mln listening session

A MEDICARE LEARNING NETWORK® (MLN) EVENT

Physician Fee Schedule Proposed Rule: Understanding 4 Key Topics

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CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Learning Network®

Acronyms in this Presentation

- AMA – American Medical Association
- APM - Alternative Payment Models
- APP - APM Performance Pathway
- ACO - Accountable Care Organization
- CMS - Centers for Medicare & Medicaid Services
- CPT - Current Procedural Technology
- CY - Calendar Year
- ED - Emergency Department
- E/M - Evaluation and Management
- EPCS - e-Prescribing of Controlled Substances
- HCPCS - Healthcare Common Procedure Coding System
- MAT - Medication Assisted Treatment
- MLN - Medicare Learning Network

Acronyms in this Presentation

- MIPS - Merit-based Incentive Payment System
- MVP - MIPS Value Pathways
- NPP – Non-Physician Practitioner
- OTP - Opioid Treatment Program
- OUD - Opioid Use Disorder
- PFS - Physician Fee Schedule
- PHE - Public Health Emergency
- QCDR - Quality Clinical Data Registry
- QPP - Quality Payment Program
- SAMHSA - Substance Abuse and Mental Health Services Administration
- TIN - Tax Identification Number

Agenda

- **Extending Telehealth & Licensing Flexibilities**
  - Feedback Session
- **Evaluation and Management (E/M) and Analogous Visits**
  - Feedback Session
- **Quality Payment Program Updates**
  - Feedback Session
- **Opioid Use Disorder/Substance Use Disorder Provisions**
  - Feedback Session

When & Where to Submit Comments

- See the proposed rule for information on submitting formal comments by October 5, 2020.
- Proposed rule includes proposed changes not reviewed in this presentation, please refer to proposed rule for complete information
- Feedback during presentation not considered as formal comments; please submit comments in writing using formal process
- See proposed rule for information on submitting comments by close of 60-day comment period on October 5 (When commenting refer to file code CMS-1734-P)
- Instructions for submitting comments can be found in proposed rule; FAX transmissions will not be accepted
- You must officially submit your comments in one of following ways:
  - Electronically through Regulations.gov
  - By regular mail
  - By express or overnight mail
  - By hand or courier

Extending Telehealth & Licensing Flexibilities

Emily Yoder
Ann Marshall
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Topics

- Telehealth & Other Virtual Services
- Virtual Supervision
- Scope of Practice & Related Issues
  - Teaching Physicians and Residents

Telehealth Overview

- Specified by Section 1834 (m) of the Social Security Act and related regulations, Medicare telehealth services are services ordinarily furnished in person that are instead furnished via a telecommunications system and are subject to geographic, site of service, practitioner, and technological restrictions.

- In response to the public health emergency (PHE) for the COVID 19 pandemic, CMS temporarily waived a number of these restrictions and adopted regulatory changes to expand access to Medicare telehealth

- Before the PHE, only 14,000 patients received a Medicare telehealth service in a week

- During the PHE, over 10.1 million patients received a Medicare telehealth service from mid-March through early-July.

Telehealth Proposals

We propose these services as permanent additions to the Medicare telehealth services list:

Service	Related Code(s)
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

Telehealth Proposals

We propose these services as Category 3, temporary additions to the Medicare telehealth services list:

Service	Related Code(s)
Domiciliary, Rest Home, or Custodial Care services, Established patients	CPT codes 99336-99337
Home Visits, Established Patient	CPT 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

Services we are NOT Proposing to Add

Services we are **not** proposing to add to the Medicare telehealth services list but **are** seeking comment:

Service	Related Code(s)
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

Services we are NOT Proposing to Add Cont'd

Services we are **not** proposing to add to the Medicare telehealth services list but **are** seeking comment:

Service	Related Code(s)
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

Other Proposed Policies

- Expand the types of practitioners who may provide communication technology-based services and clarify which practitioners may bill for eVisits
- Amend the frequency limitations on subsequent nursing facility visits
- Allow auxiliary personnel to provide certain remote monitoring services under a physician's supervision
  - Auxiliary personnel can include contracted employees
- Clarify the definition of a medical device supplied to a patient as part of a remote monitoring service and that the device must be reliable, valid, and the data must be electronically collected and transmitted rather than self-reported

Virtual Supervision

For the duration of the PHE, to limit infection exposure, we revised the definition of direct supervision to include virtual availability of the supervising physician or practitioner using interactive audio/video real-time communications technology

We propose to continue this policy through the end of the PHE or December 31, 2021, whichever is later.

- Seeking comment on:
  - Whether there should be any guardrails or limitations to ensure patient safety/clinical appropriateness, if we were to finalize this policy on this temporary basis or consider it beyond the time specified.
  - Potential concerns around induced utilization and fraud, waste, and abuse and how those concerns might be addressed

Scope of Practice Proposals

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

- Make permanent our interim final policy during the COVID-19 PHE allowing supervision of diagnostic tests as allowed by state law and scope of practice by:
  - Nurse Practitioners
  - Clinical Nurse Specialists
  - Physician Assistants
  - Certified Nurse-Midwives

- The NPPs would maintain any required statutory relationships with supervising or collaborating physicians.

Scope of Practice Proposals, Cont'd

Pharmacists Providing Services Incident to Physicians' Professional Services

- Reiterating our clarification that pharmacists can be auxiliary personnel under our "incident to" regulations
- 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 Medicare Part D

Scope of Practice Proposals, Cont'd

Therapy Assistants Furnishing Maintenance Therapy

- Make permanent our policy for the duration of the COVID-19 PHE that allows a physical therapist and occupational therapist the discretion to delegate the performance of maintenance therapy services, as clinically appropriate, to a therapy assistant

Medical Record Documentation

- Clarify that 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 also applies to therapists

- Clarify that therapy students, and students of other disciplines, working under a physician or practitioner who bills directly for their professional services to the Medicare program, may document in the record so long as it is reviewed and verified (signed and dated) by the billing physician, practitioner, or therapist

Teaching Physicians and Residents

During the PHE, we adopted the following policies on an interim basis. We are soliciting public comments on whether these policies should continue once the PHE ends:

- Teaching Physician – use of audio/video real time communications technology to interact with the resident meets the requirement that they be present for the key portion of the service, including involving the resident in furnishing Medicare telehealth services.

- Primary Care Exception – Teaching physicians at primary care centers can provide the direction, management and review of a resident's services using audio/video real time communications technology. These residents may provide an expanded set of services to patients, including levels 4-5 of an office/outpatient E/M visit, care management, and communication technology-based services.

- Resident Moonlighting – Services of residents that are not related to their approved GME programs and are provided to inpatients of the training program hospital are separately billable physicians' services under the PFS.

Feedback Session

Payment for Office/Outpatient E/M Visits and Analogous Services

Christiane LaBonte
Ann Marshall

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

Last year, we finalized aligning E/M visit coding and documentation policies with changes by the CPT Editorial Panel for office/outpatient E/M visits, beginning January 1, 2021.

- This includes:
  - Code redefinitions that rely on time or medical decision making for selecting visit level, with performance of history and exam as medically appropriate
  - Deletion of level 1 new patient code
  - A new prolonged services code specific to office/outpatient E/M visits

We also adopted revised medical decision making guidelines adopted by the CPT Editorial Panel. Additional information about the American Medical Association (AMA) CPT changes are available on the AMA website

E/M Proposals

- Clarify the reporting times for prolonged office/outpatient E/M visits (CPT 99XXX)
- Revise the times used for rate setting for this code set
- Revalue the following code sets that include, rely upon, or are analogous to office/outpatient E/M visits in line with the increases in values we finalized for office/outpatient E/M visits for 2021:
  - End-Stage Renal Disease Monthly Capitation Payment Services
  - Transitional Care Management Services
  - Maternity Services
  - Cognitive Impairment Assessment and Care Planning
  - Initial Preventive Physical Examination and Initial and Subsequent Annual Wellness Visits
  - Emergency Department Visits
  - Therapy Evaluations
  - Psychiatric Diagnostic Evaluations and Psychotherapy Services
- Seeking public comment on how to clarify the definition of HCPCS add-on code GPC1X, previously finalized for office/outpatient E/M visit complexity, and if we should refine our utilization assumptions

Feedback Session

Quality Payment Program

Molly MacHarris
Brittany LaCouture

Quality Payment Program (QPP) Proposals for 2021 Performance Year

Performance Pathways – Proposed Changes

- MIPS Value Pathways (MVPs): We will **not** introduce MVPs for the 2021 performance period; the earliest MVP implementation will for be the 2022 performance period

- APM Performance Pathway (APP): Proposed pathway for MIPS APMs participants and complementary to MVPs with a fixed set of measures for each performance category:
  - **Quality:** Composed of 6 measures available to all MIPS APM participants; ACOs participating in Medicare Shared Savings Program (Shared Savings Program) are required to submit quality measures via the APP
  - **Cost:** Reweighted to 0% to align with current MIPS APMs responsibilities
  - **Improvement Activities:** Score automatically assigned based on MIPS APMs respective requirements; in 2021, all APM participants reporting via the APP will receive a score of 100%
  - **Promoting Interoperability:** Reported and scored at the individual or group level as required in MIPS

Quality Payment Program (QPP) Proposals for 2021 Performance Year

Participation Options – Proposed Changes

- Sunset the APM Scoring Standard
- Allow MIPS eligible clinicians in a MIPS APM to participate as individuals, as a group, as a virtual group, or as an APM Entity in all MIPS performance categories

Merit-based Incentive Payment System (MIPS) Proposals for 2021 Performance Year

Performance Categories – Proposed Changes

Quality:

- Sunset the CMS Web Interface as a quality reporting option
- Updates to quality measurement set by incorporation of telehealth services
- Due to PHE, use performance period, not historical benchmarks

Cost:

- Update measures specifications to add telehealth services

MIPS Proposals for 2021 Performance Year

Performance Categories – Proposed Changes:

Improvement Activities:

- Establish 1 new criterion for nominating new improvement activities
- Allow 2 new options for nominating improvement activities
- Modify 2 existing improvement activities

Promoting Interoperability:

- Retain the Query of Prescription Drug Monitoring Program measure as an optional measure worth 10 bonus points
- Changing the *Support Electronic Referral Loops by Receiving and Incorporating Health Information* measure to the *Support Electronic Referral Loops by Receiving and* ***Reconciling*** *Health Information* measure
- Add optional Health Information Exchange bi-directional measure

MIPS Proposals for 2021 Performance Year

Performance Category Weights:

Performance Category	Performance Category Weights (2020)	Proposed Weights (2021)
Quality	45%	**40%**
Cost	15%	**20%**
Improvement Activities	15%	15%
Promoting Interoperability	25%	25%

MIPS Proposals for 2021 Performance Year

Performance Thresholds:

Performance Year	Performance Threshold	Exceptional Performance Bonus
2017	3 points	70 points
2018	15 points	70 points
2019	30 points	75 points
2020	45 points	85 points
2021	**50 points**	**85 points**

*Payment adjustment (and exceptional performer bonus) is based on comparing final score to performance threshold and additional performance threshold for exceptional performance. To ensure budget neutrality, positive MIPS payment adjustment factors are likely to be increased or decreased by an amount called a "scaling factor." The amount of the scaling factor depends on the distribution of final scores across all MIPS eligible clinicians.

MIPS Proposals for 2021 Performance Year

COVID-19 Flexibilities:

- Double the Complex Patient Bonus to 10 bonus points to account for additional difficulty in treating patients during the COVID-19 PHE (for the 2020 performance period only).
- Allow APM Entities to submit an application to reweight MIPS performance categories as a result of extreme and uncontrollable circumstances beginning with the 2020 performance period.

Third-Party Intermediaries:

- Allow Qualified Clinical Data Registries (QCDR) and Qualified Registries to support new performance pathways
- Additional proposals include strengthening data validation and corrective action plan requirements, propose additional criteria for Third Party Intermediary approval, and updating QCDR measure standards. CMS is also seeking comment on entities that should perform data validation.

Advanced Alternative Payment Models (APMs) Proposals for 2021 Performance Year

Medicare Shared Savings Program:

- Require that ACOs participating in the Shared Savings Program to report quality measures via APP instead of the CMS Web Interface; this would meet the reporting requirements under both MIPS and the Shared Savings Program.
- Revise the quality performance standard so that ACOs would be required to receive a quality performance score equivalent to or above the 40th percentile across all MIPS Quality performance category scores in order to share in savings or avoid owing maximum losses
- Strengthen Shared Savings Program policies for compliance with the quality performance standard and revise the scoring methodology under the Shared Savings Program extreme and uncontrollable circumstances policy

Additional Proposed Changes:

- Beginning in 2021, remove patients who are prospectively aligned to an APM Entity from the attribution-eligible population of APM Entities where attribution is retrospective and accept Targeted Review requests under limited circumstances.

Feedback Session

Opioid Use Disorder/Substance Use Disorder Provisions

Lindsey Baldwin
Joella Roland

Overview

Expanding access to treatment for Opioid Use Disorder is one of CMS' key areas of focus in addressing the opioid epidemic.

Today we will cover provisions related to the Opioid Treatment Program (OTP) benefit and the Request For Information on e-Prescribing of Controlled Substances.

OTP Benefit

Section 2005 of the SUPPORT Act established a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by Opioid Treatment Programs (OTPs).

Under the CY 2020 Physician Fee Schedule final rule, CMS pays OTPs through bundled payments for OUD treatment services in an episode of care provided to beneficiaries with Medicare Part B.

Under the OTP benefit, Medicare covers:

- U.S. Food and Drug Administration-approved opioid agonist and antagonist medication-assisted treatment (MAT) medications
- Dispensing and administration of MAT medications (if applicable)
- Substance use counseling
- Individual and group therapy
- Toxicology testing
- Intake activities
- Periodic assessments

CY 2021 PFS OTP Proposals

- Adding naloxone to the definition of OUD treatment services and adjusting the bundled payment rates through the use of add-on codes for when OTPs provide naloxone
    - Creating two new add-on codes, one add-on code for nasal naloxone and another add-on code for auto-injector naloxone and seeking comment on injectable naloxone
- Using Wholesale Acquisition Cost (WAC) + 0 under the section 1847A of the Act methodology for the drug component of the episode of care in instances where Average Sales Price (ASP) is not available
- Exploring enrollment and claims processing flexibilities to allow OTPs to submit claims using the institutional claim form
- Clarifying what activities qualify for billing the periodic assessment add-on code finalized for CY 2020
- Clarifying the date of service used on claims for the weekly bundles and add-on codes
- Seeking comment on stratifying the coding and payment to account for significant differences in resource costs among patients, especially related to amounts of expected counseling

Bundled Payments under the PFS for Substance Use Disorders

- In CY 2020 rulemaking, we finalized the creation of new coding and payment describing a bundled episode of care for office-based treatment of OUD
- For CY 2021, we are proposing to expand these bundled payments to be inclusive of all SUDs

Initiation of MAT in the Emergency Department (ED)

- Proposing to create one add-on G-code (GMAT1) for initiation of MAT to be billed with E/M visit codes used in the ED setting that includes:
  - Payment for assessment
  - Referral to ongoing care
  - Follow-up after treatment begins
  - Arranging access to supportive services

E-Prescribing of Controlled Substances (EPCS)

- EPCS is the e-prescribing of drugs classified as controlled substances to reduce prescription drug diversion and reduce burden on prescribers
- EPCS is **allowed** in all 50 states and the District of Columbia and more than half the states have laws **requiring** it
- Section 2003 of the SUPPORT Act requires that Schedule II, III, IV, or V controlled substances under Part D be prescribed electronically beginning January 1, 2021
- 98% of pharmacies support EPCS prescriptions

EPCS Implementation – Three Phase Approach

Solicit Comments on Exceptions and Penalties

- RFI displayed on July 31st with comments due on October 5th.

Propose Standard for Electronic Prescribing effective 1/1/22

- Proposal listed in Physician Fee Schedule Proposed Rule displayed on August 4th with comments due October 5th.

Finalize Standard with Exceptions and Penalties Listed

- Enact in future rulemaking after taking into account comments

EPCS Request For Information (RFI)

On July 30, CMS issued the Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information

The RFI solicits feedback on:

- Exceptions to the EPCS requirement
- What circumstances and whether CMS should impose penalties for noncompliance with the EPCS mandate

We will use this public feedback to draft separate rules to further implement this SUPPORT Act provision.

Comments are due by October 5.

Feedback Session

Resources

- E/M Webpage
- Quality Payment Program Website
- OTP Webpage
- SUPPORT for Patients and Communities Act
- CMS Roadmap: Fighting the Opioid Crisis

Thank You

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