



## OHIO HOSPITAL AND PHYSICIAN GROUP TO PAY \$4.4 MILLION TO RESOLVE FALSE CLAIMS ACT ALLEGATIONS

According to a Department of Justice ("DOJ") press release, dated January 4, 2013, an Elyria, Ohio, hospital and a physician group agreed to pay a total of \$4.4 million to the United States to settle allegations that they submitted false claims to Medicare and performed unnecessary cardiac procedures on Medicare patients. The hospital, EMH Regional Medical Center ("EMH"), agreed to pay \$3,863,857, while the physician group, North Ohio Heart Center Inc. ("NOHC") agreed to pay \$541,870. The press release indicated that the United States alleged that, between 2001 and 2006, "EMH and NOHC performed angioplasty and stent placement procedures on patients who had heart disease but whose blood vessels were not sufficiently occluded to require the particular procedures at issue." The press release also indicated that "the claims resolved by this settlement are allegations only, and there has been no determination of liability."

The matter was initiated by Kenny Loughner, the former manager of EMH's catheterization and electrophysiology laboratory, who filed a *qui tam*, or whistleblower complaint, under the False Claims Act ("Complaint").<sup>1</sup> The case is captioned *United States ex rel. Loughner v. EMH Regional Medical Center, et al.*, Case No. 1:06-cv-2441 (N.D. Oh.). According to the Complaint, NOHC cardiologists were performing medical procedures, namely angioplasties, that were "unnecessary, excessive and/or improper" at EMH's facility.<sup>2</sup> The Complaint also alleged that certain procedures, angioplasty and angiogram services, were inappropriately "staged" and "unbundled." Specifically, the Complaint contended that angiograms were scheduled without preparing to perform angioplasty procedures in the event a blockage were detected. This would then require a patient to schedule a separate appointment for an angioplasty in the event a blockage were detected.<sup>3</sup> The Complaint also alleged that angioplasties were scheduled with the knowledge that more than one stent should be implanted; that is, fewer stents would be implanted than necessary, "leaving blocked or occluded blood vessels to be stented at a later date."<sup>4</sup> Other allegations in the Complaint included, without limitation, that there was a pattern and practice of advising patients to complain of chest pain, "whether or not the patients were experiencing chest pain," and of individual physician defendants routinely instructing EMH nurses and technicians involved in the procedures to "record fictitious and non-existent complaints of chest pain."<sup>5</sup> There were also allegations of NOHC receiving kickbacks from EMH's catheterization lab budget and of kickbacks paid to a defendant cardiologist "under the pretense" that the payments were for service as the clinical director and coordinator of the lab.<sup>6</sup>

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<sup>1</sup> In addition to naming EMH and NOHC, the Complaint also named two cardiologists who practice at NOHC as defendants.

<sup>2</sup> Compl. at 4.

<sup>3</sup> Compl. at 7.

<sup>4</sup> *Id.*

<sup>5</sup> Compl. at 8.

<sup>6</sup> Compl. at 10-11.



The Complaint also referenced an August 2006 *New York Times* article<sup>7</sup> titled, "Heart Procedure Is Off the Charts in an Ohio City" ("Article").<sup>8</sup> The Article described Elyria, Ohio, as a place where "the statistics are so far off the charts" regarding the number of angioplasties performed there that "Medicare patients in Elyria receive angioplasties at a rate nearly four times the national average . . ." The Article stated that researchers at Dartmouth Medical School analyzed Medicare data and found Elyria to be "an outlier." According to the Article, the Dartmouth data showed that, whereas, as of 2003 (the most recent year for which information was available at that time), the national average of angioplasty procedures was 11.3 per 1,000 Medicare patients and the average throughout the State of Ohio was 13.5 per 1,000 Medicare patients, Elyria had 42 procedures per 1,000 Medicare patients. This, according to the Article, was three times the rate of procedures performed in Cleveland, Ohio, 30 miles away.

The Article went on to state that ". . . there is little doubt that hundreds of Elyria patients each year are getting angioplasties that they would not be getting if they lived elsewhere in Ohio, or in any other part of the country for that matter, at a cost of millions of dollars a year to Medicare, the federal insurance program for the elderly. Elsewhere in the state, some of the sickest of these patients might have received bypass surgery,<sup>9</sup> while many others might have simply been treated with drugs. Or, for those whose conditions were not diagnosed or were not deemed serious enough, there might have been no treatment at all."

The Article noted that nearly all the procedures at the Elyria hospital were "performed by a group of cardiologists who dominate coronary care in this city and have an unabashed enthusiasm for angioplasties, the highly profitable procedure in which they specialize." According to the Article, this group, NOHC, employed 31 cardiologists at that time.<sup>10</sup>

The Article stated that NOHC's founder and president, Dr. John W. Schaeffer, said that the high rate of angioplasties is simply a function of his doctors' detecting disease more often in their patients than physicians elsewhere might spot, and being quicker to intervene.<sup>11</sup>

Further, according to the Article, "EMH Regional, the small, nonprofit Elyria hospital where North Ohio doctors perform most of their angioplasties, says it is aware that the volume of procedures is higher than it is elsewhere." The Article

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<sup>7</sup> Abelson, Reed, *Heart Procedure Is Off the Charts in an Ohio City*, N.Y. Times, Aug. 18, 2006. Retrieved from: [http://www.nytimes.com/2006/08/18/business/18stent.html?\\_r=0](http://www.nytimes.com/2006/08/18/business/18stent.html?_r=0).

<sup>8</sup> The Complaint states: "Relator is an original source of information . . . and has based this Complaint upon the information separate and distinct from what was reported in the NYT article . . ."

<sup>9</sup> The Article stated that "[t]he Elyria cardiologists do not perform bypasses."

<sup>10</sup> The Article stated "In Elyria and its environs, . . . Dr. Schaeffer says there are perhaps two cardiologists not affiliated with his practice. . ."

<sup>11</sup> A written statement regarding the settlement posted on January 4, 2013, which is discussed below, now refers to Dr. Schaeffer as NOHC's "Chairman and President."



quoted Dr. Donald Sheldon, the hospital's Vice President for Medical Affairs,<sup>12</sup> who said "We believe we're doing a good job." But the Article noted that Dr. Sheldon conceded that the high rates raise questions and said that the hospital had decided to ask a professional society of heart specialists to review the cardiac program and "give us an honest and objective outside look."

Nevertheless, the Article noted that "one clear reason for the high number of angioplasties in Elyria, though, is the way the doctors tend to perform the procedures. In many other parts of the country, doctors who perform angioplasties try to unblock all of the blood vessels during a single session, or they may elect not to put a stent in another vessel that might require an additional session because there is only a minor blockage. But in Elyria, patients are more likely to undergo two or more procedures, sometimes requiring separate hospital stays and additional bills. As many as 31 percent of patients there who receive treatment undergo additional procedures, according to Dr. Scott Sheldon, a North Ohio Heart Center cardiologist, who is not related to the hospital's Dr. Sheldon. That would be three times the national average."

In concluding, the Article noted that "no one has accused the North Ohio doctors of inappropriate conduct. But there have been cases in which unusual patterns of medical activity that also showed up in the Dartmouth data have prompted federal law enforcement investigators to look into whether unnecessary procedures have been performed."

As noted above, the Article ran in August 2006, approximately two months before Mr. Loughner filed his *qui tam* lawsuit, which was filed on October 10, 2006. Approximately 6 1/2 years later, EMH and NOHC settled for more than \$4 million. According to the DOJ press release, as a result of the settlement, Mr. Loughner will receive \$660,859 of the United States' recovery.

After the settlement was announced, both EMH and NOHC released statements regarding the settlement. *Modern Healthcare* reported that "Dr. Donald Sheldon, President and CEO of EMH Healthcare, said in a written statement that the settlement represented a small percentage of its cardiology patients who were judged by Medicare to have not had severe-enough medical conditions to justify the procedures performed by the North Ohio Heart Center doctors. 'No patients, to our knowledge, were ever at risk, and there is no question that the patients treated had heart disease and some degree of blockage,' Sheldon's statement says."<sup>13</sup>

According to *The Morning Journal*, "Dr. Sheldon said during a phone interview, that when they became aware of the problem they worked diligently to understand and address any potential concerns. The hospital voluntarily instituted outside review of their catherization and electrophysiology laboratory beginning in October 2006. Since then, Sheldon said they continued to have external reviews." *The Morning Journal* quoted Dr. Sheldon as saying, "We take these extra

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<sup>12</sup> As noted below, according to EMH Healthcare's website, Dr. Sheldon is now President and CEO of EMH Healthcare.

<sup>13</sup> See, Carlson Joe (2013, Jan. 4) *Ohio Hospital, Cardiac Group to Pay \$4.4 Million False Claims Settlement*, Modern Healthcare. Retrieved from [www.modernhealthcare.com/article/20130104/NEWS/301049951/](http://www.modernhealthcare.com/article/20130104/NEWS/301049951/)



measures to make sure that our program maintains the highest priority standards. We participate in a national database that is overseen by the American College of Cardiology."<sup>14</sup>

Dr. John Schaeffer, Chairman and President of NOHC, released a written statement, which reads, in part: "We have mutually agreed to a civil settlement with the government following a review of stent procedures physicians in our practice provided to Medicare patients between 2001 and 2006. We will abide by the terms of the settlement. The settlement is not an admission of wrongdoing; rather, we settled this matter so we can put it behind us and move forward. It's very important to note that this settlement is only about whether or not Medicare covered some procedures we did six to ten years ago that were considered cutting edge at the time. As the physicians on the ground when these decisions were made and the procedures were performed, we felt confident we were making the correct choices for our patients. We still do, and we are gratified that NOHC has passed every Medicare audit ever done—whether regarding stent procedures, or any other service."<sup>15</sup> (Original emphasis)

Regarding the settlement, the DOJ press release quoted Steven M. Dettelbach, U.S. Attorney for the Northern District of Ohio, who stated, "Most doctors act responsibly. These few didn't. Patient health and taxpayer dollars have to come before greed."

For more information about this article and/or ways in which Jones Walker can assist with any quality of care issues, please contact Lynn M. Barrett at [lbarrett@joneswalker.com](mailto:lbarrett@joneswalker.com).

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<sup>14</sup> See, Remington, Kaylee (2013, Jan 5.) *EMH, North Ohio Heart Center Paying \$4.4 Million to Settle Federal Allegations with Department of Justice*, The Morning Journal. Retrieved from <http://morningjournal.com/articles/2013/01/05/news/doc50e7b61e13fb8596734372.txt>

<sup>15</sup> The full statement can be accessed at: <http://blog.partnersforyourhealth.com/Blog/bid/93734/North-Ohio-Heart-Reaches-Settlement-Continues-to-Provide-High-Quality-Cardiac-Care>





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