State Action Immunization of Health Care Transactions and New York’s New Regulations

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Introduction

Consolidation and collaboration in the health-care industry are on the rise. The Affordable Care Act has further promoted this trend by setting quality of care targets and encouraging providers to move toward a risk-based reimbursement model. However, this trend in consolidation is often at odds with federal enforcement of antitrust laws. Last year, the FTC successfully challenged St. Luke Health System’s acquisition of Saltzer Medical Group, in Nampa, Idaho, reiterating that the ACA by itself, is not a valid defense to an otherwise anticompetitive health-care transaction. In response to this conflict, many states including New York, are revisiting or drafting new laws and regulations that seek to immunize health-care provider collaborations from federal antitrust scrutiny. While the FTC is likely to retain primacy in antitrust enforcement in health care, these state certification schemes present an opportunity for providers to secure the support of state antitrust enforcers and health-care regulatory agencies, and possibly deter an FTC investigation and/or challenge.

The Affordable Care Act and federal antitrust enforcement

Since the ACA was enacted in 2010, health-care providers have argued that the new law fosters consolidation and integration of health-care services. The law encourages providers to move away from the costly fee-for-service reimbursement system toward a risk-based one that rewards improved patient outcomes and incentivizes the provision of higher-value care at a lower cost. Providers often see integration as the best way to achieve this. Indeed, consolidation in the health-care industry has been on the rise over the past several years.1

However, FTC officials have repeatedly stated that the ACA does not exempt health-care mergers from antitrust scrutiny.2 Earlier this year, Martin Gaynor, director of the Bureau of Economics at the FTC, wrote in a response piece in the New York Times that federal antitrust enforcement is “entirely consistent with the health law’s objective to foster new and innovative forms of health care delivery.”3 He explained the ACA’s success depends on a well-functioning health-care market, and that antitrust enforcement is an integral part of that.4 Speaking at the Accountable Care Organization (ACO) Summit, Deborah Feinstein, director of the Bureau of Competition at the FTC, echoed these statements, noting that


3 Gaynor on Antitrust in Healthcare.

4 Id.
the ACA does not alter the standard the FTC applies to efforts to coordinate care, and is not incompatible with antitrust enforcement.5

FTC Commissioner Julie Brill also recently spoke on the issue at New York University Law School.6 Brill said that although the ACA aims to improve the efficiency of U.S. health care, health systems should “carefully” look at whether a full merger is necessary to meet efficiency goals. She stated that health-care providers will face antitrust scrutiny where complete integration of the parties goes “too far,” and the efficiencies of integrated care could be achieved through less anticompetitive means.8

The FTC’s message is clear: the ACA by itself does not provide a defense to an otherwise anticompetitive health-care transaction under federal antitrust laws. Moreover, health-care providers interested in capturing the efficiencies of integrated care should consider options short of outright acquisition. At least one federal district court has sided with the FTC’s view of enforcement in the wake of the ACA. It has been almost a year since Judge B. Lynn Winmill of the U.S. District Court for the District of Idaho ordered the unwinding of St. Luke’s Health System’s 2012 acquisition of the Salt Lake Medical Group.9 The court acknowledged that the acquisition would improve delivery and quality of health care in Idaho, but concluded that there were other ways to obtain the desired efficiencies without running a risk of anticompetitive effects.10 Providers have read the decision to suggest that the goals of the ACA indeed are in conflict with strict enforcement of antitrust law, pointing to language in the opinion stating that “in a world not governed by the Clayton Act, the best result might be to approve the Acquisition.”11

The St. Luke’s decision and the statements of these high ranking FTC officials suggest the need for integration, and even the likelihood of improved outcomes and efficiencies are unlikely to be enough to save a deal where there may be alternative ways to achieve these goals. What those alternatives might be is still not clear, as neither the FTC nor the St. Luke’s court has explained what providers’ nonmerger alternatives are or why they would achieve the same efficiencies and were less anticompetitive than a merger.

State action immunity in the wake of the St. Luke’s decision

In the aftermath of the St. Luke’s decision, some state legislatures and health-care agencies have promulgated measures that attempt to immunize health-care collabora-

6 Brill on the ACA and Provider Transactions.
7 Id.
8 Id.
10 Id.
12 See e.g., N.Y. PUB. HEALTH LAW Art. 29-F (immunizing certain health-care provider transactions).
16 Id. at 1011.
17 See Id.
18 717 F.3d 359 (4th Cir. 2013), cert. granted 134 S. Ct. 1491.
federal antitrust laws.\textsuperscript{20} The regulations were formally adopted on Dec. 17, 2014.\textsuperscript{21}

The DOH promulgated the regulations pursuant to a specific grant of authority under Article 29-F of New York’s Public Health Law (PBH).\textsuperscript{22} The law stipulates that it is the policy of the state to encourage health-care collaborations to improve clinical outcomes, efficiency, and access to care in New York, and authorizes the DOH to promulgate regulations to immunize certain health-care collaborations from federal antitrust laws.\textsuperscript{23} Importantly, the statute includes a sunset clause, providing that no arrangement may be approved after Dec. 31, 2016.\textsuperscript{24}

The DOH’s Regulatory Impact Statement says the regulations are motivated by the need for increased integration and collaboration among health-care providers and among providers, payers, and other entities essential to implementing the mandate of the ACA.\textsuperscript{25} The statement also notes that many of these collaborations might be construed as anticompetitive under the antitrust laws by federal enforcers.\textsuperscript{26}

The DOH’s new rules stipulate that health-care providers that seek a Certificate of Public Advantage (COPA) will have state action immunity under the federal antitrust laws and may negotiate, enter into, and conduct business pursuant to “cooperative agreements” or planning processes covered by the issued certificate.\textsuperscript{27} The regulations define cooperative agreement as an agreement that would otherwise be prohibited by law, i.e., anticompetitive under the antitrust laws.\textsuperscript{28}

The new regulations also require the parties to file periodic reports with the DOH detailing, among other things, the collaboration’s performance with respect to quality, access, and cost of care.\textsuperscript{29} The DOH will then review such reports and any application for renewal of the certificate to determine whether the benefits of the collaboration continue to outweigh its disadvantages.\textsuperscript{30} The DOH may then continue or renew the certificate, modify its conditions, or revoke it. The regulations also stipulate that the DOH may not revoke the certificate without affording the parties an opportunity to request a hearing.\textsuperscript{31} It is not yet clear what would happen should the DOH ultimately revoke a certificate. Such a revocation would likely be accompanied by a more thorough investigation by the AG and possibly a lawsuit seeking to extract additional conditions from the parties. Revoking the certificate would also leave the parties vulnerable to investigation and/or challenge of the transaction by federal antitrust enforcers. While states are more willing to adopt conduct-based remedies, the FTC’s preferred remedy for anticompetitive health-care transactions is divestiture.\textsuperscript{32} Indeed, the FTC has recently demonstrated its willingness to pursue the breakup of consummated health-care transactions.\textsuperscript{33}

The Regulatory Impact Statement says that the periodic reporting obligations in the regulations are drafted to satisfy the “active supervision” prong of the test for state action immunity from federal antitrust laws.\textsuperscript{34}

While the statute and regulations seek to provide a complete state action defense under the federal antitrust laws, New York antitrust laws are only partially affected. New York courts have held that the state action doctrine does not apply to state antitrust claims.\textsuperscript{35} The regulations provide that the DOH must consult with the attorney general (AG) throughout the process of granting a certificate, so parties seeking to take advantage of these regulations should be mindful that the AG could raise antitrust concerns with the DOH.\textsuperscript{36} Even after a Certificate of Public Advantage has been issued, the New York AG may seek relief under state antitrust laws.\textsuperscript{37}

The regulations give a nonexhaustive list of factors that the DOH may consider before issuing a certificate. These include: (1) the financial condition of the parties to the agreement, including whether in the absence of the agreement, one or more parties would go out of business; (2) competition in the primary service area of the parties; (3) the potential benefits of the collaboration, such as the preservation of certain services at risk of elimination absent the collaboration, improvement in the quality and access of care, and control of cost of care; and (4) the disadvantages of the collaboration, such as reduced quality and access of care, reduced competition among physicians, the availability of comparable alternative combinations that are less restrictive to competition, and the cost of monitoring the collaboration to mitigate anticompetitive effects.\textsuperscript{38}

According to the regulations, the DOH may only issue a certificate once it has determined that the benefits likely to result from the cooperative agreement outweigh its disadvantages.\textsuperscript{39} If the DOH decides to issue the certificate, it must include any conditions that the DOH, in consultation with the AG determines are necessary to ensure the collaboration results in improved quality, access, and efficiency of care.\textsuperscript{40} The conditions may include the implementation of a clinical integration plan, achievement of quality benchmarks, maintaining or expanding certain services or levels of access by underserved populations, etc.\textsuperscript{41}

### Accountable Care Organizations

On Oct. 15, 2014, the DOH proposed new regulations establishing the standards the New York Commissioner of Health (commissioner) must follow when issuing ACOs certifications that immunize ACOs from federal

\textsuperscript{20} 36 N.Y. Reg. at 14 (Aug. 27, 2014).
\textsuperscript{21} 36 N.Y. Reg. at 1 (Dec. 17, 2014).
\textsuperscript{22} N.Y. PUB. HEALTH LAW Art. 29-F.
\textsuperscript{23} Id.
\textsuperscript{24} Id.
\textsuperscript{25} 36 N.Y. Reg. at 14 (Aug. 27, 2014).
\textsuperscript{26} Id.
\textsuperscript{27} Id.
\textsuperscript{28} Proposed 10 N.Y.C.R.R. § 83-1.1(c).
\textsuperscript{29} Proposed 10 N.Y.C.R.R. § 83-1.9.
\textsuperscript{30} Proposed 10 N.Y.C.R.R. § 83-1.10.
\textsuperscript{31} Proposed 10 N.Y.C.R.R. § 83-1.12.
\textsuperscript{32} See Feinstein on Antitrust Enforcement in Healthcare.
\textsuperscript{33} See Phoebe Putney Health Sys., Inc., Order Returning Matter to Adjudication, FTC, No. 9348, (Sept. 4, 2014) (voting to renew the commission’s effort to unravel Phoebe Putney’s consummated acquisition of Palmyra Park Hospital).
\textsuperscript{34} 36 N.Y. Reg. at 14 (Aug. 27, 2014).
\textsuperscript{36} Proposed 10 N.Y.C.R.R. §§ 83-1.5, 6.
\textsuperscript{37} Proposed 10 N.Y.C.R.R. § 83-1.2.
\textsuperscript{38} Proposed 10 N.Y.C.R.R. § 83-1.5.
\textsuperscript{39} Proposed 10 N.Y.C.R.R. § 83-1.6.
\textsuperscript{40} Id.
\textsuperscript{41} Id.
and state antitrust laws under the “state action” doctrine.\textsuperscript{42}

The DOH promulgated the regulations pursuant to a specific grant of authority under Article 29-E of New York’s Public Health Law (PBH). The law requires the Commissioner to establish a program governing the approval of ACOs.\textsuperscript{43} Under the law, the commissioner is authorized to issue an unlimited number of certificates to ACOs prior to Dec. 31, 2016.\textsuperscript{44} According to Article 29-E, the development of ACOs will “reduce health care costs, promote effective allocation of health care resources, and enhance the quality and accessibility of health care.”\textsuperscript{45} Certain ACOs certified pursuant to the proposed regulations will not be considered to be in violation of state antitrust laws relating to contracts or agreements in restraint of trade if they fall within the “safety zone” outlined in the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Statement of Policy Regarding ACOs), issued by the FTC and DOJ in October, 2011.\textsuperscript{46}

Under the federal agencies’ Statement of Policy Regarding ACOs, ACOs that meet certain conditions are eligible for a “safety zone,” and will not be challenged by the agencies under federal antitrust laws, absent extraordinary circumstances.\textsuperscript{47} The agencies view such ACOs as highly unlikely to raise anticompetitive concerns.\textsuperscript{48} To qualify for the safety zone, an ACO must first be eligible and intend, or have been approved, to participate in the Medicare Shared Savings Program.\textsuperscript{49} ACOs that also plan to operate in the commercial market may qualify for the safety zone as well.\textsuperscript{50}

For an ACO to fall within the safety zone, participating providers that provide a “common service” must have a combined share of 30 percent or less of each common service in each participant’s primary service area (PSA).\textsuperscript{51} For physicians, this threshold applies regardless of whether they participate in the ACO on an exclusive or nonexclusive basis.\textsuperscript{52} In addition, any participating hospital or ambulatory surgery center (ASC) must contract with the ACO on a nonexclusive basis, regardless of whether the PSA shares of competing hospitals or ASCs for any common service are 30 percent or below.\textsuperscript{53} There are two exceptions to these criteria: (1) in rural areas, certain ACOs’ market share may exceed 30 percent for any common service, and (2) ACOs may include a provider with a greater than 50 percent share in its PSA for any service not provided by another ACO participant subject to certain conditions.\textsuperscript{54}

Under New York’s proposed regulations, an ACO may seek state action immunity from state and federal antitrust laws as part of its application for a certificate of authority from the commissioner of the DOH.\textsuperscript{55}

Under the proposed regulations, the commissioner must consider a series of factors in making a state action immunity determination, including: (i) the potential benefits of the ACO’s collaborative activities, such as preservation of needed health-care services otherwise at risk of elimination, expansion of needed services, improvements in quality, efficiency, and access to care, and reductions in the cost of care; (ii) the market conditions in the PSA, including provider competition, barriers to entry, likelihood of exit of providers, and the health-care workforce; (iii) the potential disadvantages of the ACO’s collaborative activities; (iv) the availability of less competitively restrictive arrangements to achieve the same or greater benefits; and (vi) the extent to which active supervision is likely to mitigate any disadvantages.\textsuperscript{56}

The regulations stipulate that in determining whether to provide state action immunity, the DOH may impose such conditions as necessary to ensure that the activities of the ACO are consistent with the purposes of Article 29-E and/or are necessary to ameliorate any potential disadvantages.\textsuperscript{57} If it decides to grant immunity, the DOH’s determination will be reflected on the certificate, and the DOH will be responsible for actively supervising the ACO.\textsuperscript{58} The regulations empower the agency to request information as it deems appropriate to fulfill its supervisory role, but they do not provide further details about the agency’s supervision of ACOs for their effects on competition.\textsuperscript{59} Certified ACOs are subject to periodic reporting obligations with respect to health care quality metrics, but these reports do not call for competition-related information.\textsuperscript{60} It is unclear whether the federal antitrust agencies would view these provisions as enough “active state supervision” to qualify for state action immunity.

Unlike the regulations promulgated to immunize provider transactions, the AG has no role in reviewing the ACO for its effects on competition.\textsuperscript{61} However, the proposed regulations state that DOH consulted with the AG when drafting the regulations, as required by Article 29-E of the PBH.\textsuperscript{62}

**Blanket Grants of Immunity**

The new ACO and provider transaction certification schemes are not New York’s first experiment with state action immunity for health-care collaborations. In late 2013, Governor Cuomo signed a bill that would enable state-chartered Nassau Health Care Corp. to legally enter into arrangements with other health-care providers that might otherwise be deemed illegal under federal and state antitrust laws.\textsuperscript{63} The law cleared the way for

\begin{itemize}
  \item \textsuperscript{42} Accountable Care Organizations, 36 N.Y. Reg. 26 (Oct. 15, 2014).
  \item \textsuperscript{43} N.Y. Pub. Health Law § 2999-P(2).
  \item \textsuperscript{44} N.Y. Pub. Health Law § 2999-P(3).
  \item \textsuperscript{45} N.Y. Pub. Health Law § 2999-N.
  \item \textsuperscript{47} Id.
  \item \textsuperscript{48} Id.
  \item \textsuperscript{49} Id.
  \item \textsuperscript{50} Id.
  \item \textsuperscript{51} Id.
  \item \textsuperscript{52} Statement of Policy Regarding ACOs.
  \item \textsuperscript{53} Id.
  \item \textsuperscript{54} Id.
  \item \textsuperscript{55} Proposed 10 N.Y.C.R.R. § 10003.14(2).
  \item \textsuperscript{56} Id.
  \item \textsuperscript{57} Id.
  \item \textsuperscript{58} Id.
  \item \textsuperscript{59} Id.
  \item \textsuperscript{60} Proposed 10 N.Y.C.R.R. § 10003.13.
  \item \textsuperscript{61} See Proposed 10 N.Y.C.R.R. § 83-1.6; Proposed 10 N.Y.C.R.R. § 10003.
  \item \textsuperscript{62} Accountable Care Organizations, 36 N.Y. Reg. 26 (Oct. 15, 2014).
  \item \textsuperscript{63} 2013 Laws of New York ch. 458.
\end{itemize}
a private-public partnership between Nassau Health and North Shore-Long Island Jewish Health System. The New York AG vigorously opposed the blanket grant of immunity to Nassau, arguing its office should review transactions on a case by case basis for their effects on competition. Case by case review was the approach taken under the new state action immunity regulations for ACOs and health-care provider transactions.  

The trend toward state supervision of health care collaborations and immunity from federal antitrust laws

New York is but one of many states that have sought to immunize certain health-care collaborations from federal and state antitrust scrutiny. Laws relating to state supervision of health-care collaborations vary in the degree of immunity they grant, if any, the conditions parties must meet to avail themselves of that immunity, and the powers granted to state officials to scrutinize and oversee the competitive aspects of health-care collaborations. At least half a dozen states have enacted schemes akin to New York’s COPA regulations that seek to completely immunize certified health-care provider combinations from federal and state antitrust enforcement. Other states have limited immunity grants to transactions between providers in rural areas or collaborations relating to specific services like heart and kidney transplants. The majority of these statutes were enacted in the mid-1990s and early 2000s, prior to the passage of the ACA and the Supreme Court’s Phoebe Putney decision. The laws may become more relevant as health-care providers increasingly see consolidation as the best way to meet the ACA’s demands and states seek to reap the quality benefits of integrated care.  

Like New York, New Hampshire also considered the issue of state action immunity for provider transactions this year. In 2014, the New Hampshire Legislature debated S.B. 308, a bill that, as originally introduced in the Senate would have allowed parties to a health-care provider combination or cooperative agreement to apply for a COPA. If granted, the certificate would have conferred on the transaction state action immunity from federal antitrust laws. The bill was subsequently amended by the House, to instead create a specialized committee of legislators tasked with evaluating the merits of a certification scheme for health-care provider transactions. The Legislature adjourned discussion on the bill and failed to concur on an engrossed version. It remains unclear whether New Hampshire intends to consider this issue again in the legislative session that convened Jan. 7.

The FTC’s opposition to state action immunity and practical considerations

FTC officials have publicly expressed their opposition to grants of immunity from the antitrust laws. Both Chairwoman Edith Ramirez and Deborah Feinstein have stated that because procompetitive collaborations are already permitted under the antitrust laws, these grants of immunity encourage transactions that harm competition and consumers. Last week, in an article published by the New England Journal of Medicine, Chairwoman Ramirez again criticized state action immunity grants, arguing that by “permitting conduct that would ordinarily violate antitrust laws, the bills would lead to higher prices and lower-quality care—undercutting the very objectives they aim to achieve.” Ramirez also indicated that the FTC’s antitrust analysis takes into account cost as well as quality considerations, but that quality benefits arguments must be substantiated by evidence and must be only attainable by means of the merger to be persuasive to the agency.  

Moreover, FTC officials have repeatedly stated that although the commission is committed to protecting consumers from anticompetitive transactions, the agency will not stand in the way of innovative arrangements to coordinate and improve care. However, as previously mentioned, for the most part, the agency has been silent as to what kinds of collaborations it would decline to investigate or challenge. Given the FTC’s opposition to grants of immunity, providers seeking to avail themselves of these certification schemes should not disregard the risk of a potential FTC investigation and/or enforcement action. Unlike New York’s new regulations, many state action immunity schemes were enacted prior to the Supreme Court’s Phoebe Putney decision, and were likely not drafted to explicitly meet the refined standard. This means that it will be up to the parties to demonstrate that the state “affirmatively contemplated” the displacement of competition. Moreover, the FTC may have a higher threshold for what constitutes “active state supervision” than the state reviewing the collaboration. Even in cases where the state immunity scheme is based upon federal guidance and safe harbors (such as in the case of New York’s proposed ACO regulations), the FTC may disagree with the state’s interpretation of the safe harbor or definition of the relevant market and may decide to investigate or challenge the collaboration.

66 See e.g., FLA. STAT. § 381.04065 (enacted 1997).
67 See e.g., OR. REV. STAT. §§ 442.700-442.760 (Cooperative Program on Heart and Kidney Transplants) (enacted 1993, last amended 2007).
69 Id.
70 N.H. S.B. 308 (Amended May 15, 2014).
71 Id.
72 Feinstein on Antitrust Enforcement in Healthcare.
74 Id.
**Conclusion**

While the FTC is likely to retain primacy in antitrust enforcement in health care, state certification of a transaction or ACO may deter FTC action to a certain extent. The more onerous and robust the certification scheme and state supervision, the likelier the FTC is to leave investigation and enforcement to the state. Such is the case with New York’s new COPA regulations, which appear to be quite rigorous. Health-care providers entering into transactions stand to benefit from going through the certification process outlined therein. Likewise, where a scheme closely tracks federal enforcement guidelines, as in the case of New York’s proposed ACO regulations, the FTC is more likely to leave supervision and enforcement to the state.

From a practical standpoint, it is often crucial to obtain the support of the community, the state health-care regulatory agency, and the state AG, for any health-care collaboration that may raise antitrust concerns. Parties to health-care collaborations that successfully obtain certification through state regulations such as New York’s COPA and ACO schemes, ensure that they have the state’s backing for their collaborations in the face of a federal antitrust investigation and/or challenge.