

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

Updated 12/23/20

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#### **Updates to the Physician Fee Schedule**

#### Introduction

On December 2, 2020, the Centers for Medicare & Medicaid Services (CMS) published the final rule for the Medicare Physician Fee Schedule (MPFS) and the Quality Payment Program (QPP) for Calendar Year (CY) 2021. The final rule updates payment rates and polices for services supplied under the PFS on or after Jan. 1, 2021. Access the CMS <u>press release</u> for more information and links to relevant fact sheets.

For this final rule to maintain budget neutrality, the finalized 2021 conversion factor is \$32.41. However, due to legislative changes, the actual 2021 conversion factor is expected to be higher. Internal medicine will see a net positive four percent impact. According to Table A below (based on Table 106 in the final 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	\$247	5%	4%	0%	9%
CARDIOLOGY	\$2,020	1%	0%	0%	1%
CRITICAL CARE	\$378	-6%	-1%	0%	-7%
ENDOCRINOLOGY	\$508	10%	5%	1%	16%
GASTROENTEROLOGY	\$1,757	-3%	-1%	0%	-4%
GERIATRICS	\$192	1%	1%	0%	3%
HEMATOLOGY/ONCOLOGY	\$1,707	8%	5%	1%	14%
INFECTIOUS DISEASE	\$656	-4%	-1%	0%	-4%
INTERNAL MEDICINE	\$10,730	2%	1%	0%	4%
NEPHROLOGY	\$2,225	4%	2%	0%	6%
NEUROLOGY	\$1,522	3%	2%	0%	6%
PEDIATRICS	\$67	4%	2%	0%	6%
PULMONARY DISEASE	\$1,654	0%	0%	0%	1%
RHEUMATOLOGY	\$548	10%	5%	1%	15%

<sup>\*</sup>Please note that these amounts are expected to change based on legislative changes.

#### 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 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 guidelines for both options.

In the 2021 final rule, CMS will adopt the actual total times for CPT codes 99202 through 99215 on the date of encounter while moving forward with the valuation and code selection guideline changes.

# Visit Complexity

CMS has finalized its proposal to implement a Medicare-specific add-on code (G2211) for E/M office visits that describe the complexity associated with visits 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 condition or a complex condition. However, this code will not be implemented in 2021 due to legislative changes prohibiting its implementation until at least 2024.

#### <u>Psychiatric Collaborative Care Model (CoCM) Services</u>

In the 2021 proposed rule, CMS proposed establishing 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 had proposed this code to reflect stakeholder concerns that a code did not exist to reflect shorter increments of time spent with patients.

In the final rule, CMS finalized this proposal. This code will now be known as G2214 (*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*). This code will be valued at 1.90 total facility RVUs. The required elements listed for billing CPT code 99493 will also be required elements for billing G2214. CPT time rules will apply to G2214, as well.

G2214 can be billed during the same month as CCM and TCM services, provided that all requirements to report each service are met and time and effort are not counted more than once. The patient consent requirement would apply to each service independently. G2214 has been added to the list of designated care management services for which CMS will allow general supervision.

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 has finalized a proposal to revalue codes that are directly cross-walked. A list of these codes can be found in table 23 of the final rule.

#### **Prolonged Services**

In the proposed rule, CMS proposed to allow the billing of 99417 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 99417 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.

However, in the final rule, CMS noted that they will not be finalizing this proposal. The Agency notes that it "...continues to believe that CPT code 99417 as written is unclear and that allowing reporting of CPT code 99417 when the minimum required time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time." Instead, CMS is finalizing policy for 2021 to use G2212 ("Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services) in place of 99417. G2212 will be valued the same as 99417.

#### Telehealth

#### <u>Finalized Additions</u>

CMS will 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 has added to the telehealth list on a Category 1 basis:

<b>HCPCS Code</b>	Long Descriptor
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
00010	code for primary procedure)
G2212	Prolonged office or other outpatient evaluation and management service(s) beyond
	the maximum required time of the primary procedure which has been selected using
	total time on the date of the primary service; each additional 15 minutes by the
	physician or qualified healthcare professional, with or without direct patient contact
	(List separately in addition to CPT 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 did not propose to add any codes to the telehealth list on a Category 2 basis. However, CMS is finalizing its proposal to create a new, Category 3 level that would add services to the telehealth list on a temporary basis through the end of the calendar year in which the public health emergency (PHE) expires. These services include:

- Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99336-99337)
- Home Visits, Established Patient (CPT 99349-99350)
- Emergency Department Visits, Levels 1-5 (CPT 99281-99285)
- Hospital discharge day management (CPT 99238-99239)
- Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224-99226)

A list of the extensive, temporary additions to the list of telehealth services can be found on Table 14 of the <u>final rule</u>. CMS added a substantial number of additions to this list following proposed rulemaking. In addition to these expansions, the Agency announced a study which will explore the effects of the COVID-19 telehealth flexibilities to better understand the experiences and learnings of both patients and physicians utilizing these revised policies.

# **Inpatient/Nursing Facility Settings**

In the proposed rule, CMS sought comment on whether to revise the frequency limitations at nursing facilities from one visit every 30 days to one visit every three days, or whether it would enhance patient access to care to remove the frequency limitations altogether. After consideration of comments, CMS finalized a frequency limitation for subsequent nursing facility visits of one visit every 14 days. CMS is not finalizing any revisions to the frequency limitations on inpatient visits or critical care consultations provided as telehealth services.

# Coding and Payment for Virtual Services

Rather than continue separate payment for audio-only E/M services, CMS has established G2252 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion) on an interim basis for the duration of the public health emergency. The value of G2252 will be a direct crosswalk to CPT code 99442 and should be used to determine the necessity of an in-person visit. As interim final policy, this change is open to additional comment for 2022 rulemaking.

#### **Payment for Audio-only Visits**

CMS will not extend permanently coverage and payment for telephone E/M codes 99441-43 beyond the duration of the PHE. At the conclusion of the public health emergency, these services will not be covered.

#### **Direct Supervision**

In the office setting, "direct supervision" means the physician (or other supervising practitioner) must be present in the office and immediately available to furnish assistance and direction to the clinician performing the service throughout the performance of the procedure. Direct supervision does not mean that the physician/supervising practitioner must be present in the room. In an effort to limit the exposure of COVID-19, CMS proposed 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. The Agency has finalized an extension of this policy through the end of the CY in which the PHE ends, or December 31, 2021. CMS did not finalize any policy to permanently extend this. This provision applies to qualified health professionals (QHPs)/clinicians, not residents.

# **Care Management**

# Remote Physiologic Monitoring (RPM)

In the final rule, CMS clarified its payment policies related to RPM services codes 99453, 99454, 99091, 99457, and 99458. CMS also clarified that following expiration of the COVID-19 PHE, there must be an established patient-physician relationship for RPM services to be furnished – ending its interim policy permitting RPM services to be furnished to new patients. The Agency also finalized policy allowing consent to receive RPM services to be obtained at the time RPM services are furnished.

CMS' final rule further provides for a number of modifications to RPM codes beginning in 2021:

- Allowing auxiliary personnel to furnish CPT codes 99453 and 99454 services under a physician's supervision;
- That medical devices supplied to a patient as part of RPM services 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;
- After the COVID-19 pandemic ends, 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 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.

#### Transitional Care Management (TCM)

The Agency finalized its proposal to increase the valuations of TCM services. CMS also finalized a proposal to allow the concurrent billing of certain codes alongside TCM services (see table 18 in rule). The list of these codes is as follows:

Service Type	CPT Code	Descriptor

End Stage Renal Disease Services	90951	ESRD related services with 4 or more face-to-face
(for ages less than 2 months		visits per month; for patients younger than 2 years
through 20+ 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	G2058	Chronic care management services, each additional
Management Services	(Beginning	20 minutes of clinical staff time directed by a
	CY 2021,	physician or other qualified healthcare professional,
	CPT code	per calendar month
	99439)	

# **Scope of Practice**

# <u>Virtual Presence of a Teaching Physician Using Audio/Video Real-Time Communications Technology</u>

CMS has finalized for the duration of the COVID-19 public health emergency, the ability of teaching physicians to provide supervision of residents through audio/video real-time communications technology. This is different from direct supervision which applies to QHPs/clinicians.

However, at the conclusion of the PHE, only services furnished in residency training sites that are located outside of an OMB-defined metropolitan statistical area (MSA) (rural areas) will be eligible under this policy.

Virtual Presence of a Teaching Physician During Medicare Telehealth Services

CMS will finalize for the duration of the COVID-19 PHE, the ability for residents to furnish telehealth services to beneficiaries with the teaching physician present using interactive, audio/video real-time communications technology (excluding audio-only).

At the conclusion of the PHE, however, only services furnished in residency training sites that are located outside of an OMB-defined metropolitan statistical area (MSA) (rural areas) will be eligible. The Medicare beneficiary must also be located outside of an MSA, though the supervising physician may reside in or outside of the MSA.

#### <u>Supervision of Diagnostic tests by Certain Non-Physician Practitioners (NPPs)</u>

CMS will make permanent its interim final policy 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. CMS will add certified registered nurse anesthetists (CRNAs) to the list of NPPs. 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

Before the COVID-19 PHE, CMS' primary care exception allowed 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 was not present. CMS has finalized this interim policy, as well as to allow for:

- Teaching physicians to direct and review the services furnished by a resident during or immediately after the visit remotely using audio/video real-time technology; and
- Medicare to pay the teaching physician for additional services under the primary care exception, including all levels of office E/M codes, audio-only telephone E/M services, transitional care management, and communications technology-based services.

The Agency emphasized that residents will have to document that the services are separate, and that they are allowed by law to practice medicine by the state in which services are provided.

At the conclusion of the PHE, CMS has established new policy around the primary care exception that will apply to residency training programs that are located outside of an MSA (rural area). At the conclusion of the PHE, residents outside of an MSA may provide an expanded array of services that include:

- Services described by CPT codes 99421-99423, and 99452, and HCPCS codes G2010 and G2012.
- Medicare telehealth services (99202, 99203, 99211, 99212, and 99213)

Additionally, at the end of the PHE, CMS will terminate the inclusion of CPT codes 99204, 99214, 99205, 99215, 99495 and 99496 from the primary care exception for all settings.

#### **Immunization Administration**

In the proposed rule, CMS proposed 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 would have significantly increased the values of these services to levels that preceded the earlier changes.

However, in the final rule, CMS decided not to finalize the proposal to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000. This means that the 2019 vaccine payment rates will be maintained, despite concerns that this will have impacts on vaccine purchase, storage, administration, and record-keeping.

#### **Bundled Payments under the PFS for Substance Use Disorders**

CMS finalized its proposal 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). The Agency will consider whether there should be stratified coding to demonstrate any differences in the resource costs associated with providing different SUD services through future rulemaking and collaboration with the CPT Editorial Panel.

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

CMS has finalized its proposal 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 G2213 (formerly 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 will cross-walk the value of this new code to G0397 (Alcohol/subs interv > 30 min).

# 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 has finalized a proposal to revise that definition to include naloxone, which is used to treat opioid overdose. Patients will now be able to receive treatment for opioid overdose at an OTP and this medication will be covered under the OTP Medicare benefit. CMS is also revising the definition of OUD treatment services under the OTP benefit to include opioid overdose education.

CMS is finalizing two proposed add-on codes G2215 (formerly GOTP1) and G2216 (formerly GOTP2) to describe the take home supply of naloxone. The Agency clarified in the proposed rule 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 will allow these assessments to be conducted via telephone for the duration of the PHE, but will permit them to be offered via telehealth (not audio-only) 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 will 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).

# 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.

In the final rule, CMS is finalizing that prescribers be required to use the NCPDP SCRIPT 2017071 standard for EPCS prescription transmissions for all applicable Medicare Part D medications. CMS proposed an implementation date of January 1, 2022; however, the Agency finalized an effective date of January 1, 2021 and a compliance date of January 1, 2022. The Agency is encouraging practices to make the transition to ECPS as quickly as possible.

#### Updates to CEHRT due to the 21st Century Cures Final Rule

CMS has finalized changes to align CEHRT requirements in response to the ONC 21<sup>st</sup> Century Cures Act Final Rule. For Performance Periods in CY 2020, 2021, and 2022, MIPS eligible clinicians may use: Technology certified to the existing 2015 Edition certification criteria; technology certified to the 2015 Edition Cures Update certification criteria; or, a combination of both to collect and report their Promoting Interoperability data and eCQMs for the Quality performance category.

Additionally, for those clinical practices that may undergo a mid-year transition from one EHR system to another EHR system, the Agency clarified that the 12-month data completeness threshold is applicable regardless of whether there is a transition. The rule further clarifies that, in this instance, the 12-month data completeness threshold may be met by running and supplying reports in *each* of the EHR systems used before and after the transition and aggregating the data into a single 12-month report for submission. It is important to note, however, that this is only possible where both the previously utilized EHR systems and the currently used EHR system are certified to the 2015 Edition certification criteria. Where, for example, data for the full 12 months is unavailable because aggregation of both EHR reports is not possible, the measure score will reflect the inability to meet the 12-month data completeness threshold.

# **Quality Payment Program**

For more information on QPP-specific changes in the final rule, access this <u>downloadable zip file</u>, which includes several CMS resources including a 2020/2021 comparison chart, a set of frequently asked questions, and a QPP fact sheet.

# 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 population health administrative claims measures and patient reported outcomes measures. The MVP was originally scheduled to begin implementation in Performance Year (PY) 2021. Due to the COVID-19 PHE, CMS delayed 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 is not prescriptive on the number of measures or activities that will be included in MVPs. The Agency has indicated that they do intend for there to be an element of measure selection. For the Cost Category, CMS plans to include the Hospital-Wide 30-day All Cause Unplanned Readmission (HWR) Rate for eligible clinician groups and seeks feedback on cost measures that should be prioritized for future development and inclusion, including potential condition-specific measures. All measures in the Promoting Interoperability (PI) Category will be included in any new MVPs to start. CMS may customize PI measures in future years and does plan to maintain the existing hardship exception and reweighting policies for the PI Category for small practices. The Agency plans to allow reporting at the sub-TIN level and will work with stakeholders to develop subgroup reporting policies and processes for future performance years.

CMS finalized several 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. Beginning with PY 2022, stakeholders must formally submit MVPs utilizing a standardized template, which would be published in the QPP resource library. CMS will 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. QCDR measures may be included in candidate MVPs provided they were approved the previous year and meet all testing criteria.

# **Performance Year 2021 MIPS Changes**

## Extreme and Uncontrollable Circumstances Policy

CMS extended the MIPS extreme and uncontrollable circumstances policy due to the COVID-19 PHE through the PY 2021. Applications for PY 2021 are due Dec. 31, 2021. Individual clinicians, groups, and virtual groups may apply to reweight one or more performance categories. 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. CMS also extended the deadline for PY 2020 hardship applications due to the COVID-19 PHE to Feb 1, 2021.

Beginning with PY 2020, applications may also be submitted at the APM Entity level. APM Entities must demonstrate that 75% or more of clinician participants are eligible for reweighting for the Promoting Interoperability (PI) Category. If the request is approved, all MIPS Eligible Clinicians (ECs) participating in the APM Entity would be exempt 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. Such requests for reweighting would be approved or denied in their entirety. For APM Entities, data reported would <u>not</u> void the reweighting request.

# Scoring and Performance Feedback

The maximum MIPS payment penalty of 9% will apply to any MIPS total composite score of 15 points or lower. The 2021 MIPS performance threshold will be 60 points, a 15-point increase from 2020 (and 10 points higher than proposed). This is the minimum score a clinician needs to earn a neutral or positive payment adjustment, which will be applied on a linear sliding scale up to the maximum possible score of 100 points. The exceptional performance threshold will be set at 85 points, the same as 2020. Clinicians who score above this will receiving a proportionate share of a separate \$15 million pool for exceptional MIPS performers. For reference, for PY 2019, the most recent performance year for which data is available, the average MIPS final score was 79.8 and the median final score was 85.27. Looking ahead to PY 2022, CMS estimates a MIPS performance threshold of 74.01 points.

The Cost Category will be weighted 20%, a 5% increase from 2020. Quality will be weighted 40% (5% lower than 2020). Under current statute, CMS is required to weight both the Cost and Quality Categories at 30% in 2022. Promoting Interoperability will continue to be weighted 25% and Improvement Activities 15%. Reweighting policies are summarized in Table 51, though CMS will generally avoid redistributing additional weight to the Cost Category.

When multiple MIPS scores are associated with a single TIN/NPI combination, CMS will use the highest available MIPS score regardless of how data was submitted (whether by an individual clinician, group, or APM Entity). This represents a change from previous policy in which CMS used a systematic hierarchy.

CMS released PY 2019 feedback on Aug. 5, 2020. Additional information is available at https://gpp.cms.gov/about/deadlines?py=2019.

#### Cost Category

CMS increased the weight of the Cost Category to 20%. CMS proposes no new cost measures for 2021 and will continue existing cost measures, including the two generally applicable Medicare Spending Per Beneficiary and Total Per Capita Cost measures. However, CMS will count telehealth services finalized during the COVID-19 PHE toward both measures, which are included in the cost measure code list. CMS will consider additional cost measures in future rulemaking.

## **Quality Category**

CMS finalized the following policies for the Quality Category:

- **2021 benchmarks:** CMS reversed its proposal to use PY data to score 2021 measures due to the COVID-19 PHE. Instead, CMS will use historic benchmarks based on 2019 data, similar to years past.
- **Web Interface (WI):** CMS finalized its decision to terminate the WI reporting method, including for MSSP ACOs, but delayed this change until PY 2022. More than 80% of WI reporters are ACOs.
- **Data completeness thresholds** for Qualified Registry, QCDR, EHR, and claims measures will remain at 70 % of applicable patients that meet denominator criteria for all relevant payers.
- Special scoring policies: CMS will carry over several of these policies, including the 3-point floor for measures that meet case minimum and data completeness requirements, improvement scoring, and bonus points for complex patients, high-priority measures, and end-to-end electronic prescribing (see Table 49). For PY 2020 only due to the COVID PHE, the complex patient bonus will be worth up to 10 points (as opposed to 5). Total bonus points will continue to be capped at 10 points.
- **Topped out measures** will continue to be capped at 7 points, beginning the second year the measure is identified as topped out (excluding WI measures).
- Truncated and suppressed measures: For 2021 onward, if "significant" coding or specification changes occur during the PY that may impact the clinician's ability to submit a measure, lead to patient harm, or potentially misleading results, CMS may truncate the measure, i.e. assess based on nine consecutive months of data instead of 12, or suppress the measure. CMS will publish a list of affected measures on the CMS website no later than Jan. 2, 2021 for PY 2020.
- **Non-storable measures**: For each non-storable measure reported, CMS will reduce the Quality Category by 10 points.
- Measure inventory changes: CMS finalized 209 total measures, summarized in Appendix 1. CMS made "substantive changes" to 112 measures, removed 14 measures, and added two new administrative claims measures.
  - A hospital-wide 30-day all-cause unplanned readmission rate measure will replace the allcause readmissions measure. It will have a minimum of 200 cases and apply only to groups.
  - O A new hip/knee complications measure will have a case minimum of 25, apply to individual clinicians and groups, and have a three-year performance period.

- Case minimums for administrative claims measures will be individually specified on the annual list of MIPS measures.
- CAHPS for MIPS Survey: For PY 2020 and any subsequent performance year impacted by the COVID PHE, CMS will: 1) add a new measure to assess patient-reported use of telehealth; and 2) count several telehealth services towards beneficiary assignment.

The first criterion for scoring would be that the measures have been topped out for 2 or more periods based on the published 2020 MIPS performance period historical benchmarks (which are based on submissions for the 2018 MIPS performance period). The second criterion would be the measures remain topped out after the 2021 MIPS performance period benchmarks have been calculated. W

# Promoting Interoperability (PI) Category

CMS established a permanent PI performance period of a continuous 90 days up to and including the full calendar year, which aligns with the Medicare PI Program for eligible hospitals and CAHs. The Agency will continue to reweight PI to zero for non-physician ECs who do not report PI data. However, if they choose to report data, they will be scored on PI like all other ECs.

The 2021 PI measure set and applicable point values are summarized in Table 48. CMS will retain Query of Prescription Drug Management Program (PDMP) as an optional measure for PY 2021, but will increase it from 5 to 10 bonus points to reflect its significance. CMS also finalized 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 the new measure, which is worth 40 points and reported via yes/no attestation. Clinicians who report the new 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 in accordance with applicable law and policy." The new measure requires bi-directional engagement for every patient record regardless of referral or transition status. It has no exclusions, exceptions, or partial credit and is equivalent to scoring 100% on both existing measures with a wider scope of eligible cases. However, CMS will use a flexible interpretation and notes that numerous certified health IT capabilities can support bi-directional exchange with a qualifying HIE.
- "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 requirements. Examples include clinicians within a single health
  system, or networks that facilitate sharing between clinicians with the same EHR vendor.
- "I use the functions of CEHRT to support bi-directional exchange with an HIE." Physicians may use 2015 Edition EHRs until August 2, 2022, after which they must use 2015 Edition Cures Update EHRs.

Improvement Activities (IA) Category

CMS modified two IAs and removed one IA because the underlying program *Partner in Patients Hospital Engagement Network* ended in March 2020. 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, clinicians must: (1) Participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. The final inventory of PY 2021 IAs can be found in Appendix 2 of the rule and at this link.

In addition to previously finalized criteria, CMS will consider whether submitted IAs are linked to existing quality and cost measures. Moving forward, stakeholders can nominate IAs for the duration of any PHE, including outside of the standard nomination for new activities timeframe. HHS may also nominate IAs on a rolling basis to address HHS initiatives in an expedited manner.

#### Third Party Vendor Requirements

In an attempt to ensure complete and accurate MIPS data, CMS finalized more robust audit and corrective action plan criteria for all Qualified Clinical Data Registries (QCDRs) and qualified registries. When approving vendor contracts, CMS will also consider whether vendors have given clinicians inaccurate or misleading information about QPP requirements. CMS 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. In its May 8 IFR, CMS delayed both requirements until PY 2022. In response to stakeholder concerns that this may delay development of new measures, CMS finalized a more gradual implementation approach for the first requirement. Specifically, for PY 2022, a QCDR measure must be "face valid." For PY 2023 and future years, a QCDR measure must be face valid for the initial year and fully tested for any subsequent year.

#### **APM Performance Pathway (APP)**

CMS will replace the MIPS APM Scoring Standard with the new APM Performance Pathway (APP) starting in PY 2021. The APP is designed to be an optional pathway that is complementary to the MVP. Under the new APP, data can be reported at the clinician, group, or APM Entity level. The highest available TIN/NPI level score will apply to every clinician that appears on a MIPS APM's Participation List or Affiliated Practitioner List on any of CMS' three "snapshot dates" (March 31, June 30, Aug. 31). The scores for all MIPS ECs in the APM Entity group will then be averaged to calculate the APM Entity level score for each performance category, which are then combined into the total composite score. Category weights under the APP resemble those under the APM Scoring Standard. Cost would be weighted zero percent; PI: 30 percent; IA: 20 percent; and Quality: 50 percent unless reweighting applies. Improvement scores based on past performance will apply.

All clinicians under the APP will be scored on the following six quality measures (if available/applicable):

- Risk-Standardized, All-Cause, Unplanned Admissions for Multiple Chronic Conditions (MCCs) for ACOs (Revised Measure)\*
- Hospital-wide, 30-day, All-cause, Unplanned Readmission Rate for MIPS EC Groups
- CAHPS for MIPS survey (QID #321)

- Diabetes: Hemoglobin A1C Poor Control (QID #001)\*\*
- Screening for Depression and Follow Up Plan (QID #134)\*\*
- Controlling High Blood Pressure (QID #236)\*\*
- \* The finalized MCC measure aligns 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, SNF, or acute rehabilitation facility; and (3) adjusting for the AHRQ SES index and specialist density social risk factors.
- \*\* For 2021 only, in lieu of the three eCQMs, ACOs can chose to report the 10 ACO Web Interface measure set. CMS Web Interface will be removed as an available reporting mechanism in 2022.

All of the quality measures available for reporting through the APP for PY 2021 are summarized in Table 47. Reporters will receive a zero for measures they fail to report. Measures that fail to meet specified patient population or minimum case thresholds will not be counted. Scoring caps for "topped out" measures will not apply, though these measures may be removed in future years.

MIPS APMs will continue to earn automatic IA credit based on the activities inherently performed in the APM. Automatic IA points for each model will be announced prior to each year on the CMS QPP website. In the event that the automatic IA score for a particular model is not the maximum IA score, clinicians can report additional IAs.

For more information on the APP, access this CMS <u>fact sheet</u>.

#### **PY 2021 Advanced APM Changes**

#### **COVID-19 Flexibilities**

Governance structure or operational changes made in direct response to the COVID-19 PHE will not prevent an APM from qualifying as an Advanced APM. If Participation Agreement end dates are moved up in response to the COVID-19 PHE, CMS will not treat this as termination from an Advanced APM and will not revoke Qualified APM Participant (QP) status from any ECs on that basis. Beyond this, most COVID-19-related flexibilities for APMs have been made on a model-by-model basis and are summarized in this <a href="chart">chart</a>. They include a number of delays and adjustments to quality reporting and financial methodologies. 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.

#### Qualified APM Participant (QP) Thresholds

On December 27, 2020, the Consolidated Appropriations Act, 2021 was signed into law. Under this law, the Quality Payment Program's Qualifying Alternative Payment Model (APM) Participant (QP) thresholds for payment years 2023 and 2024 -- performance years 2021 and 2022 -- are frozen at 50% for the payment amount threshold and 35% for the patient count threshold for performance years 2021 and 2022. The partial QP thresholds have also been frozen at the same levels used for the 2022 payment year and 2020 performance year.

#### **QP Threshold**

	Medicare Option	All-Payer Option
	2021 & 2022	2021 & 2022
<b>Payment Count</b>	50%	50% (25%)

# **Partial QP Threshold**

	Medicare Option	All-Payer Option
	2021 & 2022	2021 & 2022
Payment Count	40%	40% (20%)
Patient Count	25%	25% (10%)

<sup>\* (</sup>xx%) denotes required Medicare percentage

#### Advanced APM Incentive Payments

Advanced APM bonus payments are paid out as a lump sum two years following the applicable performance year. CMS clarified that these payments are calculated based on the <u>paid amount</u> (as opposed to the allowed amount) of applicable Medicare Part B covered professional services. CMS also clarified that it excludes certain payments and adjustments, including MIPS payment adjustments, when calculating Advanced APM Incentive Payments.

CMS finalized major changes to its approach for selecting which TINs receive APM Incentive Payments due to clinicians leaving TINs after the performance year. Moving forward, CMS will only make payments to TINs to which qualifying NPIs are actively affiliated at the time APM Incentive Payments are made. While CMS will prioritize TINs through which clinicians earned their QP status during the performance year, if such a TIN is no longer affiliated with the qualifying NPI at the time of payment, CMS will make payments to the clinician's current TIN even if that TIN has no relation to the APM through which clinicians earned their QP status during the performance year or if that TIN has no affiliation to any APM. CMS finalized an eight-step hierarchy for making incentive payments based on varying degrees of APM participation. If multiple TINs are identified at the same step, CMS will divide the payment proportionately based on the relative paid amount for Part B services billed through each TIN.

CMS also finalized a new cutoff date for claiming Advanced APM Incentive Payments. Every year bonuses are paid, CMS will release a list of QPs for which there are no active TINs to render payment (typically in September). The QPs identified in the public notice, as well as any other ECs who believe that they are entitled to an APM Incentive Payment, must notify CMS by Nov. 1, or 60 days after CMS announces Incentive Payments have been issued, whichever is later. After such time, any such payments will be forfeited. Under current statute, Advanced APM Incentive Payments are set to expire at the end of the 2022 performance year (2024 payment year).

# Attribution-Eligible Beneficiaries

To address model overlap issues, beneficiaries who have already been prospectively attributed to one APM Entity for a performance year will now be excluded from the eligible beneficiary denominator count for any other APM Entity for which they would be automatically ineligible. This prevents beneficiaries from improperly diluting an APM Entity's QP threshold score.

#### Target Review Process for QP Determinations

CMS finalized a new 60-day targeted review process solely for cases in which an EC or APM Entity believes 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 within 30 days. If CMS identifies a pattern of error affecting EC(s) not directly involved in the initial review request, CMS will correct any identified errors for all impacted ECs. If CMS determines a clerical error was in fact made, the Agency will assign any impacted ECs the most favorable QP status determined for that APM Entity. CMS will <u>not</u> recalculate QP Threshold Scores for entire APM Entities. This review process will apply to Medicare APMs only and decisions are considered final.

# **Medicare Shared Savings Program (MSSP)**

#### **COVID-19 Flexibilities**

In two separate IFRs, CMS finalized a number of MSSP flexibilities due to COVID-19. Those changes are summarized <a href="https://mex.pubm.new.nih.gov/hee/">here</a>. Among other changes, CMS decided to forego a 2021 MSSP application cycle. However, 160 ACOs whose first or second participation agreements were set to expire Dec. 31, 2020 could extend their agreement periods for an optional fourth performance year, spanning Jan. 1, 2021 to Dec. 31, 2021. CMS adjusted program calculations to remove payment amounts for episodes of care for treatment of COVID-19 not paid under the IPPS and expanded the definition of primary care services for purposes of beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. CMS clarified that the extreme and uncontrollable circumstances policy would apply to mitigate shared losses for months and patients impacted by the COVID-19 PHE starting in January 2020. Accordingly, MSSP ACOs will not owe any shared losses for PY 2020. CMS did not finalize any additional modifications to benchmarking methodologies or ACOs' abilities to switch to a different risk tracks or terminate contracts early in this final rule but says it will continue to closely monitor PY 2020 and 2021 data and will consider additional adjustments in future rulemaking.

# **Quality Reporting Changes**

MSSP ACOs are now required to report through the APP. This will satisfy quality reporting for both MIPS and the MSSP. However, clinicians have the additional option to report as individuals or at the group level for MIPS. Quality scores will be calculated based on MIPS benchmarks, as opposed to MSSP specific benchmarks (unless ACOs opt to report WI measures for 2021 only). Data auditing will also be moved under MIPS.

For PYs 2021 and 2022, to meet the quality performance standard, ACOs must achieve a minimum quality score equal to the 30th percentile across all MIPS Quality performance category scores, excluding facility-based scoring. In PY 2023, this increases to the 40<sup>th</sup> percentile. ACOs that fail to meet the quality performance standard will automatically owe the maximum amount of shared losses. ACOs with higher quality scores will owe a lower amount of losses. ACOs that meet a minimum quality performance standard are eligible to share in the maximum amount of shared savings. Higher quality scores above the standard will not increase the amount of savings they earn. For ACOs in the first performance year of their first agreement period under the MSSP, an ACO will meet the quality performance standard if it fully satisfies reporting criteria under the APP. However, CMS removed the pay-for-reporting year for new and significantly altered quality measures.

If an ACO fails to meet quality performance standards or report on one or more quality measures, CMS may: 1) issue a warning; 2) subject the ACO to a corrective action plan and closely monitor quality performance in future years; 3) consider when approving future agreement periods; 4) depending on the severity, seek immediate termination from the program. Specifically, CMS will terminate an ACO if it fails to meet the quality performance standard for any two consecutive years or any three non-consecutive years within the same 5-year agreement period. This would apply to "re-entering ACOs," e.g. 50% or more of participants were in the same ACO within the last five years. Two-sided ACOs whose participation agreements are terminated by CMS are liable for a pro-rated share of any shared losses.

Under the APP, 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. Under the extreme and uncontrollable circumstances policy, CMS will use the affected ACO's quality score, or the applicable quality performance standard, whichever is higher. CMS will evaluate whether ACOs are eligible for the extreme and uncontrollable circumstances policy based on the quarter four list of assigned beneficiaries (20% or more of beneficiary population must be 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).
- remote evaluation of patient video/images and virtual check-ins (HCPCS codes G2010/ G2012)

CMS will 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 primary care clinician. CMS will also exclude FQHC and RHC services with CPT codes 99304-99318 when there is an overlapping SNF claim. These changes will apply to any relevant assignment windows impacted by the COVID-19 PHE for any past or future performance and benchmark years.

#### Repayment Mechanism Flexibilities

Renewing ACOs that wish to use their existing repayment mechanism for a new agreement period will no longer be required to maintain existing repayment mechanism amounts if higher than the amount for the new agreement period. Renewing ACOs can still elect to switch repayment mechanisms for the new agreement period. In such 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 current agreement period would remain. This policy will also apply to "reentering ACOs" that are the same legal entity and plan to use the former ACO's existing repayment mechanism.

ACOs whose agreement periods began July 1, 2019 or Jan. 1, 2020 have a one-time opportunity to elect to reduce the amount of their repayment mechanisms if they used an existing repayment mechanism, the original amount was greater than the new amount, and the recalculated amount for PY 2021 is less than the existing repayment mechanism amount. CMS will notify applicable ACOs of this opportunity after the start of PY 2021. Interested ACOs should submit such elections along with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS.

### Medicare Diabetes Prevention Program (MDPP) PHE Permanent Exceptions

#### PHE Permanent Exceptions

In the March 31 IFR, CMS permitted certain beneficiaries to obtain MDPP services more than once per lifetime, waived the 5% 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 preserved and refined these flexibilities for the current COVID-19 PHE and applied them to any future emergency events. The flexibilities finalized in this rule (below) supersede any policies previously announced in the March 31 COVID-19 IFR.

- MDPP beneficiaries may elect to receive MDPP services virtually during the PHE <u>or</u> suspend in-person services and resume them at a later date. Beneficiaries who change from in-person to virtual services during an applicable PHE may also continue to receive MDPP services virtually, even after the PHE has concluded. Table 45 in the rule summarizes the full list of MDPP Beneficiary Options during a qualifying emergency event.
- All sessions, including the first core session and those furnished to achieve 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 will not apply during applicable emergency events, so long as virtual services meet all applicable standards.
- MDPP suppliers may 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 (including the first core session); 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 time and date-stamped video or a picture.
- Given these new flexibilities, previously finalized temporary waivers for minimum weight loss requirements will no longer be effective as of Jan. 1, 2021. As of this date, all MDPP beneficiaries are required to achieve and maintain the required 5% weight loss goal to be eligible for ongoing maintenance sessions, even if the COVID-19 PHE remains in place.
- MDPP suppliers may continue in-kind beneficiary engagement incentives provided they have direct contact with the MDPP beneficiary, whether in person, by telephone, or via other telecommunications technology, every 90 consecutive calendar days during the MDPP services period.

• 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 emergency crises end.

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

Code List for Certain Designated Health Services (DHS) for purposes of Stark Law

The updated code list effective Jan. 1, 2021 can be found <a href="here">here</a>. Generally, COVID-19 tests and vaccines are considered designated health services, as they fall within the category of "clinical laboratory services."