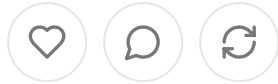


Critical Healthcare Legal Battles: Industry-Shaping Cases to Watch

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340B Program Litigation

Major Pharmaceutical Cases

Two landmark cases in federal courts are testing manufacturer restrictions on 340B pricing:

- District of New Jersey case challenging single-pharmacy restrictions
- District of DC case examining HHS enforcement authority

Combined impact: Over \$4.5B in annual drug discounts at stake

Core issue: Balance between manufacturer rights and program integrity

Medicare Advantage Risk Adjustment

Leading Cases Testing FCA Liability

Two groundbreaking False Claims Act cases in federal courts:

- Northern California case alleging \$1B+ in risk adjustment violations
- Tennessee case testing new DOJ theories on MA coding practices

Focus: Face-to-face encounter requirements

Industry impact: Will define standards for retrospective reviews

Hospital Payment Reform

Site-Neutral Payment Challenge

Major hospital association lawsuit pending Supreme Court review:

- \$800M+ annual reimbursement impact
- Testing CMS authority on payment equalization
- Implications for outpatient facility strategy
- Potential to reshape hospital expansion planning

Healthcare Antitrust Enforcement

Hospital Merger Challenge

Major Western U.S. case examining:

- \$1.2B regional hospital transaction
- Novel cross-market effect theories
- First test of new merger guidelines
- Preliminary injunction pending

Digital Health Vertical Integration

Significant case examining:

- Healthcare technology acquisition
- Data access implications
- Competitive effects in digital health
- Consent decree negotiations ongoing

Employment and Labor Law

Criminal Non-Compete Case

Precedent-setting prosecution:

- First criminal case on healthcare labor allocation
- Testing DOJ's non-compete enforcement approach
- Implications for physician contracts
- Trial scheduled Q3 2024

Key Timeline

Q2 2024:

- MA risk adjustment trial
- Hospital merger preliminary injunction

Q3 2024:

- 340B manufacturer appeal
- Criminal non-compete trial

Q4 2024:

- Site-neutral payment Supreme Court decision (if accepted)

Industry Impact Areas

These cases will redefine:

1. Drug Pricing Models

- Contract pharmacy networks
- Manufacturer obligations

- Safety-net provider access

2. Medicare Advantage Operations

- Risk adjustment practices
- Documentation requirements
- Audit protocols

3. Provider Strategy

- Facility expansion
- Payment models
- Market consolidation

4. Employment Practices

- Non-compete agreements
- Labor market competition
- Physician contracts

5. Data Management

- Security requirements
- Breach liability
- Insurance coverage

Strategic Considerations

Organizations should prepare for:

- Revised 340B compliance programs
- Enhanced risk adjustment documentation
- Updated merger analysis frameworks
- Modified employment agreements
- Strengthened data security measures

Specific case details...

340B Program Litigation

Specialty Care v. HHS (D.N.J. 2024)

- At stake: Sanofi's restrictions on 340B pricing for contract pharmacies.
- Key Issue: Whether manufacturers can limit 340B pricing to single contract pharmacy for covered entities
- Potential Impact: \$4.5B+ in annual drug discounts
- Status: Pending appeal after district court ruling supporting manufacturer restrictions

Novartis Pharmaceuticals v. United States (D.D.C. 2024)

- Centers on HHS's authority to require unrestricted 340B pricing
- Challenges HRSA's enforcement actions
- Could redefine scope of manufacturer obligations

Medicare Advantage Risk Adjustment

United States ex rel. Osinek v. Kaiser Permanente (N.D. Cal.)

- Allegations: \$1B+ in false claims through MA risk adjustment practices
- Focus: Retrospective chart reviews and diagnosis coding
- Key Issue: Whether diagnosis codes must be explicitly linked to face-to-face encounters

United States v. Cigna-HealthSpring (M.D. Ten

- DOJ intervention in whistleblower suit
- Allegations: Systematic manipulation of risk adjustment data
- Testing grounds for new theories of FCA liability in MA
- Potential industrywide implications for coding practices

Hospital Payment Models

American Hospital Association v. Becerra (No. 24-XX)

- Challenge to site-neutral payment expansion
- Testing CMS authority to equalize payments across settings
- Potential annual impact: \$800M+ in hospital reimbursements
- Status: Pending cert petition

Healthcare Antitrust

FTC v. HCA Healthcare (D. Utah)

- Challenge to \$1.2B acquisition of five Utah hospitals
- Testing new theories of cross-market effects
- First major case under new merger guidelines
- Status: Preliminary injunction hearing scheduled

Non-Compete Enforcement

Surgical Care Affiliates Criminal Antitrust Case (N.D. Tex.)

- First criminal prosecution of healthcare labor market allocation
- Testing DOJ's aggressive stance on non-competes
- Industry implications for physician employment agreements
- Trial date set for Q3 2024

Privacy & Data Security

Shields Health Care Group Data Breach Litigation (D. Mass.)

- Class action following 2M-patient data breach
- Testing theories of damages in healthcare data breaches
- Implications for cyber insurance and security requirements
- Multi-district litigation being considered

Looking Ahead: Key Dates

Q2 2024:

- Kaiser MA risk adjustment trial
- HCA preliminary injunction decision

Q3 2024:

- Sanofi 340B appeal argument
- SCA criminal trial

Q4 2024:

- AHA site-neutral payment Supreme Court decision expected (if cert granted)

These cases will reshape:

- Provider consolidation strategies
- MA program integrity requirements
- Drug pricing models
- Labor market practices
- Privacy compliance standards

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