Methodist Healthcare Accused of Paying Kickbacks to Oncologists

Methodist Le Bonheur Healthcare (MLH), a non-profit healthcare system consisting of five hospitals as well as outpatient and ancillary services, has been accused of paying kickbacks in exchange for patient referrals. Between 2012 and 2018, over \$400 million was allegedly paid by MLH for referrals from physicians at The West Clinic, a Memphis, Tennessee based, for-profit private physician group of medical oncologists, gynecologic oncologists, radiologists, and other physician specialists. The relators, a former MLH executive leadership team member and the former CEO for Methodist University Hospital, claim that MLH induced the referrals of cancer patients to their facility through kickback payments made to The West Clinic, in violation of numerous fraud and abuse laws. ³

On October 28, 2011, MLH and The West Clinic announced that beginning January 1, 2012, MLH would enter into a partnership with five of The West Clinic's eight locations "to transform cancer care in the [local region]."4 The complaint alleges that this arrangement was "not a legal partnership, but rather an alliance to enter into business agreements" and carry out business practices in violation of the Stark Law, Anti-Kickback Statute, and the Fair Claims Act.⁵ These alleged business practices include entering into an agreement in which The West Clinic would exclusively refer patients to MLH (rather than to Baptist Healthcare, a competitor of MLH to which The West Clinic physicians had historically referred patients), and in exchange, MLH would reward The West Clinic physicians with: (1) compensation per work relative value unit (wRVU) in excess of fair market value (FMV); (2) "management" service fees largely determined by the volume and value of referrals; (3) sharing of 340B drug profits based on referrals; and, (4) a \$7 million payment to The West Clinic for patient referrals, disguised as an investment in The West Clinic's research company.6

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership interest, investment interest, or compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of *designated health services* (DHS), unless the referral is protected by one or more of the numerous exceptions delineated by the statute. Notable to the allegations against MLH and The West Clinic, *group practice arrangements with a*

hospital is one of the financial relationships protected by the Stark Law's exceptions.⁸ However, this exception requires that compensation for such an arrangement: (1) be consistent with FMV; (2) be commercially reasonable; and, (3) not take into account the value or volume of any referrals provided by the group practice physicians.⁹

The Anti-Kickback Statute (AKS) makes it a felony for any person to "knowingly and willfully" solicit or receive, or to offer or pay, any "remuneration", directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program. 10 Similar to the Stark Law, the AKS contains several safe harbors, including protections for personal services and management contracts, which may shield an arrangement from regulatory liability if some or all of the requisite criteria is met.11 Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal. 12 However, as with the Stark Law, for a payment to meet the requirements of many AKS safe harbors, the compensation must: (1) be consistent with FMV; (2) be commercially reasonable; and, (3) not take into account the value or volume of any referrals provided by the group practice physicians.¹³

Violations of the Stark Law and/or AKS can trigger a violation of the False Claims Act (FCA). The FCA imposes civil monetary penalties in an amount between \$5,000 to \$10,000 per claim, as well as treble damages, upon any individual who knowingly submits a false or fraudulent claim to, or uses false records to induce payment from, the U.S. government. The FCA is a potent fraud and abuse enforcement tool, as it allows private individuals, also known as *qui tam* relators or *whistleblowers*, to bring suits on behalf of the government.

The lawsuit alleges that Methodist compensated The West Clinic physicians an above-FMV and commercially unreasonable amount. The During the partnership between MLH and The West Clinic (2012-2018), most physicians at The West Clinic were medical oncologists. The relators allege that each oncologist at The West Clinic was compensated over \$1 million annually, while senior oncologists received an annual income of over \$3 million, exceeding the Medical Group Management Association (MGMA) national 90th percentile annual compensation benchmark for oncology specialties,

which averaged \$760,600 during the time period in question.¹⁹

The relators alleged that concerns over proving that the demanded compensation packages were not in excess of FMV were discussed internally.²⁰ Allegations in the lawsuit indicate that the then-MLH CEO and CFO made an effort to find a compensation consultant that would support the level of compensation The West Clinic was demanding.²¹ The relators allege that once a company was found that agreed that the extraordinarily-high compensation packages to be awarded to The West Clinic physicians were FMV, the then-MLH CEO and CFO "admitted they would probably never be able to get such an opinion again."22 The alleged above-FMV compensation paid to The West Clinic physicians was composed of three components: (1) compensation per wRVU; (2) payments for "co-management" services; and, (3) shared 340B profits.²³

The first type of compensation that The West Clinic physicians received from MLH was compensation per wRVU.²⁴ The agreement between The West Clinic and MLH allegedly specified that The West Clinic physicians would be paid \$120 per wRVU, regardless of the physician's experience or performance.²⁵ This level of compensation was slightly higher (1.24%) than the MGMA national 90th percentile for medical oncologists in 2012.26 To support their claims of Stark Law violations, the relators allege that MLH leadership was aware that \$120 per wRVU was a commercially unreasonable level of compensation considering that almost half of The West Clinic's patients were Medicare beneficiaries, which reimbursed at a rate of \$34-35 per wRVU during the seven-year period of the West Clinic-MLH partnership.²⁷ MLH executives allegedly knew that without consideration of the \$120 million in revenues from The West Clinic's referrals, compensation of \$120 per wRVU would lead to significant financial loss.²⁸

The second component of The West Clinic physicians' compensation package was payments for comanagement services provided by the physicians.²⁹ The lawsuit alleges that as a part of the West Clinic-MLH partnership, The West Clinic entered into a management agreement with MLH requiring The West Clinic physicians to manage the oncology service lines at the four MLH hospitals located in the Memphis area.³⁰ However, the relators allege that communication within MLH and between The West Clinic and MLH indicates that The West Clinic physicians did not actually manage the oncology service line as their agreement required, and that this agreement was simply another way to disguise kickback payments to The West Clinic physicians.³¹ To support their claims of Stark Law violations, the relators allege that management fees were paid to The West Clinic during time periods in which The West Clinic was not contractually required to perform management services under their agreement and that fluctuations in management fees can be traced to fluctuations in oncology service line revenues, largely influenced by referrals from The West Clinic physicians.³²

The third component of The West Clinic physicians' compensation package was payments from shared 340B profits. 33 MLH generated between \$100 million and \$700 million in 340B profits as a direct result of The West Clinic physicians' referrals to MLH. 34 In exchange for The West Clinic physicians' referrals for chemotherapy and oral cancer drugs, MLH allegedly agreed to share their increased profits with The West Clinic, as evidenced by inconsistencies in Form 990 line items. 35 It is reported that in 2012, 2013, and 2014, total compensation for wRVUs and co-management fees only accounted for 67% to 69% of the total amount paid to The West Clinic physicians for physician services, suggesting that the additional 31% to 33% came from distributions of 340B profit savings to The West Clinic physicians. 36

In addition to physician compensation in excess of FMV, the lawsuit alleges that MLH induced referrals from The West Clinic through a \$7 million investment in Vector Oncology, a for-profit research entity controlled by The West Clinic physicians.³⁷ The \$7 million investment is alleged to have been a condition made by The West Clinic for entering into the partnership with MLH. Half of the investment made by MLH was allocated to paying off Vector Oncology's debts, which debts were personally financed by The West Clinic physicians. 38 The relators allege that Vector Oncology was unable to generate self-sustaining revenue, had no intellectual property of value, and had no viable business strategy; thus, there was no legitimate business reasoning for MLH to invest in Vector Oncology.³⁹ When concerns about the financial performance of Vector Oncology were expressed, MLH executives allegedly responded that MLH's investment was "the cost of doing business" with The West Clinic.⁴⁰ The relators emphasize that because The West Clinic physicians were personally liable for Vector Oncology's debts, \$3.5 million of the investment made by MLH was a direct kickback to The West Clinic physicians for their agreement to refer patients to MLH.⁴¹

The complaint alleges that through the illegal inducement of referrals from The West Clinic physicians, MLH received over \$1.5 billion in increased revenues from 2012 to 2018, 42 with over half of these increased revenues estimated to have been paid by Medicare and Medicaid. 43

In response to the relators' allegations, MLH and The West Clinic deny any wrongdoing.⁴⁴ MLH said in a statement that, "[o]ur payments for the services provided were appropriate. We cooperated fully in the government's investigation of these allegations, and we are pleased the government has decided not to intervene in the lawsuit at this time. The lawsuit lacks merit, and we will continue to vigorously defend ourselves."⁴⁵

The suit, originally filed in 2017, is currently in the discovery phase. The defendants have filed a motion to dismiss the plaintiff's Second Amended Complaint, but the court has yet to rule on the motion. Interestingly, as noted by MLH, the U.S. Attorney's Office has declined to intervene in the case thus far, but has stated that they will "continue to monitor the case."

As mentioned in the March 2020 Health Capital Topics article entitled, "DOJ Recovers Over \$3 Billion in False Claims Act Cases," there has been a significant number of FCA suits brought by whistleblowers, as well as by the Department of Justice (DOJ), in recent years.⁴⁹ Despite

the Trump Administration's actions to deregulate the healthcare industry during the last three years, the high number of new healthcare fraud and abuse enforcement actions suggest that regulatory scrutiny of healthcare transactions will continue in its intensity going forward.

- "United States and State of Tennessee ex rel. Jeffery H. Liebman and David M. Stern v. Methodist Le Bonheur Healthcare, et al." Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Second Amended Complaint, p. 4 and 12
- 2 Ibid.
- 3 *Ibid*, p. 4.
- 4 "Methodist and The West Clinic Form Partnership," Methodist Le Bonheur Healthcare, October 28, 2011, https://www.methodisthealth.org/articles/methodist-and-thewest-clinic-form-partnership/ (Accessed 10/20/20).
- 5 Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Second Amended Complaint, p. 12.
- 6 Ibid, p. 26 and 36.
- 7 "Prohibition on certain referrals by physicians and limitations on billing" 42 C.F.R. § 411.353.
- 8 "Exceptions to the referral prohibition related to compensation arrangements" 42 C.F.R. § 411.357.
- 9 Ibid.
 - "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
- 11 "Exceptions" 42 C.F.R. §§ 1001.952(d) (2016).
- 12 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003,
 - https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprog ram.pdf (Accessed 10/2/19), p. 1.
- 13 "Exceptions" 42 CFR §§ 1001.952(d).
- 14 "False claims" 31 U.S.C. § 3729(a)(1).
- 15 Ibid.
- 16 Ibid.
- 17 Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Second Amended Complaint, p. 94.
- 18 Ibid
- 19 Ibid, p. 94-95. The national 90th percentile compensation for medical oncologists was \$777,940 in 2013, \$922,244 in 2014, \$762,970 in 2015, \$693,452.28 in 2016, and \$646,226.73 in 2017 according to MGMA Physician Compensation and Production Survey Data.
- 20 *Ibid*, p. 95.
- 21 Ibid.
- 22 *Ibid*.
- 23 Ibid, p. 96.
- 24 Ibid.
- 25 Ibid.

- 26 Ibid, p. 96-97.
- 27 *Ibid*, p. 96. 28 *Ibid*.
- 29 *Ibid*.
- 30 Ibid, p. 80.
- 31 Ibid, p. 87.
- 32 Ibid.
- 33 Ibid, p. 96. Section 340B of the Public Health Service Act (340B) allows healthcare organizations that care for a large low income or uninsured population to purchase outpatient drugs at significantly discounted prices from pharmaceutical manufactures participating in Medicaid and Medicare Part B programs. "340B Drug Pricing Program," Health Resources & Services Administration, October 2020,
 https://www.brog.org/io.do/pi.brog/io.do/p
 - https://www.hrsa.gov/opa/index.html (Accessed 10/22/20).
- 34 *Ibid*, p. 48 and 113.
- 35 Ibid, p. 48, 53.
- 36 Ibid, p. 53.
- 37 Ibid, p. 88-89
- 38 *Ibid*, p. 89.
- 39 Ibid, p. 92-93.
- 40 *Ibid*, p. 93.
- 41 *Ibid*.
- 42 Ibid, p. 6.
- 43 *Ibid*.
- 44 "Methodist Le Bonheur accused of paying kickbacks to physicians" By Alex Kacik, Modern Healthcare, October 16, 2020, https://www.modernhealthcare.com/legal/methodist-lebonheur-accused-paying-kickbacks-physicians (Accessed 10/20/20).
- 45 *Ibid*.
- 46 Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Civil Docket (Accessed 10/19/20).
- 47 Ibia
- 48 "Lawsuit: Methodist, West Clinic defrauded healthcare programs through kickback arrangement" By Max Garland, Memphis Commercial Appeal, October 14, 2020, https://www.commercialappeal.com/story/money/business/2020/10/14/methodist-le-bonheur-healthcare-west-clinic-lawsuit-alleged-kickbacks/3649942001/ (Accessed 10/20/20).
- 49 "DOJ Recovers Over \$3 Billion in False Claims Act Cases" Health Capital Topics, Vol. 13, Issue 3 (March 2020), available at:
 - https://www.healthcapital.com/hcc/newsletter/03_20/HTML/DO J/convert_hc_topics_doj_2019_settlements.php.



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