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Overview of Selected Provisions of the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2021

On August 17, 2020, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule addressing revisions to payment policies under the Medicare Physician Fee Schedule (PFS) and other policy revisions under Part B for calendar year (CY) 2021 ("Proposed Rule").[1] CMS will accept comments on it until October 5, 2020.

CMS estimates the conversion factor for CY 2021 at 32.2605, reflecting a 10.61% decrease from the CY 2020 conversion factor of 36.0896.[2] The cumulative effect on total Medicare payments to physicians involved in the provision of oncology care, if all of the proposals in the Proposed Rule are finalized, would be:[3]

Specialty	Allowed Charges (Millions)	Combined Impact
Hematology/Oncology	$1,702	14%
Radiation Oncology And Radiation Therapy Centers	$1,803	-6%
Radiology	$5,253	-11%

At the end of this summary, we have provided tables comparing payment rates for certain drug administration and radiation therapy codes from the third quarter 2020 payment rate to the proposed CY 2021 payment rate. The addenda containing payment rates and other information referred to in this summary are available only on the CMS web site at: https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1734-p. In conjunction with the Proposed Rule release, CMS also published a fact sheet, available at: https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-4.

This Summary Addresses the Following Topics in the CY 2021 Proposed Rule:

(1) Determination of Practice Expense (PE) Relative Value Units (RVUs):
   a. Useful life for equipment
   b. Updates to prices for existing direct PE inputs
   c. Solicitation of Comments on Revisions to PE methodology

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[1] 85 Fed. Reg. 50,074. Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule; CMS-1734-P (Aug. 17, 2020), *available at* https://www.govinfo.gov/content/pkg/FR-2020-08-17/pdf/2020-17127.pdf ("Proposed Rule").
[2] *Id.* at 50,373.
[3] *Id.* at 50,375-76.

(2) Telehealth and Other Services Involving Communications Technology
   a. Coding and temporary category additions to Medicare telehealth services list
   b. Telehealth visits in inpatient and nursing facility settings
   c. Communication technology-based services
   d. Direct supervision via telehealth
   e. PFS payment for specimen collection for COVID-19 tests

(3) Care Management Services and Remote Physiologic Monitoring (RPM) Services
   a. RPM services
   b. Transitional Care Management (TCM) services

(4) 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

(5) Scopes of Practice and Related Issues

(6) Valuation of Specific Codes

(7) Clinical Laboratory Fee Schedule (CLFS)

(8) Medicare Shared Savings Program

(9) Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

(10) Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

(11) Removal of Selected National Coverage Determinations (NCDs)

(12) Delay of the Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan

(13) New Medicare Part B Multi-Source Drug Pathway for Drugs Approved Under Section 505(b)(2) of the Federal, Food, Drug and Cosmetic Act (FFDCA)

(14) CY 2021 Updates to the Quality Payment Program
   a. Changes to Merit-Based Incentive Payment System (MIPS) performance category measures and activities
   b. MIPS Value Pathway (MVP) program delay of implementation and other MVP refinements
   c. New Alternative Payment Model (APM) performance pathway

(15) Planned 30-Day Delayed Effective Date for the Final Rule

(16) Collection of Information Requirements

Details about the proposed changes are provided below.

(1) *Determination of Practice Expense Relative Value Units (PE RVUs)*

Medicare PFS payment rates are established based on the relative resource value of services, as estimated based on three categories of relative value units (RVUs): Practice expenses (PE), malpractice insurance, and practitioner work. Each item or service paid under PFS is assigned RVUs based on estimated resource expenditure associated with each applicable RVU category. RVUs then are used as the building blocks to calculate PFS payment rates. CMS periodically updates RVUs based on new information about resource expenditure. In the Proposed Rule, CMS sets out detailed information about its determination of PE RVUs, including updates to prices for certain existing PE inputs, changes and various other proposed changes to CMS's PE methodology. Below we summarize select PE RVU determination policies and proposals contained in the Proposed Rule.

a. Useful life for equipment

CMS proposes to treat equipment with a life duration of less than one year as having a duration of one year for purposes of the PE RVU "equipment price per minute formula,"[4] used as part of estimating practice equipment costs for purposes of determining the amount of PE resources attributable to such costs. CMS relies upon the American Hospital Association's (AMA's) "Estimated Useful Lives of Depreciable Hospital Assets" guidelines to establish the useful life for equipment items for purposes of said formula.[5]

CMS notes that stakeholders, including the RVS Update Committee (RUC), specialty societies, and other commenters had recommended a useful life of less than 1 year for several new equipment items for CY 2021, and as low as three months in one case.[6] CMS declines to endorse or propose changes in line with these requests, however. CMS states that it has rarely, if ever, received requests for PE equipment to be designated with a useful life of less than one year in duration and that it has concerns that very low useful life durations will fail to maintain relativity with other equipment on the PFS.[7] CMS requests comments on useful life durations for new equipment items with unique useful life durations and suggestions on alternative ways to incorporate those items into the methodology for determining equipment cost per minute.

b. Updates to prices for existing direct PE inputs

CMS accepts public submission of invoices as part of its process for developing payment rates for new, revised, and potentially misvalued codes.[8] To be included in a given year's proposed rule, the invoice generally must be received by CMS by February 10th, though CMS considers invoices submitted as public comments during the comment period following the publication of the PFS proposed rule or outside of the public comment process as part of the established annual process for requests to update supply and equipment prices.[9] For CY 2021, CMS proposes to update the prices of six supply and equipment codes (listed in Table 7 of the Proposed Rule) in response to invoices received from stakeholders.[10] Consistent with the policy finalized in CY 2018 to phase in the new supply and equipment pricing over four years, one half of the difference between the CY 2020 price and the final price will be implemented for CY 2021.[11]

c. Solicitation of comments on revisions to PE methodology

In the Proposed Rule, CMS notes that the RAND Corporation is currently studying potential improvements to CMS's PE allocation methodology (and associated data) and

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[4] *Id.* at 50,083. According to CMS, the majority of equipment items have a useful life of between five and 10 years.
[5] *Id.* at 50,082.
[6] *Id.*
[7] *Id.* at 50,083.
[8] *Id.* at 50,090.
[9] *Id.* at 50,091.
[10] *Id.* at 50,090.
[11] *Id.*

has convened a Technical Expert Panel (TEP) to facilitate this evaluation.[12] Based on the results of the TEP and RAND's work, CMS states that it is interested in potentially refining the PE methodology and updating the data used to make payments under the PFS.[13] CMS is considering how best to incorporate market-based information, such as for clinical labor data. CMS requests comment from interested parties on ways to potentially update the PE methodology and underlying inputs and intends to host a Town Hall to provide an open forum for discussion.[14]

(2) *Telehealth and Other Services Involving Communications Technology*

a. *Coding and temporary category additions to Medicare telehealth services list*

CMS proposes to add nine Healthcare Common Procedure Coding System (HCPCS) codes to the Medicare Telehealth Services List on a permanent Category 1 Basis.[15] Among these codes are codes previously added on a temporary basis for the duration of the COVID-19 public health emergency (PHE).[16]

CMS notes that other services added to the Medicare Telehealth Services List on a temporary basis for the duration of the COVID-19 PHE also may be appropriate to add to the list on a permanent basis.[17] CMS acknowledges that codes currently added on an interim basis for the duration of the PHE will *cease* to be eligible for reimbursement when provided via telehealth upon the end of the PHE (unless added permanently), potentially creating difficulties for practitioners.

In addition, CMS proposes to create a new category of telehealth codes to reflect certain codes added to the Medicare Telehealth Services List on a temporary basis that are being considered for being added on a permanent basis.[18]

Currently, CMS adds codes to the Medicare Telehealth Services List under one of two categories: Category 1, for codes sufficiently similar to codes already on this list; and Category 2, for codes not similar to those already on the list but could be furnished via telehealth and where CMS determines that the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient.[19]

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[12] *Id.* at 50,092.
[13] *Id.* at 50,093.
[14] *Id.*
[15] *Id.* at 50,097, tbl.8.
[16] *See* 85 Fed. Reg. 19,230, "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (April 6, 2020), available online at https://www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public; 85 Fed. Reg. 27,550, "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (May 8, 2020), available online at https://www.federalregister.gov/documents/2020/05/08/2020-09608/medicare-and-medicaid-programs-basic-health-program-and-exchanges-additional-policy-and-regulatory.
[17] 85 Fed. Reg. at 50,096.
[18] *Id.* at 50,099.
[19] *Id.* at 50,095.

To address the potential gap in reimbursement upon the end of the COVID-19 PHE, and to allow for the collection of evidence of clinical benefit, CMS proposes to create a new Category 3 for adding services to the Medicare telehealth services list on a temporary basis. Specifically:

- CMS proposes to define Category 3 as services "that were added during the PHE for which there is likely to be a clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria."[20]

- CMS further proposes to add 13 HCPCS codes on a Category 3 temporary basis to the Medicare Telehealth Services List.[21]

- CMS also solicits comments on 60 additional codes it does not propose to keep, on either a permanent Category 1 or temporary Category 3 basis, on the Medicare Telehealth Services List, and which would no longer be eligible for reimbursement when provided via telehealth after the end of the COVID-19 PHE.[22]

CMS's proposed additions to the Medicare Telehealth Services List are summarized in the table below.

Summary of CY 2021 Proposals for Addition of Services to the Medicare Telehealth Services List[23]

Type of Service	Specific Services and Current Procedural Terminology (CPT®)[24] Codes
1. Services CMS is proposing for permanent addition to the Medicare telehealth services list	• Group Psychotherapy (CPT code 90853) • Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99334–99335) • Home Visits, Established Patient (CPT codes 99347– 99348) • Cognitive Assessment and Care Planning Services (CPT code 99483) • Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS code GPC1X) • Prolonged Services (CPT code 99XXX) • Psychological and Neuropsychological Testing (CPT code 96121)
2. Services CMS is proposing as Category 3, temporary additions to the Medicare telehealth services list	• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99336–99337) • Home Visits, Established Patient (CPT codes

[20] *Id.* at 50,099.
[21] *Id.* at 50,101-02, tbl. 10.
[22] *Id.* at 50,104-09, tbl. 11.
[23] *Id.* at 50,110, tbl.12.
[24] CPT Copyright 2019 American Medical Association. All Rights Reserved. CPT® is a registered trademark of the American Medical Association.

Type of Service	Specific Services and Current Procedural Terminology (CPT®)[24] Codes
	99349–99350) • Emergency Department Visits, Levels 1-3 (CPT codes 99281–99283) • Nursing facilities discharge day management (CPT codes 99315–99316) • Psychological and Neuropsychological Testing (CPT codes 96130–96133)
3. Services CMS is *not* proposing to add to the Medicare telehealth services list but is seeking comment on whether they should be added on either a Category 3 basis or permanently.	• Initial nursing facility visits, all levels (Low, Moderate, and High Complexity) (CPT 99304–99306) • Psychological and Neuropsychological Testing (CPT codes 96136–96139) • Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161–97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507) • Initial hospital care and hospital discharge day management (CPT 99221–99223; CPT 99238–99239) • Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT 99468–99472; CPT 99475–99476) • Initial and Continuing Neonatal Intensive Care Services (CPT 99477–99480) • Critical Care Services (CPT 99291-99292) • End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962) • Radiation Treatment Management Services (CPT 77427) • Emergency Department Visits, Levels 4-5 (CPT 99284–99285) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324-99328) • Home Visits, New Patient, all levels (CPT 99341–99345) • Initial and Subsequent Observation and Observation Discharge Day Management (CPT 99217–99220; CPT 99224–99226; CPT 99234–99236)

CMS emphasizes that several of the codes proposed to be added to Category 1 of the Medicare Telehealth Services List related to individuals with cognitive impairment, including codes for the assessment of and care planning for patients with cognitive impairments and for other group therapy services.[25] CMS notes that, once the COVID-19

[25] 85 Fed. Reg. at 50,098.

PHE ends, a patient's home cannot serve as an originating site (i.e., where the patient is located) for purposes of most telehealth services, but the SUPPORT Act has added a provision that allows a patient's home to serve as a Medicare telehealth originating site for purposes of a *substance abuse or a co-occurring mental disorder*, if an individual has a substance use disorder diagnosis.[26]

b. *Telehealth visits in inpatient and nursing facility settings*

CMS seeks comment on whether certain COVID-19 related temporary flexibilities that allow physician and non-physician practitioners (NPPs) to perform required initial and periodic visits for nursing home residents via telehealth should be maintained on a permanent basis after the end of the COVID-19 PHE.[27] CMS also proposes to revise the frequency limitation on provision of subsequent nursing facility care services furnished through telehealth from one visit every 30 days to one visit every three days.[28] CMS seeks comment on whether frequency limitations broadly are burdensome and limit access to necessary care when services are available only through telehealth, and how best to ensure that patients are receiving necessary in-person care.

c. *Communication technology-based services*

CMS proposes to adopt permanently a policy that CMS previously adopted on a temporary, interim final emergency basis for the duration of the COVID-19 PHE and which allows certain communication technology-based services (CTBS) to be billed directly by certain NPPs, including licensed clinical social workers and clinical psychologists, physical therapists (PTs), occupational therapists (OTs), and speech language pathologists (SLPs), when the service furnished falls within the scope of these practitioner's benefit categories.[29] CMS also seeks comment on other benefit categories into which these services fall.

In addition, CMS proposes to create two additional G-codes that can be billed by practitioners who cannot independently bill for E/M services:

- G20X0 (Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment);[30] and

- G20X2 (Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot 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 a service

[26] *Id.*
[27] *Id.* at 50,111.
[28] *Id.*
[29] *Id.* at 50,112.
[30] *Id.*

or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion).[31]

CMS also solicits comments on the following additional topics related to CTBS:

- Whether CMS should develop coding and payment for a telephone-only service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value;[32]

- Whether there are services (such as chronic care management or remote physiologic monitoring) that fall outside the statutory scope of telehealth services where it would be helpful for CMS to clarify that these services are inherently non-face-to-face, and thus 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;[33] and

- Whether there are other 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.[34]

d. Direct supervision via telehealth

CMS proposes to extend a policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology through the later of the end of the calendar year in which the PHE ends or December 31, 2021.[35]

CMS does, however, caution that there may be certain populations that require greater clinical attentiveness and skill than the supervising practitioner could provide via audio/video interactive communications technology—"[f]or example, patients with cognitive impairments or dementia . . . may require the experience and skill of a physically present supervising practitioner" for purposes of specialized testing.[36]

CMS seeks information on whether there should be any additional guardrails or limitations to ensure patient safety/clinical appropriateness and to prevent fraud or inappropriate use under such a policy.

e. PFS payment for specimen collection for COVID-19 tests

CMS solicits comments on whether to extend or make permanent the policy, established currently only for the duration of the COVID-19 PHE, to allow physicians and NPPs to use CPT code 99211 to bill for services furnished incident-to their professional services,

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[31] *Id.*
[32] *Id.* at 50,114.
[33] *Id.*
[34] *Id.*
[35] *Id.* at 50,115.
[36] *Id.* at 50,116.

for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID-19 testing.[37]

(3) *Care Management Services and Remote Physiologic Monitoring (RPM) Services*

a. RPM services

RPM services describe a set of remote services related to monitoring of physiological parameters (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate). Billing and coding of RPM services has been an area of significant confusion since CMS first approved Medicare payment of RPM codes in the CY 2019 and CY 2020 PFS rules. In the Proposed Rule, CMS provides long-awaited guidance on the following RPM codes: CPT codes 99453, 99454, 99091, 99457, and 99458.

Specifically, the Proposed Rule includes a clarification of CMS's interpretation of its existing policies, as well as a handful of new proposed policies. We summarize select and notable clarifications and proposals below:

- CPT codes 99453 and 99454 are PE only codes, meaning that they are valued to include clinical staff time, supplies, and equipment, including the medical device for the typical case of remote monitoring. CPT code 99453 is valued to reflect clinical staff time that includes instructing a patient and/or caregiver about using one or more medical devices, and CPT code 99454 is valued to include the medical device or devices supplied to the patient and the programming of the medical device for repeated monitoring.

- CMS clarifies that the medical device or devices that are supplied to the patient and used to collect physiologic data are considered equipment and are a direct PE input for CPT code 99454.[38]

- CPT codes 99453 and 99454 may only be billed when monitoring occurs over at least 16 days of a 30-day period, and cannot be reported for a patient more than once during a 30-day period. CMS interprets this to mean that when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected.[39]

- The device used to collect the patient's physiologic data for RPM services must be a "medical device" as described in section 201(h) of the Federal, Food, Drug and Cosmetic Act (FFDCA), and CMS further clarifies that the medical device "should digitally (that is, *automatically*) upload patient physiologic data (that is, data are *not* patient self-recorded and/or self-reported).[40] The device must also be reasonable and necessary,[41] and used to collect and transmit reliable and valid physiologic data

[37] *Id.*
[38] *Id.*
[39] *Id.* at 50,118.
[40] *Id.* (emphasis added).
[41] *See* SSA § 1862(a)(1)(A).

that allow understanding of a patient's health status to develop and manage a plan of treatment.[42]

- CPT codes 99453, 99454, 99091, 99457, and 99458 are E/M services that can be ordered and billed only by physicians or NPPs who are eligible to bill Medicare for E/M services.[43]

- CMS provides the following clarifications and new proposals regarding who can provide (as opposed to "bill") RPM services:

  - *CPT codes 99453 and 99454* may be provided by appropriately supervised clinical staff. CMS also *proposes* to "allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing . . . practitioner."[44]

  - *CPT codes 99457 and 99458* may be provided by clinical staff under the general supervision of the physician or NPP.[45]

  - *CPT code 99091* may only be performed by a physician or other qualified health care professional whose scope of practice and Medicare benefit category includes the service and who is authorized to independently bill Medicare for the service.[46]

- CMS clarifies that practitioners may furnish RPM services to remotely collect and analyze physiologic data from patients with acute conditions as well.[47]

- CMS also clarifies that various RPM codes are intended to work in conjunction with one another over the course of an episode of care (rather than being wholly independent). According to CMS, CPT codes 99453 and 99454 describe the practice expense work associated with providing the device to the patient, assisting the patient in setting up the device, and obtaining the physiologic data from the device over the timeframes discussed above. CPT code 99091 describes the analysis and interpretation of the data that is collected and transmitted by the physician or other practitioner after obtaining the physiologic data.[48] Finally, after analyzing and

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[42] 85 Fed. Reg. at 50,118.
[43] *Id.*
[44] *Id.* at 50,119 (emphasis added). Services furnished by auxiliary personnel are billed as incident-to physicians' services and subject to various practitioner supervision (and other) requirements. Historically, outside of the context of COVID-19 PHE, CMS has required incident-to services to be furnished under direct supervision of the billing practitioner (though CMS has temporarily loosened such supervision requirements during the COVID-19 emergency in various circumstances). If adopted, CMS's proposal would loosen the historical incident-to supervision requirements and allow RPM billing services to be furnished by auxiliary personnel under *general* supervision of the billing practitioner, even once the COVID-19 PHE ends.
[45] *Id.* at 50,118-19.
[46] *Id.* at 50,118.
[47] *Id.*
[48] CMS describes CPT code 99091 as a professional work-only code, meaning that there are no direct PE inputs, but this is inconsistent with the information in Addendum B which indicates that there are 0.48 PE

interpreting a patient's remotely collected physiologic data (described by CPT code 99091), CPT codes 99457 and 99458 describe the development of a treatment plan that is informed by the analysis and interpretation of the patient's data.[49]

CMS's interpretation is at least partly inconsistent with the AMA's CPT guidance. The code descriptor for CPT code 99091 which states that CPT code 99091 may not be billed in conjunction with CPT code 99457 or within 30 days of 99457.

- CMS clarifies that RPM services are not considered to be diagnostic tests and therefore cannot be furnished and billed by an Independent Diagnostic Testing Facility (IDTF) on the order of a physician or NPP.[50]

- CMS clarifies that "interactive communication" for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission.[51] The interactive communication must total at least 20 minutes of interactive time with the patient over the course of a calendar month for CPT code 99457 to be reported. Live, face-to-face time with the patient is not required.[52]

CMS proposes to adopt as permanent policy two of the RPM-related temporary emergency flexibilities it previously adopted on an interim final basis in response to the COVID-19 PHE.[53] First, CMS proposes on a permanent basis to allow consent for RPM services to be obtained at the time the RPM services are furnished.[54] Second, as noted above, CMS proposes to allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees, or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.[55]

CMS does *not*, however, propose to extend a COVID-19 related emergency flexibility allowing RPM-services to be furnished to new patients during the COVID-19 PHE. Thus, when the PHE ends, RPM services may be furnished only to an established patient.[56]

Finally, CMS requests 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.[57] As examples, CMS suggests that new codes to describe remote

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RVUs assigned to CPT code 99091. *Id.* The valuation for CPT code 99091 also includes a total time of 40 minutes of physician or NPP work broken down as follows: 5 minutes of preservice work (*e.g.*, chart review); 30 minutes of intra-service work (*e.g.*, data analysis and interpretation, report based upon the physiologic data, and as well as a possible phone call to the patient); and 5 minutes of post-service work (*e.g.*, chart documentation). *Id.*

[49] *Id.* at 50,118-19.
[50] *Id.*
[51] *Id.* at 50,119.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*

monitoring for less than 16 days may be appropriate (*e.g.*, for 8 or more days of remote monitoring within 30 days).[58]

b. Transitional Care Management (TCM) services

CMS proposes to remove 14 actively priced (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM.[59] Nearly all of the codes on the list (which can be found at Table 14 of the Proposed Rule) are related to End Stage Renal Disease (ESRD) services.[60]

(4) <u>*Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient E/M Visits and Promote Payment Stability during the COVID-19 Pandemic*</u>

With respect to the E/M codes, CMS makes a number of proposals, partly in response to ongoing stakeholder feedback over CMS's prior decision to adopt the AMA's updated E/M codes and as part of an effort to revalue codes related to the E/M codes appropriately:

- CMS is "proposing beginning for CY 2021 to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215."[61]
- CMS is proposing to revalue certain office/outpatient services that are similar to E/M visits, including, but not limited to:
  - *Transitional care management (TCM) codes*, for which CMS is "proposing to increase the work RVUs associated with the TCM codes commensurate with the new valuations for the level 4 (CPT code 99214) and level 5 (CPT code 99215) office/outpatient E/M visits for established patients."[62]
  - *CPT code 99483 (assessment and care planning for patients with cognitive impairment)*, for which CMS is "proposing to adjust the work, time, and PE in the form of clinical staff time for CPT code 99483" given that this code is currently undervalued relative to the level 5 new patient E/M codes.[63]
  - *Annual wellness visit (AWV) codes*, which are directly tied to the E/M codes, and for which CMS is "proposing to revise the work, physician time, and direct PE inputs."[64]

    The new proposed valuations for these codes are in Table 19.[65]
  - *Emergency department visit codes,* for which CMS proposes to update the valuations' as relative to the E/M codes based on proposals submitted by the

[58] *Id.* at 50,119-20.
[59] *Id.* at 50,120.
[60] *Id.*
[61] *Id.* at 50,124.
[62] *Id*.
[63] *Id*. at 50,127.
[64] *Id*.
[65] *Id.* at 50,128-31.

American College of Emergency Physicians.[66] The proposed increases in the work RVUs for these codes are in Table 21.[67]

- *Therapy and psychiatric diagnostic evaluations codes*, for which CMS proposes to update the work RVUs to establish a similar increase to that adopted for E/M services, and to increase the work RVUs for behavioral health services as well.[68] All of these increases are in Table 21 of the Proposed Rule.[69]

Finally, CMS is soliciting comment on the definition of HCPCS code GPC1X, which is intended as an add-on code to address "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 condition."[70]

(5) *Scopes of Practice and Related Issues*

CMS seeks comment on whether it should make permanent or, alternatively, extend on a temporary basis (e.g., through December 31, 2021) various policies regarding the scope of practice of teaching physicians, residents, and various types of NPPs that CMS had previously adopted on an interim basis for the duration of the COVID-19 PHE.

With respect to policies related to teaching physicians and residents, CMS requests comment on its proposal to extend the following policies beyond the expiration of the COVID-19 PHE (and potentially permanently):

- *Teaching Physician "Key Portion" Presence via Interactive Technology*. Allowing the requirement for the presence of a teaching physician during the "key portion" of a service furnished with the involvement of a resident to be met using audio/visual real-time communications technology;[71]

- *Teaching Physician Payment for Resident Furnished Telehealth Services Supervised via Interactive Technology*. Allowing payment for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/visual real-time communications technology;[72]

- *Moonlighting for Inpatient Services by Residents.* Allowing separate billing and payment under the PFS for the "moonlightling" services of residents that are not related to their approved graduate medical education programs and that are furnished to inpatients of a hospital in which they have their training program, subject to certain conditions;[73] and

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[66] *Id*. at 50,133.
[67] *Id.* at 50,135-37.
[68] *Id*. at 50,133-34.
[69] *Id.* at 50,135-37.
[70] *Id*. at 50,138.
[71] *Id.* at 50,140.
[72] *Id.* at 50,141-42.
[73] Separate PFS payment for moonlighting residents historically has been limited only to *outpatient* services meeting certain conditions.

- *Resident Furnished E/M Visits*. Allowing all levels of office/outpatient E/M visits to be furnished by a resident and billed by the teaching physician under the primary care exception (including when furnished via telehealth for services also on the list of Medicare telehealth services). Note that CMS specifically asks whether it should extend the policy for all E/M visits or only a subset of the codes added to the primary care exception.[74]

CMS also proposes to extend a series of scope of practice policies relevant to certain other different types of NPPs (and also clarifies certain existing, permanent policies affecting such NPPs):

- *NPP Supervision of Diagnostic Tests*. CMS proposes to make permanent a policy to permit nurse practitioners, clinical nurse specialists, physician assistants, and certified nurse midwives to supervise diagnostic tests.[75]

- *Incident-to Services Performed by Pharmacists.* CMS clarifies that pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit.[76]

- *Maintenance Therapy Services*. CMS proposes to make permanent a policy to allow a PT or OT who establishes a patient's maintenance program to assign the duties to a physical therapist assistant or occupational therapist assistant, as clinically appropriate, to perform maintenance therapy services.[77]

- *Documentation Requirements for Certain Therapy Services.* CMS also clarifies that, although there are currently no documentation requirements that would impact payment for PTs, OTs, or SLPs, the broad policy principle that allows billing clinicians to review and verify documentation added to the medical record for their services by other members of the medical team applies to therapists.

Further, CMS specifically requests comment on whether applicable state laws, scope of practice, and facility policies would permit practitioners to exercise the proposed flexibilities discussed above, and to what extent practitioners would be permitted to exercise these proposed flexibilities, such as for all diagnostic tests or only a subset.[78]

(6) *Valuation of Specific Codes*

CMS proposes updates to RVUs, PE inputs, and other inputs for the following select codes or to maintain existing work RVUs for certain codes that had been nominated for revaluation this year. [79]

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[74] *Id.* at 50,142–46.
[75] *Id.* at 50,146.
[76] *Id.* at 50,146-47.
[77] *Id.* at 50,147.
[78] *Id.* at 50,140.
[79] All comparison references in this section discussing the CY 2020 PFS work RVU levels are based on CMS's CY 2020 PFS final rule July 2020 update.

a. *Fine Needle Aspiration (CPT codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, and 10012)*[80]

While CMS had previously indicated to the AMA that it was open to receiving information suggesting that the Fine Needle Aspiration codes were potentially misvalued, the AMA did not provide such information. As such, CMS is proposing to maintain the same valuation for these codes for CY 2021 as it did for CY 2020.

b. *Tissue Expander Other Than Breast (CPT code 11960)*[81]

CMS is "proposing to maintain the current work RVU of 11.49 supported by a reference code, CPT code 45560 (separate procedure), which has a work RVU of 11.50" instead of adopting the RUC recommended work RVUs.[82] CMS agrees with and proposes the RUC's recommendations of direct PE inputs.

c. *Breast Implant-Expander Placement (CPT codes 11970, 19325, 19340, 19342, and 19357)*[83]

CMS proposes the following work RVUs for the breast implant expander placement codes, disagreeing with the RUC's recommendations:

- CPT code 11970: "[A] a work RVU of 7.49 supported by a reference code CPT code 35701 (*exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian*), which has a work RVU of 7.50." This would decrease the CY 2020 PFS final rule work RVU of 8.01.

- CPT code 19325: "[A] work RVU of 8.12[,] . . . based on the recommended interval of 0.63 additional RVUs above [the] proposed work RVU of 7.49 for CPT code 11970." This would decrease the CY 2020 PFS final rule work RVU of 8.53.

- CPT code 19340: "[A] work RVU of 10.48[,] . . . based on the recommended interval of 2.36 additional RVUs above [the] proposed work RVU of 8.12 for CPT code 19325." This would decrease the CY 2020 PFS final rule work RVU of 13.99.

- CPT code 19342: "[A] work RVU of 10.48[,] . . . based on the recommended interval of 2.36 additional RVUs above [the] proposed work RVU of 8.12 for CPT code 19325." This would decrease the CY 2020 PFS final rule work RVU of 12.63.

- CPT code 19357: "[A] work RVU of 14.84[,] . . . based on the recommended interval of 7.35 additional RVUs above [the] proposed work RVU of 7.49 for CPT code 11970." This would decrease the CY 2020 PFS final rule work RVU of 18.50.

CMS is "proposing the RUC-recommended direct PE inputs for" these codes.

[80] *Id*. at 50,153.
[81] *Id*.
[82] *Id*.
[83] *Id*. at 50,153-54.

d. Breast Implant-Expander Removal (CPT codes 11971, 19328, and 19330)[84]

CMS proposes the following work RVUs for the breast implant expander removal codes, disagreeing with the RUC's recommendations:

- CPT code 11971: "[A] work RVU of 6.50[,] . . . based on the recommended interval of 0.99 RVUs below our proposed work RVU of 7.49 for CPT code 11970." This would reflect increase the CY 2020 PFS final rule work RVU of 3.41.

- CPT code 19328: An "increas[e in] the current work RVU from 6.48 to 6.92 to account for the increases in total and intraservice time" and "based on a reference code, CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*)."

CMS is proposing the RUC-recommended work RVU of 9.00 for CPT code 19330. And CMS is proposing the RUC-recommended direct PE inputs for all of these codes. This would increase the CY 2020 PFS final rule work RVU of 8.54.

e. Modified Radical Mastectomy (CPT code 19307)[85]

CMS is proposing to lower the work RVU to 17.99 for this code, consistent with the RUC recommendation, which is the 25th percentile of the work RVUs in the RUC's survey for this code. This would decrease the CY 2020 PFS final rule work RVU of 18.23. CMS is further proposing to adopt the RUC recommended direct PE inputs.

f. Breast Lift-Reduction (CPT codes 19316 and 19318)[86]

CMS is "proposing the RUC-recommended work RVU of 11.09 for CPT code 19316 (*mastopexy*) and 16.03 for CPT code 19318 (*Breast reduction*)" and the RUC recommendations for direct PE inputs for these codes. This would mean the work RVUs for these two codes are unchanged relative to the CY 2020 PFS final rule.

g. Secondary Breast Mound Procedure (CPT codes 19370, 19371, and 19380)[87]

CMS is proposing, contrary to the RUC's recommendations:

- CPT code 19370: "[T]o maintain the current work RVU of 9.17 based on a supporting reference code, CPT code 28299 (*Correction, hallux valgus (bunionectomy*), with sesamoidectomy, when performed; with double osteotomy, any method), which has a work RVU of 9.29."

- CPT code 19371: To adopt "a work RVU of 9.98[,] . . . based on the recommended interval of 0.81 additional RVUs above [the] proposed work RVU of 9.17 for CPT code 19370." This would decrease the CY 2020 PFS final rule work RVU of 10.62.

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[84] *Id*. at 50,154.
[85] *Id*.
[86] *Id*.
[87] *Id*. at 50,154-55.

- CPT code 19380: To adopt "a work RVU of 11.17 for CPT code 19380, based on the recommended interval of 1.19 additional RVUs above [the] proposed work RVU of 9.98 for CPT code 19371." This would increase the CY 2020 PFS final rule work RVU of 10.41.

CMS is proposing the RUC recommended direct PE inputs for all of these codes.

h. Lung Biopsy-CT Guidance Bundle (CPT code 324X0)[88]

The CPT Editorial Panel has deleted CPT code 32405 (*Biopsy, lung or mediastinum, percutaneous needle*)" and replaced it with "324X0 (*Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed*)." CMS disagrees with the RUC's recommended work RVUs for this new code, however, and is "proposing a work RVU of 3.18, which is the sum of the work RVUs of" CPT codes 32405 and 77012 (Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation). CMS is proposing the RUC-recommended direct-PE inputs for this code.

i. Esophagogastroduodenoscopy (EGD) with Biopsy (CPT code 43239)[89]

CMS is proposing to maintain the existing work RVU for this code of 2.39, consistent with the RUC recommendations, and to adopt the RUC recommended direct PE inputs. This means the work RVU for this code is unchanged relative to the CY 2020 PFS final rule.

j. Colonoscopy (CPT code 45385)[90]

CMS is proposing a work RVU of 4.57 and direct PE inputs consistent with the RUC recommendations for this code. This means the work RVU for this code is unchanged relative to the CY 2020 PFS final rule.

k. CT Head-Brain (CPT codes 70450, 70460, and 70470)[91]

CMS is "proposing the RUC recommendation to maintain the current work RVUs of 0.85, 1.13, and 1.27 for CPT codes 70450, 70460, and 70470, respectively." CMS is also proposing the RUC recommended direct PE inputs for these codes.

l. Radiation Treatment Delivery (CPT code 77401)[92]

CPT code 77401 is a PE input only code, and so CMS has no proposals with respect to work RVUs. With respect to those PE refinements, CMS is proposing:

- "[A] reduction of 2 minutes for the clinical labor task CA024: "Clean room/equipment by clinical staff," to the standard 3 minutes" and

[88] *Id*. at 50,156.
[89] *Id*. at 50,158.
[90] *Id*.
[91] *Id*. at 50,159-60.
[92] *Id*. at 50,162.

- Not to include "new equipment item ER119 'Lead Room,'" in these inputs due to a lack of information.

m. Proton Beam Treatment Delivery (CPT codes 77520, 77522, 77523, and 77525)[93]

While this family of codes has typically been contractor priced, the RUC has recently determined to survey these codes for PE inputs. Valuing these inputs is challenging because of the high cost of some items of equipment in these codes and because many invoices for this equipment include constructions costs related to that equipment, which CMS does not consider direct PE that should be attributed to individual patients. CMS is therefore proposing to retain contractor pricing for these codes and notes that if it were to value these codes, construction costs would need to be removed from invoices.

n. Chronic Care Management Services (CPT code 994XX and HCPCS code G2058)[94]

CMS is "proposing the RUC-recommended work RVU of 0.54 and the RUC recommended direct PE inputs for CPT code 994XX." CMS also notes that this family of codes is up for resurvey by the RUC in CY 2020 as part of the CY 2022 RUC review process and therefore updated values may be adopted in future rulemakings

(7) Clinical Laboratory Fee Schedule (CLFS)

CMS proposes to revise the definitions of "data collection period" to be January 1, 2019 through June 30, 2019 and "data reporting period" to be January 1, 2022 through March 31, 2022, consistent with revisions made by section 3718 of the CARES Act.[95] CMS also proposes to extend the phase-in of payment reductions resulting from private payor rate implementation by an additional year (through CY 2024) and to specify that for CY 2021, the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020.[96]

CMS also solicits comment on payment for specimen collection for COVID-19 clinical diagnostic tests after the PHE is over. As explained by CMS, in the "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" interim final with comment period (85 Fed. Reg. 19256-19258), CMS established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID-19 clinical diagnostic laboratory testing for homebound and non-hospital patients.[97] CMS established two level II HCPCS codes to report these services—Code G2023 and G2024. CMS requests comment on whether it should delete these HPCS codes once the COVID-19 PHE ends and why these codes and their corresponding payment amounts (which are higher than the nominal fees for specimen collection for other conditions) would be necessary or useful outside of the context of the PHE.[98]

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[93] *Id*.
[94] *Id*. at 50,168.
[95] *Id.* at 50,210.
[96] *Id.*
[97] *Id.* at 50,211.
[98] *Id.*

(8) *Medicare Shared Savings Program*

Starting with the CY 2021 performance year, CMS proposes various changes to the Medicare Shared Savings Program (MSSP), including changes to the quality performance standard and quality reporting requirements for Accountable Care Organizations (ACOs) participating in the MSSP. The changes are intended to better align the MSSP with Meaningful Measures, reduce reporting burden, and focus on patient outcomes.

Among other things, CMS proposes to modify its approach to ACO MSSP quality performance by adopting the Alternative Payment Model (APM) Performance Pathway (APP) to MSSP ACOs (which would reduce the ACO quality measure set from 23 to 6 measures); revising certain aspects of the MSSP quality performance standard methodology, monitoring policies, quality data reporting validation processes; updating the extreme and uncontrollable circumstances policy as it relates to quality performance; and revising its policy for determining the amount of repayment mechanism arrangements for certain ACOs renewing to continue their participation under a two-sided model.

CMS also proposes to update the definition of "primary care services" (used for beneficiary assignment) to add the following services:

- Online digital evaluation and management CPT codes 99421, 99422, and 99423;
- Assessment of and care planning for patients with cognitive impairment CPT code 99483;
- Chronic care management code CPT code 99491;
- Non-complex chronic care management HCPCS code G2058 and its proposed replacement CPT code, if finalized through the CY 2021 PFS rulemaking;
- Principal care management HCPCS codes G2064 and G2065; and
- Psychiatric collaborative care model HCPCS code GCOL1.

(9) *Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services*

Section 5102 of the 21st Century Cures Act establishes a new Medicare Part B benefit category for home infusion therapy-associated professional services, effective January 1, 2021. To be eligible for coverage and payment under the new benefit, section 5102 also requires the physician who establishes the plan of care to provide notification to the patient of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy.

In the CY 2020 PFS final rule, CMS solicited comments on the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment options available to their patient for infusion therapy prior to establishing a home infusion therapy plan of care.

At this time, CMS does not propose to create a mandatory form of notification or to require a specific manner or frequency of notification of available options, because CMS understands that physicians routinely discuss infusion therapy options with their patients and annotate

these discussions in their patients' medical records.[99] CMS notes it may consider additional requirements in future rulemaking if current practice is later found to be insufficient in providing appropriate notification to patients of their available infusion options.

(10) *Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020*

For performance year 2020, all ACOs are considered to be affected by the COVID-19 PHE, and the MSSP extreme and uncontrollable circumstances policy applies. For performance year 2020 only, CMS proposes to waive the requirement that ACOs administer a Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey and proposes that ACOs would receive automatic full credit for the patient experience of care measures. The proposal would have retroactive effect for performance year 2020.[100]

(11) *Removal of Selected National Coverage Determinations (NCDs)*

CMS proposes to remove nine NCDs (listed below and in Table 37 of the Proposed Rule) effective January 1, 2021, based on CMS's existing policy and administrative process for reviewing and potentially removing NCDs older than years.[101]

TABLE 37: Proposed NCDs for Removal

NCD Manual Citation	Name of NCD
20.5	Extracorporeal Immunoadsorption (ECI) using Protein A Columns (01/01/2001)
30.4	Electrosleep Therapy
100.9	Implantation of Gastroesophageal Reflux Device (06/22/1987)
110.14	Apheresis (Therapeutic Pheresis) (7/30/1992)
110.19	Abarelix for the Treatment of Prostate Cancer (3/15/2005)
190.1	Histocompatability Testing
190.3	Cytogenetic Studies (7/16/1998)
220.2.1	Magnetic Resonance Spectroscopy (09/10/2004)
220.6.16	FDG PET for Inflammation and Infection (03/19/2008)

CMS also solicits comment on modifications that could be made to the expedited administrative process for removal of NCDs, and specifically whether the time-based threshold of "older" (which is currently designated as 10 years), continues to be appropriate or whether a shorter period of time or some other threshold criterion unrelated to time is more appropriate.[102]

(12) *Delay of the Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan*

Beginning on January 1, 2021, section 2003 of the SUPPORT Act generally mandates that Schedule II, III, IV, or V controlled substances prescribed under Medicare Part D be done electronically in accordance with an electronic prescription drug program, unless the agency specifies an exception to this effective date.[103]

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[99] *Id.* at 50,252.
[100] *Id.*
[101] *Id.* at 50,255.
[102] *Id.*
[103] *Id.* at 50,260.

In the Proposed Rule, CMS encourages regulated entities to begin conducting EPCS as soon as is feasible in light of the benefits of EPCS and the SUPPORT Act mandate for a January 1, 2021 implementation. In light of the COVID-19 PHE, however, CMS proposes to revise its regulations to require the EPCS requirement to apply starting *January 1, 2022* (absent the application of an applicable exception).[104] CMS also solicits comments on whether its proposed January 1, 2022 deadline is feasible.

CMS also notes that it has authority to waive EPCS requirements, as well as to enforce and specify appropriate penalties for non-compliance with EPCS.[105] CMS requests feedback on the appropriate waivers and whether CMS should impose penalties for noncompliance with the EPCS mandate, and what should be the penalties. CMS indicates that it is planning to use such feedback in a future standalone rulemaking and does not put forward a specific proposal with respect to waivers or penalties.[106]

(13) *New Medicare Part B Multi-Source Drug Pathway for Drugs Approved Under Section 505(b)(2) of the FFDCA*

CMS proposes to adopt in regulation a policy of treating certain drugs approved by the FDA under the section 505(b)(2) pathway as multiple source drugs for purposes of Medicare Part B billing and payment.[107] CMS states that its proposed codification memorializes a policy that (purportedly) has been in effect for at least 12 years.[108]

Under CMS's proposed policy, drugs approved by FDA under the section 505(b)(2) pathway would be billed to and paid by Medicare Part B as multiple source drugs, based on an evaluation of:

- Whether an existing multiple source drug code descriptor describes the section 505(b)(2) drug product, assessed based on:
  - The active ingredient and drug name of the section 505(b)(2) drug product and other drug products paid under the existing multiple source drug code, and
  - The drug description and indications, particularly whether differences such as the salt form, additional ingredients, or uses exist;[109]
- A comparison of the labeling information (and if necessary certain other material) of the section 505(b)(2) drug product and other drugs paid under the existing multiple source drug code;[110] and
- The dosage and administration, pharmacokinetics, indications, contraindications, warnings, drug interactions, and adverse reactions.[111]

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[104] *Id.* at 50,261.
[105] The SUPPORT Act lists circumstances under which the Secretary may waive the EPCS requirements. *See id.* at 50,260 (listing such circumstances).
[106] *Id.* at 50,261.
[107] *Id.* at 50,264-65.
[108] *Id.* at 50,264.
[109] *See id.* at 50,263.
[110] *Id.* at 50,263-64 (CMS indicates it will especially focus on especially pharmacokinetics, indications, adverse reactions, drug interactions, contraindications, warnings, precautions and clinical studies).

In other words, under CMS's proposal, a section 505(b)(2) drug product would be billed and paid as a multiple source drug if CMS determines an existing multiple source code descriptor describes the section 505(b)(2) drug product, the active ingredient(s) correspond to one another, the section 505(b)(2) product's labeling (especially its prescribing information) includes information from other drug products that are paid under the multiple source drug code, and the section 505(b)(2) drug product can be used and prescribed in a manner similar to other products in the multiple source drug code.[112] If the criteria are not satisfied, the section 505(b)(2) drug product would be billed and paid as a single source drug.

Although framed as a continuation of an existing (seemingly, unwritten) policy, CMS's proposal is notable because the agency is effectively proposing to treat section 505(b)(2) drug products as "multiple source drugs" even if the drug is *not* rated as therapeutically equivalent (or bioequivalent or pharmaceutically equivalent) to another drug. As CMS itself acknowledges, the definition of "multiple source drug" at section 1847A of the Social Security Act states that "multiple source drug means, for a calendar quarter, a drug for which there are two or more drug products *which are rated as therapeutically equivalen*t *(under FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"); are pharmaceutically equivalent and bioequivalent*, as determined by the FDA; and are sold or marketed in the United States during the quarter."[113]

In the Proposed Rule, CMS defends its interpretation by asserting that it can interpret the definition of multiple source drug to be satisfied "once there are two or more drug products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent, and CMS has assigned them to a multiple source drug code," even with respect to "a subsequent product" if CMS believes that the subsequent product is effectively the same drug, and *even if* the subsequent product is not actually designated as therapeutically equivalent, bioequivalent, or pharmaceutically equivalent.[114]

CMS's proposal is likely to be highly controversial both as a matter of legal interpretation and as a policy matter. Among other things, finalization of CMS's proposal could open the door to significant changes in how payment rates are calculated and drug codes are assigned.

(14) *CY 2021 Updates to the Quality Payment Program*

CMS's Proposed Rule includes numerous proposed updates to the Quality Payment Program, including (but not limited to) a large number of proposed revisions to Merit-Based Incentive Payment System (MIPS) and associated measures. We have summarized in brief highlights from CMS's Proposed Rule related to Quality Payment Program.

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a. Changes to MIPS performance category measures and activities

CMS proposes a variety of changes related to MIPS. Among various other changes, CMS proposes to weight the MIPS quality performance category at 40 percent for the

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[111] *Id.* at 50,264.
[112] *Id.* at 50,262.
[113] *Id.* at 50,263 (emphasis added)
[114] *Id.*

2023 MIPS payment year (and 30 percent for the 2024 MIPS payment year);[115] sunset certain CMS web interface measures for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period;[116] and proposes a series of changes to its MIPS quality measures:[117]

- *Removal of existing measures*

  CMS proposes to remove the following existing measures in the 2023 MIPS payment year and future years.

  - Hematology: Multiple Myeloma: Treatment with Bisphosphonates,[118]
  - Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms,[119]
  - Opioid Therapy Follow-up Evaluation,[120]
  - Documentation of Signed Opioid Treatment Agreement,[121] and
  - Evaluation or Interview for Risk of Opioid Misuse.[122]

- *Added new measures*

  CMS proposes to add the following new measures in the 2023 MIPS payment year and future years.

  - Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the MIPS Groups,[123] and
  - Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA).[124]

In addition to the measures noted above, CMS proposes a series of changes to numerous existing quality measures.[125] Among other things, CMS proposes modifications to various aspects of 112 existing quality measures. Many of these refinements are highly granular or technical (e.g., changing measure descriptions slightly, altering technical aspects of measure methodologies, etc.). That said, a wide range of clinical areas are affected—including oncology, ophthalmology, radiology, opioids, mental health. Some examples of the proposed changes include:

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[115] CMS further proposes to weight the cost performance category at 20 percent for MIPS payment year 2023 (and 30 percent for MIPS payment year 2024). *Id.* at 50,293.
[116] *Id.* at 50,290.
[117] *Id.* at 50,288.
[118] *Id.* at 50,581.
[119] *Id.* at 50,582.
[120] *Id.* at 50,583-84.
[121] *Id.* at 50,584.
[122] *Id.*
[123] *Id.* at 50,413.
[124] *Id.* at 50,414.
[125] *See also id.* at 50,586-663, tbl. D (proposing various substantive changes to aspects of assorted existing quality measures, such as proposed revisions to activity descriptions, measure updates to align with other MIPS measures, etc.). CMS also proposes extensive revisions to its specialty measure sets for the 2023 MIPS payment year (and future years) including moving measures from some specialty sets to other specialty sets (or adding/removing measures to various specialty sets). *See id.* at 50,145-580, tbl. B.

- Proposing to change the cervical cancer screening measure[126] to, among other things, revise the description to state that the measure evaluates women aged 21 to 64 who have cervical cytology performed "within" the last years or women aged 30 to 64 who had cervical HPV testing performed "within" the last 5 years (rather than being tied to whether testing is performed "every" 3 or 5 years, respectively); to amend the numerator of the measure to make conforming changes related to the change to the measure description; and to make various other changes to associated guidance and measure logic definitions.[127]

- Proposing to change the dementia education and support of caregivers for patients with dementia measure[128] to add telehealth as an eligible encounter and to update the denominator of the measure to create exceptions for certain enumerated circumstances where the patient does not have a caregiver.[129]

A selected list of measures that are proposed to be modified is at Appendix I of this summary.

b. *MIPS Value Pathway (MVP) program delay of implementation and other MVP refinements*

CMS proposes refinements to its yet-to-be-implemented MVP, a revised MIPS framework that is intended to "mov[e] away from siloed performance category activities and measures and […] towards set of measure options more relevant to a clinician's scope of practice that is meaningful to patient care."[130]

The MVP framework was previously scheduled to begin in the 2021 performance period. But, in the Proposed Rule, CMS proposes to *delay* MVP implementation in light of the COVID-19 PHE. CMS indicates that it will decide on an MVP implementation date in a future rulemaking, and that it will "possibly" begin with the 2022 performance period.[131]

CMS also proposes various revisions to its MVP methodology. For example, CMS proposes refinements to its "guiding principles" for MVPs, including proposing to add a fifth guiding principle, which is proposed to be that "MVPs should support the transition to digital quality measures."[132] In addition, CMS proposes various refinements to the criteria

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[126] This measure currently describes the percentage of women 21 to 64 years of age who were screened for cervical cancer using either of the following criteria: (1) women age 21 to 64 who had cervical cytology performed every 3 years or (2) women age 30 to 64 years who had cervical cytology/HPV co-testing performed every 5 years.
[127] *Id.* at 50,586-663, tbl. D (D.63).
[128] This measure currently describes the percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
[129] *Id.* at 50,586-663, tbl. D (D.58).
[130] CMS, MVP Overview Fact Sheet (2019), *available at* https://qpp-cm-prod-content.s3.amazonaws.com/uploads/623/MVPs%20Overview%20Fact%20Sheet.pdf.
[131] 85 Fed. Reg. at 50,285.
[132] *Id.* at 50,281.

CMS will use when developing MVPs, such as requiring MVPs to include measures and activities from the Quality, Cost, and Improvement Activities performance categories.[133]

c. *New Alternative Payment Model (APM) performance pathway*

CMS proposes to amend its regulations to establish a new and voluntary APM performance pathway (APP) under MIPS beginning effective January 1, 2021. Under CMS's proposal, MIPS eligible clinicians may elect to report through the APP at the individual level. Groups and APM entities may also report on behalf of their MIPS eligible clinicians, but the final score earned by the group through the APP would be applied only to those MIPS eligible clinicians who appear on an applicable MIPS APM's Participation List or Affiliated Practitioner List.[134]

CMS also proposes a series of revisions to its regulations to implement its proposed APP, including revisions to the definition of MIPS APMs,[135] rules and criteria for quality performance category scoring,[136] APP performance category weights[137] (and reweighting criteria),[138] and various other procedural elements.

(15) Planned 30-Day Delayed Effective Date for the Final Rule

CMS anticipates that it will rely on its authority under 5 U.S.C. § 808(2) to waive the Congressional Review Act's (CRA's) requirement that there ordinarily be a 60-day delay after publication before a new major rule can take effect. CMS expects the PFS Final Rule instead to take effect 30 days after publication.[139] CMS states that there is good cause to waive the CRA's 60-day delay in effective date due to CMS prioritizing efforts in support of containing and combatting the COVID-19 PHE.[140] This means that the Final Rule may not be published until December 1, 2020.

(16) Collection of Information Requirements

Consistent with the requirements of the Paperwork Reduction Act of 1995 (PRA), CMS requests public comments regarding the following issues for certain proposed information collection requests (ICRs): (1) the need for information collection and its usefulness in carrying out CMS's proper functions; (2) the accuracy of CMS's published burden estimates; (3) the quality, utility, and clarity of the information to be collected; and (4) CMS's effort to

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[133] *See id.* at 50,282 (also enumerating various other proposed criteria across a range of metrics, like appropriateness, comprehensibility, and incorporation of the patient voice).
[134] *Id.* at 50,285.
[135] *Id.* at 50,285-86.
[136] *Id.* at 50,286.
[137] *Id.* at 50,287-88.
[138] *Id.* at 50,288.
[139] Separate from the CRA's requirement that major rules be delayed for 60-days after publication (absent good cause), the Administrative Procedure Act (APA) requires a 30-day delay in effective date for new substantive rule (absent good cause). Although CMS's proposes to waive the CRA's 60-day delay in effective date, CMS does *not* propose to waive the APA's 30-day delay in effective date.
[140] *Id.* at 50,336-37.

minimize the information collection burden on the affected public, including the use of automated collection techniques.[141]

In particular, CMS seeks comment on these issues and its proposed burden estimates in connection with the following proposals (summarized in more detail above):

- *OTP Enrollment Process.* CMS currently estimates a total annual increased burden would be 533 hours at a cost of $23,639 for CMS-855A applications and CMS-855B application would have a reduction in annual burden of 64 hours and $2,866.

- *Quality Payment Program.* CMS currently estimates that the proposed policies with respect to MIPS and Advanced APMs will result in a net decrease in burden of 5,488 hours and $488,115.[142]

- *505(b)(2) Pathway*. CMS states that its proposal is a continuation of “what we have characterized as longstanding policy,” and says that finalization will mean that “savings will continue” based upon said policy.[143] CMS says it is not able to provide a detailed estimate on potential continued savings—but the agency states that its rough estimate is that, over 10 years, the combined effect of not finalizing its proposed policy for 5 to 10 or more additional section 505(b)(2) drug products each year could result in “over $1 billion in additional Part B spending.”[144]

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[141] *Id.* at 50,337.
[142] *Id.* at 50,341.
[143] *Id.* at 50,381.
[144] *Id.*

Comparison of 2021 Proposed Rule and Q3 2020 Physician Fee Schedule Payment Rates for Drug Administration Services

CPT Code	Description	CY 2021 Proposed Payment		Q3 CY 2020 Payment		% Change	
		Non Facility	Facility	Non Facility	Facility	Non Facility	Facility
96360	Hydration iv infusion init	35.49	N/A	34.65	N/A	2.43%	N/A
96361	Hydrate iv infusion add-on	13.55	N/A	13.71	N/A	-1.20%	N/A
96365	Ther/proph/diag iv inf init	72.26	N/A	72.18	N/A	0.12%	N/A
96366	Ther/proph/diag iv inf addon	21.61	N/A	22.01	N/A	-1.82%	N/A
96367	Tx/proph/dg addl seq iv inf	31.62	N/A	31.40	N/A	0.69%	N/A
96368	Ther/diag concurrent inf	20.65	N/A	21.29	N/A	-3.03%	N/A
96369	Sc ther infusion up to 1 hr	156.46	N/A	162.04	N/A	-3.44%	N/A
96370	Sc ther infusion addl hr	14.84	N/A	15.52	N/A	-4.37%	N/A
96371	Sc ther infusion reset pump	65.49	N/A	64.60	N/A	1.38%	N/A
96372	Ther/proph/diag inj sc/im	13.55	N/A	14.44	N/A	-6.14%	N/A
96373	Ther/proph/diag inj ia	17.74	N/A	18.77	N/A	-5.45%	N/A
96374	Ther/proph/diag inj iv push	40.65	N/A	40.06	N/A	1.47%	N/A
96375	Tx/pro/dx inj new drug addon	16.78	N/A	16.60	N/A	1.05%	N/A
96376	Tx/pro/dx inj same drug adon	0.00	0.00	0.00	0.00		N/A
96379	Ther/prop/diag inj/inf proc	0.00	0.00	0.00	0.00		N/A
96401	Chemo anti-neopl sq/im	81.30	N/A	80.12	N/A	1.47%	N/A
96402	Chemo hormon antineopl sq/im	32.26	N/A	32.12	N/A	0.44%	N/A
96405	Chemo intralesional up to 7	82.26	26.78	84.81	30.32	-3.00%	-11.67%
96406	Chemo intralesional over 7	129.36	42.58	130.28	47.28	-0.71%	-9.93%
96409	Chemo iv push sngl drug	112.59	N/A	110.07	N/A	2.29%	N/A
96411	Chemo iv push addl drug	60.97	N/A	59.91	N/A	1.78%	N/A
96413	Chemo iv infusion 1 hr	146.14	N/A	142.55	N/A	2.52%	N/A
96415	Chemo iv infusion addl hr	30.65	N/A	30.68	N/A	-0.09%	N/A
96416	Chemo prolong infuse w/pump	145.17	N/A	142.55	N/A	1.84%	N/A
96417	Chemo iv infus each addl seq	70.65	N/A	69.29	N/A	1.96%	N/A
96420	Chemo ia push tecnique	115.17	N/A	105.74	N/A	8.92%	N/A
96422	Chemo ia infusion up to 1 hr	178.08	N/A	173.59	N/A	2.58%	N/A
96423	Chemo ia infuse each addl hr	82.26	N/A	80.48	N/A	2.22%	N/A
96425	Chemotherapy infusion method	190.34	N/A	184.06	N/A	3.41%	N/A
96440	Chemotherapy intracavitary	937.81	117.11	910.90	128.84	2.95%	-9.11%
96446	Chemotx admn prtl cavity	209.69	24.84	204.99	26.35	2.29%	-5.71%
96450	Chemotherapy into cns	171.95	72.91	183.34	81.56	-6.21%	-10.61%
96521	Refill/maint portable pump	147.75	N/A	149.05	N/A	-0.87%	N/A
96522	Refill/maint pump/resvr syst	127.75	N/A	124.51	N/A	2.60%	N/A
96523	Irrig drug delivery device	28.71	N/A	28.15	N/A	2.00%	N/A
96542	Chemotherapy injection	137.43	40.33	134.25	43.67	2.37%	-7.65%

Comparison of 2021 Proposed Rule and Q3 2020 Physician Fee Schedule Payment Rates for Radiation Therapy Services

CPT Code	Mod	Short Description	CY 2021 Proposed Payment		Q3 CY 2020 Payment		% Change	
			Non Facility	Facility	Non Facility	Facility	Non Facility	Facility
76873		Echograp trans r pros study	$171.63	N/A	$179.00	N/A	-4.12%	N/A
76873	TC	Echograp trans r pros study	$99.68	N/A	$98.89	N/A	0.81%	N/A
76873	26	Echograp trans r pros study	$71.94	$71.94	$80.12	$80.12	-10.21%	-10.21%
77280		Set radiation therapy field	$272.92	N/A	$283.30	N/A	-3.66%	N/A
77280	TC	Set radiation therapy field	$238.08	N/A	$244.69	N/A	-2.70%	N/A
77280	26	Set radiation therapy field	$34.84	$34.84	$38.62	$38.62	-9.77%	-9.77%
77285		Set radiation therapy field	$452.29	N/A	$474.58	N/A	-4.70%	N/A
77285	TC	Set radiation therapy field	$399.71	N/A	$415.03	N/A	-3.69%	N/A
77285	26	Set radiation therapy field	$52.58	$52.58	$59.55	$59.55	-11.69%	-11.69%
77290		Set radiation therapy field	$472.94	N/A	$508.14	N/A	-6.93%	N/A
77290	TC	Set radiation therapy field	$396.80	N/A	$422.97	N/A	-6.19%	N/A
77290	26	Set radiation therapy field	$76.13	$76.13	$85.17	$85.17	-10.61%	-10.61%
77295		3-d radiotherapy plan	$458.42	N/A	$498.04	N/A	-7.95%	N/A
77295	TC	3-d radiotherapy plan	$251.31	N/A	$265.62	N/A	-5.39%	N/A
77295	26	3-d radiotherapy plan	$207.11	$207.11	$232.42	$232.42	-10.89%	-10.89%
77300		Radiation therapy dose plan	$62.59	N/A	$67.85	N/A	-7.76%	N/A
77300	TC	Radiation therapy dose plan	$32.58	N/A	$34.29	N/A	-4.96%	N/A
77300	26	Radiation therapy dose plan	$30.00	$30.00	$33.56	$33.56	-10.61%	-10.61%
77301		Radiotherapy dose plan imrt	$1,819.49	N/A	$1,949.20	N/A	-6.65%	N/A
77301	TC	Radiotherapy dose plan imrt	$1,432.37	N/A	$1,516.48	N/A	-5.55%	N/A
77301	26	Radiotherapy dose plan imrt	$387.13	$387.13	$432.71	$432.71	-10.54%	-10.54%
77321		Special teletx port plan	$89.04	N/A	$96.72	N/A	-7.94%	N/A
77321	TC	Special teletx port plan	$42.91	N/A	$44.39	N/A	-3.34%	N/A
77321	26	Special teletx port plan	$46.13	$46.13	$52.33	$52.33	-11.84%	-11.84%
77331		Special radiation dosimetry	$60.33	N/A	$66.40	N/A	-9.15%	N/A
77331	TC	Special radiation dosimetry	$18.39	N/A	$19.13	N/A	-3.86%	N/A
77331	26	Special radiation dosimetry	$41.94	$41.94	$47.28	$47.28	-11.29%	-11.29%
77332		Radiation treatment aid(s)	$39.04	N/A	$48.36	N/A	-19.28%	N/A
77332	TC	Radiation treatment aid(s)	$17.10	N/A	$23.82	N/A	-28.22%	N/A
77332	26	Radiation treatment aid(s)	$21.94	$21.94	$24.54	$24.54	-10.61%	-10.61%
77333		Radiation treatment aid(s)	$126.78	N/A	$123.07	N/A	3.02%	N/A
77333	TC	Radiation treatment aid(s)	$90.33	N/A	$82.28	N/A	9.78%	N/A
77333	26	Radiation treatment aid(s)	$36.45	$36.45	$40.78	$40.78	-10.61%	-10.61%
77334		Radiation treatment aid(s)	$119.36	N/A	$130.28	N/A	-8.38%	N/A
77334	TC	Radiation treatment aid(s)	$63.88	N/A	$67.49	N/A	-5.35%	N/A
77334	26	Radiation treatment aid(s)	$55.49	$55.49	$62.80	$62.80	-11.64%	-11.64%
77336		Radiation physics consult	$78.72	N/A	$81.20	N/A	-3.06%	N/A
77338		Design mlc device for imrt	$448.10	N/A	$497.31	N/A	-9.90%	N/A
77338	TC	Design mlc device for imrt	$240.99	N/A	$264.90	N/A	-9.03%	N/A
77338	26	Design mlc device for imrt	$207.11	$207.11	$232.42	$232.42	-10.89%	-10.89%
77370		Radiation physics consult	$123.24	N/A	$126.67	N/A	-2.72%	N/A
77371		Srs multisource	$0.00	$0.00	$0.00	$0.00	N/A	N/A

CPT Code	Mod	Short Description	CY 2021 Proposed Payment Non Facility	CY 2021 Proposed Payment Facility	Q3 CY 2020 Payment Non Facility	Q3 CY 2020 Payment Facility	% Change Non Facility	% Change Facility
77372		Srs linear based	$1,017.50	N/A	$1,069.33	N/A	-4.85%	N/A
77373		Sbrt delivery	$1,110.41	N/A	$1,230.66	N/A	-9.77%	N/A
77401		Apply intrcav radiat simple	$41.62	N/A	$24.90	N/A	67.12%	N/A
77470		Apply intrcav radiat simple	$123.56	N/A	$136.78	N/A	-9.67%	N/A
77470	TC	Apply intrcav radiat interm	$24.84	N/A	$25.98	N/A	-4.40%	N/A
77470	26	Apply intrcav radiat interm	$98.72	$98.72	$110.80	$110.80	-10.90%	-10.90%
77520		Apply intrcav radiat interm	$0.00	$0.00	$0.00	$0.00	N/A	N/A
77522		Apply intrcav radiat compl	$0.00	$0.00	$0.00	$0.00	N/A	N/A
77523		Apply intrcav radiat compl	$0.00	$0.00	$0.00	$0.00	N/A	N/A
77525		Apply intrcav radiat compl	$0.00	$0.00	$0.00	$0.00	N/A	N/A
77750		Apply interstit radiat compl	$362.93	N/A	$393.38	N/A	-7.74%	N/A
77750	TC	Apply interstit radiat compl	$121.30	N/A	$122.70	N/A	-1.15%	N/A
77750	26	Apply interstit radiat compl	$241.63	$241.63	$270.67	$270.67	-10.73%	-10.73%
77761		Apply surf ldr radionuclide	$387.13	N/A	$412.87	N/A	-6.23%	N/A
77761	TC	Apply surf ldr radionuclide	$200.98	N/A	$204.27	N/A	-1.61%	N/A
77761	26	Apply surf ldr radionuclide	$186.14	$186.14	$208.60	$208.60	-10.76%	-10.76%
77762		Apply intrcav radiat interm	$508.10	N/A	$547.12	N/A	-7.13%	N/A
77762	TC	Apply intrcav radiat interm	$229.05	N/A	$234.22	N/A	-2.21%	N/A
77762	26	Apply intrcav radiat interm	$279.05	$279.05	$312.90	$312.90	-10.82%	-10.82%
77763		Apply intrcav radiat compl	$713.92	N/A	$772.32	N/A	-7.56%	N/A
77763	TC	Apply intrcav radiat compl	$294.22	N/A	$302.43	N/A	-2.72%	N/A
77763	26	Apply intrcav radiat compl	$419.71	$419.71	$469.89	$469.89	-10.68%	-10.68%
77778		Apply interstit radiat compl	$836.51	N/A	$886.36	N/A	-5.62%	N/A
77778	TC	Apply interstit radiat compl	$412.29	N/A	$411.78	N/A	0.12%	N/A
77778	26	Apply interstit radiat compl	$424.23	$424.23	$474.58	$474.58	-10.61%	-10.61%
77789		Apply surf ldr radionuclide	$123.88	N/A	$131.01	N/A	-5.44%	N/A
77789	TC	Apply surf ldr radionuclide	$68.39	N/A	$68.21	N/A	0.27%	N/A
77789	26	Apply surf ldr radionuclide	$55.49	$55.49	$62.80	$62.80	-11.64%	-11.64%
77399		Radium/radioisotope therapy	$0.00	N/A	$0.00	N/A	N/A	N/A
77399	TC	Radium/radioisotope therapy	$0.00	N/A	$0.00	N/A	N/A	N/A
77399	26	Radium/radioisotope therapy	$0.00	$0.00	$0.00	$0.00	N/A	N/A

Appendix I: Selected Previously Finalized Quality Measures with Substantive Changes Proposed for the CY 2023 MIPS Payment Year and Future Years

	Measure with Proposed Change	Page #
D.9	Advance Care Plan	50,591
D.14	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment	50,595
D.15	Preventive Care and Screening: Influenza Immunization	50,596
D.16	Breast Cancer Screening	50,597
D.17	Colorectal Cancer Screening	50,598
D.24	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan	50,603
D.25	Documentation of Current Medications in the Medical Record	50,605
D.26	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	50,606
D.27	Melanoma: Continuity of Care – Recall System	50,608
D.29	Oncology: Medical and Radiation – Pain Intensity Quantified	50,610
D.30	Oncology: Medical and Radiation – Plan of Care for Pain	50,611
D.31	Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy	50,612
D.36	Elder Maltreatment Screen and Follow-Up Plan	50,614
D.37	Functional Outcome Assessment	50,615
D.46	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	50,622
D.48	Use of High-Risk Medications in the Elderly	50,625
D.50	Biopsy Follow-Up	50,626
D.54	Dementia: Cognitive Assessment	50,627
D.55	Dementia: Functional Status Assessment	50,628
D.56	Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management	50,629
D.57	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	50,629
D.58	Dementia: Education and Support of Caregivers for Patients with Dementia	50,630
D.62	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	50,631
D.63	Cervical Cancer Screening	50,632
D.65	Falls: Screening for Future Fall Risk	50,634
D.71	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines	50,637
D.73	Closing the Referral Loop: Receipt of Specialist Report	50,638
D.83	Lung Cancer Reporting (Biopsy/Cytology Specimens)	50,643
D.84	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk	50,643
D.90	Overuse of Imaging for the Evaluation of Primary Headache	50,649
D.91	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	50,650
D.93	Age Appropriate Screening Colonoscopy	50,653
D.95	Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy	50,654
D.96	RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy	50,655
D.97	Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies	50,655

	Measure with Proposed Change	Page #
D.98	Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better	50,655
D.99	Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better)	50,656
D.100	Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)	50,656
D.104	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy	50,657
D.111	International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	50,661

This Overview of Selected Provisions of the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2021 has been prepared for ACCC members as a benefit of membership.

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 25,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer org or call 301.984.9496. Follow us on Facebook, Twitter, Instagram, and LinkedIn; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

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