



Physician Only ACOs: An Opportunity to Consider*

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The Affordable Care Act authorized the Center for Medicare and Medicaid Services (CMS) to establish the Medicare Shared Savings Program (MSSP).¹ CMS formalized the governance, clinical integration and reporting requirements of its accountable care organization (ACO) applicants. As of January 2018, there were 561 MSSP ACOs serving over 10.5 million assigned Medicare Fee-for-service (FFS) beneficiaries, a 17% increase over 2017.²

The MSSP was intended to incent providers to enable CMS to achieve the triple aim of improving the experience of care, improving the health of populations and reducing per capita healthcare costs by facilitating coordination and cooperation among providers to improve the quality of care for Medicare FFS beneficiaries. Since inception, physician owned ACOs have been leaders in quality and in achieving real savings.³ The opportunity still exists for physicians to form an ACO in their market and take a leadership position in managing patient populations.

What is a MSSP ACO?

ACOs are the entities which administer any shared savings and report on quality, but they have no direct role in FFS payments. All Medicare providers, whether or not affiliated with an ACO, continue to bill Medicare beneficiaries for their services on a FFS basis⁴ based on

that provider's tax identification number (TIN).⁵ This is true notwithstanding whether the patient is assigned to the ACO in which a provider is a member, is assigned to an ACO for which a provider has no affiliation, or is not assigned to any ACO. Despite lack of involvement in FFS payments, ACOs are held accountable for achieving and reporting on the quality of care and patient satisfaction, achieving meaningful clinical integration of their providers, and managing the overall cost of care of the Medicare FFS beneficiaries assigned to them. ACOs may contract with non-member providers such as rehabilitation centers, home health agencies, physical therapy providers, hospitals and surgery centers.

If an ACO meets specified quality performance and cost savings targets and is otherwise in compliance with the governance provisions and other program requirements, it will be eligible to share in the achieved savings above a minimum actuarial threshold based upon the number of assigned beneficiaries.⁶ Under certain permissible elections, the ACO could also be liable for excess cost of its assigned beneficiaries.⁷

What are the Different ACO models?

Over time, CMS has established a number of models some which have only upside risk and some which have

1 42 U.S.C. § 1395jjj

2 See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf>

3 Id.

4 76 Fed. Reg. 67805.

5 Id.

6 76 Fed. Reg. 67804.

7 76 Fed. Reg. 67909; 42 CFR 425.600.

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both upside and downside risk. Those with downside risk offer the opportunity for prospective beneficiary assignment which enables the ACO a greater ability to engage patients and implement care coordination and population health interventions that can limit acuity and direct patients to the most cost effective and appropriate situs of care. In 2018, 101 of the 561 ACOs are in a downside risk program, nearly 2½ times the 2017 number. Appendix A sets forth the principal differences among the models, including the Track 1 + model.

The Track 1 + Model

CMS recently announced a new Medicare ACO Track 1+ Model beginning in 2018, that will allow clinicians to join Advanced Alternative Payment Models (APMs) to improve care and potentially earn an incentive payment under the Quality Payment Program, created by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

The new Medicare ACO Track 1+ Model will test a payment model that incorporates more limited downside risk than is currently present in Tracks 2 or 3 of the MSSP in order to encourage more rapid progression to performance-based risk. The Track 1+ Model will be open to MSSP Track 1 ACOs that are within their current agreement period, initial applicants to the MSSP, and Track 1 ACOs renewing their agreement that meet Model eligibility criteria. ACOs will have additional opportunity to join the Model test as part of the 2019 and 2020 Shared Savings Program application cycles.

The new Model is based on MSSP Track 1 with maximum 50% shared savings rate, but incorporates elements of Track 3 including: prospective beneficiary assignment to allow ACOs to know in advance the patient population for which they are responsible; choice of symmetrical thresholds from which to start sharing in savings or losses; and the option to elect the Skilled Nursing Facility (SNF) 3-Day Rule Waiver to provide greater flexibility to Track 1+ ACOs to better coordinate and deliver high quality care. The model has a fixed 30% loss sharing rate and the maximum level of downside risk would vary based on the composition of ACOs with potentially lower levels of risk available to qualifying ACOs that include physicians or small rural hospitals.

Under a bifurcated approach, in 2018, the maximum loss limit would be either 8 percent of ACO participant

Medicare FFS revenue (for ACOs that are physician led or include small, rural hospitals); or 4 percent of the ACO's updated benchmark depending on the composition of the ACO (for other ACOs now in Track 1 or new or renewing ACOs). In later years, ACOs eligible for the lower sharing limit could opt for a higher percentage of revenue in 2019 and 2020 consistent with changes to the Advanced APM nominal risk requirement. The ACO's loss sharing limit, as a percentage of revenue, would not exceed the equivalent of 4 percent of the ACO's updated historical benchmark.

How have the MSSP ACOs Performed Financially?

The financial and quality successes of ACOs have continuously improved as ACOs have gained more experience. An increasing proportion of ACOs have generated savings above their minimum savings rate (MSR) each year. For performance year 2015, 31 percent of ACOs (120 of 392) generated savings above their MSR compared to 28 percent (92 of 333) in 2014 and 26 percent (58 of 220) in 2013.⁸ ACOs with more experience in the program were more likely to generate savings above their MSR. For performance year 2015, 42 percent of ACOs that started in 2012 generated savings above their MSR, compared to 37 percent of 2013 starters, 22 percent of 2014 starters and 21 percent of 2015 starters.⁹ Not surprisingly, 45 percent of ACOs participating in the Advance Payment Model or ACO Investment Model tested by the Center for Medicare and Medicaid Innovation, which models offer select Shared Savings Program ACOs pre-paid savings, generated savings above their MSR compared to 29 percent of all other ACOs.¹⁰

How have they Performed on Quality?

Shared Savings Program ACOs that reported quality in both 2014 and 2015 improved on 84 percent of the quality measures that were reported in both years.¹¹ The average quality performance improved by over 15 percent between 2014 and 2015 for four measures: screening for risk of future falls, depression screening and follow-up, blood pressure screening and follow-up, and providing pneumonia vaccinations.¹² Over 91 percent of ACOs in a second or third performance year during 2015 increased their overall quality performance score through Quality Improvement Reward points in at least one of four quality measure domains.¹³ CMS has announced 31 quality measures (29 individual measures and one composite that includes two individual component measures) over

⁸ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-25.html>

⁹ Id.

¹⁰ Id.

¹¹ Id.

¹² Id.

¹³ Id.

four quality domains of equal weighting but with varying numbers of measures for scoring: Patient/Caregiver Experience, Care Coordination/Patient Safety, Preventive Health and At-Risk Population which will govern reporting in both 2018 and 2019.

What other Benefits do Physicians Receive from ACO Participation?

Eligible professionals (EPs) who bill under the Taxpayer Identification Number of an ACO participant satisfied the Physician Quality Reporting System (PQRS) reporting requirements when their ACO satisfactorily reported quality measures on the EPs' behalf for the 2015 reporting. As a result, these EPs will avoid the adverse PQRS payment adjustments and Value Modifier downward adjustment for failure to report. In addition, they may be eligible for upward payment adjustments based on their ACO's quality performance under the 2017 Value Modifier.

Why a Physician only ACO

Physician-only ACOs comprise a significant percentage of total ACOs participating in the MSSP. As of January 2018, 171, or 30%, of the 561 ACOs in the MSSP were physician only ACOs.¹⁴

Even with new pay for performance metrics, there are strong financial incentives for hospitals to maintain high patient volume for both their in-patient and out-patient departments and active emergency departments. This FFS revenue is not offset by the potential for shared savings especially in markets where a material portion of the total Medicare spend is not within a single ACO network. Moreover, the market may have many choices in urgent care clinics, patient centered medical homes, ambulatory surgical centers and other outpatient and home health providers. These providers often have significantly lower reimbursement than hospital outpatient departments. At the core of the ACO concept is a focus on aggressive intervention and proactive and better coordinated care and patient engagement to manage chronic conditions, improve wellness and limit the number of acute events. Physician led ACOs have greater flexibility to contract with those allied providers who will comply with clinical pathways, quality reporting, and care coordination as they are building the ACOs network as a new enterprise.

One Success Story

One of the most successful physician owned ACOs, Palm Beach Accountable Care Organization with ap-

proximately 30,000 beneficiaries achieved \$22 million in shared savings in its first performance year. As it reported, the Palm Beach Accountable Care Organization did not try to control where patients went but instead fostered competition within its market and did so by defining expectations and improving coordination with all stakeholders, including specialists, hospitals, home healthcare agencies, and SNFs. A major initiative was education of physicians as to the essential elements and the benefits of quality patient-physician interactions. The Palm Beach Accountable Care Organization went so far as to create "the Big 7" patient satisfaction tips:

1. Providing patients with timely care, appointments, and information;
2. Ensuring effective communication with the doctor;
3. Creating an environment that encourages patients to rate their doctors favorably;
4. Providing easy and convenient access to specialists;
5. Offering health education;
6. Finding ways to involve patients in shared decision making; and
7. Staying current on each patient's health status.

What are the Major Challenges?

The challenge facing physician only ACOs is the lack of capital to support the infrastructure, investment necessary to document and implement MSSP compliance requirements, and to meaningfully develop better patient portals, care coordination and clinical pathways. Despite limited capital, physician only ACOs have been able to obtain management, information technology, care coordination, and compliance infrastructure from third party vendors willing to accept contingent payment from a portion of potential shared savings. Health insurers and private equity funded management companies have been active in this area as they too recognize that a properly supported physician ACO can achieve improved quality and lower costs than independent physicians or mere contracting networks.

What are the Minimum MSSP Qualification Requirements?

The application for ACO certification is on the CMS website.¹⁵ At a minimum, the ACO must identify primary care physicians who provide the majority of their primary

¹⁴ Id

¹⁵ See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Application.html>

care services to at least 5,000 Medicare enrollees.¹⁶ Given the structure of shared savings reimbursement which places a higher threshold for ACOs for fewer attributed patients, generally ACOs will fare much better with scale of at least 15,000 and optimally 50,000 attributed patients. ACOs can include hospitals, specialists, post-acute providers and even private companies like Walgreens. The only must-have element is primary care physicians, who serve as the linchpin of the program.¹⁷

Who must be Exclusive?

Under the MSSP, each Medicare beneficiary can only be assigned to a single unique ACO. Assignment of patients is based on the ACO participant who bills the majority or plurality of the patient's primary care services. As such, exclusivity applies only to those ACO participants upon which beneficiary assignment is dependent.¹⁸ Because beneficiary assignment is dependent on the TIN under which the patient's primary care services are billed,¹⁹ only those physician TINs that are used to bill for "primary care services" will be required to be exclusive to one ACO. Specifically, those ACO participants who provide the following categories of primary care services must be exclusive to one ACO: internal medicine, general practice, family practice and geriatric medicine. Treatment of Medicare Advantage patients does not affect a physician's exclusivity under the MSSP since the MSSP does not apply to patients other than Medicare FFS beneficiaries.

Those ACO participants whose TINs do not affect patient assignment, are not required to be exclusive to one MSSP ACO.²⁰ As such, those ACO participants may participate in multiple ACOs.²¹ Accordingly, hospitals, ambulatory surgery centers, SNFs and rehabilitation centers, home health agencies, imaging centers, most physician specialists, and allied professionals (not billed incident to primary care services), all may elect to affiliate with multiple ACOs. However, if one of the specialists provides primary care services under which beneficiary assignment is based, all the practitioners billing under that TIN must be exclusive to a single ACO.²²

Note, however, that an ACO participant is not necessarily an individual practitioner. As a result, exclusivity is not required for each practitioner but rather for each TIN upon which beneficiary assignment is based. A practitioner who bills under multiple TINs is not required to be exclusive to a single ACO. As CMS explained, "[t]he exclusivity necessary for the assignment process to work accurately requires a commitment of each assignment-based ACO participant to a single ACO for purposes of serving Medicare beneficiaries."²³ However, "exclusivity of an ACO participant TIN to one ACO is not necessarily the same as exclusivity of individual practitioners (ACO providers/suppliers) to one ACO."²⁴ Accordingly specialty groups who do not bill for primary care services but bill under a single TIN may participate in multiple ACOs.

Leveraging With Private Insurers/Shared Savings and Private Network Contracting

The Basics of Clinical Integration

Given that physician ACOs who contract with insurers are an organization of competing providers, they are subject to possible challenge under the antitrust laws.²⁵ The U.S. Department of Justice and the Federal Trade Commission (the Agencies) have provided significant guidance²⁶ as to when health provider organizations are significantly integrated to be viewed as a single enterprise for antitrust purposes. In addition, the Agencies advised that as to MSSP ACOs, they would apply a rule of reason analysis as to whether the ACO's operations would violate the antitrust laws.²⁷ Essentially, clinical integration arises when a group of physicians puts in place a series of procedures that modify the manner in which they provide health care services to patients and communicate with one another. MSSP ACOs which are compliant should meet the Federal Trade Commission's expectation that a clinically integrated physician network creates "a degree of interaction and interdependence among the physician participants in their provision of medical services, in order to jointly achieve

16 See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Providers_Factsheet_ICN907406.pdf

17 The entities and individuals participating in the MSSP must be one of the following types of groups of providers: ACO professionals, networks of individual practices of ACO professionals, partnerships or joint ventures arrangements between hospitals and ACO professionals, hospitals employing ACO professionals, or other Medicare providers and suppliers as determined by the Secretary. See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Providers_Factsheet_ICN907406.pdf; see also <http://khn.org/news/aco-accountable-care-organization-faq/>.

18 42 CFR 425.306

19 See Section III Assignment of Patients to ACOs for Purposes of Measuring Savings.

20 42 CFR 425.306

21 76 Fed. Reg. 67811.

22 *Id.*

23 76 Fed. Reg. 67811

24 *Id.*

25 See e.g., *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982).

26 See Statements 8 and 9 of the Statements of Antitrust Enforcement Policy in Health Care, issued by the U.S. Department of Justice and the Federal Trade Commission, August 1996, accessible at <https://www.justice.gov/sites/default/files/atr/legacy/2007/08/15/1791.pdf>.

27 See <https://www.ftc.gov/news-events/press-releases/2011/10/federal-trade-commission-department-justice-issue-final-statement>.

cost efficiencies and quality improvements in providing those services, both individually and as a group".²⁸ This "interdependence and cooperation among the physicians to control costs and ensure quality"²⁹ includes benchmarks and efforts to improve proper utilization and quality of care, sharing of treatment and prescription information to streamline and better co-ordinate care and lower costs, conditioning physician participation to submission to the protocols, and expectations and infrastructure investment.

Partnering with Management Partners

Physician only ACOs have addressed the infrastructure needs of their ACO via working with insurers and management companies for data services, general administrative services and/or care coordination. Because ACOs may start with less costly information and care coordination systems, they require enhanced infrastructure to give them the capacity to achieve and demonstrate to public and private purchasers that the ACO can deliver quality and cost-effective services. Changing physician behavior will require that the ACO can educate them first with useful information concerning their performance based on the CMS quality metrics for scoring ACOs and cost measures of the practice, and receive clinical decision support when those metrics are not satisfied due to suboptimal practices within the physicians' control. Correspondingly, patient education, active care coordinators, proactive patient engagement and support for chronic disease management are also critical elements to any effective ACO.

ACO infrastructure oftentimes include web portals, care managers, timely drug reconciliations and refill monitoring, psychological support to address depression or to motivate patient behaviors, caregiver outreach, and patient access to dietitians. Improving care coordination via registries and referral networks comprised of skilled nursing, rehabilitation centers and home health agencies which commit to proactively coordinate care in the transitions of care post discharge also requires both personnel and technological resources. Health insurers and other management firms have programs which fund much of these resources payable from a portion of future shared savings revenue. While the governance remains with the physician ACO organization, contractually these insurers provide the software and fund the personnel to begin the process of care coordination, quality reporting, and patient engagement in earnest.

At the outset the ACO must be permitted to leverage its infrastructure across payers. Accordingly, physician ACOs should resist any restrictions on their future contracting.

ACO Safe Harbors

In order to help foster ACOs, CMS adopted a number of safe harbors to address concern that the financial arrangements among the participants could be unlawful under anti-kickback, Stark and other statutes addressing prohibited financial incentives to either refer or under-treat.³⁰ These include:

- **ACO Pre-Participation Waiver**, the waiver is limited to "start-up arrangements" and the term applies to arrangements for items, services, facilities or goods (including non-medical items, goods, services) that are used to create or develop an ACO. The waiver covers a party or parties that in good faith intend to participate in an ACO that will be managed under the Shared Savings Program.
- **ACO Participation Waiver**, this provides a waiver of the physician self-referral law, i.e., Stark, law and the federal anti-kickback statute that applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the Shared Savings Program and for a specified time thereafter;
- **Shared Savings Distribution Waiver**, this provides a waiver of the physician self-referral law and the Federal anti-kickback statute that applies to distributions and uses of shared savings payments earned under the Shared Savings Program.
- **Compliance with the Physician Self-Referral Waiver**, this provides a waiver of the federal anti-kickback statute for ACO arrangements that implicate the physician self-referral law and satisfy the requirements of an existing exception.
- **Waiver for Patient Incentives**, this provides a waiver of the beneficiary inducements civil monetary penalty and the federal anti-kickback statute for medically related incentives offered by ACOs, ACO participants, or ACO providers/suppliers under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimens.

Each of the safe harbors or waivers have their own specified requirements, and should be treated individ-

²⁸ Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission to John J. Miles (June 18, 2007).

²⁹ *Supra*, note xxviii at pages 72-73.

³⁰ Medicare Program; Final Waivers in Connection with the Shared Savings Program 80 FR 66728 <https://www.federalregister.gov/d/2015-27599/page-66728>

ually in order to ensure the compliance with the safe harbor.

Recent Legislative Changes in the Bipartisan Budget Act of 2018 (“Budget Bill”)

- **Patient Engagement.** The Budget Bill establishes the ACO Beneficiary Incentive Program that would allow ACOs with two-sided risk the option to pay patients up to \$20 per qualified primary care service and for patients to designate a particular physician in an ACO as the patients’ primary care provider. This differs slightly from the Coordinated Care Reward that offered Medicare patients a \$25 payment for annual wellness visits to Next Generation ACOs.
- **Beneficiary Assignment.** For agreements entered into or renewed starting January 1, 2020, Track 1 and Track 2 ACOs will have the option to have beneficiaries assigned prospectively at the beginning of the performance year and enable beneficiaries to voluntarily align to an ACO in which their primary care provider is participating.
- **Telehealth Waiver.** Effective 2020, for Track 2 and Track 3 ACOs and two-sided risk models (such as Track 1+) with prospective assignment, the geographic component of the originating site requirement for approved sites would be eliminated and beneficiaries could receive currently allowable telehealth services in the home. Medicare would not provide a separate payment for the originating site fee if the service is provided in the home.

Conclusion

Physician led and physician only ACOs have been successful both financially and in improving the quality of their care and patient satisfaction. Critical to an ACO’s success is a strong primary care physician base, a willingness to invest in the infrastructure necessary to create the patient engagement and care coordination to meaningfully manage at risk populations often with one or more chronic conditions, and a culture of timely and effective communication among patients and their oftentimes multiple treating physicians. Experienced ACOs have been successful in early detection/early intervention, developing a stable of allied providers to assure transitions of care and to steer patients to the appropriate situs of care. This has produced significant savings on hospital admissions and readmissions, ER visits, and costly interventions by managing acuity via proactive population health management. Given the present scale of ACO participation there are resources available to advance the learning curve and to accelerate the launch and implementation. The challenges that most ACOs face is retention of the vast majority of covered services within their provider network where cost, care coordination and quality can be better managed.