Fact sheet

Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2021

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On August, 3 2020, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that announces and solicits public comments on proposed policy changes for Medicare payments under the Physician Fee Schedule (PFS), and other Medicare Part B issues, on or after January 1, 2021.

The calendar year (CY) 2021 PFS proposed rule is one of several proposed rules that reflect a broader Administration-wide strategy to create a healthcare system that results in better accessibility, quality, affordability, empowerment, and innovation.

Background on the Physician Fee Schedule

Since 1992, Medicare has paid for the services of physicians and other billing professionals under the PFS. Physicians' services paid under the PFS are furnished in a variety of settings, including physician offices, hospitals, ambulatory surgical centers, skilled nursing facilities and other post-acute care settings, hospices, outpatient dialysis facilities, clinical laboratories, and beneficiaries' homes. Payment under the PFS is also made to several types of suppliers for technical services, often in settings for which no institutional payment is made. For most services furnished in a physician's office, Medicare makes payment to physicians and other professionals at a single rate based on the full range of resources involved in furnishing the service. In contrast, PFS rates paid to physicians and other billing practitioners in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center, reflect only the portion of the resources typically incurred by the practitioner in the course of furnishing the service. For many diagnostic tests and a limited number of other services under the PFS, separate payment can be made for the professional and technical components of services. The technical component is frequently billed by suppliers like independent diagnostic testing facilities and radiation treatment centers, while the professional component is billed by the physician or practitioner.

Payments are based on the relative resources typically used to furnish the service. Relative value units (RVUs) are applied to each service for physician work, practice expense, and

malpractice. These RVUs become payment rates through the application of a conversion factor. Payment rates are calculated to include an overall payment update specified by statute.

PAYMENT PROVISIONS

CY 2021 PFS Ratesetting and Conversion Factor

We are proposing a series of standard technical proposals involving practice expense, including the implementation of the third year of the market-based supply and equipment pricing update, and standard ratesetting refinements to update premium data involving malpractice expense and geographic practice cost indices (GPCIs).

With the budget neutrality adjustment to account for changes in RVUs, as required by law, the proposed CY 2021 PFS conversion factor is $32.26, a decrease of $3.83 from the CY 2020 PFS conversion factor of $36.09.

Medicare Telehealth and Other Services Involving Communications Technology

For CY 2021, we are proposing to add the following list of services to the Medicare telehealth list on a Category 1 basis. Services added to the Medicare telehealth list on a Category 1 basis are similar to services already on the telehealth list:

Service Type	HCPCS Code	Long Descriptor
Visit Complexity Associated with Certain Office/Outpatient E/Ms	GPC1X	Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)
Prolonged Services	99XXX	Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of

		the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)
Group Psychotherapy	90853	Group psychotherapy (other than of a multiple-family group)
Neurobehavioral Status Exam	96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
Care Planning for Patients with Cognitive Impairment	99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (eg, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care

		Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.
Domiciliary, Rest Home, or Custodial Care services	99334	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; 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 presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.
Domiciliary, Rest Home, or Custodial Care services	99335	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other 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 presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.
	99347	Home visit for the evaluation and management of an established patient, which requires at least 2 of these

Home Visits		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 presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.
	99348	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other 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 presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.

Additionally, we are proposing to create a third temporary category of criteria for adding services to the list of Medicare telehealth services. Category 3 describes services added to the Medicare telehealth list during the public health emergency (PHE) for the COVID-19 pandemic that will remain on the list through the calendar year in which the PHE ends.

We are proposing to add the following list of services to the Medicare telehealth list on a Category 3 basis:

Service Type	HCPCS	Long Descriptor

Service Type	HCPCS	Long Descriptor
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other 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 presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
	99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other 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 presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.

Service Type	HCPCS	Long Descriptor
	99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other 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 presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
Home Visits, Established Patient	99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other 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 presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.

Service Type	HCPCS	Long Descriptor
Emergency Department Visits	99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and 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 presenting problem(s) are self-limited or minor.
	99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and 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 presenting problem(s) are of low to moderate severity.
	99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused 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 presenting problem(s) are of moderate severity.

Service Type	HCPCS	Long Descriptor
Nursing facilities discharge day management	99315	Nursing facility discharge day management; 30 minutes or less
	99316	Nursing facility discharge day management; more than 30 minutes
Psychological and Neuropsychological Testing	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour

Service Type	HCPCS	Long Descriptor
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)

We are soliciting comment on services added to the Medicare telehealth list during the PHE for COVID-19 that CMS is not proposing to add to the Medicare telehealth list permanently or proposing to add temporarily on a category 3 basis.

In response to stakeholders who have stated that the once every 30-day frequency limitation for subsequent nursing facility (NF) visits furnished via Medicare telehealth provides unnecessary burden and limits access to care for Medicare beneficiaries in this setting, we are proposing to revise the frequency limitation from one visit every 30 days to one visit every 3 days. We are also seeking comment on whether it would enhance patient access to care if we were to remove frequency limitations altogether, and how best to ensure that patients would continue to receive necessary in-person care.

We are also clarifying that clarify that licensed clinical social workers, clinical psychologists, physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs) practitioner can furnish the brief online assessment and management services as well as virtual check-ins and remote evaluation services. In order to facilitate billing by these practitioners for the remote evaluation of patient-submitted video or images and virtual check-ins (HCPCS codes G2010 and G2012) we are proposing to use two new HCPCS G codes.

We have also received questions as to whether services should be reported as telehealth when the individual physician or practitioner furnishing the service is in the same location as the beneficiary; for example, if the physician or practitioner furnishing the service is in the same institutional setting but is utilizing telecommunications technology to furnish the service due to exposure risks. We are, therefore, reiterating in this proposed rule that telehealth rules do not apply when the beneficiary and the practitioner are in the same location even if audio/video technology assists in furnishing a service.

In the March 31st COVID-19 IFC, we established separate payment for audio-only telephone evaluation and management services. While we are not proposing to continue to recognize these codes for payment under the PFS in the absence of the PHE for the COVID-19 pandemic, the need for audio-only interactions could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office. We are seeking comment on whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and subsequently with a higher value. We are seeking input from the public on the duration of the services and the resources in both work and practice expense associated with furnishing this service. We are seeking comment on whether this should be a provisional policy to remain in effect until a year after the end of the PHE for the COVID-19 pandemic or if it should be PFS payment policy permanently.

Remote Physiologic Monitoring Services

In recent years, CMS has finalized payment for seven remote physiologic monitoring (RPM) codes. In response to stakeholder questions about RPM, we are clarifying in this proposed rule our payment policies related to the RPM services described by CPT codes 99453, 99454, 99091, 99457, and 99458. In addition, we are proposing as permanent policy two clarifications to RPM services that we finalized in response to the PHE for the COVID-19 pandemic.

- We are clarifying that following the PHE for the COVID-19 pandemic, we will again require that an established patient-physician relationship exist for RPM services to be furnished.
- We are proposing as permanent policy to allow consent to be obtained at the time that RPM services are furnished.
- We are proposing as permanent policy to allow auxiliary personnel to furnish CPT codes 99453 and 99454 services under a physician's supervision. Auxiliary personnel include contracted employees.
- We are clarifying that the medical device supplied to a patient as part of CPT code 99454 must be a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act, that the device must be reliable and valid, and that the data must be electronically (i.e., automatically) collected and transmitted rather than self-reported.
- We are clarifying that after the PHE for COVID-19, we will maintain the current requirement that 16 days of data each 30 days must be collected and transmitted to meet the requirements to bill CPT codes 99453 and 99454. However, we are seeking comment on whether the RPM codes, as described, adequately capture the work furnished to patients with acute conditions or whether coding revisions are needed.
- We are proposing to clarify that RPM services are considered to be evaluation and management (E/M) services.

- We are clarifying that only physicians and NPPs who are eligible to furnish E/M services may bill RPM services.
- We are clarifying that practitioners may furnish RPM services to patients with acute conditions as well as patients with chronic conditions.
- We are clarifying that for CPT codes 99457 and 99458, an "interactive communication" is a conversation that occurs in real-time and includes synchronous, two-way interactions that can be enhanced with video or other kinds of data as described by HCPCS code G2012.
- Additionally, in response to the recent E.O. 13924, "Regulatory Relief To Support Economic Recovery," (85 FR 31353 through 31356), we are seeking comment from the medical community and other members of the public on whether the current RPM codes accurately and adequately describe the full range of clinical scenarios where RPM services may be of benefit to patients.

Immunization Services

In the CY 2021 PFS proposed rule we are proposing to establish new payment rates for immunization administration services described by CPT codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS codes G0008, G0009, and G0010 that better reflect the relative resources involved in furnishing all of these services, in consideration of payment stability for stakeholders, public health concerns and the import of these services for Medicare beneficiaries.

Direct Supervision by Interactive Telecommunications Technology

For the duration of the PHE for the COVID-19 pandemic, for purposes of limiting exposure to COVID-19, we adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/ video real-time communications technology (85 FR 19245). We recognized that in some cases, the physical proximity of the physician or practitioner might present additional infection exposure risk to the patient and/or practitioner.

In the CY 2021 PFS proposed rule, we are proposing to allow direct supervision to be provided using real-time, interactive audio and video technology (excluding telephone that does not also include video) through December 31, 2021. We are seeking information from commenters as to whether there should be any guardrails in effect as we finalize this policy though December 31, 2021, or consider it beyond the time specified and what risks this policy might introduce to beneficiaries as they receive care from practitioners that would supervise care virtually in this way. In addition to comments regarding patient safety/clinical appropriateness, we are seeking comment on potential concerns around

induced utilization and fraud, waste, and abuse and how those concerns might be addressed.

Payment for Office/Outpatient Evaluation and Management (E/M) and Analogous Visits

As finalized in the CY 2020 PFS final rule, in 2021 we will be largely aligning our E/M visit coding and documentation policies with changes laid out by the CPT Editorial Panel for office/outpatient E/M visits, beginning January 1, 2021. We are proposing a refinement to clarify the times for which prolonged office/outpatient E/M visits can be reported, and are proposing to revise the times used for ratesetting for this code set.

We are proposing to revalue the following code sets that include, rely upon or are analogous to office/outpatient E/M visits commensurate with the increases in values we finalized for office/outpatient E/M visits for 2021:

- End-Stage Renal Disease (ESRD) Monthly Capitation Payment (MCP) Services
- Transitional Care Management (TCM) Services
- Maternity Services
- Cognitive Impairment Assessment and Care Planning
- Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits
- Emergency Department Visits
- Therapy Evaluations
- Psychiatric Diagnostic Evaluations and Psychotherapy Services

We are also soliciting public comment regarding how we might clarify the definition of HCPCS add-on code GPC1X, previously finalized for office/outpatient E/M visit complexity, and whether we should refine our utilization assumptions for this code.

Proposals Regarding Professional Scope of Practice and Related Issues

1. Supervision of Diagnostic tests by Certain Nonphysician Practitioners (NPPs)

In the CY 2021 PFS proposed rule, we are proposing to make permanent following the COVID-19 PHE, the same policy that was finalized under the May 1st COVID-19 IFC, for the duration of the COVID-19 PHE. This proposal would allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests in addition to physicians. Prior to the May 1st COVID-19 IFC, these nonphysician practitioners were already authorized under Medicare regulations to order and furnish diagnostic tests, while as a basic rule, generally only physicians (medical doctors and doctors of osteopathy) were authorized to supervise the performance of diagnostic tests. However, if finalized on a permanent basis effective

January 1, 2021, NPs, CNSs, PAs and CNMs would be allowed under the Medicare Part B program to supervise the performance of diagnostic tests within their state scope of practice and applicable state law, provided they maintain the required statutory relationships with supervising or collaborating physicians.

2. Pharmacists Providing Services Incident to Physicians' Services

In this CY 2021 PFS proposed rule, we are reiterating the clarification we provided in the May 1st COVID-19 IFC (85 FR 27550 through 27629), that pharmacists fall within the regulatory definition of auxiliary personnel under our "incident to" regulations. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.

3. Therapy Assistants Furnishing Maintenance Therapy

In this CY 2021 PFS proposed rule, we are proposing to make permanent our Part B policy for maintenance therapy services that we adopted on an interim basis for the PHE in the May 1st COVID-19 IFC that grants a physical therapist (PT) and occupational therapist (OT) the discretion to delegate the performance of maintenance therapy services, as clinically appropriate, to a therapy assistant – a physical therapist assistant (PTA) or an occupational therapy assistant (OTA). We are making this proposal because we no longer believe all such maintenance therapy services require the PT or OT to personally perform them and to better align our Part B policy with that paid under Part A in skilled nursing facilities and the home health benefit where maintenance therapy services may be performed by a PT/OT or a PTA/OTA. Our proposed policy would allow PTs/OTs to use the same discretion to delegate maintenance therapy services to PTAs/OTAs that they utilize for rehabilitative services. We are also proposing to revise our subregulatory provisions to clarify that PTs and OTs no longer need to personally perform maintenance therapy services and to remove the prohibitions on PTAs and OTAs from furnishing such services. Should the PHE end before January 1, 2021, the PT or OT would need to personally furnish the maintenance therapy services until the proposed policy change takes effect.

4. Medical Record Documentation

In the CY 2020 PFS final rule, we finalized broad modifications to the medical record documentation requirements for the physician and certain NPPs. In this CY 2021 PFS proposed rule, we are clarifying that physicians and NPPs, including therapists can review and verify documentation entered into the medical record by members of the medical team

for their own services that are paid under the PFS. We are also clarifying that therapy students, and students of other disciplines, working under a physician or practitioner who furnishes and bills directly for their professional services to the Medicare program, may document in the record so long as it is reviewed and verified (signed and dated) by the billing physician, practitioner, or therapist.

5. PFS Payment for Services of Teaching Physicians

For the duration of the COVID-19 PHE, we implemented the following policies on an interim basis through the March 31st COVID-19 IFC and the May 1st COVID-19 IFC. The teaching physicians may use audio/video real time communications technology to interact with the resident through virtual means, which would meet the requirement that they be present for the key portion of the service, including when the teaching physician involves the resident in furnishing Medicare Telehealth services. Teaching physicians involving residents in providing care at primary care centers can provide the necessary direction, management and review for the resident's services using audio/video real time communications technology. Residents furnishing services at primary care centers may furnish an expanded set of services to beneficiaries, including levels 4-5 of an office/outpatient evaluation and management (E/M) visit, care management, and communication technology-based services. Additionally, during the COVID-19 PHE, Medicare also considers the services of residents that are furnished outside of the scope of their approved GME programs and furnished to inpatients of a hospital in which they have their training program as separately billable physicians' services.

We are considering whether these policies should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and are soliciting public comments on whether these policies should continue once the PHE ends.

We believe public comment will assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Section 2005 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit for opioid use disorder (OUD) treatment services, including medications for medication-assisted treatment (MAT), furnished by opioid treatment programs (OTPs) on or after January 1, 2020. As part of CY 2020 PFS rulemaking, we implemented coverage

requirements and creation of new coding and payment describing a bundled episode of care for treatment of OUD. In CY 2021, CMS is proposing:

- To create two new add-on codes, one add-on code for nasal naloxone and another add-on code for auto-injector naloxone. We propose to price nasal naloxone based upon the methodology set forth in section 1847A of the Act, except that the payment amount shall be average sales price (ASP) + 0. We also propose to price the auto-injector using lowest price available (lower of ASP + 0, wholesale acquisition cost (WAC), or national average drug acquisition cost). We also propose to limit payment to one box (which includes a 2-pack) every 30 days and seek comment on this.
- To use WAC + 0 when payment for the drug component of an episode of care is based on the methodology under section 1847A of the Act and ASP is not available.
- To provide enrollment flexibilities requested by some OTPs that would allow submission on institutional claims.
- To provide clarification regarding what activities qualify for billing the periodic assessment add-on code that we finalized for CY 2020. We propose to clarify that in order to bill for this add-on code, a face-to-face medical exam or biopsychosocial assessment needs to have been performed. We also propose to revise the regulation text in order to allow periodic assessments to be furnished via two-way interactive audio-video communication technology, provided all other applicable requirements are met.
- To provide clarification related to the date of service used on claims for the weekly bundles and add-on codes.
- To seek comment on stratifying the coding and payment to account for significant differences in resource costs among patients, especially as related to amounts of expected counseling.

Section 2002 of the Support Act

Section 2002 of the SUPPORT Act required the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential substance use disorders (SUDs) and a review of any current opioid prescriptions. We are proposing to implement through regulations Section 2002 of the SUPPORT Act requirements, which complement existing requirements of the IPPE and AWV. The review of medical history, and therefore, current medications, includes a review of any current opioid prescriptions. Clinicians in the course of conducting the AWV and IPPE may also determine that a referral for further evaluation and management is appropriate for patients who are identified as high risk for SUD. Referral to treatment is a critical component of getting patients who have a possible SUD the necessary care. The new IPPE and AWV elements required by the SUPPORT Act, working in tandem with our existing relevant requirements, will promote the early detection of high risk patients and help empower clinicians to offer appropriate referrals.

Section 2003 of the Support Act

We are proposing to implement section 2003 of the SUPPORT Act, which requires that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program, subject to any exceptions, which HHS may specify. To help inform CMS's implementation of section 2003, we also recently issued a Request for Information entitled "Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information," as a separate document on July 30, available here. The RFI solicits stakeholder feedback on whether CMS should include exceptions to the electronic prescribing of controlled substances (EPCS) requirement and under what circumstances and whether CMS should impose penalties for noncompliance with the EPCS mandate. We will use this public feedback to draft separate rules to further implement this SUPPORT Act provision.

To help ensure that section 2003 of the SUPPORT Act is implemented smoothly and with minimal burden to prescribers, in this rule we are proposing that prescribers be required to use the National Council for Prescription Drug Programs, (NCPDP) SCRIPT 2017071 standard for EPCS prescription transmissions, the same standard which Part D plans are already required to support. We are also proposing to require EPCS by January 1, 2022 to allow for sufficient time for us to implement feedback from our Request for Information and to help ensure that we are not burdening providers during the current public health emergency for the COVID–19 pandemic.

Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions

Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. The CLFS final rule "Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule" (CMS-1621-F) was published in the Federal Register on June 23, 2016 and implemented section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) was from January 1, 2019 through June 30, 2019.

Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that are not Advanced Diagnostic

Laboratory Tests (ADLTs) and the phase-in of payment reductions under the Medicare private payor rate-based CLFS.

In this CY 2021 PFS proposed rule, we are proposing to make conforming regulatory text changes to reflect revisions to the data reporting period and phase-in of payment reductions enacted in the FCAA and the CARES Act for the Medicare Clinical Laboratory Fee Schedule (CLFS).

In summary, the revisions are as follows:

- The next data reporting period of January 1, 2022 through March 31, 2022, will be based on the original data collection period of January 1, 2019 through June 30, 2019.
- After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2025, 2028, etc.).
- Additionally, the statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through CY 2024. There is a 0.0 percent reduction for CY 2021, and payment may not be reduced by more than 15 percent for CYs 2022 through 2024.

Principal Care Management Services in Rural Health Clinics (RHCs) and Federally Qualified Health Clinics (FQHCs)

In the CY 2020 PFS final rule, a separate payment was established for Principal Care Management (PCM) services. For PCM services furnished on or after January 1, 2020, there were 2 new HCPCS codes, G2064 and G2065, established for comprehensive care management services of a single high-risk disease. We propose to revise §405.2464 to reflect the current payment methodology that was finalized in the CY 2020 PFS final rule and add the 2 new HCPCS codes, G2064 and G2065, to the general care management HCPCS code, G0511, for PCM services furnished in RHCs and FQHCs beginning January 1, 2021.

RHCs and FQHCs that furnish PCM services would bill HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim. The current payment rate for HCPCS code G0511 is the average of the national non-facility PFS payment rate for the RHC/FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491). HCPCS G2064 and G2065 would be added to G0511 to calculate a new average for the national non-facility PFS payment rate. The payment rate for HCPCS code G0511 would be updated annually based on the PFS amounts for these codes.

Rebase and Revise the FQHC Market Basket

We are proposing to rebase and revise the FQHC market basket to reflect a 2017 base year. The proposed 2017-based FQHC market basket update for CY 2021 is 2.5 percent. The proposed multifactor productivity adjustment for CY 2021 is 0.6 percent. The proposed CY 2021 FQHC payment update is 1.9 percent.

Medicare Shared Savings Program

We are proposing changes to the Medicare Shared Savings Program (Shared Savings Program) quality performance standard and quality reporting requirements for performance years beginning on January 1, 2021 to align with Meaningful Measures, reduce reporting burden and focus on patient outcomes. For performance year 2020, we are proposing to provide automatic full credit for CAHPS patient experience of care surveys. We are also seeking comment on an alternative scoring methodology approach under the extreme and uncontrollable circumstances for performance year 2020. For more information, please see the Quality Payment Program fact sheet.

In response to new telehealth code proposals and to update the definition of primary care services to reflect services for cognitive impairment and chronic care management, we are proposing to include new evaluation and management and care management CPT and HCPCS codes in the methodology used to assign beneficiaries to ACOs. In addition, we are proposing to exclude certain services furnished in skilled nursing facilities from the assignment methodology when provided by clinicians in FQHCs and RHCs, and to modify the definition of primary care services to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting. We are also codifying in regulations our policy of adjusting an ACO's historical benchmark to reflect any regulatory changes to the beneficiary assignment methodology.

As part of our efforts to reduce burden associated with repayment mechanisms, we are proposing to establish a policy that would allow renewing ACOs that wish to continue use of their existing repayment mechanism to decrease their repayment mechanism amount if a higher amount is not needed to support their new agreement period. This proposed approach includes a revised methodology for calculation of repayment mechanism amounts beginning with the application cycle for an agreement period starting on January 1, 2022, and in subsequent years, as well as a one-time opportunity for eligible ACOs that renewed their agreement periods beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of their repayment mechanisms.

Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

Some drugs approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act share similar labeling and uses with generic drugs that are assigned to multiple source drug codes. CMS is proposing to continue assigning certain 505(b)(2) drug products to existing multiple source drug codes. This approach is consistent with our interpretation of the definition of multiple source drug in section 1847A of the Act and would be limited to 505(b)(2) drug products where a billing code descriptor for an existing multiple source code describes the product and other factors, such as the product's labeling and uses, are similar to products that are already assigned to the code.

The proposed approach is consistent with the concept of paying similar amounts for similar services and with efforts to curb drug prices. The proposal also encourages competition among products that are described by one billing code and share similar labeling.

Removal of Outdated National Coverage Determinations (NCDs)

We are proposing to seek stakeholder feedback to remove nine outdated or obsolete National Coverage Determinations (NCDs). Removing outdated NCDs means Medicare Administrative Contractors no longer are required to follow those outdated coverage policies when it comes to covering services for beneficiaries. The result will allow flexibility for these contractors to determine coverage for beneficiaries in their geographic areas based on more recent evidence and information.

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