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Learning from a diverse clinical background

an interview with **Lori Strauss**

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Are you prepared for ACO contracting?

» Before joining an ACO, provider organizations should "kick the tires" and ensure they understand how an ACO will operate.

» In negotiations, provider organizations must determine whether an ACO is committed to compliance, or if compliance is merely an afterthought.

» Provider organizations must ensure that an ACO's treatment of quality measures, financial terms and medical costs is reasonable from a provider perspective.

» Provider organizations should understand different types of ACOs and the legal implications of each type, before choosing to contract with an ACO.

» Provider organizations must verify that the terms of an ACO agreement adequately protect the ACO's providers.

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Providers and provider networks increasingly have the opportunity to participate in an Accountable Care Organization (ACO) arrangement, sometimes under a different name (e.g., care coordination arrangements). These models give providers the opportunity to play a more active role in managing care for a particular population, but they can raise a number of tricky compliance issues.

The original ACO model is the Medicare Shared Savings Program (MSSP) model, born of the Affordable Care Act, which quickly inspired many other value-based models and variations in the commercial world. In essence, in all of these models a group of providers agrees to be "accountable" for the cost and quality of care provided to a defined population. The providers continue to be paid on a fee-for-service basis, but the quality of care they provide is measured against agreed-upon metrics, and the cost of care per covered life is measured against a target budget. If the quality metrics are met and the providers come in under budget, then the savings are shared between the payer and the providers. Commercial health plans commonly enter into these arrangements with providers or provider networks, and large employers have even started contracting directly with providers and provider networks to develop ACOs for their self-funded plans.

The following points offer general guidance for providers to consider as they begin the process of analyzing and negotiating these arrangements, and avoiding common compliance pitfalls.

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Types of ACOs

Is the agreement with an MSSP ACO, or with a commercial health plan, or is it a "direct-to-employer" contract with a self-funded employer plan? Under each of these models, a different set of laws and regulations will govern the arrangement.

Does the agreement cover a single service line in which all the covered lives have identical benefits and benefit structures, or does the agreement cover multiple service lines, in which different patient populations have different benefit designs (e.g., with a large, commercial health plan)? The latter type of arrangement will generally be more complex to manage.

Do you know the payer (e.g., a large, national plan) or is it a relative newcomer? Are you satisfied with the financial wherewithal, integrity and reputation of the payer?

ACO patients

Do the patients whose cost and quality of care will be attributed to the ACO providers "opt into" the ACO model and select an ACO provider to serve as their primary care physician (PCP)? Or, are they "attributed" to the ACO (e.g., based on the providers from whom they receive services) and potentially unaware that they have a PCP? Are patients aware that there is a network of providers "accountable" for the cost and quality of their care, who may be trying to coordinate the care they receive? It is generally easier to manage the care of patients who have opted into an ACO and selected a PCP. Engaged and informed patients may also be more likely to visit their PCP and use low-cost (or free) preventive health care services that can improve patient outcomes and improve an ACO's performance.

In what service area do patients attributed to the ACO work or reside? How is the service area defined? Is the service area of a reasonable size, or is it so large that patients will be required to travel unreasonable distances to obtain services?

If patients are attributed to the ACO providers, how is this done? Is it based on where the patient receives a plurality of the patient's primary care, or the patient's last visit to a primary care physician, or are other specialties involved? What time period is being measured? It is important for providers to consider whether an ACO's attribution process was guided by thoughtful, patient-oriented principles. An ACO that attributes patients to providers without the requisite level of care may be a cause for concern.

When will the ACO provider be notified of which patients are attributed to the ACO? Will patients be assigned or attributed to the ACO for short periods, or is there a minimum timeframe? How, if at all, will patients be involved in this process?

If the patient "opts into" the ACO and selects a PCP, does the benefit design of the patient's health plan create a financial incentive for the patient to stay within the ACO network? Such incentives can be powerful motivators for patients and increase an ACO's chances of obtaining financial success.

Medical costs

Who establishes the medical cost targets for the population covered by the ACO? Is it the payer alone, is it negotiated, or is an independent third party (e.g., an actuarial firm) used? If the payer alone establishes them, on what basis does the payer do so?

Is there good data for establishing the historical expenditures, which then can be used to set the target medical costs for the upcoming year? Will the historical costs be adjusted up, down, or held constant? Will they be adjusted for changes to the patient population (e.g., changes in health risks, age, or medical conditions)?

Will there be "carve outs" from the cost of care for which the ACO is accountable, for certain conditions or services (e.g., organ transplants, out-of-area emergencies, prescription drugs) or a stop-loss for high-costs patients?

Quality measures

Who determines the quality metrics? Is it the payer, or do the payer and providers/provider network agree on the metrics? Provider involvement can be crucial to ensuring that quality metrics are clinically appropriate.

Is there good historical data on quality that the parties can use in establishing the targets for future years? Are the quality goals realistic and/or achievable?

Will a quality bonus be paid if metrics are met, even in the absence of cost savings, or are quality metrics a minimum threshold that must be met for any payment to be made? Alternatively, does the percentage of savings paid to providers vary based on quality scores (i.e., the percentage of savings-paid increases if quality scores are higher)?

Provider involvement can be crucial to ensuring that quality metrics are clinically appropriate.

Financial terms

Do the financial terms of the ACO arrangement entail only negotiating the shared savings and/or quality metric payment arrangements, or does the ACO also negotiate the payments to the providers for patient care services (e.g., fee schedules)? Providers must use extreme caution if the ACO is jointly negotiating rates on behalf of unaffiliated providers, because this can constitute price-fixing, which is per se illegal under antitrust law unless the providers share sufficient financial risk or are sufficiently clinically integrated.

Are the ACO providers limited to upside risk (i.e., they can share in any savings realized based on the actual medical costs compared to budget, but they owe nothing if actual costs exceed budget)? Or, are they also subject to downside risk (i.e., they owe the ACO money if actual costs exceed budget)?

If the ACO providers are subject to downside risk, is it a deficit that accrues, to be offset against any future savings, or must it be repaid in cash?

Are there caps that limit the downside and upside risks and/or minimum thresholds that must be reached before savings are shared and/or a deficit is created?

Is there any care coordination or practice improvement payment to ACO providers? It is common for ACO providers to receive payments, separate and apart from fee-for-service for treating patients, that are intended to help them defray the increased costs of improving their care coordination capabilities. If such payments are made on a per patient/per month basis, the ACO should review applicable state insurance and/or HMO laws to ensure that receiving such payments does not bring the ACO within the definition of an HMO or insurance company as a result of receiving prepaid periodic payments in exchange for providing or arranging for the provision of health care services.

How is the revenue received by the ACO (e.g., payments for shared savings or quality measures achieved, or for undertaking practice improvements) allocated among its providers? How are liabilities shared (e.g., funding

startup or ongoing operational costs, or repayments if the ACO accepts downside risk)? The allocation of revenue and expenses raises important practical, operational, and financial issues, but it can also raise critical compliance concerns. The ACO and its providers may be important referral sources for and among each other, not only for ACO-related business, but also outside of the ACO context. If revenue and expenses are not shared in a fair, commercially reasonable manner, if payments are not consistent with fair market value, and if returns are not commensurate with investments made, then federal fraud and abuse laws and the physician self-referral law (Stark Law), as well as their state law counterparts, can be implicated.

Although the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General of the Department of Health and Human Services (OIG) have issued a series of "waivers" that allow ACOs that comply with all of the conditions set forth in a waiver to enjoy immunity from prosecution under federal fraud and abuse and Stark laws, these waivers have important limitations. CMS and the OIG have made clear that the waivers do not protect providers from their financial arrangements relating to commercial ACOs; instead, the waivers offer protection only within the confines of Medicare and/or Medicaid ACO activities. Furthermore, the CMS/OIG waivers do not purport to offer any protection from state fraud and abuse or physician self-referral laws. Finally, if the ACO or any of its participants is a tax-exempt organization, it is well-advised to consider carefully the impact that tax-exempt organization rules will have on its ACO-related financial arrangements.

Care coordination

How advanced are the care coordination capabilities of the ACO providers? Do they operate on a common EMR platform? Do they adhere to care protocols and coordinate quality assurance (QA) or utilization management (UM) activities? Does the ACO make use of care managers, nurse helplines or websites, or other patient engagement techniques? Such steps can be tremendously helpful to ACOs, as they can improve clinical outcomes and access while limiting or even reducing costs.

Will the ACO providers have access to frequent, robust data reports so that the ACO providers can track their performance, in real time, against the quality and cost of care targets? If so, who is responsible for issuing these reports? Does the ACO have mechanisms for monitoring ACO providers' performance against these metrics and the ability to coach providers to guide improvement? Does the ACO exclude providers who cannot or will not improve their outcomes? Are policies and procedures or other written guidelines available that detail how they will coach certain providers?

To what extent can ACO providers "control" patients' care under the patient's benefit plans? Do patients have complete freedom to choose their own providers and care settings? Do any services require pre-authorization or concurrent authorization? Is there retrospective review and/or denial?

Policies and procedures

Has the ACO developed policies and procedures dictating how the ACO will function operationally, and detailing what will be expected of the ACO providers? Functional, integrated and logical policies and procedures can be a sign that an ACO has the administrative infrastructure required for success. They can also help providers to understand whether they will be treated as true partners in an ACO arrangement.

In addition, an established ACO is likely to have well-developed compliance policies and

procedures, tailored to the size of the ACO, as well as its structure and design, operations, and activities. In fact, any ACO participating in MSSP is required to have an operational compliance plan from the start, and to regularly update the plan to reflect changes in law. For greater efficiency, it may be optimal for the ACO's compliance efforts to be designed in coordination with the existing and ongoing compliance efforts of the ACO's providers.

Claims processing

Who processes, adjudicates, and/or is responsible for claims payment? What is the timeframe for payment? Is there a penalty or interest owed for late payment?

Is there an appeal process for denied claims? How does it work?

Does the agreement provide for termination on short notice if payments are delayed or denied?

Use of name and data

Can the payer use the ACO providers' names and report cost and/or quality data on their behalf, or does the ACO have approval rights?

What rights does the ACO provider retain to its name and data?

Dispute resolution

Does the agreement dictate the laws of the state that will govern the agreement and/or the courts that will have jurisdiction over a dispute?

Does the agreement mandate alternative dispute mechanisms, such as mediation or arbitration? If so, is the method fair, reasonable, and satisfactory?

Are there indemnification provisions, limitation of loss, or disclaimer of liability provisions, and if so, are they fair and reasonable?

Documentation

Are all the contract documents, including exhibits, schedules, and other attachments, available for review, analysis, and negotiation?

Does the agreement purport to bind the ACO and/or its providers to other documents (e.g., benefit plan documents, provider manuals), and if so, have they been made available? Does the agreement purport to bind the ACO and/or its providers even if those non-contractual documents are revised? If so, how are the ACO and/or its providers involved in the revision process, and how are they notified of such revisions?

Conclusion

ACOs can present an exciting opportunity for providers to manage the cost and quality of their patients' care, but providers should be careful to scrutinize proposed ACO agreements before deciding whether to participate, and must proceed carefully to avoid potential compliance risks.

***Disclaimer**: This article is intended as a handy reference for the initial review of an ACO or ACO-type agreement, but it is not intended to be a substitute for legal advice and should not be used to resolve legal issues. For legal advice, providers and provider networks should consult their attorney.*