BakerHostetler's Healthcare 2024 Year in Review

BakerHostetler

Transaction Review Laws

Sarah Browning

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Healthcare transactions have experienced a sea change in the past three years with the introduction of several new healthcare-specific transaction review laws (TRLs) at the state level. While some sections of the healthcare industry have already weathered heavy transaction scrutiny for many years, these new TRLs capture a broader range of entities, activities and transaction sizes. This means that smaller organizations conducting transactions well below the Hart-Scott-Rodino threshold can nonetheless be pulled into a heavy transaction review process requiring voluminous disclosures and sensitive antitrust review.

Twelve states[1] have adopted TRLs so far, and several TRLs are heavily influenced by the Model Act for State Oversight of Proposed Health Care Mergers from the National Academy for State Health Policy (the Model Act). TRLs that follow the Model Act use a similar formula: Certain defined "health care entities" that engage in certain defined "transactions" must provide notice to state regulators (typically to the state attorney general's office) prior to closing. State regulators will review a transaction for its impact on market consolidation, access to quality care and transparency in ownership. Beyond policy concerns stated in the statutes, regulators also frequently focus on a transaction's impact on the labor market.

BakerHostetler's Healthcare team expects the TRL trend to continue. Some state legislatures that attempted to adopt a TRL in prior years (like North Carolina and Pennsylvania) may see similar proposed legislation in 2025. In New Mexico's case, legislators have already indicated that TRL legislation will be on the agenda. Further still, some states that have already adopted a TRL may propose a TRL specifically targeted toward private equity-backed organizations, similar to California's attempt under AB 3129.

Next year, BakerHostetler's Healthcare team expects TRLs to materially extend transaction timelines and increase transaction parties' cost and risk, based on its experience at the front lines of TRL activity in 2023 and 2024. Healthcare clients that plan to engage in transactions in 2025 should expect discussions on whether a TRL applies, steps to protect confidentiality and coordination of notice efforts among the transaction parties.

[1] California, Colorado, Connecticut, Illinois, Indiana, Massachusetts, Minnesota, Nevada, New Mexico, New York, Oregon and Washington

Compliance

Amy Fouts

Greg Tanner

Updates to Hospital Price Transparency. New requirements for the CMS Hospital Price Transparency rules took effect in July 2024. These changes included several new definitions, requiring hospitals to use one of three CMS-designed templates for their machine readable files (MRFs) of standard charges, inserting a new attestation statement on the MRF, and multiple updates to data element requirements.

Clair Bass

Abortion Legislation and Litigation. In June 2024, SCOTUS issued two decisions: (1) It preserved access to mifepristone by holding that the plaintiff lacked standing to challenge the FDA's regulation of the drug; and (2) it declined to rule on the merits of a case contemplating whether EMTALA preempted Idaho's abortion law in certain circumstances, vacating its stay of the lower court's preliminary injunction preventing enforcement of the law. In November 2024, ballot measures to preserve abortion rights were successfully passed in Arizona, Colorado, Maryland, Missouri, Montana, Nevada and New York. Lawsuits have been filed to enforce these newly preserved rights. Similar measures failed in Florida, Nebraska and South Dakota.

340B: Legality of the 'Rebate Model.' In August 2024, Johnson & Johnson (J&J) proposed a rebate model that would remit 340B discounts for two drugs via post-purchase rebates rather than an up-front discount. The Health Resources and Services Administration notified J&J that this proposal violated the 340B statute and the agency would implement sanctions if the company moved forward. Although it abandoned the proposal, J&J sued in November, asking a court to find the model is legal. Following J&J's lead, other drug manufacturers have filed similar suits while multiple 340B-covered entities have sued to maintain that the model is illegal.

New OB Conditions of Participation. CMS announced new health and safety requirements for hospitals to address the maternal health crisis through new obstetrical services-specific conditions of participation. Among other things, the new requirements set baseline standards for organizations, outline staffing and delivery of care requirements within OB units, establish training standards, and utilize their QAPI programs to assess and improve health outcomes and disparities among OB patients.

FCA Qui Tam Provision in Dispute. In September 2024, a federal court in Florida dismissed *U.S. ex rel. Zafirov*, a False Claims Act (FCA) qui tam case, finding that the FCA's qui tam provision is unconstitutional. The basis for the dismissal follows the rationale that U.S. Supreme Court Justice Clarence Thomas outlined in a dissent to another FCA case from 2023. This result is an outlier and faces substantial opposition on appeal.

Litigation

Derek Bauer

Kevin Bradberry

Our Healthcare Litigation team continues to be active and successful in 340B reimbursement litigation, helping 340B providers recover millions of dollars in underpayments by Medicare Advantage Organizations. In November 2023, after the United States Supreme Court unanimously held that CMS' four-year, 30 percent reduction of payment rates for 340B-eligible medications was an illegal exercise of agency authority, CMS finalized its rule to repay affected Medicare providers more than $9 billion in lump-sum repayments. Although private Medicare Advantage Organizations routinely incorporate CMS rates and methodologies in their contracts with healthcare providers and were quick to apply those illegal rates, they uniformly refused to pay the lump sum remedy when CMS announced its intent to "turn back the clock" and repay providers as if the unlawful cuts had never existed. On October 21, 2024, our Litigation team achieved a complete victory against United Healthcare, first by winning summary judgment on liability, where the panel of arbitrators unanimously held that United, by incorporating CMS methodologies in its contract with our client, also incorporated the CMS remedy, and second by prevailing after a four-day trial, when the arbitrators ordered United to pay more than $15.7 million in damages and prejudgment interest. The Healthcare Litigation team continues to litigate similar issues against several other national payors and expects to achieve similar results in those matters in the coming year.

Healthcare Privacy & Cyber Security

Lynn Sessions

The headline from 2024 was the **Change Healthcare ransomware** attack in February, which not only impacted the operations and payment for services of thousands of healthcare providers and health plans, it also affected the protected health information of over 100 million Americans. Change brought to the light the interconnected relationship of healthcare vendors and the systemic impact when a cyber security incident affects one of those vendors. Nearly a year later, Change is still notifying its customers of affected patients and plan members. The Change incident received a great deal of attention and scrutiny from HHS, which has already prompted action with new proposed rules and guidance for ransomware and other cyber security incidents.

The Change incident kicked off another active year of **ransomware attacks on healthcare entities**. The threat actors behind these attacks were prolific and aggressive in their tactics and communications. Change learned that paying a ransom is not a guarantee that the threat actors will do as they promise while other threat actor groups resorted to egregious tactics to pressure healthcare entities into paying. While law enforcement was successful in breaking up some of these organizations, they continued to attack healthcare on a large scale.

On the regulatory front, HHS continues to focus on the **HIPAA Security Rule** So much so, that HIPAA regulated entities, received the Notice of Proposed Rule Making as a holiday present with significant proposed changes to the Security Rule in late December. These changes include a 72 hour recovery period following a cyber incident, and new requirements for business associates. New Year's Eve saw several healthcare organization receive HIPAA audits with a focus on Security Rule compliance that were fairly comprehensive in nature with 30 days to respond.

On the privacy front, HHS strengthened protections around **Reproductive Health Privacy** with a comprehensive, and somewhat burdensome, regulatory framework to protect this information. HHS' final rule not only protects what is commonly thought of as women's reproductive care, but extends to transgender care and men's care with a very broad definition. Compliance dates have already passed for some sections, and even with the new administration, it is prudent for healthcare organizations to assess their compliance posture.

HHS took a blow last year related to **Website Tracking Technologies** when the American Hospital Association successfully won a declaratory judgment for HHS' December 2022 guidance regarding this use. While class action lawsuits against healthcare providers across the country raged on, the AHA, with some brave providers in Texas, carried the flag to defeat the HHS position on this issue. We continue to defend healthcare providers in OCR investigations and in litigation, but this win gave HIPAA regulated entities some relief in support of reaching their communities on their websites.

Health Tech

Vimy Devassy

Artificial Intelligence. This past year saw an explosion in the use and deployment of artificial intelligence (AI) industry-wide as regulators at both the federal and state levels attempted rather unsuccessfully throughout the year to grab the reins of this runaway train of rapidly advancing technology and put in much-needed guardrails in a patchwork fashion. The use of AI in the healthcare industry continues to be heralded for its tremendous potential, ranging from predictive diagnostics to labor shortage solutions and beyond, with a multitude of new use cases being touted at every turn. However, without a meaningful regulatory safety net in place that can keep up with the ever-evolving technology, the use of AI in the healthcare industry has also been met with considerable concern for the potential risks and dangers that AI poses, particularly from a patient safety and cybersecurity perspective. Payors' reported use of AI as a tactic to deny clinical care has further increased the crescendo of voices within the industry calling for meaningful regulation of the use of AI. As a result, 2025 will see continued widespread evolution of AI within the healthcare industry, as well as more concerted efforts to regulate its use at both the federal and state levels as evidenced by the FDA taking the first crack in 2025 with its issuance of *Comprehensive Draft Guidance for Developers of Artificial Intelligence-Enabled Medical Devices* on January 6, 2025, followed closely by HHS publishing its *Artificial Intelligence Strategic Plan* on January 10, 2025.

Telehealth. As the healthcare industry waited with bated breath, Congress finally extended Medicare telehealth flexibilities that were set to expire on December 31st as part of its end-of-year appropriations bill, but such flexibilities have only been extended until March 2025. The short duration of this extension continues to plague the industry with uncertainty and unpredictability as to the future of telehealth. While there is widespread support within the healthcare industry for permanently enabling and reimbursing telehealth, the industry has also seen a significant decline in telehealth utilization (other than in the behavioral health setting) since the pandemic. At the same time, 2024 also saw the entry of significant Fortune 500 players into the telehealth market seeking to meet the growing demand for direct-to-consumer telehealth, most of which is self-pay, with state regulators simultaneously recognizing the increasing need to regulate this growing market to ensure patient safety.

Information Blocking. The 21st Century Cures Act regulations prohibiting interference with the access, exchange, or use of electronic health information (referred to as "information blocking") also grew significant regulatory teeth this past year as additional regulations were finalized that established significant monetary disincentives against providers who are found to be engaging in information blocking. The draconian nature of the enforcement penalties alarmed the provider community, particularly since the public comments regarding information blocking in various instances of rulemaking this past year indicate that considerable confusion and concern remain regarding the information-blocking regulations. 2025 is likely to bring enforcement actions for information blocking that will be revealing in terms of how the regulators will approach many of the inherent technological and patient-care nuances related to information blocking.

Licensure/Enrollment

Charlotte Combre

Ernessa Brawley

Provider Enrollment Pit Stop: Maintain Your PECOS Record to Prevent Future Setbacks

- **Full Service Necessary:** ***Additional Ownership Disclosures Required for Skilled Nursing Facilities.*** On October 1, 2024, CMS revised the 855A enrollment form to include a new Attachment A, which requires more detailed ownership and control information from skilled nursing facilities (SNFs). To obtain the additional disclosures, CMS announced off-cycle revalidations for all SNFs across the country and required revisions to any applications pending as of October 1, 2024. Initially, SNF providers had 90 days from receipt of the revalidation notice letter to complete the revalidation. Recently, CMS extended the deadline for all SNFs to submit their required off-cycle revalidation to May 1, 2025, regardless of when the facility receives a notice letter of revalidation. Attachment A includes extensive details regarding individuals with operational, managerial, financial, administrative and clinical consulting control within a facility. Providers must conduct an in-depth analysis of individuals and organizations that meet the definition of "Additional Disclosable Party."
  - **Slow Down:** ***Hospices Subject to Same 36-Month Rule as Home Health Agencies and Required to Enroll or Opt Out of Medicare.*** Effective January 1, 2024, CMS extended its 36-month rule to include Medicare-enrolled hospices. The 36-month rule now prohibits hospices and home health agencies (HHAs) from undergoing a change in majority ownership within 36 months of their initial Medicare enrollment or most recent change in ownership. A change in majority ownership is defined as a change in more than 50 percent of the hospice's or HHA's direct ownership interest through an asset sale, stock transfer, consolidation or merger. If a hospice or HHA violates the 36-month rule, its Medicare provider agreement and billing privileges will not transfer to the new owner. The new owner will be required to undergo the initial Medicare enrollment and credentialing process, which can take between 50 and 85 calendar days. Effective June 3, 2024, all physicians who certify hospice care, including the hospice medical director and the patient's primary provider, must be enrolled in Medicare or have opted out for the certification to be valid.
- **Caution Approaching:** ***Unannounced Site Visits.*** CMS is conducting site visits to Medicare-certified providers outside of the survey and certification process. CMS is conducting site visits at existing enrollment locations or newly added enrollment locations where an address cannot be verified. These site visits are typically unannounced, and providers may not know they are being conducted. However, providers can verify that CMS ordered a provider enrollment site visit by contacting their MAC.
  - **Provider New Year's Resolution:** ***Maintain Your PECOS Records!*** Ensure the ownership and location information reported in PECOS is up to date, as these actions may signal future CMS enforcement action.

FDA

Winston S. Kirton

Payal Cramer

The BIOSECURE Act. The House version of the BIOSECURE Act (the Act) was passed on September 9, 2024 and is currently and is awaiting Senate approval. If signed into law, the Act would prohibit (a) federal agencies from obtaining biotechnology equipment or services produced or provided by "biotechnology companies of concern," and (b) federal agencies from contracting with a company that uses equipment or services produced or provided by "biotechnology companies of concern" with limited exceptions, and (c) recipients of a loan or grant from a federal agency from using those funds to purchase equipment or services from a "biotechnology company of concern." The Act defines a "biotechnology company of concern" as any entity that is subject to the jurisdiction, direction or control of, or operates on behalf of, the government of a foreign adversary (defined as China, Cuba, Iran, North Korea and Russia); is involved in the manufacturing, distribution, provision or procurement of biotechnology equipment or service; and poses a risk to U.S. national security. This would include any subsidiary, parent, affiliate or successor entities of "biotechnology companies of concern." The Act explicitly lists several Chinese "biotechnology companies of concern," including BGI, MGI, WuXi AppTec and WuXi Biologics, but leaves room for the addition of more companies based on certain criteria. While exact language of the Act is still being sorted out, it remains likely that the prohibitions will have a disruptive impact on pharmaceutical and biotechnology companies, especially those with relationships with the current named "biotechnology companies of concern." Pharmaceutical and biotechnology companies are encouraged to seek counsel to assess the impacts to their supply chains, develop alternative sourcing strategies and make tough decisions on third-party relationships.

Long-Term Care

Emily Crosby

OIG Issues First Industry Segment-Specific Compliance Program Guidance for Nursing Facilities

On November 20, 2024, the U.S. Health and Human Services (HHS) Office of the Inspector General (OIG) issued new industry segment-specific compliance program guidance for nursing facilities (the ICPG). The ICPG is the first in a planned series of compliance program guidance for various healthcare sectors and updates OIG's 2000 and 2008 nursing facility compliance program guidance. Although nonbinding, the ICPG is intended to complement the minimum requirements for nursing facilities to participate in the Medicare and Medicaid programs.

The ICPG identifies four key risk areas described below:

- **Quality of Care and Quality of Life.** Substandard quality of care has become a frequent basis for federal and state agency investigations and enforcement actions against nursing facilities in recent years. The ICPG makes various quality-related recommendations in areas such as staffing levels and competencies, resident care and activity planning, managing changing resident demographics and higher-acuity residents, appropriate medication use and management, resident safety against abuse and neglect, staff screening, infection control, emergency preparedness, and life safety and nursing facility-initiated discharges.
- **Medicare and Medicaid Billing Requirements.**The ICPG identifies duplicate billing, insufficient documentation, and false or fraudulent cost reports, as well as compliance with the Three-Day Rule and consolidated billing as ongoing risk areas that warrant vigilance by nursing facilities. The ICPG also makes recommendations regarding other risk areas such as value-based payment models and programs, Medicare Advantage and Medicaid managed care plans, Medicare Part D, and nursing facility resident Medicare health plan enrollment.
- **Federal Anti-Kickback Statute.** OIG recommends that nursing facilities structure arrangements with referral sources and recipients in a manner that satisfies a Federal Anti-Kickback Statute (AKS) exception or safe harbor wherever possible and ensure that the arrangement complies in how it is actually conducted, not just by the terms of any written agreement. The ICPG also identifies potentially problematic arrangements in areas such as free (or below fair market value) goods and services, discounts, arrangements for services or supplies, long-term care pharmacy arrangements, hospital arrangements, hospice arrangements, care coordination and value-based care arrangements, and joint ventures.
- **Other Risk Areas.** The ICPG describes several other risk areas that nursing facilities should include in their compliance and quality training, risk assessment, monitoring, and internal review practices. These areas include related-party transactions, physician self-referral law, anti-supplementation of Medicare or Medicaid payments, HIPAA, and civil rights laws. Section III contains additional compliance, quality and resident safety considerations for nursing facilities, including the crucial roles that governing bodies and members, executive leadership, owners, operators, and investors play in oversight.

Although not intended as a model compliance program for nursing facilities, the ICPG is an important resource for compliance teams to review in implementing and updating compliance and quality programs to ensure that they align with OIG guidance.

Labor and Employment

Shareef Farag

Caroline Landt

While 2024 saw FTC and NLRB attempts to rein in the use of noncompetes for nonexecutives and agreements that require repayment of educational and other benefits provided to an employee if they resign before a minimum period of time, we expect the Trump administration in 2025 to effectively halt these efforts. Even so, we expect certain states to push similar legislation on the state level. For this reason, monitoring of state laws will be important in 2025.

For those clients with operations in California, a new minimum wage law took effect on October 16, 2024. The law is sweeping in scope. Specifically, the definition of "covered health care facility" includes licensed general acute care hospitals, urgent care clinics, physician groups, community and rural health care clinics, and more. The definition of "covered health care employee" is very broad and includes even employees who support "the provision of health care," such as janitorial and gift shop employees. This law establishes five separate minimum wage schedules based on the type of employer. All the schedules include gradual increases in the minimum wage to eventually reach $25 per hour.

Antitrust

Justin Murphy

Federal Level – Refocus on Healthcare. We expect antitrust – including in the healthcare space – to play a prominent role in President-elect Trump's administration. The announcement of President-elect Trump's lead Antitrust enforcer nominees in early December 2024 – many weeks before inauguration – is itself an indication of the important role that the President-elect expects antitrust to play within the DOJ, FTC, and his administration. This includes the healthcare space, and he has recently highlighted his expected focus on the healthcare industry. For example, in December 2024, in discussing pharmacy benefit managers, he stated "We're going to knock out the middleman."

In addition, President-elect Trump's antitrust-related actions in his first term demonstrate that the healthcare industry will remain an important priority in his new administration. In his first term, the Trump-led DOJ and FTC were active in the healthcare space. This includes the DOJ and FTC challenging healthcare-related transactions, as well as a variety of significant civil and criminal enforcement actions.

President-elect Trump's administration also has two new antitrust enforcement tools that specifically target the healthcare industry – the DOJ Task Force on Health Care Monopolies and Collusion and Healthycompetition.org. The Task Force leads the Antitrust Division's policy and enforcement strategies relating to the healthcare industry, and it includes a mixture of civil and criminal prosecutors, economists, healthcare industry experts, data scientists and investigators. Healthycompetition.org is an online portal where the public can report complaints about potentially anticompetitive practices in the healthcare industry. Together, they reflect a recent broadening of antitrust-related focus – as well as resources – towards federal healthcare policy and enforcement.

State Level Enforcement. We also expect State attorneys general to play a significant role in antitrust enforcement during the second Trump administration. States have authority to enforce federal antitrust laws as well as their own state antitrust statutes, and since they are not bound by the federal executive or federal agencies, they often pursue enforcement priorities where federal enforcers chose not to do so. Healthcare is a focus industry that may garner increased scrutiny, even if federal enforcers decline to express interest.