HEALTH CARE'S PERFECT STORM OF 2024

National Antitrust Regulations Collide With State Developments for a Tidal Wave of Deal Scrutiny

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Mergers and acquisitions (M&A) have influenced health care for years, creating everything from megasystem consolidations to small- and mid-scale provider partnerships.

But is that about to change — or at least significantly slow down?

Experts say it might, thanks to what they're calling a "perfect storm" of federal and state regulations. An overhaul in how the Federal Trade Commission (FTC) and Department of Justice (DOJ), and most recently the Department of Health and Human Services (HHS) review and approve agreements now coexists with a new era of state regulations and filing requirements, such as that seen across New York, California and other states.

Together, these forces could affect which types of transactions get approved, increase review times, and even slow or kill the kinds of deals that would have passed muster just years ago. As those agreements encounter more barriers, it's raising new questions about how antitrust activity affects providers' concomitant business considerations, such as reimbursement models.

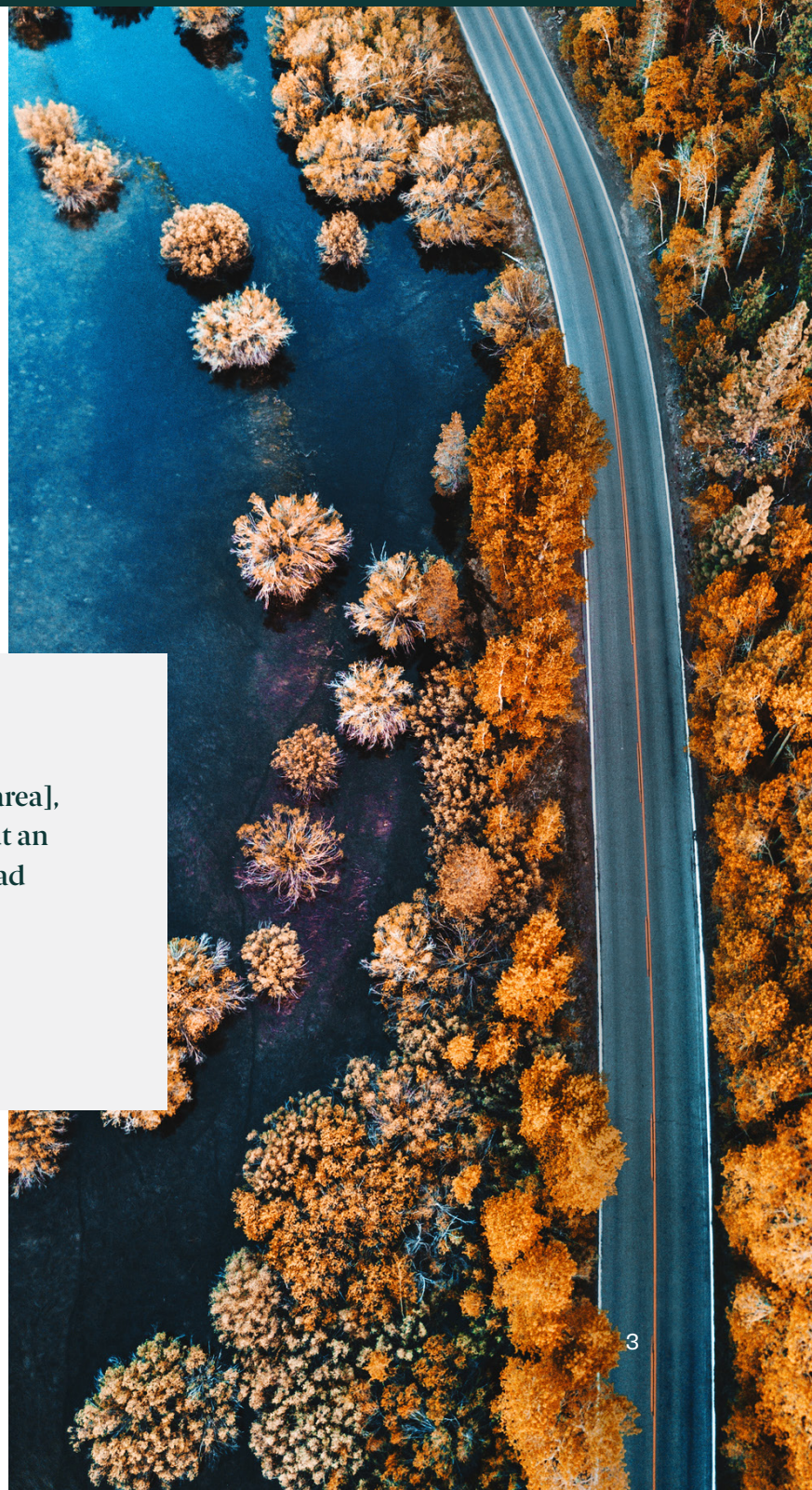
HERE'S WHAT HEALTH CARE LEADERS SHOULD KNOW.

An "Antitrust Revolution" From the FTC and DOJ

Increased attention and regulatory hurdles from national agencies stand to put new pressures on deals moving into 2024. The DOJ and FTC are devoting much of their focus on health care, in some cases disproportionally: While health care accounts for roughly one-sixth of the gross domestic product,[1] the health care industry represented almost half of federal antitrust enforcement between 2016 and 2020,[2] according to John Carroll, partner in the antitrust and competition practice group at Sheppard Mullin.

> "The FTC has lost some cases, but one area where they've been extraordinarily successful is in hospital merger enforcement. [In that area], they've lost very few cases in the last 20 years. So if you're talking about an in-market strategic transaction between hospitals, that's the FTC's bread and butter, and it's one of the crown jewels of their enforcement."
>
> **JOHN CARROLL,** Partner, Antitrust and Competition Practice Group, Sheppard Mullin
> The 2023 Moss Adams Annual Health Care Conference

Just in 2023, there have been three significant changes to the federal antitrust enforcement and regulatory framework that affects the health care industry.



First, in December 2023, the FTC and DOJ jointly issued their new Final Merger Guidelines — which describe how the FTC and DOJ examine mergers in all industries.[3] Those guidelines presume a deal to be unlawful based on substantially lower combined market shares (30%) than in prior versions of the guidelines. Many experts say that a 30% market share is not dominant, and by instituting that standard, it's likely to kill deals that pose no real monopolizing threat.

Does that mean providers should only consider agreements that would consume up to 29.99% of the market? Not hardly, Carroll said. For one thing, market shares can be challenging to quantify. But second, it's just one of many factors.

"If you're evaluating potential bidders and a bidder would be considered dominant in a market by these standards, that gets factored into the scope of review," Carroll said. "It's about evaluating the overall competitive presence and factoring antitrust into all the other things involved in a transaction. Also keep in mind that the Final Merger Guidelines will be subject to challenges in court, though that would require merging parties to have the appetite for litigating against the FTC or DOJ."

The second change came in June 2023, when the FTC and DOJ proposed changes to the Hart-Scott-Rodino (HSR) regulations[4] **— which require that parties in a transaction provide certain information to the FTC and DOJ in their HSR forms** — potentially mandating that parties in a transaction provide information regarding investors and other information not currently required. These changes are not yet final but are raising concerns about deal structuring, costs, and timelines. For example, every new draft of substantive merger agreements must be filed with the FTC and DOJ, indicating a need to plan for a bumpy and potentially extended and expensive pathway toward deal approval.[5]

Finally, the FTC and DOJ each withdrew decades of healthcare guidance and have stated they do not intend to replace them.[6] Those guidelines represented a cornerstone of federal antitrust enforcement and have provided U.S. healthcare industry providers, payers, employers, and others with detailed guidance regarding the application of the U.S. federal antitrust laws to the healthcare industry and provided certain "safety zones" for rural hospital transactions and information exchanges.

Additionally, a recent FTC press release announced a partnership between the DOJ, FTC, and Department of Health and Human Services (HHS) to — among other things — exchange data to identify high-risk deals that would have otherwise not been flagged.[7] HSS has also named a chief competition officer.[8]

New Developments in State Regulation and Review

By the end of 2023, 13 states had passed regulations requiring M&A transactional reviews by state regulatory bodies, including New York, Illinois and California.[9] Similar to the federal scrutiny, many states have set lower transaction thresholds — not defined by market share but by transaction value.

For example, under California's SB 184[10] and its implementing regulations,[11] "health care entities," which include payers and several types of providers will need to notify the Office of Health Care Affordability (OHCA) of certain transactions, including those valued at $25 million or more.[12] Similarly, New York requires "heath care entities," including physician practices and management services organizations, to submit notice to the State Department of Health before finalizing certain transactions, but it exempts deals that won't raise an entity's in-state revenue by at least $25 million.[13]

These state requirements could exacerbate the pressures from national antitrust activities, making already burdened deals even harder to complete. But unlike federal regulations and enforcements channeled through the FTC and DOJ, state requirements are much more nuanced, complex and dispersed across different agencies, sometimes with overlapping scopes of review.

Besides understanding what to file, when and to whom, there's also the concern about confidentiality, which is not automatically assumed when filing with state agencies (unlike federal processes).[14] Under the recently released OHCA Cost and Market Impact Review (CMIR) regulations, much of the filing materials and information is treated as a public record unless OHCA accepts a submitter's confidentiality designation.[15]

These and related state-based requirements can clash with other market dynamics, such as one that William Barcellona, executive vice president, government affairs of America's Physician Groups, said was particularly concerning: a recommended 3% cap on cost growth over the next seven years that OHCA has contemplated in connection with its cost-target setting authority under SB 184 (which is in addition to OHCA's CMIR authority.)[16]

Barcellona pointed to the fact that at least in California — and many other places, too — transactions occur because the providers involved are financially distressed. If a new wave of transaction scrutiny comes at providers from both federal and state agencies, without meaningful exemptions and expedited review processes for distressed entities, it may jeopardize the last-ditch efforts those organizations have left.

> "The reason why physician groups have aligned with hospitals over the last decade is not because the doctors were looking to make more money. They were looking to stay solvent. I worry about this taking us back to where we were in the late 1990s and early 2000s, when we had so many insolvencies."[17]
>
> **WILLIAM BARCELLONA,** Executive Vice President, Government Affairs of America's Physician Groups

Tensions Between Reimbursement Models and Transactional Pullbacks

As a transactional revolution takes place on a national and state scale, the reimbursement revolution does, too. And the effects of one are deeply enmeshed in — and potentially in conflict with — that of the other, creating an even more challenging road ahead.

Consider, for example, the Centers for Medicare & Medicaid Services (CMS), which has encouraged alternative payment models (APMs), such as risk-based and value-based arrangements, instead of fee for service (FFS). By 2030, CMS aims to have 100% of Medicare beneficiaries in accountable care programs.

To achieve that reimbursement shift, hospitals need resources, people, technologies, systems and, most of all, scale. In turn, they ink large agreements, the same type now less favored by national and state agencies.[18]

It seems like a Catch-22: Providers need deals to make APMs more feasible, and yet those deals are at risk of being blocked (or at least made to be longer and more expensive) by anti-merger policies. What's a hospital system to do as it bridges from one reimbursement model to the next?

The best choice is to keep moving away from FFS and toward risk-based reimbursement systems that reward keeping patients healthy, recommended Eric Klein, national health care practice team leader and partner at Sheppard Mullin.

> "When you have this type of additional regulation and this uncertainty, it slows down progress toward a new system as everybody hunkers down. What's going to happen is we're going to get stuck in betwixt and in between. What happens when you're there? We don't get the full quality or cost benefits that we could with a more complete system transformation."
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> **ERIC KLEIN,** National Health Care Practice Team Leader and Partner, Sheppard Mullin

At the same time, the consumer benefit of a potential transaction could tip the scales toward regulatory approval, even if it poses an antitrust risk, Carroll added. Nothing is cut and dry.

"Even if the deal would be combining or reducing competition, you then get into the next level of questions about market share and benefits," he said. "And namely, what are the benefits of what they're doing to bring together? In that way, the potential good of the transition to value-based care could be something that the people reviewing the deal could consider a positive."

Preparing for the Perfect Storm

Leaders have a lot to consider as they balance regulatory forces that may chill deals with market demands that drive the need for them.

In the context of evaluating potential partners, experts recommend focusing on current and forecasted needs across market strategy and growth: Where do you anticipate growing revenue over the next two to five years, for example? What major capital investments are you considering across EHRs, facilities, analytics, and population health management? What initiatives are you considering, for example in AI or payer platforms?

Additional contributors to that analysis could be those that account for other financial and economic factors, including cost trends, Barcellona added.

"You should make sure that your cost trend is under 4%, and potentially now lower with the OHCA's recent recommendation," he said. "And you have to get ready for transparency. Organizations will need to prove their value within the system and also get more efficient within the network. And, of course, you have to embrace the trend toward equity and inclusion. There's a lot to consider."

In the context of evaluating potential partners, experts recommend focusing on current and forecasted needs across market strategy and growth:

- Where do you anticipate growing revenue over the next two to five years, for example?
- What major capital investments are you considering across EHRs, facilities, analytics, and population health management?
- What initiatives are you considering, for example in artificial intelligence (AI) or payor platforms?
- Have you factored possible alignment strategies with payors and large employers to either prepare for a long-term merger play or compare to a merger strategy?
- What efficiencies can you demonstrate with a merger strategy?
- Have you factored in regulatory cost growth caps at state levels?

By assessing potential partners to ensure strengths and needs align, providers can demonstrate that deals are worth the expected increases in time, labor and costs. And by exploring potential alignment strategies with payers and large employers before transaction talks occur, it could potentially support the review process given the FTC's reliance on payers as a proxy for consumers.

Even so, there's still the need to be realistic about a deal's odds, Klein added. If a transaction is unlikely to be approved — no matter how great the offer is — it might not be worth the time and effort.

"When you are thinking about where you want to go with your business, you have to think about the criteria that need to be satisfied from your potential partner," he said. "It's not just about what value will I receive, will my patients be better supported, but it's also: What's the certainty of getting this done in a reasonable time frame?"

When navigating those many complexities and considerations, weigh the value that third-party consultants like Moss Adams can provide, Barcellona added. "What these trends tell us, and what I think we'll all find out very soon, is that we have to be very careful about the actuarial value of rates in the market for risk-bearing providers," he said. "Providers are going to need a lot of consulting help as we move forward."

> "After speaking with clients about the federal and state scrutiny occurring, many are unaware of the challenges on the horizon – whether they're in the middle of a deal now, or planning for deals in the next few years."
>
> **CHRIS PRITCHARD,** Group Leader,
> Moss Adams National Health Care Practice

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Contact Chris Pritchard, Group Leader of Moss Adams LLP National Health Care Practice to understand further the new overview of the key components and practical regulations promulgated by OCHA. We can help you: discuss the extensive application process, develop a strategy to address the new OCHA requirements, develop cost surveys, conduct market impact review analyses, undergo DMHC licensing and approval, and navigate other OCHA requirements affecting your business.

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