

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, and 495

[CMS-1524-FC and CMS-1436-F]

RINs 0938-AQ25 and 0938-AQ00

Medicare Program; Payment Policies under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also addresses, implements or discusses certain statutory provisions including provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. In addition, this final rule with comment period discusses payments for Part B drugs; Clinical Laboratory Fee Schedule: Signature on Requisition; Physician Quality Reporting System; the Electronic Prescribing (eRx) Incentive Program; the Physician Resource-Use Feedback Program and the value modifier; productivity adjustment for ambulatory surgical center payment system and the ambulance, clinical laboratory, and durable medical equipment prosthetics orthotics and supplies (DMEPOS) fee schedules; and other Part B related issues.

- Recommendation 5-5: CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare and Medicaid Services.
- Recommendation 5-6: A new source of information should be developed to determine the variation in the price of commercial office rent per square foot.
- Recommendation 5-7: Nonclinical labor-related expenses currently included under practice expense office expenses should be geographically adjusted as part of the wage component of the practice expense.

We note that the GPCI revisions we are finalizing in this final rule with comment period address three of the IOM recommendations referenced above. Specifically, our final GPICs utilize the full range of non-physician occupations in the non-physician employee wage calculation consistent with IOM recommendation 5-4. Additionally, we created a new purchased service index to account for non-clinical labor-related expenses similar to IOM recommendation 5-7. Lastly, we have consistently used national cost share weights (MEI) to determine the appropriate weight attributed to each GPCI component, which is supported by recommendation 5-1. We may propose further improvements to the GPCI methodology in future rulemaking to address the remaining IOM recommendations once we have had an opportunity to assess IOM's recommendations in their entirety.

E. 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, or electrocardiogram, or 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 which would have been made to the consultant for the service provided. 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 (Pub. L. 106-554) (BIPA) added a new 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 the practitioner at the distant site. 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 does allow the use of asynchronous "store-and-forward" technology in delivering these services 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 provided to an eligible telehealth individual notwithstanding the fact that the individual practitioner providing 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. As specified in BIPA, originating sites are 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, a critical access hospital (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 hospital-based renal dialysis centers, skilled nursing facilities (SNFs), and community mental health centers (CMHCs). In order to serve as a telehealth originating site, these sites must be located in an area designated as a rural health professional shortage area (HPSA), in a county that is not in a metropolitan statistical area (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 of Health and Human Services as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be presented by a practitioner 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 an 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. In general, originating sites must be located in a rural HPSA or in a county outside of an MSA. 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 services (DSMT).

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 being furnished 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 are located at a distant site, and they 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 of Health and Human Services 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).

2. Requests for 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 Medicare telehealth services to one of the following categories:

- 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 use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the in-person delivery of the same service. Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person delivery of the requested service.

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 in order 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 skilled nursing facilities (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 services (with a minimum of 1 hour of in-person instruction to ensure effective injection training).

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 2011 will be considered for the CY 2013 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 Web site at www.cms.gov/telehealth/.

3. Submitted Requests for Addition to the List of Telehealth Services for CY 2012

We received requests in CY 2010 to add the following services as Medicare telehealth services effective for CY 2012: (1) smoking cessation services; (2) critical care services; (3) domiciliary or rest home evaluation and management services; (4) genetic counseling services; (5) online evaluation and management services; (6) data collection services; and (7) audiology

services. The following presents a discussion of these requests, including our proposals for additions to the CY 2012 telehealth list.

a. Smoking Cessation Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add smoking cessation services, reported by CPT codes 99406 (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and 99407 (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes) to the list of approved telehealth services for CY 2012 on a category 1 basis.

Smoking Cessation services are defined as face-to-face behavior change interventions. We believe the interaction between a practitioner and a beneficiary receiving smoking cessation services is similar to the education, assessment, and counseling elements of individual KDE reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per 1 hour), and individual MNT services, reported by HCPCS code G0270 (Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in the same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face-to-face with the patient, each 15 minutes); CPT code 97802 (Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes); and CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes), all services that are currently on the telehealth list.

Therefore, we proposed to add CPT codes 99406 and 99407 to the list of telehealth services for CY 2012 on a category 1 basis. Additionally, we proposed to add HCPCS codes G0436 (Smoking and tobacco cessation counseling visit for the asymptomatic patient;

intermediate, greater than 3 minutes, up to 10 minutes) and G0437 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes) to the list of telehealth services for CY 2012 since these related services are similar to the codes for which we received formal public requests.

Consistent with this proposal, we also proposed to revise our regulations at §410.78(b) and §414.65(a)(1) to include these smoking cessation services as Medicare telehealth services.

Comment: All commenters expressed support for CMS' proposal to add smoking cessation services to the list of Medicare telehealth services for CY 2012. One commenter stated that the proposal would contribute to ensuring that all Medicare beneficiaries – regardless of where they reside – have access to these services that are a valuable step toward reducing tobacco use among the Medicare population. Another commenter stated that the proposal would go far in helping many rural Americans gain access to these services that they would otherwise not have.

Response: We agree with the commenters that adding smoking cessation services to the list of Medicare telehealth services will help to provide greater access to the services for beneficiaries in rural or other isolated areas.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to add CPT codes 99406 and 99407 to the list of telehealth services for CY 2012 on a category 1 basis. Additionally, we are finalizing our proposal to add HCPCS codes G0436 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes) and G0437 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes) to the list of telehealth

services for CY 2012 and to revise our regulations at §410.78(b) and §414.65(a)(1) to include smoking cessation services as Medicare telehealth services.

b. Critical Care Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add critical care service CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes) to the list of approved telehealth services. We previously received this request for the CY 2009 and CY 2010 PFS rulemaking cycles (73 FR 38517, 73 FR 69744 and 69745, 74 FR 33548, and 74 FR 61764) and did not add the codes on a category 1 basis due to the acute nature of the typical patient. We continue to believe that patients requiring critical care services are more acutely ill than those patients typically receiving any service currently on the list of telehealth services. Therefore, we cannot consider critical care services on a category 1 basis.

In the CY 2009 PFS proposed rule (73 FR 38517), we explained that we had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the in-person delivery of critical care services; therefore, we would not add the services on a category 2 basis. Requestors submitted new studies for CY 2012, but none demonstrated that comparable outcomes to a face-to-face encounter can be achieved using telehealth to deliver these services. The studies we received primarily addressed other issues relating to telehealth services. Some studies addressed the cost benefits and cost savings of telehealth services. Others focused on the positive outcomes of telehealth treatment when compared with no treatment at all. One submitted study addressed the equivalency of patient outcomes for telehealth services delivered to patients in emergency rooms, but the study's authors specifically restricted their population to

patients whose complaints were not considered to be genuine emergencies. Given that limitation, it seems unlikely that any of these patients would have required critical care services as defined by CPT codes 99291 and 99292.

We note that consultations are included on the list of Medicare telehealth services and may be billed by practitioners furnishing services to critically ill patients. These services are described by the following HCPCS codes: G0425 (Initial inpatient telehealth consultation, typically 30 minutes communicating with the patient via telehealth), G0426 (Initial inpatient telehealth consultation, typically 50 minutes communicating with the patient via telehealth), G0427 (Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth), G0406 (Follow-up inpatient telehealth consultation, limited, physicians typically spend 15 minutes communicating with the patient via telehealth), G0407 (Follow-up inpatient telehealth consultation, intermediate, physicians typically spend 25 minutes communicating with the patient via telehealth), and G0408 (Follow-up inpatient telehealth consultation, complex, physicians typically spend 35 minutes or more communicating with the patient via telehealth). Critical care services, as reported by the applicable CPT codes and described in the introductory language in the CPT book, consist of direct delivery by a physician of medical care for a critically ill or injured patient, including high complexity decision-making to assess, manipulate, and support vital system functions. Critical care requires interpretation of multiple physiologic parameters and/or application of advanced technologies, including temporary pacing, ventilation management, and vascular access services. The payment rates under the PFS reflect this full scope of physician work. To add the critical services to the telehealth list would require the physician to be able to deliver this full scope of services via telehealth. Based on the code descriptions, we have previously believed that it is not possible to

deliver the full range of critical care services without a physical physician presence with the patient.

We note that there are existing Category III CPT codes (temporary codes for emerging services that allow data collection) for remote real-time interactive video-conferenced critical care services that, consistent with our treatment of other Category III CPT codes, are not nationally priced under the PFS. The fact that the CPT Editorial Panel created these additional Category III CPT codes suggests to us that these video-conferenced critical care services are not the same as the in-person critical care services requested for addition to the telehealth list.

Because we did not find evidence that use of a telecommunications system to deliver critical care services produces similar diagnostic or therapeutic outcomes as compared with the face-to-face deliver of the services, we did not propose to add critical care services (as described by CPT codes 99291 and 99292) to the list of approved telehealth services. We reiterated that our decision not to propose to add critical care services to the list of approved telehealth services does not preclude physicians from furnishing telehealth consultations to critically ill patients using the consultation codes that are on the list of Medicare telehealth services.

Comment: One commenter supported CMS's decision not to add critical care services because the use of a telecommunications system to deliver critical services is unlikely to produce “similar diagnostic findings or therapeutic interventions as compared with the in-person delivery of the same service.”

Response: We appreciate this support for our proposal. As we stated in the CY 2012 PFS proposed rule (76 FR 42843), none of the submitted requests to add these services included evidence that demonstrated delivery via telehealth resulted in comparable outcomes to in-person care.

Comment: One commenter disagreed with CMS' decision not to add critical care services to the list of Medicare Telehealth Services. The commenter argued that because the patient who requires critical care is more acutely ill than patients receiving any of the services currently on the list of approved codes, these services should be added to the list. This commenter also suggested that the proposal to allow consulting physicians to use the inpatient telehealth g-codes to report care of critically ill patients through telehealth was inappropriate because not all critically ill patients are inpatients.

Response: We appreciate and share the commenter's concern for beneficiary access to care. However, we reiterate that no evidence that we received meets the criteria to add these services to the list of Medicare telehealth services. Regarding the appropriateness of the telehealth consultation g-codes in the emergency department setting, we refer the commenter to section II.E.5. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our decision not to add critical care services to the list of Medicare telehealth services for CY 2012.

c. Domiciliary or Rest Home Evaluation and Management Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add the following domiciliary or rest home evaluation and management CPT codes to the telehealth list for CY 2012:

- 99334 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: a problem focused interval history; a problem focused examination; or straightforward medical decision making. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting

problem(s) are self-limited or minor. Physicians typically spend 15 minutes with the patient and/or family or caregiver).

- 99335 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Physicians typically spend 25 minutes with the patient and/or family or caregiver).

- 99336 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: a detailed interval history; a detailed examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 40 minutes with the patient and/or family or caregiver).

- 99337 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: a comprehensive interval history; a comprehensive examination; medical decision making of moderate to high complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention.

Physicians typically spend 60 minutes with the patient and/or family or caregiver).

A domiciliary or rest home is not permitted under current statute to serve as an originating site for Medicare telehealth services. Therefore, we did not propose to add domiciliary or rest home evaluation and management services to the list of Medicare telehealth services for CY 2012.

Comment: One commenter disagreed with our proposal not to add domiciliary or rest home evaluation and management services because neither domiciliaries nor rest homes are permitted under current statute to serve as an originating site for Medicare Telehealth services. The commenter argued that because CMS added new ESRD-related G-codes to the list of approved Medicare Telehealth services in 2005 despite the fact that dialysis centers were not then permitted under statute to serve as originating sites, CMS' current reasoning is invalid.

Comment: We acknowledge that we previously added certain ESRD services to the list of Medicare telehealth services when dialysis centers were not permitted under statute to serve as telehealth originating sites. However, the services in question can also be furnished in sites that were eligible originating sites when the codes were added to the list. At this time, we do not believe that domiciliary or rest home evaluation and management services can be furnished outside of domiciliaries or rest homes.

After consideration of the public comments we received, we are finalizing our decision not to add domiciliary or rest home evaluation and management services to the list of Medicare telehealth services for CY2012.

d. Genetic Counseling Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT code 96040 (Medical genetics and genetic counseling services, each 30 minutes

face-to-face with patient/family) to the telehealth list for CY 2012. We note that CPT guidance regarding reporting genetic counseling and education furnished by a physician to an individual directs physicians to evaluation and management (E/M) CPT codes and that services described by CPT code 96040 are provided by trained genetic counselors. Physicians and nonphysician practitioners who may independently bill Medicare for their service and who are counseling individuals would generally report office or other outpatient evaluation and management (E/M) CPT codes for office visits that involve significant counseling, including genetic counseling, and these office visit CPT codes are already on the list of telehealth services. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. These practitioners cannot bill Medicare directly for their professional services and they are also not on the list of practitioners who can furnish telehealth services (specified in section 1834(m)(4)(E) of the Act). As such, we do not believe that it would be necessary or appropriate to add CPT code 96040 to the list of Medicare telehealth services. Therefore, we did not propose to add genetic counseling services to the list of Medicare telehealth services for CY 2012.

Comment: One commenter expressed concerns about beneficiary access concerns to genetic counseling but acknowledged the statutory constraints faced by CMS.

Response: We appreciate the commenter's concerns and their agreement with our conclusions regarding our statutory limitations.

After consideration of the public comments we received, we are finalizing our decision not to add genetic counseling services to the list of Medicare telehealth services for CY 2012

e. Online Evaluation and Management Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT code 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).

According to section 1834(m)(2)(A) of the Act, Medicare is required to pay for telehealth services at an amount equal to the amount that a practitioner would have been paid had such service been furnished without the use of a telecommunications system. As such, we do not believe it would be appropriate to make payment for services furnished via telehealth when those services would not otherwise be covered under Medicare. Because CPT code 99444 is currently noncovered, we did not propose to add online evaluation and management services to the list of Medicare Telehealth Services for CY 2012.

Comment: One commenter argued that adding online evaluation and management and other services to the list of Medicare telehealth services would support chronic care management and care coordination. The same commenter also asserted that adding these services would be administratively easy for CMS to implement.

Response: While we appreciate the potential value of maximizing the use of communication technology in care coordination and chronic care management, we cannot consider adding services that are not otherwise payable under the physician fee schedule to the Medicare telehealth benefit, as defined in 1834 (m) of the Act. Our decision not to add online

evaluation and management or any other requested services to the list of Medicare telehealth services does not result from concern about administrative burden.

After consideration of the public comments we received, we are finalizing our decision not to add online evaluation and management services to the list of Medicare telehealth services for CY 2012.

f. Data Collection Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT codes 99090 (Analysis of clinical data stored in computers (eg, ECGs, blood pressures, hematologic data)) and 99091 (Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, requiring a minimum of 30 minutes of time) to the list of Medicare telehealth services.

As we explained in the in CY 2002 PFS final rule with comment period (66 FR 55309), we assigned a status indicator of "B" (Payment always bundled into payment for other services not specified) to these services because the associated work is considered part of the pre- and post-service work of an E/M service. We note that many E/M codes are on the list of Medicare telehealth services.

According to section 1834(m)(2)(A) of the Act, Medicare is required to pay for telehealth services an amount equal to the amount that a practitioner would have been paid had such service been furnished without the use of a telecommunications system. Similar to the point noted previously for online E/M services, we do not believe it would be appropriate to make separate payment for services furnished via telehealth when Medicare would not otherwise make separate payment for the services. Moreover, we believe the payment for these data

collection services should be bundled into the payment for E/M services, many of which are already on the Medicare telehealth list. Because CPT codes 99090 and 99091 are currently bundled, we did not propose to add data collection services to the list of Medicare telehealth services for CY 2012.

Comment: Two commenters argued that CMS should pay separately for services like data collection since when furnished they often mitigate the need for an in-person visit and in those cases cannot logically be considered to be bundled with other services.

Response: We thank the commenters for conveying their perspective on the value of such services. However, we continue to believe it would be inappropriate to add services that are not otherwise separately payable under the physician fee schedule to the Medicare telehealth benefit, as defined in 1834 (m) of the Act.

After consideration of the public comments we received, we are finalizing our decision not to add data collection services to the list of Medicare telehealth services for CY 2012.

g. Audiology Services

The American Academy of Audiology submitted a request that CMS add services that audiologists provide for balance disorders and hearing loss to the list of Medicare telehealth services. The request did not include specific HCPCS codes. Nevertheless, it is not within our administrative authority to pay audiologists for services furnished via telehealth. The statute authorizes the Secretary to pay for telehealth services only when furnished by a physician or a practitioner as physician or practitioner are defined in sections 1834(m)(4)(D) and (E) of the Act. Therefore, we did not propose to add services that are primarily provided by audiologists to the list of Medicare telehealth services for CY 2012.

Comment: Several commenters stated broad support for the value of audiology services when furnished through telehealth. These commenters urged CMS to consider other ways of implementing programs that allow audiology services to be furnished through telehealth.

Response: We appreciate the commenters' perspective on the value of audiology services. The statute authorizes payment for telehealth services only when furnished by a physician or practitioner as defined in sections 1834(m)(4)(D) and (E) of the Act. Audiologists do not fall within either of these definitions, and we do not believe there is another way to make payment to audiologists for telehealth services.

After consideration of the public comments we received, we are finalizing our decision not to add audiology services to the list of Medicare telehealth services for CY 2012.

4. The Process for Adding HCPCS Codes as Medicare Telehealth Services

Along with its submission of codes for consideration as additions to the Medicare telehealth list for CY 2012, the American Telemedicine Association (ATA) also requested that CMS consider revising the annual process for adding to or deleting services from the list of telehealth services. The existing process, adopted in the CY 2003 PFS rulemaking cycle (67 FR 43862 through 43863 and 67 FR 79988 through 79989), is described in section II.E.1. of this final rule with comment period. The following discussion includes a summary of recent requests by the ATA and other stakeholders for changes to the established process for adding services to the telehealth list, an assessment of our historical experience with the current process including the request review criteria, and our proposed refinement to the process for adding services to the telehealth list that would be used in our evaluation of candidate telehealth services beginning for CY 2013.

The ATA asked CMS to consider two specific changes to the process, including--

- Broadening the factors for consideration to include shortages of health professionals to provide in-person services, speed of access to in-person services, and other barriers to care for beneficiaries; and

- Equalizing the standard for adding telehealth services with the standard for deleting telehealth services by adopting a standard that allows services that are safe, effective or medically beneficial when furnished via telehealth to be added to the list of Medicare telehealth services. Similarly, we have received recommendations that CMS place all codes payable under the PFS on the telehealth list and allow physicians and practitioners to make a clinical determination in each case about whether a medically reasonable and necessary service could be appropriately furnished to a beneficiary through telehealth. Under this scenario, stakeholders have argued that CMS would only remove services from the telehealth list under its existing policy for service removal; specifically, that a decision to remove a service from the list of telehealth services would be made using evidence-based, peer-reviewed data which indicate that a specific service is not safe, effective, or medically beneficial when furnished via telehealth (67 FR 79988).

While we share the interests of stakeholders in reducing barriers to health care access faced by some beneficiaries, given that section 1834(m)(2)(F)(ii) of the Act requires the Secretary to establish a process that provides, on an annual basis, for the addition or deletion of telehealth services (and HCPCS codes), as appropriate, we do not believe it would be appropriate to add all services for which payment is made under the PFS to the telehealth list without explicit consideration as to whether the candidate service could be effectively furnished through telehealth. For example, addition of all codes to the telehealth list could result in a number of services on the list that could never be furnished by a physician or nonphysician practitioner who

was not physically present with the beneficiary, such as major surgical procedures and interventional radiology services. Furthermore, we do not believe it would be appropriate to add services to the telehealth list without explicit consideration as to whether or not the nature of the service described by a candidate code allows the service to be furnished effectively through telehealth. Section 1834(m)(2)(A) of the Act requires that the distant site physician or practitioner furnishing the telehealth service must be paid an amount equal to the amount the physician or practitioner would have been paid under the PFS had such service been furnished without the use of a telecommunications system. Therefore, we believe that candidate telehealth services must also be covered when furnished in-person; and that any service that would only be furnished through a telecommunications system would be a new service and, therefore, not a candidate for addition to the telehealth list. In view of these considerations, we will continue to consider candidate additions to the telehealth list on a HCPCS code-specific basis based on requests from the public and our own considerations.

We also believe it continues to be most appropriate to consider candidate services for the telehealth list based on the two mutually exclusive established categories into which all services fall - specifically, services that are similar to services currently on the telehealth list (category 1) and services that are not similar to current telehealth services (category 2). 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 (67 FR 43862). Since CY 2003, we have added 35 services to the telehealth list on a category 1 basis based on public requests and our own identification of such services. We believe it is efficient and valuable to maintain the existing policy that allows us to consider

requests for additions to the telehealth list on a category 1 basis and proposed to add them to the telehealth list if the existing criteria are met. This procedure expedites our ability to identify codes for the telehealth list that resemble those services already on this list, streamlining our review process and the public request and information-submission process for services that fall into this category. Therefore, we believe that any changes to the process for adding codes to the telehealth list should be considered with respect to category 2 additions, rather than category 1 additions.

Our existing criteria for consideration of codes that would be category 2 additions, specifically those candidate telehealth services that are not similar to any current telehealth services, include an assessment of whether the use of a telecommunications system to deliver the services produces similar diagnostic findings or therapeutic interventions as compared with a face-to-face in-person delivery of the same service (67 FR 43682). In other words, the discrete outcome of the interaction between the clinician and patient facilitated by a telecommunications system should correlate well with the discrete outcome of the clinician-patient interaction when performed face to-face. In the CY 2003 PFS proposed rule (67 FR 43862), we explained that requestors for category 2 additions to the telehealth list should submit evidence that the use of a telecommunications systems does not affect the diagnosis or treatment plan as compared to in-person delivery of the service. We indicated that if evidence shows that the candidate telehealth service is equivalent when furnished in person or through telehealth, we would add it to the list of telehealth services. We refer to this standard in further discussion in this final rule with comment period as the "comparability standard." We stated in the CY 2003 PFS proposed rule (67 FR 43862) that if we determine that the use of a telecommunications system changes the nature or outcome of the service, for example, as compared with the in-person delivery of the

service, we would review the telehealth service addition request as a request for a new service, rather than a different method of delivering an existing Medicare service. For coverage and payment of most services, Medicare requires that a new service must: (1) fall into a Medicare benefit category; (2) be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act; and (3) not be explicitly excluded from coverage. In such a case, the requestor would have the option of applying for a national coverage determination for the new service.

We believe it is most appropriate to address the ATA and other stakeholder requests to broaden the current factors we consider when deciding whether to add candidate services to the telehealth list - to include factors such as the effects of barriers to in-person care and the safety, effectiveness, or medical benefit of the service furnished through telehealth, as potential refinements to our category 2 criteria. We initially established these category 2 criteria in the interest of ensuring that the candidate services were safe, effective, medically beneficial, and still accurately described by the corresponding codes when delivered via telehealth, while also ensuring that beneficiaries furnished telehealth services receive high quality care that is comparable to in-person care. We believed that the demonstration of comparable clinical outcomes (diagnostic findings and/or therapeutic interventions) from telehealth and in-person services would prove to be the best indicator that all of these conditions were met. While we continue to believe that safety, effectiveness, and medical benefit, as well as accurate description of the candidate telehealth services by the CPT or HCPCS codes, are necessary conditions for adding codes to the list of Medicare telehealth services, our recent experience in reviewing public requests for telehealth list additions and our discussions with stakeholders regarding contemporary medical practice and potential barriers to care, have led us to conclude that the comparability standard for category 2 requests should be modified.

In our annual evaluation of category 2 requests since we adopted the process for evaluating additions to the telehealth list almost 10 years ago, we have consistently observed that requestors have difficulty demonstrating that clinical outcomes of a service delivered via telehealth are comparable to the outcomes of the in-person service. The medical literature frequently does not include studies of the outcomes of many types of in-person services that allow for comparison to the outcomes demonstrated for candidate telehealth services. Furthermore, we know that in some cases the alternative to a telehealth service may be no service rather than an in-person service. The comparability standard may not sufficiently allow for the opportunity to add candidate services to the telehealth list that may be safe, effective, and medically beneficial when delivered via telehealth, especially to beneficiaries who experience significant barriers to in-person care. While we continue to believe that beneficiaries receiving services through telehealth are deserving of high quality health care and that in-person care may be very important and potentially preferable for some services when in-person care is possible, we are concerned that we have not added any services to the telehealth list on a category 2 basis as a result of our reviews. While some candidate services appear to have the potential for clinical benefit when furnished through telehealth, the requests have not met the comparability standard.

Therefore, we proposed to refine our category 2 review criteria for adding codes to the list of Medicare telehealth services beginning in CY 2013 by modifying the current requirement to demonstrate similar diagnostic findings or therapeutic interventions with respect to a candidate service delivered through telehealth compared to in-person delivery of the service (the comparability standard). We proposed to establish a revised standard of demonstrated clinical benefit when the service is furnished via telehealth. We refer to this proposed standard in further

discussion in this final rule with comment period as the "clinical benefit standard." To support our review using this revised standard, we would ask requestors to specify in their request how the candidate telehealth service is still accurately described by the corresponding HCPCS or CPT code when delivered via telehealth as opposed to in-person.

We proposed that our refined criteria for category 2 additions would be as follows:

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests would include 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. Requestors should submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient.

The evidence submitted 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. 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.

We believe the adoption of this clinical benefit standard for our review of candidate telehealth services on a category 2 basis is responsive to the requests of stakeholders that we broaden the factors taken into consideration to include barriers to care for beneficiaries. It allows us to consider the demonstrated clinical benefit of telehealth services for beneficiaries who might otherwise have no access to certain diagnostic or treatment services. Furthermore, we believe the focus on demonstrated clinical benefit in our review of category 2 requests for addition to the telehealth lists is equivalent to our standard for deleting services from the telehealth list that rests upon evidence that a service is not safe, not effective, or not medically beneficial. Finally, we believe the proposed clinical benefit standard for our review of candidate telehealth services on a category 2 basis is fully consistent with our responsibility to ensure that telehealth services are safe, effective, medically beneficial, and still accurately described by the corresponding codes that would be used for the services when delivered in-person.

We solicited public comments on the proposed refinement to our established process for adding codes to the telehealth list, including the information that requestors should furnish to facilitate our full review of requests in preparation for the CY 2013 PFS rulemaking cycle during which we will use the category 2 review criteria finalized in this final rule with comment period.

Comment: Many commenters supported the proposal to revise the category 2 criteria to

incorporate the clinical benefit standard. Many of these commenters stated that they expect the revised criteria to result in both an expanded list of telehealth services and better medical care for beneficiaries who might otherwise not have access to certain diagnostic or treatment services. Several of these commenters explicitly stated that the criteria as described in the proposal presented a rigorous evidentiary standard for demonstrating clinical benefit.

Response: We appreciate the broad support for the proposal. We believe that the proposed clinical benefit standard would allow us to consider the demonstrated clinical benefit of telehealth services for beneficiaries who might otherwise have no access to certain diagnostic or treatment services. We also believe that the proposal would ensure that Medicare telehealth services are safe, effective, and medically beneficial.

Comment: Some commenters advocated for eliminating the process for adding and deleting codes. These commenters argued that the determination of which services can be furnished through telehealth should be left to the judgment of individual physicians. One commenter suggested that CMS should evaluate clinical equivalence for telemedicine procedures by limiting the scope to clinical procedures and interventions that would normally be performed in the hospital setting as a part of ongoing care. A commenting organization informed CMS that it had conducted an extensive study of services and determined a list of services that should be eligible based on positive correlation of discrete outcomes of those services furnished through telehealth and those same services furnished in-person. However, the organization did not provide this analysis with their comments.

Response: We understand the commenters' interests in making broader changes to the way that services are added to or deleted from list of Medicare telehealth services. As we stated in the proposal, we believe that because section 1834(m)(2)(F)(ii) of the Act requires the

Secretary to establish a process that provides, on an annual basis, for the addition or deletion of telehealth services (and HCPCS codes), as appropriate, we do not believe it would be appropriate to add all services for which payment is made under the PFS to the telehealth list without explicit consideration as to whether the candidate service could be effectively furnished through telehealth. Furthermore, because section 1834(m)(2)(A) of the Act requires that the distant site physician or practitioner furnishing the telehealth service must be paid an amount equal to the amount the physician or practitioner would have been paid under the PFS had such service been furnished without the use of a telecommunications system, we do not believe it would be appropriate to add services to the telehealth list without explicit consideration as to whether or not the nature of the service described by a candidate code allows the service to be furnished as effectively through telehealth as in an in-person encounter. We believe continuing the current annual process, with the proposed amendment to the category 2 criteria, provides the appropriate opportunity to evaluate whether to add or delete specific services to the list of Medicare telehealth services. Although Medicare has not received many studies comparing clinical outcomes for in-person and telehealth delivery of the same service, we encourage stakeholders that conduct such comparison studies to submit such evidence to support category 2 requests for the addition of particular services to the list.

Comment: One commenter expressed support for the proposal but urged CMS to carefully evaluate its impact if implemented. That commenter suggested that the addition of new services under the proposed standard could incentivize changes in practice patterns where Medicare beneficiaries in remote areas receive consistently a lower level of care if clinical benefit has no relationship to the equivalent of an in-person visit. Another commenter disagreed with the proposal to amend the “comparability standard” for adding services to the list of

Medicare telehealth services. The commenter asserted that telehealth services can be effective as a step to help patients get the care they need, but should not be used to replace in-person care. The commenter argued that paying for telehealth services that may have some minor benefit as equivalent to an in-person service is misleading to patients and would prevent Medicare beneficiaries from getting the actual in-person care they need.

Response: We appreciate these concerns and agree that Medicare beneficiaries in remote areas deserve access to high quality health care. As we noted in the proposal, we also believe that in-person care may be very important and potentially preferable for some services when in-person care is possible. However, we also know that in some cases the alternative to a telehealth service may be no service rather than an in-person service.

We continue to believe safety, effectiveness, and medical benefit, as well as accurate description of the candidate telehealth services by the CPT or HCPCS codes, are necessary conditions for adding codes to the list of Medicare telehealth services. While we believe that in many cases, the existing standard has led to appropriate category 2 determinations not to add services to the telehealth benefit, we also believe that the current standard has prevented consideration of some services that could be clinically beneficial because there are no studies that compare patient outcomes when services are delivered via telehealth versus in person. This does not support our interests in identifying beneficial services for the telehealth benefit. Specifically, we observe that the medical literature frequently does not include studies of the outcomes of many types of in-person services that allow for comparison to the outcomes demonstrated for candidate telehealth services. We believe that the proposed revision to the existing criteria will allow thorough consideration of a greater number of requests for addition to the list. We would also remind commenters that the annual process will continue to provide

stakeholders who support or oppose adding particular services to the list the opportunity to contribute to our evaluations of particular requests through public comment.

Additionally, we note that the established process for deleting services from the list would allow Medicare to consider any available evidence suggesting that the addition of particular services to the list of Medicare telehealth services had detrimentally changed the quality of medical care for Medicare beneficiaries in remote areas. Such evidence could be considered in the context of either a public request or internally generated proposal to delete services from the list of Medicare telehealth services during annual PFS rulemaking. This process was established during CY 2003 PFS rulemaking. (67 FR 7988)

Finally, we agree with the commenter that argued that we should not add services to the telehealth list based on demonstrated evidence of minor benefit. We would like to clarify that our evidentiary standard of clinical benefit would not include minor or incidental benefits.

Comment: Some commenters offered feedback on the specific kind of information that requestors should furnish to facilitate CMS review of requests to add specific services. One commenter suggested that CMS should recognize any biometrics or clinical parameters known to affect morbidity/mortality as appropriate supporting evidence. Another commenter suggested that CMS should make clear that its list of clinical benefits that could be conferred by the use of telehealth services, as featured in the proposed rule, is not exhaustive. Rather, the list is illustrative. The commenter asked CMS to clarify that there are many kinds of clinical benefits that are possible for telehealth services as well as face-to-face services, and that CMS will consider clinical benefits on a case-by-case basis based on studies submitted by requestors. Another commenter expressed concern that the proposed evaluation criteria are inappropriate since they resemble the criteria for a Medicare coverage determination.

Response: We agree with the commenter who stated that the list of examples of demonstrated clinical benefits as presented in the proposed rule (76 FR 42827) is not exhaustive, but rather illustrative. Furthermore, we acknowledge that our proposal allows us to consider clinical benefits on a case-by-case basis depending on studies submitted by requestors, our own internal evaluation, and information submitted by commenters. While we acknowledge a similarity between some of the examples provided in the proposal and Medicare coverage criteria, we believe that such resemblance is appropriate given our interest in ensuring that services the Secretary adds to the telehealth benefit demonstrate clinical benefit to Medicare beneficiaries.

Comment: Several commenters requested that CMS provide more specific information about how the new criteria will be used to evaluate the requests to add services to the list of Medicare telehealth services. One of these commenters asked CMS to provide workshops and other outreach efforts related to the review criteria.

Response: We appreciate the commenters' interest in requesting greater specificity regarding how the new criteria will be used in evaluation of annual requests. In proposing the new category 2 criteria, we provided some examples of demonstrated benefit instead of establishing a series of specified clinical metrics because we expect the choice of appropriate evaluation criteria should be identified on a case-by-case basis specific to the information submitted with requests to add services through the established annual process.

We believe that establishing more rigid evaluation criteria (for example, criteria that rely on measurement of a series of demonstrated clinical outcomes specified by CMS) might present as many problems as has the current category 2 criteria, because under such a process requestors would be required to submit medical literature that passes a series of hurdles established by us

prior to receiving a particular request. We would not be able to assess the benefit of the requested service within the context of the submitted evidence and the specific services. We also believe that such a process might lead to greater administrative burden for requestors and might require constant revision through annual rulemaking to adapt any specific criteria to changes in medical and communication technology as well as developments in medical literature.

Additionally, we note that the application of the proposed criteria to each request will remain subject to public notice and comment. Since we implemented the process to add or delete services, including the existing category 2 criteria, we have used the PFS notice and comment rulemaking process to propose, accept public comments, and ultimately explain how the established evaluation criteria apply to each service we evaluate for addition to the list of Medicare telehealth services. We are not proposing a change to that aspect of the process with this proposed change in category 2 criteria.

Comment: One commenter expressed concern regarding the aspect of the proposed criteria that includes CMS' review of whether the service is accurately described by the corresponding code when delivered via telehealth. The commenter asserted that that aspect of the criteria is self-fulfilling and might prevent the addition of otherwise appropriate services to the list of Medicare telehealth services since the codes were written to describe in-person services. Similarly, one commenter was concerned that accurate description of the code when delivered via telehealth might prevent CMS from adding critical care services to the list of Medicare telehealth services because there are category III CPT codes that describe remote real-time interactive videoconferenced critical care services.

Response: In general, we do not believe it would be appropriate to add services to the Medicare telehealth list if those services cannot be accurately described by CPT or HCPCS codes

that could otherwise describe in-person services. Medicare payment for the services is based upon the services that the CPT or HCPCS code describes. As we explained in the CY 2012 PFS proposed rule with comment period (76 FR 42826), Section 1834(m)(2)(A) of the Act requires that the distant site physician or practitioner furnishing the telehealth service must be paid an amount equal to the amount the physician or practitioner would have been paid under the PFS had such service been furnished without the use of a telecommunications system. Therefore, we believe that candidate telehealth services must also be covered when furnished in-person; that the CPT and HCPCS code that is the basis for payment must accurately describe the service; and that any service that would only be furnished through a telecommunications system would be a distinct service from an in-person service, and therefore, not a candidate for addition to the Medicare telehealth list even when covered by Medicare. For example, 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). Medicare coverage for these types of services is distinct from the Medicare telehealth benefit.

With regard to the request to add critical care services to the list of Medicare telehealth Services, the application of the proposed category 2 criteria to that request is contingent on both the finalization of the proposed criteria and our receipt of a new request to add the services. However, as we noted in the CY 2012 PFS proposed rule with comment period (76 FR 42824), the fact that the CPT Editorial Panel created the Category III CPT codes suggests to us that these video-conferenced critical care services are not the same as the in-person critical care services

requested for addition to the telehealth list.

After consideration of the public comments we received, we are finalizing our proposal to revise the criteria we use to review category 2 requests to add services to the list of Medicare telehealth services beginning in CY 2013. We are modifying the current requirement to demonstrate similar diagnostic findings or therapeutic interventions with respect to a candidate service delivered through telehealth compared to in person delivery of the service (the comparability standard). Instead, we will assess category 2 requests to add services to the telehealth list using a standard of demonstrated clinical benefit (the clinical benefit standard) when the service is furnished via telehealth. To support our review using this revised standard, we ask requestors to specify in their request how the candidate telehealth service is still accurately described by the corresponding HCPCS or CPT code when delivered via telehealth as opposed to in person.

Our revised criteria for category 2 additions are as follows:

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests will include 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. Requestors should submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient.

The evidence submitted 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 will 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.

5. Telehealth Consultations in Emergency Departments

We have recently been asked to clarify instructions regarding appropriate reporting of telehealth services that, prior to our policy change regarding consultation codes, would have been reported as consultations furnished to patients in an emergency department. When we eliminated the use of consultation codes under the PFS beginning in CY 2010, we instructed practitioners, when furnishing a service that would have been reported as a consultation service, to report the E/M code that is most appropriate to the particular service for all office/outpatient or inpatient visits. Since section 1834(m) of the Act includes "professional consultations" (including the initial inpatient consultation codes "as subsequently modified by the Secretary") in the definition of telehealth services, we established several HCPCS codes to describe the

telehealth delivery of initial inpatient consultations. For inpatient hospital and skilled nursing facility care telehealth services, we instructed practitioners to use the inpatient telehealth consultation G-codes listed in Table 12 to report those telehealth services (74 FR 61763, 61774). However, we neglected to account for the fact that E/M emergency department visit codes (99281-99285) are not on the telehealth list. As a result, there has not been a clear means for practitioners to bill a telehealth consultation furnished in an emergency department. In order to address this issue, we proposed to change the code descriptors for the inpatient telehealth consultation G-codes to include emergency department telehealth consultations effective January 1, 2012. However, we requested public comment regarding other options, including creating G-codes specific to these services when furnished to patients in the emergency department.

TABLE 12: INPATIENT TELEHEALTH CONSULTATION G-CODES

HCPCS Code	CY 2011 Long Code Descriptor
G0425	Initial inpatient telehealth consultation, typically 30 minutes communicating with the patient via telehealth
G0426	Initial inpatient telehealth consultation, typically 50 minutes communicating with the patient via telehealth
G0427	Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth
G0406	Follow-up inpatient telehealth consultation, limited, physicians typically spend 15 minutes communicating with the patient via telehealth
G0407	Follow-up inpatient telehealth consultation, intermediate, physicians typically spend 25 minutes communicating with the patient via telehealth
G0408	Follow-up inpatient telehealth consultation, complex, physicians typically spend 35 minutes or more communicating with the patient via telehealth

Comment: Many commenters supported the proposal to change the code descriptors for the inpatient telehealth consultation G-codes to include emergency department telehealth consultations effective January 1, 2012. These commenters asserted that changing the code descriptors is an appropriate way for CMS to provide a clear means for practitioners to bill

telehealth consultations furnished to emergency department patients.

Response: We appreciate the support for the proposal. We agree that changing the code descriptors will ensure that telehealth consultations can be reported appropriately when furnished to emergency department patients.

Comment: A few commenters expressed concerns that the proposal would blur the line between inpatient and outpatient services. One commenter disagreed with the proposal and suggested that CMS should create new G-codes since it is important to maintain the distinction between outpatient and inpatient services.

Response: We thank the commenters for bringing these concerns to our attention. While we understand that emergency department services are considered outpatient services, at this time we believe that allowing practitioners to report the G-codes we created for initial inpatient telehealth consultations when furnishing telehealth consultations to emergency department patients is the most appropriate way to resolve the immediate issue. We note that the G-codes we created for telehealth consultations are used exclusively under the telehealth benefit. In this unique circumstance, we believe that the use of single codes to describe what can be an inpatient or an outpatient emergency department service is an appropriate mechanism to allow practitioners to report these telehealth services.

However, the comments regarding site of service coding distinctions have prompted us to reconsider the need to provide a mechanism for follow-up consultations in the emergency department. While follow-up consultative services are furnished to hospital and SNF inpatients, we do not believe these services are furnished to patients in emergency departments since patients do not spend enough time in the emergency department to warrant a second consultative service by the same practitioner. Therefore, we are amending our proposal to pertain only to the

G-codes that describe initial telehealth consultations.

Comment: One commenter disagreed with the code descriptor change based on the assertion that the existing G-codes do not sufficiently cover the intensity, risk and medical judgment involved in providing teleICU services to critically ill patients.

Response: We agree that the telehealth consultation codes do not fully describe critical care services. For additional information regarding the request to add critical care services to the list of Medicare telehealth services, we refer the commenter to our discussion in section II.E.1.b. of this final rule with comment period.

Comment: One commenter requested additional information regarding why Medicare only pays for consultations furnished through telehealth.

Response: While Medicare no longer recognizes CPT consultation codes for payment purposes, practitioners furnishing services that could be described by CPT consultation codes are still paid for those services when they are reported using the the most appropriate office or inpatient evaluation and management code. The telehealth consultation G-codes are intended to provide a mechanism for reporting telehealth consultation services to patients in the inpatient and SNF settings. We created these codes because inpatient and SNF evaluation and management codes were not included in the telehealth benefit and a practitioner could not bill an evaluation and management code when providing consultation services via telehealth furnished to patients in those settings. We refer the reader to our most recent thorough discussion of this issue in the CY 2010 PFS final rule with comment period (74 FR 61763 and 61767 through 61775).

After consideration of the public comments we received, we are finalizing our proposal to change the code descriptors for initial inpatient telehealth consultation G-codes to reflect telehealth consultations furnished to emergency department patients in addition to inpatient

telehealth consultations effective January 1, 2012. The descriptors for these codes for CY 2012 appear in table 13. After consideration of the public comments we received, we are not finalizing our proposal to change the code descriptors for follow-up inpatient telehealth consultations, since we do not believe follow-up consultations are furnished to emergency department patients.

TABLE 13: INPATIENT TELEHEALTH CONSULTATION G-CODES

HCPCS Code	CY 2012 Long Code Descriptor
G0425	Telehealth consultation, emergency department or initial inpatient, typically 30 minutes communicating with the patient via telehealth
G0426	Telehealth consultation, emergency department or initial inpatient, typically 50 minutes communicating with the patient via telehealth
G0427	Telehealth consultation, emergency department or initial inpatient, typically 70 minutes or more communicating with the patient via telehealth

6. 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. 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 2012 is 0.6 percent. Therefore, for CY 2012, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or \$24.24. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 14.

TABLE 14: 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

III. Addressing Interim Final Relative Value Units (RVUs) from CY 2011, Proposed RVUs from CY 2012, and Establishing Interim RVUs for CY 2012

Under section 1848(c)(2)(B) of the Act, we review and make adjustments to RVUs for physicians' services at least once every 5 years. Under section 1848(c)(2)(K) of the Act (as added by section 3134 of the Affordable Care Act), we are required to identify and revise RVUs for services identified as potentially misvalued. Section 1848(c)(2)(K)(iii) specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In accordance with section 1848(c)(2)(K)(iii) of the Act, we develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the AMA RUC, the Medicare Payment Advisory Commission (MedPAC), and others. To respond to concerns expressed by MedPAC, the Congress, and other stakeholders regarding the accuracy of values for services under the PFS, the AMA RUC has used an annual process to systematically identify, review, and provide CMS with recommendations for revised work values for many existing potentially misvalued services.