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I. INTRODUCTION

The Patient Protection and Affordable Care Act ("ACA")[2] withstood constitutional challenge in June 2012 and will define the shape of the U.S. healthcare system for years to come. Provisions within the ACA address the dual policy goals of controlling healthcare costs and ensuring high quality care, and often do so through incentivizing providers to work together and share the responsibility for delivering high-quality care (and the risk for failing to do so). Through provisions encouraging the creation of accountable care organizations ("ACOs") and other measures that reward providers who demonstrate quality and efficiency, providers are encouraged to achieve scale and ensure a continuum of care. However, this activity may confront a number of potential existing roadblocks, not the least of which is antitrust concern about market power and related price-fixing issues. This article will address this tension, and discuss how organizations looking to consolidate may proceed.

II. HEALTHCARE REFORM HAS PRODUCED PRESSURE TO CONSOLIDATE

As part of the federal government's ongoing effort to improve the quality of healthcare and to reduce costs, the ACA provides incentives for healthcare providers to consolidate. The ACA and its implementing regulations primarily do this by establishing the Medicare Share Savings Program (the "Shared Savings Program") and encouraging the creation of ACOs. ACOs are groups of healthcare providers that join together for the purpose of delivering coordinated care to Medicare beneficiaries and sharing a portion of the Medicare savings that may result.

To form an ACO, the participating providers must enter into a contract with the Centers for Medicare and Medicaid Services ("CMS") and meet certain eligibility standards.[3] Among those standards are requirements that participating providers display a measure of clinical integration by, for example, establishing metrics for monitoring and reporting on quality and cost, and coordinating care across primary care physicians, specialists, and other providers. ACOs that satisfy those requirements and achieve certain quality standards in the provision of care are eligible to participate in the Shared Savings Program, which allows an ACO to share in a portion of cost savings that the ACO generates relative to benchmarks established by CMS.

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[2] Pub. L. No. 111–148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C.) [hereinafter "ACA"].

[3] Medicare Shared Savings Program: Accountable Care Organizations, 42 C.F.R. pt. 425 (2011).

The theory behind ACOs is that cost savings are best obtained by promoting shared accountability for costs and quality across the continuum of care, rather than focusing on the accountability of individual providers at any particular stage of care. Consolidation can also facilitate improved quality and reduced costs through improved monitoring of costs across the spectrum of care, and by encouraging providers to make joint investments in infrastructure that improves efficiency, such as electronic health records. The Shared Savings Program went into effect on January 1, 2012, and on April 10, 2012, CMS announced that an initial group of twenty-seven ACOs had been approved to participate in the program.

The Shared Savings program and the promotion of ACOs is just one example of how the federal government is encouraging new payment models that spread risk and cost-savings between the government and healthcare providers. The Center for Medicare and Medicaid Innovation ("CMMI"), which was created by the ACA, has developed a number of initiatives promoting such alternative payment models. For example, CMMI has launched the Bundled Payment for Care Improvement Initiative to experiment with the concept of paying a group of providers a single "bundled" payment for services received by a patient in a single episode of care.[4] The pilot program will evaluate such alternative payment methodologies for 10 conditions.

The ACA is therefore at the forefront of a larger trend of shifting away from a fee for service payment system towards alternative payment methods such as global or bundled payments, which are expected to contain costs and result in the efficient provision of care. This shifting reimbursement landscape, including planned reductions in reimbursement (such as the downward productivity-related adjustment to the annual Medicare market basket increase for inpatient and outpatient hospital services that began in FY 2012)[5] may be more easily borne by larger networks that can share certain centralized functions and take advantage of bulk purchasing to reduce costs system wide.

In addition to the explicit incentives to consolidate, several aspects of the recent health care reform initiatives create an implicit pressure to consolidate or achieve scale. Healthcare providers are being required to contain costs and demonstrate quality under a number of different measures, and new reporting and performance targets may be more easily met by larger, integrated organizations. The ACA will pose new challenges for healthcare providers because some of the reforms will place new financial pressure on inefficient providers or lower quality providers. Maximizing efficiency and implementing system-wide best practices will be critical for thriving in this environment, and providers that are networked will likely be in the best position to meet these new targets.

One example is the ACA's readmission provision, pursuant to which Medicare will be able to withhold a portion of reimbursement as a result of a hospital's track record on readmissions.[6] Readmissions are high cost and may be perceived as an indicator of poor quality care. While the readmissions reduction provision itself does not specifically encourage consolidation among healthcare providers, and there are methods by which a stand-alone hospital might attempt to reduce its readmission rate, ensuring that patients receive the

[4] Authorized by the National Pilot Program on Payment Bundling, ACA § 3023, 124 Stat. 119, 399.
[5] *Id.* § 3401, 124 Stat. 119, 480.
[6] *Id.* § 3025, 124 Stat. 119, 408.

appropriate follow-up treatment in the right outpatient setting requires coordination among healthcare providers and may be better achieved through shared incentives to reduce hospital readmission rates. In another example, the federal government will also be expanding its efforts to reduce or prohibit Medicare and Medicaid payments for services rendered to treat patients with hospital acquired conditions ("HACs").[7] Standardized hospital policies and procedures across a broader network will help avoid HACs and the associated payment penalties.

Beginning in FY 2013, hospitals will receive Medicare incentive payments for achieving quality-based performance scores;[8] at the same time, Medicare inpatient prospective payment system disbursements will be reduced to fund these incentive payments. Larger, integrated systems will be able to coordinate quality efforts, providing opportunities for greater incentive payments to offset the payment reductions. Independent providers' ability to achieve the necessary scores could be jeopardized. This value-based purchasing program incorporates a 1 percent reduction in hospital payments redistributed back to hospitals based on achievement and improvement, which gradually increases until reaching a full 2 percent in 2017.

Additional Medicare and Medicaid payments have been, or will be, made available to incentivize healthcare providers to adopt meaningful use of health information technology ("IT").[9] Medicare incentive payments became available in 2010, and Medicaid incentive payments became available in 2011, though rollout varies by state. Providers that fail to adopt meaningful use by FY 2016 will face penalties. Investment in health IT is costly, but significant efficiencies can be achieved by aligning systems under one network. Stand-alone providers may have difficulty coming up with the capital to invest in a system that meets federal standards.

III. ANTITRUST AGENCIES RETAIN SAME FOCUS ON ANTICOMPETITIVE CONSOLIDATION

A. Guidance for ACOs

In conjunction with CMS's final rule implementing the Shared Savings Program and ACOs published on November 2, 2011, the Antitrust Division of the Department of Justice and the Federal Trade Commission released a joint Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.[10] Much like other enforcement policies issued by antitrust regulators, the ACO Statement provides that ACOs that are sufficiently integrated will be evaluated under a "rule of reason" analysis. Because ACO eligibility already requires a degree of clinical integration, the ACO Statement recognizes that ACOs that meet CMS eligibility requirements are likely sufficiently clinically integrated to warrant "rule of reason" analysis. Accordingly, the ACO

[7] *Id.* § 3008, 124 Stat. 119, 376.

[8] *Id.* § 3001, 124 Stat. 119, 353.

[9] Meaningful use of electronic health records is governed by the Health Information Technology and Clinical Health (HITECH) Act (42 U.S.C. § 17930 *et seq.*), signed into law in February 2009 as part of the American Recovery and Reinvestment Act.

[10] FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS PARTICIPATING IN THE MEDICARE SHARED SAVINGS PROGRAM 5-6 (2011) [hereinafter "ACO Statement"], http://www.justice.gov/atr/public/health_care/276458.pdf.

Statement places heavy emphasis on the market share that a proposed ACO will command in the relevant markets where it will operate.

The ACO Statement creates a "safety zone" for ACOs that are unlikely to raise competitive concerns because of their low market shares. An ACO will fall within the safety zone if it has less than a 30 percent market share in all services provided by two or more participants in the ACO.[11] The ACO Statement defines service as (1) the primary specialty for physicians, (2) major diagnostic categories for inpatient providers, and (3) certain categories to be defined by CMS for outpatient providers.[12] Subject to exceptions for certain rural providers participating in an ACO, and certain providers whose already-dominant market share will not be increased by participation in the ACO, an ACO with market shares in excess of the safety-zone threshold is potentially subject to antitrust scrutiny and a close examination of the competitive and anticompetitive effects the ACO is likely to produce.[13]

B. Application of Antitrust Laws to Merging Healthcare Providers

In addition to the ACO Statement, the broadly applicable Horizontal Merger Guidelines[14] and the agencies' Antitrust Guidelines for Collaborations Among Competitors[15] and Statements of Antitrust Enforcement Policy in Health Care[16] continue to serve as the guideposts for healthcare providers seeking to form a venture or affiliate with other providers. Generally for ACOs, and other combinations that will likely result from the incentives created by the ACA, providers must be aware of the agencies' analytical framework and potential areas of risk as they contemplate consolidation. Under the ACO Statement, market share continues to be the focus of the agencies' inquiry, and will continue to be an important consideration for non-ACO affiliations as well. For those providers looking to collaborate without an affiliation, the agencies will continue to look at the levels of clinical and financial integration of the joint venture.

The ACO Statement's safety zone reflects an emphasis on market share that is consistent with antitrust regulators' traditional approach to healthcare consolidation. But by relying heavily on market share as a proxy for an ACO's competitive effects, antitrust regulators risk overlooking the pro-competitive benefits of alternative payment methods. Coordination and consolidation are often a necessary byproduct of alternative payment models like the Shared Savings Program and bundled payments. The government's shift toward promoting these payment models over the traditional fee for service model may warrant a parallel shift in antitrust analysis. In particular, although market share will undoubtedly remain an important factor, antitrust regulators should take into account that some amount of coordination and consolidation is often

[11] *Id.* at 7.

[12] *Id.*

[13] *Id.* at 8-9. The ACO Statement permits proposed ACO's to seek expedited voluntary antitrust review from the DOJ and FTC. *Id.* at 11–14. Unlike earlier proposals, however, the final ACO Statement does not require mandatory antitrust review of ACOs whose market share exceeds 50 percent in any service provided by two or more ACO participants. *Id.* at 1.

[14] HORIZONTAL MERGER GUIDELINES (2010), http://www.justice.gov/atr/public/guidelines/hmg-2010.pdf.

[15] ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS (2000), www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

[16] STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996), www.justicegov/atr/public/guidelines/0000.pdf.

necessary for alternative payment models to deliver on their promise of lowering healthcare costs.

According to the traditional FTC analysis, if a transaction increases the market power wielded by an entity, the entity will have leverage to negotiate higher payments regardless of whether the method is fee for service or a global payment. It remains unlikely that the agency will be persuaded that a hospital merger can be justified by the argument that the providers need to effect the affiliation to better manage the transition from fee for service to global payment. Nonetheless, this shift in the reimbursement landscape may exert countervailing pressures on providers that could serve to constrain them in a way that their competitors' pricing may have done under the old model. It remains to be seen whether the bargaining dynamics between healthcare consumers and providers ultimately is altered so as to render the emphasis on a structural analysis misplaced.

IV. PRACTICE TIPS

A. For ACO's, Be Aware of Limitations on Market Share at the Outset

For organizations considering consolidating in the form of an ACO, antitrust counsel should be engaged at the outset of the process. It is important to involve counsel and to perform at least some elementary market share analysis at the earliest planning stages because that analysis can often impact the business decision to form an ACO. Healthcare providers must understand the very real implications that antitrust enforcement can have on their ability to form the organization at all. Even providers who have invested heavily in preparing to form an ACO may wish to modify the proposed scope of participants should market shares exceed the ACO Statement's safety-zone threshold. Antitrust counsel can identify potential red flags and help participants avoid substantial investment in a venture that may be deemed anticompetitive by the antitrust agencies.

In addition, healthcare providers that anticipate forming an ACO should be alert to the scrutiny that will be focused on the market share of each category of service providers joining the organization. A large proportion of participating providers in any one specialty may increase the risk that the proposed entity will not pass antitrust muster, or that the venture will need to be restructured in order to avoid enforcement activity. Identifying these issues during the initial phases of constructing the ACO will lessen obstacles and costs down the road.

B. For All Combinations or Proposed Ventures, Identify and Document Anticipated Pro-Competitive Efficiencies

In addition to the specific guidance for ACOs, organizations anticipating a consolidation should be prepared to look closely at all possible affected business units to identify specific, pro-competitive benefits that will result from the affiliation. These benefits should consist of more than simply the cost savings inuring to the parties themselves, and those that result in lower overall costs for healthcare services to payers, employers, and patients will receive the most weight in the agencies' analysis. Entities may want to emphasize the extent to which the new organization will be in a position to implement changes that will substantially lower costs, while also demonstrating the specific benefits to patients and the community of a broader scope of delivered services and a coordinated continuum of care.

In addition, the agencies often contact customers of the affiliating entities to learn their views on the transaction and its likely impact on competition. For healthcare providers, the primary proxy for patients, in the agencies' view, are typically managed care payers. Conducting a communications effort that informs such payers of the entities' plans and the benefits expected to result from the transaction can help set the stage for a positive portrayal of the proposed deal. Similarly, managing document creation from the early stages of planning a combination will help ensure that a favorable message is transmitted to the agencies during their review. Effective document management will promote the thorough documentation of the efficiencies likely to arise from the transaction as well as help avoid the creation of documents that could later be misinterpreted to suggest anticompetitive intentions.

V. CONCLUSION

The ACA and related healthcare reform measures are intended to improve the quality and lower the cost for healthcare services by putting in place provisions that create methods and incentives to providers to effectuate these goals. The ACO provisions explicitly encourage coordination of care through the development of larger networks of providers, while others reward or penalize organizations based on their ability to achieve targets that may be more readily achieved by larger entities. The landscape is shifting in ways that will make it increasingly difficult for smaller players to remain independent, and, in this new environment, the antitrust agencies may ultimately need to adapt and consider modifications to their approach to analyzing combinations in the healthcare industry.