Medicare and Other Value-Based Payment Programs and Compliance Oversight

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Overview

- Continued expansion of Medicare value-based payment programs
- Changes to Medicare Shared Savings Program (MSSP)
- MSSP compliance and oversight
- Changes to Merit-Based Incentive Payment System (MIPS)
- Compliance oversight for Medicare value-based payment programs
- New proposed rules for value-based arrangements under Stark and Anti-Kickback Statute

Medicare and Value-Based Payment

- For more than two decades, "traditional" fee-for-service Medicare has been shifting towards value-based payment
- An alphabet soup of programs:
  - For hospitals: Hospital Inpatient and Outpatient Quality Reporting; Hospital Value-Based Purchasing, Hospital Compare, CMS Innovation Center "alternative payment models"
  - For clinicians: Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VM), Physician Compare
- The Affordable Care Act expanded, accelerated and launched many new value-based payment initiatives in Medicare
- The Medicare Access and CHIP Reauthorization Act of 2015 and the Medicare Quality Payment Program marked a significant step towards tying payment for clinicians' professional services to quality and value
- Congress, the President, HHS, and CMS continue to support value-based payment initiatives and grant enhanced flexibility to further those initiatives

MACRA

- The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) creates the Quality Payment Program (QPP) that:
  - Repealed the Sustainable Growth Rate formula
  - Changes the way that Medicare rewards clinicians for value over volume
  - Streamlines multiple quality programs under the Merit-Based Incentive Payments System (MIPS)
  - Gives bonus payments for participation in eligible alternative payment models (APMs)
- Physicians and other eligible professionals ("Eligible Clinicians") can choose to participate in the Quality Payment Program in two ways:
  1. The Merit-Based Incentive Payment System (MIPS): Medicare reimbursement for professional services subject to a performance-based payment adjustment
  2. Advanced Alternative Payment Models (APMs): Qualifying Participants (based on share of Medicare payment or patients) in an Advanced APM may earn a Medicare incentive payment (5%)

MIPS

- Clinicians performance measured in four areas:
  1. Quality
  2. Promoting interoperability
  3. Improvement activities
  4. Cost
- Data reported/performance scored at physician group or individual level
  - Option for "virtual groups" for solo practitioners and practices with 10 or fewer clinicians
- Medicare Part B payment adjustment based on final composite score
- Two-year lag between performance year and payment year

Advanced APMs

- Requires participants to use certified EHR technology
- Provides payment for Medicare covered professional services based on quality measures comparable to those used in MIPS
- Either:
  1. Is a Medical Home Model expanded under CMS Innovation Center authority; OR
  2. Requires participants to bear significant financial risk (at least 8% downside risk)

What's new in QPP?

- Eligible Clinicians: Starting in 2019 (for payment year 2021)
  - physicians, PAs, and NPs
  - clinical nurse specialists and certified RNAs
  - physical or occupational therapists - *new*
  - qualified speech-language pathologists - *new*
  - qualified audiologists - *new*
  - clinical psychologists - *new*
  - Registered dieticians or nutrition professionals - *new*
- Incentive Payments: Generally larger for Advanced APMs than in MIPS

QPP Participation in 2017 and 2018

QPP General Participation Numbers in 2017 vs. 2018

The following data outlines general participation in MIPS among **individuals, groups,[1] and those who participated through a MIPS APM**. It also includes data on the number of Qualifying APM Participants (QPs) that were excluded from MIPS and the total number of Partial QPs, some of whom elected to participate in MIPS.

	2017	vs.	2018
Total clinicians receiving a MIPS payment adjustment (positive, neutral, or negative)	1,057,824		916,058
Percent of clinicians above the performance threshold[2]	93.12%		97.63%
Percent of clinicians at the performance threshold	2.01%		0.42%
Percent of clinicians below the performance threshold	4.87%		1.95%
Total number of QPs	99,076		183,306
Total number of Partial QPs	52		139

[1]*Under MIPS, an individual is a single TIN/NPI; a group is two or more NPIs billing under a single TIN.*
[2]*The performance threshold in 2017 was 3, and in 2018, it was 15.*

Other Medicare Alternative Payment Models

- Medicare Shared Savings Program ACOs*
- Bundled Payments for Care Improvement (BCPI) & BPCI Advanced*
- Comprehensive Care for Joint Replacement Model*
- Comprehensive ESRD Care Model
- Comprehensive Primary Care Plus*
- Oncology Care Model*
- *Proposed* Radiation Oncology Model
- *Proposed* ESRD Treatment Choices Model
- …and many more

* Advanced APMs under Quality Payment Program

Common Features of Advanced APMs

- Criteria for 5% professional fee bonus under MACRA:
  - More than nominal downside risk (8% minimum)
  - Payment also tied to quality
- Clinicians must use Certified Electronic Health Record Technology (CEHRT)
- Participating organizations enter into contracts with CMS
  - Downstream arrangements with physicians and other providers
- Conditional fraud and abuse law waivers

Common Regulatory Waivers in CMS Models

- Limited Stark, AKS, Beneficiary Inducement
- NOT antitrust
  - CMS shares ACO applications with DOJ and FTC
- Telehealth coverage
- 3-day inpatient stay for SNF
- Not all APM models enjoy the same waiver protection
- Some waivers require CMS pre-approval
- Specific compliance program and documentation requirements for use of waivers
- CMS contracts may also require reporting of investigations or sanctions by other agencies

Medicare Shared Savings Program

- Established in 2012 pursuant to Section 3022 of the Affordable Care Act in 2010 (Social Security Act Section 1899)
- Groups of providers, suppliers and professionals establish "Accountable Care Organizations" (ACOs) to manage and coordinate the costs, quality and overall care delivered to a Medicare fee-for-service population
- ACOs that meet quality standards are eligible to share in savings (or losses) generated for Medicare program relative to target (i.e., benchmark) Part A and B expenditures for overall care
- "Pathways to Success" intended to push ACOs towards accepting downside risk more quickly

What's new in MSSP?

- Participation Options
  - Different "tracks" allow ACOs to assume one-sided or two-sided financial risk over a 5-year agreement period
  - BASIC Track: "glide path" to facilitate transition to performance-based risk more quickly over 5 years
  - ENHANCED Track: Two-sided performance-based risk starting first year
- Beneficiary Assignment
  - Beneficiaries "assigned" based on where they receive a plurality of their primary care services
  - Starting in 2019, ACOs allowed to select assignment methodology prior to each performance year
  - Beneficiaries also can select primary care provider for use for assignment to ACO
- Enhanced benefits and Beneficiary Incentives

Enhanced Benefits & Beneficiary Incentives

- Waiver of 3-day stay prior to SNF coverage
  - For ACOs using preliminary prospective or prospective assignment only
- Expanded access to telehealth services
  - Inclusion of "home" as originating site
  - No "rural" geographic limitation for home visits
- Beneficiary Incentive Programs
  - Permits incentive payments to beneficiaries for qualifying primary care services
  - Up to $20 per service, uniformly applied
  - Must have CMS permission in advance

Other Key Features of Medicare ACOs

- Physician-centered organization and governance
  - Plus at least one Medicare beneficiary on the ACO's board
- Qualifies participating physicians and other clinicians for 5% MACRA Bonus as an Advanced APM
- Potentially broad Stark, AKS waivers if an activity is approved by the ACO governing body as furthering the objectives of the ACO

MSSP Compliance Plan

- ACO compliance plan must at least include:
  - A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body
  - Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance
  - Method for employees or contractors of ACO, ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services to anonymously report suspected problems
  - Compliance training for the ACO, ACO participants and ACO providers/suppliers
  - Requirement for ACO to report probably violations of law to an appropriate law enforcement agency
- Compliance plan must meet regulatory requirements and be updated periodically to reflect changes in law and regulations

MSSP Program Safeguards

- Certification of the accuracy, completeness and truthfulness of data submitted and on annual basis
- Screening of ACO, ACO participants and ACO providers/suppliers
- Prohibition on conditioning participation in the ACO on referrals or Federal Health Care Program business
- Prohibition on requiring beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any provider or supplier
  - Except employees or contractors operating within the scope of their employment/contract may restrict referrals as long as:
    - No restriction or limitation on referrals if beneficiary expresses a preference or
    - Referral is not in beneficiary's best medical interests
- Public reporting and transparency requirements
- CMS monitoring, audits and record retention requirements

Value-Based Payment Programs: Opportunities & Challenges for Compliance Oversight

- Innovative payments
- Collaboration with new partners
- Beneficiary protections and choice
- Enhanced benefits
- Coding compliance
- Compliance with fraud & abuse laws
  - Program/model-specific waivers
  - New proposed Stark, AKS and beneficiary inducement CMP regulations

Innovative Payments

- Permitted only for participants that meet all program requirements, including specific conditions for payment arrangements
  - Math can be complicated! (especially when subject to more than one retrospective reconciliation/adjustment)
- Program overlap; CMS has defined rules for when beneficiaries/care episodes will be assigned to each model
- Many programs/models require a financial guarantee for shared losses
- Must ensure compliance with fraud & abuse waivers
- Must ensure compliance with contract terms

Vendor Collaboration

- EHR vendor design and implementation of quality measure specifications
- Tech companies and other new non-health care partners
  - E.g., Uber/Lyft for patient rides to appointments
  - E.g., patient engagement apps
  - E.g., companies backed by private equity or commercial health insurers that offer to assist with data analysis or ACO management

Beneficiary Protections and Choice

- Medicare fee-for-service beneficiaries are free to seek care from any Medicare-enrolled health care provider, supplier or professional
- Beneficiaries must be notified of provider/supplier participation in an alternative payment model; CMS requirements for marketing materials
  - Patients can opt out of sharing data in some models (e.g., ACOs)
- Public reporting on model participation and required data submissions to CMS
- Model participant safeguards to prevent cherry-picking, stinting on medically necessary care, or otherwise steering Medicare FFS patients
- CMS monitoring to identify trends or patterns suggesting avoidance of at-risk beneficiaries

Enhanced Benefits

- Conditional; participants must meet **all** of the program requirements in order for Medicare to cover and pay for these services
- If not, risk of non-payment or other regulatory compliance issues
- Updating CMS on changes in program participants providing enhanced benefits is critical
- Recordkeeping required

Coding Concerns

- Accurate, complete, and truthful data submission
  - Certification required
- Quality measure specifications and reporting
- Risk Adjustment Factor (RAF) and Hierarchical Condition Codes used in risk adjustment

Fraud & Abuse Compliance

- Program/model-specific waivers of the Stark Law, Anti-Kickback Statute, and Beneficiary Inducement CMP
  - Published in Federal Register
  - On CMMI website
  - In model participation agreement
- Must meet all conditions and requirements of the program/model **and** each waiver in order to qualify for protection
- New proposed regulations creating Stark exception and Anti-Kickback Statute safe harbors for value-based arrangements

New AKS Safe Harbors and Stark Exceptions

- Value-Based Enterprises
  - Arrangements with any level of risk
    - Care Coordination and Management (AKS)
    - Value-based physician arrangements (Stark)
  - Arrangements with Substantial Downside Risk (both)
  - Arrangements with Full Financial Risk (both)
- CMS Innovation Center projects and shared savings ACOs
- Patient Engagement Tools and Supports
- ACO Beneficiary Incentive Programs

Proposed AKS Safe Harbors and Stark Exceptions

- Value-Based Enterprises – all payers
  - Arrangements with any level of risk
    - Care Coordination and Management (AKS)
    - Value-based physician arrangements (Stark)
  - Arrangements with Substantial Downside Risk (AKS/Stark)
  - Arrangements with Full Financial Risk (AKS/Stark)
- CMS Innovation Center projects and MSSP ACOs
- More financial risk → more flexibility

Proposed Value-Based Arrangements Exceptions/ Safe Harbors

Value-Based Enterprise:

- A collaboration by two or more participants,
- That are parties to an arrangement with each other, or at least one other participant,
- To achieve at least one value-based purpose.
- A VBE does not have to be a separate legal entity with ability to contract on its own
- The VBE has
  - An accountable body or person responsible for financial and operational oversight; and
  - A governing document describing the VBE and how the participants plan to achieve the VBE's goals.
- Drug/device manufacturers, DME suppliers, and labs can't participate.

Care Coordination Safe Harbor

- In-kind remuneration
- Recipient pays 15% of cost
- Directly connected to care coordination for a target patient population
- Doesn't take into account referrals involving other patients
- Doesn't induce over- or under-utilization
- Doesn't involve a third party
- Does not limit parties' ability to make other referral decisions in a patient's best interest
- Does not restrict patient choice
- Doesn't involve patient recruitment/marketing
- VBE monitors the progress of the arrangement, and must terminate if not working

Sample Analysis

- Hospital and SNF wish to coordinate care for patients with specified behavioral health diagnoses.
- Hospital to send a behavioral health RN to the SNF to follow patients with those diagnoses who have been discharged from Hospital to SNF.
- Arrangement is planned to last for 1 year.
- VBE = Hospital + SNF
- AKS is implicated because both providers can refer to each other.

Example – Next Steps

- Hospital and SNF establish evidence-based outcome measures that the SNF will be measured against.
- The time the RN spends at the SNF must be commercially reasonable (given the volume of patients with mental health needs), for this specific arrangement and any others in the VBE.
- Hospital and SNF execute a signed writing documenting the details of this project before the RN goes to the SNF.
- SNF agrees to pay for 15% of the cost of the RN's services, at reasonable intervals.
- SNF cannot divert the RN to do other work.

Measure Selection

- Focused on a priority area for quality improvement
- Useable and relevant for making decisions
- Feasible to collect / auditable
- Aligns with S.M.A.R.T. goals:
  - Specific, Measurable, Achievable/Actionable, Relevant, Time-bound
- OIG recommendations for value-based arrangements:
  - Outcome measures (not process or patient satisfaction)
  - Evidence-based
  - Continuous improvement – maintaining the status quo is not enough

Patient Engagement and Support

- Tools and supports directly connected to care coordination and management
- Recommended by patient's licensed healthcare provider
- From a VBE participant
- Max value of $500 per patient per year
- Not likely to be diverted for non-health related uses or duplicative of something the patient already has
- Might include supports to address social determinants of health
- In addition to current safe harbors for transportation, preventive care, promoting access, and new ACO beneficiary incentives safe harbor

Additional Proposals for New or Revised AKS Safe Harbors and Stark Exceptions

- Cybersecurity Donations
- EHR Donation made permanent
- Personal Services Contracts: increased flexibility for outcomes-based pay for performance and part-time arrangements with physicians
- Warranties for bundles of products/services
- Local Transportation: increased mileage limits for rural areas and transporting discharged patients to home

Caveats

- Proposed rules only
- May change substantially when final
- Only protects prospective arrangements after the final rule's effective date
- Detailed requirements
- Must meet all criteria in a given safe harbor or exclusion to enjoy the protection
- Does not affect state law prohibitions on fee splitting, payment for referrals, or other state regulations
- Does not affect tax or antitrust issues
- Value-based arrangements may trigger state insurance rules

New Compliance Risks

CMS and OIG requested comments on safeguards for new types of compliance risks:

- Withholding necessary care (stinting)
- "Cherry picking" healthier patients and "lemon dropping" sicker patients
- Falsification or manipulation of quality and performance data
- Inappropriate influence on medical judgment or patient choice
- Potential benefits to physicians or other professionals that vary "inappropriately" based on their ordering decisions
- "Swapping" patients covered by an APM for referrals of patients under traditional fee-for-service reimbursement
- Decreased competition

What's Next?

- No fixed timeline for finalizing either proposed rule.
- CMS could choose to finalize technical Stark rule changes separate from the coordinated effort with OIG to address value-based arrangements.
- Impact of the 2020 election is unknown.
- Comment period remains open until December 31.