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Expanded Enforcement of Federal False Claims Act, RICO, and Antitrust Law Changes the Legal Landscape for Healthcare Providers

by Richard H. Cunningham and John D. W. Partridge

During the last several years, the FCA, RICO, and the antitrust laws have been enforced with renewed vigor against healthcare providers. As summarized below, healthcare providers now confront new theories of liability, more onerous remedies, and a willingness by both the government and private plaintiffs to pursue actions on more ambiguous facts.

The healthcare services sector is among the strongest and most dynamic components of Colorado's economy. According to the Colorado Health Institute, Colorado's healthcare and wellness industry accounts for more than 15% of Colorado's gross state product and employs more than 360,000 workers statewide. As the healthcare services sector has grown, the laws and regulations governing conduct in the industry have multiplied as well, resulting in an increasingly complex legal and regulatory landscape. The Patient Protection and Affordable Care Act (PPACA), the Health Insurance Portability and Accountability Act (HIPAA), state licensure programs, and numerous other laws and regulations impose a daunting number of obligations on healthcare providers. In recent years, reinvigorated and expanded enforcement of the False Claims Act (FCA); the Racketeering Influenced and Corrupt Organizations Act (RICO); and the Sherman, Clayton, and Federal Trade Commission (FTC) Acts has added to the legal exposure of healthcare providers. Although these federal laws are decades old (and industry-agnostic), they are being asserted with renewed vigor—and notable success—by government enforcers and private plaintiffs against healthcare providers. This article discusses trends in the enforcement of these laws against providers.[1]

Healthcare Providers Are Increasingly Targeted in FCA Suits

The FCA empowers the federal government, via the Department of Justice (DOJ), to seek monetary penalties and recompense from those who defraud the government. The FCA also authorizes private whistleblowers, known as "relators," to bring *qui tam* suits on behalf of the government (and recover a share of any proceeds that result from the case). During the Civil War era, when the law was enacted, the FCA targeted war profiteers who sold the government lame horses or gunpowder mixed with sawdust. Today, the government wields the FCA as its primary weapon against fraud and abuse involving government-funded healthcare programs.

The FCA packs a significant punch from a liability perspective: providers may submit thousands of claims to government payors and each claim is subject to the FCA's per-claim penalty of $5,500

Coordinating Editors

Katherine M.L. Pratt, Boulder, of Berg Hill Greenleaf & Ruscitti LLP—(303) 402-1600, kmlp@bhgrlaw.com; Todd Seelman, Denver, of Lewis Brisbois Bisgaard & Smith LLP—(720) 292-2002, todd.seelman@lewisbrisbois.com

About the Authors

Rich Cunningham and John Partridge are attorneys at Gibson Dunn & Crutcher LLP in Denver. Cunningham's practice focuses on antitrust and consumer protection matters. Before joining Gibson Dunn, he served as senior trial counsel in the FTC's Bureau of Competition. Partridge advises clients in the healthcare and life sciences industries as they navigate government investigations and related FCA litigation. In addition, he counsels clients on their healthcare fraud and abuse compliance programs. The authors thank Sara Carlisle, an attorney at Gibson Dunn, and Jasper Hicks, a University of Texas law student who worked as a summer associate with Gibson Dunn, for their substantial contributions to the preparation of this article.

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to $11,000, and the FCA imposes mandatory treble damages. Since January 2009, DOJ has recovered more than $26.2 billion in FCA cases, with more than $16.4 billion resulting from actions alleging fraud related to federal healthcare programs.[2] Of that sum, approximately $1.2 billion came from healthcare providers in 2014 alone—and recoveries are on track to exceed that total in 2015.[3]

In pursuing those recoveries, the government and relators continue to rely on several well-worn FCA theories, which are outlined below. In addition, recent comments by Leslie Caldwell, the assistant attorney general of DOJ's Criminal Division, suggest that the government is considering more expansive theories and areas that, to date, have not been a focus of FCA enforcement, including "laboratory services, hospital-based services, and hospice care."[4]

Ongoing Scrutiny of Medical Necessity and Other Billing Issues

During the past few years, a significant portion of settled FCA cases targeting healthcare providers have involved allegations that the provider knowingly provided care that was medically unnecessary for the patient or a level of care that was unnecessary.

Settlements in medical necessity cases often climb into the tens—if not hundreds—of millions of dollars. For example, in April 2014, Amedisys Home Health Companies, a leading provider of home health services, agreed to pay $150 million to resolve allegations that it billed for medically unnecessary nursing and therapy care.[5] The government also alleged that Amedisys inappropriately boosted its reimbursements from Medicare by misrepresenting its patients' conditions.[6] Just a few months later, Community Health Systems, the nation's largest acute hospital operator, paid nearly $100 million to the government to resolve allegations that it billed for medically unnecessary levels of care by submitting claims for inpatient services that should have been provided on an outpatient basis.[7]

Like many recent FCA settlements involving providers, the Community Health Systems settlement encompassed alleged conduct at multiple facilities over a long period of time (119 hospitals over five years).[8] Similarly, in May 2015, DOJ announced that it had resolved an extensive investigation into alleged fraudulent billing for intensive outpatient psychotherapy by 16 hospitals located in seven states throughout the South.[9] Those hospitals, a majority of which were formerly owned or operated by Health Management Associates Inc. (HMA), agreed to pay approximately $15.7 million to resolve the FCA claims against them.[10] According to DOJ, the hospitals submitted claims for psychotherapy services that the hospitals knew were not reimbursable under federal health programs because the patients and the care the hospitals provided them did not meet specified requirements.[11]

Continuing Anti-Kickback Statute and Stark Law Enforcement Using the FCA

Laws governing financial relationships among participants in the healthcare sector, including the federal anti-kickback statute and the physician self-referral law (known as the Stark Law), also continue to result in significant FCA settlements. In a typical case,

the government alleges that claims submitted by the provider are tainted because the provider paid physicians for patient referrals underlying the claims, by, for example, doling out exorbitant compensation to the physicians to act as consultants or medical directors while receiving little or no work in return.

Just a few months ago, Hebrew Homes Health Network settled an FCA action involving kickback allegations for $17 million—the largest recovery to date against a nursing facility.[12] The government asserted that Hebrew Homes often hired physicians as "medical directors"—and paid them thousands of dollars—even though they were required to do little if any work while serving in these "ghost positions."[13]

Colorado healthcare providers have not been immune from scrutiny relating to allegedly inappropriate relationships with referrals sources. Late last year, Colorado-based DaVita HealthCare Partners, Inc. agreed to pay $350 million (and $39 million in a civil forfeiture) to resolve allegations that it provided inappropriate remuneration to physicians in return for patient referrals.[14]

The government and relators have also pursued providers under the FCA for violating the Stark Law on the theory that federal health programs condition payment on compliance with the Stark Law. To date in 2015, FCA actions premised on providers' alleged Stark Law violations have resulted in tens of millions of dollars of recoveries (including a settlement of approximately $22 million).[15]

Attempts to Expand the Worthless Services Theory

When pursuing providers under the FCA, the government and relators often advance FCA claims stemming from services that were allegedly so deficient as to be worthless.[16]

In a recent opinion, *United States ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, the Seventh Circuit analyzed two relators' attempts to expand the worthless services theory to situations where a healthcare provider's care was allegedly deficient.[17] There, two former nurses of the defendant alleged that it fraudulently sought reimbursement for substandard treatment and secured a judgment against the defendant after a jury trial.[18] The Seventh Circuit reversed, holding that an FCA plaintiff cannot satisfy its burden by merely showing that a defendant's services are "worth less."[19] The court set a much higher bar: the services must be "so deficient that for all practical purposes [they are] the equivalent of no performance at all."[20] Given that the government surveyed Momence Meadows' facilities and permitted it to continue providing care, the Seventh Circuit rejected the assertion that the care was entirely worthless.[21]

Despite the Seventh Circuit's narrow construction of the worthless services theory, the government and relators continue to pursue—at times successfully—cases against providers on the basis of allegedly insufficient care. For example, just weeks after the *Momence Meadows* decision, DOJ announced a $38 million settlement with Extendicare Health Services, which operates skilled nursing facilities.[22] According to the government, Extendicare Health Services' facility had too few staff, provided inadequate care, and failed to take measures to prevent ulcers and falls.[23] Although this alleged misconduct would seem to fall in the category of substandard care—rather than entirely worthless care—the government warned in its comments on the settlement that providers that "bill Medicare and Medicaid while failing to provide essential services or bill for services so grossly substandard as to be effectively worthless will be pursued for false claims."[24]

Efforts to Rely on Statistical Sampling

Another jurisprudential issue that may increase providers' legal exposure is the use of statistical sampling evidence in FCA cases. In the past two years, several federal district courts have accepted the government's argument that sampling evidence may establish liability under the FCA (not just damages). For example, in *United States ex rel. Martin v. Life Care Centers of America*, the government alleged that the defendant, which operated skilled nursing facilities, pushed its personnel to extend patient stays and take other steps that maximized revenue.[25] In support, the government offered a sample of 400 patients, from which the government extrapolated liability for more than 54,000 patients at 82 facilities during the same time period.[26] The district court denied the defendant's motion to exclude expert testimony, holding that statistical sampling may be used to "estimate the number of claims submitted for non-covered services to Medicare and TRICARE" in an FCA case.[27]

In contrast, another district court recently rejected the use of statistical sampling in an FCA case targeting a network of South Carolina nursing homes.[28] The court reasoned that the case was not "suited for statistical sampling" because it "present[ed] the question of whether certain services furnished to nursing home patients were medically necessary," which demanded a "fact-intensive inquiry involving medical testimony."[29] The district court certified the question for interlocutory review, and the Fourth Circuit recently agreed to decide whether the relators may use statistical sampling to establish FCA liability.[30] Absent guidance from the Fourth Circuit and other circuit courts, certain courts' willingness to rely on statistical sampling evidence may well allow the government and relators to impose both liability and increased damages on healthcare providers.

RICO Suits Against Healthcare Providers

The FCA's reach is generally limited to fraud relating to federal health program expenditures. RICO, by contrast, has no such limit. Accordingly, private parties in the healthcare sector that believe they have suffered injury as a result of a provider's improper conduct (e.g., private payors such as insurance companies or self-funded employer health plans) are increasingly resorting to RICO, even though the statute is typically associated with mafia-style enterprises rather than healthcare providers.

Broadly speaking, RICO prohibits engaging in "a pattern of racketeering activity,"[31] defined by reference to a series of federal and state criminal laws (so-called RICO predicates).[32] The statutory list of predicates includes both mail and wire fraud.[33] Under RICO, "[a]ny person injured in his business or property by reason of a violation" of the statute may sue in federal district court and recover treble damages, costs, and attorney fees.[34] Aside from showing an economic injury, a civil RICO plaintiff must show that the injury occurred "by reason of" the alleged RICO violation, which requires proof of both but-for and proximate causation.[35]

Although plaintiffs have, in the past, pursued providers under RICO for various types of alleged misconduct,[36] payors are increasingly martialing RICO against providers for the same type of conduct that often underlies FCA claims (e.g., billing for medically unnecessary care or increasing claims through the use of inappropriate financial relationships with referral sources). Indeed, over the past few years, multiple RICO claims premised on this

type of alleged misconduct by providers have proceeded into discovery after surviving motions to dismiss.[37]

Several private insurers have invoked RICO in cases alleging that healthcare providers submitted medically unnecessary claims. In *Liberty Mutual Fire Insurance Co. v. Acute Care Chiropractic Clinic, P.A.*, for example, the U.S. District Court for the District of Minnesota denied several chiropractic providers' and clinics' motions to dismiss a RICO claim brought by insurers that paid claims for insured car accident victims.[38] According to the insurers, the providers and clinics committed mail and wire fraud by submitting invoices and thereby "implicitly represent[ing] that they were operating in accordance with federal and state law" (e.g., that they were not violating Minnesota's corporate practice of medicine doctrine).[39] The court concluded that the plaintiffs' allegations satisfied Rule 9(b)'s particularity standard by pleading, among other details, "the content of the alleged fraud, namely, the ownership misrepresentation in each HCFA-1500 [insurance claim] form submitted to" the insurers.[40] The plaintiffs' theory is noteworthy in that it mirrors the implied certification theory that the government and relators often advance in FCA cases (i.e., that by submitting a claim to a federal payor, the submitting entity impliedly certifies that it has complied with certain laws, regulations, or contractual provisions).[41]

Although billing issues have predominated in recent RICO cases targeting providers, insurers have also pursued RICO cases premised on kickbacks against providers. For example, in *Government Employees Insurance Co. v. MLS Medical Group LLC*, the plaintiff insurers alleged that the defendants, a physician and his practice, paid referring providers "kickbacks disguised as leasing fees."[42] In addition, the insurers asserted that the practice billed for treatment and tests that were unnecessary (or never provided).[43] Although the court concluded that the insurers did not adequately plead the RICO claim, it dismissed with leave to refile.[44]

RICO claims may be difficult to plead and prove, but they represent an expanding area of potential exposure for healthcare providers.

Federal Antitrust Enforcers Have a Renewed Focus on Healthcare Providers

In February 2015, FTC Chair Edith Ramirez described healthcare as "one of my top priorities for the FTC's competition agenda"[45] and William Baer, the assistant attorney general who leads DOJ's Antitrust Division, stated that DOJ "stand[s] ready" to challenge "anticompetitive activity in the healthcare area."[46] As outlined below, the agencies' recent enforcement record amply supports these objectives.[47]

Aggressive Merger Enforcement

After the FTC and DOJ suffered a string of eight losses in hospital merger cases during the mid- and late-1990s, the FTC initiated a retrospective study in 2002 to examine in hindsight whether such mergers harmed consumers through price increases or diminished quality or service.[48] The results of that study led the agency to challenge the consummated acquisition of Highland Park Hospital by Evanston Northwestern Hospital.[49] In *In re Evanston Northwestern Healthcare Corp.*, the FTC found that the merger harmed competition, but elected not to require divestiture and instead ordered relatively limited behavioral remedies.[50]

Evanston, as it has turned out, portended a reboot of the FTC's merger enforcement program in the healthcare services sector. During the eight years since the FTC issued its decision in *Evanston*, the agency has built a record of five-for-five litigating hospital merger challenges.[51] In addition, the FTC has expanded its enforcement efforts in the healthcare provider sector well beyond hospitals. The FTC successfully challenged a hospital's acquisition of a physician group in Nampa, Idaho.[52] The hospital system, St. Luke's Health System, appealed the trial court's decision, and the Ninth Circuit affirmed the FTC's win in February 2015.[53] The FTC has also scrutinized and required divestitures in transactions involving dialysis clinics,[54] ambulatory service centers (ASCs),[55] and physician groups.[56]

The FTC's expansion beyond hospitals and into healthcare services that are less capital intensive is notable and raises questions regarding how the agency accounts for the much lower barriers to entry that generally apply to such services. As recently as a decade ago, attorneys could counsel clients operating ASCs, imaging centers, physician practices, diagnostic laboratories, dialysis clinics, and other outpatient services that the risk of the FTC scrutinizing a merger, acquisition, or joint venture that faced at least some local competition was relatively low in light of the absence of enforcement activity. But now, the signals from the FTC are clear: any transaction involving healthcare providers that results in concentration levels in excess of the thresholds specified in the Horizontal Merger Guidelines may be reviewed closely, whether or not the transaction is reportable pursuant to the Hart-Scott-Rodino Act, and the FTC is ready to defend its positions in court if necessary. Indeed, in its most recent annual report on merger activity, the FTC noted that it "continues to challenge mergers between healthcare providers such as hospitals, because competition helps keep healthcare costs down while providing incentives to improve care."[57]

Ongoing Scrutiny of Information Exchange

The exchange of information among competitors—for example aggregated historical salary information (subject to certain conditions) and many types of clinical information—can be procompetitive and appropriate under the antitrust laws. However, the agencies have expressed that the exchange of sensitive competitively relevant information can reduce competition and facilitate collusion, and thus may raise antitrust concerns. In 1996, the FTC and DOJ jointly issued guidance on the exchange of competitively relevant information by competitors as part of a statement titled "Enforcement Policy in Healthcare."[58] In the policy statement, the agencies established "safety zones" for certain types of information that, if shared, were unlikely to implicate antitrust laws.[59] For example, the agencies stated that "a medical society's collection of outcome data from its members about a particular procedure that they believe should be covered by a purchaser" was information that was unlikely to raise anticompetitive concerns if exchanged.[60] The agencies also provided some additional clarity regarding when a provider's sharing of both non-fee-related and fee-related information might raise antitrust concerns.[61]

Very recently, the FTC and DOJ have signaled renewed interest in information exchange among healthcare providers. In a recent blog post on the topic, the FTC expressed that "[t]oo much transparency can harm competition in any industry, including healthcare" and that "broad disclosures of bids, prices, costs, and other

sensitive information that may chill competition among healthcare providers" can, in some instances, "risk harm to the competitive process," though the FTC inserted the important caveat that "[a]s with all things, details matter."[62] In late June of this year, the FTC sent an open letter to two members of the Minnesota House of Representatives after the state enacted a law to classify health plan provider contracts as public data.[63] While the FTC applauded the "laudable goal" of increasing transparency, the agency warned that certain exchanges of information "may chill competition by facilitating or increasing the likelihood of unlawful collusion" among providers.[64] These statements, particularly given their context as commentary on state laws, signal that the FTC remains attuned to information exchange in the healthcare sector.

Renewed Assertion of the Authority to Obtain Monetary Equitable Relief

Neither Section 5 nor Section 13(b) of the FTC Act, which authorize the FTC's antitrust enforcement authority, explicitly states that the FTC may obtain monetary relief. Nevertheless, the FTC has asserted that its authorization to seek to enjoin antitrust violations in Section 13(b) of the FTC Act allows courts to award monetary equitable relief, namely disgorgement and equitable restitution.[65] Although case law sometimes uses these terms in different ways, generally speaking, disgorgement focuses on the wrongdoer and is intended to prevent a malfeasor from retaining ill-gotten gains, and restitution is calculated from the perspective of the victim and is the amount of monetary harm the victim(s) has suffered.[66]

This interpretation of Section 13(b) is untested in the appellate courts in antitrust cases,[67] but that did not stop the FTC from asserting this authority earlier this year to obtain $26.8 million from Cardinal Health in a negotiated consent order to settle allegations that Cardinal "illegally monopolized 25 local markets for the sale and distribution of low-energy radiopharmaceuticals and forced hospitals and clinics to pay inflated prices for these drugs."[68] According to the FTC, Cardinal's anticompetitive conduct included threats to cancel, and actual termination of, various supplier and customer relationships and conditioning future business relationships on a supplier's refusal to grant access to potentially competing product to other distributors.[69] The FTC's complaint alleges that these and other acts allowed Cardinal to obtain "*de facto* exclusive distribution rights to the only [radiopharmaceuticals] on the market and prevented numerous potential entrants from gaining access to those radiopharmaceuticals."[70]

The FTC's action against Cardinal demonstrates that the agency will pursue cases throughout the healthcare sector, and further that it is not shy about seeking potent monetary remedies.

Conclusion

Government and private enforcement of the FCA, RICO, and federal antitrust laws in the healthcare provider sector has shifted significantly in recent years. Because employees at many organizational levels, including salespeople, billing specialists, and executives, are engaged in conduct that can implicate these laws, maintaining and updating compliance efforts, including company policies, handbooks, trainings, and audits, is an important investment

for healthcare providers. Indeed, as enforcement trends and priorities become clear, healthcare providers must respond accordingly.

Notes

1. This article focuses on enforcement of these federal laws, but each has a Colorado analogue. *See* Colorado Medicaid False Claims Act, CRS §§ 25.5-4-303.5 *et seq.*; Colorado Organized Crime Control Act, CRS §§ 18-17-101 *et seq.*; Colorado Antitrust Act of 1992, CRS §§ 6-4-101 *et seq.*; Colorado Unfair Practices Act, CRS §§ 6-2-101 *et seq.* Although outside the scope of this article, actions under these Colorado statutes may give rise to exposure on another flank for healthcare providers.

2. *See* Press Release, DOJ Office of Public Affairs, "Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay $125 Million to Resolve Criminal Liability and False Claims Act Allegations" (Oct. 29, 2015), www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.

3. *See* Gibson, Dunn & Crutcher LLP, "2014 Year-End Healthcare Compliance and Enforcement Update—Providers" (Jan. 14, 2015), www.gibsondunn.com/publications/pages/2014-Year-End-Health-Care-Compliance —Enforcement-Update—Providers.aspx.

4. Press Release, DOJ Office of Public Affairs, "Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the American Bar Association's 25th Annual National Institute on Healthcare Fraud" (May 14, 2015), www.justice.gov/opa/speech/assistant-attorney-general-leslie-r-caldwell-delivers-remarks-american-bar-association-s.

5. *See* Press Release, DOJ Office of Public Affairs, "Amedisys Home Health Companies Agree to Pay $150 Million to Resolve False Claims Act Allegations" (April 23, 2014), www.justice.gov/opa/pr/amedisys-home-health-companies-agree-pay-150-million-resolve-false-claims-act-allegations.

6. *See id.*

7. *See* Press Release, DOJ Office of Public Affairs, "Community Health Systems Inc. to Pay $98.15 Million to Resolve False Claims Act Allegations" (Aug. 4, 2014), www.justice.gov/opa/pr/community-health-systems-inc-pay-9815-million-resolve-false-claims-act-allegations.

8. *See id.*

9. *See* DOJ, *supra* note 2.

10. *See id.*

11. *See id.*

12. *See* Press Release, DOJ Office of Public Affairs, "Florida Skilled Nursing Facility Agrees to Pay $17 Million to Resolve False Claims Act Allegations" (June 16, 2015), www.justice.gov/opa/pr/florida-skilled-nursing-facility-agrees-pay-17-million-resolve-false-claims-act-allegations.

13. *Id.*

14. *See* Press Release, DOJ Office of Public Affairs, "DaVita to Pay $350 Million to Resolve Allegations of Illegal Kickbacks" (Oct. 22, 2014), www.justice.gov/opa/pr/davita-pay-350-million-resolve-allegations-illegal-kickbacks.

15. *See* Press Release, DOJ Office of Public Affairs, "Texas-Based Citizens Medical Center Agrees to Pay United States $21.75 Million to Settle Alleged False Claims Act Violations" (April 21, 2015), www.justice.gov/opa/pr/texas-based-citizens-medical-center-agrees-pay-united-states-2175-million-settle-alleged.

16. *See, e.g.*, *Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001); *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001).

17. *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699 (7th Cir. 2014).

18. *Id.* at 702, 704-05.

19. *Id.* at 710.

20. *Id.* (quoting *Mikes*, 274 F.3d at 703).

21. *Id.*

22. *See* Press Release, DOJ Office of Public Affairs, "Extendicare Health Services Inc. Agrees to Pay $38 Million to Settle False Claims Act Allegations Relating to the Provision of Substandard Nursing Care and Medically Unnecessary Rehabilitation Therapy" (Oct. 10, 2014), www.justice.gov/opa/pr/extendicare-health-services-inc-agrees-pay-38-million-settle-false-claims-act-allegations.

23. *See id.*

24. *Id.*

25. *United States ex rel. Martin v. Life Care Ctrs. of America*, No. 1:08-cv-251 Complaint at 14.

26. *See United States ex rel. Martin v. Life Care Ctrs.*, 2014 WL 4816006 at *5-6 (E.D.Tenn. Sept. 29, 2014).

27. *Id.* at *5, *19. *See also United States v. AseraCare Inc.*, 2014 WL 6879254 at *12 (N.D.Ala. Dec. 4, 2014) (allowing the government, over the defendant's objections, to rely on the statistical sample to prove FCA violations); *United States v. Robinson*, No. 13-cv-27-GFVT, 2015 WL 1479396 at *10-11 (E.D.Ky. March 31, 2015) (denying a defendant's motion for summary judgment on the ground that the government could use statistical sampling evidence to prove both liability and damages in FCA cases).

28. *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 WL 3903675 at *1, *8 (D.S.C. June 25, 2015).

29. *Id.* at *8.

30. *Id.*; Order at 2, *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 15-2147 (4th Cir. Sept. 29, 2015).

31. 18 USC § 1962(c) and (d).

32. *See* 18 USC § 1961(1) (defining "racketeering activity").

33. *See id.*

34. 18 USC § 1964(c).

35. *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 265-68 (1992).

36. *See, e.g.*, *Rotella v. Wood*, 120 S.Ct. 1075, 1077 (2000) (RICO suit brought by patient against psychiatrists and related entities that allegedly kept him at psychiatric facility to increase their revenues rather than treat him appropriately).

37. The rise in these types of claims tracks a similar rise in payor-initiated RICO claims against pharmaceutical companies for conduct that gave rise to an FCA settlement. *See, e.g.*, *In re Neurontin Mktg. and Sales Practice Litig.*, 712 F.3d 21, 25-26 (1st Cir. 2013) (affirming $140 million jury verdict in RICO case brought by private third-party payor against pharmaceutical companies that settled allegations that they engaged in off-label promotion in violation of the Federal Food, Drug, and Cosmetic Act and FCA).

38. *See Liberty Mutual Fire Ins. Co. v. Acute Care Chiropractic Clinic, P.A.*, No. 14-cv-2651, __ F.Supp.3d __, 2015 WL 632187 at *1, *5 (D.Minn. Feb. 13, 2015).

39. *Id.* at *8, *11.

40. *Id.* at *12. Notably, in denying the motion to dismiss, the District of Minnesota relied heavily on several FCA cases. *See id.* at *11 (relying on *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552 (8th Cir. 2006) and *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914 (8th Cir. 2014)).

41. Other federal courts have permitted similar RICO claims to proceed into discovery. *See, e.g.*, *Puerto Rico Med. Emergency Grp., Inc. v. Iglesia Episcopal Puertorriqueña, Inc.*, ___ F.Supp.3d ___, No. 14-1616, 2015 WL 4669814 at *9 (D.P.R. Aug. 7, 2015) (denying motions to dismiss filed by defendant hospitals in RICO suit relating to double billing); *State Farm Mut. Auto. Ins. Co. v. Fayda*, No. 14-cv-9792 at *1-2 (S.D.N.Y. June 18, 2015) (denying motion to dismiss RICO suit filed by defendant acupuncture providers that allegedly billed insurer for medically unnecessary care or care they never provided); *State Farm Mut. Auto. Ins. Co. v. Universal Health Grp., Inc.*, No. 14-cv-10266, 2014 WL 5427170 at *1 (E.D.Mich. Oct. 24, 2014) (denying several providers' motions to dismiss RICO claims targeting the providers' billing for "allegedly unnecessary treatment"); *State Farm Auto. Ins. Co. v. Kugler*, No. 11-80051, 2011 WL 4389915 at *1, *11 (S.D.Fla. Sept. 21, 2011) (denying motion to dismiss RICO claim brought by insurers against providers who allegedly performed "medically unnecessary diagnostic tests and surgical procedures").

42. *Government Emp. Ins. Co. v. MLS Med. Grp. LLC*, No. 12-7281, 2013 WL 6384652 at *1 (D.N.J. Dec. 6, 2013). *See also Gov't Emps. Ins.*

Co. v. Badia, No. 13-cv-1720, 2015 WL 1258218 at *1 (E.D.N.Y. March 18, 2015).

43. *MLS Med. Grp.*, 2013 WL 6384652 at *9.

44. *Id.* at *11.

45. FTC, "Workshop Transcript: Examining Healthcare Competition" 5 (Feb. 24, 2015), www.ftc.gov/system/files/documents/public_events/618591/transcript-day1.pdf.

46. FTC, "Workshop Transcript: Examining Healthcare Competition" 8 (Feb. 25, 2015), www.ftc.gov/system/files/documents/public_events/618591/transcript-day2.pdf.

47. In addition to the matters and initiatives outlined below, the agencies' activity in the healthcare provider sector includes close attention to the structure of Accountable Care Organizations. *See, e.g.*, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program; Notice, 76 Fed. Reg. 67,026, 67,028-31 (Oct. 28, 2011), www.gpo.gov/fdsys/granule/FR-2011-10-28/2011-27944. It also includes an effort to narrow the "state action defense" that has resulted in two recent wins in the U.S. Supreme Court involving healthcare providers. *See FTC v. Phoebe Putney Health Sys., Inc.*, 133 S.Ct. 1003 (2013) (holding that establishing the first requirement of the state-action defense requires showing more than mere "foreseeability" that anticompetitive conduct would result from state legislation authorizing an entity to act on its behalf); *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S.Ct. 1101 (2015) (holding that state-authorized boards must be "actively supervised" by the state to receive antitrust immunity).

48. *See* Muris, "Everything Old is New Again: Healthcare and Competition in the 21st Century," Remarks Before the 7th Annual Competition in Healthcare Forum at 19 (Nov. 7, 2002), www.ftc.gov/sites/default/files/documents/public_statements/everything-old-new-again-healthcare-and-competition-21st-century/murishealthcarespeech0211.pdf (explaining the origins of the retrospective study of hospital mergers); Ramirez, "Retrospectives at the FTC: Promoting an Antitrust Agenda," Remarks at the George Washington University Law School Merger Transactions Symposium (June 28, 2013), www.ftc.gov/sites/default/files/documents/public_statements/retrospectives-ftc-promoting-antitrust-agenda/130628aba-antitrust.pdf (describing the history of merger retrospective analyses).

49. *See* Hass-Wilson and Garmon, "Two Hospital Mergers on Chicago's North Shore: A Retrospective Study" 2 (FTC Working Paper No. 294, 2009), www.ftc.gov/reports/two-hospital-mergers-chicagos-north-shore-retrospective-study (noting that the investigation of Evanston Northwestern Hospital "led to an administrative complaint by the FTC challenging the transaction as anticompetitive").

50. *In re Evanston Nw. Healthcare Corp.*, No. 9315, slip op. at 90 (Aug. 6, 2007), www.ftc.gov/sites/default/files/documents/cases/2007/08/070806opinion.pdf (imposing "an injunctive remedy that requires respondent to establish separate and independent negotiating teams" instead of mandating divestiture).

51. The FTC's wins include three mergers that were preliminarily enjoined by a federal court. *See FTC v. ProMedica Health Sys., Inc.*, No. 3:11 CV 47, 2011 WL 1219281 at *1, *61 (N.D. Ohio March 29, 2011); *FTC v. OSF Healthcare Sys.*, 852 F.Supp.2d 1069, 1095 (N.D.Ill. 2012); *FTC v. Phoebe Putney Health Sys., Inc.*, No. 1-11-CV-00058-WLS, slip op. at 2 (M.D.Ga. June 5, 2013) (entering a stipulated preliminary injunction barring further consolidation of Palmyra and Phoebe Putney), www.ftc.gov/enforcement/cases-proceedings/111-0067/phoebe-putney-health-system-inc. Wins also include two transactions that were abandoned by the parties during litigation with the FTC. *See* Press Release, FTC, "FTC Approves Order Dismissing Administrative Complaint Against Inova Health System Foundation and Prince William Health System, Inc." (June 17, 2008), www.ftc.gov/news-events/press-releases/

2008/06/ftc-approves-order-dismissing-administrative-complaint-against; *In re Reading Health Sys.*, No. 9353, 2012 WL 6188557 at *1 (FTC Dec. 7, 2012).

52. *See* Press Release, FTC, "Statement by FTC Chairwoman Edith Ramirez on Appellate Ruling in the St. Luke's Hospital Matter" (Feb. 10, 2015), www.ftc.gov/news-events/press-releases/2015/02/statement-ftc-chairwoman-edith-ramirez-appellate-ruling-st-lukes (describing the Ninth Circuit decision that upheld the District of Idaho's holding that St. Luke's Health System's acquisition of Saltzer Medical Group violated Section 7 of the Clayton Act and required St. Luke's to divest Saltzer).

53. *Saint Alphonsus Med. Ctr. Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 793 (9th Cir. 2015).

54. *See, e.g.*, *In re DaVita Inc.*, 140 F.T.C. 609, 615-16 (Nov. 14, 2005) (issuing a final decision and order settling an FTC investigation of DaVita's proposed acquisition of Gambro Healthcare Inc.); *In re DaVita Inc.*, No. C-4334, 2011 WL 11798462 at *4 (FTC Oct. 20, 2011) (issuing a final decision and order to settle the FTC's investigation of DaVita's acquisition of CDSI Holding Company); *In re Fresenius AG*, No. C-4161, 2006 WL 6679061 at *5-6 (June 19, 2006) (issuing a decision and order to settle the FTC's investigation of Fresenius AG's proposed acquisition of Renal Care Group, Inc.).

55. *See In re H.I.G. Bayside Debt & LBO Fund II, L.P.*, No. C-4494, slip op. at 1-2 (FTC Dec. 24, 2014), www.ftc.gov/enforcement/cases-proceedings/141-0183-c-4494/hig-bayside-debt-et-al (issuing a decision and order to settle the FTC's investigation of Surgery Center Holdings, Inc.'s proposed acquisition of Symbion Holdings Corporation).

56. *See In re* Keystone Orthopaedic Specialists, LLC, and Orthopaedic Associates of Reading, Ltd., FTC File No. 141 0025 (Oct. 21 2015), www.ftc.gov/enforcement/cases-proceedings/141-0025/keystone-orthopaedic-specialists-llc-orthopaedic-associates.

57. Hawthorne and Signs, "Notable Trends in Merger Review: Inside the HSR Annual Report" (Aug. 12, 2015), www.ftc.gov/news-events/blogs/competition-matters/2015/08/notable-trends-merger-review-inside-hsr-annual-report?utm_source=govdelivery.

58. *See generally* DOJ and FTC, "Statements of Antitrust Enforcement Policy in Healthcare" (Aug. 1996), www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf.

59. *Id.* at 40-52.

60. *Id.* at 41.

61. *Id.* at 41-42, 45-48.

62. Koslov and Jex, "Price Transparency or TMI?" Office of Policy Planning, FTC (July 2, 2015), www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.

63. Letter from Lao *et al.* to the Honorable Joe Hoppe and the Honorable Melissa Hortman, Minn. House of Representatives (June 29, 2015), www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf.

64. *Id.* at 1.

65. *See, e.g.*, *FTC v. Cardinal Health, Inc.*, No. 15 CV 3031 Complaint at 1, 13 (S.D.N.Y. April 20, 2015) (seeking "disgorgement of ill-gotten gains" pursuant to § 13(b) of the FTC Act); *FTC v. Cephalon, Inc.*, No. 2:08-CV-2141, 2015 WL 1724597 at *2-3 (E.D.Pa. April 15, 2015) (noting that the FTC sought "equitable monetary remedies," asserting that "Section 13(b) grants district courts authority to order monetary equitable relief").

66. *See, e.g.,* Park and Wolfram, "The FTC's Use of Disgorgement in Antitrust Actions Threatens to Undermine the Efficient Enforcement of Federal Antitrust Law," *The Antitrust Source* (Sept. 2002), www.americanbar.org/content/dam/aba/publishing/antitrust_source/disgorgement.authcheckdam.pdf.

67. To the authors' knowledge, no appellate courts have addressed whether the FTC may obtain monetary equitable relief in a competition case. Several district courts have held that such relief is available to the FTC. *See, e.g., FTC v. Mylan Labs., Inc.*, 62 F.Supp. 2d 25, 36-37 (D.D.C. 1999); *Cephalon, Inc.*, 2015 WL 1724597 at *4. However, several circuit courts have found that the FTC may seek equitable monetary relief under § 13(b) in cases involving consumer protection issues. *See, e.g., Cephalon, Inc.*, 2015 WL 1724597 at *3 (listing cases).

68. Press Release, FTC, "Cardinal Health Agrees to Pay $26.8 Million to Settle Charges It Monopolized 25 Markets for the Sale of Radiopharmaceuticals to Hospitals and Clinics" (April 20, 2015), www.ftc.gov/news-events/press-releases/2015/04/cardinal-health-agrees-pay-268-million-settle-charges-it.

69. *See id.*

70. *Id.* ■