Information Exchange in the Formation of an ACO

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The Patient Protection and Affordable Care Act seeks to promote increased accountability, integration, coordination, and quality of healthcare delivery to Medicare fee-for-service beneficiaries through the Medicare Shared Savings Program (MSSP), which encourages the creation of Accountable Care Organizations (ACOs).\(^1\) ACOs are loosely defined networks of healthcare providers that voluntarily agree to coordinate healthcare services. By contracting with the Centers for Medicare & Medicaid Services (CMS) through participation in the MSSP, ACOs that meet both quality performance standards and cost containment goals are allowed to share in the financial savings generated.

The cost to implement and successfully manage an ACO has been projected, however, to be in the millions, and sometimes tens of millions of dollars for larger networks.\(^2\) Accordingly, providers and suppliers want assurance in the early planning and organization stages of ACO formation that there are opportunities for savings. This typically requires a certain amount of due diligence and exchanges of information. The exchange of certain types of information prior to the formation of an ACO has the potential to implicate antitrust laws and, in turn, places providers at potential risk of

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\(^2\) THE WORK AHEAD: ACTIVITIES AND COSTS TO DEVELOP AN ACCOUNTABLE CARE ORGANIZATION, AMERICAN HOSPITAL ASSOCIATION (2011).
incurred hefty costs associated with agency investigations into, and agency enforcement actions against, potentially unlawful activity.

In this article, the authors provide an overview of what information is permitted and forbidden to be exchanged in the pre-closing stages of a healthcare merger, acquisition, or joint venture from an antitrust perspective and discuss in greater detail agency guidance specific to ACOs.

**Overview of the Application of Antitrust Law to Information Exchanges**

Section 1 of the Sherman Act prohibits activities and arrangements that *unreasonably* restrain trade.\(^3\) Short of blatant market allocation or price-fixing agreements, which are considered *per se* illegal, a court will use the “rule of reason” to evaluate joint activities among competitors for any potential anticompetitive effects resulting from the conduct and balance these effects with the procompetitive benefits or business justifications a certain arrangement may possess.\(^4\) Under this prevailing standard, a large number of competitor collaborations, including numerous joint-purchasing efforts in the healthcare arena, are procompetitive.

Due diligence and transition planning relating to these collaborative efforts often necessarily require parties to exchange certain competitively sensitive information. The exchange of such information is also analyzed under the rule of reason. Each party, therefore, should assess whether certain competitively sensitive information should be

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\(^3\) 15 U.S.C. § 1; *Nw. Wholesale Stationers v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289 (1985) (“[E]very commercial agreement restrains trade. Whether this action violates § 1 of the Sherman Act depends on whether it is adjudged an unreasonable restraint.”). Parties engaged in the formation of ACOs may also be governed by the Hart-Scott-Rodino Antitrust Improvements Act, 15 U.S.C. § 18a (2011) (HSR Act), and Section 5 of the FTC Act, 15 U.S.C. § 45. The HSR Act, which applies to certain mergers, acquisitions, and joint ventures that must be reported to the Federal Trade Commission and U.S. Department of Justice, prohibits premature transfers of beneficial ownership. Section 5 of the FTC Act prohibits “unfair methods of competition,” including conduct that violates Section 1 of the Sherman Act as well.

exchanged prior to formation of a collaboration and, if so, how best to protect that information from being used commercially by the other party.

The agencies recognize that the exchange of certain competitively sensitive information can be reasonably related to negotiating the transaction. To avoid risk of antitrust liability associated with this exchange, information of a potentially competitive nature should be subject to a written nondisclosure agreement and protocol to ensure the information is not used commercially. A nondisclosure agreement provides useful documentation of the legitimate purposes for an information exchange and identifies limitations on the parties’ use and dissemination of information. Additionally, a formalized protocol for the handling of such information can identify the nature of the information to be shared (with more detailed information being shared as the parties achieve milestones in their negotiations and their transaction becomes increasingly likely) and can identify the individuals or departments with which the information may be shared.

Any information exchange generally should include only historical data, and should not include current or predicted pricing, cost, margin, or other forward-looking plans. Where practical, the data may be aggregated so that it cannot be attributed to a particular party or product. There may be instances during due diligence or integration planning where the parties have a reasonable need to exchange highly competitively sensitive data, such as customer-specific price, cost, and margin data; existing customer and supplier-specific contracts, pricing, and discount levels; and nonpublic financial information. Under such situations, the parties should consider hiring a third-party consultant to

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6 See Omnicare, Inc. v. UnitedHealth Group, Inc., 629 F.3d 697, 709-11 (7th Cir. 2011) (explaining that premerger information exchanges between competing health insurers did not violate antitrust laws where the shared price information was aggregated, did not contain specific pricing strategies, and was shared with limited group of high-level executives less than a month before signing of the merger agreement); Insilco Corp., 125 F.T.C. 293, 307 (1998) (permitting non-aggregated competitively sensitive current and future pricing information to be supplied to independent third party to aggregate and summarize for the parties); see also Competitor Collaborations, supra note 4, § 3.34(e).

7 U.S. Dep’t of Justice & Fed. Trade Comm’n, Statements of Antitrust Enforcement Policy in Health Care (1996), available at www.ftc.gov/reprots/hlth3s.pdf (describing antitrust enforcement issues regarding mergers and joint ventures between healthcare providers) [hereinafter Health Care Statements], Statement 5 at 45; Omnicare, supra note 6, 629 F.3d at 710.
manage and analyze the information being exchanged. If such an approach is not feasible, the parties should put in place appropriate safeguards such as written protocols designed to limit access of this information to exclude individuals with marketing, pricing, or competitive decision-making responsibilities from having access to the information.

**Antitrust Law and the Formation of ACOs**

*Overview of Antitrust Law as Applied to ACOs*

Antitrust law applies with equal force to healthcare entities, generally without exception. Given the importance of competition in healthcare markets to benefit consumers through lower prices, quality services, and innovation, the Federal Trade Commission (FTC) and U.S. Department of Justice (DOJ) have devoted significant resources to providing industry guidance to help market participants comply with the law. Most recently, in October 2011, the FTC and the DOJ Antitrust Division issued a joint final *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (Final Statement), which provides antitrust guidance to healthcare providers who are eligible and intend to seek approval, or have been approved, as ACO participants in the MSSP.

Similar to previous guidance issued by the FTC to healthcare providers, the Final Statement provides that the rule of reason will be used to evaluate joint price agreements among healthcare competitors who are “financially or clinically integrated

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8 See, e.g., *Boulware v. Nevada*, 960 F.2d 793, 797 (9th Cir. 1992) (“The antitrust laws apply to hospitals in the same manner that they apply to all other sectors of the economy. Health care providers are exposed to the same liability and entitled to the same defenses as businesses in other industries.”).

9 See, e.g., Health Care Statements, *supra* note 7.


and the agreement is reasonably necessary to accomplish the procompetitive benefits of integration\textsuperscript{12} and establishes a safety zone for ACO participants subject to this guidance that are “highly unlikely to raise significant competitive concerns.”\textsuperscript{13} The Final Statement specifically warns that all ACOs should avoid “Improper Sharing of Competitively Sensitive Information,” regardless of market power and regardless of whether an ACO falls into the safety zone.\textsuperscript{14} It states:

Significant competitive concerns can arise when an ACO’s operations lead to price-fixing or other collusion and reduce competition in the provision of services outside the ACO, leading to increased prices or reduced quality or availability of health care services. ACOs should refrain from, and implement appropriate firewalls or other safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO.\textsuperscript{15}

The Final Statement points providers to previous information-sharing guidance issued by the DOJ and FTC in Statements of Antitrust Enforcement Policy in Health Care (Health Care Statements) for additional direction regarding information exchange.

The Health Care Statements apply to healthcare competitors and, as such, are applicable to healthcare providers who are contemplating ACO formation since providers are treated as competitors in the pre-closing stages of joint ventures. Statement 4 provides a safety zone for the provision of non-fee-related information, such as medical data and standards for patient management and clinical decision-making, to a purchaser. It explicitly excludes from the safety zone the use of non-fee-\textsuperscript{12} Final Statement, 76 Fed. Reg. at 67027.

\textsuperscript{13} Final Statement, 76 Fed. Reg. at 67028–29. To qualify for safety zone protection, participating providers who provide a “common service” must have a combined share of 30% or less in each participant’s Primary Service Area (PSA) if the participants service patients in the same PSA. A PSA is defined as “the lowest number of postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients], separately for all physician, inpatient, or outpatient services.” Hospitals and ACS must participate on a non-exclusive basis in order to fall into this safety zone. This safety zone applies to physicians regardless of exclusivity unless they fall into the rural or dominant participant limitation exception. \textit{Id.}

\textsuperscript{14} Final Statement, 76 Fed. Reg. at 67029 and n.8, The statement also identifies four other categories of “Conduct to Avoid” but four of these apply only to ACOs that fall outside the safety zone because they have a high PSA or other attributes that raise anticompetitive concerns. \textit{Id.} at 67029–30.

\textsuperscript{15} \textit{Id.} at 67029.
related information to strong-arm purchasers into following provider recommendations regarding plan decisions.\textsuperscript{16}

Statement 5 provides a safety zone for the provision of fee-related information to healthcare purchasers, such as current and past fees related to services or reimbursement, as long as the collection of the information is managed by an independent third party. Regarding information exchange among the competing providers, the data must be from at least five providers and sufficiently weighted such that the origin of the data is not identifiable, and any current fee-related information available to the competing providers must be at least three months old. The safety zone excludes use of fee-related information by competing providers to collectively coerce purchasers into particular fee- or reimbursement-related structures, and the collective provision of information regarding prospective fee arrangements. Ultimately, the Agencies note that the exchange of prospective fee-related information will be evaluated on a case-by-case basis and advise the use of confidentiality agreements and independent third-party management.\textsuperscript{17}

Statement 6 provides a safety zone for participation by competing providers in surveys regarding prices of healthcare services and employee compensation, provided the data is more than three months old, based on data from at least five providers, sufficiently weighted and aggregated such that the origin of the data is not identifiable, and managed by an independent third party. Similar to fee-related information exchanges with purchasers, surveys regarding future healthcare service prices and employee compensation are not protected in the safety zone.\textsuperscript{18}

\textit{Potential Benefits from the MSSP for ACOs}

If a MSSP participant ACO meets certain financial and quality performance measures, the ACO will be eligible to receive a shared savings payment. ACOs are required to

\textsuperscript{16} Statement 4, Health Care Statements, supra note 7.
\textsuperscript{17} Statement 5, Health Care Statements, supra note 7.
\textsuperscript{18} Statement 6, Health Care Statements, supra note 7.
serve a minimum population of 5,000 Medicare fee-for-beneficiaries in order to participate in the MSSP.\textsuperscript{19} Once accepted to the MSSP, shared savings and losses are calculated using a multi-step process. First, an average per-capita Medicare expenditures “benchmark” for a certain population of Medicare beneficiaries is determined by “using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO.”\textsuperscript{20} Data from the three years are weighted and the benchmark is risk adjusted for accuracy. The benchmark is increased each year of the Shared Savings program term according to the national average per-capita expenditures growth. From this benchmark, CMS calculates Minimum Savings Rates (MSRs) and Minimum Loss Rates (MLRs), which account for normal expenditure variation in a given beneficiary population size. For the one-sided models, MSRs vary from 2% to 3.9% according to the size of the ACO, with the MSR decreasing as the size of the ACO population increases. For the risk-sharing two-sided model, both the MSR and MLR are established at 2%.

Savings and losses are calculated by comparing the ACO’s per capita risk-adjusted Medicare expenditures with the established annual benchmark. The ACO will be eligible for shared savings if the ACO’s expenditures are lower than the benchmark and the savings at least meet the MSR. Only if expenditures exceed the benchmark and losses meet or exceed the MLR might an ACO in the risk-sharing track be liable for losses.

Finally, the ACOs that achieve savings according to the methodology described above will share in savings only if the ACO meets established quality standards.

\textit{Types of Information Potentially Exchanged Pre-Formation and Certain Antitrust Considerations}

Accordingly, in forming an ACO for purposes of participating in the MSSP, entities may be interested in and free to exchange, among other items, the following information:

\textsuperscript{19} 42 C.F.R. 425.110 (2011).
• Number of Medicare beneficiaries served;

• An average per-capita cost of care for Medicare fee-for-service beneficiaries, based on the most recent three years of per-beneficiary expenditures for parts A and B services; and

• Quality measures and performance.

As ACOs may also operate in the commercial market, they may also be interested in understanding more about the various participants’ financials as it relates to third-party payers. In these instances, ACOs must keep in mind the guidance outlined in the FTC/DOJ Policy Statement. The Policy Statement cautions that “significant competitive concerns can arise when an ACO’s operations lead to price-fixing or other collusion among ACO participants in their sale of competing services outside the ACO.” Accordingly, the agencies suggest that “ACOs should refrain from, and implement appropriate firewalls, or other safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO.” This suggestion reiterates the same guidance provided for providers’ collective provision of fee-related information to purchasers of healthcare services as well as other competitor collaborations.

Ultimately the parties must be mindful that they should maintain a firewall between the activities of the ACO and the activities of the other entities and narrowly tailor the competitively sensitive information exchanged to only that which is reasonably related to the parties’ participation in the MSSP or other legitimate joint activities.

22 Id.
23 Id.
24 See Statement 5, Health Care Statements, supra note 7; Competitor Collaboration Guidelines, supra note 4, § 3.34(e).