination with direct-care workers and family caregivers, and requiring that this communication be documented as well.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

- All practitioners, including advanced practice registered nurses or physicians assistants, involved in the furnishing of chronic care management services must have access at the time of service to the beneficiary's EHR that includes all of the elements necessary to meet the most recent HHS regulatory standard for meaningful use. This includes any and all clinical staff furnishing after hours care to ensure that the chronic care management services are available with this level of EHR support in the practice or remotely through a Virtual Private Network (VPN), a secure website, or a health information exchange (HIE) 24 hours per day and 7 days a week.

Comment: Commenters were generally in support of the concept that 24/7 access to the beneficiary's EHR would be a tremendous enhancement to furnishing chronic care management. Some commenters noted that many physicians practice in more than one setting, which can make it more challenging for them to furnish all beneficiaries with 24/7 EHR support to providers and care staff. Commenters noted that many of their members do not have the resources to evaluate patients 24/7; therefore, commenters urged CMS to clarify the 24/7 support can be furnished by members of the chronic care team by phone, or allow more flexibility in this requirement until the agency can assess the impact it may have on beneficiary access to chronic care management services. Some commenters noted that many

physicians can access their own organization's EHR both in and outside typical business hours, but do not currently have "real-time" access to all of the EHR data for beneficiaries under their care, especially if they are moving provider settings.

Response: We appreciate commenters' suggestions and will consider these suggestions for any future rulemaking.

Some have suggested that, to furnish these services, practices could be recognized as a medical home by one of the national organizations (including the National Committee for Quality Assurance (NCQA), the Accreditation Association for Ambulatory Health Care, The Joint Commission, URAC, etc.), which are formally recognizing primary care practices as a patient-centered medical home. We understand there are differences among the approaches taken by national organizations that formally recognize medical homes and therefore, we solicited comment on these and other potential care coordination standards, and the potential for CMS recognizing a formal patient-centered medical home designation as one means for a practice to demonstrate it has met any final care coordination standards for furnishing chronic care management services.

Comment: Some commenters supported recognizing a patient centered medical home model to meet the care coordination standards. Commenters recommended that CMS allow for multiple pathways for accreditation recognition, and/or certification of patient centered medical homes and patient centered medical home neighborhood practices, noting other entities offer these programs, such as URAC and The Joint Commission. Some commenters supported the specialty practice recognition program, under NCQA, to be included to enable specialists to be able to participate. Commenters also suggested that CMS include other approaches to recognize medical homes as developed by private health plans and within CMS via its Innovation Center Comprehensive Primary Care Initiative, some of which may not have been formally certified by an accreditation entity. Commenters noted medical homes would be good candidates to provide chronic care management, but Patient Centered Medical Homes represent a relatively small percentage of medical groups across the country.

Other commenters noted they do not support a requirement that physician practices be certified as a primary care medical home to receive payment for chronic care management. Other commenters urged elimination of this requirement, noting it is too burdensome and would disqualify many practices furnishing these care coordination services. Commenters believe that in general, medical societies have been reluctant to accept proposals that would require medical homes or patient-centered practices to obtain accreditation/recognition by external entities; and therefore, urged CMS to work with the medical community to develop an alternative to accreditation as a path for furnishing chronic care management services. Other commenters noted this approach ignores the fact that many patients—especially the poor—do not have a primary care provider and by default, may receive substantial services from the Emergency Department, especially when other sources of primary care are unavailable or inaccessible. Some commenters conveyed that many standards for accreditation as a patient centered medical home do not consider the needs of those with dementia; adding, accreditation bodies should include quality measures on dementia care as a standard for accreditation. Some commenters encouraged CMS to consider using QIOs to help determine if a provider is meeting the requirements for chronic care management, instead of relying on a formal recognition program.

Some commenters noted that, instead of requiring any particular certification or designation, any physician practice should be able to qualify for payment of chronic care management services as long as the individual practice meets the practice requirements established to report these individual codes. Other commenters recommended that CMS instead require practices to have certain capabilities (that is, 24/7 access to care, 24/7 access to the individual's medical record, those involved with the care of a patient are identified and accessible, the health risk assessment data be addressed in the care of the patient, etc.); moreover, commenters suggested that CMS should clearly articulate that the ultimate goal is for primary care practices to achieve patient-centered medical home certification by a certain date (for instance 2019) as this would satisfy the agency's intention without being overly restrictive. Commenters also recommended that if CMS decides to recognize certified medical homes—through accreditation organizations or otherwise—the certification standards should fully reflect the Joint Principles for the

Patient-Centered Medical Home (http://tinyurl.com/ccbhvzz). Some commenters noted that requiring practice certification, such as that offered by NCQA for Patient-Centered Medical Homes, will undoubtedly limit access to chronic care management services for many beneficiaries, especially those in smaller practices and rural areas; and recommended CMS not make additional voluntary certifications mandatory, but rather look to those voluntary standards as it collaborates with the medical professional community to develop robust standards for chronic care management. Other commenters urged CMS to consider allowing practices to self-attest that they meet the protocol. Some commenters believe there needs to be an accountability mechanism for chronic care management which goes beyond "standards," such as quality measures that demonstrate improved outcomes and benefits for relevant patients.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

4. Billing for Separately Payable Chronic Care Management Services

To recognize the additional resources required to provide chronic care management services to patients with multiple chronic conditions, we proposed to create two new separately payable alphanumeric G-codes.

> Complex chronic care management services furnished to patients with multiple (two or more) complex chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
>
> GXXX1, initial services; one or more hours; initial 90 days
>
> GXXX2, subsequent services; one or more hours; subsequent 90 days

Typically, we would expect the one or more hours of services to be provided by clinical staff directed by a physician or other qualified health care professional.

We also proposed that billing for subsequent chronic care management services (GXXX2) would be limited to those 90-day periods in which the medical needs of the patient require substantial revision of the care plan.

We proposed that the resources required to furnish care management services for patients that do not have multiple chronic conditions would continue to be reflected in the payment for face-to-face E/M services. We also proposed that the resources required to furnish care management services consisting of less than one or more hours of clinical staff time over a 90-day period, and for patients residing in facility settings, would continue to be reflected in the payment for face-to-face E/M visits.

We proposed that chronic care management services would include transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), and hospice care supervision (HCPCS G0182). If furnished, to avoid duplicate payment, we proposed that these services may not be billed separately during the 90 days for which either GXXX1 or GXXX2 are billed. For similar reasons, we proposed that GXXX1 or GXXX2 cannot be billed separately if ESRD services (CPT 90951-90970) are billed during the same 90 days.

We proposed to pay only one claim for chronic care management services billed per beneficiary at the conclusion of each 90-day period.

We proposed that all of our proposed chronic care management services that are relevant to the patient must be furnished to bill for a 90-day period.

If a face-to-face visit is provided during the 90-day period by the practitioner who is furnishing chronic care management services, we proposed that the practitioner should report the appropriate evaluation and management code in addition to billing for chronic care management.

We note that to bill for these services, we proposed that at least 60 minutes of chronic care management services must be provided during a 90-day period. Time of less than 60 minutes over the 90 day period could not be rounded up to 60 minutes to bill for these services.

We also proposed that for purposes of meeting the 60-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

Comment: Many commenters requested that we either adopt the current CPT codes (CPT 99487-99489) for complex chronic care coordination services or work with the AMA to revise the current CPT codes rather than establish G-codes. Commenters also requested that we shorten the billing period from 90 days to 30 days, monthly, or weekly out of concern that it would be administratively burdensome for some practices to keep track of the amount of time they had furnished the service over a 90-day period. Many commenters also encouraged us to reconsider the need for separate G-codes for the initial delivery of chronic care management services versus subsequent delivery of these services since these commenters indicated that the resource use is similar. Some commenters supported our proposal that if a face-to-face visit is provided during the period by the practitioner who is furnishing chronic care management services, the practitioner should report the appropriate E/M code in addition to billing for chronic care management. Some commenters requested that we consider creating codes for chronic care management services to reflect different patient severity levels or create an add-on code, similar to the current CPT add-on code for 30 minutes of additional time (CPT 99489), that recognizes additional time for more complex patients within the eligible patient population. Some commenters agreed with our proposal that time less than the time specified in the code (60 minutes in our proposal) could not be rounded up to bill for these services. Some commenters also requested that we provide more detailed billing information for the services.

Response: Regarding the suggestion to work with CPT to avoid the need to establish G-codes, since we expect to implement payment for chronic care management services in 2015, there is time for CPT to establish a billing code that sufficiently reflects our policy. We would consider using such a new or revised code. The current CPT codes do not meet our policy requirements (for example, the eligible patient population, the time required for the code); therefore, we are not adopting these codes in this final rule.

We agree with commenters who suggested that we shorten the billing period for chronic care management services from 90 days to 30 days to reduce the administrative timekeeping burden on practices. We believe that a weekly billing interval would increase the administrative billing burden and note that very few commenters supported this option relative to 30 day or monthly billing.

We also agree with commenters that the resources required to furnish the initial and subsequent services are not sufficiently different to require the establishment of separate codes to distinguish initial and subsequent services.

In response to commenters' concerns, we are adopting a 30-day billing interval for chronic care management services. Given the shorter 30-day period, we are establishing a billing code that corresponds to 20 minutes of service during the 30-day period. Similar to our proposal, at least 20 minutes of chronic care management services must be provided during the 30-day billing interval. Time of less than 20 minutes over the 30-day period could not be rounded up to 20 minutes to bill for these services. For purposes of meeting the 20-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

With respect to comments requesting that we consider creating billing codes for chronic care management services to reflect different patient severity levels or create an add-on code that recognizes additional time for more severe patients within the eligible patient population, we are not adopting such a coding structure at this time. As recognized by the vast majority of commenters, paying separately for non-face-to-face chronic care management services is a significant policy change. As we gain more experience with separate payment for this service, we may consider additional changes in the coding structure in future rulemaking.

In response to comments asking that we provide more detailed billing information for these services, we intend to provide guidance to our contractors and make any necessary revisions to the relevant manual provisions to implement the chronic care management policy.

In summary, to recognize the additional resources required to provide chronic care management services to patients with multiple chronic conditions, we will be creating one new separately payable alphanumeric G-code for CY 2015.

> GXXX1 Chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days

Typically, we would expect that the 20 minutes or more of chronic care management services to be provided by clinical staff directed by a physician or other qualified health care professional.

At least 20 minutes of chronic care management services must be provided during the 30-day period. Time of less than 20 minutes over the 30-day period may not be rounded up to 20 minutes in order to bill for these services. For purposes of meeting the 20-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of

time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

We would consider using a revised CPT code that meets our policy requirements instead of creating a new G-code.

Comment: Some commenters stated that limiting the use of the billing code for subsequent delivery of chronic care management services to those circumstances in which the beneficiary requires "substantial revision of the care plan" undervalues the work the practitioner and practice care team does in furnishing ongoing assistance to beneficiaries in monitoring and implementing their care plans. Some commenters indicated that this restriction would reduce the potential benefits of chronic care management to the patient since in the absence of separate payment the services might be provided too intermittently. Other commenters, however, supported the restriction to time periods when the care plan has undergone significant revision since they believed that separately billable chronic care management should be for intense services delivered over a short period of time. Generally, these commenters were also ones who also favored narrowing the eligible patient population.

Response: As we stated in the discussion of the eligible patient population, we believe the resources required to furnish chronic care management services to beneficiaries with two or more chronic conditions are not adequately reflected in the existing E/M codes. We agree with commenters who argued that these resources could potentially be required during periods of time when the care plan is not undergoing substantial revision.

Therefore, after considering all the comments received, we are revising our proposed policy to specify that the chronic care management service may be billed for periods in which the

medical needs of the patient require establishing, implementing, revising, or monitoring the care plan, assuming all other billing requirements are met.

Comment: Some commenters objected to our proposal that chronic care management services include transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), and hospice care supervision (HCPCS G0182) and that these services cannot be billed separately during the time period when the chronic care management services are billed. Some commenters also objected to our proposal that chronic care management services cannot be billed separately if certain ESRD services (CPT 90951-90970) are billed during the same time period. Some commenters believed that there was insufficient overlap between the resources required to perform these services and chronic care management to justify restricting the billing in the manner we proposed. Other commenters indicated that more than one practitioner should be allowed to bill for chronic care management services for the same time period.

Response: Given that, in response to comments, we have modified our new separately payable alphanumeric G-code for chronic care management services to describe services furnished for 20 minutes or more over a 30-day period, it may not always be the case that the additional resources required to provide chronic care management services to beneficiaries with multiple chronic conditions are the same as the additional resources required provide transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), hospice care supervision (HCPCS G0182), or certain ESRD services (CPT 90951-90970). Nevertheless, given that care management is an integral part of all of these services, we believe there is significant overlap, and that paying separately both for chronic care management and the care management included in these services would result in duplicate payment for the

overlapping care management. Similarly, allowing multiple practitioners to bill for GXXX1 during a particular billing interval would result in duplicate payment for overlapping care management. Therefore, we are finalizing our policy that GXXX1 and any of CPT 99495-99496, HCPCS G0181-G0182, or CPT 90951-90970 cannot be billed during the same 30-day period; nor can GXXX1 be billed by multiple practitioners for the same time period.

Comment: Some commenters objected to our proposal that the resources required to provide care management services to patients residing in facility settings continues to be reflected in the payment for face-to-face E/M visits. Commenters believed there was insufficient overlap between the scope of these care management services and the care management services provided by facilities to justify restricting the billing in the manner we proposed.

Response: We disagree with these comments. The resources required to provide care management services to patients residing in facility settings significantly overlaps with care management activities by facility staff that is included in the associated facility payment. We are finalizing this part of our proposal without modification.

Comment: MedPAC recommended that practitioners employed or furnishing services under arrangement with hospice or home health agencies should not be eligible to bill for these chronic care management services, citing the Medicare claims processing manual requirements for care plan oversight services.

Response: There is a requirement in the Medicare Claims Processing Manual (see http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf) for hospice care plan oversight (CPO) that states:

"The attending physician or nurse practitioner (who has been designated as the attending physician) may bill for hospice CPO when they are acting as an 'attending physician.' An

'attending physician' is one who has been identified by the individual, at the time he/she elects hospice coverage, as having the most significant role in the determination and delivery of their medical care. They are not employed nor paid by the hospice."

We will consider MedPAC's comment further, but are not adopting this suggestion at the current time. We note that, as stated earlier in this section, home health care supervision (HCPCS G0181) and hospice care supervision (HCPCS G0182) cannot be billed separately during the time period when the chronic care management services are billed.

Comment: Many commenters requested that we clarify that billing for chronic care management is not restricted to primary care physicians and that specialist physicians can bill for these services if they meet the requirements. Some non-physician practitioners similarly requested confirmation that they can bill for these services if they meet the requirements.

Response: We appreciate these comments and take this opportunity to confirm that, while we expect the chronic care management code to be billed most frequently by primary care physicians, specialists who meet the requirements may also bill for these services. As for nonphysician qualified health care professionals, we believe only NPs, PAs, CNSs, and certified nurse midwives (CNMs) can furnish the full range of these services under their Medicare benefit, and only to the extent permitted by applicable limits on their state scope of practice. We believe other nonphysician practitioners (such as registered dieticians, nutrition professionals or clinical social workers) or limited-license practitioners, (such as optometrists, podiatrists, doctors of dental surgery or dental medicine), would be limited by the scope of their state licensing or their statutory Medicare benefit to furnish the complete scope of these services such that they would not be able to furnish chronic care management services; and there is no Medicare benefit

category that allows payment under the PFS to some of the other health professionals (such as pharmacists and care coordinators) mentioned by commenters.

We also note that given our longstanding restriction on the use of E/M codes by clinical psychologists and the fact that payment for these chronic care management services is currently included in the payment for E/M services, clinical psychologists are also not permitted to bill for these services. However, similar to transitional care management, we expect practitioners furnishing chronic care management services to refer patients to psychologists and other mental health professionals as part of chronic care management when doing so is warranted by an evaluation of the patient's psychosocial needs.

5. Obtaining Agreement from the Beneficiary

We stated in the proposed rule that not all patients who are eligible for separately payable chronic care management services may necessarily want these services to be provided**.** Therefore, before the practitioner can furnish or bill for these services, we proposed that the eligible beneficiary must be informed about the availability of the services from the practitioner and provide his or her consent, or synonymously in this context "agreement," to have the services provided, including the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient about what chronic care management services are, how these services are accessed, how their information will be shared among other providers in the care team, and that cost-sharing applies to these services even when they are not delivered face-to-face in the practice. To bill for the services, the practitioner would be required to document in the patient's medical record that all of the chronic care management services were explained and offered to the patient, noting the patient's decision to accept these services. Also, a written or electronic copy of the care plan

would be provided to the beneficiary and this would also be recorded in the beneficiary's electronic medical record.

We proposed that a practitioner would need to reaffirm with the beneficiary at least every 12 months whether he or she wishes to continue to receive chronic care management services during the following 12-month period.

We proposed that the agreement for chronic care management services could be revoked by the beneficiary at any time. However, if the revocation occurs during a current chronic care management period, the revocation would not be effective until the end of that period. The beneficiary could notify the practitioner either verbally or in writing. At the time the agreement is obtained, the practitioner would be required to inform the beneficiary of the right to stop the chronic care management services at any time and the effect of a revocation of the agreement on chronic care management services. Revocation by the beneficiary of the agreement must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the practitioner would not be providing chronic care management services beyond the current period.

We proposed that a beneficiary who has revoked the agreement for chronic care management services from one practitioner may choose instead to receive these services from a different practitioner, which can begin at the conclusion of the current period. The new practitioner would need to fulfill all the requirements for billing these services.

We proposed that prior to submitting a claim for chronic care management services, the practitioner must notify the beneficiary that a claim for these services will be submitted to Medicare. The notification must indicate: that the beneficiary has been receiving these services over the previous period (noting the beginning and end dates for the period); the reason(s) why

the services were provided; and a description of the services provided. The notice may be delivered by a means of communication mutually agreed to by the practitioner and beneficiary such as mail, email, or facsimile, or in person (for example, at the time of an office visit). The notice must be received by the beneficiary before the practitioner submits the claim for the services. A separate notice must be received by the beneficiary for each period for which the services will be billed. A copy of the notice should be included in the medical record.

Comment: While most commenters endorsed the general concept that that there should be a process whereby a practitioner would obtain agreement from an eligible beneficiary for the delivery of the service, we received comments on specific aspects of our proposal.

Some commenters supported our beneficiary agreement policies as proposed. Other commenters believed that notifying the beneficiary would be sufficient and that a formal agreement should not be required. Some commenters raised concern about the burden of having to obtain an annual agreement rather than obtaining just one agreement at the outset of furnishing the services. Many commenters recommended that CMS remove the requirement that practitioners notify beneficiaries in writing prior to each billing for chronic care management services, while other commenters supported this requirement. The commenters opposed to the pre-billing notification requirement viewed this as administratively burdensome and unnecessary given the informed agreement process for this service. Some commenters indicated that beneficiary agreement would be much easier to obtain if the service were not subject to coinsurance. Many commenters requested that we provide beneficiary education on this issue.

Response: We appreciate commenters recognizing the value of our requiring practitioners to inform beneficiaries about their eligibility to receive chronic care management services. We note that we do not have the statutory authority to waive the cost-sharing for these services. Since beneficiaries who receive these services will be billed for cost-sharing, we believe it is prudent to

require their written agreement prior to initiating the service. We agree that to reduce administrative burden, the informed agreement process need only occur once at the outset of furnishing the service, rather than annually as we had proposed, and that it only needs to be repeated if the beneficiary opts to change the practitioner who is delivering the services. We also agree with commenters who suggested that we relax the requirement that a practice inform a beneficiary prior to each time a bill is submitted. While we believe that this approach could reduce any potential confusion around cost-sharing charges, we agree that practitioners can address this in the informed agreement process.

In response to comments recommending that we educate beneficiaries about chronic care management services, we note that we provide extensive beneficiary education regarding Medicare benefits, including Medicare and You and other publications, Medicare.gov, and 1-800-MEDICARE. We will include information concerning chronic care management in our outreach efforts.

The final beneficiary agreement requirements for CY 2015 are as follows. Before the practitioner can furnish or bill for these services, the eligible beneficiary must be informed about the availability of the services from the practitioner and provide his or her written agreement to have the services provided, including agreeing to the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient, and caregiver when applicable, about what chronic care management services are, how these services are accessed, how the patient's information will be shared among other providers in the care team, and that cost-sharing applies to these services even when they are not delivered face-to-face in the practice. To bill for the services, the practitioner would be required to document in the patient's medical record that all of the chronic care management

services were explained and offered to the patient, noting the patient's decision to accept these services. Also, a written or electronic copy of the care plan is required to be provided to the beneficiary, and the provision of the plan to the patient must also be recorded in the beneficiary's electronic medical record.

The agreement for chronic care management services could be revoked by the beneficiary at any time. However, if the revocation occurs during a current chronic care management 30-day period, the revocation is not effective until the end of that period. The beneficiary could notify the practitioner of revocation either verbally or in writing. At the time the agreement is obtained, the practitioner is required to inform the beneficiary of the right to stop the chronic care management services at any time (effective at the end of a 30-day period) and the effect of a revocation of the agreement on chronic care management services. The practitioner is also required to inform the beneficiary that only one practitioner is able to be separately paid for these services during the 30-day period. Revocation by the beneficiary of the agreement must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the practitioner would not be providing chronic care management services beyond the current 30-day period.

A beneficiary who has revoked the agreement for chronic care management services from one practitioner may choose instead to receive these services from a different practitioner, which can begin at the conclusion of the current 30-day period. If a beneficiary chooses to receive these services from a different practitioner, the beneficiary should revoke the agreement with the current practitioner. The new practitioner would need to fulfill all the requirements for billing these services.

5. Chronic Care Management Services and the Annual Wellness Visit (AWV) (HCPCS codes G0438, G0439)

We proposed that a beneficiary must have received an AWV in the past 12 months for a practitioner to be able to bill separately for chronic care management services. We believe that the linking of these services to the AWV makes sense for several reasons. First, the AWV is

designed to enable a practitioner to systematically capture information that is essential for the development of a care plan. This includes the establishment of a list of current practitioners and suppliers that are regularly involved in providing medical care to the beneficiary, the assessment of the beneficiary's functional status related to chronic health conditions, the assessment of whether the beneficiary suffers from any cognitive limitations or mental health conditions that could impair self-management of chronic health conditions, and an assessment of the beneficiary's preventive health care needs including those that contribute to or result from a beneficiary's chronic conditions. Second, the beneficiary's selection of a practitioner to furnish the AWV is a useful additional indicator to assist us in knowing which single practitioner a beneficiary has chosen to furnish chronic care management services. Although a beneficiary would retain the right to choose and change the practitioner to furnish chronic care management services, we do not believe that it is in the interest of a beneficiary to have more than one practitioner at a time coordinating the beneficiary's care and we do not intend to pay multiple practitioners for furnishing these services over the same time period. Third, the AWV is updated annually which is consistent with the minimal interval for reviewing and modifying the care plan required for the chronic care management services.

We would expect that the practitioner the beneficiary chooses for the AWV would be the practitioner furnishing the chronic care management services. For the less frequent situations when a beneficiary chooses a different practitioner to furnish the chronic care management services from the practitioner who in the previous year furnished the AWV, the practitioner furnishing the chronic are management services would need to obtain a copy of the assessment and care plan developed between the beneficiary and the practitioner who furnished the AWV prior to billing for chronic care management services.

Because a beneficiary is precluded from receiving an AWV within 12 months after the effective date of his or her first Medicare Part B coverage period, for that time period we proposed the Initial Preventive Physical Examination (G0402) can substitute for the AWV to allow a beneficiary to receive chronic care management services.

Comment: Although some commenters supported our proposal, there were numerous comments recommending that we remove the requirement for an Annual Wellness Visit prior to a practitioner being able to furnish chronic care management services. While some commenters acknowledged that the Annual Wellness visit could provide valuable information for establishing a care plan and for ensuring that only one practitioner billed for the chronic care management services, many expressed concern that this could present a significant barrier to otherwise eligible beneficiaries receiving the services.

Response: We believe that both the practitioner and the beneficiary would benefit if an AWV or an Initial Preventive Physical Examination (IPPE) occurs at the outset of chronic care management services. It would allow the practitioner to systematically gather information that can inform the care plan and it would allow the beneficiary the opportunity to address questions and concerns about wellness issues that may be important for those with multiple chronic conditions. With their required services, the IPPE or AWV assures that at least once a year there is a focus on the broad wellness aspects of care, which can easily be dominated by the more chronic conditions when they exist. In addition to the clinical benefits of the AWV or IPPE, these services provide administrative benefits as well. They allows us to know the one practitioner the beneficiary has chosen to furnish chronic care management services and assure that multiple practitioners cannot provide the service to the same patient. However, in light of the widespread concerns raised by commenters about this requirement, we have changed the

requirement to a recommendation for a practitioner to furnish an AWV or IPPE to a beneficiary prior to billing for chronic care management services furnished to that same beneficiary. As an alternative, a practitioner who meets the practice standards that will be established to bill for chronic care management services may initiate services with an eligible beneficiary as a part of an AWV, an IPPE, or a comprehensive E/M visit.

6. Chronic Care Management Services Furnished Incident to a Physician's Service under General Physician Supervision

In the proposed rule, we discussed the requirements for billing for services furnished in the office, but not personally and directly performed by the physician or qualified nonphysician practitioner (referred to as a "practitioner" in the following discussion), under our "incident to" requirements at 410.26 and in section 60, Chapter 15, of Medicare Benefit Policy Manual (100-02). One key requirement of "incident to" services is that a physician directly supervise the provision of services by auxiliary personnel by being in the office suite and be immediately available to furnish assistance and direction throughout the provision of the service. Section 60.4 of the Manual specifically discusses the one exception, which allows for general supervision of "incident to" services furnished to homebound patients in medically underserved areas. Under that exception, we identify more specific requirements for the personnel who can provide "incident to" services under general supervision. For example, we require that the personnel must be employed by the physician billing the "incident to" services.

One of the required capabilities for a physician to furnish chronic care management services is 24-hour-a-day, 7-day-a-week beneficiary access to the practice to address the patient's chronic care needs. We would expect that the patient would be provided with a means to make timely contact with health care providers in the practice when necessary to address chronic care needs regardless of the time of day or day of the week. If the patient has a chronic care need outside of the practice's normal business hours, the patient's initial contact with the practice to address that need could be with clinical staff

employed by the practice, (for example, a nurse) and not necessarily with a physician. Those services could be furnished incident to the services of the billing physician.

We also proposed to require a minimum amount of time of chronic care services be furnished to a patient during a period for the physician to be able to bill separately for the chronic care services. The time, if not personally furnished by the physician, must be directed by the physician. We proposed that the time spent by a clinical staff person providing aspects of chronic care services outside of the practice's normal business hours during which there is no direct supervision would count towards the time requirement even though the services do not meet the direct supervision requirement for "incident to" services.

We stated our belief that the additional requirements we impose for auxiliary personnel under the exception for general supervision for homebound patients in medically underserved areas should apply in these circumstances where we are allowing a physician to bill Medicare for chronic care management services furnished under their general supervision and incident to their professional services. In both of these unusual cases, these requirements help to ensure that appropriate services are being furnished by appropriate personnel in the absence of the direct supervision. Specifically, we proposed that if a practice meets all the conditions required to bill separately for chronic care management services, the time spent by a clinical staff employee providing aspects of these services to address a patient's chronic care need outside of the practice's normal business hours can be counted towards the time requirement when at a minimum the following conditions are met:

- The clinical staff person is directly employed by the physician
- The services of the clinical staff person are an integral part of the physician's chronic care management services to the patient (the patient must be one the physician is treating and for which an informed agreement is in effect), and are performed under the general supervision of the physician. General supervision means that the physician need not be physically present when the services are performed; however, the services must be performed under the physician's overall supervision and control. Contact is maintained between the clinical staff person and the physician (for example, the

employed clinical staff person contacts the physician directly if warranted and the physician retains professional responsibility for the service.)

- The services of the employed clinical staff person meet all other "incident to" requirements, compliance with applicable state law, with the exception of direct supervision.

Comment: The vast majority of commenters supported the idea of general rather than direct supervision, although we did receive comments on specific aspects of our proposal. A few commenters said they recognized the difficulties in making exceptions to the "incident to" policies. Some commenters supported the proposal as stated in the proposed rule. Many commenters objected to the proposed requirement that the clinical staff person be directly employed by the physician, indicating that this would be a barrier to widespread adoption of the policy. Some commenters requested that we remove the employment requirement entirely, especially given that eligible practices will need to meet certain standards to be able to separately bill for chronic care management services. Other commenters indicated that if CMS were to keep the employment requirement it should be modified to allow the clinical staff person to be an employee of the physician or an employee of the practice. Some commenters recommended that the policy be modified to allow the clinical staff person be either an employee or an independent contractor. These commenters stated a distinction between the clinical staff person as an independent contractor and having the services provided under arrangement since typically the practice would directly supervise the contracted individual. A few commenters stated that a requirement to have all possible chronic care management services provided by employees would undermine access to these services. Some commenters indicated that CMS should allow general rather than direct supervision for more situations, not just time spent by clinical staff outside of the practices normal business hours. For example, one commenter indicated that time spent by clinical staff providing chronic care management services to homebound patients in the patient's homes should count towards the time requirement if provided under general supervision. Some commenters expressed concern that our use of the word "physician" in this discussion could potentially create confusion that we are not also referring to qualified non-physician practitioners.

Response: We appreciate the general support for our proposal as well as the recognition by some commenters of the challenges presented by the issue of an exception to "incident to related requirements," even for this unusual case. We agree with the commenters who supported our policy as stated in the proposed rule since we continue to believe that within eligible practices the employment requirement helps ensure that appropriate services are being furnished by appropriate personnel under the lesser requirement of general supervision. We are clarifying that the clinical staff person furnishing the chronic care management services could be employed either by the physician or the practice.

Given the potential risk to the patient that exceptions to the direct physician supervision requirement could create, we believe it is appropriate to proceed deliberately in this area. We believe that this exception in this unusual case should be designed as narrowly as possible while still facilitating the chronic care management policy. Therefore, we disagree at the current time with commenters who requested broader exceptions to the direct physician supervision requirement to remove the employment requirement entirely, to include independent contractors, or to include other situations for CY 2015.

In response to commenters who stated that a requirement to have all possible chronic care management services provided by employees would undermine access to these services, we note that we did not propose such a requirement. Our proposed employment requirement was limited to allowing the time spent by a clinical staff employee in providing aspects of chronic care management services to address a patient's chronic care need outside of the practice's normal business hours to count towards the time requirement for these services to be separately billed. To bill for "incident to" services, practitioners should follow all the usual "incident to" requirements except when furnishing services outside of normal business hours under conditions that meet the requirements for the general supervision exception as described above.

We also note that our "incident to" policies apply to all pracitioners who can bill Medicare directly for services, and thus apply to physicians and other nonphysician practitioners. As discussed in section II.J, we are aligning the requirements for "incident to" services to make clear that all practitioners

who can bill Medicare for "incident to" services are subject to the same regulations at 410.26. We intend that the exception to the direct supervision requirement for after-hours chronic care management services furnished on an "incident to" basis will apply to all practitioners who can bill Medicare for services incident to their services and who can provide chronic care management services.

In summary, we are finalizing our proposal for CY 2015 without modification except for our clarification that the clinical staff person furnishing the chronic care management services could be employed either by the physician or the practice.

In light of the concerns by some commenters that our use of the word "physician" in this discussion could potentially create confusion that we are not also referring to qualified non-physician practitioners, we reiterate that, as we stated in the proposed rule, "physician" in this discussion also refers to qualified non-physician practitioners.

7. Chronic Care Management Services and the Primary Care Incentive Payment Program (PCIP)

Under section 1833(x) of the Act, the PCIP provides a 10 percent incentive payment for primary care services within a specific range of E/M services when furnished by a primary care physician. Specific physician specialties and qualified nonphysician practitioners can qualify as primary care practitioners if 60 percent of their PFS allowed charges are primary care services. As we explained in the CY 2011 PFS final rule (75 FR 73435 through 73436), we do not believe the statute authorizes us to add codes (additional services) to the definition of primary care services. However, to avoid inadvertently disqualifying community primary care physicians who follow their patients into the hospital setting, we finalized a policy to remove allowed charges for certain E/M services furnished to hospital inpatients and outpatients from the total allowed charges in the PCIP primary care percentage calculation. In the CY 2013 final rule (77 FR 68993), we adopted a policy that the TCM code should be treated in the same manner as those services for the purposes of PCIP because post-discharge TCM services are a complement in the community setting to the hospital-based discharge day management services already excluded from the PCIP denominator. Similar to the codes already excluded from the PCIP denominator, we expressed concern that inclusion of the TCM code in the denominator of the primary care percentage

calculation could produce unwarranted bias against ‘‘true primary care practitioners’’ who are involved in furnishing post-discharge care to their patients.

Chronic care management services are also similar to the services that we have already excluded from the from the PCIP denominator. For example, chronic care management includes management of care transitions within health care settings including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. Therefore, while physicians and qualified nonphysician practitioners who furnish chronic care management services would not receive an additional incentive payment under the PCIP for the service itself (because it is not considered a ‘‘primary care service’’ for purposes of the PCIP), we proposed that the allowed charges for chronic care management services would not be included in the denominator when calculating a physician’s or practitioner’s percent of allowed charges that were primary care services for purposes of the PCIP.

Comment: Many commenters supported, and no commenters opposed, our proposed treatment of chronic care management services in the PCIP calculation given that these services are not eligible for the incentive payment under the PCIP.

Response: We agree with the commenters and are finalizing our proposal for CY 2015 without modification.