Summary of 2021 Changes to the Medicare Physician Fee Schedule, Quality Payment Program, and Other Federal Programs

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Updates to the Physician Fee Schedule

Introduction

On August 3, 2020, the Centers for Medicare & Medicaid Services (CMS) published the proposed rule for the Medicare Physician Fee Schedule (MPFS) and the Quality Payment Program (QPP) for Calendar Year (CY) 2021. The proposed rule updates payment rates and polices for services supplied under the PFS on or after Jan. 1, 2021. Access the CMS press release for more information and links to relevant fact sheets. When used in this document, the word **"proposed"** refers to matters which are scheduled (but not final) to be implemented in the 2021 payment year, but could change and which are subject to review and comments by the public. When the word **"finalized"** is used in this document, it refers to matters which will go into effect in 2021 and are not currently subject to changes.

For this proposed rule to maintain budget neutrality, the proposed 2021 conversion factor is $32.26. Internal medicine will see a positive four percent impact. According to Table A below (based on Table 90 in the proposed rule), the overall estimated impact on total allowed charges for internal medicine and its subspecialties will be:

Regulatory Impact Analysis (CMS)

Table A: Overall estimated impact on total allowed charges for internal medicine and subspecialties

Specialty	Allowed Charges (mil)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact**
ALLERGY/IMMUNOLOGY	$246	5%	4%	0%	9%
CARDIOLOGY	$2,011	-7%	-1%	0%	-8%
CRITICAL CARE	$376	-6%	-2%	0%	-8%
ENDOCRINOLOGY	$506	11%	6%	1%	17%
GASTROENTEROLOGY	$1,749	-3%	-1%	0%	-5%
GERIATRICS	$190	2%	2%	0%	4%
HEMATOLOGY/ONCOLOGY	$1,702	9%	5%	1%	14%
INFECTIOUS DISEASE	$653	-4%	-1%	0%	4%
INTERNAL MEDICINE	$10,654	2%	2%	0%	4%
NEPHROLOGY	$2,213	4%	2%	0%	6%
NEUROLOGY	$1,513	3%	2%	0%	6%
PEDIATRICS	$66	4%	2%	0%	6%
PULMONARY DISEASE	$1,647	0%	0%	0%	1%
RHEUMATOLOGY	$546	10%	6%	1%	16%

Payment and Documentation Proposals for Evaluation and Management (E/M) Services

In the 2020 MPFS final rule, CMS finalized acceptance of the E/M codes, CPT guidelines, and RVS Update Committee (RUC) recommended values as implemented by the CPT Editorial Panel and submitted by the RUC for the 2021 payment year. These coding changes retained the existing five levels of coding for

established patients, reduced the number of levels to four for office/outpatient E/M visits for new patients, and revised the code definitions.

CMS also confirmed in the 2020 final rule the decision to allow medical decision-making (MDM) or time to decide the level of office/outpatient E/M visit, along with updated CPT documentation guidelines for both options.

In the 2021 proposed rule, CMS proposes to adopt the actual total times (defined as the sum of the pre-visit, intra-visit, and post-visit times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215 while moving forward with the valuation and documentation changes adopted during previous cycles. As CMS notes, "In developing its recommendations to us, the AMA RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time."

Psychiatric Collaborative Care Model (CoCM) Services

CMS proposes to establish a new code, GCOL1 that would describe 30 minutes of behavioral health care manager time. The code would be described as: *"Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional."* CMS is proposing this code to reflect stakeholder concerns that a code did not exist to reflect shorter increments of time spent with patients.

Proposed Add-On Code GPC1X

The agency is proposing to finalize its proposal to implement a Medicare-specific add-on code for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient's single, serious, or complex chronic condition. Additionally, the agency seeks to finalize for payment year 2021 its proposal to increase the work RVUs for this code from 0.25 to 0.33, representing a 32 percent increase in work RVUs. The revised code descriptor will read, "*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management.)"*

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

There are a number of codes that are directly cross-walked to office visit E/M codes. Due to the revaluing of the E/M office visit codes, CMS is proposing to revalue codes that are directly cross-walked. A list of these codes can be found in table 19 of the proposed rule.

Prolonged Services

CMS is proposing to allow the billing of 99XXX when time is used to select the E/M office visit level of coding and when the minimum time for the level 5 office visit (99205 or 99215) is exceeded by at least 15 minutes. For example, practitioners could bill 99XXX in conjunction with 99205 (60-74 minutes of total time) when they have spent at least 89 minutes with the patient and with 99215 (40-54 minutes) when they have spent at least 69 minutes with the patient.

Telehealth

Proposed Additions

CMS is proposing to add a number of services to the list of available telehealth services. CMS distinguishes these codes on a Category 1 basis (services similar to services already on the telehealth list) and a Category 2 basis (services not similar to codes already on the telehealth list).

Below is a list of the codes CMS proposes to add to the telehealth list on a Category 1 basis:

HCPCS Code	Long Descriptor
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) *Note that this description differs from the language finalized in last year's rule.
90853	Group psychotherapy (other than of a multiple-family group)
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)
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)
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.
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.
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 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 HCPCS Code Long Descriptor 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.

The agency is not proposing to add any codes to the telehealth list on a Category 2 basis. However, CMS is proposing to create a new, Category 3 level that would add services to the telehealth list on a temporary basis through the calendar year in which the public health emergency (PHE) expires. Factors CMS considers for Category 3:

- Whether, outside of the circumstances of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service;
- Whether, outside of the circumstances of the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care; and
- Whether all elements of the service could be fully and efficiently performed by a remotely located clinician using two-way, audio/video telecommunications technology.

A list of the temporary additions to the list of telehealth services is listed below:

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.
Home Visits, Established Patient	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.
	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.
Emergency Room 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 Service Type HCPCS Long Descriptor severity.
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.
	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).

CMS is not proposing to add the following codes to the telehealth list, but is interested in feedback on whether they should be added on a Category 3 basis or permanently. The list of possible additions:

- Initial and final/discharge interactions (CPT codes 99234-99236 and 99238-99239);
- Higher level emergency department visits (CPT codes 99284-99285); and
- Hospital, Intensive Care Unit, Emergency care, Observation stays (CPT codes 99217-99220, 99221-99226, 99484-99485, 99468-99472, 99475-99476, and 99477-99480).

Table 11 lists Medicare telehealth services that are covered during the PHE, but not proposed to be covered after the PHE ends. CMS is seeking comment on whether PT, OT, and speech-language pathology services should be added to the list of Medicare telehealth services. CMS is also seeking comment on which specific aspects of these services are appropriate to deliver via telehealth. Table 12 summarizes the list of telehealth services proposed to be added and those not proposed to be made permanent after the PHE.

Inpatient/Nursing Facility Settings

CMS is seeking comment on whether to extend permanently flexibilities put in place during the COVID-19 pandemic to allow physicians and non-physician practitioners to conduct certain visits via telehealth. At the same time, the agency is considering whether to revise the frequency limitation at nursing facilities from one visit every 30 days to one visit every three days and whether to remove the frequency limitations altogether. CMS is seeking comment on whether frequency limitations broadly are burdensome and limit access to care when services are only available via telehealth. Additionally, the Agency is seeking comment on whether it would enhance patient access to care if CMS were to remove frequency limitations altogether, and how best to ensure that patients would continue to receive necessary in-person care.

Coding and Payment for Virtual Services

CMS is seeking comment on whether there are additional services that fall outside the scope of telehealth services under Section 1834(m) of the Act where it would be helpful for the Agency to clarify that the services are inherently non-face-to-face, so do not need to be on the Medicare telehealth services list in order to be billed and paid when furnished using telecommunications technology rather than in person with the patient present. They are also seeking comment on physicians' services that use evolving technologies to improve patient care that may not be fully recognized by current PFS coding and payment, including, for example, additional or more specific coding for care management services. CMS is broadly seeking comment on any impediments that contribute to health care clinician burden and that may result in practitioners being reluctant to bill for communication technology-based services (CTBS).

Payment for Audio-only Visits

CMS is not proposing to extend permanently coverage and payment for telephone E/M codes 99441-43 beyond the duration of the PHE. Instead, the agency is seeking input on whether to develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. Additionally, CMS is seeking feedback on whether to extend coverage and payment for telephone E/M services for a period after the PHE ends or if it should be extended indefinitely.

Direct Supervision

The agency is proposing to extend until the end of 2021, the ability of supervising physicians or practitioners to use interactive audio/video real-time communications technology to supervise directly. "Direct supervision" in the office setting means the physician (or other supervising practitioner) must be present in the office and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision does not mean that the physician/supervising practitioner must be present in the room. CMS is proposing that the presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only). The Agency is seeking comment on:

- Whether there should be any guardrails or limitations to ensure patient safety/clinical appropriateness if CMS finalizes this policy through December 31, 2021;
- What risks this policy might introduce to beneficiaries as they receive care from practitioners that would supervise care virtually in this way; and
- Potential concerns around induced utilization and fraud, waste, and abuse, and how those concerns might be addressed.

Care Management

Remote Physiologic Monitoring (RPM)

CMS is proposing to make a number of modifications to RPM codes, including:

- Resuming the requirement that an established patient-physician relationship exist for RPM services to be furnished once the PHE ends;
- Making permanent the policy to allow consent to be obtained at the time that RPM services are furnished;
- Allowing auxiliary personnel to furnish CPT codes 99453 and 99454 services under a physician's supervision;
- 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;
- Clarifying that RPM services are considered to be evaluation and management (E/M) services;
- Clarifying that only physicians and NPPs who are eligible to furnish E/M services may bill RPM services;
- Noting that practitioners may furnish RPM services to patients with acute conditions as well as patients with chronic conditions; and
- 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.

CMS is seeking comment on whether the current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients.

Transitional Care Management (TCM)

CMS is proposing to allow the concurrent billing of certain codes alongside TCM services (see table 14 in rule). The Agency is also proposing to increase the valuations of TCM services. The list of codes is as follows:

Service Type	CPT Code	Descriptor
End Stage Renal Disease Services (for ages less than 2 months through 20+ years)	90951	ESRD related services with 4 or more face-to-face visits per month; for patients younger than 2 years
	90954	ESRD related services with 4 or more face-to-face visits per month; for patients 2-11 years
	90955	ESRD related services with 2-3 face-to-face visits per month; for patients 2-11 years

	90956	ESRD related services with 1 face-to-face visit per month; for patients 2-11 years
	90957	ESRD related services with 4 or more face-to-face visits per month; for patients 12-19 years
	90958	ESRD related services with 2-3 face-to-face visits per month; for patients 12-19 years
	90959	ESRD related services with 1 face-to-face visit per month; for patients 12-19 years
	90963	ESRD related services for home dialysis per full month; for patients younger than 2 years
	90964	ESRD related services for home dialysis per full month; for patients 2-11 years
	90965	ESRD related services for home dialysis per full month; for patients 12-19 years
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90967	ESRD related services for dialysis less than a full month of service; per day; for patients younger than 2 years
	90968	ESRD related services for dialysis less than a full month of service; per day; for patients 2-11 years
	90969	ESRD related services for dialysis less than a full month of service; per day; for patients 12-19 years
Complex Chronic Care Management Services	G2058	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month

Scope of Practice

Supervision of Diagnostic tests by Certain Non-Physician Practitioners (NPPs)

CMS is proposing to make permanent interim final policy during the PHE, which allowed supervision of diagnostic tests as permitted by state law and scope of practice by: Nurse Practitioners, Clinical Nurse Specialists, Physician Assistants, and Certified Nurse-Midwives. NPPs would maintain any required statutory relationships with supervising or collaborating physicians. CMS also clarifies in this rule that pharmacists can be auxiliary personnel under "incident to" regulations. CMS notes that pharmacists may provide "incident to" services under the appropriate level of supervision of the billing physician or NPP if payment for the services is not made under Medicare Part D.

Primary Care Exception Flexibilities

During the COVID-19 PHE, CMS allowed all levels of outpatient E/M services to be provided in teaching hospitals by residents and billed by teaching physicians without the presence of a physician under the primary care exception rules. CMS is contemplating whether to extend this flexibility through the end of 2021. Before the COVID-19 pandemic, the primary care exception policy allows residents in teaching

hospitals to provide and teaching physicians to bill for low to mid-level complexity outpatient E/M services when a teaching physician is not present. The Agency is also seeking comment on whether specific services added under the primary care exception should be extended temporarily or made permanent. CMS is soliciting public comment on whether these services should continue as part of the primary care exception once the PHE ends.

Additionally, CMS is considering whether, upon expiration of the PHE, the Agency should extend on a temporary basis some or all of the services added to the primary care exception list during the PHE and are soliciting public comment on whether these services should continue as part of the primary care exception after the PHE ends. CMS also notes that it is considering whether their interim final policy that PFS payment could be made to the teaching physician when residents furnish telehealth services under the primary care exception should be extended on a temporary basis or be made permanent.

Potentially Mis-valued Services

Immunization Administration

In the proposed rule, CMS is planning to revalue the immunization administration codes by cross-walking the values of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000. This change will significantly increase the values of these services to levels that preceded the earlier changes.

Bundled Payments under the PFS for Substance Use Disorders

CMS is proposing to modify the code descriptors for G codes G2086, G2087, and G2089 to be inclusive of all substance use disorders (SUD), instead of just opioid use disorder (OUD). At the same time, the Agency is seeking feedback on whether there should be stratified coding to demonstrate any differences in the resource costs associated with providing different SUD services.

Initiation of Medication Assisted Treatment (MAT) in the Emergency Department

CMS is proposing to create a new G-code to account for the provision of medication to treat OUD in the emergency department setting. The new code is *GMAT1: Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (List separately in addition to code for primary procedure).* CMS is proposing to cross-walk the value of this new code to *G0397 (Alcohol/subs interv > 30 min),* which CMS believes is similar in nature and magnitude.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Currently, statute defines covered OUD treatment services to include oral, injected, and implanted opioid agonist and antagonist treatment medications approved by the FDA for the treatment of OUD. CMS is proposing to revise that definition to include naloxone, which is used to treat opioid overdose.

Should this proposal be finalized, patients would be able to receive treatment for opioid overdose at an OTP and this medication would be included in the OTP Medicare benefit. CMS is also seeking feedback on whether the definition of OUD treatment services under the OTP benefit should be revised to include opioid overdose education and, if so, whether payment for this service should be included in the weekly OTP bundled payment.

CMS is proposing two add-on codes GOTP1 and GOTP2 to describe the take home supply of naloxone. Additionally, the Agency is clarifying that in order to bill for HCPCS code G2077 (periodic assessments), a face-to-face medical exam or biopsychosocial assessment would need to have been performed. CMS is also proposing to allow these assessments to be conducted via telephone for the duration of the PHE, but will permit them to be offered via telehealth even after the conclusion of the PHE.

Payment for Principal Care Management (PCM) Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

CMS is proposing to add HCPCS codes G2064 *(at least 30 minutes of PCM services furnished by physicians or non-physicians during a calendar month with certain required elements)* and G2065 *(at least 30 minutes of PCM services furnished by clinical staff under the direct supervision of a physician or non-physician practitioner with certain required elements)* to G0511 (*a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month)* as a comprehensive care management service for RHCs and FQHCs starting January 1, 2021. The payment rate for HCPCS G0511 is the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491). CMS is proposing to add G2064 and G2065 to this list to determine the calculation of the G0511 payment rate.

Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

CMS is amending regulations to incorporate section 2002 of the SUPPORT Act, Comprehensive Screening for Seniors, where Congress 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.

Electronic Prescribing of Controlled Substances

The Drug Enforcement Administration has the primary responsibility of establishing requirements for prescribing and dispensing controlled substances. In 2010, DEA issued an Interim Final Rule, "Electronic Prescriptions for Controlled Substances", that provided practitioners with the option of writing prescriptions for controlled substances electronically and permitted pharmacies to receive, dispense, and archive these electronic prescriptions. Any electronic controlled substance prescription issued by a practitioner must meet the requirements in the 2010 DEA EPCS Interim Final Rule.

CMS adopted its first set of standards for e-prescribing in 2005, which included the National Council for

Prescription Drug Programs (NCPDP) SCRIPT Standard, Version 5. CMS has since continued to adopt updated standards, and currently requires that Part D plans support the NCPDP SCRIPT standard version 2017071 for certain defined e-prescribing transactions as finalized in 83 FR 16440. Signed in 2018, Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act mandates that EPCS under Medicare Part D begin on January 1, 2021, subject to any exceptions, which HHS may specify. Balancing its intent not to provide too large of a burden on clinicians and to help ensure that the benefits of EPCS are realized quickly, CMS is proposing that all prescribers conduct electronic prescribing of Section II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 by January 1, 2022, except where the Secretary waives the requirement.

CMS is requesting comment on the feasibility for prescribers to meet the proposed January 1, 2022 deadline with minimal burden to those prescribers participating in the Part D program during and after the PHE, as well as the impact of this proposal on overall interoperability and the impact on medical record systems. In the Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information, CMS is requesting feedback on the appropriate waivers and whether CMS should impose penalties for noncompliance with the EPCS mandate (and what those penalties should be). Separate from the proposed rule, CMS intends to conduct future standalone rulemaking that would address these topics and believes the proposal to require EPCS by January 1, 2022 would allow time to solicit and consider feedback from the aforementioned RFI.

Updates to Certified Electronic Health Record Technology (CEHRT) due to the 21st Century Cures Final Rule

The Agency is proposing that the technology used by health care clinicians to satisfy the definitions of CEHRT must be certified under the Certification Program in accordance with the updated 2015 Edition of health IT certification criteria as finalized in the 21st Century Cures Act final rule. This would include technology used to meet the 2015 Edition Base EHR definition, technology certified to the criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and technology certified to the criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, as specified in the CEHRT definitions. After the current transition period ends in which health IT certified to either the existing 2015 Edition criteria or the 2015 Edition Cures Update is considered certified, health care clinicians must use technology certified to only the updated version of the criteria finalized in the 21st Century Cures final rule to meet the CEHRT definitions and demonstrate meaningful use.

Quality Payment Program

COVID-19 PHE Flexibilities

In a series of earlier interim final rules (IFRs), executive orders, and announcements, CMS finalized a number of flexibilities for the 2019-2020 performance years (PYs) due to the COVID-19 PHE. In this proposed rule, CMS proposes several additional policies for PY 2021. QPP-specific COVID-19 flexibilities are summarized in detail in this CMS fact sheet.

Major MIPS flexibilities are summarized below. Additional policies are covered in other sections of this analysis as relevant.

Performance Year	Payment Year	COVID-19 MIPS Flexibilities
2019	2021	- Individual clinicians who do not submit data will be automatically exempted from MIPS penalties. - Clinicians, groups, and virtual groups that did submit data could submit a COVID-19-related extreme and uncontrollable circumstances request through **April 30, 2020**. These requests would supersede any data previously received.
2020	2022	- Clinicians, groups, virtual groups, and if finalized, APM Entities may apply for an extreme and uncontrollable circumstances exception to reweight one or more performance categories due to the COVID-19 PHE through **Dec. 31, 2020**. **Note:** If data is received for two or more performance categories, this will supersede exception requests and the clinician would receive a MIPS score and payment adjustment.
2021	2023	**** Proposed!*** - Lowering the MIPS performance threshold to 50 points (previously finalized at 60). - Will score 2021 PY quality measures against benchmarks based on current, as opposed to historic, data. - No broad COVID-19-related hardship exclusions.

Alternative Payment Model (APM) flexibilities to date have mostly been made on a model-by-model basis and are summarized in this chart. They include a number of delays and adjustments to quality reporting and financial methodologies. CMS does propose in this rule to exercise enforcement discretion for Advanced APM determinations. Specifically, the Agency will not reconsider a model's status as an Advanced APM for CY 2020 even if the APM makes changes to its governance structure or operations in such a way that it would no longer meet the criteria. Furthermore, changes made in direct response to the COVID-19 PHE will not prevent the APM from qualifying as an Advanced APM for future performance years. Aside from this, CMS proposes no additional changes to Qualified APM Participant (QP) determinations due to the COVID-19 PHE. Finally, in the event that Participation Agreement end dates are moved up in response to the COVID-19 PHE, CMS proposes not to treat this as termination from an Advanced APM and would not revoke QP status from any eligible clinicians (ECs) on that basis. CMS anticipates that the COVID-19 PHE may warrant additional APM-related changes, which the Agency may publish through additional regulations or amended Participation Agreements.

MIPS Value Pathway (MVP)

The MIPS Value Pathway (MVP) was introduced in last year's PFS/QPP rule. Its intent, according to CMS, is to create more cohesion and reduce burden by aligning activities and measures from the four MIPS performance categories that are relevant to a particular specialty, medical condition, or a patient population, as well as relying more on administrative claims data.

The MVP was scheduled to begin implementation in Performance Year (PY) 2021. Due to the COVID-19 PHE, CMS proposes to delay implementation of an initial set of MVPs until at least PY 2022. CMS acknowledged the importance of transitioning to MVPs gradually without immediately eliminating the current MIPS program, but reiterates that it may eventually require participation in MIPS through either an MVP or the new APM Performance Pathway (APP).

CMS continues to consider the Promoting Interoperability (PI) Category a "foundational component" and proposes to include the entire set of PI measures in the MVP. CMS seeks feedback on cost measures that should be prioritized for future development and inclusion in the MVP, including potential condition-specific measures. The Agency also proposes to allow sub-TIN reporting and emphasizes the importance of meaningful data at the individual clinician level.

CMS proposes modifications and additions to the MVP guiding principles and development criteria to emphasize the importance of patient voice and supporting the transition to digital quality measures. CMS intends to establish a set of MVP development criteria and seeks suggestions from stakeholders. Beginning with PY 2022, CMS proposes that stakeholders must include patients in their MVP development process and formally submit MVPs utilizing a standardized template, which would be published in the QPP resource library. CMS proposes to host an annual MVP development webinar detailing development criteria, timeline, and process. The Agency will not communicate to stakeholders whether an MVP candidate has been approved, disapproved, or is being considered for a future year prior to the publication of the proposed rule. CMS seeks comment on the development process, including how to make it more transparent, with possible review by a third party advisory committee or technical expert panel.

CMS continues to support development of QCDR measures and their possible inclusion in MVPs. The Agency proposes that beginning with PY 2022, only QCDR measures that were approved in the previous year may be considered for inclusion within a candidate MVP. Candidate MVPs must also be proposed and finalized through rulemaking. Therefore, QCDR measures would be eligible for two-year approval for inclusion in an MVP. CMS intends to establish a formal process for QCDRs and qualified registries to identify which MVPs they plan to support and seeks comment on this.

PY 2021 MIPS Changes

In general, CMS intentionally kept the overall structure and requirements of the program consistent for PY 2021 to minimize burden as it looks to transition to MVPs and as physicians continue to deal with the COVID-19 PHE. However, the Agency did finalize several changes, summarized below.

PY 2021 Scoring and PY 2019 Performance Feedback (701)

CMS estimates in the rule that there will be approximately 930,000 MIPS Eligible Clinicians (ECs) in performance year (PY) 2021. The Agency estimates that approximately 92.5 percent of ECs who submit data will receive a positive or neutral payment adjustment, but suspects these estimates may change due to the COVID-19 PHE.

The maximum MIPS payment penalty for PY 2021 is nine percent and would be applied to any total MIPS composite score of 12.5 points or lower. CMS proposes a PY 2021 MIPS performance threshold of 50 points. This represents the minimum score a clinician would need to achieve in order to earn a neutral or positive payment adjustment. This is a 5-point increase from the PY 2020 performance threshold of 55 points but is 10 points lower than the previously finalized PY 2021 threshold of 60 points, which CMS attributes to the COVID-19 PHE. CMS proposes a PY 2021 exceptional performance threshold of 85 points, the same as it was for PY 2020.

CMS proposes the following performance category weights for PY 2021: Quality: 40 percent; Cost: 20 percent; Promoting Interoperability: 25 percent; and Improvement Activities: 15 percent. This represents a five percent decrease in Quality and a five percent increase in Cost from PY 2020. Under current statute, CMS is required to weight the Cost Category at least 30 percent starting with PY 2022. Proposed category reweighting policies are summarized in Table 45 of the proposed rule.

Typically, CMS provides performance feedback for the previous performance year by July 1 of the following year. The Agency notes that PY 2019 feedback will likely be delayed as a result of the COVID-19 PHE. CMS anticipates late July or early August, but notes this is subject to change.

Quality Category

Most notably, CMS proposes to use performance year data as opposed to historic data to score quality measures for PY 2021 due to the COVID-19 PHE.

CMS proposes to terminate the web interface (WI) reporting method, including for Medicare Shared Savings Program (MSSP) ACOs. The Agency notes that all WI measures have equivalent CQM and/or eCQMs. For more on MSSP-specific quality-reporting changes, refer to the MSSP section at the end of this analysis. The data completeness criteria threshold for Qualified Registry, QCDR, EHR, and Medicare Part B claims measures remains at 70 percent of applicable patients that meet denominator criteria for all relevant payers.

CMS proposes to continue scoring policies and flexibilities for the Quality Category, including the three-point floor for measures that meet case minimum and data completeness requirements, improvement scoring policies, and bonus points for treating complex patients, reporting high-priority measures, and end-to-end electronic prescribing. These policies are summarized in Table 43 of the proposed rule. CMS proposes to remove temporarily the cap on complex patient bonus points for PY 2021 only due to COVID-19. Total bonus points will continue to be capped at 10 points. For "topped out" measures, CMS would only apply the seven-point cap if the measure is considered topped out for two or more years based on 2020 benchmarks *and* based on 2021 performance year data.

If warranted due to significant changes to clinical guidelines, measure specifications, or codes during the performance year that would impact a clinician's ability to submit accurate data, CMS proposes to assess the measure based on nine months of data (as opposed to 12). If nine consecutive months of data were not available, CMS would suppress the measure by reducing the total available number of points for the Quality Category by 10 points for every impacted measure submitted. CMS would publish

a list of measures requiring a nine-month assessment period on the CMS website as soon as technically feasible, but no later than the beginning of the data submission period, which is January 2, 2021 for PY 2020.

As it does every year, CMS proposes changes to the measure inventory. In PY 2021, this would include "substantive changes" (i.e. changes to the specifications, title, and/or domain) to 112 measures, removal of 14 measures, and two new administrative claims measures. The hospital-wide 30-day all-cause unplanned readmission rate measure would replace the all-cause readmission measure and an additional administrative claims-based measure for hip/knee complications would be added. CMS notes that proposed changes reflect stakeholder recommendations for potential new specialty measure sets or revisions to existing specialty measure sets. In total, CMS proposes 206 measures for 2021. The summarized changes can be found in Appendix 1 of the proposed rule.

The new readmission measure would have a minimum of 200 cases and apply only to groups. The hip/knee complications measure would have a minimum of 25 cases and apply to individual clinicians and groups. In all other cases, case minimums would remain at 20. CMS proposes that different performance periods be considered on a case-by-case basis for administrative claims measures since they do not require active data reporting. The total hip/knee arthroplasty complications measure would have a three-year performance period that would start on Oct. 1 of the calendar year three years prior to the applicable performance year and conclude on Sept. 30 of the calendar year of the applicable performance year with a three-month numerator assessment period followed by a two-month claims run-out period.

For the 2021 CAHPS for MIPS Survey, CMS proposes to 1) add a new measure to assess patient-reported use of telehealth; and 2) add the following telehealth services to the list of codes used for beneficiary assignment:

- Online digital E/M services (i.e. "e-visits") (CPT codes 99421-99423);
- Telephone E/M services (CPT codes 99441-99443);
- Administration of Health Risk Assessment (CPT codes 96160-96161);
- Remote evaluation of patient video/images (HCPCS code G2010); and
- Virtual check-ins (HCPCS code G2012).

Promoting Interoperability (PI) Category (669)

CMS proposes to establish a permanent PI performance period of a continuous 90 days up to and including the full calendar year. This aligns with the proposed reporting period for the Medicare PI Program for eligible hospitals and critical access hospitals. The Agency proposes to continue the existing policy of reweighting PI to zero for non-physician ECs who do not report any PI data. However, if they choose to report data, they will be scored for PI like all other ECs.

CMS proposes to retain *Query of Prescription Drug Management Program (PDMP)* as an optional measure for PY 2021 but proposes to increase it from five to 10 bonus points to reflect its significance.

CMS proposes to add a new *Health Information Exchange (HIE) Bi-Directional Exchange* measure as an

optional alternative to two existing measures: 1) *Support Electronic Referral Loops by Sending Health Information*; and 2) *Support Electronic Referral Loops by Receiving and Incorporating Health Information*. Clinicians may choose to report the two existing measures (and associated exclusions) or report the new measure. The new HIE Bi-Directional Exchange measure would be worth 40 points and reported via yes/no attestation. Clinicians who report the measure would attest to the following:

- ***"I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period."*** (Notably, the new measure would require bi-directional engagement for all new and existing patients and patient records seen by the EC regardless of known referral or transition status, or the timing of any potential transition or referral. It would not allow for exclusion, exception, or allowances for partial credit. This is equivalent to achieving a score of 100 percent on both existing measures, while completing required actions for additional cases beyond the scope of the denominators for both existing measures. CMS does propose to use a flexible interpretation and notes in the rule that there are numerous certified health IT capabilities that can support bi-directional exchange with a qualifying HIE. For example, using 2015 CEHRT Cures Update to transmit C-CDAs (Consolidated Clinical Data Architectures) to the HIE. Alternatively, using certified Application Programming Interface (API) technology to enable an HIE to obtain data in the CCDS (Certified Clinical Documentation Specialist) or USCDI (United States Core Data for Interoperability) from a participant's EHR.)

- ***"The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners."*** (Certain HIE arrangements may not have the capacity to enable bi-directional exchange for every patient transition or referral made by clinician, and thus would not meet necessary requirements. Examples include exchange networks that only support information exchange between affiliated entities, such as clinicians that are part of a single health system, or networks that only facilitate sharing between clinicians that use the same EHR vendor.)

- ***"I use the functions of CEHRT for this measure."*** Physicians would be required to use only technology considered certified under the ONC Health IT Certification Program according to the timelines finalized in the 21st Century Cures Act final rule. Physicians may use the current 2015 Edition EHRs and/or 2015 Edition Cures Update EHRs until August 2, 2022. After August 2, 2022, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

Improvement Activities (IA) Category (660)

CMS proposes that moving forward, stakeholders can nominate IAs for the duration of any PHE, including outside of the standard nomination for new activities timeframe, provided the activity is still relevant. The Agency also proposes to consider HHS-nominated IAs on a rolling basis in order to address HHS initiatives in an expedited manner. Any HHS-nominated IAs would be subject to the same criteria and proposed through rulemaking and subject to public comment. In addition to previously finalized criteria, CMS would consider whether submitted IAs are linked to existing quality and cost measures.

CMS proposes to modify two existing IAs, changes for which are summarized in Appendix 2. In its March 31 IFR, CMS finalized a new IA that promotes clinician participation in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection. To receive credit for this clinical improvement, clinicians must report their findings through an open source clinical data repository or clinical data registry.

Cost Category (655)

For PY 2021 and subsequent performance periods, CMS proposes to include costs associated with telehealth services towards existing cost measures. Some telehealth services are already included, but the additional proposed codes were not originally included because they were newly added to the Medicare telehealth services list in the March 31 and May 8 Interim Final Rules (IFRs) or because they were not previously billed widely prior to the COVID-19 PHE. To view a full list of telehealth services proposed for inclusion for each cost measure, download the CMS zip file (codes are labeled 2020 but are correct).

Third Party Vendor Requirements (248-258)

CMS proposes to codify that as a precondition of approval, all Qualified Clinical Data Registries (QCDRs) and qualified registries must conduct annual data validation audits for all performance categories and all submission types for which it reports data. Should any data deficiencies or errors arise, the vendor would be required to perform a targeted audit to identify root causes and correct any and all deficiencies prior to submitting data to CMS. Vendors would be required to provide the results of any and all audits, as well as clinical documentation to validate that the actions or outcomes measured actually occurred or were performed. When approving current and future vendor contracts, CMS proposes to consider whether vendors met these requirements in previous performance years, as well as whether they gave clinicians inaccurate or misleading information about QPP requirements. The Agency seeks comment on adding similar requirements for health IT vendors and CAHPS survey vendors, but proposes none. However, CMS does propose health IT vendors and CMS-approved survey vendors be required to participate in annual meetings and training calls as deemed necessary by CMS.

CMS had previously finalized that QCDRs must: 1) fully develop and test measures with complete results at the clinician level; and 2) collect data on all measures prior to submitting the measure starting with PY 2021. In its May 8 IFR, CMS delayed both requirements until PY 2022. In response to stakeholder concerns, the Agency proposes in this rule a more gradual implementation approach for the first requirement regarding development and testing. Specifically, in order to be approved for PY 2022, a QCDR measure would have to be "face valid." To be approved for PY 2023 and future years, a QCDR measure would have to be face valid for the initial MIPS payment year for which it is approved and fully tested for the second and any subsequent MIPS payment year for which it is approved. Timing for the second data collection requirement would remain PY 2022.

Finally, CMS proposes new criteria for corrective action plans, which includes: (1) issues contributing to non-compliance; (2) scope of clinician impact/harms; (3) corrective actions; and (4) a detailed timeline for achieving compliance.

APM Performance Pathway (APP) (626)

CMS proposes to terminate the MIPS APM Scoring Standard and replace it with the new APM Performance Pathway (APP) starting in PY 2021. The APP is designed to be an optional, complementary pathway to the MVP. Unlike in the past, data could be reported at the clinician, group, or APM Entity level and the highest available TIN/NPI level score would apply. However, the final score earned by the group or APM Entity would be applied only to clinicians who appear on a MIPS APM's Participation List or Affiliated Practitioner List on an applicable snapshot date during the performance year (March 31, June 31, Aug. 31, Dec. 31). MSSP ACOs would be required to report through the APP for purposes of assessing their quality performance for that program, but participating clinicians would have the option to report within or outside the APP at an individual or group level for purposes of being scored under MIPS.

Category weights under the APP would resemble those under the APM Scoring Standard. Cost would be weighted zero percent; PI: 30 percent; IA: 20 percent; and Quality: 50 percent. In cases where PI is reweighted to zero, CMS would reweight Quality to 75 percent and IA to 25 percent. If Quality is reweighted to zero, CMS would reweight PI to 75 percent and IA to 25 percent.

Under the APP, MIPS APMs would continue to automatically earn at least half IA credit. Typically maximum IA credit is based on IAs inherently performed in the APM, as they do now. The assigned IA score for each model would be announced prior to the beginning of each MIPS performance period on the CMS QPP website. In the event that the assigned score for a MIPS APM does not represent the maximum IA score, clinicians could report additional IAs to maximize their score.

All clinicians scored under the APP would be scored on the following six quality measures.

TABLE 41: APM Performance Pathway Quality Measure Set

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Quality ID:001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID: 236	Controlling High Blood Pressure	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions

Measures that fail to meet specified patient population or minimum case thresholds would not be counted. Scoring caps for "topped out" measures would not apply, though those measures may be

removed in future performance years.

Beginning with the 2020 performance year, APM Entities may submit applications for reweighting due to extreme and uncontrollable circumstances. Such applications would apply to all four MIPS performance categories and all eligible clinicians (ECs) in the APM Entity. APM Entities would have to demonstrate that 75 percent or more of its clinician participants are eligible for reweighting for the PI Category. If the request is approved, all ECs participating in the APM Entity would be exempted from MIPS reporting for the applicable performance period, and the APM Entity would receive a final score equal to the performance threshold and a neutral payment adjustment, notwithstanding any data submitted.

PY 2021 Advanced APM Changes

Qualified APM Participant (QP) Thresholds

CMS estimates between 196,000 and 252,000 clinicians will become Qualified APM Participants (QPs) and therefore be excluded from MIPS and qualify for the five percent Advanced APM Incentive Payment. This number is lower than estimates for 2019 and 2020 due mostly to an expected increase in the QP performance thresholds (below).

QP Threshold

	Medicare Option		All-Payer Combination Option	
	2020	2021	2020	2021
Payment Count	50%	75%	50% (25%)	75% (25%)
Patient Count	35%	50%	35% (20%)	50% (20%)

Partial QP Threshold

	Medicare Option		All-Payer Combination Option	
	2020	2021	2020	2021
Payment Count	40%	50%	40% (20%)	50% (20%)
Patient Count	25%	35%	25% (10%)	35% (10%)

** (xx%) denotes required Medicare percentage*

As a result, CMS expects fewer clinicians to qualify as QPs and more clinicians to qualify as Partial QPs. To date, CMS' method for contacting Partial QPs has been to send letters to APM Entity contacts. The Agency is considering options to make the Partial QP election process less burdensome. CMS seeks comment on whether to allow an APM Entity to make the Partial QP election on behalf of all of its ECs and how to handle potentially conflicting elections.

Advanced APM Incentive Payment Distribution Methodology

CMS proposes changes to the APM Incentive Payment distribution methodology that would essentially require the QP to be actively affiliated with the TIN(s) at the time payment is made. Under the proposal, CMS would continue to prioritize TIN(s) through which the clinician earned QP status during the performance year, but if the QP were no longer affiliated with any such TIN at the time of payment, CMS

would make the payment to another TIN. The Agency lays out an eight-step hierarchy based on varying degrees of APM participation, but in each case, the QP would have to be actively associated with that TIN(s) at the time of payment. Ultimately, CMS would disburse the APM Incentive Payment to any TIN(s) with which the QP is actively affiliated on the date payment is made, even if that TIN(s) is not affiliated with an APM in any way. The detailed step-by-step hierarchy can be found in the proposed rule. When CMS identifies multiple TINs at a single step, it would divide the payment proportionately based on the relative paid amount for Part B-covered professional services billed through each TIN. CMS proposes to issue a public notice requesting updated payment information for any QPs for which there are no active TINs to render payment, and for rare cases where a QP's payment was calculated solely based on supplemental services payments and no Medicare claims. The QPs identified in the public notice, or any other ECs who believe that they are entitled to an APM Incentive Payment, must notify CMS by Nov. 1 of the payment year, or 60 days after CMS announces Incentive Payments have been issued, whichever is later. After such time, any payments would be forfeited for the applicable payment year.

Changes to Attribution Methodology for Prospectively Assigned Beneficiaries

CMS proposes that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period would be excluded from the attribution eligible beneficiary count for any other APM Entity for which he/she would be ineligible to be attributed due to model overlap rules. This would prevent beneficiaries from diluting an APM Entity's QP threshold score by adding to the denominator with no chance of being counted towards the numerator.

Establishing a Limited Target Review Process for Qualified APM Participant (QP) Determinations

CMS proposes to establish a limited targeted review process solely for cases in which an EC or APM Entity believes in good faith that, due to a CMS clerical error, an EC was omitted from a Participation List used for purposes of QP threshold determinations. CMS may request additional information, which must be provided and received by CMS within 30 days. Otherwise, a final decision will be made based on information available. If CMS identifies a pattern of error affecting EC(s) not directly involved in the initial review request, CMS would correct any identified errors for all ECs. If CMS determines a clerical error was in fact made, the Agency proposes to assign the impacted EC the most favorable QP status determined for that APM Entity for the relevant QP Performance Period. CMS would not recalculate the QP Threshold Score for the entire APM Entity. The timing for the QP Determination targeted review process would align with the MIPS targeted review process, after which there would be no opportunities for further review or appeal. CMS does not propose to conduct targeted reviews of potential omissions from Affiliated Practitioner Lists or Participation Lists for Other Payer Advanced APMs.

Medicare Shared Savings Program (MSSP) (424-510)

COVID-19 Flexibilities

In two separate IFRs, CMS finalized a number of MSSP flexibilities due to COVID-19. Those changes are summarized here. In the May 8 COVID-19 IFR, CMS announced that it will forego a 2021 MSSP application cycle. However, ACOs whose first or second participation agreements are set to expire Dec. 31, 2020 may elect to extend their agreement period for an optional fourth performance year, spanning Jan. 1, 2021 to Dec. 31, 2021. This would apply to ACOs in Track 1+.

Quality Reporting Changes

Under the new APP (mentioned above), all MSSP ACOs would be scored on six static quality measures (instead of 23) and actively report three measures (instead of 10). The CAHPS for MIPS survey, which currently counts as 10 separate measures and comprises 25 percent of the MSSP quality score, would count as one measure. CMS would use the revised All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure, which uses slightly revised measure specifications to align the ACO MCC measure with the MIPS MCC measure by: (1) adding a diabetes cohort; (2) excluding any admissions within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility; and (3) adjusting for the AHRQ socioeconomic status index and specialist density social risk factors.

This would satisfy reporting requirements for both MIPS and the MSSP. Quality scores would be calculated based on MIPS benchmarks, as opposed to MSSP specific benchmarks. CMS MIPS staff would assume data validation and auditing for MSSP ACOs. Web Interface (WI) would be removed as a reporting option so MSSP ACOs would select one of the other available mechanisms to report quality data.

CMS proposes to eliminate the pay-for-reporting phase-in period for new measures; all six measures would be scored on a pay-for-performance basis for all ACOs regardless of contract year. The Agency would raise the minimum quality performance standard from the 30th percentile on at least one measure per domain to a total Quality score at or above the 40th percentile for all MIPS Quality scores, excluding facility-based scoring. In addition to terminating an ACO's participation agreement if it fails to meet the quality performance standard for any two consecutive years, CMS proposes that it may also do so if an ACO fails to meet the quality performance standard for any three years within the same five-year agreement period. This new policy would also apply to "re-entering ACOs," e.g. 50 percent or more of the participants were in the same ACO within a five-year lookback period.

ACOs would no longer automatically receive zero points for the Quality Category if they fail to report completely on all required measures, but they would receive zero points for each measure they fail to report. ACOs would receive a score between three and 10 points for each measure that meets the data completeness and case minimum requirements. Under the APP, measures that fail to meet specified patient population or minimum case thresholds would not be counted and scoring caps for "topped out" measures would not apply, though those measures may be removed in future performance years.

CMS proposes to adjust the extreme and uncontrollable circumstances policy so that it would apply the higher of the affected ACO's quality score or the 40th percentile MIPS Quality score, as opposed to the mean ACO score. CMS solicits feedback on alternatives that would continue to incentivize reporting, such as adjusting savings similar to losses by multiplying the maximum possible savings by the percentage of total months and beneficiaries affected.

Adding to Covered Primary Care Services List used for Patient Assignment

CMS proposes to add the following services to the list of primary care services for patient assignment and for other purposes:

- online digital E/M services i.e. “e-visits” (CPT codes 99421-99423);
- assessment of and care planning for patients with cognitive impairment (CPT code 99483);
- chronic care management (CCM) services (CPT code 99491);
- non-complex CCM (HCPCS code G2058 and its replacement CPT code);
- principal care management (HCPCS codes G2064 and G2065); and
- psychiatric collaborative care model codes, if finalized (HCPCS code GCOL1).

CMS proposes to exclude advance care planning services (CPT codes 99497-99498) when billed in an inpatient care setting because it may attribute beneficiaries based on inpatient care rather than their regular primary care clinician. CMS additionally proposes to exclude Federally Qualified Health Center and Rural Health Center services with CPT codes 99304-99318 when there is an overlapping Skilled Nursing Facility claim. CMS would adjust historical benchmarks to account for changes in patient assignment methodologies finalized under this rule.

Repayment Mechanism Flexibilities

For renewing ACOs that wish to use their existing repayment mechanism for a new agreement period, CMS proposes to discontinue the policy that currently requires them to maintain existing repayment mechanism amounts if higher than the amount specified for the new agreement period. Starting with the 2022 application cycle, such ACOs would only be required to meet the remaining criterion, i.e. an amount equal to: (1) one percent of total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the most recent calendar year; or (2) two percent of total Medicare Parts A and B FFS revenue of its ACO participants for the most recent calendar year, whichever is less. Renewing ACOs could still choose to switch repayment mechanisms for the new agreement period. In these cases, the ACO would maintain its existing repayment mechanism at the previously required amount until it is able to terminate the first repayment mechanism, after which only the new mechanism for the ACO’s current agreement period would remain. CMS is considering finalizing an additional policy that would require renewing ACOs to maintain existing, higher repayment mechanism amounts until they have fully repaid any shared losses owed for the most recent performance year.

CMS is considering finalizing provisions that would specify “re-entering ACOs” (i.e. more than 50 percent of its ACO participants were included on the ACO participant list for the same ACO in any of the five most recent performance years) as the same legal entity as an ACO that previously participated in the program, and may therefore use that ACO’s existing repayment mechanism to support its participation in a new agreement period in the MSSP.

CMS additionally proposes to allow ACOs whose agreement periods began July 1, 2019 or Jan. 1, 2020 a one-time opportunity to elect to reduce the amount of their repayment mechanisms if they elected to use an existing repayment mechanism, the original amount was greater than the new amount, and the recalculated amount for performance year 2021 is less than the existing repayment mechanism amount. If finalized, CMS will notify applicable ACOs of this opportunity to reduce their repayment mechanism amounts after the start of the 2021 performance year. Interested ACOs would submit such an election,

together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS, likely within 30 days from the date of the written notice from CMS.

Medicare Diabetes Prevention Program (MDPP) PHE Permanent Exceptions (581-591)

In the March 31 COVID-19 IFR, CMS permitted certain beneficiaries to obtain the set of MDPP services more than once per lifetime, waived the five percent weight loss eligibility requirements, and allowed certain MDPP suppliers to either pause the delivery of services or deliver virtual MDPP sessions on a temporary basis. In this rule, CMS proposes to preserve and refine these flexibilities for the current COVID-19 PHE and apply them to future emergency events. If finalized, these proposed flexibilities will supersede policies announced in the March 31 COVID-19 IFR. In this rule, CMS proposes:

- MDPP beneficiaries who elect to receive MDPP services virtually during the PHE are not eligible to restart the set of MDPP services at a later date.
- MDPP beneficiaries in their first year of MDPP services as of the start of an emergency would have the choice to either restart the set of MDPP services at the beginning or resume with the relevant attendance session after the emergency period has ended. MDPP beneficiaries in their second year of MDPP services as of the start of the emergency event must resume the set of MDPP services with the relevant attendance session.
- All sessions, including the first core session and those furnished to achieve both attendance and weight loss goals, may be offered virtually during the remainder of the COVID-19 PHE and future emergency events. The limit normally placed on the number of virtual make-up sessions would not apply during applicable emergency events, so long as the virtual services are furnished in a manner consistent with all applicable CDC and other standards.
- The MDPP supplier could still only furnish one session on the same day as a regularly scheduled session and a maximum of one virtual make-up session per week. In total, an MDPP supplier may offer: 16 virtual sessions weekly during the core session period; six virtual sessions monthly during the core maintenance session interval periods; and 12 virtual sessions monthly during the ongoing maintenance session interval periods.
- MDPP suppliers may obtain weight measurements from beneficiaries through the following methods: (1) in-person; (2) via digital technology, such as “Bluetooth™ enabled” scales; or (3) self-reported weight measurements from an at-home digital scale via video.
- Given these new flexibilities, the Agency would end the previously finalized temporary waivers for minimum weight loss requirements. Thus, effective January 1, 2021, all MDPP beneficiaries would be required to achieve and maintain the required five percent weight loss goal in order to be eligible for the ongoing maintenance sessions, even if the COVID-19 PHE remains in place.
- An exception for continuing in-kind beneficiary engagement incentives in cases where contact has lapsed due to a qualifying emergency event, the MDPP beneficiary is receiving services virtually, and services eventually resume or restart. CMS is soliciting comment on whether it should impose a cutoff if MDPP services are not eventually resumed or the PHE remains in effect for a certain period of time, such as one year.
- All MDPP suppliers must be authorized to furnish services in-person, even if they elect to do so virtually during emergencies. This is intended to minimize disruption when the emergency ends.

For a summary of MDPP specific policies included in this proposed rule, access this CMS fact sheet.