

## **I. Introduction**

Changes to health law have wide ranging effects on medical malpractice litigation. This paper examines three areas where changes to existing health law can impact medical malpractice cases. The first section discusses how the changes to the federal government's approach to the regulation of Medicare and Medicaid fraud can impact health care liability claims. The second section discusses how the advent of electronic health records has impacted health care liability. Finally, the third section of this paper addresses how existing law provides for significant shifts in liability in the event of a public health disaster.

## **II. Medicare and Medicaid Fraud**

Medicare accounts for approximately 20% of health care and Medicaid accounts for approximately 15% of healthcare spending.<sup>1</sup> Accordingly, both programs have a significant impact on American healthcare and, therefore, also impact healthcare litigation. Given the role Medicare and Medicaid have in the American healthcare system, it is not surprising that efforts to combat fraud impact other areas of health law.

### **a. Regulation and Prevention of Fraud**

The actual percentage of fraud in Medicare and Medicaid is a subject of much debate, with estimates ranging from 7 to 10 percent.<sup>2</sup> Regardless of which estimate is correct, fraud constitutes a serious issue and the government has stepped up its approach to combating fraud in recent years and the increase in these efforts may impact health care litigation.

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<sup>1</sup> Center for Medicare and Medicaid Services. *National Health Expenditures 2013 Highlights*. Center for Medicare and Medicaid Services. available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>

<sup>2</sup> Abelson, Reed and Lichblau *Pervasive Medicare Fraud Proves Hard to Stop*, New York Times. August 15, 2014. available at: [http://www.nytimes.com/2014/08/16/business/uncovering-health-care-fraud-proves-elusive.html?\\_r=0](http://www.nytimes.com/2014/08/16/business/uncovering-health-care-fraud-proves-elusive.html?_r=0)

Medicare and Medicaid fraud are governed by both criminal and civil laws. The applicable criminal penalty, codified at 18 U.S.C § 1347 imposes imprisonment of up to ten years for knowingly and willfully executing a scheme to defraud a health care benefit program or obtain money from a health care benefit program through fraud. Similarly, 18 U.S. Code § 1035 imposes fines and imprisonment for up to five years for an individual or entity who “falsifies, conceals or covers up by any trick scheme or device a material fact” or makes materially false statements or representations in connection with the delivery of or payment for health care benefits.

Federal law also imposes Civil Punishment for Medicare and Medicaid fraud. Under 42 U.S.C. 1320a-7a(a)(1) and (2), the Health and Human Services Office of Inspector General can bring an administrative action to obtain civil penalties of up to \$2,000 for each false healthcare claim, plus twice the claimed amount. Under 42 U.S.C. 1320a-7a(a)(3), HHS OIG can bring administrative penalties of up to \$15,000 plus an assessment of twice that claim against a provider that gives information that it knows or should have known was false, in order to influence the discharge of a patient. The purpose of section 42 U.S.C. 1320a-7a(a)(3) is to deter hospitals from improperly charging Medicare beneficiaries for inpatient services covered by Medicare and also to deter hospitals from providing Medicare patients with false or misleading information that is intended to encourage premature discharge to the financial advantage of the hospital.

#### **b. The False Claims Act**

Though other civil penalties exist for Medicare and Medicaid fraud, the primary mechanism for enforcement of civil punishment for fraud is the False Claims Act. The Civil False Claims Act prohibits “knowingly making, or conspiring to make, false claims to the

government.”<sup>3</sup> The statute defines “knowingly” as 1) with actual knowledge, 2) with deliberate ignorance of the truth, or 3) with reckless disregard for the truth.<sup>4</sup> Civil penalties under the False Claims Act include a fine of \$5,000 to \$10,000 per claim as well as treble damages.<sup>5</sup> While penalties of \$5,000 to \$10,000 may not appear to be significant, these penalties incur for each false statement and can result in a very large number of claims from a single invoice or bill.<sup>6</sup>

Under the FCA, a civil action may be brought in federal court by the Attorney General or by a relator for the person and for the U.S. Government in a *qui tam* action.<sup>7</sup> Under previous versions of the law, a court did not have jurisdiction over a claim that is based upon public disclosure of information 1) in a criminal, civil, or administrative hearing, 2) in a congressional, administrative, or Government Accountability Office (GAO) report, hearing, audit, or investigation, or 3) from the news media, unless the action is brought by the Attorney General or the relator bringing the action is an “original source” of the information.<sup>8</sup> The FCA defined an “original source” as a relator who has “direct and independent knowledge of the information on which the allegations of the FCA claim are based and had voluntarily provided the information to the government before filing an action.”<sup>9</sup>

Section 1313(a)(6) of the Affordable Care Act (ACA) amended the FCA’s public disclosure bar to allow more leniency to the public disclosure requirement.<sup>10</sup> Under the changes

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<sup>3</sup> Sarah Q. Wirskye. *Healthcare Fraud Facing the Government Challenge*, State Bar of Texas 20<sup>th</sup> Annual Advanced Medical Torts Course. March 14-15, 2013. Chapter 9.1, page 5.

<sup>4</sup> 31 U.S.C. §3729(b)(1).

<sup>5</sup> Wirskye, *supra* note 3.

<sup>6</sup> *Id.*

<sup>7</sup> 31 U.S.C. §3730(b).

<sup>8</sup> Jennifer Staman. *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, Congressional Research Service. June 3, 2013. Page 9. *available at*:

[http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS22743\\_06032013.pdf](http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS22743_06032013.pdf)

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

to the FCA, a court is compelled to dismiss an FCA action or claim by public disclosure “unless opposed by the government, if substantially the same” allegations or transactions had been publicly disclosed.<sup>11</sup> The change gives discretion to the federal government to allow some actions to proceed that would otherwise be barred by public disclosure.<sup>12</sup> The ACA changed the prohibition on information that had been disclosed in a congressional, GAO, or other report to “other federal report.”<sup>13</sup> This provision of the ACA overrules the Supreme Court’s decision in *Wilson v. Graham County soil and Water Conservation District* which held that publically available information on state or local government reports constituted a public disclosure.<sup>14</sup> The ACA overruled this decision and limits the public disclosure bar to information disclosed in federal reports or in the news media.<sup>15</sup>

Finally, the ACA altered the definition of what constitutes an “original source” under the FCA. Under the ACA changes, an original source is one who 1) has voluntarily disclosed to the government the information on which allegations or transactions in a claim are based, or 2) has knowledge that is independent of and materially adds to the publicly disclosed allegations or transaction, and who has voluntarily provided the information to the government before filing an action.

## **2. Use of FCA in Medicare Fraud Cases**

The FCA is one of, if not the most useful tools to the government in prosecuting fraud against Medicare and Medicaid.<sup>16</sup> The changes from the ACA have increased the ability of *quit*

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<sup>11</sup> *Id.* at page 9-10.

<sup>12</sup> Staman, *supra* note 8.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> See Christopher L. Martin Jr. Reining in Lincoln’s Law: A Call to Limit the Implied Certification Theory Under the False Claims Act. California Law Review. Volume 101, Issue 1, Article 4, 2-1-2013, page 238 Available at: <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=4195&context=californialawreview>; Press Release. *Justice Department Recovers 3.8 Billion from False Claims Act Cases in Fiscal Year 2013.* United States

*tam* plaintiffs to bring suits under the ACA. In June 2012, the Justice Department stated that approximately \$7.4 billion of the \$11 billion recovered under the Act since 2009 came from cases against the health care industry.<sup>17</sup> In the healthcare context, FCA claims commonly arise from billing for services not rendered, billing for unnecessary medical services, double billing for the same service or equipment, or billing for services at a higher rate than provided (“upcoding”).<sup>18</sup>

The federal government recovered \$2.6 billion in healthcare fraud recoveries in fiscal year 2013.<sup>19</sup> The 2013 recovery marked the fourth year in a row that the government recovered more than \$2 billion in fraud cases.<sup>20</sup> From January 2009 through the end of the 2013 fiscal year, the government recovered \$12.1 billion in health care dollars using the False Claims Act.<sup>21</sup> The vast majority of these recoveries were related to Medicare and Medicaid.<sup>22</sup>

### **3. Applicability to in Healthcare Fraud Cases**

To prevail in a FCA action, a plaintiff must show that the defendant ““(1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury.”<sup>23</sup> In the healthcare context, the majority of false claims issues center around the third element, whether the claim was false or fraudulent. A claim

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Department of Justice. Office of Public Affairs. December 20, 2013. Available at:

<http://www.justice.gov/opa/pr/justice-department-recovers-38-billion-false-claims-act-cases-fiscal-year-2013>

<sup>17</sup> Christopher L. Martin Jr. Reining in Lincoln’s Law: A Call to Limit the Implied Certification Theory Under the False Claims Act. California Law Review. Volume 101, Issue 1, Article 4, 2-1-2013, page 238 Available at: <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=4195&context=californialawreview>

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<sup>19</sup> Press Release. *Justice Department Recovers 3.8 Billion from False Claims Act Cases in Fiscal Year 2013*. United States Department of Justice. Office of Public Affairs. December 20, 2013. Available at:

<http://www.justice.gov/opa/pr/justice-department-recovers-38-billion-false-claims-act-cases-fiscal-year-2013>

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001) (discussing elements of a claim under § 3729(a)(1)(A)); Gregory Klass and Michael Holt, *Implied Certification Under the False Claims Act*, Public Contract Law Journal, Vol. 41, No. 1, American Bar Association, Fall 2011. Available at: <http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1641&context=facpub>

can be false or fraudulent in several ways. First, if a claim is for goods or services that have not been rendered, the claim is called a “factually false” claim.<sup>24</sup> Second, a claim may be false or fraudulent if the contractor expressly certifies compliance with a particular regulation or condition despite the fact that it breached the requirement.<sup>25</sup> Such claims are called “legally false” claims based on express certification.<sup>26</sup> Third, some courts have recognized that “a claim for payment itself implicitly represents material compliance with contract terms, statutes, or regulations.”<sup>27</sup> As the implied certification is false, “the claim is again termed ‘legally false’ but now by virtue of an implied certification.”<sup>28</sup>

Each of these three types of claims have the potential to impact medical malpractice cases. In the late 1990s and early 2000s, several commenters began questioning whether the FCA could be used in “quality of care cases” rather than traditional fraud cases.<sup>29</sup> While fears of the FCA replacing traditional medical malpractice law have not been realized, the FCA does have relevance in the medical malpractice world.

### **i. Factually False Claims**

At first glance, the “factually false” claim appears to be the most basic of FCA claims. In the healthcare area, “factually false” claims traditionally centered around payment for medical procedures and services that simply were not performed. However, the advent of the “worthless service” standard has led to an expansion of the “factually false” claim with particular relevance to health care claims. The term “worthless services” first appeared in the Ninth Circuit in *United*

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<sup>24</sup> *Id. citing United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *Mikes*, 274 F.3d at 697.

<sup>25</sup> Klass, *supra* note 15, *citing Mikes*, 274 F.3d at 700; *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994).

<sup>26</sup> *Id. citing Conner*, 543 F.3d at 1218; *Mikes*, 274 F.3d at 699.

<sup>27</sup> *Id.*

<sup>28</sup> Klass, *supra* note 15, page 7.

<sup>29</sup> Patrick A. Scheiderer. *Medical Malpractice as a Basis for a False Claims Action?* Indiana Law Review, Vol. 33, No. 3 (2000). Available at: <https://mckinneylaw.iu.edu/ilr/pdf/vol33p1077.pdf>

*States ex rel. Lee v. SmithKline Beecham, Inc.*<sup>30</sup> In *United States ex rel. Lee*, the relator claimed a laboratory falsified medical test results and submitted claims to Medicare for those tests.<sup>31</sup> The relator claimed that the FCA applied to his claim through an express false certification theory based on a failure to comply with federal testing regulations but the district court dismissed his complaint on the grounds that regulatory violations cannot support an FCA action.<sup>32</sup> However, the Ninth Circuit reversed and granted the relator leave to amend his complaint to include a claim for worthless service. The court held:

In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under §3729, regardless of any false certification conduct... Neither false certification nor a showing of government reliance on false certification for payment need be proven if the fraud claim asserts fraud in the provision of goods and services.<sup>33</sup>

Subsequently, the 2<sup>nd</sup> Circuit further explained the requirements of a “worthless service” claim in *United States ex. Rel. Mikes v. Straus*. In recognizing the “worthless service” claim the 2<sup>nd</sup> Circuit held:

It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided. In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.<sup>34</sup>

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<sup>30</sup> George B. Breen and Daniel C. Fundakowski. *Quality of Care, Medical Necessity, and Worthless Services Under the False Claims Act: Where Are We Headed Now?*. American Health Lawyers Association Physicians and Physicians Organizations Law Institute, February 13, 2013, Page 7. Available at: [https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L\\_breen\\_article.pdf](https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L_breen_article.pdf)

<sup>31</sup> *Id.*; *United States ex. rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048 (9<sup>th</sup> Cir. 2001).

<sup>32</sup> *Lee*, 245 F.3d at 1048; Washington Legal Foundation.

<sup>33</sup> *Id.*

<sup>34</sup> *Mikes*, 274 F.3d at 699.

Virtually every jurisdiction that has adopted the “worthless service” theory uses the standard articulated in *Mikes* that the service must be so deficient as to be the equivalent of no performance at all.<sup>35</sup>

Since *Mikes*, claimants have sought to expand the interpretation of “worthless services” under the FCA. The “worthless service” argument was considered in *United States v. NHC Healthcare Corp.*, where the government alleged that a nursing home submitted false claims for payment because the nursing home was so short staffed that it could not possibly have complied with its obligations under Medicare and Medicaid.<sup>36</sup> The government alleged that a nursing home violated the FCA by submitting claims for services that were “so insufficient and negligent that the claims for reimbursement amounted to fraud.”<sup>37</sup> The Court distinguished between care administered poorly and care not being administered at all.<sup>38</sup> The court held:

[a]t some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient's quality of life. When the provider reaches that point, and still presents claims for reimbursement to Medicare, the provider has simply committed fraud against the United States.<sup>39</sup>

While the Court acknowledged that the line between a standard of care claim and a FCA claim is a “blurry point”, it is worth noting that the Court still set the bar at a fairly high point. An

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<sup>35</sup> See *United States v. Houser*, 754 F.3d 1335, 1344 (11th Cir. Ga. 2014); *United States ex rel. Davis v. U.S. Training Ctr., Inc.*, 498 Fed. Appx. 308, 315 (4th Cir. Va. 2012); *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. Minn. 2009).

<sup>36</sup> James Utterback, *Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care – A Legal and Economic Perspective*, 10 *Quinnipac Health L.J.* 113 (2007); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000).

<sup>37</sup> *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000); George B. Breen and Daniel C. Fundakowski. *Quality of Care, Medical Necessity, and Worthless Services Under the False Claims Act: Where Are We Headed Now?*. American Health Lawyers Association Physicians and Physicians Organizations Law Institute, February 13, 2013, Page 7. Available at: [https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L\\_breen\\_article.pdf](https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L_breen_article.pdf)

<sup>38</sup> George B. Breen and Daniel C. Fundakowski. *Quality of Care, Medical Necessity, and Worthless Services Under the False Claims Act: Where Are We Headed Now?*. American Health Lawyers Association Physicians and Physicians Organizations Law Institute, February 13, 2013, Page 7. Available at: [https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L\\_breen\\_article.pdf](https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L_breen_article.pdf)

<sup>39</sup> *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000).

alleged failure to “perform the minimum necessary care activities required to promote the patient’s quality of life” involves conduct far more egregious than a simple failure to meet the applicable standard of care.

In a more recent case, *United States v. Villaspring Health Care Center, Inc.* a district court held that when alleging claims for worthless service “[i]t is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that ‘patients were not provided the quality of care’ which meets the statutory standard.”<sup>40</sup>

The language in the Court’s opinion has led to some concern that *Villaspring* will lead to quality of care claims under the FCA which would prolong many relators cases and expose providers to pre-trial discovery.<sup>41</sup> Despite these concerns, *Villaspring* does not truly expand the reach of the “worthless service” theory. The “statutory standard” referred to by the Court is the same standard articulated in *NHC* and, as discussed above, it is a high standard for a plaintiff to meet. While there are some fact patterns where a plaintiff could bring an action for worthless service under the FCA as well as a medical malpractice suit, the “worthless service” theory is not likely to permit much overlap with traditional quality of care claims.

## 1. False Express Certifications

“False express certifications are, from a doctrinal point of view, the easy cases.”<sup>42</sup> A contractor expressly represents to the Government that it has complied with a particular

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<sup>40</sup> [https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L\\_breen\\_article.pdf](https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L_breen_article.pdf); George B. Breen and Daniel C. Fundakowski. *Quality of Care, Medical Necessity, and Worthless Services Under the False Claims Act: Where Are We Headed Now?*. American Health Lawyers Association Physicians and Physicians Organizations Law Institute, February 13, 2013, Page 7. Available at:

[https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L\\_breen\\_article.pdf](https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L_breen_article.pdf)

<sup>41</sup> George B. Breen and Daniel C. Fundakowski. *Quality of Care, Medical Necessity, and Worthless Services Under the False Claims Act: Where Are We Headed Now?*. American Health Lawyers Association Physicians and Physicians Organizations Law Institute, February 13, 2013, Page 7. Available at:

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<sup>42</sup> *Klass*, supra note 15, citing *Mikes*, 274 F.3d at 700; *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994).

regulation or requirement when it knows that statement is false.<sup>43</sup> In *United States ex rel. Riley v. St. Luke's Episcopal Hospital*, a nurse brought a qui tam suit against a hospital claiming it filed false claims certifying that the patient hospitalizations and upgrades to its intensive care unit were medically necessary.<sup>44</sup> The key portion of the express certification claim was that the hospital submitted Medicare claim forms stating that “the services shown on this form were medically indicated and necessary for the health of the patient.”<sup>45</sup> The 5<sup>th</sup> Circuit held that the plaintiff had stated a claim under the FCA because it claimed the hospital executed the forms with the knowledge that its certifications of medical necessity were false and not merely scientifically debatable or erroneous.<sup>46</sup> Unlike the theories of factually false claims and implied false certifications, the express false certification theory leaves little room for expansion because, by its nature, it requires an express certification.

## 2. Implied False Certification

While express false certification cases may be “the easy cases”, implied false certification cases are among the most challenging FCA cases and have produced the most disagreement among federal courts. The theory of implied false certification itself is controversial and not accepted universally by the circuit courts. Additionally, the theory has wide-ranging implications that have the potential to reshape medical malpractice law throughout the country.

An implied false certification claim arises from a certification, either express or implied, that a provider complied with applicable statutes, rules, and/or regulations.<sup>47</sup> The theory was

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<sup>43</sup> *See Id.*

<sup>44</sup> *United States ex rel. Riley v. St. Luke's Episcopal Hospital*, 355 F.3d 370, 376-78 (5th Cir. 2004); Brian Stimson, *The False Claims Act: A Proper Tool for Enforcing Health Care Quality Standards?*, Washington Legal Foundation Critical Legal Issues. Working Paper Series No. 156, April 2008. available at: <http://www.wlf.org/upload/stimsonfinal.pdf>

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> James Utterback, *Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care – A Legal and Economic Perspective*, 10 Quinnipac Health L.J. 113, 125 (2007).

first applied in *Ab-Tech Construction, Inc. v. United States* in a case involving a business' implied certification that it adhered to the requirements for participation in the minority contractor program.<sup>48</sup> The theory was first applied in the health care context in *Aranda v. Community Psychiatric Centers of Oklahoma*, where a plaintiff claimed that a psychiatric center implicitly certified that Community Psychiatric Center ("CPC") was abiding by applicable statutes, rules, and regulations requiring minimum staffing levels and that CPC knew it was not providing staffing at required level which led to substandard care.<sup>49</sup> The Center filed a 12(b)(6) motion to dismiss the case arguing that the government did not identify an objective standard of safety or quality of care as a billing requirement and that without an objective standard, CPC could not knowingly fail to comply with it. CPC also argued there was a separate regulatory scheme designed to assure compliance with conditions of participation in the Medicaid program. The district court held that the fact that the standards were not objective presented a problem of measurement but held that "a problem of measurement should not pose a bar to pursuing an FCA claim against a provider of substandard health care services under appropriate circumstances."<sup>50</sup>

At the time of the decision, *Aranda* was considered to be a highly influential case. Proponents of increased regulation in quality of care cases were encouraged by the potential use of the FCA as a mechanism of enforcement and deterrence<sup>51</sup> Conversely, opponents of the use of the FCA to enforce quality of care standards found the decision to set a dangerous precedent

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<sup>48</sup> Christopher L. Martin Jr. Reining in Lincoln's Law: A Call to Limit the Implied Certification Theory Under the False Claims Act. California Law Review. Volume 101, Issue 1, Article 4, 2-1-2013, page 240 Available at: <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=4195&context=californialawreview>; citing *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 431-36 (1994), aff'd mem., 57 F.3d 1084 (Fed. Cir. 1995) (unpublished table decision).

<sup>49</sup> *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc.*, 945 F. Supp. 1485 (W.D. Okla. 1996);

<sup>50</sup> *Id.*; James Utterback, *Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care – A Legal and Economic Perspective*, 10 Quinnipac Health L.J. 113 (2007); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000).

<sup>51</sup> David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*. Annals of Health Law. Vol 6. Issue I 1997, Article 8, p.156.

<http://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1309&context=annals>

which might allow the federal government to take control of quality of care cases from the states.<sup>52</sup> However, the influence of *Aranda* was short-lived.<sup>53</sup>

The Second Court of Appeals drastically changed the landscape of FCA quality of care claims in *United States ex. Rel. Mikes v. Straus*, which was discussed above with reference to the worthless service theory.<sup>54</sup> In *Mikes*, the Second Court of Appeals considered whether the FCA applied to a claim from a pulmonologist relator who argued that the spirometers used in pulmonary tests were not calibrated and the technicians were inadequately trained which rendered the test results virtually useless.<sup>55</sup> The relator based the claim on a Form 1500 filed for payment with Medicare included a certification that the tests were medically necessary. The 2nd Circuit, however, rejected this claim because the Form 1500 only requires the certification that the tests were medically necessary and did not require certification of compliance with other regulations. The Court held that a claim is not “legally false simply because the particular service furnished failed to comply with the mandates of a statute, regulation, or contractual term that is only tangential to the service for which reimbursement is sought...” The Court held that the FCA “does not encompass those instances of regulatory non-compliance that are irrelevant to the government’s disbursement decisions.” The Court held:

the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations-but rather only those regulations that are a precondition to payment-and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach. Moreover, a

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<sup>52</sup> James Utterback, *Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care – A Legal and Economic Perspective*, 10 Quinnipac Health L.J. 113, 177 (2007); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000); Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act*, Indiana Law Journal, Vol. 73, Issue 3, p. 544 (discussing potential FCA liability from breaches of any of the 100,000 Medicare and Medicaid Regulations).

<sup>53</sup> Devin S. Schindler, *Pay for Performance, Quality of Care and the Revitalization of the False Claims Act*, Health Matrix, Vo. 19:387, page 403, available at: <http://www.law.cwru.edu/studentLife/organizations/healthmatrix/files/Schindler%20PDF.pdf>

<sup>54</sup> *United States ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001).

<sup>55</sup> *Id.*

limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the federal government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that "the regulation of health and safety matters is primarily, and historically, a matter of local concern."<sup>56</sup>

The court held that "Liability under the Act may properly be found therefore when a defendant submits a claim for reimbursement while knowing-as that term is defined by the Act, that payment expressly is precluded because of some noncompliance by the defendant."<sup>57</sup> The court also noted that "permitting *qui tam* plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as plaintiff."<sup>58</sup> The Second Circuit thus limited the application of the implied certification theory to only those regulations that are a precondition to payment.

The *Mikes* decision was and continues to be highly influential. The court's holding, that implied certification may only be applied when the underlying statute or regulation upon which the plaintiff relies expressly state that the provider must comply in order to be paid has been called the "compliance-condition rule."<sup>59</sup> The "compliance-condition rule" established by *Mikes* is considered the majority view on the implied false certification theory and it is "followed almost universally throughout the circuits."<sup>60</sup>

Conversely, the rule established in *Aranda* and subsequently followed in *NHC Healthcare Corp.* is termed the "condition of participation" theory. In essence, this theory holds

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<sup>56</sup> *Id.* at 700.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*, citing Patrick A. Scheiderer, Note, *Medical Malpractice as a Basis for a False Claims Action?*, 33 Ind. L. Rev. 1077, 1098-99 (2000).

<sup>59</sup> Gregory Klass and Michael Holt, *Implied Certification Under the False Claims Act*, Public Contract Law Journal, Vol. 41, No. 1, American Bar Association, Fall 2011. Available at: <http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1641&context=facpub>

<sup>60</sup> *United States v. Dialysis Clinic, Inc.*, 2011 U.S. Dist. LEXIS 4862 (N.D.N.Y. Jan. 19, 2011).

that when a contractor submits a claim for payment to Medicare or Medicaid, the contractor “impliedly certifies compliance with all preconditions for payment, plus all health care quality requirements for participating in the program.”<sup>61</sup> Widespread adoption of the “condition of participation” theory would have enormous implications for medical malpractice law because it would open up the False Claims Act as a vehicle for traditional malpractice cases when there is an allegation of failure to comply with federal regulations.<sup>62</sup>

At present, only the U.S. District Court for the Western Districts of Oklahoma and Missouri have endorsed the condition of participation theory in Medicare or Medicaid cases.<sup>63</sup> The 5<sup>th</sup> Circuit has not yet recognized the implied certification theory. However, the 5<sup>th</sup> Circuit has “repeatedly upheld the dismissal of false-certification claims (implied or otherwise) when a contractor’s compliance with federal statutes, regulations, or contract provisions was not a “condition” or “prerequisite” for payment under a contract.”<sup>64</sup> Similarly, the 5<sup>th</sup> Circuit noted that “even if a contractor falsely certifies compliance (implicitly or explicitly) with some statute, regulation, or contract provision, the underlying claim for payment is not “false” within the meaning of the FCA if the contractor is not required to certify compliance in order to receive payment.”<sup>65</sup> Thus, while the 5<sup>th</sup> Circuit has not recognized implied certification, if it did ultimately accept the theory, the Court would likely follow *Mikes* in its application.

At present, the majority of jurisdictions follow the “condition of payment” rule. However, the Supreme Court has not yet ruled on this issue and this area of law will continue to develop as FCA claims continue to increase. Medical malpractice attorneys on both sides of the

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<sup>61</sup> Brian Stimson, *The False Claims Act: A Proper Tool for Enforcing Health Care Quality Standards?*, Washington Legal Foundation Critical Legal Issues. Working Paper Series No. 156, April 2008. Page 10, available at: <http://www.wlf.org/upload/stimsonfinal.pdf>

<sup>62</sup> See *Id.* at p. 16-17.

<sup>63</sup> *Id.* at

<sup>64</sup> *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. Tex. 2010)

<sup>65</sup> *Id.*

bar should keep careful watch on this area of the law as it has the potential to greatly influence medical malpractice law.

### **c. Conclusion**

While the False Claims Act is not applicable to the vast majority of Texas health care liability claims, it may touch on issues germane to health care liability cases. First, though rare, there are certain fact patterns that give rise to both medical malpractice and FCA cases. Such cases might include instances where a provider claimed to perform a service that was not done and the patient experienced harm as a result. Admittedly, such cases would be charitably considered “challenging” for defense attorneys but practitioners should be prepared for the additional complications the False Claim Act could bring to such suits. Also, particularly significant for defense counsel are situations where they may uncover potential FCA violations during the investigation of a medical malpractice suit. While such violations may not give rise to an independent malpractice suit, they may merit referral or further investigation. Finally, as a result of increased recovery in fraud cases, it is likely that prosecution of fraud cases will only increase in coming years and these cases will continue to have implications in the world of medical malpractice.

## **III. Electronic Health Records**

### **a. Definitions and Use**

An Electronic Health Record (EHR) “is an electronic version of a patient’s medical history, that is maintained by the provider over time and may include all of the key administrative clinical data relevant to that persons care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history,

immunizations, laboratory data and radiology reports.”<sup>66</sup> CMS describes EHRs as “the next step in the continued progress of healthcare that can strengthen the relationship between patients and clinicians.”<sup>67</sup> According to Medicare, EHRs can help lower the chances of medical errors, eliminate duplicate tests, improve the overall quality of care, and help providers have up to date information.<sup>68</sup>

### **b. Regulation and expansion**

In 2011, CMS started an EHR incentive program to encourage providers to utilize electronic medical records.<sup>69</sup> Under the incentive program, providers who demonstrated meaningful use could receive up to \$43,720 for five continuous years.<sup>70</sup> However, beginning in 2015, the program changes from an incentive program to a penalty.<sup>71</sup> After 2015, eligible professionals who do not successfully demonstrate meaningful use will be subject to a payment adjustment that starts at 1% of each payment and increases by 1% each year a provider does not demonstrate “meaningful use” up to a maximum of 5%.<sup>72</sup>

As of May 2014, CMS had paid \$14.6 billion in incentive payments to hospitals and health systems for the adoption and use of EHRs.<sup>73</sup> The EHR market is expected to reach \$9.3 billion annually by the end of 2015.<sup>74</sup> By 2013, at least 59% of non-federal acute care hospitals

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<sup>66</sup> *Electronic Health Records*. Center for Medicare and Medicaid Services. *available at*: <https://www.cms.gov/Medicare/E-Health/EHealthRecords/index.html?redirect=/ehealthrecords/>

<sup>67</sup> *Id.*

<sup>68</sup> *Electronic Health Records (EHRs)*. Medicare.gov. *available at*: <http://www.medicare.gov/manage-your-health/electronic-health-records/electronic-health-records.html>

<sup>69</sup> Medicare and Medicaid EHR Incentive Program Basics. Center for Medicare and Medicaid services. *available at*: <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Basics.html>

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> Helen Gregg. 50 Things to Know About Epic, Cerner, MEDITECH, McKesson, athenahealth and Other Major EHR Vendors, Becker’s Hospital Review, July 14, 2014, *available at*: <http://www.beckershospitalreview.com/healthcare-information-technology/50-things-to-know-about-epic-cerner-meditech-mckesson-athenahealth-and-other-major-ehr-vendors.html>

<sup>74</sup> *Id.*

had at least a basic EHR system.<sup>75</sup> Despite the concerns addressed below, EHRs are likely here to stay and will continue to influence healthcare and malpractice cases.

### **c. Practical Concerns for Providers**

Despite the high expectations from both regulatory agencies and commenters, EHRs have not been universally successful in clinical practice and providers have reported practical concerns with EHRs. A 2013 study by the RAND Corporation found that EHRs can worsen physicians' professional satisfaction in multiple ways. Physicians complained of poor usability, time-consuming data entry, interference with face to face patient care, inefficient and less fulfilling work content, inability to exchange health information, and degradation of clinical documentation.<sup>76</sup> Following this survey, the AMA issued a call for solutions to EHR systems that have neglected usability as a necessary feature.<sup>77</sup> While both the AMA and Rand Studies show that physicians do not want to return to paper records, physicians do believe that EHR systems require too much data entry which leaves less time for patients.<sup>78</sup>

Another concern for health care providers is the possibility of a system failure or other type of technology failure. In 2012, Trinity Medical Center in North Dakota filed a lawsuit against its EHR vendor alleging the system, which was purchased in 2008, was defective and did not deliver the expected business benefits.<sup>79</sup> The matter went to arbitration and ultimately settled

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<sup>75</sup>Dustin Charles, MPH; Meghan Gabriel, PhD; Michael F. Furukawa, PhD, Adoption of Electronic Health Record Systems Among U.S. Non-Federal Acute Care Hospitals: 2008-2013; ONC Data Brief No. 16, May 2014. *available at:* <http://www.healthit.gov/sites/default/files/oncdatabrief16.pdf>

<sup>76</sup> Mark W. Friedberg, et. al. Factors Affecting Physician *Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy*, Rand Corporation. 2013. *available at:* [http://www.rand.org/pubs/research\\_reports/RR439.html](http://www.rand.org/pubs/research_reports/RR439.html)

<sup>77</sup> AMA Calls for Design Overhaul of Electronic Health Records to Improve Usability. Press Release. American Medical Association. September 16, 2014. *available at:* <http://www.ama-assn.org/ama/pub/news/news/2014/2014-09-16-solutions-to-ehr-systems.page>

<sup>78</sup> *Id.*

<sup>79</sup> Helen Gregg, *Cerner, Trinity Settlement Totals \$106m*, Becker's Hospital Review. March 10, 2014, *available at:* <http://www.beckershospitalreview.com/healthcare-information-technology/cerner-trinity-settlement-totals-106m.html>

for \$106 million.<sup>80</sup> In 2013, Sutter Health in Northern California experienced a system wide crash that left providers without access to records of the medications patients were taking, patient history data, and other information.<sup>81</sup> Additionally, health care providers can find themselves particularly vulnerable in billing disputes with EHR vendors. In some instances, EHR vendors have shut down a system when a provider failed to pay in a timely manner.<sup>82</sup> While shutting down service for non-payment is hardly uncommon to any communication or service provider, the practice can have devastating results in the field of health care. Healthcare providers can be exposed to a host of liability exposure from a failure to make a simple payment.

#### **d. Liability Concerns**

In addition to systems underperformance in general, healthcare providers may also encounter a single failure that could have devastating consequences for the patient. One example of a dispute over EHR use arose during the first reported case of Ebola in the United States.<sup>83</sup> The hospital initially indicated that the functionality of the EHR system contributed to a delay in diagnosis.<sup>84</sup> The EHR vendor strongly denied this claim.<sup>85</sup> Many commentators suspected that the EHR vendor invoked a “gag order” in its contract with the hospital to prevent further public

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<sup>80</sup> *Id.*

<sup>81</sup> Erin McCann. *Setback for Sutter After \$1B EHR Crashes*. Healthcare IT News. August 28, 2013. available at: <http://www.healthcareitnews.com/news/setback-sutter-after-1b-ehr-system%20crashes>

<sup>82</sup> Christopher Rowland. *Billing Dispute Leads to Blocked Patient Data in Maine*. Boston Globe. September 22, 2014. Available at: <http://www.bostonglobe.com/news/nation/2014/09/21/electronic-health-records-vendor-compugroup-blocks-maine-practice-from-accessing-patient-data/6ILpMv78NARDsrdU500T9N/story.html>

<sup>83</sup> Miles Mofeit and Reese Dunklin, *Hospital E-Records Systems Like Presbyterian’s Cited in Failures Across U.S.* Dallas Morning News. October 10, 2014. available at: <http://www.dallasnews.com/news/metro/20141010-hospital-record-system-failures-seen-across-u.s.-cited-in-errors.ece>

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

discussion.<sup>86</sup> The episode highlights the challenges that integrating EHRs into real world practices can present.<sup>87</sup>

Another example of EHR system errors occurred in 2009, when the Veterans Affairs' EHR system experienced several software errors that put patients at risk through drug dosage errors.<sup>88</sup> Between 2008 and 2010, the FDA conducted a study of adverse events from EHRs reported to the FDA. The study determined that out of 899,768 reports, 436 unique events involved health information technology, including EHRs, and 46 were associated with patient harm.<sup>89</sup>

Dean F. Sittig, Ph.D and Hardeep Singh, M.D., M.P.H., writing in *Pediatrics*, identified several key areas of concern for expanded liability for healthcare providers who use integrated EHR systems. EHRs can store “virtually unlimited amounts of perfectly legible and instantly accessible records” which can lead to “information overload.”<sup>90</sup> Additionally, EHRs often rely on documentation templates and forms that automatically import information. The use of templates, according to Sittig and Singh, may increase the risk of repeated errors and additionally may make it more difficult to spot errors if they are contained in a long string of similar-looking information.<sup>91</sup>

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<sup>86</sup> *Id.*

<sup>87</sup> Miles Mofeit and Reese Dunklin, *Hospital E-Records Systems Like Presbyterian's Cited in Failures Across U.S.* Dallas Morning News. October 10, 2014. available at: <http://www.dallasnews.com/news/metro/20141010-hospital-record-system-failures-seen-across-u.s.-cited-in-errors.ece>

<sup>88</sup> Sharona Hoffman, Andy Podgurski. *E-Health Hazards: Provider Liability and Electronic Health Record Systems.* Berkley Technology Law Journal. Volume 24, Issue 4 Fall, Article 6, page 1544, September 2009. <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1813&context=btlj>

<sup>89</sup> Jordan Robertson. *Digital Health Records' Risks Emerge as Deaths Blamed on Systems*, Bloomberg Business. June 25, 2013, available at: <http://www.bloomberg.com/news/2013-06-25/digital-health-records-risks-emerge-as-deaths-blamed-on-systems.html>; CITE TO STUDY ALSO

<sup>90</sup> Dean F. Sittig, PhD, Hardeep Singh, M.D., MPH, *Legal, Ethical and Financial Dilemmas in Electronic Health Record Adoption and Use.* *Pediatrics*. 2011 Apr; 127(4): e1042–e1047. available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3065078/>

<sup>91</sup> *Id.*

CRICO, a malpractice insurance company, conducted a study of Harvard affiliates and discovered 147 instances in which EHRs were a contributing factor to the claim.<sup>92</sup> The study demonstrates that several of the fears articulated by Sittig and Singh have been realized in real world application. The study further broke down the various cases of the EHR-related error and the results are instructive regarding potential areas of exposure for healthcare providers who use EHRs. In 20% of the 147 cases incorrect information was placed in the EHR.<sup>93</sup> The study listed faulty data entry, unexpected auto-conversion of data, data entered into the wrong field, and repeated errors persisting in the chart as examples. The study estimated 16% of the CRICO cases involved issues with the conversion of the paper records to the EHR system. In these instances, information between the paper chart and EHR was not consistent. Most of the cases in the study involved either medication ordering or medication administration or diagnosis.

Despite the increased risk of liability from both a practical and technological standpoint to healthcare providers, in many instances providers will find themselves without recourse against their EHR vendor in the instance of a system failure. Many EHR vendors have provisions in their contracts that significantly limit their liability to their customers.<sup>94</sup> In fact, the Texas Medical Association and many other medical associations provide warnings to physicians regarding these types of contractual provisions.<sup>95</sup> Accordingly, in the event of litigation, the contracts between vendors and providers could be very important in determining liability.

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<sup>92</sup> Debra Bradley Ruder. *Malpractice Claims Analysis Confirms Risks in EHRs*. Patient Safety & Quality Healthcare vol. 11, issue 1, January/February 2014.

[https://www.rmhf.harvard.edu/~media/Files/\\_Global/KC/News/psqhruder\\_r3\\_jmm.pdf](https://www.rmhf.harvard.edu/~media/Files/_Global/KC/News/psqhruder_r3_jmm.pdf)

<sup>93</sup> *Id*

<sup>94</sup> *EHR Contracts: Key Contract Terms for Users to Understand*, Westat, Prepared for the Office of the National Coordinator for Health Information Technology, June 25, 2013, available at:

[http://www.healthit.gov/sites/default/files/ehr\\_contracting\\_terms\\_final\\_508\\_compliant.pdf](http://www.healthit.gov/sites/default/files/ehr_contracting_terms_final_508_compliant.pdf); EHR Buyer Beware: Issues to Consider When Contracting with EHR Vendors. Texas Medical Association. 2011. available at: <http://www.texmed.org/Template.aspx?id=21977>

<sup>95</sup> EHR Buyer Beware: Issues to Consider When Contracting with EHR Vendors. Texas Medical Association. 2011. available at: <http://www.texmed.org/Template.aspx?id=21977>

#### **e. Regulation of EHR Vendors**

EHR Vendors are not subject to mandatory reporting and the FDA does not enforce its regulatory requirements regarding HIT.<sup>96</sup> While there are guidelines that EHR vendors must meet in order to be a certified system, EHR vendors are not regulated by any other means. Use of a certified EHR vendor allows a provider to obtain funds under the EHR incentive program and thus certification is an attractive asset to an EHR vendor. However, certification is not mandatory and the guidelines for certification pale in comparison to regulation of other health industries.

#### **f. Patient Claims Against Vendors**

Whether an EHR vendor is entitled to the protections of Chapter 74 of the Texas Civil Practice and Remedies Code is currently an open question. Section 74.001(12)(a) provides that a healthcare provider is “. . . any person, partnership, professional association, corporation, facility, or institution duly licensed, certified, registered, or chartered by the State of Texas to provide health care...”<sup>97</sup> However, subsection B(ii) provides that the term includes: an employee, independent contractor, or agent of a health care provider or physician acting in the course and scope of the employment or contractual relationship.”<sup>98</sup> In the event of such a suit against a vendor, the vendor may rely on §74.001(12)(B)(ii) to argue that it is a “health care provider” because it is a contractor of a health care provider or physician. Though this provision has never been applied to EHR vendors, several outside contractors have attempted this argument with varying degrees of success.

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<sup>96</sup> Farah Magrabi, PhD, et. al. *Patient Safety Problems Associated With Healthcare Information Technology: an Analysis of Adverse Events Reported to the US Food and Drug Administration*. AMIA Annu Symp Proc. 2011; 2011: 853–857. available at: [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243129/#b5-0853\\_amia\\_2011\\_proc](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243129/#b5-0853_amia_2011_proc)

<sup>97</sup> Tex. Civ. Prac. & Rem. Code §74.001(12)(a).

<sup>98</sup> *Id.* at (B)(ii).

In *Doctor's Data Inc. v. Stemp*, the Defendant laboratory argued on appeal it was an independent contractor of a clinic and thus entitled to the protections of Chapter 74. Doctor's data did not argue the issue at the trial court level and the Court of Appeals thus held it could not be a ground for reversal. However, in dicta the Court noted that the laboratory did not offer evidence it is licensed, certified, registered, or chartered by the State of Texas to provide health care. The Court thus observed that even if Doctor's Data were an independent contractor of the clinic, it would not be a healthcare provider.

In *ProPath*, the Court held a laboratory was entitled to the protections of Chapter 74. The Plaintiff argued that a laboratory was not specifically mentioned in §74.001(12)(A) and therefore the laboratory could not be entitled to the protections of the statute. However, the Court noted a significant distinction between former article 4590i and Chapter 74. Under former article 4590i, the list of health care providers was an exclusive list of individuals and entities. However, Chapter 74 does not contain an exclusive list.<sup>99</sup> The Court held that the language of Chapter 74 did not preclude a laboratory from the protections of Chapter 74. However, it should be noted that though the Court in *Propath* found that the laboratory was entitled to the provisions of Chapter 74 the court actually found the laboratory was a "physician" under the statute because it was organized by a group of physicians. While *Pro Path* clearly demonstrates that §74.001(12)(A) is not an exclusive list, it provides little precedent that dictates EHR vendors are entitled to the protections of Chapter 74.

Another potential hurdle for EHR vendors is that the State of Texas does not currently license, certify, register, or charter EHR vendors. As discussed above, EHR vendors are encouraged but not required to participate in federal certification. However, this requirement is only a federal requirement and is not imposed by the State of Texas. While distinction may

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<sup>99</sup> *Pro Path Servs., L.L.P. v. Koch*, 192 S.W.3d 667, 671 (Tex. App. Dallas 2006).

appear technical, the Court in *Stemp* explicitly noted that the State of Texas does not license “homeopathic, naturopathic, or such facilities” and that Doctor’s Data, thus, could not be considered a health care provider. Similarly, a court may not consider EHR vendors to be health care providers because they are not regulated by the State of Texas.

### **g. Use in Medical Malpractice Cases**

EHRs also present challenges to attorneys prosecuting and defending medical malpractice suits. Just as physicians and healthcare providers can suffer from “information overload”, attorneys and their experts can also find themselves overwhelmed by the sheer volume of information available in the medical chart. Another issue is that many EHR systems are not always designed to be read in printed form. While EHRs can almost always be physically printed, they are often difficult to read and interpret when not linked to their companion systems.<sup>100</sup> Additionally, EHR systems are not universal and attorneys may make faulty assumptions when interpreting EHRs. Like physicians and healthcare providers, medical malpractice attorneys are adjusting to the new challenges brought by EHRs.

## **I. Public Health Emergencies**

### **a. Background**

Public health emergencies present unique challenges to the health care system. Federal, state, and local health care systems change to reflect many of these unique challenges and these changes can have wide-ranging effects on litigation. A public health emergency may appear to be a distant possibility to some but in 2014 the State of Texas very seriously considered

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<sup>100</sup> Chris Dimick. *EHRs Prove a Difficult Witness in Court*. Journal of AHIMA. September 24, 2010. *available at*: <http://journal.ahima.org/2010/09/24/ehrs-difficult-witness-in-court/>

declaring a public health emergency related to the presence of Ebola in Dallas.<sup>101</sup> The example of a highly contagious virus highlights the fact that public health crises can emerge quickly and without warning. Thus, healthcare litigators should have a basic understanding of how public health emergencies can change healthcare liability.

#### **b. Basic Structure of Texas Public Health Disaster Response**

Depending on the nature of the emergency, a public health emergency can involve local, state and federal resources. A full summary of the intricacies of the various resources is beyond the scope of this paper. However, the information below serves as a short primer on the key actors involved in such a response. Under both Texas and federal law, a declaration of a public health emergency or public health disaster is the key triggering event for many changes in the health care system. Under section 319 of the Public Health Act, the Secretary of the Department of Health and Human Services may “determine that: a) a disease or disorder presents a public health emergency; or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.”

In Texas, the Communicable Disease Prevention and Control Act provides the authority for control measures including detention, restriction and quarantine. Pursuant to Texas Health and Safety Code §81.003, a declaration of a “public health disaster” requires the governor’s declaration of a state of disaster and the commissioner’s determination of an immediate threat from communicable disease with a high risk of death or serious long-term disability to a large number of people or with a substantial risk of public exposure due to the disease’s high level of contagion or the method of transmission.<sup>102</sup> A “public health disaster” may continue for no more

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<sup>101</sup> Lindsey Bever, *Dallas County Officials Seeking Travel Restrictions to Keep Ebola in Check*. The Washington Post, October 16, 2014, available at: <http://www.washingtonpost.com/news/morning-mix/wp/2014/10/16/dallas-county-officials-seeking-travel-restrictions-to-keep-ebola-in-check/>

<sup>102</sup> Tex. Health and Safety Code 81.003(7).

than 30 days with one 30-day renewal and the governor may terminate a declaration of a public health disaster at any time. The declaration of a “public health disaster” triggers many changes that drastically change Texas health care.

### **1. Powers Granted in Public Health Disasters**

Once a disaster has been declared, the commissioner or health authority are granted many increased powers. If the governor declares a state of disaster, he or she has the authority to waive regulatory requirements, including licensing laws and rules.<sup>103</sup> Pursuant to section 241.026(c) of the Texas Health and Safety Code, the Board of Health may waive or modify hospital licensing laws or rules to facilitate “the creation or operation of the hospital and if the waiver or modification is in the best interests of the individuals served or to be served by the hospital.”<sup>104</sup> The Board of Health delegated its authority to exercise this power to the Commissioner of Health.<sup>105</sup> The procedures for obtaining a waiver are located at 25 T.A.C. 133.81.<sup>106</sup> While this rule appears written for requests from individual hospitals, it “is broad enough to allow the commissioner to apply a particular waiver to all hospitals in an area that is affected.” Such a waiver would significantly impact malpractice cases in the area during the time of the waiver because regulations and standards would no longer be applicable. Any cases filed during the waiver period would thus have to adjust the formulation and determination of the applicable standard of care.

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<sup>103</sup> *Communicable Disease Control Measures in Texas: A Guide for Health Authorities in a Public Health Emergency*. Texas Department of State Health Services. February 2007, page 50. available at: <http://www.dshs.state.tx.us/layouts/contentpage.aspx?pageid=8589954779&id=8589959402&terms=Communicable+Disease+Control+Measures+in+Texas%3a+A+Guide+for+Health+Authorities+in+a+Public+Health+Emergency>

<sup>104</sup> Tex. Health & Safety Code §241.026(c).

<sup>105</sup> *Communicable Disease Control Measures in Texas: A Guide for Health Authorities in a Public Health Emergency*. Texas Department of State Health Services. February 2007, page 50. available at: <http://www.dshs.state.tx.us/layouts/contentpage.aspx?pageid=8589954779&id=8589959402&terms=Communicable+Disease+Control+Measures+in+Texas%3a+A+Guide+for+Health+Authorities+in+a+Public+Health+Emergency>

<sup>106</sup> *Id.*

The health authority also has powers to place control measures on contaminated property. Once the health authority has determined the property is infected or contaminated, the health authority may issue a written order requiring the person who owns or controls the property to impose “control measures to disinfect or decontaminate the property or to secure or destroy the property.”<sup>107</sup> Unlike orders for control measures on a person, there is no requirement that a judge or court approve orders to impose control measures on property.

According to Department of Health and Human Services, it is theoretically possible for a city, county, or portion of a political subdivision to be isolated in the event of an outbreak.<sup>108</sup> The Department of Health and Human Services identifies the governor’s broad authority under the Texas Disaster Act as the likely source of authority should such measures be required.

## **2. Immunities**

Texas provides immunities that significantly change the landscape of health care liability in public health emergency situations. The most broad and significant of the immunities is Section 81.007 of the Texas Health and Safety Code which provides:

A private individual performing duties in compliance with orders or instructions of the department or a health authority issued under this chapter is not liable for the death of or injury to a person or for damage to property, except in a case of wilful misconduct or gross negligence.<sup>109</sup>

Section 81.007 broadly applies immunity but the real world application of the provision is somewhat limited because it is limited to individuals performing duties in compliance with orders or instructions from the Department of Health or a health authority. As discussed above,

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<sup>107</sup> See Tex. Health & Safety Code § 81.084(c)–(d).

<sup>108</sup> *Communicable Disease Control Measures in Texas: A Guide for Health Authorities in a Public Health Emergency*. Texas Department of State Health Services. February 2007. available at: <http://www.dshs.state.tx.us/layouts/contentpage.aspx?pageid=8589954779&id=8589959402&terms=Communicable+Disease+Control+Measures+in+Texas%3a+A+Guide+for+Health+Authorities+in+a+Public+Health+Emergency>

<sup>109</sup> Tex. Health & Safety Code §81.007

many of the powers granted under Chapter 81 are effectively triggered by a declaration of a public health disaster. Thus, immunity for acts related to the quarantine of persons or property would not attach until after a declaration of a public health disaster. However, once a disaster is declared, section 81.007 would provide broad immunity to health care providers (among other individuals) who act in compliance with orders from the department or health authority. Given the broad powers granted to the health authority once a public health disaster is declared, immunity under section 81.007 could impact a significant number of health care providers.

Section 79.003 of the Texas Civil Practice and Remedies Code also provides protection for persons giving care, assistance or advice regarding an incident that is a disaster (man made or natural) and in which the care, assistance or advice is provided at the request of local, state, or federal agencies.<sup>110</sup> Section 79.003 does not specifically state that communicable diseases are considered a disaster. However, the provision applies to an incident “that is a man-made or natural disaster that endangers or threatens to endanger individuals, property, or the environment...”<sup>111</sup> The Texas Department of Health and Safety’s Communicable Disease Manual takes the position that “a health authority issuing control measure orders may be considered to be involved in “management of an incident and therefore covered by this provision.”<sup>112</sup> Presumably, the provision would also apply to health care providers rendering care at the request of local, state, or federal agencies. However, the provision does not apply to

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<sup>110</sup> Tex. Civ. Prac. & Rem. Code §79.003.

<sup>111</sup> *Id.* at (a)(1).

<sup>112</sup> *Communicable Disease Control Measures in Texas: A Guide for Health Authorities in a Public Health Emergency*. Texas Department of State Health Services. February 2007, page 47. available at: <http://www.dshs.state.tx.us/layouts/contentpage.aspx?pageid=8589954779&id=8589959402&terms=Communicable+Disease+Control+Measures+in+Texas%3a+A+Guide+for+Health+Authorities+in+a+Public+Health+Emergency>

care that is provided by a person who expects or receives compensation.<sup>113</sup> Additionally, the immunity does not apply to “reckless conduct or intentional, willful or wanton misconduct.”<sup>114</sup>

Texas also provides protection to individuals who provide immunizations to prevent potential outbreaks. Section 161.001 of the Texas Occupations Code provides immunity to providers who administer or authorize the administration of vaccines for injuries caused by the vaccine or immunizing agent.<sup>115</sup> Notably, this immunity exists as long as the vaccine is required by the board or “otherwise required by law.”<sup>116</sup> It would not necessarily apply to a vaccination that was provided ahead of an order of the Health and Safety Department. Additionally, the provision does not protect a provider from negligence in administering the vaccine or immunizing agent.<sup>117</sup>

While both sides of bar undoubtedly hope the need for this information does not arise, both Plaintiff’s and Defense counsel should have a basic working knowledge of the changes a public health disaster can cause to Texas healthcare law to evaluate potential cases and provide appropriate guidance to their clients.

#### **IV. Conclusion**

Health law both directly and indirectly impacts the rights of plaintiffs and defendants in healthcare liability cases. As it is subject to changes from regulations and new technology, health law is in a state of constant flux. Health law can shift as a result of changes in regulatory emphasis, the emergence of new technologies, and even from outside events setting off triggers that exist within the regulatory framework. Healthcare litigation attorneys should follow developments in health law closely as they have the potential to shape medical malpractice law.

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<sup>113</sup> Tex. Civ. Prac. & Rem. Code §79.003(b). .

<sup>114</sup> *Id.* at (a)

<sup>115</sup> Tex. Occ. Code. §161.001(a).

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at (d).