

Summary of the MACRA Final Rule with Comment Period

CMS released a final rule with comment period on October 14, 2016, implementing the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA). The final rule sets out the standards for participation in the Quality Payment Program (QPP), which is a new initiative that creates two value-based payment programs for physician reimbursement. This document is intended to provide a summary of the final rule's provisions for ASCO membership.

Quality Payment Program (QPP) Overview:

Congress passed MACRA to address long-standing issues with the existing physician payment system. MACRA repealed the troubled sustainable growth rate formula and reorganized Medicare physician payment mechanisms to focus on value rather than volume. The new physician payment program is called the Quality Payment Program (QPP) and is composed of two value-based payment programs.

The default QPP program is the Merit-Based Incentive Payment System (MIPS), which assesses physicians on their performance across four categories and provides a positive or negative overall payment adjustment that is based on that performance. Alternatively, physicians may elect to participate in an advanced Alternative Payment Model (APM) in lieu of MIPS participation. Advanced APMs are payment models that are predicated on sharing two-sided risk with CMS. Qualifying participation in an advanced APM allows providers to access incentive payments in 2019-2024. The financial implications of participation in each QPP program are discussed below.

When does the Quality Payment Program Begin? MIPS reporting and Advanced APM participation begin in 2017. The QPP uses performance periods and payment periods. The performance period is the year in which QPP performance is assessed and takes place two years prior to the payment period. For example, physician performance in MIPS or participation in an APM in 2017 will be used to apply payment adjustments or incentive payments in 2019.

What are the reporting requirements in the 2017 transition year? CMS finalized 2017 as a transition period during which a physician can avoid a negative payment adjustment by reporting minimal data in any MIPS performance category to CMS. Providers also have the option of participating in an Advanced Alternative Payment Model, which exempts them from MIPS and creates eligibility for an incentive payment in 2019.

Are there exclusions that exempt physicians from participating in MIPS? Yes. Providers that meet the requirements for MIPS exemptions are exempted from the QPP and will be paid exclusively through the Medicare Physician Fee Schedule—unless they opt to participate in a qualifying Advanced APM.

The following providers are excluded from MIPS:

- Providers that meet the criteria of the low-volume threshold. These providers either have less than \$30,000 in Medicare Part B allowed charges <u>or</u> treat less than 100 Medicare beneficiaries per year.
- Providers that are in their first year of Medicare participation.
- Qualifying APM participants (QPs) or Partial Qualifying APM Participants.

The Merit-Based Incentive Payment System (MIPS):

MIPS Overview: MACRA established MIPS as Medicare's default physician payment system. MIPS maintains the current fee-for-service construct for physician payment, but will assess physicians on their performance across four performance categories and provide positive or negative payment adjustments based on performance relative to other professionals.



The performance categories are:

- The Quality Performance Category
- The Cost Performance Category
- The Improvement Activity Performance Category
- The Advancing Care Information (ACI) Performance Category

With the exception of the Improvement Activity performance category, the new performance categories are based on existing CMS quality and value improvement programs.

New Performance Category	Existing Precursor Program
Quality	Physician Quality Reporting System (PQRS)
Cost	Value-Based Payment Modifier Program
Improvement Activity	Not applicable
Advancing Care Information	Meaningful Use Program, which is also called the EHR Incentive Program

What is the proposed reporting period for MIPS? Providers would be assessed on the calendar-year performance period that occurs two years before the payment adjustment applies. The initial year for data collection for MIPS is calendar year 2017. The first payment adjustments based on MIPS would occur in 2019 (based on performance data collected from services performed in 2017).

CMS deemed 2017 as a transition year in the final rule. The Agency shortened the 2017 reporting period for each performance category to 90 days in 2017. Further, CMS permits providers to report MIPS data at one of three levels in 2017 to avoid a negative MIPS payment adjustment in 2019. These decisions were made in response to widespread concerns that MACRA was being implemented too quickly. There are three MIPS reporting pathways available under MIPS in 2017 that allow participants to avoid a negative payment adjustment.

2017 Transition Period MIPS Reporting Options

Level of Participation	Reporting Requirements in 2017	Payment Adjustments in 2019
None	No MIPS data reported	Automatic negative 4% adjustment
Minimal	Submit one measure or one activity under the quality or improvement activity categories, or report the required measures of the ACI performance category	Neutral or Slightly Positive Adjustment
Medium	Submit data on all performance categories for at least 90 days	Potential/modest positive adjustment
High	Submit data on all performance categories for more than 90 days, and up to a full year	Potential/higher Positive adjustment, and if warranted an additional positive adjustment for high performance



CMS has not committed to extending the transition period past the 2017 reporting period. In 2018, the quality and improvement activity performance periods will be a full calendar year, while advancing care information will remain at 90 days.

Is group reporting available under MIPS? Yes. MIPS eligible clinicians can choose to be evaluated individually or as groups. Each of the four performance categories allows for individual or group assessment. If an entity elects to report as a group, then group scoring applies to all four MIPS performance categories.

When can I expect to know how I've performed under MIPS? The final rule requires CMS to announce payment adjustments at least 30 days prior to January 1 of the applicable payment year. This means that CMS will announce your payment adjustment no later than December 1 of the year preceding the payment adjustment year(for example: adjustments for data reported in 2017 will be announced by December 1, 2018 and paid in 2019).

What are the contemplated uses for a qualified clinical data registry (QCDR) under MIPS? CMS approves the collection of medical and/or clinical data for the purpose of tracking measures and other information patient/clinical information. QCDRs can be used as conduits to report data under all MIPS categories that require reporting, including the quality, practice improvement activity, and advancing care information performance categories. Providers may also use QCDRs to demonstrate several practice improvement activities.

How is performance measured under the Quality performance category? Providers or groups are assessed on their performance of quality measures that are included in the final MIPS quality measure list and quality measures that are used by qualified clinical data registries (QCDRs). An annual list of quality measures that may be used in MIPS will be published in the Federal Register no later than November 1 of the year prior to the first day of a performance year.

The reporting requirements for MIPS eligible clinicians and groups are similar to the existing PQRS requirements, i.e. the MIPS quality reporting will require reporting on 50% of patients.

- Eligible clinicians or groups are required to report at least six quality measures, including one outcome measure. If fewer than six measures apply to a clinician or group, the clinician or group must report on all measures that are applicable. If there is no applicable outcome measure, then clinicians or groups must report a high priority measure instead.
- Eligible clinicians also have the option of choosing their measures from the specialty specific measure set.

Clinicians and groups can choose from measures listed in the MIPS measures list or report on a specialty-specific measure set (which is an organized subset of the MIPS measure list). There is a measure set for general oncology that includes 19 oncology measures. There is also a 4 measure radiation oncology subspecialty measure set. Since the general oncology measure set includes more than 6 measures, oncologists may choose any six measures (including at least one outcome measure, or if no outcome measure exists a high-priority measure) from the set and meet their reporting obligations. Radiation oncologists may report all four measures in the radiation oncology subspecialty measure set and meet their quality reporting requirements.

One innovative pathway for physicians to report quality data is through a qualified clinical data registry. Using a QCDR allows physicians to access quality measures that are not available in the MIPS measure set and may have a stronger link to a physician's area of practice. The reporting requirements for QCDR measures are identical to other MIPS quality reporting mechanisms. If a physician or group elects to use a QCDR, they must report on 6 measures and at least one outcome measure. If there is no outcome measure that applies to the physician or group, then they may report a high-priority measure in lieu of the outcome measure.



In addition to the quality measures that are reported by physicians and groups, CMS also finalized the All Cause Hospital Readmission measure that will be used to assess groups of more than 15 eligible clinicians where an applicable case minimum has been met.

Scores for each quality measure will be quantified. For example, the reported quality measures would be compared to benchmarks and would earn between 1 to 10 points per measure. Similarly, the population-based measures would also receive scores.

The Quality performance category would account for 60 percent of the total MIPS score for the 2017 performance period. CMS proposes to reduce the overall weight of the quality performance category to 50 percent in the 2018 performance period and 30 percent in the 2019 performance period.

How does the Cost performance category measure performance? The cost performance category (renamed from "resource use" in the proposed rule) has no data reporting requirements. All cost measures are based on Medicare claims data collected by CMS. The 2017 measure set used to evaluate costs will only include measures that have been used in the value modifier program in 2017 or that physicians have previously received feedback reports on. The measures include the "total per capita costs" measure and the "Medicare spending per beneficiary" measure used in the value modifier program and ten episode-based measures for specific conditions or procedures. The mastectomy episode is the only episodes or measure in the cost performance category that has a strong clinical connection to cancer care.

CMS will include the costs of Part B drugs in its assessment of cost performance. The Agency is initially excluding Part D drug costs, but is exploring ways to include these costs in future years. Costs will be attributed to physicians at the individual level, and attributed costs from physicians in the same group will be aggregated at the TIN level for group assessment.

CMS will score the resource use category in a similar manner to the quality performance category. CMS will assign one to ten points to each measure based on the eligible clinician's performance against a benchmark. The benchmark would be based on the performance period, rather than a previous baseline period. CMS believes that benchmarking performance based on the performance period is appropriate because of new technologies and changes in Medicare reimbursement that occur year over year. If no resource use measures are attributed to a clinician, then the resource use category would not be scored.

The Cost performance category will be weighted at 0% in the 2017 performance period. Cost will account for 10 percent of a physician's MIPS score in 2018 and 30 percent of a physician's MIPS score in 2019.

How is performance measured under the Improvement Activity category? The Improvement Activity performance category (renamed from "clinical practice improvement activities" category in the proposed rule) is the only performance category in MIPS that is not based on a preexisting CMS quality or value initiative. Improvement activities are activities that have a proven association with improved health outcomes.

Physicians and groups are scored on a 40-point scale in the Improvement Activity performance category. Under MACRA, Congress required CMS to award the maximum performance score (40) to clinicians and groups that are certified as patient-centered medical homes or comparable specialty practices. MACRA also required that APM participants receive half of the maximum score (20) for the improvement activity performance category.

CMS proposes a list of activities for 2017 that providers can pursue to score points under this category in Table H of the final rule. Several of the listed improvement activities may interest oncology providers, such as participation in and use of data reported to a QCDR, participation in payment reform models sponsored by the CMS Innovation Center, and longitudinal and episodic care management initiatives. In particular, there are multiple different activities that providers can perform using QCDRs to earn points toward the improvement activity requirement. The proposed QCDR-related activities are reproduced in Exhibit 1 at the end of this memorandum.



To receive points, providers must choose improvement activities from the list and perform them for at least 90 days during the performance year. Improvement activities are categorized as medium or high weight. Performance of a high weight improvement activity receives 20 points and performance of a medium weight improvement activity receives 10 points.

The Improvement Activity performance category accounts for 15 percent of the MIPS score for the 2017 performance period. CMS proposes to maintain the overall weight of the improvement activity performance category at 15 percent in the 2018 and 2019 performance periods.

How is performance measured under the proposed Advancing Care Information category? The Advancing Care Information performance category is a new name for the existing EHR Incentive Program, which is commonly referred to as the Meaningful Use program. The rule reinstates a 90-day reporting period for 2017 and 2018 rather than the year-long reporting period contemplated by the proposed rule and allows group reporting of EHR utilization for the first time. The rule also permits participants to use qualified registries or QCDRs to report the EHR utilization for the first time.

Advancing care information creates a new scoring mechanism to assess EHR use. All ACI measures are based on modified stage 2 or stage 3 meaningful use measures. Providers or groups must demonstrate participation across a defined set of measures that make up the "base score." Physicians or groups successfully achieve the base score when they meet the measure criteria for at least one case for each of the base score measures. The base score is worth 50% of the ACI performance category score and providers do not receive any partial credit. The second component of ACI is the performance score. The performance score is worth 50% of the ACI score. There are also opportunities to earn bonus points under ACI through additional registry reporting and reporting improvement activities using CEHRT.

The certification requirements and the timeline for adoption of 2015 edition certified technology remain unchanged under the final rule. Physicians or groups may use technology certified to the 2014, 2015, or a combination of 2014 and 2015 ONC Certification standards in the 2017 performance period. All MIPS participants are required to use technology certified to the 2015 Certification Standards beginning with the 2018 reporting period.

Reporting electronic clinical quality measures (eCQMs) is not required as part of the advancing care information performance category. However, CMS hopes to encourage eCQM reporting under the quality performance category by providing bonus points for reporting measures submitted via CEHRT, qualified registry, QCDR, or CMS Web Interface mechanisms.

The weight of the Advancing Care Information performance category score in the 2017 performance period is 25 percent of the total MIPS score. CMS proposes to maintain the overall weight of the Advancing Care Information performance category at 25 percent in the 2018 and 2019.

How would the total score be calculated for the 2017 performance period? CMS would calculate a clinician's or group's MIPS Composite Performance Score (CPS) by assigning their score in each of the four performance categories a weight. CMS has the discretion to adjust these weights in future years and has proposed the following values for 2019 and beyond as shown below:

Performance Category	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year and Beyond
Quality	60%	50%	30%
Resource Use	0%	10%	30%
Improvement Activities	15%	15%	15%
Advancing Care Information	25%	25%	25%



Based on the 2017 performance year, positive and negative adjustments of up to 4 percent would be implemented in 2019 on a sliding scale. The negative adjustments paid in 2019 would not exceed 4 percent, and the positive adjustments could be higher or lower than 4 percent depending on refinements CMS may have to make to achieve overall budget neutrality.

In subsequent years, the maximum penalties under MIPS would be: 5 percent in payment adjustment year 2020, 7 percent in payment adjustment year 2021, and 9 percent in payment adjustment year 2022.

Exceptional MIPS performers may receive additional upward payment adjustments in addition to the MIPS payment adjustment, due to targeted funding made available in MACRA for the first six years of the program.

Advanced Alternative Payment Models (APMs):

Alternative Payment Model Overview: Alternative Payment Models are value-driven payment models that focus on lowering the cost of care while attempting to increase quality of care for Medicare beneficiaries through the use of financial incentives and quality reporting.

MACRA contemplates several types of APMs. The statutory and regulatory definition of the term "alternative payment model" means a Medicare payment arrangement authorized by section 1115A of the Social Security Act, the Medicare Shared Savings Program, a demonstration under section 1866C of the Social Security Act, or certain other Medicare demonstrations.

An advanced APM is an APM that meets certain statutory and regulatory criteria (discussed below). Other Payer Advanced APMs are payment models that are funded by Medicaid, private payers, or Medicare Advantage and meet the statutory and regulatory criteria to be an Other Payer Advanced APM.

Incentive payments are only available for clinicians that meet the standards for qualifying participation in an Advanced APM from 2017-2022 or qualifying participation in a combination of Advanced APM and Other Payer Advanced APM from 2019 to 2022. Incentive payments in 2019 and 2020 are earned by achieving qualifying APM participant (QP) status through Advanced APM participation. Beginning in performance year 2019, eligible clinicians may achieve QP status through participation in a combination of Other Payer Advanced APMs and Advanced APMs. Eligible clinicians may not qualify for an incentive payment in any year without meeting a minimum Medicare Advanced APM participation threshold.

What are the requirements to receive an incentive payment for participation in an Advanced APM? Eligible clinicians that meet the Medicare threshold requirements to be considered qualifying APM participants (QPs) will receive a 5% incentive payment from CMS in payment years 2019-2024. The payment is made to the TIN associated with the eligible clinician's participation in an APM entity. CMS determines whether a clinician is a QP by analyzing whether the APM entity met thresholds for treating a qualifying portion of Medicare Part B patients or receiving a qualifying portion of its Medicare Part B revenue from Advanced APM participation in the performance year.

An eligible clinician that meets the threshold requirement to be a partially qualifying APM participant (PQAP) will be exempted from MIPS but will not receive an APM incentive payment.

The chart below shows the Part B payment amount threshold and Part B patient threshold amounts that are necessary to achieve QP and PQAP status through participation in an Advanced APM.



Medicare-Only Option

Incentive Payment Year	Payment Am	ount Threshold	Patient Count Threshold		
	QP	PQAP	QP	PQAP	
2019-2020	25%	20%	20%	10%	
2021-2022	50%	40%	35%	25%	
2023 and beyond	75%	50%	50%	35%	

Beginning in performance year 2019, eligible clinicians can achieve qualifying APM participant or partially qualifying APM participants through lower levels of Medicare APM participation by meeting the requirements of "All-Payer Combination Option." This option allows eligible clinicians to use participation in Other Payer Advanced APMs and Advanced APMs to qualify for incentive payments and MIPS exemption. Other Payer Advanced APMs may include Medicare, private payer and Medicare Advantage payer arrangements. The All-Payer Combination Option still requires eligible clinicians to meet minimum Medicare APM threshold requirements, so a "commercial only" entity cannot be used to achieve QP status.

All-Payer Combination Option

Incentive Payment Year	Payment Amount Threshold			Patient Count Threshold				
	QP	Min. Medicare	PQAP	Min. Medicare	QP	Min. Medicare	PQAP	Min. Medicare
2019-2020	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2021-2022	50%	25%	40%	20%	35%	20%	25%	10%
2023 and beyond	75%	25%	50%	20%	25%	10%	35%	10%

What are the minimum criteria that an APM must meet to be an Advanced APM? There are three requirements that differentiate an Advanced APM from an APM. An Advanced APM must:

- Require at least 50 percent of eligible clinicians in each participating APM Entity group, or, for APMs in which hospitals are the APM Entities, each hospital, to use Certified Electronic Health Records Technology (CEHRT) to document and communicate clinical care to their patients or other health care providers;
- An Advanced APM must include quality measure performance results as a factor when determining payment to participants under the terms of the APM and include at least one outcome measure; and
- An Advanced APM must meet the applicable general financial risk and nominal financial risk standards.

(1) Use of certified electronic health record technology: The same CEHRT definition used in MIPS will be used for Advanced APMs to align health information technology requirements across programs. CMS will require at least 50% of eligible clinicians in each participating APM entity to use CEHRT in 2017 and 2018. CMS will consider increasing the threshold in later years. Where hospitals are APM Entities, each hospital is required to use CEHRT.

(2) Payment Based on Quality Measures: An Advanced APM must base payment, in part, on quality measure performance. An Advanced APM must require APM entities to report at least one outcome measure and one quality measure with an evidence-based focus that is reliable and valid. APMs can demonstrate that quality measures are evidence based, reliable, and valid when the measure is used in the MIPS quality performance category, the measure is



endorsed by a consensus based entity, the measure is developed under the quality measure development plan, the measure is submitted in response to the MIPS Call for Quality Measures, or the measure is deemed to have an evidence-based focus by CMS.

(3) Meet the General and Nominal Financial Risk Standards: APMs must meet a general and nominal risk standard to be considered an Advanced APM. There are two types of risk standards for APMs – those that apply to Medical Home Models and those that apply to all other APMs (non-Medical Home Models).

(a) General Financial Risk Standards: The general financial risk standards apply to both Medical Home and non-Medical Home models and require that the APM must:

- Withhold payments to the APM Entity or APM Entity's eligible clinicians;
- Reduce payments to the APM Entity or APM Entity's eligible clinicians; or
- Require the APM entity to owe payments to CMS.

Medical Home Model APMs may also meet the general financial risk standard where the APM entity loses its right to all or part of an otherwise guaranteed payment or payments.

(b) Nominal Financial Risk Standard. The MACRA statute requires APM entities to bear more than nominal financial risk.

The non-Medical Home APM nominal risk standards were significantly amended in the final rule. The proposed rule required Advanced APMs to meet three financial risk standards. The final rule simplifies the risk standards in an effort to minimize confusion and alleviate stakeholder concerns about their complexity. The proposed financial risk standards were too confusing and overly ambitious for some providers and practices.

The total amount that an APM Entity must potentially owe CMS or forgo in a non-Medical Home Advanced APM must be either: (1) at least 8 percent of the estimated average total Medicare Parts A and B revenues of participating APM Entities; or (2) at least 3 percent of the expected expenditures for which an APM Entity is responsible under the APM.

CMS noted that it plans to increase the revenue-based standards to 10-15% of the APM entity's Medicare Part A and B revenues beginning in the 2019 performance period.

There are separate nominal risk standards for Medical Home Models that are based on estimated average total Medicare Parts A and B revenues of participating APM entities, which is detailed below.

Medical Home Nominal Risk Criteria by Performance Year

Performance Year	Amount Medical Home Model APM Entity Owes CMS or Forgoes under APM Arrangement
2017	2.5%
2018	3%
2019	4%
2020 and beyond	5%

What are the ongoing Advanced APM Initiatives that are available for participation in 2017? CMS published a list of programs that it expects to be Advanced APMs in 2017 on its website. The Agency plans to publish a final list prior to January 1, 2017. The programs identified as Advanced APMs for 2017 are:



- The Oncology Care Model Two sided risk
- Comprehensive ESRD Care Two sided risk
- Comprehensive Primary Care Plus (CPC+)
- Next Generation ACO Model
- Shared Savings Track 2
- Shared Savings Track 3

<u>Conclusion</u>: ASCO remains engaged in working with policymakers to improve MACRA. Please reach out to <u>Sybil Green</u> with any additional questions regarding MACRA implementation.

Exhibit 1

QCDR-Related Activities from Table H of Proposed Rule

Table H of the proposed rule includes several CPIAs that involve the use of a QCDR. These include:

- Use of a QCDR to generate regular performance feedback reports that summarizes local practice patterns and treatment outcomes, including for vulnerable populations.
- Participation in a QCDR, demonstrating performance of activities that promote the use of standard practices, tools and processes for quality improvement (e.g., documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).
- Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
- Participation in a QCDR, that promotes the use of patient engagement tools.
- Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.
- Use of a QCDR patient experience data to inform and advance improvements in beneficiary engagement.
- Participation in a QCDR, that promotes implementation of patient self-action plans.
- Participation in a QCDR, that promotes the use of processes and tools that engage patients for adherence to treatment plan.
- Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.
- Use of QCDR data, for ongoing practice assessment and improvements in patient safety.
- Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology.
- Participation in a QCDR, demonstrating performance of activities for prompting use of patient-reported outcome (PRO) tools and corresponding collection of PRO data (e.g., use of PQH-2 or PHQ-9 and PROMIS instruments.)
- Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status.

