J. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Several conditions must be met for Medicare to make payments for telehealth services under the PFS. The service must be on the list of Medicare telehealth services and meet all of the following additional requirements:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished by a physician or authorized practitioner.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the service must be located in a telehealth originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and makes a separate payment to the distant site practitioner furnishing the service.

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 furnished via a telecommunications system. We first implemented this statutory provision, which was effective October 1, 2001, in the CY 2002 PFS final rule with comment period (66 FR 55246). We established a process for annual updates to the list of Medicare telehealth services as required by section 1834(m)(4)(F)(ii) of the Act in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified 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 stand-alone electronic mail systems that are not integrated into an electronic health record system 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 part of a federal telemedicine demonstration program in Alaska or Hawaii. As specified in §410.78(a)(1), asynchronous store-and-forward is the transmission of medical information from an originating site for review by the distant site physician or practitioner at a later time.

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 is an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Practitioners furnishing Medicare telehealth services are reminded that these services are subject to the same non-discrimination laws as other services, including the effective communication requirements for persons with disabilities of section 504 of the Rehabilitation Act and language access for persons with limited English proficiency, as required under Title VI of the Civil Rights Act of 1964. For more information, see http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication.

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare Administrative 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.

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a fee under the PFS a facility fee for each Medicare telehealth service. The statute specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. With regard to geographic qualifications, §410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical areas (MSAs).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration (HRSA) (78 FR 74811). Defining ''rural'' to include geographic areas located in rural census tracts within MSAs allows for broader inclusion of sites within HPSAs as telehealth originating sites. Adopting the more precise definition of ''rural'' for this purpose expands access to health care services for Medicare beneficiaries located in rural areas. HRSA has developed a website tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see the CMS website at www.cms.gov/telehealth/.

An entity participating in a federal telemedicine demonstration project that has been approved by, or received funding from, the Secretary as of December 31, 2000 is eligible to be an originating site regardless of its geographic location.

Effective January 1, 2014, we also changed our policy so that geographic status for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies (78 FR 74400). Geographic status for Medicare telehealth

originating sites for each calendar year is now based upon the status of the area as of December 31 of the prior calendar year.

For a detailed history of telehealth payment policy, see 78 FR 74399.

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. Under this process, we assign any qualifying request to make additions to the list of telehealth services to one of two categories. Revisions to criteria that we use to review requests in the second category were finalized in the November 28, 2011 **Federal Register** (76 FR 73102). 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, a practitioner who is present with the beneficiary in the originating site. 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 furnished 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 furnishing 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.

For the list of covered telehealth services, see the CMS website at www.cms.gov/telehealth/. 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, qualifying requests submitted before the end of CY 2015 will be considered for the CY 2017 proposed rule. 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. 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, see the CMS website at www.cms.gov/telehealth/.

3. Submitted Requests to the List of Telehealth Services for CY 2016

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 final rule with comment period (76 FR 73098), we believe that the category 1 criteria not only streamline our review process for publicly 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.

a. Submitted Requests

We received several requests in CY 2014 to add various services as Medicare telehealth services effective for CY 2016. The following presents a discussion of these requests, and our proposals for additions to the CY 2016 telehealth list. Of the requests received, we find that the following services are sufficiently similar to psychiatric diagnostic procedures or office/outpatient visits currently on the telehealth list to qualify on a category one basis. Therefore, we propose to add the following services to the telehealth list on a category 1 basis for CY 2016:

• CPT code 99356 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (list separately in addition to code for inpatient evaluation and management service); and 99357 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged service).

The prolonged service codes can only be billed in conjunction with hospital inpatient and skilled nursing facility evaluation & management (E/M) codes, and of these, only subsequent hospital and subsequent nursing facility visit codes are on list of Medicare telehealth services. Therefore, CPT codes 99356 and 99357 would only be reportable with codes for which limits of one subsequent hospital visit every three days via telehealth, and one subsequent nursing facility visit every thirty days, would continue to apply.

• CPT codes 90963 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90964 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90965 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); and 90966 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older).

Although these services are for home-based dialysis, and a patient's home is not an authorized originating site for telehealth, we recognize that many components of these services

would be furnished from an authorized originating site and, therefore, can be furnished via telehealth.

The required clinical examination of the catheter access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, certified nurse specialist (CNS), nurse practitioner (NP), or physician's assistant (PA). An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit Monthly Capitation Payment (MCP) code and the 4 or more visit MCP code. See the final rule for CY 2005 (69 FR 66276) for further information on furnishing ESRD services via telehealth.

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We are not proposing to add the following procedures for the reasons noted:

• All evaluation and management services, telerehabilitation services, and palliative care, pain management and patient navigation services for cancer patients.

None of these requests identified the specific codes that were being requested for addition as telehealth services, and two of the requests did not include evidence of any clinical benefit when the services are furnished via telehealth. Since we did not have information on the specific codes requested for addition or evidence of clinical benefit for these requests, we cannot evaluate whether the services are appropriate for addition to the Medicare telehealth services list.

• 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 (list separately in addition to code for primary service).

We previously considered and rejected adding these codes to the list of Medicare

telehealth services in the CY 2009 PFS final rule (74 FR 69744) on a category 1 basis because, due to the acuity of critically ill patients, we did not consider critical care services similar to any services on the current list of Medicare telehealth services. In that rule, we said that critical care services must be evaluated as category 2 services. Because we would consider critical care services under category 2, we needed to evaluate whether these are services for which telehealth can be an adequate substitute for a face-to-face encounter. We had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the face-to-face delivery of this type of care.

The American Telemedicine Association (ATA) submitted a request, which cited several studies to support adding these services on a category 2 basis. To qualify under category 2, we would need evidence that the service produces a clinical benefit for the patient. However, in reviewing the information provided by the ATA and a study entitled, "Impact of an Intensive Care Unit Telemedicine Program on Patient Outcomes in an Integrated Health Care System," published July 2014, in "JAMA Internal Medicine," which found no evidence that the implementation of ICU TM significantly reduced mortality rates or hospital length of stay, we do not believe that the evidence demonstrates a clinical benefit to patients. Therefore, we are not proposing to add these services on a category 2 basis to the list of Medicare telehealth services for CY 2016.

- CPT code 99358 (prolonged evaluation and management service before and/or after direct patient care; first hour) and 99359 (prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (list separately in addition to code for prolonged service).

As we indicated in the CY 2015 PFS final rule with comment period (79 FR 67600), these services are not separately payable by Medicare. It would be inappropriate to include a

service as a telehealth service when Medicare does not otherwise make a separate payment for it. Therefore, we are not proposing to add these non-payable services to the list of Medicare telehealth services for CY 2016.

- CPT code 99444 (online evaluation and management service provided by a physician or other qualified health care professional who may report an evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided within the previous 7 days, using the internet or similar electronic communications network).

As we indicated in the CY 2014 PFS final rule with comment period (78 FR 74403), we assigned a status indicator of "N" (Noncovered service) to this service because: (1) this service is 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 code 99444 is currently noncovered, there would be no Medicare payment if this service was furnished without the use of a telecommunications system. Since this service is noncovered under Medicare, we are not proposing to add it to the list of Medicare telehealth services for CY 2016.

- CPT code 99490 (chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;

comprehensive care plan established, implemented, revised, or monitored).

This service is one that can be furnished without the beneficiary's face-to-face presence, and using any number of non-face-to-face means of communication. Therefore, the service is not appropriate for consideration as a Medicare telehealth service. It is unnecessary to add this service to the list of Medicare telehealth services. Therefore, we are not proposing to add it to the list of Medicare telehealth services for CY 2016.

- CPT codes 99605 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient); 99606 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient); and 99607 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; each additional 15 minutes (list separately in addition to code for primary service).

These codes are noncovered services for which no payment may be made under the PFS. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2016.

In summary, we are proposing to add the following codes to the list of Medicare telehealth services beginning in CY 2016 on a category 1 basis: Prolonged service inpatient CPT codes 99356 and 99357 and ESRD-related services 90933 through 90936. As indicated above, the prolonged service codes can only be billed in conjunction with subsequent hospital and subsequent nursing facility codes. Limits of one subsequent hospital visit every three days, and one subsequent nursing facility visit every thirty days, would continue to apply when the services are furnished as telehealth services. For the ESRD related services, the required clinical examination of the catheter access site must be furnished face-to-face "hands on" (without the

use of an interactive telecommunications system) by a physician, certified nurse specialist (CNS), nurse practitioner (NP), or physician's assistant (PA).

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 2017, these requests must be submitted and received by December 31, 2015. 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/.

4. Proposal to amend §410.78 to Include Certified Registered Nurse Anesthetists as Practitioners for Telehealth Services

Under section 1834(m)(1) of the Act, Medicare makes payment for telehealth services furnished by physicians and practitioners. Section 1834(m)(4)(E) of the Act specifies that, for purposes of furnishing Medicare telehealth services, the term "practitioner" has the meaning given that term in section 1842(b)(18)(C), which includes a certified registered nurse anesthetist (CRNA) as defined in section 1861 (bb)(2).

We initially omitted CRNAs from the list of distant site practitioners for telehealth services in the regulation because we did not believe these practitioners would furnish any of the service on the list of Medicare telehealth services. However, CRNAs in some states are licensed to furnish certain services on the telehealth list, including E/M services. Therefore, we propose to revise the regulation at §410.78(b)(2) to include a CRNA, as described under §410.69, to the list of distant site practitioners who can furnish Medicare telehealth services.