Chapter S

MACRA: Physician Payment Reform and Legal Perspectives

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Table of Contents

Chapter S
MACRA: Physician Payment Reform and Legal Perspectives ........................................ S-1
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I. Overview of Medicare Access and CHIP Reauthorization Act of 2015
   ("MACRA") ........................................................................................................ S-5
   A. Legislative History ............................................................................................. S-5
   B. MACRA Amends the Medicare Act at Section 1848 ........................................ S-5
   C. MACRA Establishes the “Quality Payment Program” ("QPP") ......................... S-5
   D. Aims of MACRA According to CMS ............................................................... S-5
   E. MACRA Is Effective January 1, 2017 ............................................................... S-5
   F. Financial Risks for Eligible Physicians and Other Professionals ................... S-6
   G. Who Is In and Who Is out? ............................................................................. S-6

II. Merit-Based Incentive Payment Systems (MIPS) .................................................. S-6
   A. Important Features of MIPS ............................................................................ S-6
   B. Which Professionals Does MIPS Affect? ....................................................... S-6
   C. Professionals Excluded from MIPS ............................................................... S-7
   D. MIPS Options .................................................................................................. S-7
   E. Advanced APMs ............................................................................................. S-7
   F. MIPS Reporting ............................................................................................... S-8
   G. Calculating MIPS Performance ....................................................................... S-8

III. Advanced APMs/Other Payer Advanced APMs ................................................ S-11
   A. Scope .............................................................................................................. S-11
   B. APMs Are Payment Approaches .................................................................. S-11
   C. Advanced APM Lump-Sum Bonus Payments ............................................... S-11
   D. Criteria to Be Considered an Advanced APM ............................................... S-11
   E. Qualifying APM Participants (QPs) ............................................................... S-11
   F. Advanced APM Criteria ................................................................................ S-11
   G. Advanced APMs (2017) ............................................................................... S-12

IV. Legal Considerations ......................................................................................... S-13
   A. MACRA Amends the Medicare Act at Section 1848 .................................... S-13
   B. Organizational Structure/Antitrust ................................................................ S-13
   C. Data Privacy, Security and Use Issues ......................................................... S-17
I. Overview of Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA")

A. MACRA was passed by Congress on a bipartisan basis and signed into law on April 16, 2015, to convert the current Medicare fee-for-service physician payment system to a value-based reimbursement system. It also replaced the use of the sustainable growth rate ("SGR") formula to annually determine physician payments. Because the application of the SGR formula threatened significant physician payment reductions, Congress had annually passed a “doc fix” to ensure adequate payments to physicians. This approach did not contain physician costs as intended. MACRA has been called the “permanent doc fix.”


C. MACRA establishes the “Quality Payment Program” ("QPP") to promote payment based on the quality of services rendered by clinicians and other professionals. The Quality Payment Program is comprised of two tracks: the Merit-Based Incentive System ("MIPS") and Alternative Payment Models ("APMs").

D. According to CMS, MACRA aims to:

1. Offer multiple pathways with varying levels of risk and reward for providers to tie more of their payments to value.

2. Over time, expand the opportunities for a broad range of providers to participate in APMs.

3. Minimize additional reporting burdens for APM participants.

4. Promote understanding of each physician’s or practitioner’s status with respect to MIPS and/or APMs.

5. Support multi-payer initiatives and the development of APMs in Medicaid, Medicare Advantage, and other payer arrangements.


E. MACRA is effective January 1, 2017, for purposes of determining Medicare payment beginning January 1, 2019. There are several available participation options for eligible professionals:

1. Under the MIPS track, report specific data according to one of three reporting options based on readiness; or
2. Under the APM track, join an “Advanced APM”, a type of APM created under MACRA. MIPS-eligible clinicians who choose not to report (at least one measure) will receive a full negative 4% payment adjustment.

F. Initially, most eligible physicians and other professionals will participate in one of the three MIPS options because each imposes less financial risk and operational challenges than participation in or the creation of an APM. In 2016, approximately 30% of Medicare payments were made through APMs; however CMS expects that under the QPP, 50% of payments made by Medicare will be made through APMs by 2019, thus transitioning from the fee-for-service to a value-based reimbursement system.

G. Who is in and who is out? According to CMS estimates, the numbers of physicians to be impacted by MACRA are as follows:

1. Under the MIPS track: ~590,000 - 640,000
2. Under the Advanced APMs track: ~70,000 - 120,000
3. Excluded from MIPS and Advanced APMs: ~580,000

II. Merit-Based Incentive Payment Systems (MIPS)

A. Important features of MIPS:

1. MIPS grows out of, and consolidates, the following existing Medicare payment programs: the Physician Quality Reporting Program, the Value-Based Payment Modifier, and the Medicare Electronic Health Records Incentive Program (the Meaningful Use EHR Incentive Program).

2. MIPS focuses on quality, cost, and use of Certified Electronic Health Record Technology in a cohesive program that avoids redundancies.

3. MIPS measures physicians and other participating professionals based on four performance categories:

   a. Quality;
   b. Cost;
   c. Advancing care information; and
   d. Clinical practice improvement.

B. Which professionals does MIPS affect?

1. Years 1 and 2:
   a. Physicians (MD/DO & DDS/DCM/DMD);
b. PAs, NPs, Clinical nurse specialists;
c. Certified registered nurse anesthetists; and
d. Groups that include such professionals.

2. Possible Expansion in Years 3 and later:
   a. Physical or occupational therapists;
   b. Speech-language pathologists;
   c. Audiologists;
   d. Nurse midwives;
   e. Clinical social workers and clinical psychologists; and/or
   f. Dietitians/Nutritionists.

C. Professionals excluded from MIPS:

1. Newly enrolled professionals (defined as first-year Medicare Part B enrollees).

2. Low-volume threshold allows small practices to be excluded from new requirements for transitional year 2017. Threshold is less than or equal to $30,000 in Medicare Part B allowed charges or less than 100 Medicare patients.

3. “Qualified APM Participants” participating in Advanced APMs.

4. Partial Qualified APM Participants (“Partial QPs”) who do not report data under MIPS.

D. MIPS Options:

1. MIPS-participating physicians and other professionals may choose how they will be measured beginning January 1, 2017 (“Pick Your Pace”); payments change in 2019.

2. Payment differentials are substantial: +/- 4% initially, to +/- 9% by 2022.

3. Performance scored on a curve (compared to physicians nationally).

4. Commercial plans may mimic MIPS.

E. Other physicians will be in Advanced APMs, which include downside risk and give physicians a 5% lump-sum bonus.
F. MIPS Reporting

1. Eligible clinicians have four options for MIPS reporting:
   a. Taxpayer Identification Number (TIN)
   b. National Provider Identifier (NPI)
   c. Virtual Group (clinicians in different locations)
   d. Accountable Care Organization (ACO)

2. Payment will lag reporting and performance measurement period by two years. So, calendar year 2017 performance on reported metrics will apply to calendar year 2019 payment adjustments.

3. To ease providers into MIPS reporting, CMS is offering a “Pick Your Pace” program with four options for reporting 2017 data:
   a. Do not participate and receive the maximum penalty (4%).
   b. Submit something (for example, one measure for any point in 2017) and receive a neutral adjustment.
   c. Submit a partial year (90 contiguous days) and receive either a neutral or small positive adjustment.
   d. Submit a full year and receive either a neutral or positive moderate adjustment (likely greater than partial submission).

G. Calculating MIPS Performance: Composite Score and Supporting Performance Categories

1. Pre-MACRA Programs:
   a. Physician Quality Reporting System (PQRS)
   b. Value-Based Payment Modifier (VM)
   c. Meaningful Use EHR Incentive Program (MU)

2. MIPS Performance Categories:
   a. Quality
   i. Six quality measures, or one specialty-specific or subspecialty-specific measure set
ii. For transition year 2017, meeting ONE quality measure will meet the MIPS performance threshold

b. Cost
i. Will not be considered for transition year 2017

c. Advancing Care Information
i. Five required measures

d. Improvement Activities
i. May engage in up to four activities
ii. Attesting to at least ONE improvement activity will be sufficient to meet the MIPS performance threshold for 2017

3. Relative weighting of performance categories over time:

a. 2019 (based on 2017 performance):
   i. Quality = 60%
   ii. Advancing Care Information = 25%
   iii. Improvement Activities = 15%
   iv. Cost = 0%

b. 2020 (based on 2018 performance):
   i. Quality = 50%
   ii. Advancing Care Information = 25%
   iii. Improvement Activities = 15%
   iv. Cost = 10%

c. 2021 and beyond (based on 2019 performance):
   i. Quality = 30%
   ii. Advancing Care Information = 25%
   iii. Improvement Activities = 15%
   iv. Cost = 30%
4. Four performance category scores are weighted and roll up into one MIPS “composite score.”
   a. For each performance year, CMS will establish a performance threshold.
   b. Composite scores above the performance threshold will receive a positive fee schedule adjustment.
   c. Scores equal to the performance threshold receive no adjustment.
   d. Scores above the performance threshold receive a negative adjustment.
   e. While the transition year performance threshold has been set to 3, CMS has indicated plan to increase the performance threshold to closer to the median score by year three of the program.
   f. Scoring on specific measures is on a curve relative to other MIPS providers reporting for similar quality and improvement activity metrics.

5. MIPS Payment Adjustments
   a. Inflation adjustments are relatively flat from 2017 to 2020.
   b. Beginning in 2019, MIPS adjustments will be applied to fee schedule payments based on performance in calendar year 2017.
   c. MIPS adjustment ranges will increase over time.
   d. MIPS is budget-neutral, meaning that penalties will fund positive adjustments.
   e. CMS has established a maximum penalty of -4% in 2019, -5% in 2020, -7% in 2021 and -9% in 2022 and beyond. Since the penalties will fund positive adjustments, it is expected that positive adjustments will range from +4% to +9% from 2019 to 2022.
   f. Since many providers will likely meet or exceed the performance threshold in the transition year, it expected that maximum positive payment adjustments will be less than 4%, given the penalty pool is likely to be small.
   g. “Exceptional performers” are eligible to receive an additional positive adjustment factor. For each year from 2019 to 2024, a pool of $500 million has been established to fund these additional
positive adjustments for performers that exceed a second “additional performance threshold.”

h. In addition to MIPS adjustments, minor inflation adjustments of 0.25% will be made to the fee schedule in 2026 and beyond.

III. Advanced APMs/Other Payer Advanced APMs

A. Program supports the goals of transitioning from fee-for-service payments to payments for quality and value, focusing on better care, smarter spending, and healthier individuals.

B. APMs are payment approaches, developed in partnership with the clinician community, that provide added incentives to deliver high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population.

C. Through Advanced APMs, clinicians who would otherwise be eligible for MIPS can earn lump-sum bonus payments.

D. To be considered an Advanced APM, or an Other Payer Advanced APM, an APM or its payment arrangement with a payer must meet all three of the following criteria:

1. The APM must require participants to use CEHRT;  
2. The APM must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS and;  
3. The APM must either require that participating APM entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model.

E. Qualifying APM Participants (QPs)

1. Qualifying clinicians in an Advanced APM who have a certain percentage of their patients or payments through an Advanced APM:
   a. Are excluded from MIPS; and  
   b. Receive 5% lump-sum bonus payments at the beginning of each year from 2019-2024, based on qualifying in 2017-2022.

F. Advanced APM qualifies if it is either:

1. At risk of losing at least 8% of its own revenues when Medicare expenditures are higher than expected; or
2. At risk of repaying CMS up to 3% of total Medicare expenditure for an episode or for which the clinician is responsible.

G. Advanced APMs (2017):

1. Advanced APMs require a separate application and approval process. Current Advanced APMs are:
   
a. Comprehensive End Stage Renal Disease Care Model (Two-Sided Risk Arrangement)
      
i. Dialysis clinics, nephrologists and other providers join together to create an End-Stage Renal Disease Seamless Care Organizations to coordinate care for matched beneficiaries.
   
   ii. Shared savings as well as shared risk for organizations of over 200 dialysis facilities.
   
b. Medicare Shared Savings Program (ACO) Track 2.
   
c. Medicare Shared Savings Program (ACO) Track 3.
   
d. Comprehensive Primary Care Plus
      
i. Advanced primary care medical home model.
      
   ii. Three payment elements: (1) care management fee; (2) performance-based incentive payment; and (3) payment under the Medicare Physician Fee Schedule.
   
e. Oncology Care Model (Two-Sided Risk Arrangement)
      
i. Next Generation ACO Model
      
   (a) Allows provider groups to assume higher levels of financial risk and reward than are available under the current Pioneer Medicare Shared Savings Program (ACO).
      
   (b) Allows an aligned Next Generation ACO beneficiary to receive telehealth services in their home, regardless of whether they live in a rural area.
   
   (c) Allows for a physician to contract with licensed clinicians to provide a home visit to a patient at the patient’s home, under the general supervision (as
opposed to direct supervision) of a Next Generation ACO Participant or Preferred Provider following discharge from an inpatient facility.

(d) Allows for a Medicare patient, aligned to a Next Generation ACO that is participating in the waiver, admission to approved SNFs from their home, a physician’s office, or an observation status in the emergency room; or when they have been in the hospital for fewer than three days.

2. CMS has proposed additional APMs that are anticipated to be qualify as Advanced APMs in 2018, including Comprehensive Care for Joint Replacement Model (CEHRT Track), Episode Payment model CEHRT Track, New Voluntary Bundled Payment Model, and Vermont All-Payer ACO Model.

3. Payment Adjustments:
   a. Inflation adjustments are relatively flat from 2017 to 2020.
   b. Potential for 5% “lump sum” bonus to be applied from 2019 to 2024 for qualifying Advanced APMs.
   c. Qualifying Advanced APMs will get a 0.75% adjustment to the fee schedule in 2026 and beyond (compared to 0.25% for MIPS-eligible clinicians)

IV. Legal Considerations

   B. Organizational Structure/Antitrust

    1. MACRA payment models promote greater alignment among smaller providers looking for ways to share risk and to monitor and oversee care by other providers who are involved in patients’ care.

    2. Providers may be attracted to Clinically Integrated Networks (“CINs”), i.e., networks of providers that use a common electronic health record system and work to develop clinical initiatives and programs to allow participants to deliver better quality and coordination of care in a more cost-efficient manner. CINs can provide the “best of both worlds” for independent providers, since participating organizations preserve their independence while achieving many benefits similar to a merger.
3. CINs are typically structured as joint ventures, in which the participants do not combine their entire businesses and operations into the CIN. Because of this, each provider is able to maintain autonomy and independence, but still benefit from the integrated structure of a group practice.

4. Such alignment among independent providers offers providers potential economic benefits, but also creates risks that non-aligned providers and groups do not necessarily face.

5. For example, antitrust compliance is critical for CINs that enable their members to contract with third-party payors on a joint basis, because price-fixing arrangements and agreements not to compete among competitors, without financial and/or clinical integration, are per se illegal under the antitrust laws.

   a. Specific antitrust “safety zones” have been established by the Federal Trade Commission/Department of Justice (“DOJ”), which describe conduct that these agencies will not challenge, absent extraordinary circumstances:

      i. Hospital joint ventures involving specialized clinical or other expensive health care services. Such joint ventures can be useful because the development of these services usually requires investments that a single hospital may not be able to support.

      ii. Group purchasing arrangements, which allow healthcare providers to realize savings and efficiencies by aggregating purchasing volume negotiating with manufacturers, distributors and other vendors.

      iii. ACOs which offer healthcare providers the opportunity to share in the savings they achieve for the Medicare program through the provision of integrated and efficient healthcare.

      iv. Multi-provider networks, which are “ventures among providers that jointly market their health care services to health plans and other purchasers” and “may contract to provide services to subscribers at jointly determined prices and agree to controls aimed at containing costs and assuring quality.”

See the DOJ’s “Statements Of Antitrust Enforcement Policy In Health Care,” available at: https://www.justice.gov/atr/statements-antitrust-enforcement-policy-health-care.
b. If a CIN’s organizational structure falls within a “safety zone,” that CIN only needs to focus on avoiding collusion outside of the scope of the CIN’s activities.

c. If the “rule of reason” applies under the antitrust laws (i.e., not per se illegal, but no “safety zone”):
   i. CINs need to consider whether their organizational structure is likely to have anti-competitive effects (e.g., higher prices, less consumer choice).
   ii. If so, the CIN must evaluate whether potential pro-competitive effects (e.g., enhancing efficiency) are likely to outweigh anti-competitive effects.

d. Consider relevant market(s), competitive effects and efficiencies, and limit restraints on competition to those reasonably necessary to achieve efficiencies.

6. Virtual groups and other reporting models may pose similar legal compliance challenges as CINs.

7. Fraud and Abuse Concerns
   a. In general, financial arrangements between providers must be structured such that they do not violate referral laws and prohibitions. Specifically, such arrangements cannot influence physicians’ judgment or incentivize them to treat Medicare beneficiaries different than other patients. The provision of health care should always continue to meet community standards of care, and quality metrics should be widely recognized, regardless of the organizational structure of an organization.
   
   b. The Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b) prohibits the exchange of anything of value in exchange for the referral of federal health care program business. Referrals amongst providers who are integrated, but not fully, can violate the Anti-Kickback Statute. Analyses must be performed to ensure that organizational structures either (i) do not violate the Anti-Kickback Statute, or (ii) fall within a safe harbor, in which case the conduct would not be considered to violate the Anti-Kickback Statute.

   i. Many states have promulgated laws that mimic the federal Anti-Kickback Statute. In certain instances, these laws are more restrictive or prohibitive than their federal counterpart.
c. The Federal Stark Law (42 U.S.C. § 1395nn) prohibits physician self-referrals for specified “designated health services”, including inpatient and outpatient hospital services, clinical laboratory services, etc., if the physician (or an immediate family member) has a financial relationship with the referral entity.

i. Clinically integrated practices may or may not fall within the scope of the Stark Law prohibitions, depending on their organizational structure. Providers referring to ancillary providers, e.g., laboratory services, within the same CIN or other structured group organization have to ensure that they are not violating Stark Law’s self-referral prohibitions.

ii. As with the Anti-Kickback Statute, many states have enacted laws that are similar to, and in some cases (more stringent than the federal Stark Law (e.g., New Jersey).

8. Gainsharing and Civil Monetary Penalties

a. The Office of Inspector General (“OIG”) of the Department of Health and Human Services could take the position that gainsharing arrangements trigger the Federal Civil Monetary Penalties (“CMP”) provisions at 42 USC § 1320-7a because physicians’ cost-cutting behavior could affect Medicare and Medicaid patients. The CMP provisions prohibits a hospital from knowingly making “a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided” to Medicare beneficiaries and Medicaid recipients who are under the direct care of the physician.

b. “Gainsharing” typically refers to an arrangement in which a hospital gives physicians a share of any reduction in the hospital’s costs for patient care attributable in part to the physicians’ efforts. Advanced APMs may implicate gainsharing as relationships between hospitals and physicians become more intertwined.

c. The OIG has issued guidance and opinions on gainsharing arrangements. See, e.g., OIG Special Advisory Bulletin, July 1999; OIG Opinions Nos. 08-15, 08-16, 08-21 and 12-22.

9. In ensuring compliance with fraud and abuse laws, an important factor to consider is compensation. Compensation amounts should always be supported by quality metrics: it is easier and “cleaner” to pay clinicians per capita rather than based on individual performance.
C. Data Privacy, Security and Use Issues

1. The collection, analysis and exchange of protected health information and trade secret information (e.g., hospital-specific outcomes information) that is required under MACRA pose privacy, security and data use issues, e.g., does data disclosure comply with privacy and breach protections under the Health Information Portability and Accountability Act (“HIPAA”) and other privacy and security laws; is data adequately secure; is only the minimum amount of data disclosed; and is data properly used by third party information technology (“IT”) vendors? Also, there is a recognition that most clinicians and organizational structures reporting under MACRA are not sufficiently sophisticated to undertake the reporting function.

   a. Clinicians and organizations reporting under MACRA are not legally responsible for breaches and other inappropriate uses and disclosures caused by the government. However, an inappropriate use or disclosure by the government may impact the reporter adversely and lead to legal issues, e.g., privacy lawsuits.

2. Third Party Intermediaries. Clinicians may submit measures, objectives and activities for the quality, improvement activities and advancing care information activities through specific third-party intermediaries and vendors. In general, these intermediaries must have the capability to measure performance, aggregate Medicare claims data with existing claims data, allow clinicians to review and correct their data, and comply with data privacy and security procedures. Permitted third party intermediaries specifically include:

   a. A Qualified Registry, defined as a medical registry, a maintenance of certification program operated by a specialty program of the American Board of Medical Specialties or other data intermediary that has self-nominated and been vetted by CMS to demonstrate compliance with the MIPS qualification requirements for a specific reporting period;

   b. A Qualified Clinical Data Registry, defined as a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients;

   c. A health IT vendor or other authorized third party that obtains data from a MIPS-eligible clinician’s CEHRT; or

   d. A CMS-approved survey vendor, defined as a vendor approved by CMS for a particular performance period to administer
Consumer Assessment of Healthcare Providers and Systems ("CHAPS") for MIPS survey and to transmit survey measures to CMS.


3. Given that a clinician’s Medicare reimbursement will be determined based on its data, it is critical that the clinician enter into robust service and data use agreements with third parties intermediaries. These contracts must clearly address issues including indemnification, warranties, liabilities and disputes resolution in a manner that adequately protects the data provider.

4. The reliance on the third party intermediaries raises specific privacy, security and abuse concerns, including the inappropriate disclosure of protected health information under HIPAA; the use of information for marketing purposes or to sell; and the use of data analyses for purposes not intended under MIPS, such as for private insurer-provider negotiations. As appropriate, parties must enter into HIPAA business associate agreements and data use agreements to ensure the appropriate use of data and data analyses.