Finance in Five Minutes

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Healthcare Finance Checkup

By Paul Hastings Global Finance & Healthcare

While mergers and acquisitions, and attendant financings may not be moving at a blistering pace globally, the prognosis for deal activity in the healthcare sector remains healthy, in particular as the consolidation of providers, the vertical integration of healthcare services, and acquisitions and investments in the life sciences and medtech sectors continue. Therefore, in this report we focus on recent developments that stand to impact healthcare financings.

1. NY Healthcare Transactions Law

On May 3, 2023, New York Governor Kathy Hochul signed a law that follows a recent trend in other states that increases scrutiny of deals between physician practices and other practices and management entities. Effective August 1, new Article 45-A of the New York State Public Health Law requires that notice of "material transactions" between "health care entities" be provided to the state's health department at least 30 days before the transaction's closing date. The statute includes physician practices and management service organizations as health-care entities, but excludes insurers and pharmacy benefit managers. The law is a part of a broader trend, as six other states (California, Connecticut, Massachusetts, Nevada, Oregon, and Washington) have enacted laws requiring review or notice of specified healthcare transactions by a state authority, and bills to enact such laws are pending in four more states (Illinois, Maine, North Carolina, and Minnesota).

For more information, click **here**.

2. FTC Proposed Rule on Non-Compete Clauses

In January, the FTC proposed a rule to ban non-competition clauses in most employment contracts. The rule would bar restrictions on competition after the employment ends, on the basis

that such restrictions violate Sec. 5 of the FTC Act. The proposed rule is not limited to workers in the healthcare industry but, as part of its stated rationale for the rule, the FTC cited research showing, perhaps non-intuitively, that non-competition clauses actually increase consumer prices in the health care industry.

If issued, the rule applies on a forward-looking basis and also retroactively; employers would be required to nullify existing non-compete clauses within 180 days after the rule goes into effect, and to notify employees thereof within 45 days thereafter. The rule would not, however, affect the validity of a restriction on competition if the employee had ceased working for the employer before the rule takes effect.

The proposed rule contains an exception for non-compete clauses entered into by a person selling a business but only if the person owns at least 25% of the business. Accordingly, the rule might significantly affect the value of a health care business being sold and might significantly affect the structuring of financing to providers in states that are otherwise deferential to non-compete clauses in the health care industry. Moreover, in states with a stringent corporate practice of medicine statute, the proposed rule might necessitate a review of both: (i) the agreements between management services organizations ("MSOs") and the licensed providers they hire to provide services; and (ii) the financing agreements between MSOs and their lenders. That said, the rule purports to apply only to non-compete clauses in contracts with employers. Clarification on these points will not happen until the FTC reviews the comments from the public and determines whether and how to proceed. Therefore, at this stage, we must watch, wait and prepare.

For more information, click **here**.

3. Antitrust Enforcement

The federal government remains focused on the antitrust implications of consolidations in the healthcare industry. Last year, the DOJ unsuccessfully tried to block UnitedHealth Group's acquisition of Change Healthcare, a deal which was finalized in October for $13 billion. Undeterred by that loss, in April 2023 the FTC sought to enjoin LMCH Health's purchase of three Louisiana hospitals, a deal already approved by Louisiana state regulators, until the FTC had time to review the transaction. Then, in May 2023, the FTC filed a lawsuit to prevent biopharmaceutical company Amgen from acquiring Horizon Therapeutics for $27.8 billion, claiming the acquisition would allow Amgen to leverage a portfolio of drugs to allegedly entrench monopoly positions of Horizon medications used to treat thyroid eye disease and chronic refractory gout.

We expect antitrust to remain a central focus of the DOJ in large healthcare acquisitions. Lenders should be mindful of this focus when underwriting potential exit strategies, such as a sale to another large-scale healthcare system, because such a sale may not be ultimately available due to antitrust concerns. Fortunately, if the parties are properly advised and represented, antitrust concerns may delay or require changes to a transaction; but they rarely derail it.

4. Medicare Changes

Continuous Medicaid enrollments ended on March 31, 2023. The Centers for Medicare and Medicaid Services ("CMS") is requiring states to find strategies to handle this transition. The likely short-term effect will be that up to 18 million people will lose health insurance coverage. States have been given until May 2024 to complete the "unwinding" process of unenrolling people who are no longer eligible for Medicaid coverage. This will, in turn, likely result in a notable decline in provider revenue for those providers servicing Medicaid patients.

5. Updates to Medicare Drug Negotiation Program

The Inflation Reduction Act, which was signed on August 16, 2022, permits the Department of Health and Human Services ("HHS") to negotiate drug prices on a phased schedule, focusing on single-source drugs with limited market competition. On March 15, 2023, HHS released its Initial Guidance regarding the program.

To be eligible for negotiation a drug: (i) must be approved by the FDA; (ii) must have been on the market for a specified number of years (7 years for small molecule drugs; and 11 years for biologics); and (iii) cannot have a generic or biosimilar substitute. A list of the first ten negotiation-eligible drugs will be selected by the HHS Secretary by September 1, with the "maximum fair price" applied to such drugs starting in 2026. The total number of negotiation-eligible drugs will increase to fifteen in 2027 and to twenty by 2029. The program comes amid reports that several pharmaceutical companies are ending or scaling back arrangements with health insurers that cover patients' co-payments or free drugs to treat chronic medical conditions. In addition, in the last few years, at least 17 companies have reduced or ended their participation in the federal discount program known as 340B, which provides drugs to hospitals and clinics that provide care regardless of patients' ability to pay.

What to be aware of:

- CMS is presently evaluating public comments received so far, and this summer will revise its initial guidance as needed.
- On September 1, 2023, CMS will publish its initial list of up to 10 drugs selected for negotiation.
- By October 1, 2023, each manufacturer of a selected drug must sign an agreement to participate in the negotiation process.
- On February 1, 2024, CMS will send an initial offer to each manufacturer participating in the negotiation program.
- By March 2, 2024, participating manufacturers must accept the offer or propose a counteroffer.
- On August 1, 2024, the negotiation period ends.
- On September 1, 2024, CMS will publish the negotiated maximum fair price for each selected drug.
- On January 1, 2026, the negotiated price for each selected drug becomes effective.

6. Medical Technology Investment

Private equity investment is expected to remain high in medical technology, healthcare IT and other technology-related aspects of healthcare. Although the COVID-19 public health emergency has officially ended, the 2023 Consolidated Appropriations Act extended various telehealth-related flexibilities (e.g., Medicare recipients can receive telehealth services from any geographic location and telehealth can continue with audio-only communication at least through 2024). The potential impact of AI in medical care continues to make investments in this space particularly appealing, even if the precise magnitude, effectiveness and profit margins remain unknown. Efforts are reportedly underway to use AI to assist triage nurses and to augment the capabilities of wearable medical devices that gather, record, and process patient information.

7. Surprise Medical Billing Litigation

In April 2023, three federal departments – HHS, Labor, and Treasury – appealed (to the Fifth Circuit Court of Appeals) a February ruling by the U.S. District Court for the Eastern District of Texas that invalidated aspects of a final rule implementing the No Surprises Act. The Act protects patients with private medical insurance who are treated by an out-of-network provider by limiting the patient's financial liability to the amount that would have applied if the patient were treated by an in-network provider (a protection that Medicare and Medicaid recipients already enjoyed). The Act then provides

for insurers and providers to negotiate the amount to be paid and, if they fail to reach agreement, to arbitrate the matter in a baseball-style proceeding in which each party suggests an amount and the arbitrator must select one of the amount suggested.

The final rule requires the arbitrator to consider first the amount closest to the insurer's in-network rate, and only then consider other factors relevant to the amount that should be paid. It was this aspect of the rule – not the financial protection for patients or the requirement to arbitrate – that the district court invalidated. Other, more broad-based attacks on the No Surprises Act remain pending. Meanwhile, collections for providers may be slow as they await arbitration results on pending claims for payment.

8. HIPAA Potential Changes

Two years ago, HHS and the Office for Civil Rights proposed changes to the HIPAA Privacy Rule that would shorten the time by which providers must provide patients (and their representatives) access to medical records. Instead of having 30 days (with the potential to obtain a 30-day extension), providers would have to respond "as soon as practical" but within 15 days (with a potential 15-day extension). It is difficult to predict when, if ever, these changes will go into effect, but experience suggests that a final determination may be on the horizon. If these changes are made, they could present compliance challenges and leave many healthcare companies open to fines and enforcement actions related to failure to comply with the new compressed delivery timeframes. Stay tuned.

9. New OIG Developments Provide Additional Avenues for Feedback and Compliance Guidance

In recent months, the Department of Health and Human Services, Office of Inspector General ("OIG" or "the agency") announced two major developments in its effort to provide enhanced health care and life sciences industry guidance. First, OIG will be expanding the topics that it will provide feedback to in the form of informal frequently asked questions ("FAQs"). Second, OIG announced that it would be updating its current compliance program guidance and issuing new guidance in the form of a general compliance program guidance and industry-specific compliance program guidance. Read more details about these recent developments click **here**.

Paul Hastings lawyers and the Paul Hastings Life Sciences and Healthcare Consulting Group team are available to assist lenders in ensuring their interests are protected in healthcare finance deals. If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers and consultants:

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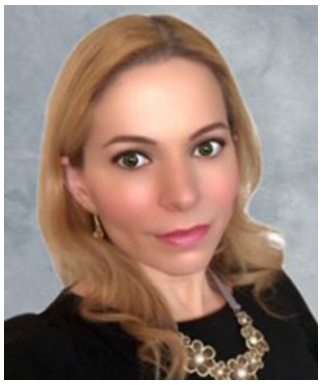

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