D. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

The health care community uses the term "telehealth" broadly to refer to medical services furnished via communication technology. Under current PFS payment rules, Medicare routinely pays for many of these kinds of services. This includes some kinds of remote patient monitoring (either as separate services or as parts of bundled services), interpretations of diagnostic tests when furnished remotely, and, under conditions specified in section 1834(m) of the Act, services that would otherwise be furnished in person but are instead furnished via real-time, interactive communication technology. Over the past several years, CMS has also established several PFS policies to explicitly pay for non-face-to-face services included as part of ongoing care management.

While all of the kinds of services stated above might be called "telehealth" by patients, other payers and health care providers, we have generally used the term "Medicare telehealth services" to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. Section 1834(m)(4)(F)(i) of the Act enumerates certain Medicare telehealth services and section 1834(m)(4)(F)(ii) of the Act allows the Secretary to specify additional Medicare telehealth services using an annual process to add or delete services from the Medicare telehealth list. Section 1834(m)(4)(C) of the Act limits the scope of Medicare telehealth services for which payment may be made to those furnished to a beneficiary who is located in certain types of originating sites in certain, mostly rural, areas. Section 1834(m)(1) of the Act permits only physicians and certain other types of practitioners to furnish and be paid for

Medicare telehealth services. Although section 1834(m)(4)(F)(ii) of the Act grants the Secretary the authority to add services to, and delete services from, the list of telehealth services based on the established annual process, it does not provide any authority to change the limitations relating to geography, patient setting, or type of furnishing practitioner because these requirements are specified in statute. However, we note that sections 50302, 50324, and 50325 of the Bipartisan Budget Act of 2018 (BBA 18) have modified or removed the limitations relating to geography and patient setting for certain telehealth services, including for certain home dialysis end-stage renal disease-related services, services furnished by practitioners in certain Accountable Care Organizations, and acute stroke-related services, respectively.

In the CY 2018 PFS proposed rule, we sought information from the public regarding ways that we might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies. Commenters were very supportive of CMS expanding access to these kinds of services. Many commenters noted that Medicare payment for telehealth services is restricted by statute, but encouraged CMS to recognize and support technological developments in healthcare.

We believe that the provisions in section 1834(m) of the Act apply particularly to the kinds of professional services explicitly enumerated in the statutory provisions, like professional consultations, office visits, and office psychiatry services. Generally, the services we have added to the telehealth list are similar to these kinds of services. As has long been the case, certain other kinds of services that are furnished remotely using communications technology are not considered "Medicare telehealth services" and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of the provisions in section 1834(m) of the Act and do not usually include patient interaction (such as remote interpretation of diagnostic imaging tests), and for services that were

not discretely defined or separately paid for at the time of enactment and that do include patient interaction (such as chronic care management services).

As we considered the concerns expressed by commenters about the statutory restrictions on Medicare telehealth services, we recognized that the concerns were not limited to the barriers to payment for remotely furnished services like those described by the office visit codes. The commenters also expressed concerns pertaining to the limitations on appropriate payment for evolving physicians' services that are inherently furnished via communication technology, especially as technology and its uses have evolved in the decades since the Medicare telehealth services statutory provision was enacted.

In recent years, we have sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients, and have relied on the medical community to identify and define discrete physicians' services through the CPT Editorial Panel (82 FR 53163). In response to our comment solicitation on Medicare telehealth services in the CY 2018 PFS proposed rule (82 FR 53012), commenters provided many suggestions for how CMS could expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies, such as waiving portions of the statutory restrictions using demonstration authority. After considering those comments we recognize that concerns regarding the provisions in section 1834(m) of the Act may have been limiting the degree to which the medical community developed coding for new kinds of services that inherently utilize communication technology. We have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded,

and paid for as if they were furnished during an in-person encounter between a patient and a health care professional.

For CY 2019, we are aiming to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. Accordingly, we have several proposals for modernizing Medicare physician payment for communication technology-based services, described below. These services would not be subject to the limitations on Medicare telehealth services in section 1834(m) of the Act because, as we have explained, we do not consider them to be Medicare telehealth services; instead, they would be paid under the PFS like other physicians' services. Additionally, we note that in furnishing these proposed services, practitioners would need to comply with any applicable privacy and security laws, including the HIPAA Privacy Rule.

1. Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVCI1)

The traditional office visit codes describe a broad range of physicians' services. Historically, we have considered any routine non-face-to-face communication that takes place before or after an in-person visit to be bundled into the payment for the visit itself. In recent years, we have recognized payment disparities that arise when the amount of non-face-to-face work for certain kinds of patients is disproportionately higher than for others, and created coding and separate payment to recognize care management services such as chronic care management and behavioral health integration services (81 FR 80226). We now recognize that advances in communication technology have changed patients' and practitioners' expectations regarding the quantity and quality of information that can be conveyed via communication technology. From the ubiquity of synchronous, audio/video applications to the increased use of patient-facing

health portals, a broader range of services can be furnished by health care professionals via communication technology as compared to 20 years ago.

Among these services are the kinds of brief check-in services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted. When these kinds of check-in services are furnished prior to an office visit, then we would currently consider them to be bundled into the payment for the resulting visit, such as through an evaluation and management (E/M) visit code. However, in cases where the check-in service does not lead to an office visit, then there is no office visit with which the check-in service can be bundled. To the extent that these kinds of check-ins become more effective at addressing patient concerns and needs using evolving technology, we believe that the overall payment implications of considering the services to be broadly bundled becomes more problematic. This is especially true in a resource-based relative value payment system. Effectively, the better practitioners are in leveraging technology to furnish effective check-ins that mitigate the need for potentially unnecessary office visits, the fewer billable services they furnish. Given the evolving technological landscape, we believe this creates incentives that are inconsistent with current trends in medical practice and potentially undermines payment accuracy.

Therefore, we are proposing to pay separately, beginning January 1, 2019, for a newly defined type of physicians' service furnished using communication technology. This service would be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit. We understand that the kinds of communication technology used to furnish these kinds of services has broadened over time and has enhanced the capacity for medical professionals to care for patients. We are seeking comment on what types

of communication technology are utilized by physicians or other qualified health care professionals in furnishing these services, including whether audio-only telephone interactions are sufficient compared to interactions that are enhanced with video or other kinds of data transmission.

The proposed code would be described as GVCI1 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). We further propose that in instances when the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable, which is consistent with code descriptor language for CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion) on which this service is partially modeled. We propose that in instances when the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service would be considered bundled into the pre- or post- visit time of the associated E/M service, and therefore, would not be separately billable. We also note that this service could be used as part of a treatment regimen for opioid use disorders and other substance use disorders, since there are several components of

Medication Assisted Therapy (MAT) that could be done virtually, or to assess whether the patient's condition requires an office visit.

We propose pricing this distinct service at a rate lower than existing E/M in-person visits to reflect the low work time and intensity and to account for the resource costs and efficiencies associated with the use of communication technology. We expect that these services would be initiated by the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services. For the same reason, we believe it is important for patients to consent to receiving these services, and we are specifically seeking comment on whether we should require, for example, verbal consent that would be noted in the medical record for each service. We are also proposing that this service can only be furnished for established patients because we believe that the practitioner needs to have an existing relationship with the patient, and therefore, basic knowledge of the patient's medical condition and needs, in order to perform this service. We are not proposing to apply a frequency limit on the use of this code by the same practitioner with the same patient, but we want to ensure that this code is appropriately utilized for circumstances when a patient needs a brief non-face-to-face check-in to assess whether an office visit is necessary. We are seeking comment on whether it would be clinically appropriate to apply a frequency limitation on the use of this code by the same practitioner with the same patient, and on what would be a reasonable frequency limitation. We are also seeking comment on the timeframes under which this service would be separately billable compared to when it would be bundled. We believe the general construct of bundling the services that lead directly to a billable visit is important, but we are concerned that establishing strict timeframes may create unintended consequences regarding scheduling of care. For example, we do not want to bundle only the services that occur within 24 hours of a visit only to see a significant number of visits occurring at 25 hours after the initial service. In order to mitigate these incentives, we are

seeking comment on whether we should consider broadening the window of time and/or circumstances in which this service should be bundled into the subsequent related visit. We note that these services, like any other physicians' service, would need to be medically reasonable and necessary in order to be paid by Medicare. We are seeking comment on how clinicians could best document the medical necessity of this service, consistent with documentation requirements necessary to demonstrate the medical necessity of any service under the PFS. For details related to developing utilization estimates for these services, see section VII. Regulatory Impact Analysis, of this proposed rule. For additional details related to valuation of these services, see section II.H. Valuation of Specific Codes, of this proposed rule. We are seeking comment on our proposed definition and valuation of this code.

2. Remote Evaluation of Pre-Recorded Patient Information (HCPCS code GRAS1)

Stakeholders have requested that CMS make separate Medicare payment when a physician uses recorded video and/or images captured by a patient in order to evaluate a patient's condition. These services involve what is referred to under section 1834(m) of the Act as "store-and-forward" communication technology that provides for the "asynchronous transmission of health care information." We note that we believe these services involve pre-recorded patient-generated still or video images. Other types of patient-generated information, such as information from heart rate monitors or other devices that collect patient health marker data, could potentially be reported with CPT codes that describe remote patient monitoring. Under section 1834(m) of the Act, payment for telehealth services furnished using such store-and-forward technology is permitted only under Federal telemedicine demonstration programs conducted in Alaska or Hawaii, and these telehealth services remain subject to the other statutory restrictions governing Medicare telehealth services. Much like the virtual check-in described above, these services are not meant to substitute for an in-person service currently separately

payable under the PFS, and therefore, are distinct from the telehealth services described under section 1834(m) of the Act. Effective January 1, 2019, we are proposing to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. These services would not be subject to the Medicare telehealth restrictions in section 1834(m) of the Act, and the valuation would reflect the resource costs associated with furnishing services utilizing communication technology.

Much like the brief communication technology-based services discussed above, these services may be used to determine whether or not an office visit or other service is warranted. When the review of the patient-submitted image and/or video results in an in-person E/M office visit with the same physician or qualified health care professional, we propose that this remote service would be considered bundled into that office visit and therefore would not be separately billable. We further propose that in instances when the remote service originates from a related E/M service provided within the previous 7 days by the same physician or qualified health care professional, that this service would be considered bundled into that previous E/M service and also would not be separately billable. In summary, we propose this service to be a stand-alone service that could be separately billed to the extent that there is no resulting E/M office visit and there is no related E/M office visit within the previous 7 days of the remote service being furnished. The proposed coding and separate payment for this service is consistent with the progression of technology and its impact on the practice of medicine in recent years, and would result in increased access to services for Medicare beneficiaries. The proposed code for this service would be described as GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided

within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). We are seeking comment as to whether these services should be limited to established patients; or whether there are certain cases, like dermatological or ophthalmological services, where it might be appropriate for a new patient to receive these services. For example, when a patient seeks care for a specific skin condition from a dermatologist with whom she does not have a prior relationship, and part of the inquiry is an assessment of whether the patient needs an in-person visit, the patient could share, and the dermatologist could remotely evaluate, pre-recorded information. We also note that this service is distinct from the brief communication technology-based service described above in that this service involves the practitioner's evaluation of a patient-generated still or video image, and the subsequent communication of the resulting response to the patient, while the brief communication technology-based service describes a service that occurs in real time and does not involve the transmission of any recorded image.

For details related to developing utilization estimates for these services, see section VII. Regulatory Impact Analysis, of this proposed rule. For further discussion related to valuation of this service, please see the section II.H. Valuation of Specific Codes, of this proposed rule. We are seeking public comment on our proposed definition and valuation of the code.

3. Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

As part of our standard rulemaking process, we received recommendations from the RUC to assist in establishing values for six CPT codes that describe interprofessional consultations. In 2013, CMS received recommendations from the RUC for CPT codes 99446 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other

qualified health care professional; 5-10 minutes of medical consultative discussion and review), 99447 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review), 99448 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review), and 99449 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review). CMS declined to make separate payment, stating in the CY 2014 PFS final rule with comment period that these kinds of services are considered bundled (78 FR 74343). For CY 2019, the CPT Editorial Panel created two new codes to describe additional consultative services, including a code describing the work of the treating physician when initiating a consult, and the RUC recommended valuation for new codes, CPT codes 994X0 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes) and 994X6 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time). The RUC also reaffirmed their prior recommendations for the existing CPT codes. The six codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare

professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional. Currently, the resource costs associated with seeking or providing such a consultation are considered bundled, which in practical terms means that specialist input is often sought through scheduling a separate visit for the patient when a phone or internet-based interaction between the treating practitioner and the consulting practitioner would have been sufficient. We believe that proposing payment for these interprofessional consultations performed via communications technology such as telephone or Internet is consistent with our ongoing efforts to recognize and reflect medical practice trends in primary care and patient-centered care management within the PFS.

Beginning in the CY 2012 PFS proposed rule (76 FR 42793), we have recognized the changing focus in medical practice toward managing patients' chronic conditions, many of which particularly challenge the Medicare population, including heart disease, diabetes, respiratory disease, breast cancer, allergies, Alzheimer's disease, and factors associated with obesity. We have expressed concerns that the current E/M coding does not adequately reflect the changes that have occurred in medical practice, and the activities and resource costs associated with the treatment of these complex patients in the primary care setting. In the years since 2012, we have acknowledged the shift in medical practice away from an episodic treatment-based approach to one that involves comprehensive patient-centered care management, and have taken steps through rulemaking to better reflect that approach in payment under the PFS. In CY 2013, we established new codes to pay separately for transitional care management (TCM) services. Next, we finalized new coding and separate payment beginning in CY 2015 for chronic care management (CCM) services provided by clinical staff (81 FR 80226). In the CY 2017 PFS

final rule, we established separate payment for complex CCM services, an add-on code to the visit during which CCM is initiated to reflect the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan, and established separate payment for Behavioral Health Integration (BHI) services (81 FR 80226 through 80227).

As part of this shift in medical practice, and with the proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, we believe that making separate payment for interprofessional consultations undertaken for the benefit of treating a patient will contribute to payment accuracy for primary care and care management services. We are proposing separate payment for these services, discussed in section II.H. Valuation of Specific Codes, of this proposed rule.

While we are proposing to make separate payment for these services because we believe they describe resource costs directly associated with seeking a consultation for the benefit of the beneficiary, we do have concerns about how these services can be distinguished from activities undertaken for the benefit of the practitioner, such as information shared as a professional courtesy or as continuing education. We do not believe that those examples would constitute a service directly attributable to a single Medicare beneficiary, and therefore neither the Medicare program nor the beneficiary should be responsible for those costs. We are therefore seeking comment on our assumption that these are separately identifiable services, and the extent to which they can be distinguished from similar services that are nonetheless primarily for the benefit of the practitioner. We note that there are program integrity concerns around making separate payment for these interprofessional consultation services, including around CMS' or its contractors' ability to evaluate whether an interprofessional consultation is reasonable and necessary under the particular circumstances. We are seeking comment on how best to minimize potential program integrity issues, and are particularly interested in information on whether these

types of services are paid separately by private payers and if so, what controls or limitations private payers have put in place to ensure these services are billed appropriately.

Additionally, since these codes describe services that are furnished without the beneficiary being present, we are proposing to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record, similar to the conditions of payment associated with the care management services under the PFS. Obtaining advance consent includes ensuring that the patient is aware of applicable cost sharing. We welcome comments on this proposal.

4. Medicare Telehealth Services under Section 1834(m) of the Act

a. Billing and Payment for Medicare Telehealth Services under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, see the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006).

b. Adding Services to the List of Medicare Telehealth Services

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us. Under this process, we assign any submitted request to add to the list of telehealth services to one of the following two 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, 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 service; for example, the use of interactive audio and video equipment.

- Category 2: Services that are not similar to those on 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 furnish the service produces demonstrated 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.

The list of telehealth services, including the proposed additions described below, is included in the Downloads section to this proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

Historically, requests to add services to the list of Medicare telehealth services had to be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. However, for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC. To be considered during PFS rulemaking for CY 2020, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2019. 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 the vehicle to make changes to the list of Medicare telehealth services, requesters should be advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the list of Medicare telehealth services, including where to mail these requests, see our website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.

c. Submitted Requests to Add Services to the List of Telehealth Services for CY 2019

Under our current 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 for 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 PFS 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, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We received several requests in CY 2017 to add various services as Medicare telehealth services effective for CY 2019. The following presents a discussion of these requests, and our proposals for additions to the CY 2019 telehealth list. Of the requests received, we found that two services were sufficiently similar to services currently on the telehealth list to be added on a Category 1 basis. Therefore, we are proposing to add the following services to the telehealth list on a Category 1 basis for CY 2019:

- HCPCS codes G0513 and G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service) and (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service).

We found that the services described by HCPCS codes G0513 and G0514 are sufficiently similar to office visits currently on the telehealth list. We believe that all the components of this service can be furnished via interactive telecommunications technology. Additionally, we believe that adding these services to the telehealth list would make it administratively easier for practitioners who report these services in connection with a preventive service that is furnished via telehealth, as both the base code and the add-on code would be reported with the telehealth place of service.

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 to the Medicare telehealth services list the following procedures for chronic care remote physiologic monitoring, interprofessional internet consultation, and initial hospital care; or to change the requirements for subsequent hospital care or subsequent nursing facility care, for the reasons noted in the paragraphs that follow.

(1) Chronic Care Remote Physiologic Monitoring: CPT Codes

- CPT code 990X0 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).
- CPT code 990X1 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days).
- CPT code 994X9 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month).

In the CY 2016 PFS final rule with comment period (80 FR 71064), we responded to a request to add 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) to the Medicare

telehealth list. We discussed that the services described by CPT code 99490 can be furnished without the beneficiary's face-to-face presence and using any number of non-face-to-face means of communication. We stated that it was therefore unnecessary to add that service to the list of Medicare telehealth services. Similarly, CPT codes 990X0, 990X1, and 994X9 describe services that are inherently non face-to-face. As discussed in section II.H. Valuation of Specific Codes, we instead are proposing to adopt CPT codes 990X0, 990X1, and 994X9 for payment under the PFS. Because these codes describe services that are inherently non face-to-face, we do not consider them Medicare telehealth services under section 1834(m) of the Act; therefore, we are not proposing to add them to the list of Medicare telehealth services.

(2) Interprofessional Internet Consultation: CPT Codes

- CPT code 994X0 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes).

- CPT code 994X6 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time).

As discussed in section II.H. Valuation of Specific Codes, we are proposing to adopt CPT codes 994X0 and 994X6 for payment under the PFS as these are distinct services furnished via communication technology. Because these codes describe services that are inherently non face-to-face, we do not consider them as Medicare telehealth services under section 1834(m) of the Act; therefore we are not proposing to add them to the list of Medicare telehealth services for CY 2019.

(3) Initial Hospital Care Services: CPT Codes

- CPT code 99221 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity.)

- CPT code 99222 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity.)

- CPT code 99223 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity.)

We have previously considered requests to add these codes to the telehealth list. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73315), 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 course of the hospital stay. Therefore, consistent with prior rulemaking, we do not

propose that initial hospital care services be added to the Medicare telehealth services list on a category 1 basis.

The initial hospital care codes describe the first visit of the hospitalized patient by the admitting practitioner who may or may not have seen the patient in the decision-making phase regarding hospitalization. Based on the description of the services for these codes, we believed 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. Additionally, the requester submitted no additional research or evidence that the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient; therefore, we also do not propose adding initial hospital care services to the Medicare telehealth services list on a Category 2 basis.

We note that Medicare beneficiaries who are being treated in the hospital setting can receive reasonable and necessary E/M services using other HCPCS codes that are currently on the Medicare telehealth list, including those for subsequent hospital care, initial and follow-up telehealth inpatient and emergency department consultations, as well as initial and follow-up critical care telehealth consultations.

Therefore, we are not proposing to add the initial hospital care services to the list of Medicare telehealth services for CY 2019.

(4) Subsequent Hospital Care Services: CPT Codes

- CPT code 99231 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other

physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.

- CPT code 99232 (Subsequent hospital care, per day, for the evaluation and management of a 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 moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.)

- CPT code 99233 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.)

CPT codes 99231-99233 are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 3 days. The requester asked that we remove the frequency limitation. We stated in the CY 2011 PFS final rule with comment period (75 FR 73316) that, while we still believed the potential acuity of hospital inpatients is greater than those

patients likely to receive Medicare telehealth services that were on the list at that time, we also believed 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. We also noted that we 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. Because of our concerns regarding the potential acuity of hospital inpatients, we finalized the addition of CPT codes 99231-99233 to the list of Medicare telehealth services, but limited the provision of these subsequent hospital care services through telehealth to once every 3 days. We continue to believe that admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Our concerns and position on the provision of subsequent hospital care services via telehealth have not changed. Therefore, we are not proposing to remove the frequency limitation on these codes.

(5) Subsequent Nursing Facility Care Services: CPT Codes

- CPT code 99307 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 10 minutes are spent at the bedside and on the patient's facility floor or unit.

- CPT code 99308 (Subsequent nursing facility care, per day, for the evaluation and management of a 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 physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.)

- CPT code 99309 (Subsequent nursing facility care, per day, for the evaluation and management of a 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 physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient has developed a significant complication or a significant new problem. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)

- CPT code 99310 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A comprehensive interval history; a comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)

CPT codes 99307-99310 are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 30 days. The requester asked that we remove the frequency limitation when these services are provided for psychiatric care. We stated in the CY

2011 PFS final rule with comment period (75 FR 73317) that we believed 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, but because of our concerns regarding the potential acuity and complexity of SNF inpatients, we limited the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. Since these codes are used to report care for patients with a variety of diagnoses, including psychiatric diagnoses, we do not think it would be appropriate to remove the frequency limitation only for certain diagnoses. The services described by these CPT codes are essentially the same service, regardless of the patient's diagnosis. We also continue to have concerns regarding the potential acuity and complexity of SNF inpatients, and therefore, we are not proposing to remove the frequency limitation for subsequent nursing facility care services in CY 2019.

In summary, we are proposing to add the following codes to the list of Medicare telehealth services beginning in CY 2019 on a category 1 basis:

- HCPCS code G0513 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service).

- HCPCS code G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service).

5. Expanding the Use of Telehealth under the Bipartisan Budget Act of 2018

a. Expanding Access to Home Dialysis Therapy under the Bipartisan Budget Act of 2018

Section 50302 of the BBA of 2018 amended sections 1881(b)(3) and 1834(m) of the Act to allow an individual determined to have end-stage renal disease receiving home dialysis to choose to receive certain monthly end-stage renal disease-related (ESRD-related) clinical assessments via telehealth on or after January 1, 2019. The new section 1881(b)(3)(B)(ii) of the Act requires that such an individual must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

As added by section 50302(b)(1) of the BBA of 2018, subclauses (IX) and (X) of section 1834(m)(4)(C)(ii) of the Act include a renal dialysis facility and the home of an individual as telehealth originating sites but only for the purposes of the monthly ESRD-related clinical assessments furnished through telehealth provided under section 1881(b)(3)(B) of the Act. Section 50302(b)(1) also added a new section 1834(m)(5) of the Act which provides that the geographic requirements for telehealth services under section 1834(m)(4)(C)(i) of the Act do not apply to telehealth services furnished on or after January 1, 2019 for purposes of the monthly ESRD-related clinical assessments where the originating site is a hospital-based or critical access hospital-based renal dialysis center, a renal dialysis facility, or the home of an individual. Section 50302(b)(2) of the BBA of 2018 amended section 1834(m)(2)(B)(ii) of the Act to require that no originating site facility fee is to be paid if the home of the individual is the originating site.

Our current regulation at §410.78 specifies the conditions that must be met in order for Medicare Part B to pay for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system. In accordance with the new subclauses (IX) and (X) of section 1834(m)(4)(C)(ii) of the Act, we are proposing to revise our regulation at §410.78(b)(3) to add a renal dialysis facility and the home of an individual as Medicare

telehealth originating sites, but only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act. We propose to amend §414.65(b)(3) to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid a when the originating site for these services is the patient's home. Additionally, we are proposing to add new §410.78(b)(4)(iv)(A), to reflect the provision in section 1834(m)(5) of the Act, added by section 50302 of the BBA of 2018, specifying that the geographic requirements described in section 1834(m)(4)(C)(i) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, in originating sites that are hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, or the patient's home, respectively under sections 1834(m)(4)(C)(ii)(VI), (IX) and (X) of the Act, for purposes of section 1881(b)(3)(B) of the Act.

b. Expanding the Use of Telehealth for Individuals with Stroke under the Bipartisan Budget Act of 2018

Section 50325 of the BBA of 2018 amended section 1834(m) of the Act by adding a new paragraph (6) that provides special rules for telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services), as determined by the Secretary. Specifically, section 1834(m)(6)(A) of the Act removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. Section 1834(m)(6)(B) of the Act specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. Section 1834(m)(6)(C) of the Act limits payment of an originating site facility fee to acute stroke

telehealth services furnished in sites that meet the usual telehealth restrictions under section 1834(m)(4)(C) of the Act.

To implement these requirements, we are proposing to create a new modifier that would be used to identify acute stroke telehealth services. The practitioner and, as appropriate, the originating site, would append this modifier when clinically appropriate to the HCPCS code when billing for an acute stroke telehealth service or an originating site facility fee, respectively. We note that section 50325 of the BBA of 2018 did not amend section 1834(m)(4)(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. Practitioners would be responsible for assessing whether it would be clinically appropriate to use this modifier with codes from the Medicare telehealth list. By billing with this modifier, practitioners would be indicating that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke. We believe that the adoption of a service level modifier is the least administratively burdensome means of implementing this provision for practitioners, while also allowing CMS to easily track and analyze utilization of these services.

In accordance with section 1834(m)(6)(B) of the Act, as added by section 50325 of the BBA of 2018, we are also proposing to revise §410.78(b)(3) of our regulations to add mobile stroke unit as a permissible originating site for acute stroke telehealth services. We are proposing to define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke and are seeking comment on this definition, as well as additional information on how these units are used in current medical practice. We are therefore proposing that mobile stroke units and the current eligible telehealth originating sites, which include hospitals and critical access hospitals as specified in section 1834(m)(6)(B) of the Act, but excluding renal dialysis facilities and patient homes because they are only allowable

originating sites for purposes of home dialysis monthly ESRD-related clinical assessments in section 1881(b)(3)(B) of the Act, would be permissible originating sites for acute stroke telehealth services.

We also seek comment on other possible appropriate originating sites for telehealth services furnished for the diagnosis, evaluation, or treatment of symptoms of an acute stroke. Any additional sites would be adopted through future rulemaking. As required under section 1834(m)(6)(C) of the Act, the originating site facility fee would not apply in instances where the originating site does not meet the originating site type and geographic requirements under section 1834(m)(4)(C) of the Act. Additionally, we are proposing to add §410.78 (b)(4)(iv)(B) to specify that the requirements in section 1834(m)(4)(C) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

6. Modifying §414.65 Regarding List of Telehealth Services

In the CY 2015 PFS final rule with comment period, we finalized a proposal to change our regulation at §410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth, noting that we revised §410.78(f) to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS Web site (79 FR 67602). In accordance with that change, we are proposing a technical revision to also delete the description of individual services and exceptions for Medicare payment for telehealth services in §414.65, by amending §414.65(a) to note that Medicare payment for telehealth services is addressed in §410.78 and by deleting §414.65(a)(1).

7. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

There is an evidence base that suggests that routine counseling, either associated with medication assisted treatment (MAT) or on its own, can increase the effectiveness of treatment for substance use disorders (SUDs). According to a study in the *Journal of Substance Abuse Treatment*[1], patients treated with a combination of web-based counseling as part of a substance abuse treatment program demonstrated increased treatment adherence and satisfaction. The federal guidelines for opioid treatment programs describe that MAT and wrap-around psychosocial and support services can include the following services: physical exam and assessment; psychosocial assessment; treatment planning; counseling; medication management; drug administration; comprehensive care management and supportive services; care coordination; management of care transitions; individual and family support services; and health promotion (https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf). Creating separate payment for a bundled episode of care for components of MAT such as management and counseling treatment for substance use disorders (SUD), including opioid use disorder, treatment planning, and medication management or observing drug dosing for treatment of SUDs under the PFS could provide opportunities to better leverage services furnished with communication technology while expanding access to treatment for SUDs.

We also believe making separate payment for a bundled episode of care for management and counseling for SUDs could be effective in preventing the need for more acute services. For example, according to the *Healthcare Cost and Utilization Project*[2], Medicare pays for one-third

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[1] Van L. King, Robert K. Brooner, Jessica M. Peirce, Ken Kolodner, Michael S. Kidorf, "A randomized trial of Web based videoconferencing for substance abuse counseling," *Journal of Substance Abuse Treatment,* Volume 46, Issue 1, 2014, Pages 36-42, http://www.sciencedirect.com/science/article/pii/S0740547213001876.

[2] Pamela L. Owens, Ph.D., Marguerite L. Barrett, M.S., Audrey J. Weiss, Ph.D., Raynard E. Washington, Ph.D., and Richard Kronick, Ph.D. "Hospital Inpatient Utilization Related to Opioid Overuse Among Adults 1993-2012," Statistical Brief #177. Healthcare Cost and Utilization Project (HCUP). July 2014. Agency for Healthcare Research and Quality, Rockville, MD, https://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.jsp.

of opioid-related hospital stays, and Medicare has seen the largest annual increase in the number of these stays over the past 2 decades. We believe that separate payment for a bundled episode of care could help avoid such hospital admissions by supporting access to management and counseling services that could be important in preventing hospital admissions and other acute care events.

As indicated above, we are considering whether it would be appropriate to develop a separate bundled payment for an episode of care for treatment of SUDs. We are seeking public comment on whether such a bundled episode-based payment would be beneficial to improve access, quality and efficiency for SUD treatment. Further, we are seeking public comment on developing coding and payment for a bundled episode of care for treatment for SUDs that could include overall treatment management, any necessary counseling, and components of a MAT program such as treatment planning, medication management, and observation of drug dosing. Specifically, we are seeking public comments related to what assumptions we might make about the typical number of counseling sessions as well as the duration of the service period, which types of practitioners could furnish these services, and what components of MAT could be included in the bundled episode of care. We are interested in stakeholder feedback regarding how to define and value this bundle and what conditions of payment should be attached. Additionally, we are seeking comment on whether the concept of a global period, similar to the currently existing global periods for surgical procedures, might be applicable to treatment for SUDs.

We also seek comment on whether the counseling portion and other MAT components could also be provided by qualified practitioners "incident to" the services of the billing physician who would administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment, similar to the

structure of the Behavioral Health Integration codes which include services provided by other members of the care team under the direction of the billing practitioner on an "incident to" basis (81 FR 80231). We welcome comments on potentially creating a bundled episode of care for management and counseling treatment for SUDs, which we will consider for future rulemaking.

Additionally, we invite public comment and suggestions for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. We seek comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage. Consistent with our "Patients Over Paperwork" Initiative, we are interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.