

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 409, 410, 411, 413, 414, 415, and 424

[CMS-1503-P]

RINs 0938-AP79

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

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

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses proposed 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 provisions of both the Affordable Care Act and the Medicare Improvements for Patients and Providers Act of 2008. In addition, this proposed rule discusses payments under the Ambulance Fee Schedule, Clinical Laboratory Fee Schedule, payments to ESRD facilities, and payments for Part B drugs. Finally, the proposed rule includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for Durable Medical Equipment and Provider and Supplier Enrollment Issues associated with Air Ambulances. (See the Table of Contents for a listing of the specific issues addressed in this proposed rule.)

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR—insert date 60 days after the date of filing for public inspection at OFR.]

requested that all of these services be priced nationally on the PFS, including the one service (CPT code 93229) that is currently contractor- priced.

We also considered that the services currently priced nationally on the PFS are scheduled to receive lower payment rates under the 4-year transition to the PPIS data and that the contractor's price for CPT 93229 was recently reduced in the area where the majority of the billings for this service currently occur.

After taking all these factors into consideration, we are not proposing CY 2011 methodological or direct cost input changes for CPT codes 93012, 93268, or 93271 - the services that are currently nationally priced under the PFS. We are also proposing to continue contractor-pricing for CPT 93229 for CY 2011. We continue to be interested in public comments on this issue, including responses to our analysis of alternative approaches to establishing PE RVUs for 24/7 services, and further discussion of the issues we have identified in our alternative pricing methodologies. In addition, while we have focused the 24/7 services analysis to date on developing the PE RVUS for remote cardiac monitoring services, there may be 24/7 services in other areas of medicine, either currently paid under the PFS or in development for the future. Therefore, we are also interested in public comments on these current or emerging 24/7 services, including descriptions of the similarities or differences between these other services and remote cardiac monitoring services, particularly with respect to the issues we have identified in our analysis of alternative approaches to establishing PE RVUs for remote cardiac monitoring services under the PFS.

IV. Medicare Telehealth Services For The Physician Fee Schedule

A. Billing and Payment for Telehealth Services

1. 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) 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 statute 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 statute 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. 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 participate 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 statute does not require the eligible telehealth individual to be presented by a practitioner at the originating site.

2. Current Telehealth Billing and Payment Policies

As noted above, 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 medical nutrition therapy (MNT)
- Neurobehavioral status exam
- Individual health and behavior assessment and intervention (HBAI).

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 authenticates 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 described above, 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). 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).

B. Requests for Adding Services to the List of Medicare Telehealth Services

As noted above, 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. 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 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 MNT; neurobehavioral status exam; and initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and skilled nursing facilities (SNFs).

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 2010 are considered for the CY 2012 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/.

C. Submitted Requests for Addition to the List of Telehealth Services for CY 2011

We received requests in CY 2009 to add the following services as Medicare telehealth services effective for CY 2011: (1) individual kidney disease education (KDE) services; (2) individual diabetes self-management training (DSMT) services; (3) group KDE, DSMT, MNT, and HBAI services; (4) initial, subsequent, and discharge day management hospital care services; (5) initial, subsequent, discharge day management, and other nursing facility care services; (6) neuropsychological testing services; (7) speech-language pathology services; and (8) home wound care services. The following

presents a discussion of these requests, including our proposals for additions to the CY 2011 telehealth list.

1. Individual KDE Services

The American Society of Nephrology, Dialysis Patient Citizens, AMGEN, and Kidney Care Partners submitted requests to add individual KDE services, reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour), to the list of approved telehealth services for CY 2011 on a category 1 basis.

Individual KDE services, covered under the new Medicare KDE benefit effective for services furnished beginning in CY 2010, are defined as face-to-face educational services provided to a patient with stage IV chronic kidney disease (CKD). We believe the interaction between a practitioner and a beneficiary receiving individual KDE services is similar to the education, assessment, and counseling elements of individual MNT services, reported by HCPCS code G0270 (Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in 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 are proposing to add HCPCS code G0420 to the list of telehealth services for CY 2011 on a category 1 basis. Consistent with this proposal, we are also

proposing to revise our regulations at §410.78(b) and §414.65(a)(1) to include individual KDE as a Medicare telehealth service.

2. Individual DSMT Services

The Tahoe Forest Health System and the Marshfield Clinic submitted requests to add individual DSMT services, reported by HCPCS code G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes), to the list of telehealth services for CY 2011 on a category 1 basis. In the CY 2009 PFS final rule with comment period (73 FR 69743), we stated that we believe individual DSMT services are not analogous to individual MNT services because of the element of skill-based training that is encompassed within individual DSMT services that is not an aspect of individual MNT services (or any other services currently approved for telehealth). Due to the statutory requirement that DSMT services include teaching beneficiaries the skills necessary for the self-administration of injectable drugs, we have stated our belief that DSMT, whether provided to an individual or a group, must be evaluated as a category 2 service as specified in the CY 2009 PFS proposed rule (73 FR 38516). We have considered several previous requests to add DSMT to the list of Medicare telehealth services. We have not added individual DSMT to the list of telehealth services because we believe that skill-based training, such as teaching patients how to inject insulin, would be difficult to accomplish effectively without the physical presence of the teaching practitioner (70 FR 45787 and 70157, and 73 FR 38516 and 69743).

In considering the new request to add individual DSMT services to the list of telehealth services in CY 2011, we have taken into account requestors' argument that individual DSMT services are highly similar to individual MNT services and that injection training constitutes just a small proportion of DSMT services. Except for the

component of individual DSMT services that involves instruction in self-administration of injectable drugs for eligible beneficiaries, we agree with the requestors that individual DSMT services are similar to individual MNT services, which are currently on the list of Medicare telehealth services. We note that Medicare coverage of DSMT services was initially authorized in the Balanced Budget Act of 1997. After more than a decade of Medicare coverage, the most recent information shows that DSMT continues to be significantly underutilized in the context of the eligible population of Medicare beneficiaries. While we are uncertain to what extent geographic barriers to care contribute to this underutilization, given the morbidity associated with poorly managed diabetes and the growing evidence-base regarding effective DSMT services, we believe it is very important to facilitate Medicare beneficiary access to these underutilized services. While we have previously been concerned about treating the components of DSMT services differently in the context of considering DSMT services for the telehealth list, we believe that our concern regarding the skill-based injection training component of DSMT services can be addressed by imposing a requirement that a minimum portion of the training be furnished in-person. We note that for beneficiaries who meet the coverage criteria, Medicare covers 10 hours of DSMT services in the year following the initial training, as described in the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 15, Section 300.3). Taking into consideration the initial year coverage of DSMT services, we are proposing that a minimum of 1 hour of instruction in injection training must be furnished in-person during the year following the initial DSMT service. Imposing this condition would allow us to expand access to DSMT services by adding individual DSMT services to the list of telehealth services, while ensuring effective injection training for beneficiaries.

Therefore, we are proposing to add HCPCS code G0108 to the list of telehealth services beginning in CY 2011. We are also proposing that, as a condition of payment for individual DSMT services furnished as telehealth services to an eligible telehealth individual, a minimum of 1 hour of in-person instruction in the self-administration of injectable drugs must be furnished to the individual during the year following the initial DSMT service. The injection training may be furnished through either individual or group DSMT services. By reporting the –GT or –GQ modifier with HCPCS code G0108 as a telehealth service, the distant site practitioner would certify that the beneficiary has received or will receive 1 hour of in-person DSMT services for purposes of injection training during the year following the initial DSMT service. Consistent with this proposal, we are proposing to revise our regulations at §410.78(b) and §414.65(a)(1) to include individual DSMT services as a Medicare telehealth service, with the exception of 1 hour of in-person instruction in self-administration of injectable drugs which must be furnished to the eligible telehealth individual as individual or group DSMT services during the year following the initial DSMT service.

We note that, as specified in §410.141(e), individual DSMT services may be furnished by a physician, individual, or entity that furnishes other services for which direct Medicare payment may be made and that submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS. However, consistent with the statutory requirements of section 1834(m)(1) of the Act and as provided in §410.78(b)(1) and (b)(2) of our regulations, Medicare telehealth services, including individual DSMT furnished as a telehealth service, could only be furnished by a licensed PA, NP, CNS, certified nurse-midwife, clinical psychologist, clinical social worker, or registered dietitian or nutrition professional.

3. Group KDE, MNT, DSMT, and HBAI Services

The American Society of Nephrology, Dialysis Patient Citizens, AMGEN, Tahoe Forest Health Systems, Kidney Care Partners, the American Telemedicine Association, and the Marshfield Clinic submitted requests to add one or more of the following group services to the telehealth list for CY 2011:

- Group KDE services, reported by HCPCS code G0421 (Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour);
- Group MNT services, reported by CPT code 97804 (Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes);
- Group DSMT services, reported by HCPCS code G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes); and/or
- Group HBAI services, reported by CPT code 96153 (Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)) and 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)).

When furnished as individual services, HBAI and MNT services are currently on the list of Medicare telehealth services. Furthermore, we are proposing to add individual KDE and DSMT services to the list of Medicare telehealth services beginning in CY 2011 as described above.

In the CY 2007 and CY 2010 PFS rulemaking cycles (70 FR 45787 and 70157, and 74 FR 33543 and 61764), we stated that we did not believe that group services could be appropriately delivered through telehealth. We have observed that currently there are no group services approved as Medicare telehealth services and that there is a different

interactive dynamic between the practitioner and his or her patients in group services as compared to individual services. We previously have considered requests to add various group services to the list of Medicare telehealth services on a category 2 basis because we have believed that, especially given the interactive dynamic between practitioners and their patients, group services are not similar to other services on the list of Medicare telehealth services. Therefore, we have maintained that it is necessary to evaluate the addition of group services by comparing diagnostic findings or therapeutic interventions when services are furnished via telehealth versus when services are furnished in-person.

We continue to believe that the group dynamic may be a critical and defining element for certain services, and that this characteristic precludes many group services from being considered on a category 1 basis for addition to the list of Medicare telehealth services. For example, we believe that due to the therapeutic nature of the group dynamic that is integral to group psychotherapy, group psychotherapy is fundamentally different from other Medicare telehealth services and, therefore, could not be considered on a category 1 basis for addition to the telehealth services list. For the same reason, in the absence of evidence to the contrary, we do not believe group psychotherapy services could be appropriately delivered through telehealth.

However, upon further consideration, with regard to the particular group education and training services for which we received requests for addition to the Medicare telehealth services list, we believe the group dynamic is not central to the core education and training components of these particular services, specifically DSMT, MNT, KDE, and HBAI services. We believe that these group services are sufficiently similar to the individual, related services that are already on the telehealth services list or are proposed for addition beginning in CY 2011. Specifically, we believe that for these

group services, which consist principally of an information exchange for the purpose of education and training, the roles of, and interactions between, the patients and the practitioner are sufficiently similar to the related individual education and training services that the services can be furnished appropriately as a telehealth service.

Therefore, we are proposing to add HCPCS code G0421 for group KDE services, CPT code 97804 for group MNT services, HCPCS code G0109 for group DSMT services, and CPT codes 96153 and 96154 for group HBAI services to the Medicare telehealth services list on a category 1 basis. Furthermore, because the concerns we raised above regarding adequate injection training with the addition of individual DSMT are also present for group DSMT, we are proposing to require the same minimum of 1 hour of in-person instruction for injection training within the year following the initial DSMT service for any beneficiary that receives DSMT services via telehealth. By reporting the –GT or –GQ modifier with HCPCS code G0109, the distant site practitioner would certify that the beneficiary has received or will receive 1 hour of in-person DSMT services for purposes of injection training during the year following the initial DSMT service. Consistent with this proposal to add these group education and training services, we are also proposing to revise our regulations at §410.78(b) and §414.65(a)(1) to include group KDE, MNT, DSMT, and HBAI services as Medicare telehealth services, with the exception of 1 hour of in-person instruction of individual or group DSMT services in the year following the initial DSMT service.

As described above for individual DSMT services, we note that group DSMT services may be furnished by a physician, individual, or entity that furnishes other services for which direct Medicare payment may be made and that submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS,

as specified in §410.141(e) for DSMT services. However, consistent with the statutory requirements of section 1834(m)(1) of the Act and as provided in §410.78(b)(1) and (b)(2) of our regulations, Medicare telehealth services, including group DSMT furnished as a telehealth service, could only be furnished by a licensed PA, NP, CNS, certified nurse-midwife, clinical psychologist, clinical social worker, or registered dietitian or nutrition professional.

4. Initial, Subsequent, and Discharge Day Management Hospital Care Services

The University of Louisville School of Medicine, the American Telemedicine Association, and Mille Lacs Health System submitted various requests to add initial hospital care services (reported by CPT codes 99221 (Level 1 initial hospital care), 99222 (Level 2 initial hospital care), and 99223 (Level 3 initial hospital care)); subsequent hospital care services (reported by CPT codes 99231 (Level 1 subsequent hospital care), 99232 (Level 2 subsequent hospital care), and 99233 (Level 3 subsequent hospital care)); and/or hospital discharge day management services (reported by CPT codes 99238 (Hospital discharge day management; 30 minutes or less) and 99239 (Hospital discharge day management; more than 30 minutes) to the Medicare telehealth services list beginning in CY 2011, generally on a category 1 basis. Some of the requestors also recommended that we limit the delivery of these services through telehealth to the provision of services to patients with a psychiatric diagnosis or to those treated in a psychiatric hospital or licensed psychiatric bed.

We appreciate the recommendations of the requestors to substantially expand the list of Medicare telehealth services. The requestors submitted a number of studies regarding the outcomes of telehealth services in caring for patients with psychiatric diagnoses. However, we note that the CPT codes for hospital care services are used to

report care for hospitalized patients with a variety of diagnoses, including psychiatric diagnoses. We do not believe it would be appropriate to add services to the telehealth list only for certain diagnoses because the service described by a HCPCS code is essentially the same service, regardless of the patient's diagnosis. When evaluating the addition of services for telehealth on a category 1 basis, our focus is on the roles of, and interactions among, the beneficiary, the physician or practitioner, and the telepresenter (if applicable), which generally are similar across diagnoses for services that may be reported with the same HCPCS codes. Even in the unique case of certain ESRD services, we limited additions to the list of Medicare telehealth services based on the appropriateness of certain specific codes, taking into consideration the full service descriptions (69 FR 47511). Therefore, we continue to believe that it is most appropriate to consider additions to the list of telehealth services based on the overall suitability of the services described by the relevant HCPCS codes to delivery through telehealth.

In the CY 2005, CY 2008, and CY 2009 PFS rulemakings (69 FR 47510 and 66276, 72 FR 38144 and 66250, and 73 FR 38517 and 69745, respectively), we did not add initial, subsequent, or discharge day management hospital care services to the list of approved telehealth services because of our concern regarding the use of telehealth for the ongoing evaluation and management (E/M) for the generally high acuity of hospital inpatients. While we continue to have some concern in this area, we also share the requestors' interest in improving access for hospitalized patients to care furnished by treating practitioners. Therefore, we have reevaluated these services in the context of the CY 2011 requests, including considering the possibility that these services could be added on a category 1 basis based on their resemblance to services currently on the telehealth list, such as initial and follow-up inpatient telehealth consultations. The

following presents a discussion of our review of the subcategories of hospital care services included in these requests.

Currently, one of the three codes for an initial hospital care service (specifically CPT codes 99221, 99222, or 99223) is reported for the first hospital inpatient E/M visit to the patient by the admitting or a consulting practitioner when that visit is furnished in-person. In addition, we note that currently there are several HCPCS G-codes on the Medicare telehealth services list that may be reported for initial and follow-up inpatient consultations through telehealth, specifically HCPCS codes 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); 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); and G0427 (Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth).

While initial inpatient consultation services are currently on the list of approved telehealth services, there are no services on the current list of telehealth services that resemble initial hospital care for an acutely ill patient by the admitting practitioner who has ongoing responsibility for the patient's treatment during the hospital course.

Therefore, we are unable to consider initial hospital care services on a category 1 basis for the telehealth list.

We have reviewed the documentation submitted in support of adding the initial hospital care codes to the Medicare telehealth services list as category 2 requests. Most of the studies provided by the requestors were specific to the treatment of patients with particular diagnoses. Additionally, the studies were not specific to initial hospital care visits by admitting practitioners. Finally, most of the studies concluded that more research was required in order to establish medical equivalence between telehealth and in-person services. Therefore, we received no information that provides robust support for the addition of initial hospital care services to the approved telehealth list on a category 2 basis. The initial hospital care codes describe the first visit to the hospitalized patient by the admitting practitioner who may or may not have seen the patient in the decision-making phase regarding hospitalization. We believe it is critical that the initial hospital visit by the admitting practitioner be conducted in-person to ensure that the practitioner with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination. Therefore, we are not proposing to add initial hospital care services to the Medicare telehealth services list for CY 2011.

We have again considered adding subsequent hospital care services reported by CPT codes 99231 through 99233 to the telehealth list for CY 2011 on a category 1 basis. In the CY 2005 and CY 2008 PFS proposed rules (69 FR 47511 and 72 FR 38155), we stated that the potential acuity of patients in the hospital setting precludes consideration of subsequent hospital visits as similar to existing telehealth services. However, as stated earlier, we also note that HCPCS codes for initial and follow-up inpatient consultation services are on the list of telehealth services. These E/M services are furnished to high acuity hospitalized patients, although not by the admitting practitioner himself or herself.

However, in light of the increasingly prevalent care model that entails multidisciplinary team care for patients with complex medical illnesses that involve multiple body systems, consulting practitioners may often play a key, intensive, and ongoing role in caring for hospitalized patients. Therefore, we believe that subsequent hospital care visits by a patient's admitting practitioner may sufficiently resemble follow-up inpatient consultation services to consider these subsequent hospital care services on a category 1 basis for the telehealth list. While we still believe the potential acuity of hospital inpatients is greater than those patients likely to receive currently approved Medicare telehealth services, we also believe that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth in order to ensure that hospitalized patients have frequent encounters with their admitting practitioner. However, we also continue to believe that the majority of these visits should be in-person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis.

Therefore, we are proposing that subsequent hospital care services, specifically CPT codes 99231, 99232, and 99233, be added to the list of telehealth services on a category 1 basis for CY 2011, but with some limitations on the frequency that these services may be furnished through telehealth. Because of our concerns regarding the potential acuity of hospital inpatients, we are proposing to limit the provision of subsequent hospital care services through telehealth to once every 3 days. We are confident that admitting practitioners will continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Consulting practitioners should continue to use the inpatient telehealth consultation HCPCS G-codes, specifically

G0406, G0407, G0408, G0425, G0426, or G0427 when reporting consultations furnished to inpatients via telehealth.

Consistent with this proposal, we are proposing to revise §410.78(b) and §414.65(a)(1) to include subsequent hospital care services as Medicare telehealth services, with the limitation of one telehealth subsequent hospital care service every 3 days.

We also considered adding hospital discharge day management services to the list of telehealth services. These services, reported by CPT codes 99238 and 99239, include the final examination of the patient, discussion of the hospital stay, instructions for continuing care to all relevant caregivers, and preparation of discharge records, prescriptions, and referral forms. These services are furnished when a practitioner deems it medically reasonable and necessary to assess a patient's readiness for discharge and to prepare a patient for discharge from an acute care environment to a less intensive setting. There are no services on the current list of telehealth services that resemble such preparation of a patient for discharge. We believe it is especially important that, if a practitioner furnishes a discharge day management service, the service be furnished in-person in order to allow the practitioner to comprehensively assess the patient's status in preparation for discharge so that the patient will have a higher likelihood of making a successful transition to the less intensive setting. Therefore, we are not considering hospital discharge day management services for addition to the Medicare telehealth services list on a category 1 basis.

We have reviewed the documentation submitted by requestors in support of adding these codes to the Medicare telehealth services list on a category 2 basis. Most of the submitted studies were specific to the treatment of patients with specific diagnoses

and were not specific to discharge services. Additionally, most of the studies concluded that more research was required in order to establish medical equivalence between telehealth and in-person services. The submitted documentation did not provide the necessary evidence to alter our previous conclusion that hospital discharge day management services should be provided in-person in light of the acuity of hospitalized patients, their typically complex post-hospitalization care needs, and the importance of patient education by the admitting practitioner who had ongoing responsibility for the patient's treatment during the hospital stay. Therefore, we are not proposing to add hospital discharge day management services to the list of telehealth services for CY 2011.

5. Initial, Subsequent, Discharge Day Management, and Other Nursing Facility Care Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add nursing facility care codes, covering the spectrum of initial (reported by CPT codes 99304 (Level 1 initial nursing facility care), 99305 (Level 2 initial nursing facility care) and 99306 (Level 3 initial nursing facility care)); subsequent (reported by CPT codes 99307 (Level 1 subsequent nursing facility care), 99308 (Level 2 subsequent nursing facility care), 99309 (Level 3 subsequent nursing facility care), and 99310 (Level 4 subsequent nursing facility care)); discharge day management (reported by CPT codes 99315 (Nursing facility discharge day management; 30 minutes or less) and 99316 (Nursing facility discharge day management; more than 30 minutes)); and other (reported by CPT code 99318 (Evaluation and management of a patient involving an annual nursing facility assessment)) services, to the Medicare telehealth services list beginning in CY 2011. The requests for the addition of these services expressed concerns regarding limited access to care if we do not allow these services to be furnished through telehealth,

and requested that CMS acknowledge the recent Congressional inclusion of nursing facilities as telehealth originating sites by adding these codes to the list of Medicare telehealth services.

In the CY 2010 PFS proposed and final rules (74 FR 33544 and 74 FR 61762), we discussed concerns about potential disparities in patient acuity between nursing facility services and the current list of Medicare telehealth services. We have also declined to add HCPCS codes to the Medicare telehealth services list that are used exclusively to describe Federally-mandated nursing facility visits. As discussed in the CY 2010 PFS proposed rule (74 FR 33543), the long-term care regulations at §483.40(c) require that residents of SNFs receive initial and periodic personal visits. These regulations ensure that at least a minimal degree of personal contact between a practitioner and a SNF resident is maintained, both at the point of admission to the facility and periodically during the course of the resident's stay. We continue to believe that these Federally-mandated visits should be conducted in-person, and not as Medicare telehealth services. Therefore, in the CY 2010 PFS final rule with comment period, we revised §410.78 to preclude physicians and other practitioners from furnishing the physician visits required under §483.40(c) through telehealth.

We reviewed the use of telehealth for each of the subcategories of nursing facility services included in the requests for CY 2011. We identified the E/M services that fulfill Federal requirements for personal visits under §483.40(c), and we are not proposing for CY 2011 to add any HCPCS codes to the Medicare telehealth services list that are used exclusively to describe these Federally-mandated visits. These codes include the CPT codes for initial nursing facility care (CPT codes 99304 through 99306) that are used to report the initial E/M visit that fulfills Federally-mandated requirements under §483.40(c)

and other nursing facility service (CPT code 99318) that is only payable by Medicare if the visit is substituted for a Federally-mandated visit under §483.40(c).

The nursing facility discharge day management services reported under CPT code 99315 and 99316 are E/M visits that prepare a nursing facility resident for discharge from the facility. There are no Medicare requirements that such a service be furnished. If a practitioner chooses to furnish this service, we continue to believe that an in-person visit is most appropriate in order to ensure the resident is prepared for discharge from the nursing facility. These services are furnished when a practitioner deems it medically reasonable and necessary to assess a patient's readiness for and to prepare a patient being discharged from the monitored nursing facility environment to another typically less intensive setting. There are no services on the current list of telehealth services that resemble such preparation of a patient for discharge. As in the case of hospital discharge day management services, we believe it is especially important that, if a practitioner furnishes a nursing facility discharge day management service, the service be furnished in-person. The practitioner must be able to comprehensively assess the patient's status in preparation for discharge so that the patient will have a higher likelihood of making a successful transition from the nursing facility to another setting. Therefore, we are not considering nursing facility discharge day management services for addition to the Medicare telehealth services list on a category 1 basis. When we considered the addition of these services under category 2, we had no evidence that nursing facility discharge services furnished through telehealth are equivalent to in-person discharge services. Therefore, we are not proposing to add nursing facility discharge day management services to the CY 2011 telehealth list.

Subsequent nursing facility services, reported by CPT codes 99307 through 99310, may be used to report either a Federally-mandated periodic visit under §483.40(c) or another E/M visit, prior to or after the initial nursing facility care visit, as long as the subsequent nursing facility care visit is medically reasonable and necessary for the resident's care. While we continue to believe that many SNF residents have complex medical care needs, we believe that it is appropriate to consider the addition of these codes to the telehealth list on a category 1 basis. As we state above in the context of our discussion of subsequent hospital care services, the HCPCS codes for initial and follow-up inpatient consultation services for nursing facility patients are on the list of Medicare telehealth services, and subsequent nursing facility services are similar to those services. These E/M services are furnished to high acuity, complex SNF patients, although not by the admitting practitioner himself or herself. Therefore, we believe that subsequent nursing facility visits by a patient's admitting practitioner sufficiently resemble follow-up inpatient consultation services to consider them on a category 1 basis for the telehealth list. We have concluded that it would be appropriate to permit some subsequent nursing facility care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, although we continue to believe that the Federally-mandated visits should be in-person to facilitate the comprehensive, coordinated, and personal care that these complex patients require on an ongoing basis.

Therefore, we are proposing that subsequent nursing facility care services, specifically CPT codes 99307, 99308, 99309 and 99310, be added to the list of Medicare telehealth services on a category 1 basis beginning in CY 2011, with some limitations on furnishing these services through telehealth. Because of our concerns regarding the

potential acuity and complexity of SNF inpatients, we are proposing to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. We are especially interested in public comments, including any evidence regarding patterns of high quality care and clinical outcomes, regarding this proposal to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. We remain committed to ensuring that SNF inpatients receive appropriate in-person visits and that Medicare pays only for medically reasonable and necessary care. Currently and continuing in CY 2011, an unlimited number of initial and follow-up consultation services may be furnished through telehealth to these patients so we believe that only a limited number of subsequent nursing facility care services by the admitting practitioner would be appropriate for SNF inpatients. Finally, we are specifying that subsequent nursing facility care services reported for a Federally-mandated periodic visit under §483.40(c) may not be furnished through telehealth. In light of this proposal for CY 2011, we remain confident that admitting practitioners will continue to make appropriate in-person visits to all patients who need such care during their SNF stay.

Consistent with this proposal, we are proposing to revise §410.78(b) and §414.65(a)(1) to include subsequent nursing facility care services as Medicare telehealth services, with the limitation of one telehealth subsequent nursing facility care service every 30 days. Federally-mandated periodic visits may not be furnished through telehealth, as specified currently in §410.78(e)(2).

6. Neuropsychological Testing

The American Telemedicine Association submitted a request to add neuropsychological testing services, described by CPT codes 96119 (Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and

Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and 96119 (Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory scales and Wisconsin Card Sorting Test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face), to the list of telehealth services for CY 2011 based on their similarity to other telehealth services.

In the CY 2008 PFS final rule with comment period (72 FR 66251), we stated that we have received conflicting comments and data regarding the appropriateness of furnishing neuropsychological testing via telehealth. While we appreciate the recent request for addition of these same services to the Medicare telehealth services list, we do not believe that these services are similar to services currently on the Medicare telehealth services list and, therefore, we conclude that they would not be appropriate for consideration or addition under category 1. In this year's request for the addition of these services, we received no information to indicate that the diagnostic findings of neuropsychological testing through telehealth are similar to those based upon in-person testing, and therefore, that testing through telehealth does not affect the patient's diagnosis. Therefore, we are not proposing to add neuropsychological testing services to the list of approved Medicare telehealth services for CY 2011.

7. Speech-Language Pathology Services

The Marshfield Clinic submitted a request to add various speech-language pathology services to the list of approved telehealth services for CY 2011. Speech-language pathologists are not permitted under section 1842(b)(18)(C) of the Act to furnish and receive payment for Medicare telehealth services. Therefore, we are not

proposing to add any speech-language pathology services to the list of Medicare telehealth services for CY 2011. For further discussion of these services in the context of telehealth, we refer readers to the CY 2005 and CY 2007 PFS proposed and final rules with comment period (69 FR 47512 and 66276, and 71 FR 48995 and 69657).

8. Home Wound Care Services

Wound Care Associates, LLC, submitted a request to add wound care in the home setting to the list of Medicare telehealth services. A patient's home is not permitted under current statute to serve as an originating site for Medicare telehealth services. Therefore, we are not proposing to add home wound care services to the list of Medicare telehealth services for CY 2011.

D. Summary of CY 2011 Telehealth Proposals

In summary, we are proposing to add the following requested services to the list of Medicare telehealth services for CY 2011:

- Individual and group KDE services (HCPCS codes G0420 and G0421, respectively);
- Individual and group DSMT services, with a minimum of 1 hour of in-person instruction to be furnished in the year following the initial DSMT service to ensure effective injection training (HCPCS codes G0108 and G0109, respectively);
- Group MNT and HBAI services (CPT codes 97804, and 96153 and 96154, respectively);
- Subsequent hospital care services, with the limitation for the patient's admitting practitioner of one telehealth visit every 3 days (CPT codes 99231, 99232, and 99233); and
- Subsequent nursing facility care services, with the limitation for the patient's

admitting practitioner of one telehealth visit every 30 days (CPT codes 99307, 99308, 99309, and 99310).

Furthermore, we are proposing to revise §410.78(b) and §414.65(a)(1) accordingly. Specifically, we are proposing to add individual and group KDE services, individual and group DSMT services, group MNT services, group HBAI services, and subsequent hospital care and nursing facility care services to the list of telehealth services for which payment will be made at the applicable PFS payment amount for the service of the practitioner. In addition, we have reordered the listing of services in these two sections and removed "initial and follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals and SNFs" in §410.78(b) because these are described by the more general term "professional consultations" that is in the same section. Finally, we are continuing to specify that the physician visits required under §483.40(c) may not be furnished as telehealth services.

V. Provisions of the Patient Protection and Affordable Care Act of 2010

The following section addresses certain provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) enacted on March 30, 2010 (collectively known as the Affordable Care Act (ACA)).

A. Section 3002: Improvements to the Physician Quality Reporting System

Section 3002 of ACA makes a number of changes to the Physician Quality Reporting Initiative (PQRI), including authorizing incentive payments through 2014, and requiring a penalty beginning in 2015, for eligible professionals who do not satisfactorily submit quality data. For a more detailed discussion of the provisions of section 3002 of the ACA, please refer to section VI.G.1. of this proposed rule.