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Dealmaker's Corner: Direct to Employer ACOs – What They Are and How They Work

This is the second article in a series in which Polsinelli health-care principal Paul A. Gomez and other dealmakers will discuss legal issues arising in health-care sector mergers and acquisitions.

By Paul Gomez and Donald Thompson

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Why Employers and Health-Care Providers Are Pursuing Direct-to-Employer ACOs

A growing number of employers have expressed frustration with persistently increasing costs of health care as well as the resulting quality of care and the results that are achieved. Frustrations and dissatisfaction in this regard include a perceived lack of transparency and information from third party insurance providers and their efficacy in facilitating improved quality care and results, and more manageable and predictable costs.

As a potential remedy to some of these concerns, more employers, and particularly large employers with self-funded health plans, are turning to various alternative models of obtaining health-care benefit packages for their respective employees. Some of the alternative models include direct contracting with health-care providers for either certain limited, or a very broad and comprehensive array of health-care services. Examples of more narrow (relatively speaking) types of such arrangements include the Pacific Business Group on Health–Employers Centers of Excellence Network (ECEN) which is a value-based purchasing program launched in January 2014 with Wal-Mart, Lowe's, McKesson, and JetBlue as initial participants. ECEN's value proposition offers high employee satisfaction, cost predictability, downstream savings, and, for participating provider organizations, an ROI within two years. ECEN initially focused on total hip and knee joint replacement and a variety of spine procedures, including spinal fusion, total disk replacement, treatment for scoliosis, and laminectomy under a bundled payment arrangement. Other examples include a direct-to-employer arrangement between Cleveland Clinic and Wal-Mart for certain agreed upon and defined complex surgeries at no out of pocket cost to eligible Wal-Mart employees. Other more broad and comprehensive sorts of direct contracting arrangements include those entered into by The Boeing Company with Providence–Swedish Health Alliance ACO for its employees based in the Pacific Northwest and with MemorialCare Health System and certain partners

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and affiliates for its employees and their dependents located in Southern California. This article focusses on the latter, more comprehensive types of direct contacting arrangements, which are sometimes referred to as "direct-to-employer ACOs."

The direct-to-employer ACO arrangement sets forth the range and scope of the health-care services to be covered, as well as required metrics and standards to be met by the health-care providers that are participating in the ACO. In such arrangements, the self-funded employer and the health-care provider(s) may, among other things, elect to share in certain agreed upon savings that may be achieved. For example, the employer and health-care provider(s) may agree that both parties will share in savings to the extent that actual amounts spent on health care by the employer for its employees in the arrangement are less than the agreed targeted health-care spending amount for a defined period, services and patient population. Similarly, the parties may also elect to share in any risk for net deficits to the extent that the employer's health-care spend exceeds an agreed upon target spend level for a certain agreed upon time period and services.

Direct-to-employer ACOs can provide employers with an opportunity to fashion a health benefit that is more tailored to its particular employee (and dependent) population. In many cases the premiums are less than those of other options that may be available to the employee beneficiaries as are the cost-sharing obligations, provided that the employee or his or her dependent family members (as applicable) receive care from a provider or providers that are in the defined network.

Self-insured employers want a better comprehension of the drivers of their respective health-care spending and the patient care results that are being obtained. As a result, patient care data is absolutely critical for the self-insured employer to help achieve better health-care results for its employees, to better tailor availability of health-care services and resources and in order to create conditions that result in health-care costs that are more predictable and more contained. For participating providers in the ACO ("ACO Providers"), the ACO arrangement may lead to a more defined and predictable patient population for which to manage care, and to better, more accessible and timely data to target patient care initiatives more precisely.

Key Agreements

There is no one-size fits all approach to structuring a direct-to-employer ACO. The substance of the agreements and the types may vary, depending on the scope of services to be provided, how payment and submission of claims are handled, how the ACO Providers are compensated, how they may share in any savings or losses and the patient population to be served, among other things. Nevertheless, key agreements may include a Master Accountable Care Services Agreement ("Master Agreement") directly between the employer and the health-care provider or other entity serving as the ACO, Network Administrator Agreements, Claims Administrator Agreement, Participating Partner Provider Agreements, Affiliate Provider Agreements and Ancillary Provider Agreements (titles may vary as may the substance of the agreements themselves).

Master Accountable Care Services Agreement

This agreement sets the structure and parameters for the entire "ACO" arrangement. The Master Agreement sets for the major participating parties and providers, and what their respective roles, rights and responsibilities are.

The parties to the Master Agreement generally set forth goals and purposes for the arrangement, which include a broad network of ACO Providers, including, without limitation, hospitals, physicians, clinics, laboratories, post-acute care providers and others. That broad spectrum of ACO Providers will collaborate and accept shared responsibility for delivery of comprehensive health-care items and services that are described as covered benefits in the summary plan description for the employer's self-insured plan ("Plan") to a defined patient population ("Covered Services"), that being the participating employees and dependents of the employer. The ACO agrees to maintain a network of ACO Providers that can provide all Covered Services to ACO Members ("ACO Members" being either Designated ACO Members or Attributed ACO Members, as defined further below) without unreasonable delay, and will be of the quality required by the Master Agreement. If the ACO fails to sufficiently maintain such network it may be required to notify the employer and cooperate in an effort to cure the failure. If it cannot do so within a certain period of time, the ACO and Employer may agree to direct certain ACO Members, as applicable and appropriate, to receive certain Covered Services from other providers who are not ACO Providers.

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Claims Administrator and Network Administrator Agreements

Approaches may vary, but employers may contract with a network administrator to administer the ACO Provider network. The Network Administrator may, in turn, then contract with the ACO Providers for agreed upon amounts to be paid for the Covered Services and report claims with negotiated pricing to the applicable claims administrator for processing of payment for the particular agreed upon Covered Services. The employer may also contract with another entity, often an insurance provider or its affiliate, to provide the claims administration and other administrative services for its employee benefit plans pursuant to an administrative services agreement. Some of these services could be consolidated with one such administrative services provider or even performed in house, depending upon the employer's internal resources.

Required Partner Provider Agreements and Other Provider Agreements

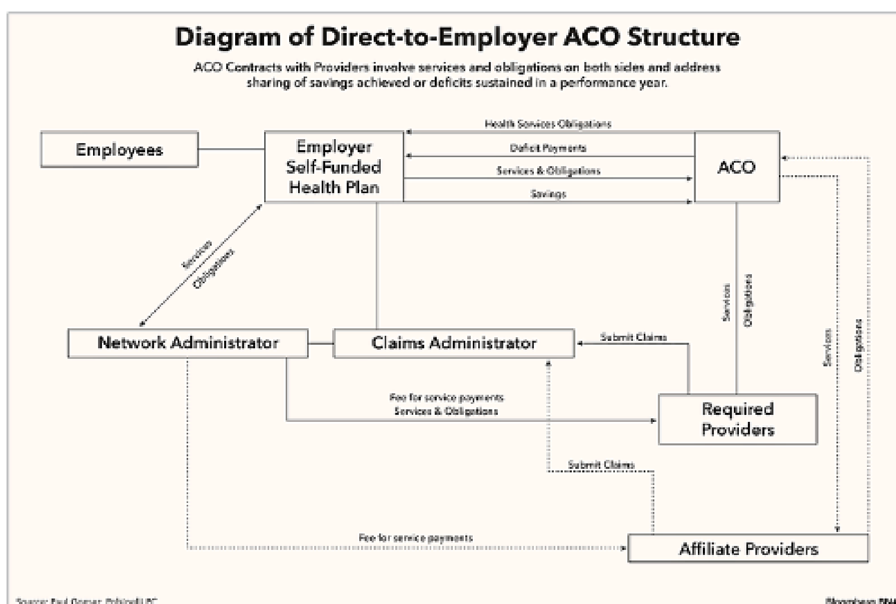
Agreements must be entered into with ACO Providers. In some instances, this may require entering into new participating provider agreements that set forth all the applicable rights, duties and obligations of the parties. In other instances, it may require review and amendment of certain existing ACO or other services agreements that may already be in place between the entity serving as the "ACO" and the ACO Providers. It is important to review these existing contractual arrangements to ensure there is nothing that would conflict with or prohibit participation in the "ACO" and to ensure that core duties, rights and obligations set forth in the Master Agreement align appropriately and bind each ACO Provider for effective operation of the network.

Required Program Providers

Depending on the scope of services, the population to be cared for and the geographic area for which service coverage is needed, the ACO may be obligated to include certain ACO Providers in the ACO Provider network. This could refer to multiple different systems and providers participating within the ACO, or it may be a matter of identifying key components, divisions or providers within one health system, depending on the circumstances. Arrangements between the employer and the ACO may include more substantive and procedural requirements for specified ACO Providers that the employer has required to be part of the ACO Provider network ("Required Providers") as opposed to other Participating Providers and other Ancillary or Affiliate Providers (more discussion on Participating Providers, Ancillary or Affiliate Providers to follow below).

Affiliate/Ancillary Providers

The ACO arrangement may provide that, in addition to certain Required Providers and other key participating partner providers, the ACO may also select and contract with other affiliate or ancillary services providers. These providers may be selected as needed, to provide certain Covered Services to ACO Members, such as DME or other specialty services or to fill a geographic gap in provision of services of ACO Providers. Generally, these providers may have fewer clinical reporting, data and notification obligations to abide by as compared with Required Providers.



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Core Obligations of the Employer and "ACO" Health-Care Providers /Compensation

Pre-Launch Period and Implementation

A tremendous amount of advance planning and coordination go into large scale direct-to-employer arrangements. The Master Agreement sets forth how the parties will arrive at the necessary structure and alignment needed to coordinate better and more cost-efficient care for what may be thousands or tens of thousands of people.

DIRECT TO EMPLOYER ACO PRE-LAUNCH CHECKLIST

Pre-Launch

- Parties engage actuarial analysis.
- Establish meeting schedule for work groups to discuss planning, member experience, data transfer, care management, data reporting and supplier integration.[1]
- Develop master implementation work plan. (6 months pre-launch)
- Develop communication plan for potential members. (9 months pre-launch)[2]
- Contracts/ACO Structure.
    - ❑ Execute ACO Provider Agreements with Partner Providers meeting network adequacy requirements. (6 months pre-launch)
    - ❑ Establish schedule for periodic updated rosters of partner and affiliate providers.
    - ❑ Identify gaps in network and establish action plan.
- Data/Reports and functionality.
    - ❑ Execute Data Sharing Agreements with plan suppliers, data warehouses and data analytics. (6 months pre-launch)[3]
    - ❑ Test distribution of actual data and health status metrics by and between ACO, employer, plan suppliers and plan participants, including monthly claims files and requested data reports and analytics.
- Member Support (all items 4 - 6 months pre-launch)
    - ❑ Test go-live of customized member website.
        - ❒ Test annual enrollment functionality.
        - ❒ Test members' registration and access to health record.
        - ❒ Test appointment scheduling functions.
        - ❒ Test prescription refill function.
        - ❒ Test administrative support for members.
    - ❑ Test of go-live for patient contact center.
    - ❑ Prepare implementation of intensive outpatient care initiative and train partners, affiliates and their staff.
- Finalize financial incentives per contract.
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    - ❑ Train member administrative support personnel.
    - ❑ Educate partner providers, affiliate providers, and staff regarding the preferred provider program; member experience; health status and quality metrics.

[1] This list illustrates the extensive organization necessary to implement a comprehensive direct-to-employer ACO. It is advisable that an Executive Steering Committee consisting of principals at the Employer and ACO entity oversee the implementation and that each of the subcommittees listed here have an executive level sponsor.

[2] The communication plan to employees will likely be complex, involving written marketing materials, websites, and in-person opportunities for employees to ask questions of Employer benefits representatives and representatives of the ACO. Planning is important, because Employee understanding of the concept and thus broad based employee participation in the ACO is important to its success for the Employer and the ACO.

[3] Each plan supplier, data warehouse and data analytics provider will likely need a data sharing agreement, and each will have different priorities related to indemnity, liability caps, frequency of audits, and other issues that can be time consuming to negotiate.

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The pre-launch period involves the activities that the parties will undertake to offer the ACO Program as an option for the employer's eligible employees who want to be members of the ACO ("Pre-Launch Period"). Such activities and key benchmarks can take several months to nearly a year to put into place prior to the ACO Program being ready to "go live" and operate as a functioning benefit for eligible employees and their dependents. The parties should give careful thought to what metrics and milestones they will need to achieve and may also want to consider what contractual incentives or disincentives may be needed in order to keep the parties moving toward achievement of such metrics and milestones. For instance, during the pre-launch period, key ACO pre-launch obligations might include deadlines for execution of provider and required partner agreements; continuous updates of providers and specialists added to the network, identifying program gaps in ACO covered services and action plans needed for corrections and improvement; submit test data files and test customized ACO website/member portals. The attached "checklist" to certain such metrics and milestones that may be considered may be helpful to the process.

Covered Services and Network

As noted above, the Network Administrator will maintain a network of ACO Providers to provide the Covered Services to ACO Members pursuant to contracts with such Providers. The Network Administrator may have the right to exclude remove or decline to credential or re-credential an ACO Provider if it does not remain in good standing with the applicable credentialing and participation requirements, or otherwise fails to comply with its material obligations under its particular participating provider agreement.

As discussed in some additional detail below, data flow and reporting obligations are of great importance to facilitating a successful direct-to-employer ACO. For example, the ACO may obligate the employer to provide required reports and data pertaining to patient care and cost and maintain certain prescribed data interfacing requirements to the ACO. Material failure to supply such data and reports in timely fashion can impact operation of compensation provisions. For instance, in the event such reports and data are produced late, it may reduce the amount of any net deficits (if any) for which the ACO might otherwise be liable, and/or result in a material breach by the employer that could give rise to termination of the Master Agreement by the ACO.

Designated and Attributed ACO Members

As with any other form of ACO, it is critical to understand which patients are receiving care from ACO Providers and which patients it is "accountable" for. Making these determinations in a logical and consistent manner that the parties can agree upon is challenging. As one might expect, some patients will deliberately choose to receive care from ACO Members by electing to participate and enroll in the Plan (along with, as applicable, family members and dependents) for a particular Plan performance year. Such patients and their dependents are referred to herein as "Designated ACO Members."

A more complicated and no less important matter is discussing and agreeing upon what additional employees and their dependents might be "attributed" to the ACO even though they did not elect to participate and enroll in the ACO benefit option. There is no one-size fits all method for making these sort of attributions, but the method selected should adhere to a logical and consistent process and criteria for determining that a given employee and dependent is receiving a high enough proportion or percentage of care and/or certain types of care from ACO Providers over a certain period of time (typically the Plan performance year) that they should be "attributed" to the ACO. Clarity and agreement amongst the employer, the ACO and the ACO Providers about which patients should be properly considered ACO Members, whether they are Designated ACO Members, Attributed ACO Members or some other form of designation or attribution is critical as it pertains directly to clinical data and other patient information reporting, to measurement of the quality of care provided and to cost efficiency goals. It is also critical to methods to determine whether ACO Providers will ultimately share in any "savings" that the ACO manages to generate for the employer, or any "deficits" that that may be realized related to costs for health care for applicable employees (and their dependents).

Quality Achievement and Measurement

The parties may choose to set quality standards to promote quality medical services as well as high ACO Member experience and satisfaction. These standards may be threshold goals to trigger payment of savings to the ACO or savings may be based on the percentage of the goal achieved, compared to NCQA quality goals or other quality targets. For example, health status quality achievement standards may include patient adherence to statin use, or blood pressure targets for diabetic patients, intensive outpatient care standards (key for cost savings) may include discharge transition best practices

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and development of readmission policies and a nurse advice line, and patient access and timelines standards may include timeliness metrics for primary care physician visits, urgent care clinic visits and after-hours care at urgent care clinics and other facilities.

Quality standards change, improve, and on occasion fall out of use. As a result, the parties could agree to meet annually to assess the quality measures in use and to replace or revise the quality measure targets as needed and as appropriate.

Member Incentives

The ACO may want to ensure that the employer has appropriately incentivized members to join the ACO when more than one plan is available to the employees and while the employees (and the employer) become comfortable with the ACO and the overall benefits of a narrow network. Potential contractual language: For example, the agreement may provide that in each Plan year, the total employee cost share for active designated ACO members will be at least X percentage points lower than any other plan offering and in the first performance year, at least X percentage points lower than what the total employee cost sharing would be under any other plan offering.

Compensation and Risk, Net Savings and Deficits

The baseline for compensation to ACO Providers under the contemplated direct-to employer ACO remains agreed upon fee-for-service compensation amounts for the applicable services and items provided. How the ACO and its ACO Providers achieve key quality metrics and how they align to achieve that, including, without limitation sharing responsibility for any achieved savings or deficits suffered is where a substantial amount of the accountability comes into play.

The ACO will be entitled to payment by the employer of an agreed upon portion of savings achieved and the employer will be entitled to payment by the ACO for deficits. Savings achieved and to be paid remain subject to the ACO achieving agreed upon patient care and quality measures. “Savings” for purposes of this article refers to the amount by which the total cost paid by employer for provision of Covered Services to ACO Members that is less than an agreed upon base line cost for such employees and dependents (ACO Members) that are attributed to the ACO for the Plan performance period. “ Deficits” for purposes of this article refer to amounts of total cost for provision of Covered Services that exceed the agreed upon base line for cost for such employees and dependents (ACO Members) that are attributed to the ACO for the Plan performance period. For example, if the employer and ACO agree that the base line health-care cost for a particular performance period for ACO Members is $75,000,000 and compensation paid to ACO Providers for Covered Services for employees and dependents attributed to the ACO for said time period amounts to $65,000,000, the ACO would be entitled to payment of an agreed upon portion of the $10,000,000 in savings achieved, provided that other obligations and metrics, including quality care metrics, were also achieved at prescribed levels. Conversely, if the employer and ACO agree that the base line health-care cost for a particular performance period for ACO Members is $75,000,000 and compensation paid to ACO Providers for Covered Services for employees and dependents attributed to the ACO for said time period amounts to $85,000,000, the employer would be entitled to payment of the $10,000,000 “deficit” sustained. The degree to which ACO Providers will either share in the ACO savings or the ACO deficit is a matter for negotiation to be addressed in the ACO's contracts with the ACO Providers. The potential to share in such savings or deficits serves to underscore the importance of well-thought out, logical and consistent methodologies for attributing employees and dependents to the ACO, as well as the well-coordinated flow and access to patient care and services data and reports and use of appropriate clinical and quality measures.

Data and Reports

The parties will likely find that it is imperative to ensure that quality, cost savings and member satisfaction targets are assessed on an ongoing basis so that targets are being met or do not fall too far behind, and so that corrective action can be taken before missed targets, which could jeopardize the network, occur. Therefore, the Master Agreement will likely have extensive data reporting requirements and scheduled periodic meetings between the parties to analyze the data and develop corrective action plans where necessary. In one example, reports are provided on a quarterly basis and the parties meet quarterly to evaluate the data. Such data and reports might include claims data, including medical claims and pharmacy claims, inpatient admission reports, tentative and definitive ACO Member attribution lists, utilization summaries, wellness program participation and health assessments.

Governance, Communication and Decision Making

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Governance and communication amongst the parties in decision making is key to ensure that the ACO remains on track to benefit all parties. Providing for periodic meetings (e.g., quarterly) and extensive data reporting of quality measures, finances and patient satisfaction help meet this goal. Also, providing for pre-launch deadlines (as discussed above) and obligations as a practical matter ensure that nothing goes too far off track or has the opportunity to fall behind. This approach is perhaps unavoidable when a complex transaction has to meet hard, immovable deadlines like the annual open enrollment period. From the in-house perspective, extensive internal organization on the operational side is also required.

This "delegate and follow-up – often" scheme, including quarterly and yearly reviews of data, is reflected in many ACO transactions. These approaches may include use of extensive pre-launch deadlines, an executive level steering committee, compliance committee, designated relationship managers, operations committees both during the launch and following the "go live" date of the ACO, a quality and standards committee and other committees and processes.

Data Use and Confidentiality

There is a vast amount of Protected Health Information and other sensitive data flowing between the ACO, the network/claims administrator, medical providers, suppliers (including pharmacy and behavioral health benefit managers. Some of these relationships will require a Business Associate Agreement (BAA); most will certainly require data use and confidentiality agreements. The HIPAA Privacy Rule requires an entity covered by the Privacy Rule ("covered entity"), including health-care providers, health plans, etc., to obtain written assurances from a business associate that the business associate will appropriately safeguard medical information protected by the Privacy Rule.

Business Associate Agreements

Typically there is a BAA between the network/claims administrator—usually a health plan—and the employer. A BAA between the ACO and the employer may also be prudent since the ACO, although usually a covered entity under HIPAA and provides medical services to the employees, the ACO is also providing administrative services to the employer. At the next level, the arrangements between the ACO and Partner Providers, for example, may not require a BAA since all of the contracting entities are Covered Entities. However, the Partner Provider's provision of administrative services to the ACO or the employer may need to be considered.

Data Use/Data Sharing Agreements

Most all of the relationships between the entities forming the ACO will require some kind of data use or data sharing agreement. While a BAA defines the privacy obligations between the parties, a data use agreement is often useful to define the practical procedures of data transfer. Typical provisions of an ACO data use/data sharing agreement might include:

• Administrative data security and employment precautions. The parties will want to address commitments to industry standards concerning administrative, physical, and technical safeguards prohibiting unauthorized use, and/or require that each entity maintain an information security program that addresses appropriate digital security related to equipment, hardware, software code, high speed connectivity and cabling, as well as associated off-site facilities. Employment precautions might mean that the entities need to commit to employee background checks and limitations on access to data for those employees of each entity with a need to know.

• Network security program. Include safeguards to prevent unauthorized use, preclude accidental destruction or loss of data, and ensure strong authentication of users.

• Data storage safeguards. Require industry standard encryption and other safeguards and ensure that Employer data is compartmentalized from other ACO data.

• Domestic storage and access. Some employers may insist that unless otherwise agreed to in writing by employer, ACO will ensure that all employer data resides in, and may be accessed only from inside the United States.

• Breach notification. Typical breach notification language may include: "In the event that the ACO is notified of or discovers any actual or suspected unauthorized use or other access to employer data, the ACO will immediately notify the employer (unless delayed for law enforcement or investigation).

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The ACO will investigate and cure the breach and will assist employer in investigating and remedying the breach. The ACO will provide employer with assurances that such security event or potential security event will not recur.”

• Cyber Insurance. Will cyber insurance be required, and by which entities participating in the ACO?

• Security Contact. Many information technology contracts require that the participating entity ensure that a security contact is available to the employer 24 hours per day, seven days per week.

• Security Audit. The ACO will be interested in limiting the number of security audits, especially where there are multiple data use agreements. Many will at least limit audits to not more often that once every 12 months to avoid expense and disruption. Audit provisions will often contain provisions for corrective action if a material vulnerability is discovered. The employer may require additional audit rights for downstream ACO facilities and ACO systems. An annual information security audit at a level sufficient to implement the HIPAA audit security requirements also will likely be required.

Data Use Agreement Special Issues

The network administrator and data clearing house are contracted to the employer in connection with group health plan administration activities, utilization review and case management, benefit administration and medical management programs. The employer often requests that the network administrator supply claims data to the data clearing house and ACO for the purpose of assisting the ACO in the performance of population health management. However, when dealing with ACO Providers that are also competitive peers, such as a competing hospital, sharing proprietary information about provider-specific discounts and reimbursement amounts may have potential business tort and antitrust implications. Therefore, certain contractual and other precautions for the protection or blinding of pricing information should be considered. For instance, the parties may agree that data will not be reverse engineered to ascertain the specific payer discounts connected to a specific provider. They may also agree that neither party will share cost and pricing information with any person directly involved in performing, developing or selling services in direct competition with the network administrator or another provider, including but not limited to people in network contracting, or directly or indirectly involved in health insurance or administrative services for individual and group policies, plans or programs.

Certain Legal Issues and Practical Considerations

Potential Insurance License Requirements

Depending on the jurisdiction, a license may be required for the ACO from the State's Department of Insurance or Department of Managed Care, as applicable. Some states have laws or regulations related to advisory opinions from regulators, other states do not. In the latter case, the parties will need to decide at an early juncture whether and how to approach the State regulatory authorities. Compensation structure may impact whether such a license, depending upon the jurisdiction, may be required.

Network Adequacy Requirements

Parties must take care not to run afoul of applicable network adequacy requirement that aim to balance attempts to hold down health-care costs with ensuring that health plan members have sufficient and reasonable access to health care. Many such network adequacy requirements apply to fully-insured health plans offered through the public exchanges. Like traditional commercial insurers, employers are becoming more adept in their attempts to control costs by limiting the size of their provider networks. However, self-funded employers are not subject to all of the same network rules and requirements that apply to plans offered through the exchange. This is because self-funded plans are subject to ERISA which generally pre-empts such rules and requirements. Moreover, comprehensive direct-to-employer ACO arrangements may not be “narrow” enough to raise concerns about lack of reasonable and sufficient access to care. Still, it would be wise to continue to monitor the level of interest of legislators and regulators in these kinds of arrangements the more that they proliferate.

HIPAA/Privacy/Security Issues

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Direct-to-employer ACOs involve coordination and management of comprehensive health care and Covered Services for potentially tens of thousands of people by potentially dozens of ACO Providers. Collection, reporting and sharing of patient-related data and other data is critical to the success or failure of the ACO arrangement in achieving better quality care and patient satisfaction while managing and containing costs. All or many of the Providers in the ACO are likely "covered entities" for purposes of HIPAA, so HIPAA and other privacy concerns and requirements (patient specific, and otherwise) have to be borne in mind.

Fraud and Abuse Concerns

The fraud and abuse rules, for the time being, remain too often designed for a fee-for-service world, and are not particularly accommodating for the developing, value-based payment schemes. While the federal MSSP and bundled payment programs confer waivers of federal Stark, Anti-kickback, and civil monetary law provisions on the participating providers, private payment structures do not. And while there are specific Anti-kickback safe harbors and Stark exceptions directly addressing certain payer-generated incentive programs, provider-created incentive programs do not necessarily enjoy the same protections.

It is important to remember to structure compensation carefully and to be mindful about what is being paid for. For example, the clinical protocols and quality metrics of the ACO may call for certain clinics or physicians to refer patients that present with certain characteristics or symptoms for wellness activities or certain other health-care follow up to certain ACO Providers. Although the direct-to-employer ACO itself does not involve payment by any government health-care payer program for the Covered Services delivered under the ACO arrangement, it would not be advisable to agree to compensate physicians per patient that is so referred. Part of the reason for this is that it may well be that the parties also have contractual or other arrangements that pertain to services that are payable by a federal health-care payer program, potentially supporting an argument that payment per patient referral under the (non-government payer) ACO arrangement is "disguised remuneration" for other patients and services for which a federal health-care payer program is implicated. It is also important to remember that some state corollaries of the Federal Anti-Kickback statute may not require that a federal or state payer program be involved to be implicated.

Certain Antitrust Considerations

Antitrust concerns focus on whether providers will exercise market power to raise prices above competitive levels. Joint negotiations by competing providers are assessed under the Sherman Act. Joint negotiations by independent health-care service competitors may be pursued as price fixing arrangements, which may result in serious consequences But if the providers are economically or clinically integrated — for example, sharing financial risk for improving quality or reducing costs, as is the case in a direct-to-employer ACO — their conduct likely would not be dismissed as price fixing but should be evaluated under the more favorable "rule of reason" analysis to assess its effect on competition.

MSSP ACOs may generally raise fewer antitrust issues than other collaborations since they will not be negotiating payment terms with the Department of Health and Human Services, but antitrust issues can arise if ACOs also seek to contract with private health plans. However, in the case of the direct-to-employer ACO, it is the employer payer, through its self-insured health plan, that is expressly seeking to help design and partner with the ACO for the express goals of improving quality of health care and patient satisfaction of its eligible employees (and their dependents), while also containing and possibly even reducing costs, both for the employer itself and cost sharing obligations of its participating employees. If that same ACO Provider network might also contract with other commercial payers, it may give rise to a more challenging analysis depending on such issues as relevant market share of the ACO for various services. But it appears unlikely at the moment that antitrust enforcers would prioritize enforcement with respect to a direct-to-employer arrangement that is expressly desired by the employer payer and participating employees for the purposes of containing or reducing costs (among other things). As of the publication of this article, the authors are not aware of any ongoing antitrust cases or investigations targeting any ACO of any type.

Conclusion/Take Away

An increasing number of employers are either participating in or considering participation in some form and scope of a direct-to-employer ACO. These arrangements involve tremendous coordination and alignment of patient care and services, clinical, patient satisfaction and cost efficiency metrics, data collection and reporting and compensation structure, all to help facilitate both clinical and financial integration and alignment for improved patient care and cost containment. Employers are hopeful that such a strategy will help to better contain and manage their health-care costs and provide better

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information and leverage to design health-care provider networks and benefit options that deliver more convenient, more responsive, and better care. Health-care providers are attracted to such arrangements because it gives them opportunities to care for and collaborate more directly with defined patient populations. Better and more timely data from the employer and others—enabling providers to better ascertain the health needs of the managed population and better target care and initiatives to deliver better quality, results, and higher patient satisfaction—is also attractive.

Many large employers are expressing great enthusiasm for direct-to-employer ACOs and their potential. Some early results, both clinical and financial, offer support for their promise as an innovative model to improve care and contain costs for significant patient populations. Nevertheless, the further development and proliferation of these models will need to be monitored to see how clinical outcomes, patient satisfaction, cost metrics, and related administrative and data collection reporting obligations pan out in the longer term. It also remains to be seen how such models fare over a longer term with various potential legal risks, including those pertaining to fraud and abuse laws, insurance and network adequacy requirements, HIPAA and privacy requirements, antitrust enforcement and other potential compliance regimes. In the meantime, it appears that these models will continue to proliferate in various forms in the years ahead.

For More Information

The "Direct to Employer ACO Pre-Launch Checklist" is at http://src.bna.com/rtH.

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