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The *Online* Health Policy and Law Review of  
Loyola University Chicago School of Law

**BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW**

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# ANNALS OF HEALTH LAW

## *ADVANCE DIRECTIVE*

THE *ONLINE* HEALTH POLICY AND LAW REVIEW OF  
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**ANNALS OF HEALTH LAW**  
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Editor's Note

The *Annals of Health Law* is proud to present the fourth Issue of our online journal, *Advance Directive*. Consistent with our goal of promoting student health law scholarship, this Issue features articles addressing the quality of our current healthcare system.

This Issue begins with a look at the different types of health care options that could improve the quality of care in the United States. First, our authors examine concierge medicine as a high quality health care option. Second, our authors explore the quality of care currently provided at retail health clinics. Finally, home healthcare programs are analyzed for their ability to ensure high quality of care for the aging population of baby boomers.

Next, the Issue transitions into examining the advancements in technology that can contribute to improving quality of care. Specifically, our authors suggest that providing education and preventing consumer misconceptions regarding direct-to-consumer genetic testing could improve quality of care; the use of telemedicine can be improved to increase quality by removing licensing and reimbursement barriers; and ; and that telemedicine has the potential to improving quality of care for patients living in rural areas.

The Issue then proposes future changes to the health care system that could improve quality of care for patients. First, our authors propose ways to improve the quality of care in response to disasters. Second, our authors suggest that preventing a physician's morals from interfering with the fiduciary duty of care can improve quality. Third, our authors discuss that health care can be improved through the use of the Physician's Quality Reporting Initiative as a way to

measure a physician's performance. Finally, our authors support that the PROMETHEUS model is a better payment system to improve quality of care because it factors in a patient's health.

Finally, the Issue delves into the financial and legal issues affecting quality of care in the United States. In particular, our authors investigate utilizing a business case for quality of care initiatives; how defensive medicine, as it applies to physicians, patients, lawyers, and Congress, affects the quality of care; the effect of medical malpractice on the quality of care; and how implementing medical malpractice damage caps can improve the quality of care.

We would like to thank Mallory Golas, our *Advance Directive* Senior Editor, and Themistocles Frangos, our Technical Production Editor, for their invaluable contributions in launching this Issue. We would like to specially thank our *Annals* Editor-in-Chief, Kendell Coker, for increasing access to *Advance Directive*. We also are grateful to our *Annals* Executive Board members— Amy Fuetterer, Kevin Lichtenberg, and Victor Allen—for their editorial assistance. Our *Annals* members deserve particular recognition for writing timely, thoughtful articles and for editing the work of their peers. Finally, we extend our warmest appreciation to the Beazley Institute and our faculty advisors, Professors Lawrence Singer and John Blum, for their continued support, encouragement, and mentorship.

We hope you enjoy our fourth Issue of *Advance Directive*.

Sincerely,

Jana E. Harris  
Advance Directive Editor  
*Annals of Health Law*  
Loyola University Chicago School of Law

# ANNALS OF HEALTH LAW

## *ADVANCE DIRECTIVE*

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### *Concierge Medicine: Quality Care for a Price*

*James Stathopoulos\**

#### I. INTRODUCTION

Amidst a considerable amount of debate, a relatively small, but steadily increasing method of providing healthcare has purported to shift the focus of primary care from quantity to quality.<sup>1</sup> “Concierge care” is a method of providing healthcare where patients pay retainer fees for more personalized and comprehensive services from their physicians.<sup>2</sup> This article will discuss the effects that concierge medicine has had on the quality of primary care. First, this article will provide a general description of concierge care and its origins. Second, this article will discuss some of the criticisms of the concierge medicine model. Third, this article will address arguments in support of the concierge care approach. Finally, this article will assess whether concierge care is a viable option for improving the quality of primary care.

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<sup>1</sup> See David E. Williams, *Boutique Medicine: When Wealth Buys Health*, CNN, Oct. 20, 2006, <http://www.cnn.com/2006/US/10/19/bil.healthy.wealthy/index.html>.

<sup>2</sup> See *id.*

## II. CONCIERGE CARE GENERALLY

Concierge care refers to a variety of healthcare practices in which physicians charge patients membership fees in exchange for what may be considered higher quality care, including enhanced services and easier access to a physician.<sup>3</sup> In addition to the membership fees, physicians can also decide whether they will accept Medicare or private insurance payments for services that are not covered by the initial retainer.<sup>4</sup> In general, physicians who practice concierge care see a significantly smaller number of patients, allowing them to spend more time with the patients that have joined the concierge service.<sup>5</sup> Typically, these practices involve primary care physicians who offer around the clock accessibility, same-day or next-day appointments, no waiting times at office visits, comprehensive physical examinations, personalized healthcare plans, and house calls.<sup>6</sup>

The concept of concierge medicine can be traced back to Seattle in the mid-1990s when two former doctors for the Seattle Supersonics decided to open a family practice called MD<sup>2</sup> (pronounced MD squared).<sup>7</sup> This practice was centered on providing families the same level of personalized, high quality care

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<sup>3</sup> U.S. GOV. ACCOUNTABILITY OFFICE, GAO-05-929, PHYSICIAN SERVICES: CONCIERGE CARE CHARACTERISTICS AND CONSIDERATIONS FOR MEDICARE 1 (2005), *available at* <http://www.gao.gov/cgi-bin/getrpt?GAO-05-929> [hereinafter GAO REPORT].

<sup>4</sup> AM. MED. ASS'N, CASH PRACTICE ALTERNATIVES: CONSIDERATIONS FOR PHYSICIANS 1 (2008), *available at* <http://www.ama-assn.org/ama1/pub/upload/mm/368/cash-practice.pdf>.

<sup>5</sup> Williams, *supra* note 1.

<sup>6</sup> John R. Marquis, *Concierge Medical Practices Expanding Across the Nation*, Feb. 2004, [http://www.wnj.com/concierge\\_medicine\\_expansion/](http://www.wnj.com/concierge_medicine_expansion/).

<sup>7</sup> Eric Wahlgren, *Concierge Medicine: Patients Pay Up for a Doctor's Undivided Attention*, DAILY FIN., Feb. 2, 2010, <http://www.dailyfinance.com/story/concierge-medicine-patients-pay-up-for-a-doctors-undivided-att/19349963/>.

that was available to athletes.<sup>8</sup> Today, MD<sup>2</sup> is one of the most expensive concierge medicine practices, requiring an annual fee of about \$25,000 per family.<sup>9</sup> In return, patients are provided unlimited access to their primary care physician who deals with no more than fifty families.<sup>10</sup> However, not all concierge practices are as costly as MD<sup>2</sup> and not all practices are as comprehensive. For instance, the range of concierge services can cost anywhere from a few hundred dollars to tens of thousands of dollars, with variation among the services that are provided.<sup>11</sup>

### III. PROBLEMS WITH CONCIERGE CARE

Although concierge medicine began with just a small handful of doctors and patients, the number of physicians involved in this practice has been steadily increasing.<sup>12</sup> Today, it is estimated that there are about 5,000 physicians practicing concierge care compared to the roughly 120 physicians that practiced this type of care in 2004.<sup>13</sup> These concierge physicians treat nearly 500,000 patients throughout the nation.<sup>14</sup> As the number of physicians and patients continues to grow, so does criticism of this type of practice. Critics tend to focus on the legal and ethical issues that are implicated by the practice of concierge

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<sup>8</sup> *Id.*

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

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

<sup>11</sup> Jeff Levine, *Boutique Medicine: For Your Well-Being? Or the Doctor's?*, AARP BULL. TODAY, Apr. 18, 2008, [http://bulletin.aarp.org/yourhealth/policy/articles/boutique\\_medicine.html](http://bulletin.aarp.org/yourhealth/policy/articles/boutique_medicine.html).

<sup>12</sup> GAO REPORT, *supra* note 3, at 11.

<sup>13</sup> *Id.*; Wahlgren, *supra* note 7.

<sup>14</sup> JoNel Aleccia, *Patients Face Bitter Choice: Pay Up or Lose Care*, MSNBC, Nov. 23, 2009, [http://www.msnbc.msn.com/id/34019606/ns/health-health\\_care/](http://www.msnbc.msn.com/id/34019606/ns/health-health_care/).

medicine.<sup>15</sup> The legal issues are related to compliance with third party payor programs such as Medicare and private insurance contracts.<sup>16</sup> The ethical issues tend to deal with the fear that limiting the number of patients a doctor sees will create a shortage in primary care physicians and concerns that concierge medicine will widen the health disparities in America.<sup>17</sup>

One of these concerns was brought to light in 2002 when House Representative, Henry Waxman, issued a letter to the Secretary and the Inspector General of the Department of Health and Human Services urging them to ensure that concierge medical services were in compliance with the requirements of Medicare.<sup>18</sup> Specifically, Representative Waxman was concerned that some of the services included in patients' membership fees overlapped with services that were also covered by Medicare, which could result in illegal overcharges to patients.<sup>19</sup> These potential Medicare violations could mean that the concierge physicians would be subjected to substantial penalties and may be excluded from Medicare and other federal healthcare programs.<sup>20</sup>

In addition to potential problems concierge medicine may cause with Medicare compliance, this type of service may also generate risks with private

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<sup>15</sup> Vasilios J. Kalogredis J.D., *Should You Consider Concierge Medicine?*, PHYSICIAN'S NEWS DIG., Feb. 2004, <http://www.physiciansnews.com/business/204.kalogredis.html>.

<sup>16</sup> Levine, *supra* note 11.

<sup>17</sup> *Id.*

<sup>18</sup> Letter from Henry A. Waxman, U.S. House of Rep., to Tommy G. Thompson, Sec'y, Dep't of Health & Human Servs., & Janet Rehnquist, Inspector Gen., Dep't of Health & Human Servs. 1 (Mar. 4, 2002), [http://www.conciergemedicinetoday.com/medi\\_030402\\_HHSletter.pdf](http://www.conciergemedicinetoday.com/medi_030402_HHSletter.pdf) [hereinafter Waxman Letter].

<sup>19</sup> *Id.* at 3.

<sup>20</sup> DEP'T OF HEALTH & HUMAN SERVS., OIG ALERTS PHYSICIANS ABOUT ADDED CHARGES FOR COVERED SERVICES 1 (2004), *available at* <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA033104AssignViolationI.pdf>.

insurance companies.<sup>21</sup> Some insurance companies believe that charging membership fees to guarantee services could violate contractual obligations between those companies and the concierge care provider.<sup>22</sup> Some insurers have dropped physicians from their networks because they disapprove of the concierge medicine model.<sup>23</sup> On the other hand, there are several insurers that do not take issue with concierge care, noting that doctors are free to charge for extra services as long as the patients recognize that the insurance company will not reimburse the membership fees.<sup>24</sup>

Another common criticism of concierge care is that it contributes to a growing shortage of primary care physicians<sup>25</sup> and physicians that accept Medicare.<sup>26</sup> Critics argue that allowing doctors to reduce the number of patients they see by the thousands is unconscionable.<sup>27</sup> The remaining, overburdened physicians who are not practicing concierge care will likely be responsible for treating the leftover patients in addition to tending to their own.<sup>28</sup> The fear is that if a growing number of physicians begin to practice concierge medicine and treat fewer patients, overall access to healthcare will be limited.<sup>29</sup>

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<sup>21</sup> Lynn Cook, *Insurers, Doctors at Odds Over 'Concierge' Care*, HOUS. CHRON., Mar. 13, 2008, at B1, available at <http://www.chron.com/disp/story.mpl/headline/biz/5618372.html>.

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

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> Kevin Sack, *Despite Recession, Personalized Healthcare Remains in Demand*, N.Y. TIMES, May 11, 2009, at A12, available at <http://www.nytimes.com/2009/05/11/health/policy/11concierge.html>.

<sup>26</sup> Jeanne Schulte Scott, *Boutique Health Care: Opportunity or Inequity?*, 56 HEALTHCARE FIN. MGMT. 26, 26 (2002).

<sup>27</sup> Marquis, *supra* note 6.

<sup>28</sup> *Id.*

<sup>29</sup> Sack, *supra* note 25.

## IV. THE BENEFITS OF CONCIERGE CARE

Despite these criticisms, proponents of concierge medicine emphasize that such practices are dedicated to providing patients with better quality care.<sup>30</sup> These practices continue to gain popularity, in part, due to physicians' frustrations with the managed care system.<sup>31</sup> Many physicians rush dozens of patients in and out of their offices just to cover the overhead costs that accompany managed care practices.<sup>32</sup> This leaves many doctors feeling unfulfilled and burnt out.<sup>33</sup> Concierge care is also gaining popularity with patients who are tired of visiting their doctors only to get a ten-minute appointment after a two-hour wait.<sup>34</sup> These frustrations, from the standpoint of both patients and physicians, have created an opportunity for concierge care to continue to grow.<sup>35</sup>

One of the nation's largest concierge care services, MDVIP, boasts that more attention focused on fewer patients, results in better health for its patients.<sup>36</sup> Compared to patients with regular insurance, MDVIP patients are up to 40% less likely to end up in a hospital and are up to 74% less likely to be hospitalized than Medicare beneficiaries.<sup>37</sup> The services offered at MDVIP include: extensive physical examinations each year, and include electrocardiograms; vision, hearing, exercise, nutrition, sleep and mental status screenings; risk factor assessments

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<sup>30</sup> See Amanda Cuda, *Put Your Doctor on a Retainer*, CONN. POST, Apr. 18, 2007, available at 2007 WL 7432458.

<sup>31</sup> See Marquis, *supra* note 6.

<sup>32</sup> See Sack, *supra* note 25.

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

<sup>34</sup> *Id.*

<sup>35</sup> See *id.*

<sup>36</sup> Wahlgren, *supra* note 7.

<sup>37</sup> *Id.*

focusing on the patient's lifestyle and family history; electronic medical records; and personal websites that allow patients to track their own health.<sup>38</sup> In addition, doctors at MDVIP are personally available twenty-four hours a day and office visits may typically last about fifty minutes.<sup>39</sup>

In light of concerns that charging patients retainer fees while still accepting Medicare payments may violate provisions of Medicare, the Government Accountability Office (GAO) issued a report in 2005, after investigating these practices.<sup>40</sup> Although the report recognized that there may be circumstances where concierge practices could violate Medicare requirements, the GAO concluded that charging patients a retainer fee is not a per se violation.<sup>41</sup> Ultimately, the GAO found that concierge practices are permitted as long as the membership does not result in additional charges for items or services that are already covered by Medicare.<sup>42</sup> In addition, concierge care practitioners often implement various practice strategies to ensure that their practices comport with the requirements of the Medicare program.<sup>43</sup>

The GAO also expressed interest in the potential adverse effects that concierge care could have on Medicare beneficiaries' access to physician services.<sup>44</sup> At the time the report was issued, the GAO concluded that the small number of concierge physicians was unlikely to create widespread access

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<sup>38</sup> Cuda, *supra* note 30.

<sup>39</sup> *Id.*

<sup>40</sup> See GAO REPORT, *supra* note 3.

<sup>41</sup> *Id.* at 4.

<sup>42</sup> *Id.*

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

<sup>44</sup> *Id.*

problems; however, at that time, the report only found that about 146 physicians were practicing concierge care.<sup>45</sup> Recognizing the steadily increasing number of concierge physicians,<sup>46</sup> the GAO decided to keep track of developments in the area of concierge care,<sup>47</sup> but has yet to find any widespread access problems stemming from this practice.

Despite the criticism that concierge care exacerbates the shortage of primary care physicians by leaving an increasing number of patients to be treated by a decreasing number of doctors, some concierge physicians claim that they may have left the practice of medicine entirely, but-for the concierge model.<sup>48</sup> Proponents of concierge medicine believe that the reduced number of patients and increased personal interactions have created a vehicle by which many primary care physicians can actually extend their careers and continue treating patients.<sup>49</sup>

In addition, the American Medical Association (AMA) found that concierge care is consistent with the AMA's support of diversity in the delivery and financing of healthcare, but notes that physicians must observe their ethical obligations when making the transition to fee-based services.<sup>50</sup> The AMA requires that physicians who leave their traditional practice for the concierge model facilitate the transfer of their non-participating patients to other doctors.<sup>51</sup> Once in the practice of concierge medicine, it is important that the physicians and

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<sup>45</sup> *Id.* at 4, 9.

<sup>46</sup> *See id.* at 11.

<sup>47</sup> *Id.* at 4.

<sup>48</sup> Sack, *supra* note 25.

<sup>49</sup> Wahlgren, *supra* note 7.

<sup>50</sup> Kalogredis, *supra* note 15.

<sup>51</sup> *Id.*

the patients fully understand the terms of the relationship, including the services that are covered by the retainer fee and those that are not.<sup>52</sup> In addition, the AMA requires the inclusion of an opt out provision of the retainer contract for patients, so that they may do so without undue inconvenience or financial penalty.<sup>53</sup>

## V. CONCLUSION

The effects of concierge care on both physicians and patients seem to have many potential benefits. From the physician's perspective, a limited patient-base means that the doctors are not rushing through thousands of patients per year in ten to fifteen minute increments.<sup>54</sup> Some physicians believe that this allows them to provide superior treatment because they can spend more time listening to patients and focusing on wellness and prevention, while spending less time worrying about paperwork and coverage restrictions.<sup>55</sup> From the patient's perspective, it remains a viable method for providing higher quality care by allowing more personalized services and greater accessibility to one's primary care physician.

Although there exists a considerable amount of criticism relating to the practice of concierge medicine, the GAO concluded that concierge medicine does not implicate any legal issues as long as physicians comply with the relevant Medicare requirements.<sup>56</sup> The AMA recognized that as long as patients are well informed about the nature of their relationships with their concierge physicians

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<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> Levine, *supra* note 11.

<sup>55</sup> Marquis, *supra* note 6.

<sup>56</sup> GAO Report, *supra* note 3, at 4.

and the physicians adhere to the applicable ethical standards, the practice is consistent with the AMA's policy of providing patients with diversity in the delivery and financing of healthcare.<sup>57</sup> As long as the increasing numbers of concierge practitioners does not inhibit access to primary care physicians, concierge medicine should continue to be an option for those seeking high quality care, so long as they can afford it.

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<sup>57</sup> Kalogredis, *supra* note 15.

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### *Retail Healthcare Clinics: A Measure of Quality*

*Naomi Rivas Gonzalez*\*

#### I. INTRODUCTION

Healthcare is a capital intensive industry that is constantly evolving in its methods of providing care. Relative newcomers to the healthcare scene are retail clinics, which offer a new business model of urgent care.<sup>1</sup> Strategically located in pharmacies, discount stores, and other retail stores, retail clinics emphasize convenience to their patients.<sup>2</sup> Retail clinics operate on a walk-in basis offering patients short waiting times for treatment of minor acute conditions as well as immunizations.<sup>3</sup> Furthermore, instead of seeing a physician, patients almost exclusively are treated by nurse practitioners and physician assistants, which greatly reduce patients' cost of service.<sup>4</sup> Since their inception in 2000, the

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<sup>1</sup> Ateev Mehrotra et al., *Comparing Costs and Quality of Care at Retail Clinics with that of Other Medical Settings for 3 Common Illnesses*, 151 ANNALS INTERNAL MED. 321, 321 (2009).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> Ateev Mehrotra et al., *Retail Clinics, Primary Care Physicians, and Emergency Departments: A Comparison of Patients' Visits*, 27 Health Aff. 1272, 1272 (2008); Mehrotra et al., *supra* note 1, at 324.

number of retail clinics in the United States has grown significantly to roughly 1000 clinics nationwide in 2009.<sup>5</sup>

Although the increased use of retail clinics may reduce stress on overcrowded emergency rooms, some physician groups have voiced concerns about this trend.<sup>6</sup> These physician groups have expressed concern that retail clinics fall short in the quality of care they provide to patients, which may result in increased misdiagnosis, overuse of antibiotics and other medications, and a decrease in the administration of preventative care.<sup>7</sup> The number of people utilizing retail clinics is rapidly growing, and currently, 15% of children and 19% of adults are likely to visit a retail clinic.<sup>8</sup> Therefore, the question of whether retail clinics are able to provide high quality of care is paramount and must be answered. This article will focus on the quality of care patients receive at retail clinics, looking at several quality indicators such as frequency of misdiagnosis, patient overmedication, and preventative care. Moreover, this article will provide a brief background describing patient demographics of retail clinics, retail clinic providers, and then discuss the quality of retail clinics.

## II. RETAIL CLINIC PATIENT PROFILE

Retail clinics offer care for a limited amount of acute illnesses and preventative services, and they are only able to serve patients with certain illnesses.<sup>9</sup> Approximately 90% of retail clinic patients receive treatment or

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<sup>5</sup> Mehrotra et al., *supra* note 1; Mehrotra et al., *supra* note 4, at 1273.

<sup>6</sup> Mehrotra et al., *supra* note 1, at 326; Mehrotra et al., *supra* note 4, at 1280.

<sup>7</sup> Mehrotra et al., *supra* note 1, at 326; Mehrotra et al., *supra* note 4, at 1273.

<sup>8</sup> Mehrotra et al., *supra* note 1; Mehrotra et al., *supra* note 4, at 1281.

<sup>9</sup> Mehrotra et al., *supra* note 4.

preventative care for one of the following: “upper respiratory infections, sinusitis, bronchitis, sore throat, immunizations, inner ear infections, swimmer’s ear, conjunctivitis, urinary tract infections, and screenings or blood tests.”<sup>10</sup>

Although nurse practitioners offer services to patients over the age of eighteen months who pay either out of pocket or with insurance,<sup>11</sup> the patient mix is not uniform. Of the patients with conditions that retail clinics treat, roughly 54% to 63% of retail clinic patients are female.<sup>12</sup> In a study conducted by the RAND Corporation, it was determined that females accounted for 62.8% of patients in the retail clinics studied.<sup>13</sup> In addition to a sex disparity, the study revealed that an age disparity also exists in retail clinic patients. Approximately 43% of retail clinic patients are between eighteen and forty-four years of age.<sup>14</sup> The overall age demographics of patients as determined by the RAND study showed children and elderly adults utilized retail clinics at a much lower rate than adults younger than sixty-five.<sup>15</sup> In addition, retail clinics have a relatively high amount of self-pay patients.<sup>16</sup> Of patients visiting retail health clinics in the RAND study, 32.9% paid completely out of pocket while 67.1% had some form

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<sup>10</sup> Betty Joyce Nash, *Health Care Aisle: Retail Medicine Pushes Competition, Price Transparency*, REGION FOCUS, Summer 2009, at 20; *see also* RAND Health, *Health Care on Aisle 7: The Growing Phenomenon of Retail Clinics*, [http://www.rand.org/pubs/research\\_briefs/2009/RAND\\_RB9491.pdf](http://www.rand.org/pubs/research_briefs/2009/RAND_RB9491.pdf) (last visited Mar. 9, 2010); Mehrotra et al., *supra* note 4, at 1276.

<sup>11</sup> Press Release, CVS Caremark, *MinuteClinic Says Rand Corporation Study in Annals of Internal Medicine Study on Quality, Affordable Care at Retail Clinics Affirms Internal Information* (Aug. 31, 2009), *available at* <http://investor.cvs.com/phoenix.zhtml?c=99533&p=irol-newsArticle&ID=1326056&highlight>.

<sup>12</sup> Mehrotra et al., *supra* note 4, at 1275-76.

<sup>13</sup> *Id.* at 1277.

<sup>14</sup> Mehrotra et al., *supra* note 4, at 1276-77; RAND Health, *supra* note 10.

<sup>15</sup> Mehrotra et al., *supra* note 4, at 1277.

<sup>16</sup> *Id.* at 1276.

of insurance.<sup>17</sup> However, the study did not compare patient demographics related to the method of payment.<sup>18</sup>

### III. RETAIL CLINIC HEALTHCARE PROVIDERS

Both nurse practitioners and physician assistants undergo extensive training in order to provide care at retail clinics.<sup>19</sup> Physician assistants are highly trained and board certified.<sup>20</sup> Similarly, nurse practitioners at retail clinics are typically registered nurses possessing master's degrees.<sup>21</sup> These nurses are board certified to independently diagnose and treat illnesses, prescribe medications, and administer preventative care.<sup>22</sup> Moreover, many retail clinics impose additional requirements on their nurse practitioners. For example, MinuteClinic, which is the largest provider of retail clinics in the United States, requires its nurse practitioners to have graduate level training specializing in family healthcare.<sup>23</sup>

Although nurse practitioners at retail clinics are trained to administer care autonomously, they receive guidance in treating illnesses.<sup>24</sup> Retail clinics follow established clinical practice guidelines and regulations.<sup>25</sup> Some retail clinics provide physician supervision for their nurse practitioners.<sup>26</sup> A significant source

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<sup>17</sup> *Id.* at 1276, 1277.

<sup>18</sup> *Id.* at 1277.

<sup>19</sup> Convenient Care Ass'n, Fact Sheet Convenient Care Clinic: High Quality Care, [http://www.ccaclinics.org/images/stories/downloads/factsheets/cca\\_factsheet\\_quality\\_care.pdf](http://www.ccaclinics.org/images/stories/downloads/factsheets/cca_factsheet_quality_care.pdf) (last visited Mar. 29, 2010); Sue Horrocks et al., *Systematic Review of Whether Nurse Practitioners Working in Primary Care Can Provide Equivalent Care to Doctors*, 324 BRIT. MED. J. 819, 819 (2002).

<sup>20</sup> Convenient Care Ass'n, *supra* note 19.

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

<sup>22</sup> *Id.*; Horrocks et al., *supra* note 19.

<sup>23</sup> CVS Caremark, *supra* note 11.

<sup>24</sup> Convenient Care Ass'n, *supra* note 19.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

of guidance at retail clinics comes from evidence-based protocols, which nurse practitioners use to diagnose and treat illnesses as well as provide preventative care.<sup>27</sup> Nurse practitioners at retail clinics strictly adhere to their evidence-based protocols and, in some instances, follow the protocols more than practitioners in more traditional medical centers.<sup>28</sup> For minor conditions, some retail clinics use computer kiosks to help nurse practitioners diagnose and treat patients.<sup>29</sup> Following the proper protocols creates “precision medicine” by lessening the likelihood of judgment errors by nurse practitioners.<sup>30</sup>

#### IV. RETAIL CLINIC QUALITY

Retail clinics utilize nurse practitioners to provide high quality care. To obtain a complete representation of the quality provided at retail clinics, several factors should be examined, including: the frequency of misdiagnosis; the likelihood of over medicating patients; the frequency of preventative care administration; convenience of service; and technological sophistication.<sup>31</sup>

##### A. Frequency of Misdiagnosis

Whenever a patient seeks medical treatment, there is a possibility the patient will be misdiagnosed. However, some physician groups have voiced concerns that retail clinics have a higher amount of misdiagnosed patients than other medical settings because nurse practitioners are generally administering care

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

<sup>28</sup> *Id.*

<sup>29</sup> Mehrotra et al., *supra* note 4, at 1280.

<sup>30</sup> Nash, *supra* note 10, at 19.

<sup>31</sup> Mehrotra et al., *supra* note 1, at 325-26.

instead of physicians.<sup>32</sup> Since nurse practitioners have less formal training than physicians, there is a belief that the level of care at retail clinics is of diminished quality.

In response to these concerns, the RAND Corporation conducted a quality study of retail clinics considering three conditions: “middle ear infections, sore throats, and urinary tract infections, which comprise [48%] of acute care visits at retail clinics.”<sup>33</sup> RAND investigated 2100 episodes of medical care provided to patients at retail clinics by examining the care given to a patient for three months after their original incident.<sup>34</sup> The RAND study found that patients who received initial care at retail clinics did not have a high occurrence of follow-up visits to urgent care centers or hospital emergency departments.<sup>35</sup> The lack of further treatment suggests that patients receive accurate diagnoses and effective treatment during their initial visit to retail clinics.<sup>36</sup>

#### *B. Likelihood of Over-prescribing Medication*

Another area of concern for physician organizations is in patient medication prescriptions.<sup>37</sup> Retail clinics are primarily owned by pharmacies or chain stores; 73% percent are owned by CVS, Walgreens, or Target stores.<sup>38</sup> Since retail clinics are typically located in stores, they attract business for those stores because patients may choose to fill their prescriptions at the most

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<sup>32</sup> Mehrotra et al., *supra* note 4, at 1217.

<sup>33</sup> CVS Caremark, *supra* note 11; Mehrotra et al., *supra* note 1, at 322.

<sup>34</sup> CVS Caremark, *supra* note 11; Mehrotra et al., *supra* note 1, at 324.

<sup>35</sup> Mehrotra et al., *supra* note 1, at 326.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 321.

<sup>38</sup> RAND Health, *supra* note 10, at 2-3.

convenient place, the pharmacy of the store in which the clinic is located.<sup>39</sup> This tendency may create a perceived financial incentive on the part of the store owners to run a clinic and on behalf of the nurse practitioners to over-prescribe medication to give their company business.<sup>40</sup> That is, the company has an incentive to maintain a clinic if the clinic brings in business for the company, and if the clinic remains open then nurses continue to have work, so nurse practitioners also have an indirect financial incentive to over-prescribe medication.<sup>41</sup>

This concern is compounded by the belief that nurse practitioners are not as competent as physicians to prescribe medications. While nurse practitioners are not trained as extensively as physicians for prescribing medication, they overcome this limitation by following evidence-based protocols.<sup>42</sup> For example, one study of antibiotic prescriptions for negative strep test patients found that retail clinic practitioners adhered to evidence-based protocols about twice as much as practitioners in traditional settings.<sup>43</sup> This result suggests that nurse practitioners in retail clinics effectively prescribe medication.<sup>44</sup> The RAND study found that for “middle ear infections, sore throats, and urinary tract infections,” practitioners at retail clinics prescribed about as much medicine for patients as

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<sup>39</sup> Mehrotra et al., *supra* note 4.

<sup>40</sup> Mehrotra et al., *supra* note 1, at 321, 326.

<sup>41</sup> *Id.*

<sup>42</sup> RAND Health, *supra* note 10, at 3-4.

<sup>43</sup> Convenient Care Ass’n, *supra* note 19.

<sup>44</sup> RAND Health, *supra* note 10, at 3-4.

practitioners in physician offices, urgent care centers, and emergency room departments.<sup>45</sup>

### C. Implementation of Preventative Care

Preventative care is important for quality because, if delivered correctly, it may keep patients healthy. Although preventative care is sensible, the rates for such care in the United States remain low.<sup>46</sup> Comparing retail clinics to more traditional environments of care may indicate whether retail clinics deliver an appropriate amount of preventative care.<sup>47</sup> The rate of preventative care administered to patients in retail clinics is similar to that of physician offices.<sup>48</sup> However, the RAND study found that retail clinics administered preventative care more often than emergency departments.<sup>49</sup> This result may be largely due to the fact that retail clinics primarily provide preventative care in the form of immunizations.<sup>50</sup> A separate RAND study found that for patients sixty-five years and older, about 73% of retail clinic visits were for immunizations.<sup>51</sup> In addition to immunizations, retail clinics also administered other forms of preventative care, including preventative health examinations and screenings for diabetes, hypertension, and obesity.<sup>52</sup>

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<sup>45</sup> RAND Health, *supra* note 10, at 3-4; CVS Caremark, *supra* note 11.

<sup>46</sup> Mehrotra et al., *supra* note 4, at 1279.

<sup>47</sup> Mehrotra et al., *supra* note 1.

<sup>48</sup> RAND Corp., Retail Medical Clinics Perform Well Relative to Other Medical Settings, <http://www.rand.org/publications/randreview/issues/winter2009/news.html#medclinics> (last visited Apr. 11, 2010).

<sup>49</sup> Mehrotra et al., *supra* note 1, at 326.

<sup>50</sup> Mehrotra et al., *supra* note 4, at 1276-77.

<sup>51</sup> *Id.*

<sup>52</sup> CVS Caremark, *supra* note 11; RAND Health, *supra* note 10, at 2; Mehrotra et al., *supra* note 1, at 326.

*D. Convenience of Service and Technological Sophistication*

Convenience also contributes to the quality of service patients receive at retail clinics. Having clinics located in stores allows patients convenient access to clinics.<sup>53</sup> For example, one statistic shows that 36% of people in urban areas live within a ten minute drive of a retail clinic.<sup>54</sup> In addition, retail clinics offer quick service by not requiring appointments and having short waiting times.<sup>55</sup> Wait times may vary, however, depending on day of the week and season, such as longer wait times during weekends and flu seasons.<sup>56</sup>

Another indicator of quality is the sophistication of retail clinics technology. Retail clinics have generally implemented electronic medical records technology into their record keeping, which provides a valuable way to keep accurate records of patient care, prevents medication conflicts, and facilitates provider communication in treatment.<sup>57</sup> These electronic records can be printed out and given to patients or can be faxed to a patient's primary care provider at their request.<sup>58</sup> In addition to electronic medical records, some clinics have implemented a greater level of technology.<sup>59</sup> For example, MinuteClinic nurse practitioners utilize software while treating patients, which allows them to automatically generate diagnostic records, and visit invoice, prescriptions, as well

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<sup>53</sup> Mehrotra et al., *supra* note 1; RAND Health, *supra* note 10, at 2.

<sup>54</sup> RAND Health, *supra* note 10, at 2.

<sup>55</sup> Mehrotra et al., *supra* note 1; Mehrotra et al., *supra* note 4.

<sup>56</sup> Nash, *supra* note 10, at 20.

<sup>57</sup> Convenient Care Association, *supra* note 9; Mehrotra et al., *supra* note 1, at 327; Nash, *supra* note 10, at 21.

<sup>58</sup> Convenient Care Association, *supra* note 9; Mehrotra et al., *supra* note 1, at 327.

<sup>59</sup> CVS Caremark, *supra* note 11.

as educational materials.<sup>60</sup> MinuteClinic also automatically sends patients' diagnostic records to their primary care physicians.<sup>61</sup> Thus, the use of technology, such as electronic records, by retail clinics helps patients to keep track of their health.

For the limited amount of illnesses treatable at retail clinics, nurse practitioners are able to accurately diagnose patients and prescribe effective dosages of medication on par with the amount normally prescribed by physicians. In addition, patients enjoy preventative care at retail clinics through immunizations and various screenings. These services occur at convenient locations and are carried out with little wait time. Finally, retail clinics use electronic medical records that permit patients to keep track of their health and can even keep their primary care physicians informed. Retail clinics performed well on all the individual factors of quality, thus, patients receive a high quality of health care at retail clinics. With increasing numbers of people utilizing them, retail clinics may provide a popular alternative to emergency rooms and doctor offices for the limited services offered.

## V. CONCLUSION

Retail clinics offer quality services to the community. As the RAND study found for selected illnesses, retail clinics have quality scores equal to or greater than other care settings.<sup>62</sup> This finding is true even though retail clinics primarily utilize nurse practitioners instead of physicians. However, the RAND

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<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> Mehrotra et al., *supra* note 1, at 325-26.

study is limited in scope because it only looked at “middle ear infections, sore throats, and urinary tract infections,” so the study analyzed a little over half of ailments treated at retail clinics.<sup>63</sup> Retail clinic’s high performance in quality may not generalize fully to the conditions not examined by RAND.<sup>64</sup> Even so, the future of retail clinics is promising. If the growth rate continues, the number of retail clinics should increase in the future, as a part of the evolving healthcare system. Although retail clinics began as exclusively self-paid clinics, many insurance companies have begun covering treatment in retail clinics because nurse practitioners offer quality care to patients at lower rates than hospitals and doctor offices, which may sustain retail clinic growth in the future.

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<sup>63</sup> *Id.* at 326.

<sup>64</sup> *Id.*

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***Improvements in the Modern Home Healthcare Industry:  
Responses to Nursing Shortages & New  
Technological Advancements***

*Leilani Pino* \*

I. INTRODUCTION

A radical change is sweeping the 21st century: the baby boomers are now aging, and they are beginning the “Geezer Boom.”<sup>1</sup> It is estimated that by 2030, one-third of the American population will be senior citizens, those sixty-five and older, which would represent the greatest percentage in history.<sup>2</sup> In addition, the aging population is expected to remain old longer because of increasing life expectancies.<sup>3</sup> The baby boomers have more recently become aware of the impending strains their aging population will have on society; thus, they have begun seeking healthcare reforms, particularly focusing on improving the conditions of long-term care. Traditionally, the model for long-term care has included nursing homes, however, many baby boomers believe ‘there is no place

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<sup>1</sup> Melinda Beck et al., *The Geezer Boom*, NEWSWEEK, Winter 1990/ Spring 1991, at 62.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

like home,' and they are seeking to enhance the quality of home healthcare services.<sup>4</sup>

Home healthcare is a formal, regulated, Medicare and Medicaid sponsored program that provides care delivered by health professionals in the patient's home.<sup>5</sup> Currently, home healthcare is the fastest-growing sector in the healthcare industry.<sup>6</sup> Demands for home care services continue to increase "because of the aging population, consumer preference, and technological advances" that make it more convenient to provide care in homes.<sup>7</sup> These demands, however, are being harmed by the shortage of nurses. In 2009, the "Home Healthcare Nurse Promotion Act" was proposed to increase home healthcare services by improving training, recruitment, and retention of home healthcare nurses.<sup>8</sup> Although this bill acknowledges the increasing elderly population and proposes programs to alleviate the shortage of home healthcare nurses,<sup>9</sup> Congress cannot overlook the other issues affecting the quality of care. The government must continue to recognize the needs of home healthcare and seek improvements since the burdens of the aging population ultimately affect every member of society.

This Article will discuss the importance of improving the home healthcare industry in order to ensure high quality of care for the baby boomers that will

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<sup>4</sup> Vickie Ragsdale & Graham J. McDougall, *The Changing Face of Long-Term Care: Looking at the Past Decade*, 29 ISSUES MENTAL HEALTH NURSING 992, 992 (2008).

<sup>5</sup> Susan Louisa Montauk, *Home Health Care*, 1998 AM. FAM. PHYSICIANS 1608, 1608, available at <http://www.aafp.org/afp/981101ap/montauk.html>.

<sup>6</sup> Kenneth Brummel-Smith, *Home Health Care: How Long Will it Remain "Low Tech"?*, 65 S. CAL. L. REV. 491, 502 (1991-92).

<sup>7</sup> Carol Hall Ellenbecker et al., *Predictors of Home Healthcare Nurse Retention*, 40 J. NURSING SCHOLARSHIP 151, 151 (2008).

<sup>8</sup> Home Healthcare Nurse Promotion Act, H.R. 1928, 111th Cong. (2009) [hereinafter H.R. 1928].

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

soon inundate the system. This article begins with a brief history of the home healthcare industry and a review of recent reforms that have led to the current administration of the home healthcare program. Next, this article evaluates the importance of funding home care programs through Medicare and Medicaid. Finally, solutions to nursing shortages and technological advancements will be explored to provide insight to the prevailing improvements in the quality of home healthcare.

## II. HISTORY OF HOME HEALTHCARE

At its inception, home healthcare was developed to provide transitional services for those discharged from hospitals in the earlier phases of recovery.<sup>10</sup> This system was designed by Medicare regulations as a means for cutting back costs by decreasing hospital stays.<sup>11</sup> Before 1980, Medicare only supported post-hospitalization care to individuals already receiving benefits.<sup>12</sup> After 1980, a new face of home healthcare emerged with the liberalization of restrictions on Medicare benefits.<sup>13</sup> Among the first restrictions removed was the requirement that home care be limited to those who had been recently hospitalized.<sup>14</sup> Later, in 1988, the significant decision in *Duggan v. Bowen*<sup>15</sup> eliminated limits on the number of days per year one could receive home care, as long as it was less than

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<sup>10</sup> H. Gilbert Welch et al., *The Use of Medicare Home Health Care Services*, 335 NEW ENG. J. MED. 324, 324 (1996).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Alan M. Jette et al., *Quality of Medicare-Reimbursed Home Health Care*, 36 GERONTOLOGIST 492, 492 (1996).

<sup>14</sup> Welch et al., *supra* note 10, at 324.

<sup>15</sup> See *Duggan v. Bowen*, 691 F. Supp. 1487 (D.D.C. 1988).

seven days each week.<sup>16</sup> Other critical changes included barring denial of care to patients with chronic diseases and allowing all patients to receive physician prescribed home care.<sup>17</sup> Collectively, all of these changes led to an increase in availability of home care, especially for those suffering from ongoing medical problems that require long-term care.<sup>18</sup>

### III. CURRENT HOME HEALTHCARE PROGRAM

Home healthcare is the fastest growing expense in the Medicare program,<sup>19</sup> primarily because of the “aging population, the increasing prevalence of chronic disease, and increasing hospital costs.”<sup>20</sup> Between 1980 and 1996, the number of patients receiving home care increased by more than 400%.<sup>21</sup> As a result of such a demand, there has been a substantial growth in the home care industry. In 1961, there were only 208 home care agencies present throughout the United States,<sup>22</sup> but by 2002, that number increased to more than 17,000.<sup>23</sup>

The rise in the development of the home care industry can also be attributed to preferences for home-care services. Home healthcare offers skilled

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<sup>16</sup> Brian Davis, *The Home Health Care Crisis: Medicare's Fastest Growing Program Legalizes Spiraling Costs*, 6 ELDER L.J. 215, 229 (1998).

<sup>17</sup> Welch et al., *supra* note 10, at 325.

<sup>18</sup> STAFF OF H. COMM. ON WAYS & MEANS, 108TH CONG., BACKGROUND MATERIAL AND DATA ON THE PROGRAMS WITHIN THE JURISDICTION OF THE COMMITTEE ON WAYS AND MEANS 2-78 (Comm. Print 2004) [hereinafter 2004 GREEN BOOK].

<sup>19</sup> Davis, *supra* note 16, at 216.

<sup>20</sup> Montauk, *supra* note 5.

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

<sup>22</sup> Jette et al., *supra* note 13.

<sup>23</sup> Beth Piskora, *Home Health Care for Your Elderly Parents*, BUSINESSWEEK, Sept. 10, 2008, available at [http://www.businessweek.com/print/investor/content/sep2008/pi20080910\\_761489.htm](http://www.businessweek.com/print/investor/content/sep2008/pi20080910_761489.htm); U.S. CENSUS BUREAU, INDUSTRY STATISTICS SAMPLER: NAICS 621610 HOME HEALTH CARE SERVICES (2004), <http://www.census.gov/econ/census02/data/industry/E621610.HTM>.

nursing, health assistance, and companionship.<sup>24</sup> In addition, many find it an appealing option to remain in their homes and receive nursing care.<sup>25</sup> Home healthcare is also generally less expensive than institutional care<sup>26</sup> because visits to the physician's office are significantly decreased.<sup>27</sup> Finally, these services may be necessary for those who lack care from family or friends.<sup>28</sup> Above all, most prefer home care because Medicare covers virtually all costs.<sup>29</sup>

Since the 1960s, Medicare has included home healthcare as a benefit.<sup>30</sup> Although this benefit is not given freely, it has several restrictions that ensure regulations on quality and costs control. In order to receive Medicare-covered home healthcare there are four requirements: a beneficiary must be under medical care of a physician, require skilled nursing care, be homebound, and the home healthcare agency providing care must be approved by the Medicare program.<sup>31</sup> While the number of home healthcare visits is unlimited, covered costs for care will require a physician to prescribe home care and include all pertinent diagnoses, estimate of required visits, rehabilitation potential, and necessary

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<sup>24</sup> Davis, *supra* note 16, at 221.

<sup>25</sup> Jennifer Rae Fleming, *The Blurred Line Between Nursing Homes & Assisted Living Facilities: How Limited Medicaid Funding of Assisted Living Facilities Can Save Tax Dollars While Improving the Quality of Life of the Elderly*, 15 U. MIAMI BUS. L. REV. 245, 267 (2006-07).

<sup>26</sup> Gina M. Reese & Joseph H. Hafkenschiel, *Hot Topics in Home Health Care*, 20 WHITTIER L. REV. 365, 365 (1997-98).

<sup>27</sup> Kristen R. Jakobsen, *Space-Age Medicine, Stone-Age Government: How Medicare Reimbursement of Telemedicine Services is Depriving the Elderly of Quality Medical Treatment*, 8 ELDER L.J. 151, 176 (2000).

<sup>28</sup> Welch et al., *supra* note 10, at 328.

<sup>29</sup> Fleming, *supra* note 25.

<sup>30</sup> *Id.*

<sup>31</sup> CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE AND HOME HEALTH CARE 1, 3 (2007), available at <http://www.medicare.gov/Publications/Pubs/pdf/10969.pdf> [hereinafter MEDICARE & HOME HEALTH CARE BOOKLET].

care.<sup>32</sup> In addition, Medicare only provides support for skilled nursing care, which includes physical therapy, speech-language pathology services, and continued occupation therapy.<sup>33</sup> A homebound individual is defined as one who cannot leave home without a taxing effort, requires the aid of supportive devices, such as a cane, or one who cannot leave home at all.<sup>34</sup> Although, a home healthcare agency can provide skilled nursing, it must be Medicare-certified to receive reimbursements for care services.<sup>35</sup> Among the many requirements for certification, a home health agency must be engaged in providing skilled nursing services through registered professional nurses and physicians, is licensed pursuant to State law, meets federal requirements in the interest of the health and safety of beneficiaries, and meets any additional requirements necessary for effective and efficient care.<sup>36</sup>

The foundation of home healthcare is nursing care. Physicians merely order the patient's treatment and prescribe personalized therapy.<sup>37</sup> Physician oversight on home healthcare patients can be attributed to lack of home care training, an increasing concern about medical liability, and loss of interest in making less profit.<sup>38</sup> Services in home care are passed onto skilled nurses and home health aides. A licensed nurse must perform skilled nursing care.<sup>39</sup> A skilled nurse is responsible for such services as: monitoring vital signs, managing

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<sup>32</sup> Davis, *supra* note 16, at 225.

<sup>33</sup> MEDICARE & HOME HEALTH CARE BOOKLET, *supra* note 31, at 3.

<sup>34</sup> 2004 GREEN BOOK, *supra* note 18, at 2-71.

<sup>35</sup> Home Health Agency, 42 U.S.C.A. §1395x(o) (West 2009).

<sup>36</sup> *Id.*

<sup>37</sup> Brummel-Smith, *supra* note 6, at 492, 494.

<sup>38</sup> *Id.* at 492.

<sup>39</sup> MEDICARE & HOME HEALTH CARE BOOKLET, *supra* note 31, at 6.

diabetic side-affects, evaluating drug reactions,<sup>40</sup> and changing catheters.<sup>41</sup> Other care provided by skilled nurses includes physical therapy, training to use special equipment, therapy to regain speaking, listening or memory skills, and occupational therapy.<sup>42</sup> Medicare will only cover costs of home health aides if the beneficiary is also receiving skilled care.<sup>43</sup> Home health aides perform “personal care activities under the direct supervision of a registered nurse.”<sup>44</sup> Personal care and assistance provided by home health aides includes: assistance with grooming, bathing, and providing medications.<sup>45</sup> They may also provide homemaker care, such as house cleaning, changing bed linens,<sup>46</sup> and meal preparation.<sup>47</sup> Clearly, for the home healthcare system to function efficiently, care provided by nurses is essential; however, the ever increasing shortage of nurses is causing a lack in quality.

#### IV. RELIEF OF NURSING SHORTAGES

Contrary to current trends of increasing unemployment rates, the growth of employment in the long-term care sector is rising. Currently, the demand for long-term care is continuing to increase while there is a limited supply of licensed nurses to deliver high-quality care to the elderly.<sup>48</sup> The nursing industry is

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<sup>40</sup> *Id.*

<sup>41</sup> Brummel-Smith, *supra* note 6, at 492, 494.

<sup>42</sup> MEDICARE & HOME HEALTH CARE BOOKLET, *supra* note 31, at 6.

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

<sup>44</sup> Brummel-Smith, *supra* note 6, at 494.

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

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

<sup>47</sup> Kristin Jenkins Gerrick, *An Inquiry into Unionizing Home Healthcare Workers: Benefits for Workers and Patients*, 29 AM. J.L. & MED. 117, 120 (2003).

<sup>48</sup> Robyn Stone & Mary F. Harahan, *Improving the Long-Term Care Workforce Serving Older Adults*, 29 HEALTH AFF. 109, 111 (2010).

projected to increase from 6.5% in 2000<sup>49</sup> to 109% in 2020.<sup>50</sup> It is estimated that one million newly registered nurses will be needed to cover all home care demands by 2016.<sup>51</sup> The shortage of competent and licensed long-term care nurses is attributed to several factors, including: a large retiring nursing population,<sup>52</sup> lack of traditional sources of labor, low wages, decrease in retention, and inadequate work settings.<sup>53</sup> The market for long-term care will continue to surge due to a strong preference for home-based care, increase in chronic diseases, and the escalating population of elderly.<sup>54</sup> Fortunately, Congress has recently recognized the negative effects of imminent shortages and has proposed solutions that concentrate on improving recruitment, education, and training for long-term care nurses.<sup>55</sup> While these congressional proposals may help to alleviate shortages, other reforms must not be overlooked. These reforms include focusing on retention, starting incentive programs, allocating more resources to elder care, defining competencies, improving working conditions, and creating specialized training.

#### A. *The Home Healthcare Nurse Promotion Act*

Even though the new era of healthcare is focusing on a myriad of reforms, initiatives for accessibility to elderly care appears to be paramount. This is evident in the enactment of the Home Healthcare Nurse Promotion Act. This Act

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<sup>49</sup> Ellenbecker et al., *supra* note 7.

<sup>50</sup> Home Healthcare Nurse Promotion Act, H.R. 1928, 111th Cong. § 2(a)(3) (2009).

<sup>51</sup> *See Id.* § 2(a)(4).

<sup>52</sup> *Id.*

<sup>53</sup> Stone & Harahan, *supra* note 48.

<sup>54</sup> H.R. 1928 § 2(a)(2).

<sup>55</sup> *See id.* § 2(b)

recognizes that the significant shortage of home healthcare nurses is hindering access to cost-effective care.<sup>56</sup>

The Nurse Promotion Act provides three approaches to provide relief, yet fails to describe how the proposed programs will be administered. The first approach focuses on assisting non-profit home health agencies and visiting nurse associations to improve training and development of home healthcare nurses.<sup>57</sup> The Act does not specify any particular program, but research has found successful training and educational programs combine classroom and on-the-job training tailored for long-term care service delivery.<sup>58</sup> The second approach includes “promoting and facilitating academic-practice collaborations.”<sup>59</sup> In order to promote a joint effort between academic and practice, policymakers, educators, and employers should jointly assess the developmental needs for the home healthcare workforce.<sup>60</sup>

Finally, the last approach aims to improve recruitment and retention of home healthcare nurses.<sup>61</sup> The driving force for improving recruitment is providing home health nurse training grants.<sup>62</sup> This grant program under the Act will begin as a pilot program and will terminate within five years of being implemented, at which point Congress will report all findings.<sup>63</sup> The grants will provide funding for home nurse training and will give priority to non-profit

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<sup>56</sup> See *id.* § 2(a)(1).

<sup>57</sup> See *id.* § 2(b)(1).

<sup>58</sup> Stone & Harahan, *supra* note 48, at 113.

<sup>59</sup> H.R. 1928 § 2(b)(2).

<sup>60</sup> Stone & Harahan., *supra* note 48, at 113.

<sup>61</sup> H.R. 1928 § 2(b)(3).

<sup>62</sup> See *id.* § 832.

<sup>63</sup> See *id.* § 833.

nursing associations.<sup>64</sup> This program, however, will only provide grants to no more than ten accredited schools of nursing that have an existing home healthcare curriculum.<sup>65</sup> Although there are limited grants initially disbursed, implementing this pilot program will allow Congress to determine whether grants are successful in recruiting nurses.

*B. Initiatives to Improve Recruitment for Home Healthcare Nurses*

The Home Healthcare Nurse Promotion Act highlighted the importance of recruitment in securing the supply of high-quality home healthcare through a pilot program; however, in order to meet future demands of long-term care, more action is required. Along with expanding financial support through grants and scholarships, education should be reformed and long-term care nursing policies should be defined.<sup>66</sup>

Along with grants, incentives should be created to entice those considering entering the long-term home care field.<sup>67</sup> These incentives can range from scholarships, grants, and loan forgiveness programs.<sup>68</sup> Aside from providing financial rewards to potential students, incentives should be used to recruit qualified faculty to educate and prepare long-term care nurses.<sup>69</sup> Admittedly, a plan for long-term care incentives may take more time to develop because it will require government funds, but it remains a vital key in persuading people to enter the home care field. In addition, a simple solution to improving recruitment of

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<sup>64</sup> *See id.* § 833(a).

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

<sup>66</sup> Stone & Harahan, *supra* note 48, at 112-114.

<sup>67</sup> *Id.* at 113.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

home care nurses is to expose students to long-term care roles and settings through education and training.<sup>70</sup> For instance, participation in a clinical rotation in long-term care may encourage students to enter the field.

### *C. Improvements in Home Healthcare Nurse Retention*

It is apparent that Congress is making strides to mitigate the shortage in elder nursing care, but it has failed to acknowledge other improvement initiatives. The Home Health Care Nurse Promotion Act emphasized a system for recruitment instead of retention. A focus on retention is required since staff turnover is not only costly, but is detrimental to both staff morale and the care of patients.<sup>71</sup> During these times of nurse shortages, it has become increasingly difficult to replace home care nurses.<sup>72</sup> Studies have concluded that “job satisfaction, job benefits, comparable wages, and agency size and ownership” all affect retention.<sup>73</sup> A recent study, conducted to determine the predictors of home care nurse retention, found that 50% of the nurses left their job because of overwhelming, stressful demands, and poor relationships with the administration.<sup>74</sup> Job stress in home healthcare also negatively affects a nurse’s ability to provide patients high quality care.<sup>75</sup> The major source of job stress for home care nurses is attributed to the administration and paperwork.<sup>76</sup> Home healthcare nurses with supportive management and positive communication from

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<sup>70</sup> *Id.* at 112-113.

<sup>71</sup> Ellenbecker et al., *supra* note 7.

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

<sup>73</sup> *Id.* at 159.

<sup>74</sup> *Id.* at 156.

<sup>75</sup> Carol Hall Ellenbecker, *A Theoretical Model of Job Retention for Home Health Care Nurses*, 47 J. ADVANCED NURSING 303, 307 (2004).

<sup>76</sup> *Id.*

supervisors are more likely to stay at their job.<sup>77</sup> Therefore, to significantly increase home healthcare nurse retention, policymakers, and administrators must address high workload demands and remedy such issues in order to decrease stress.<sup>78</sup> Just a mere recognition of nurses' complaints and developing a plan for enhancing the workplace should be sufficient to considerably reduce staff turnover.

#### V. TECHNOLOGICAL ADVANCEMENTS IN HOME HEALTH CARE

The advent of new technologies has begun a trend to provide health care services via information technology to home care patients, even to those not technologically savvy. The benefits of integrating such technology are numerous, but mostly include cost-savings, eliminating travel for the elderly, enhancing communication, and providing patient autonomy. Health-related technology is referred to as "telehealth" or "telemedicine," and includes the use of electronic communication and information technologies to provide support from a distance.<sup>79</sup> The numerous benefits of telehealth in home healthcare continue to increase as technology becomes more accessible. The importance of telemedicine is most present in rural areas with a shortage of physicians.<sup>80</sup> In rural areas, it is likely that the elderly patient would have to travel long-distances to access physician care.<sup>81</sup> By being able to communicate with physicians either by telephone or television monitor, the elderly patient is relieved from the taxing

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<sup>77</sup> *Id.* at 306-07.

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

<sup>79</sup> Jakobsen, *supra* note 27, at 156.

<sup>80</sup> *Id.* at 168.

<sup>81</sup> *Id.* at 169.

energy of having to travel and in some cases, with constant supervision, patients may be diagnosed and treated earlier, before their disease advances.<sup>82</sup> Telemedicine also attributes to cost-savings benefits, “as low as one-third of the cost of on-site care.”<sup>83</sup> The savings begin by allowing the patient to live in their home while recuperating instead of receiving treatment at the hospital.<sup>84</sup> Additionally, patients can receive primary care by a midlevel practitioner while being supervised remotely by a physician, which will save costs from frequent physician visits.<sup>85</sup> Finally, telemedicine provides an increase in autonomy by allowing the patient to become more involved in his own health care and consequently, learning how to improve his own health.<sup>86</sup>

In-home telemedicine continues to grow and initiatives for improving technology have become the focus of some technological healthcare companies. In 2010, the Mayo Clinic, GE Healthcare, and Intel launched a yearlong study to research the care and cost-benefits of home based care for the elderly.<sup>87</sup> The study will monitor 200 patients over the age of sixty who suffer chronic conditions as they use at-home medical devices daily.<sup>88</sup> The medical devices will be able to measure “vital signs, such as blood pressure, peak air flow, weight, or blood sugar readings.”<sup>89</sup> The study aims to determine whether technological at

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<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at 170.

<sup>84</sup> *Id.* at 170, 177.

<sup>85</sup> *Id.* at 168-69.

<sup>86</sup> *Id.* at 177.

<sup>87</sup> Marianne Kolbasuk McGee, *In-Home Telemedicine Study Launched*, INFORMATIONWEEK, Feb. 23, 2010, <http://www.informationweek.com/news/healthcare/patient/showArticle.jhtml?articleID=223100390>.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

home monitoring will be effective in reducing emergency visits, hospitalization, and if remote clinicians can successfully recognize critical signs of patients' health issues.<sup>90</sup> This study will likely find successful results as other countries such as the United Kingdom and Norway have reported substantial savings and improvements due to telemedicine.<sup>91</sup>

## VI. CONCLUSION

Modern technological advancements in medicine have allowed baby boomers to receive high quality care throughout their lives and this should not be any different as they continue to age. The "Geezer Boom" will undoubtedly have a great impact on all of society and reforms on health care should accommodate these changes. Above all, the aging population should be allowed to personally make decisions regarding their preference for long-term care. The preference for home healthcare will only continue to rise and improvements must be made now to prepare for the high demand. An initiative to alleviate the shortage of home healthcare nurses is a powerful start in improving long-term care, but more must be done in order to ensure high-quality home care. Education and training for home healthcare nurses should be reformed and standardized in order to guarantee overall quality standards. Technological advancements should continue to be improved and more importantly a widespread database should be implemented to allow home care nurses, physicians, and patients to communicate easily. These technological advancements will also improve nurse retention since most nurses

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<sup>90</sup> *Id.*

<sup>91</sup> Jakobsen, *supra* note 27, at 169-70.

find the paperwork required daunting and stressful. Finally, Congress must be more transparent with healthcare reforms and produce structured and comprehensive plans for all states to follow in providing high quality care. Ultimately, the effectiveness of home healthcare depends on the improvements made to the current system and with such a large part of the population demanding high-quality care it cannot be overlooked.

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***Direct-to-Consumer Genetic Testing: Evolving Challenges***

*Christopher Freet*<sup>\*</sup>

I. INTRODUCTION

In today's society, consumers have seemingly developed the expectation of countless informational resources at their fingertips. The evolution of the internet and the availability of a staggering amount of information have turned the average consumer into an active researcher, deciphering the answers to life's questions one web page at a time. A consequence of this conduct has been an inability to guarantee the reliability of information obtainable through the internet. The availability of often inaccurate information has found its way into our healthcare system as many turn to the internet for medical advice or assistance with self-diagnosis. This new trend in consumer orientation with respect to healthcare has recently become "particularly evident in the proliferation of direct-to-consumer (DTC) advertising for health-related products."<sup>1</sup> A popular example

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<sup>1</sup> Sarah E. Gollust et al., *Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 J. AM. MED. ASS'N. 1762, 1762 (2002).

of this advertising is present in pharmaceutical advertisements in print and television commercials.<sup>2</sup>

In addition to pharmaceuticals, DTC advertised health-related products have included testing for traditional genetic conditions.<sup>3</sup> Such traditional conditions have included hereditary colon cancer syndromes or factor V Leiden deficiencies, among others.<sup>4</sup> Recently, there has been a substantial shift in the sophistication and availability of DTC genetic tests that has prompted the interest of state and federal regulatory bodies as well as genetic research organizations.<sup>5</sup> The interest in DTC genetic testing has centered on both a potential need for regulation and the potential issues that may prevent efficient regulation.

This article will examine the potential impact that DTC genetic testing may have on the quality of care that consumers receive, and focus on inaccurate expectations that can result from a lack of genetic counseling accompanied with consumer concerns regarding their genetic privacy. Part II of this article will establish the current uses and prevalence of DTC genetic testing. Part III will assess some of the risks and benefits that coincide with the implementation of DTC genetic testing. Again, a particular focus will be paid to concerns with respect to ill-informed consumers and the potential for inaccurate or unrealistic expectations concerning genetic testing benefits and its effect on consumer's quality of care. Part IV will explore issues with the government's limited role and

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<sup>2</sup> *Id.*

<sup>3</sup> Greg Feero, *Keep an Eye on Direct-to-Consumer Testing: Genomic Medicine*, 38 FAM. PRAC. NEWS 46, 46 (2008).

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

<sup>5</sup> *Id.*

arguably ineffective regulation of DTC genetic testing and advertising. Finally, part V will discuss the implications of implementing stricter genetic counseling requirements with an emphasis on the role of primary care physicians in promoting consumer education and preventing consumer misconception.

## II. USES AND PREVALENCE OF DTC GENETIC TESTING

Our understanding of the human genome has exponentially increased following the completion of the Human Genome Project in 2003.<sup>6</sup> In fact, the Human Genome Project has resulted in the discovery of more than 1,800 disease genes and the potential identification of additional disease causing genes.<sup>7</sup> Though the exact number has been changing, there are currently more than 1,000 genetic tests that correlate to human diseases or conditions on the market today.<sup>8</sup> These clinical genetic tests include: carrier gene testing, prenatal testing, newborn screening, pharmacogenomic testing, diagnostic testing, and predictive testing.<sup>9</sup> Additionally, DTC tests have been created for multifactorial behavioral disorders<sup>10</sup> as well as nutrigenomic testing, which involve the testing of genetic variants and combining those results with a consumer's diet and lifestyle.<sup>11</sup>

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<sup>6</sup> Cynthia Marietta & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Is It the Practice of Medicine?*, 37 J. L. MED. ETHICS 369, 369 (2009).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> Gollust et al., *supra* note 1.

<sup>10</sup> See generally Alex Wilde et al., *Public Interest in Predictive Genetic Testing, Including Direct-to-Consumer Testing, for Susceptibility to Major Depression: Preliminary Findings*, 18 EUR. J. HUM. GENETICS 47, 48 (2010).

<sup>11</sup> Katrina A.B. Goddard et al., *Public Awareness and Use of Direct-to-Consumer Genetic Tests: Results from 3 State Population-Based Surveys, 2006*, 99 AM. J. PUB. HEALTH 442, 443 (2009).

Further, genetic testing can be used “at any stage in the developmental lifecycle.”<sup>12</sup>

Genetic tests are ordered for a variety of reasons including: “(1) to identify carriers of genetic disease; (2) to test embryos, fetuses, and newborns for disease-causing genetic abnormalities; (3) to establish clinical diagnoses or prognoses and inform clinical care; (4) to determine whether there is increased risk of developing a disease in the future; or (5) to predict response to a medication.”<sup>13</sup> Basically, DTC genetic testing “provides consumers with access to their genetic information without involving a doctor in the process.”<sup>14</sup> Genetic tests analyze DNA, RNA, chromosomes, or gene products contained in one of several different patient submitted samples.<sup>15</sup> Currently, approximately thirty-five DTC genetic companies reach consumers via the internet.<sup>16</sup>

### III. RISKS AND BENEFITS OF DTC GENETIC TESTING

There have been several disputes as to whether the alleged benefits of DTC genetic testing outweigh potential risks that it may impose. Specifically, the American College of Medicine Genetics issued a policy statement in 2004 opposing DTC genetic testing with the stance that genetic testing should only be provided through “appropriately qualified” healthcare professionals.<sup>17</sup> Further, the American College of Medicine Genetics stated that those healthcare

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<sup>12</sup> Gail H. Javitt et al., *Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can't) Do to Protect the Public's Health*, 57 OKLA. L. REV. 251, 257 (2004).

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

<sup>14</sup> Marietta & McGuire, *supra* note 6.

<sup>15</sup> Javitt et al., *supra* note 12, at 257.

<sup>16</sup> Marietta & McGuire, *supra* note 6.

<sup>17</sup> *Id.* at 371.

professionals would be responsible for pre-test and post-test counseling involving the medical significance of the test results or follow-up.<sup>18</sup> The opposition to DTC genetic testing focuses on the potential vulnerability of “at home” genetic test consumers and the negative impact on the quality of care that those consumers may receive.<sup>19</sup> DTC genetic testing allegedly: “(1) fails to adequately explain complex genetic information; (2) is misleading in its failure to disclose the risks and limitations of testing; (3) allows tests without established clinical validity or utility to be promoted; and (4) does not include the counseling needed to put test results in proper context.”<sup>20</sup> Finally, DTC genetic testing also fosters consumer concerns with respect to privacy risks with potential discrimination that could result from determined genetic susceptibility to disease.<sup>21</sup>

Due to the complexity of genetic testing, ambiguity of test results, and challenges in interpretation, DTC genetic testing has inherent limitations.<sup>22</sup> For example, the presence of a specific gene sequence that has been associated with a particular disease would yield a positive test for that disease.<sup>23</sup> This positive test is limited because it only represents some probability of developing the identified disease and is far from deterministic.<sup>24</sup> In addition, if a variance is discovered on a genetic test and has not been associated with a disorder in other people, it can be

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<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> Javitt et al., *supra* note 12, at 253.

<sup>21</sup> Marietta & McGuire, *supra* note 6, at 370.

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

<sup>23</sup> Javitt et al., *supra* note 12, at 260.

<sup>24</sup> *Id.*

very difficult to determine “whether it is a harmless polymorphism or a disease-causing mutation.”<sup>25</sup>

Further, the lack of genetic counseling in DTC genetic testing can have far reaching effects. With potentially inappropriate expectations derived from DTC genetic testing, primary care physicians could be required to expend precious time and resources to meet patients’ expectations, while simultaneously reducing time spent on other types of patient care and negatively impacting the quality of care the patient may receive.<sup>26</sup> Further, it may be very difficult to completely “modify consumers’ inaccurate expectations” potentially compounding patient care concerns.<sup>27</sup>

It is also very possible that physicians may not have the necessary skills to analyze the specifics of genetic inheritance, to accurately calculate genetic risks, or communicate genetic information that the patient has obtained in a nondirective way.<sup>28</sup> Further complicating what may be a primary care physician’s “suboptimal knowledge” of genetics, advertisements for genetic services in medical journals, mailers, and DTC genetic test kits may be a physician’s primary source of information about many genetic tests.<sup>29</sup> Informational brochures alone may not contain enough information to properly prepare physicians for patient questions.<sup>30</sup> The inadequacy of these possibilities indicate that primary care

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<sup>25</sup> Marietta & McGuire, *supra* note 6, at 370.

<sup>26</sup> Wylie Burke & Amy McGuire, *An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing*, 300 J. AM. MED. ASS’N 2669, 2669 (2008).

<sup>27</sup> Gollust et al., *supra* note 1, at 1765.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

physicians may not be prepared for the potential flood of patients that have already received genetic testing or may seek it.<sup>31</sup> A physician's professional obligation to educate patients concerning DTC genetic test results, which may have a questionable value, could detract from more pertinent health related issues and negatively impact the patient's quality of care.<sup>32</sup>

Another realistic concern pertains to the security of DTC genetic test results.<sup>33</sup> Consumer concern relating to fears of privacy risks include the potential discrimination that could result from determined genetic susceptibility to disease.<sup>34</sup> Concerns relating to the security of results carry their own weight, but these concerns can be compounded with the ever-changing ownership of battling corporations responsible for genetic data they have collected.<sup>35</sup> Significant differences in company privacy policies that exist in DTC companies, coupled with issues that can arise regarding ownership of data collected following a company buyout or bankruptcy, present a complex problem concerning security.<sup>36</sup> These security concerns may impact consumer choices to obtain genetic testing while a breach of consumer security would negatively impact the effected consumer's quality of care.

After considering the potential risks, it is important to note a few benefits that supporters of DTC genetic testing have advanced. Proponents of DTC genetic testing believe that its implementation will result in an increase in

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<sup>31</sup> *Id.*

<sup>32</sup> Burke & McGuire, *supra* note 27.

<sup>33</sup> Wilde et al., *supra* note 10, at 49.

<sup>34</sup> Marietta & McGuire *supra* note 6, at 370.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

personal responsibility among consumers for their health by making risk-assessment available to them.<sup>37</sup> Further, the absence of a licensed physician is argued to increase the utilization of DTC genetic testing.<sup>38</sup> It has even been suggested that DTC genetic testing advertisements may have an educational effect by promoting awareness of disease in community groups.<sup>39</sup> Despite recognized benefits of DTC genetic testing, the prevalence of consumer quality of care concerns shared by multiple organizations and agencies substantiate the need for oversight.<sup>40</sup>

#### IV. PROBLEMS WITH GOVERNMENT REGULATION OF DTC TESTING

With the variety of DTC genetic tests available, and information tested for, it can be difficult to determine whether test results are being provided for recreational purposes or whether the information is intended for medical diagnosis.<sup>41</sup> This difficulty in differentiation raises concerns about what services are actually being rendered. Some genetic tests strictly determine genetic information such as ancestry, while others test for single hereditary disorders, such as Huntington disease.<sup>42</sup> When genetic tests are conducted on a non-symptomatic patient, the results are solely predictive, not diagnostic.<sup>43</sup> But the difficult question becomes: when does genetic risk assessment information for

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> Gollust et al., *supra* note 1, at 1763.

<sup>40</sup> Marietta & McGuire, *supra* note 6, at 371.

<sup>41</sup> *Id.* at 369.

<sup>42</sup> *Id.* at 369-70.

<sup>43</sup> Javitt et al., *supra* note 12, at 260.

disorders constitute the practice of medicine?<sup>44</sup> If determined, when and how should this medical practice be regulated? How do we treat companies that provide DTC genetic testing and claim that results are for “educational purposes?”<sup>45</sup>

The United States government has the legal authority to regulate or limit consumer access to products and services that impact consumer health.<sup>46</sup> Regulatory supervision falls within the reach of the Food and Drug Administration (FDA), the Center for Medicare & Medicaid Services (CMS), and the Federal Trade Commission (FTC).<sup>47</sup> The FDA and CMS regulatory powers relate to the sale of products and services, including “development, testing, production, and distribution.”<sup>48</sup> The FTC’s oversight pertains to the advertising of commercial products and services.<sup>49</sup> Due to the ambiguity concerning the legal status of different types of genetic testing and how they are utilized, along with an arguably “underzealous exercise over available authority by CMS,” insufficient oversight has resulted.<sup>50</sup> In fact, genetic testing regulation and these regulating bodies have been described as ambiguous and insufficient.<sup>51</sup> The “cracks” between these regulations and their promulgation have seemingly allowed many of these DTC tests to slip past appropriate regulation.<sup>52</sup>

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<sup>44</sup> Marietta & McGuire, *supra* note 6, at 370.

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

<sup>46</sup> Javitt et al., *supra* note 12, at 253.

<sup>47</sup> *Id.* at 268.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 253-54.

<sup>52</sup> *Id.* at 254.

A specific example of governmental issues with the regulation of direct-to-consumer marketing pertains to the doctrine of commercial speech.<sup>53</sup> Under the First Amendment to the U.S. Constitution, both state and federal governments are constrained from suppressing speech.<sup>54</sup> This general prohibition has been applied to commercial business and advertising resulting in the commercial speech doctrine.<sup>55</sup> One of the more recent and pertinent applications of the commercial speech doctrine by the Supreme Court was in the 2002 case of *Thompson v. Western States Medical Center*.<sup>56</sup> In *Thompson*, the Supreme Court determined the governmental interest in prohibiting pharmacists from advertising compounded drugs to be insufficient where the actual impact of the advertising was minimal and struck down the FDA Modernization Act of 1997.<sup>57</sup>

With the strict view taken by the Supreme Court in *Thompson*, it is likely that any restriction that the government or governmental agencies attempt to place on the advertising of DTC genetic testing would be subject to the assessment of actual impact of the advertising on the consumer and the governmental interest in regulating it.<sup>58</sup> Further, a court may be apprehensive to accept arguments that advertising restrictions are necessary due to consumer ignorance or difficulty in the consumer's ability to make decisions.<sup>59</sup> This essentially divests the

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<sup>53</sup> See generally *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

<sup>54</sup> Javitt et al., *supra* note 12, at 287.

<sup>55</sup> *Id.* at 289.

<sup>56</sup> See generally *Thompson*, 535 U.S. at 357-90.

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

<sup>58</sup> Javitt et al., *supra* note 12, at 300.

<sup>59</sup> *Id.* at 300-01.

government's ability to regulate the advertisement and marketing of DTC genetic testing and further complicates effective regulation.

#### V. PRIMARY CARE PHYSICIAN'S ROLE IN POTENTIAL SOLUTIONS TO PERCEIVED RISKS OF DTC GENETIC TESTING

The limitations on the role the government can play in the effective regulation of DTC genetic testing encourages us to look to other avenues to protect consumers. This search for alternatives appears to lead to primary care physicians who may be best equipped to counsel patients with DTC genetic testing results.<sup>60</sup> Physicians will continue to play a role in both the education of consumers as well as ensuring a sufficient quality of care when interacting with those consumers after they have obtained DTC genetic tests.<sup>61</sup> Because “patient...decisions [are often based] on unconscious associations and assumptions rather than conscious deliberation” physicians must focus on patient counseling with respect to their choice to obtain DTC genetic testing.<sup>62</sup> It is important for physicians to utilize techniques during patient counseling such as “elicit[ing] underlying motivations and correct[ing] false assumptions.”<sup>63</sup> This can be done by focusing on the fact that DTC personal genetic tests currently offered are not supported with any data pertaining to the outcomes of testing.<sup>64</sup> It is possible that this approach, through education of patients who have went the route of DTC genetic testing, will positively impact the quality of care received while encouraging those patients to perpetuate a more accurate understanding of

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<sup>60</sup> Burke & McGuire, *supra* note 26, at 2669.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 2671.

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

<sup>64</sup> *Id.*

risks, benefits, and limitations of DTC genetic testing to family, friends, and consumers on a broad scale.

## VI. CONCLUSION

It is clear that many obstacles to appropriate regulation of DTC genetic testing exist. Equally clear is the growing availability and versatility of genetic testing. With little dispute as to the benefits of genetic testing and the insight that it can provide under optimal circumstances, there is little doubt that its implementation will continue and likely increase. With more research, we can better understand the risks and benefits to consumers while ensuring a sufficient quality of care and effectively controlling the application of DTC genetic testing with insightful physicians and more effective legislative regulation.

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***Improving Quality of Care Through Telemedicine:  
The Need to Remove Reimbursement and  
Licensure Barriers***

*Jaime Bennett*<sup>\*</sup>

I. INTRODUCTION

Technological and internet advancements continue to create opportunities for telemedicine to improve both access to care and, ultimately, quality of care for patients. Telemedicine can be traced as far back as the 1950s. Given that technology was not as advanced as it is today, the lack of interoperability among telemedicine devices, and the lack of technical know-how that many users had, frequently led to user dissatisfaction.<sup>1</sup> While telemedicine has come a long way since its inception, it has yet to reach its full potential to increase the quality of health care for Americans due to barriers, specifically in the areas of licensure and reimbursement.

The advancements in the field of radiology demonstrate the quality of care possible when doctors overcome their resistance to telemedicine and embrace new

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<sup>1</sup> DAVID BRANTLEY ET AL., U.S. DEP'T OF COMMERCE, INNOVATION, DEMAND AND INVESTMENT IN TELEHEALTH 25 (2004), *available at* [http://www.atp.nist.gov/eao/innovation\\_demand\\_invest\\_telehealth\\_022004.pdf](http://www.atp.nist.gov/eao/innovation_demand_invest_telehealth_022004.pdf).

technology. Radiology is often considered the most successful field in telemedicine technology, largely because radiology professionals already have a technical background.<sup>2</sup> Specifically, the field of radiology developed “private teleradiology services,” and “x-rays, sonograms and other images have been consistently reimbursed by Medicare and other payers.”<sup>3</sup> These advancements lead to more cost effective systems that are easier to use, which in turn results in a greater acceptance by the medical community.<sup>4</sup>

Despite such advancements, current applications of telemedicine remain relatively primitive.<sup>5</sup> In fact, according to a 2004 report from the Technology Administration, “only a fraction of the potential for technology to increase access to, improve quality of, and reduce the cost of the nation’s healthcare has been realized to date.”<sup>6</sup> Reasons for slow telemedicine advancements include cost, infrastructure, privacy concerns, and uncertainty about legal and regulatory issues.<sup>7</sup> The increase in our retired population and longer life expectancies, however, coupled with cutbacks on health benefits are creating higher medical costs that telemedicine can help lower, while improving the quality of our healthcare system.<sup>8</sup>

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<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 25-26.

<sup>4</sup> *See id.* at 26.

<sup>5</sup> Roger Allan, *Telemedicine: A Shot In The Arm For Healthcare*, ELEC. DESIGN, June 29, 2006, <http://electronicdesign.com/Articles/ArticleID/12860/12860.html>.

<sup>6</sup> BRANTLEY ET AL., *supra* note 1, at 9.

<sup>7</sup> *See* Allan, *supra* note 5; *see also* THE CTR. FOR TELEMEDICINE LAW, OFFICE FOR THE ADVANCEMENT OF TELEHEALTH, TELEMEDICINE LICENSURE REPORT 3 (2003), *available at* <ftp://ftp.hrsa.gov/telehealth/licensure.pdf> [hereinafter LICENSURE REPORT].

<sup>8</sup> Allan, *supra* note 5.

This article argues that telemedicine has the potential to improve our healthcare system, with a particular focus on improving quality. This article then claims that both licensing and reimbursement barriers hinder the growth of telemedicine. Finally, this article suggests that these barriers must be removed before widely implementing and improving telemedicine.

## II. TELEMEDICINE'S POTENTIAL TO IMPROVE QUALITY OF CARE

Currently, federal and state governments, the military, universities, and the private sector are all researching and funding telemedicine. Private sources primarily fund most telemedicine research, which seeks to make telemedicine technology efficient and, more importantly, cost-effective.<sup>9</sup> The internationally accepted definition of telemedicine is “the use of information technology to deliver medical services and information from one location to another.”<sup>10</sup> Examples of telemedicine today range from simple uses, such as physicians researching diagnoses for obscure diseases, to complex uses, like the Korean company, Healthpia's, cell phones for diabetics that have glucose-monitoring devices embedded in them.<sup>11</sup>

Another example of how telemedicine is able to improve quality of care is a device that patients can hold to their chests to record the electrical activity of their hearts, also known as an electrocardiogram, which can be sent directly to physicians.<sup>12</sup> CardioNet also developed a three-lead sensor that patients can wear

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<sup>9</sup> See BRANTLEY ET AL., *supra* note 1, at 50.

<sup>10</sup> Mark A. Cwiek et al., *Telemedicine Licensure in the United States: The Need for a Cooperative Regional Approach*, 13 TELEMEDICINE & E-HEALTH 141, 141 (2007).

<sup>11</sup> See Allan, *supra* note 5.

<sup>12</sup> *Id.*

on their belt that records electrocardiograms<sup>13</sup> The sensor is in constant communication with a monitor that the patients also carry with them, and if the sensor detects arrhythmia, which is abnormal electrical activity of the heart, it sends the electrocardiogram to the nearest CardioNet center.<sup>14</sup> Microsoft has even come up with Bluetooth technology that can connect physiological monitors to phones.<sup>15</sup>

Proponents of telemedicine suggest that barriers to the widespread use of telemedicine prevent society from reaping the benefits of the increased quality of care that telemedicine stands to offer.<sup>16</sup> Telemedicine is already “being provided at home, in prisons, at VA hospitals, in urban settings and in rural areas, in acute and long-term facilities, and by medical specialties and nurses,” but it could be much more widely used.<sup>17</sup> Some indicate that one of the largest barriers is our legal and political approach to healthcare.<sup>18</sup> Part of the problem lies in the lack of coordination among states with respect to licensure. Reimbursement, or lack thereof, is the other major area that poses problems for the integration of telemedicine into our healthcare system. The entire population stands to benefit from removal of these barriers or obstacles. The Technology Administration Report suggests that a more organized and well-coordinated approach by

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

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

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

<sup>16</sup> See Susan E. Volkert, *Telemedicine: RX For The Future Of Health Care*, 6 MICH. TELECOMM. & TECH. L. REV. 147, 149 (2000), see also Cwiek et al., *supra* note 10.

<sup>17</sup> See Volkert, *supra* note 16, at 153.

<sup>18</sup> See generally *id.* at 149 (introducing reasons for hindrance of telemedicine in the United States); see also BRANTLEY ET AL., *supra* note 1, at 10.

government, academic, and private stakeholders is necessary to allow telemedicine to reach its full potential in our healthcare system.<sup>19</sup>

### III. LICENSURE BARRIER

Licensure becomes a problem when a physician practices telemedicine from one state on a patient in another state.<sup>20</sup> Some states have attempted to overcome the licensure barriers that exist from state to state, but critics suggest that until a more uniform approach is taken, telemedicine will not reach its full potential. The outmoded licensure laws of the fifty state jurisdictions prohibit efficient implementation of telemedicine because they limit physicians' practice to specific state geographic boundaries.<sup>21</sup> While some recommend national licensure laws, in 1889, the Supreme Court in *Dent v. State of West Virginia* recognized individual states' jurisdictional right to regulate medical practice.<sup>22</sup> As a result, any proposed national licensure system will likely face resistance from lobbyists, physician organizations, and state licensure boards.<sup>23</sup>

The location of the patient determines the applicable jurisdiction for regulatory purposes.<sup>24</sup> If physicians could easily and affordably obtain licensure in multiple states, this could dramatically affect the cost and quality of care. For example, a stroke patient living in Wisconsin could be treated by a physician in Illinois without ever having to travel, would be afforded convenience, and would

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<sup>19</sup> BRANTLEY ET AL., *supra* note 1, at 14.

<sup>20</sup> Cwiek et al., *supra* note 10, at 142.

<sup>21</sup> *See id.* at 141.

<sup>22</sup> *Id.* at 142, n.9.

<sup>23</sup> *Id.* at 143.

<sup>24</sup> N.Y. State Dep't of Health, Statements on Telemedicine Board for Professional Medical Conduct, <http://www.health.state.ny.us/professionals/doctors/conduct/telemedicine.htm> (last visited Feb. 24, 2010).

avoid travel costs if the physician were licensed in both states.<sup>25</sup> These are the types of innovations that telemedicine can offer if America develops a national or even regional licensure system, but it will not be easy to achieve since the current “system lends itself to a diverse set of approaches taken by states in the licensure of telemedicine.”<sup>26</sup>

States currently vary in their approach to telemedicine licensure. Telemedicine licensures fall into one of four categories: 1) full licensure; 2) mutual recognition; 3) consultation exceptions; and 4) special licensure.<sup>27</sup> First, full licensure is when physicians need an unrestricted license in each state where they plan to interact on any level with patients.<sup>28</sup> According to the 2003 report from the Office for the Advancement of Telehealth, twenty-one states still required full licensure.<sup>29</sup> Second, mutual recognition is the recognition of licensure policies of one state by another state.<sup>30</sup> A state grants reciprocity if the physician’s state license requires the same standards as the state where the physician wishes to interact with patients.<sup>31</sup> Third, consultation exceptions allow physicians from states to *occasionally* consult with patients in another state so long as the physician is not the patient’s primary physician.<sup>32</sup> Finally, a special purpose license allows physicians to use equipment in states where they are not licensed, to transfer patients’ medical information across state lines if the

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<sup>25</sup> See Allan, *supra* note 5.

<sup>26</sup> Cwiek et al., *supra* note 10, at 142.

<sup>27</sup> *Id.* at 143.

<sup>28</sup> *Id.*

<sup>29</sup> LICENSURE REPORT, *supra* note 7, at 7.

<sup>30</sup> Cwiek et al., *supra* note 10, at 143.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

physician is board certified and has no disciplinary actions against him.<sup>33</sup> Special purpose licensure is the closest attempt at eliminating the current geographical barriers to telemedicine, but still requires additional licensure for physicians on a scaled-down level.<sup>34</sup> In 2003, eight states adopted variations of the model law authorizing a special purpose license.<sup>35</sup>

The Federation of State Medical Boards and the National Council of State Boards of Nursing are the only organizations to “officially propose[] licensure models to address practice across state lines.”<sup>36</sup> The Office for the Advancement of Telehealth suggests that a more collaborative approach among states is necessary to incentivize physicians to practice telemedicine across state lines when necessary.<sup>37</sup> One solution would be to establish regional, rather than national, licensing standards for physicians.<sup>38</sup> It is possible to develop uniform state statutes through cooperative action with respect to medical licensure, such as demonstrated by the Uniform Commercial Code.<sup>39</sup> Therefore, states should examine their laws with regard to physician licensing and coordinate by setting standards together in an effort to address major areas that require telemedicine regulation, namely, credentialing, informed consent, and patient confidentiality.<sup>40</sup> If a regional credentialing system were in place, physicians would be encouraged

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

<sup>34</sup> *Id.*

<sup>35</sup> LICENSURE REPORT, *supra* note 7, at 7.

<sup>36</sup> *Id.*

<sup>37</sup> *See id.* (explaining the different approaches that currently exist among states and the slow progress of regulatory reforms).

<sup>38</sup> Cwiek et al., *supra* note 10, at 144.

<sup>39</sup> *Id.* at 145.

<sup>40</sup> *See* Volkert, *supra* note 16, at 158-59.

to practice telemedicine especially in rural areas where it is difficult for patients to obtain care, thus increasing both access to and, ultimately, quality of care.

#### IV. REIMBURSEMENT BARRIER

The other major area where attempts have been made to eliminate barriers to telemedicine is for the reimbursement of telemedicine services. Not providing reimbursement for telemedicine services prevents further investments in telemedicine technologies and creates a disincentive for physicians to use it.<sup>41</sup>

“Traditionally, the three major health care insurers, Medicare, Medicaid, and private insurers, have not reimbursed providers for most telemedicine services.”<sup>42</sup>

A study by Michigan State University’s Department of Telecommunications, however, found that the United States is inching towards more private reimbursement for telemedicine services, although the pace is slower than telemedicine proponents would like to see.<sup>43</sup> Ultimately, the lack of a uniform telemedicine reimbursement system may cause society, and those in the healthcare industry, to view traditional delivery methods as superior to telemedicine as a delivery method.<sup>44</sup>

Historically, telemedicine was reimbursed only in rural areas where access to care was a problem for patients. Gradually, government grants promoted

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<sup>41</sup> BRANTLEY ET AL., *supra* note 1.

<sup>42</sup> Kirsten Rabe Smolensky, *Telemedicine Reimbursement: Raising The Iron Triangle To A New Plateau*, 13 HEALTH MATRIX 371, 374 (2003).

<sup>43</sup> PAMELA WHITTEN & LAURIE BUIS, PRIVATE PAYER REIMBURSEMENT FOR TELEMEDICINE SERVICES IN THE UNITED STATES 2 (2006), available at [http://www.americantelemed.org/files/public/policy/Private\\_Payer\\_Report.pdf](http://www.americantelemed.org/files/public/policy/Private_Payer_Report.pdf) (providing a picture of private payer reimbursement for telemedicine services in the United States and a follow-up to a survey conducted by the American Telemedicine Association and AMD Telemedicine in 2003).

<sup>44</sup> *Id.* at 8.

healthcare organizations to launch telemedicine programs, but when the grants ran out, the organizations often ended these programs.<sup>45</sup> Initially, few public or private payers would reimburse physicians for telemedicine costs, and it was not until the Balanced Budget Act of 1997 (BBA), that Congress required Medicare to reimburse for telemedicine.<sup>46</sup>

During the first two years following the enactment of the BBA on January 1, 1999, Medicare reimbursed a total of \$20,000 for 301 claims resulting from telemedicine consultations.<sup>47</sup> This amount is relatively low and can be attributed to several factors that limit the BBA's reimbursement requirements. First, the BBA limited Medicaid reimbursement to patients in Health Professional Shortage Areas, which excluded many patients living in rural areas where there is access to primary care physicians or nurses, but not specialists, who are often more costly.<sup>48</sup> Second, the BBA imposed a fee-sharing requirement that was problematic for accounting and fee tracking, especially for rural physicians without the resources to track the fee splitting.<sup>49</sup> Finally, in rural areas, clinics often employ only nurses or health technicians, who were ineligible presenters according to the BBA.<sup>50</sup>

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 went into effect in October, 2001 and aimed to eliminate

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<sup>45</sup> *Id.* at 7.

<sup>46</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., 2001 TELEMEDICINE REPORT TO CONGRESS 17 (2001), available at <ftp://ftp.hrsa.gov/telehealth/report2001.pdf>.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

some of the requirements that were problematic under the BBA.<sup>51</sup> Now, there are twenty state Medicaid programs, several state Blue Cross/Blue Shield plans, and some other private insurers that pay for at least some telemedicine services.<sup>52</sup> State Medicaid programs, however, vary in what is covered, who is covered, billing, licensure, and store-and-forward versus live consultation coverage.<sup>53</sup> Store-and-forward is a term used to describe medical data that is recorded and stored by a device like a camera and forwarded through telecommunication to a different site for consultation by a physician.<sup>54</sup>

According to the Centers for Medicare and Medicaid Services, “[w]hile telemedicine is not considered a distinct Medicaid service, any State wishing to cover/reimburse for telemedicine services should submit a State Plan Amendment to the Centers for Medicare and Medicaid Services for approval.”<sup>55</sup> Many states are waiting to review results from other state programs before pursuing telemedicine reimbursement.<sup>56</sup> Thus, as more states adopt reimbursement policies, they will encourage other states to follow their lead. While advancements in reimbursement for telemedicine services have been made both on the state and federal levels, these policies need to be made more clear so that

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<sup>51</sup> *See id.* at 19.

<sup>52</sup> *Id.*

<sup>53</sup> *See* TELEHEALTH CONNECTIONS FOR CHILDREN & YOUTH, INST. FOR CHILD HEALTH POLICY, TELEMEDICINE FOR CSHCN: A STATE-BY-STATE COMPARISON OF MEDICAID REIMBURSEMENT POLICIES AND TITLE V ACTIVITIES 5 (2005), available at <http://www.ichp.ufl.edu/documents/Telemedicine%20in%20Medicaid%20and%20Title%20V%20Report.pdf> [hereinafter CSHCN REPORT].

<sup>54</sup> *See id.* at 34.

<sup>55</sup> Cts. for Medicare & Medicaid Servs., Overview: Telemedicine and Telehealth, <http://www.cms.hhs.gov/Telemedicine/> (last visited Apr. 1, 2010).

<sup>56</sup> *See* CSHCN REPORT, *supra* note 53, at 6.

physicians are more inclined to perform telemedicine, thereby improving the quality and access to care for many Americans.

#### V. THE FUTURE OF TELEMEDICINE

Telemedicine has gained many supporters, and its potential to improve access and quality of care for patients has attracted the attention of the government and the medical community. At the moment, there are several pending telemedicine bills in Congress.<sup>57</sup> As of October 15, 2009, the majority of the pending telemedicine bills dealt with applying telemedicine to medically underserved areas, and there was a lack of reimbursement-based bills.<sup>58</sup>

A key to encouraging private payers to reimburse for telemedicine is to persuade Medicare to broaden its reimbursement policies.<sup>59</sup> As one author aptly stated, it is “[a] generally accepted maxim in health care: Where Medicare goes, the rest of the country follows.”<sup>60</sup> The Medicare Telehealth Enhancement Act, which was introduced in May 2009, proposed to expand Medicare reimbursement to those left currently without access.<sup>61</sup> Congressmen are beginning to recognize the potential for telemedicine to lower costs and increase access.<sup>62</sup> In fact, Democratic representative, Mike Thompson of California, noted that “[t]he Obama administration has indicated that telemedicine will be an important part of

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<sup>57</sup> See generally AM.TELEMEDICINE ASS’N, PENDING TELEMEDICINE BILLS IN CONGRESS 2-5 (2009), <http://www.americantelemed.org/files/public/policy/Pending%20Bills.pdf> (list of pending telemedicine bills as of October 15, 2009).

<sup>58</sup> See *id.*

<sup>59</sup> See George Lauer, *Medicare Telemedicine Bill Could Change Landscape*, iHEALTHBEAT, May 8, 2009, <http://www.ihealthbeat.org/features/2009/medicare-telemedicine-bill-could-change-landscape.aspx>.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

their health care reform agenda” as an effort to expand access to the important technology.<sup>63</sup> The current administration demonstrated their support by including \$7.2 billion for broadband deployment, including telemedicine and educational systems in the American Recovery and Reinvestment Act.<sup>64</sup>

## VI. CONCLUSION

Due to technological advancements in telemedicine, there has been an increase in quality healthcare. Thus, if the major licensing and reimbursement barriers can be overcome, the result will be better quality of care for Americans. Though slow to evolve, there is an awareness of the problems that licensing and reimbursement pose to telemedicine, and attempts are being made to solve these problems. Cooperation and awareness among state legislatures about possible regional or national licensing approaches will lead to better solutions for patients that need access to physicians across state lines.

Additionally, if Medicare reimbursement for telemedicine is expanded, it is likely that private insurers will follow suit. Furthermore, the more data and research that is collected about telemedicine and its advantages to patients’ quality of care, the more likely private insurers are to reimburse for telemedicine services. The future looks promising for the growth of telemedicine and its ability to reduce costs to patients while also improving the quality of their care.

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

<sup>64</sup> *Id.*

# ANNALS OF HEALTH LAW

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### *Telemedicine: Revamping Quality Healthcare in Rural America*

*Dominique LeVert*\*

#### I. INTRODUCTION

For everywhere we look, there is work to be done. The state of our economy calls for action: bold and swift. And we will act not only to create new jobs but to lay a new foundation for growth. We will build the roads and bridges, the electric grids and digital lines that feed our commerce and bind us together. We will restore science to its rightful place and wield technology's wonders to raise health care's quality and lower its costs.<sup>1</sup>

These words by President Obama reflect the need to expand the use of technology in healthcare. The media and opinion polls convey the general public sentiment that the healthcare system needs revamping.<sup>2</sup> Healthcare reform policies consistently emphasize three areas where change is necessary: cost, access, and quality.<sup>3</sup> Telemedicine offers a medium through which the healthcare system can improve healthcare costs, increase patient access to the system, and potentially improve the quality of care patients receive.<sup>4</sup>

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<sup>1</sup> President Barack Obama, Inaugural Address (Jan. 20 2009), available at <http://www.whitehouse.gov/blog/inaugural-address/>.

<sup>2</sup> Thomas Bodenheimer, *The Political Divide In Health Care: A Liberal Perspective*, 24 HEALTH AFF. 1426, 1429 (2005).

<sup>3</sup> Heather L. Daly, *Telemedicine: The Invisible Legal Barriers to the Health Care of the Future*, 9 ANNALS HEALTH L. 73, 74 (2000).

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

In addressing the need for improvement in quality care for rural residents, the advantages of telemedicine are endless. In 2005, only 25% of the entire medical community used telemedicine.<sup>5</sup> Providing better quality care to rural residents is a major issue today. A nationwide shortage of primary care professionals affects rural healthcare providers at higher rates than their urban counterparts.<sup>6</sup> Roughly 10% of physicians practice in rural America, which represents nearly one-fourth of the national population.<sup>7</sup> Factors that influence where physicians choose to practice include locations offering higher incomes, professional status, and prestige.<sup>8</sup> Reasons that deter physicians from moving to and practicing in rural areas include professional isolation, unavailability of continuing education, limited support services, lack of complete medical facilities, excessive work loads, and time demands.<sup>9</sup>

“Some rural areas do not have a sufficient number of medical personnel and lack facilities to provide basic health care services.”<sup>10</sup> As rural hospitals close their doors, patients in need of care must travel further distances to receive health care services.<sup>11</sup> If patients have to travel long distances to receive care, they are less likely to receive regular physicals and are more likely to wait for a medical

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<sup>5</sup> Lisa Rannefeld, *The Doctor Will E-mail You Now: Physician's Use of Telemedicine to Treat Patients Over the Internet*, 19 J.L. & HEALTH 75, 78 (2005).

<sup>6</sup> Ann Davis Roberts, *Telemedicine: The Cure for Central California's Rural Health Care Crisis?*, 9 SAN JOAQUIN AGRIC. L. REV. 141, 150 (1999).

<sup>7</sup> Nat'l Rural Health Ass'n, *What's Different about Rural Health Care?*, <http://www.nrharural.org/go/left/about-rural-health> (last visited February 26, 2010).

<sup>8</sup> Daniel McCarthy, Note and Comment, *The Virtual Health Economy: Telemedicine and the Supply of Primary Care Physicians in Rural America*, 21 AM. J.L. & MED. 111, 120 (1995).

<sup>9</sup> Roberts, *supra* note 6, at 151.

<sup>10</sup> Ira Moscovice & Roger Rosenblatt, *Quality-of-Care Challenges for Rural Health*, 16 J. RURAL HEALTH 168, 171 (2000).

<sup>11</sup> Roberts, *supra* note 6, at 152.

crisis to occur before receiving care.<sup>12</sup> Thus, a major obstacle to providing better quality care to rural residents is attracting and retaining providers to serve in these communities and hospitals.<sup>13</sup>

This article will examine the potential telemedicine has to improve quality of care for patients living in rural areas. First, this article will discuss the background of telemedicine in health care. Second, it will address the issue of quality of care and discuss the lack of quality medical care rural patients receive. Finally, the paper will provide insight as to whether telemedicine will help address quality of care issues for rural patients.

## II. HISTORY OF TELEMEDICINE

The advent of telecommunication has forever changed the way society conducts daily affairs.<sup>14</sup> Telecommunication is the “communication over a distance by cable, telegraph, telephone, or broadcasting.”<sup>15</sup> The healthcare industry began employing telecommunication in the 1950s at the National Institute of Mental Health when it connected seven state hospitals in four states through a closed-circuit telephone system.<sup>16</sup> The use of telecommunication in healthcare continued to expand as technology advanced, and today, this is referred to as telemedicine, telehealth, and cybermedicine. Although some organizations

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<sup>12</sup> Nicole Winbush, M.D. & Renee Circhlow, M.D., *Rural Health Care—A Perport from Montana and Beyond*, WOMEN’S HEALTH ACTIVIST NEWSLETTER, January 2005, <http://nwhn.org/rural-health-care-perport-montana-and-beyond>.

<sup>13</sup> Moscovice & Rosenblatt, *supra* note 10.

<sup>14</sup> LILLIAN GOLENIOWSKI, *Understanding the Telecommunications Revolution*, in TELECOMMUNICATIONS ESSENTIALS: THE COMPLETE GLOBAL SOURCE FOR COMMUNICATIONS FUNDAMENTALS, DATA NETWORKING AND THE INTERNET, AND NEXT-GENERATION NETWORKS 3, 3 (2001), available at <http://www.informit.com/articles/article.aspx?p=24667>.

<sup>15</sup> OXFORD MODERN ENGLISH DICTIONARY 504 (2d ed. 1996).

<sup>16</sup> Shannon S. Venable, *A Call to Action: Georgia Must Adopt New Standard of Care, Licensure, Reimbursement, and Privacy Laws for Telemedicine*, 54 EMORY L.J. 1183, 1185 (2005).

prefer to keep telehealth and cybermedicine as distinct categories separate from telemedicine, others incorporate the terms into the broader category of telemedicine, and still others believe that the definition of telehealth is the most expansive definition by including telemedicine and cybermedicine.<sup>17</sup> For the purposes of this paper, telemedicine will not be a distinct classification, but instead will include telehealth and cybermedicine in its characterization.

Due to the vast array of services telemedicine encompasses, defining “telemedicine” is complex. Simply defined, telemedicine is the provision of healthcare consultation and education using telecommunication networks to transfer information.<sup>18</sup> This refers to all health care practiced at a distance, ranging from a telephone call to remote surgery.<sup>19</sup> The World Health Organization states that “telemedicine consists of using remote transmission of video, audio, and text data to provide information to individuals involved in a patients care.”<sup>20</sup> Telemedicine is applied by “transporting medical data through phone or fax machines” and the use of “interactive video conferencing by satellites or fiber optic technology.”<sup>21</sup> Telemedicine provides numerous programs and services such as “specialist referral services, patient consultations, remote patient monitoring, medical education, and consumer medical and health information.”<sup>22</sup>

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<sup>17</sup> See *Id.*; See also Rannefeld, *supra* note 5, at 77.

<sup>18</sup> Daly, *supra* note 3, at 76.

<sup>19</sup> *Id.* at 75.

<sup>20</sup> Venable, *supra* note 16.

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

<sup>22</sup> Holly Carnell, *How Illinois is Using Telemedicine to Improve Health Care Access in Rural Communities*, 13 PUB. INT. L. REP. 159, 160 (2008).

Following the start of the closed-circuit telephone system in the 1950s,<sup>23</sup> NASA implemented the use of telemedicine in the 1960s to monitor the health of astronauts in space via satellite transmissions of voice and data.<sup>24</sup> The information and technology boom that occurred in the mid-1990s greatly expanded the use of telemedicine by allowing more sophisticated applications to be used, such as electronic patient records and the use of smart cards.<sup>25</sup> Today, telemedicine uses are commonly divided into four broad categories of programs: (i) electronic records; (ii) store and forward technology; (iii) interactive video conferencing; and (iv) remote surgery.<sup>26</sup>

The technology and information boom prompted the federal government to examine the barriers and implications in expanding telemedicine applications within the healthcare system.<sup>27</sup> The first step came with the enactment of the Telecommunications Act of 1996 which required telephone companies to provide universal service in remote areas and prohibited excessive charges to residents accessing telephone services.<sup>28</sup> Additional provisions required the “[Federal Communications Commission] to assure that health care providers serving rural areas have access to telecommunication services necessary for the delivery of health care.”<sup>29</sup> Rural areas rank the lowest in accessibility to high quality and

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<sup>23</sup> Venable, *supra* note 16.

<sup>24</sup> Rannefeld, *supra* note 5.

<sup>25</sup> *Id.*; See also Venable, *supra* note 16, at 1186.

<sup>26</sup> Daly, *supra* note 3, at 78.

<sup>27</sup> See DEPARTMENT OF HEALTH AND HUMAN SERVICES, TELEMEDICINE REPORT TO CONGRESS 1 (2001), available at <ftp://ftp.hrsa.gov/telehealth/report2001.pdf>.

<sup>28</sup> Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANNALS HEALTH L. 205, 216 (2005).

<sup>29</sup> THE JOINT WORKING GROUP ON TELEMEDICINE, TELEMEDICINE REPORT TO CONGRESS 54 (1997), available at [http://telehealthlawcenter.org/loadattachment.php?attachmentid=127\\_1356\\_179](http://telehealthlawcenter.org/loadattachment.php?attachmentid=127_1356_179) [hereinafter TELEMEDICINE REPORT].

high capacity modern telecommunications.<sup>30</sup> The current lack of accessibility to broadband services hinders the furtherance of telemedicine because broadband services are needed to achieve “meaningful use” of electronic health records.<sup>31</sup>

Furthermore, the Act granted the use of up to \$400 million annually to subsidize the improvement to rural providers’ telecommunication networks.<sup>32</sup> The federal subsidies combined with a restriction on providers from charging higher rates in rural areas than urban, the intervention by the federal government allowed urban specialists to communicate with rural practitioners or patients in a cost-effective manner.<sup>33</sup> Although this Act provided a means to improve healthcare access and address the issue of cost, it failed to address the standards by which telemedicine practice should be governed.<sup>34</sup> Thus, although access improved between the urban and rural populace, legal barriers prohibited the expansion across state lines.<sup>35</sup>

In 1997, the Joint Working Group on Telemedicine (the Group) issued a Telemedicine Report to Congress stating that before telemedicine can flourish, numerous legal, technical, and political issues must be resolved.<sup>36</sup> Key areas the Group highlighted include the licensure of telemedicine health professionals, reimbursement for telemedicine services, and the infrastructure costs and

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<sup>30</sup> *Id.* at 53.

<sup>31</sup> Kendra Casey Plank, *Providers, Payers Praise FCC Broadband Plan as Practical for Advancing Health IT*, 15 HEALTH CARE DAILY REP. (2010), <http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-83NM8C?OpenDocument>.

<sup>32</sup> Erin K. Grunzke, *Long-Distance Doctors: The Crossroads of Telemedicine Licensure in Illinois*, 89 ILL. B.J. 362, 362 (2001).

<sup>33</sup> McLean, *supra* note 28.

<sup>34</sup> Grunzke, *supra* note 32.

<sup>35</sup> *Id.* at 363.

<sup>36</sup> TELEMEDICINE REPORT, *supra* note 29, at 1.

accessibility for telemedicine use.<sup>37</sup> Additionally, the Group emphasized the critical role the federal government would need to play in the expansion of telemedicine.<sup>38</sup> The Report also stressed that the issue of reimbursement remained a critical barrier to the expansion of telemedicine.<sup>39</sup>

### III. QUALITY OF CARE AND THE RURAL PATIENT

Despite the legal barriers telemedicine must overcome before it proliferates throughout the healthcare industry, telemedicine proponents stress that the technology will vastly improve the quality of care patients will receive, especially in underserved rural areas.<sup>40</sup> But how does one define “quality of care?” The Institute of Medicine defines “quality of care” as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”<sup>41</sup> Elements of quality care include: (i) recognizing patients at risk for diseases; (ii) conducting the appropriate evaluation(s); (iii) making the appropriate diagnosis; (iv) starting the appropriate treatment; (v) scheduling the appropriate follow-up; and (vi) encouraging adherence to treatment plan.<sup>42</sup>

Policymakers and providers face the daunting task of improving quality care while enacting policies to curb the rising costs associated with the delivery of

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 41.

<sup>40</sup> Telemedicine Info. Exch., HHS Details Impact of Telehealth and Broadband Funding, <http://telemed.org/news/archive.asp?ID=1624> (last visited Mar. 30, 2010).

<sup>41</sup> Stanley Feld, What is the Definition Of Quality Medical Care?, [http://stanleyfeldmdmace.typepad.com/repairing\\_the\\_healthcare\\_/2007/03/what\\_is\\_the\\_def.html](http://stanleyfeldmdmace.typepad.com/repairing_the_healthcare_/2007/03/what_is_the_def.html) (last visited Apr. 12, 2010).

<sup>42</sup> *Id.*

health care.<sup>43</sup> The quality of care a patient receives depends on various factors, such as the healthcare provider itself, training of healthcare personnel, where the patient lives, and the types of technology available to providers.<sup>44</sup> The criteria for evaluating the quality of care providers offer patients are considered on various levels. Accrediting bodies, such as the National Committee for Quality Assurance or the Joint Commission on the Accreditation of Healthcare Organizations, check medical providers to ensure providers are meeting specific standards of care.<sup>45</sup> These standards of care are applicable not only to the institutions, but healthcare personnel as well.<sup>46</sup> Furthermore, agencies, such as the Agency for Healthcare Research and Quality, instituted programs that allow consumers to offer their opinion on the quality of health plans and providers from the enrollee's perspective.<sup>47</sup>

Ensuring that quality care is provided means different things at various levels in the delivery of health care. Proper procedures and staffing ratios must be met.<sup>48</sup> If a provider cannot maintain an appropriate staff, then the quality of care will likely suffer due to a higher patient to staff ratio.<sup>49</sup> Providers must strike the

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<sup>43</sup> See The Henry J. Kaiser Family Found., Quality of Care, <http://www.kaiseredu.org/topics.asp?id=70&isID=30&refID=31&sidenav=249&smart=59&tuID=65> (last visited Mar. 6, 2010) [hereinafter Kaiser].

<sup>44</sup> Agency for Healthcare Research & Quality, Understanding Health Care Quality, <http://www.ahrq.gov/consumer/guidetoq/guidetoq4.htm> (last visited Mar. 6, 2010) [hereinafter AHRQ]; see also Kaiser, *supra* note 43.

<sup>45</sup> Denise Wang, *Definition of Quality Health Care*, EHOW, [http://www.ehow.com/about\\_5085075\\_definition-quality-health-care.html](http://www.ehow.com/about_5085075_definition-quality-health-care.html).

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

<sup>47</sup> Agency for Healthcare Research & Quality, The CAHPS Program, [https://www.cahps.ahrq.gov/content/cahpsOverview/OVER\\_Program.asp?p=101&s=12](https://www.cahps.ahrq.gov/content/cahpsOverview/OVER_Program.asp?p=101&s=12) (last visited Apr. 12, 2010).

<sup>48</sup> Wang, *supra* note 45.

<sup>49</sup> John M. Welton, *Mandatory Hospital Nurse to Patient Staffing Ratios: Time to Take a Different Approach*, 12 ONLINE J. ISSUES IN NURSING (2007), <http://www.nursingworld.org/>

right balance when supplying health care services, such as avoiding overuse, avoiding underuse, and eliminating misuse.<sup>50</sup> Establishing measures that outline what services should be provided to patients and under what conditions, helps providers maintain this balance when delivering patient care.<sup>51</sup> Providers set procedures for screening, immunizations, and other preventive care.<sup>52</sup> Often, patients do not receive proven therapies or preventative measures, resulting in a high rate of preventable medical errors.<sup>53</sup> Quality care involves not only the proper measures for evaluating patients, but also the diagnosis, treatment, and follow-up.<sup>54</sup>

Proponents continue to push for more legislation to aid the expansion of telemedicine usage in the healthcare industry.<sup>55</sup> They argue telemedicine improves the quality of care patients receive, especially in rural areas where quality care is especially hard to find.<sup>56</sup> A recent study found that patients reported a higher rate of satisfaction with patient-physician communication during telemedicine consultations as opposed to in-person visits.<sup>57</sup> Based upon this study, telemedicine poses to improve quality care in rural areas because it offers

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<sup>50</sup> AHRQ, *supra* note 44.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> Kaiser, *supra* note 43.

<sup>54</sup> Feld, *supra* note 41.

<sup>55</sup> Andrew Noyes, *Tech Groups Push for Telehealth Provisions in Health Reform Bill*, CONGRESSDAILY, <http://www.ihealthbeat.org/articles/2009/7/29/tech-groups-push-for-telehealth-provisions-in-health-reform-bill.aspx>.

<sup>56</sup> Charles Casey, *Telehealth Resource Center Breaks Ground*, <http://www.universityofcalifornia.edu/news/article/22673> (last visited Apr. 12, 2010).

<sup>57</sup> Zia Agha et al., *Patient Satisfaction with Physician-Patient Communication During Telemedicine*, 15 *TELEMEDICINE & E-HEALTH* 830, 834 (2009).

rural patients the opportunity for more health care services without negatively affecting patient satisfaction levels.

#### IV. TELEMEDICINE AND THE RURAL PATIENT

Proponents boast that telemedicine will minimize the non-financial factors associated with physician's aversion to practice in rural areas.<sup>58</sup> First, telemedicine decreases physician isolation by allowing physicians to consult with other physicians without having to travel long distances.<sup>59</sup> Second, telemedicine will expand physicians' educational resources by providing up to date information on medical studies and technology; thus, allowing physicians to continue their education without having to travel long distances.<sup>60</sup> In addition, telemedicine will fuel medical knowledge by connecting physicians from all over the world.<sup>61</sup> Third, support services will increase because telemedicine connects physicians in rural areas to specialists located in urban centers, permitting concurrent examination and consultations regarding a patient.<sup>62</sup> Rural physicians' connections to specialists will also increase the physicians' medical knowledge as they will learn the skills needed to treat the same or similar conditions on their own in the future.<sup>63</sup> This decreases the effect of isolation by allowing the physician to easily consult with another physician or specialist when difficult cases arise, as would occur in larger urban hospitals.<sup>64</sup>

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<sup>58</sup> Roberts, *supra* note 6; *see also* McCarthy, *supra* note 8, at 126.

<sup>59</sup> Roberts, *supra* note 6.

<sup>60</sup> *Id.* at 151.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 152.

<sup>64</sup> *Id.* at 151.

In addition to diminishing the factors that deter physicians from practicing and remaining in rural areas, telemedicine can improve the quality care rural patients receive by diminishing the distance the patients must travel to receive care.<sup>65</sup> Proponents argue that telemedicine will address the intangible physician concerns because it decreases the need for primary care physicians, while not completely replacing them.<sup>66</sup> Telemedicine offers rural patients the choice of being examined by a primary physician at a distant site.<sup>67</sup> Rural facilities linked to an off-site location that houses a primary care physician will enable rural residents to receive complete physical examinations by an off-site physician.<sup>68</sup> Mid-level practitioners are able to act as primary care providers for rural patients because they are supervised by primary care physicians via telemedicine systems.<sup>69</sup> Furthermore, telemedicine decreases the need for patients to see primary care physicians. Physicians can do follow up care after emergency treatment remotely, instead of face-to-face.<sup>70</sup>

Telemedicine increases the quality of care provided to rural patients because it expands the services rural facilities can offer.<sup>71</sup> The quality of physicians increases when providers use telemedicine.<sup>72</sup> Local physicians become more educated through the use of telemedicine, and increased access to

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<sup>65</sup> McCarthy, *supra* note 8, at 126-27.

<sup>66</sup> *Id.* at 126.

<sup>67</sup> Roberts, *supra* note 6, at 152.

<sup>68</sup> *Id.*

<sup>69</sup> McCarthy, *supra* note 8, at 127.

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

<sup>71</sup> BRIAN E. WHITACRE ET AL., NAT'L CTR. FOR RURAL HEALTH WORKS, ECONOMIC IMPACT OF TELEMEDICINE CAPABILITY IN A RURAL HOSPITAL 8 (2007), [http://www.ruralhealthworks.org/downloads/Economic/Telemedicine\\_EI\\_Study.pdf](http://www.ruralhealthworks.org/downloads/Economic/Telemedicine_EI_Study.pdf).

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

specialists allows rural facilities to offer better quality care.<sup>73</sup> Furthermore, even when mid-level practitioners supply services under the supervision of an off-site physician, quality care for rural patients is enhanced because the patients receive services that they may have otherwise gone without.<sup>74</sup>

#### V. CONCLUSION

The delivery of health care forever changed with the onset of telecommunication. As technology advanced, the concept of telemedicine expanded and includes the electronic delivery of health records, remote consultations, remote surgeries, and remote patient monitoring. President Obama's proposed budget for 2011 cut rural healthcare projects by \$44 million dollars.<sup>75</sup> However, Obama defended this by stating that the budget slated \$142 million for improving rural residents' access to quality care.<sup>76</sup> Additionally, the proposal to improve access in rural areas further stated that "[the Health Resources Services Administration] will develop stronger links between telehealth activities and other investments in rural health."<sup>77</sup> Rural health care needs help, and telecommunication can provide the answer with higher quality services.

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<sup>73</sup> *Id.*

<sup>74</sup> McCarthy, *supra* note 8, at 127.

<sup>75</sup> Cheryl Clark, *Obama's Proposed Budget is a Mixed Bag for Rural Health*, HEALTHLEADERS MEDIA, Feb. 2, 2010, <http://www.healthleadersmedia.com/content/COM-245925/Obamas-Proposed-Budget-is-a-Mixed-Bag-for-Rural-Health>.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

# ANNALS OF HEALTH LAW

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### *Righting the Stereotypes in Quality of Care Between Rural and Urban Hospitals*

*Drew Steven Kushnick\**

#### I. INTRODUCTION

Rural hospitals are important to the rural landscape because they are the primary source of health care for a rural community, since the next nearest hospital may be hours away.<sup>1</sup> They also attract physicians and health care providers to the area.<sup>2</sup> Despite their importance in the community, rural hospitals have historically been considered substandard in comparison to urban hospitals.<sup>3</sup> Rural hospitals have dealt with hardships, most of which are economic, but they also have been unable to shed the stereotype of providing a lesser quality of care

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<sup>1</sup> Claude Earl Fox, M.D., Adm'r. of Health Resources & Servs. Admin., Dep't of Health & Human Serv., Testimony on the Potential Crisis Facing Rural Hospitals and the Impact on Rural Communities (July 14, 2009), *available at* <http://www.hhs.gov/asl/testify/t990714c.html> [hereinafter Testimony of Fox]; Robert A Berenson, M.D., Dir. of the Ctr. for Health Plans & Providers, Dep't of Health & Human Serv., Testimony on the Balanced Budget Act and Rural Hospitals (July 14, 2009), *available at* <http://www.hhs.gov/asl/testify/t990714b.html> [hereinafter Testimony of Berenson"].

<sup>2</sup> Testimony of Fox, *supra* note 1.

<sup>3</sup> See Reuters Health. *Heart Care in Rural Hospitals Matches Urban Ones*. REUTERS, Dec. 3, 2009, *available at* <http://www.reuters.com/article/idUSTRE5B24W820091203> [hereinafter *Heart Care*].

to patients.<sup>4</sup> A 1979 report illustrated this perceived deficiency by stating “that the number of procedures performed at a hospital (hospital volume) and mortality rates for many surgical procedures were inversely related.”<sup>5</sup> Exacerbating this stigma, rural hospitals generally do not have specialists that provide more specific care, due to the lower volume of patients.<sup>6</sup>

In the past, rural hospitals may have provided a lesser quality of care; however, rural hospitals have closed the gap in care and are now equal to smaller urban hospitals for many health care treatments, including care for myocardial infarctions, also known as heart attacks, and Cesarean sections.<sup>7</sup> In some areas, such as strokes, rural care lags behind urban hospitals, but many new procedures are being used to lower differences in care.<sup>8</sup>

Rural hospitals have proven to be an integral part of their communities by providing necessary care as well as maintaining the economic stability of the area.

With many rural hospitals struggling financially and being forced to close in the

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<sup>4</sup> James Rohrer, *Closing Rural Hospitals: Reducing “Institutional Bias” or Denial of Access*, 10 J. PUB. HEALTH POL’Y 353, 356 (1989); Emmett Keeler, et al., *Hospital Characteristics and Quality of Care*, 268 J. AM. MED. ASS’N, 1709, 1709 (1992). (“Many studies have shown that better outcomes for specific procedures are related to the number of such procedures that hospitals and physicians perform”).

<sup>5</sup> Arnold Epstein, *Volume and Outcome - It is Time to Move Ahead*, 346 NEW ENG. J. MED. 1161, 1161 (2002).

<sup>6</sup> Paul James, et al., *Myocardial Infarction Mortality in Rural and Urban Hospitals: Rethinking Measures of Quality of Care*, 5 ANNALS FAMILY MED. 105, 105 (2007).

<sup>7</sup> See *infra* notes 13-35 and accompanying text (discussing statistical analyses that assessed myocardial infarction and Cesarean section rates in rural versus urban hospitals); see also *Heart Care*, *supra* note 3; Sandra Greene, et al., N. CAROLINA RURAL HEALTH RESEARCH AND POL’Y ANALYSIS CTR., CESAREAN SECTION RATES IN RURAL HOSPITALS 1 (Mar. 2005), available at [http://www.shepscenter.unc.edu/rural/pubs/finding\\_brief/FB79.pdf](http://www.shepscenter.unc.edu/rural/pubs/finding_brief/FB79.pdf) (noting that a Cesarean section is a “major abdominal surgery that carries risk to both mother and baby” and that best practices including vaginal birth “to women with previous deliveries by Cesarean section.”).

<sup>8</sup> See Enrique C. Leira, et al., *Rural-Urban Differences in Acute Stroke Management Practices: A Modifiable Disparity*, 65 ARCHIVES NEUROLOGY 887, 889 (2008); Jacques Joubert, et al., *Stroke in Rural Areas and Small Communities*, 39 J. AM. HEART ASS’N 1920, 1922 (2008).

1980s and 1990s,<sup>9</sup> it appeared that many rural lives would change, but the federal government stepped in to provide economic relief by enacting the Balanced Budget Act (BBA) of 1999.<sup>10</sup> This allowed many rural hospitals to remain open and kept the quality of care in those communities higher than they would be without a local hospital.

This article is going to address whether the stereotypes about rural hospitals having lower quality of care are actually true. It will also look at how rural hospitals improve their care and economic stability since they are an important component of health care in the American landscape.

## II. QUALITY OF CARE

Rural hospitals may have provided a lower quality of care in the past; however, rural hospitals have almost eliminated the gap in care for myocardial infarctions and Cesarean sections.<sup>11</sup> In some areas, such as strokes, rural care lags behind urban hospitals, but many new procedures are being used to lower differences in care.<sup>12</sup> These three procedures and conditions are discussed because they are common to both the rural and urban landscape and can have serious impacts on a patient.

### A. *Myocardial Infarctions*

In 2007, a study was published focusing on the quality of care between Iowa's rural and urban hospitals based on in-hospital mortality rates for patients

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<sup>9</sup> Testimony of Fox, *supra* note 1.

<sup>10</sup> Testimony of Berenson, *supra* note 1 (discussing rationale behind and effect of the BBA).

<sup>11</sup> See *infra* notes 13-35 and accompanying text; see also *Heart Care*, *supra* note 3; Greene, et al., *supra* note 7.

<sup>12</sup> See Leira, et al., *supra* note 8; Joubert, et al., *supra* note 8.

that had myocardial infarctions.<sup>13</sup> The crude numbers showed rural hospitals having a significantly higher mortality rate (14%) than urban hospitals (6.4%).<sup>14</sup> Certain variables were discovered, however, that may have caused rate exaggeration,<sup>15</sup> suggesting that the disparities between rural hospitals and their urban counterparts were not quite as great.

First, the study found that patient demographics were very different between the two types of hospitals.<sup>16</sup> Patients admitted to urban hospitals were younger, while patients admitted to rural hospitals were substantially older and sicker.<sup>17</sup> Also, patients who were originally admitted to a rural hospital, and later transferred to an urban hospital had lower risk profiles than patients who remained at rural hospitals.<sup>18</sup> Since the sickest patients are kept at rural hospitals and the ones with a lower risk profile are transferred, it is sensible that the in-hospital mortality rates would be higher. Once the study controlled the selection bias and evaluated the mortality of comparable patients between rural and urban hospitals, different numbers resulted.<sup>19</sup> The study “showed that patients with myocardial infarction admitted to urban hospitals no longer have reduced in-hospital mortality compared with their counterparts admitted to rural hospitals.”<sup>20</sup>

Another study, running over eight years, used more than 350,000 patients who were treated for heart problems, including heart attack, severe chest pain, and

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<sup>13</sup> James et al., *supra* note 6, at 106.

<sup>14</sup> *Id.* at 107.

<sup>15</sup> *Id.* at 107-08.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 106, 108.

<sup>18</sup> *Id.* at 108.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* at 110.

blocked heart arteries.<sup>21</sup> Without controlling for any demographic variables the death rate for patients at urban hospitals was 4.5% while only 5.7% at rural hospitals.<sup>22</sup> Once the researchers accounted for other variables, such as patient age and co-existing medical conditions, the study found no significant difference in rural and urban patients' risk of dying, and concluded that "similar patients getting similar procedures at rural and urban centers fare equally well."<sup>23</sup>

The research study revealed two differences between rural and urban hospitals in the facilities and resources provided by the hospital.<sup>24</sup> First, only 46% of rural hospitals provided onsite cardiac surgery, while 82% of urban hospitals were able to provide similar cardiac surgery.<sup>25</sup> Second, rural hospitals had lower rates for providing patients with guideline recommended therapies, but when accounting for patients' health and other characteristics, there were no substantial difference in receiving the recommended therapies.<sup>26</sup> The study concluded that there was no difference in care between rural and urban hospitals.<sup>27</sup>

The two studies show that crude numbers may exaggerate rural hospitals' mortality rates, but when accounting for patient characteristics, the statistical difference between rural and urban hospitals becomes negligible.

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<sup>21</sup> *Heart Care*, *supra* note 3.

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

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *See id.* (noting that guideline therapies include giving aspirin within twenty-four hours of heart attack symptoms, smoking-cessation counseling, and prescriptions for blood pressure and cholesterol drugs).

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

*B. Cesarean Sections*

A Cesarean section is a major abdominal surgery used to deliver babies.<sup>28</sup> Cesarean sections are more dangerous to the mother and baby than vaginal delivery; thus, they are usually performed only when a doctor anticipates a problem or a problem occurs during delivery.<sup>29</sup> The rates for performing Cesarean sections are only slightly higher between rural (25.3%) and urban (24.9%) hospitals.<sup>30</sup> Furthermore, when urban hospitals were classified into teaching and non-teaching hospitals, it was found that “the rate in the urban non-teaching hospitals was identical to the [total] rural [hospital] rate.”<sup>31</sup>

Rural hospitals had a higher rate of Cesarean sections on weekdays and a lower rate on weekends, almost a 10% drop,<sup>32</sup> than their urban counterparts.<sup>33</sup> Based on these statistics, some people have assumed that rates for Cesarean sections may be higher in rural hospitals because of the lack of or inadequate surgical coverage on weekends.<sup>34</sup> Since there is less surgical coverage on weekends, many rural doctors schedule Cesarean sections during the week in anticipation of possible weekend deliveries that could have problems.<sup>35</sup> This use of preventative care is one reason that there is a dramatic decrease of Cesarean sections on weekends. Therefore, even though a Cesarean section may be more

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<sup>28</sup> Greene et al., *supra* note 7, at 1.

<sup>29</sup> *See id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 3.

<sup>33</sup> *Id.* at 1.

<sup>34</sup> *See, e.g., id.* (positing that slower diffusion of best practices or lack of surgical care on weekends might affect Cesarean section rates at rural hospitals).

<sup>35</sup> *Id.*

risky than a vaginal birth, higher rates of performing Cesarean sections do not necessarily correlate to a lower quality of care.

### C. Strokes

Notwithstanding the relatively equitable care between rural and urban hospitals with respect to Cesarean sections and myocardial infarctions, there appears to be a larger difference in quality of care for strokes. One reason may be that “rural areas ... [have] increased stroke related disability because of lack of access to and usage of preventative services.”<sup>36</sup> A few other causes may be contributing to the apparent lower quality of care in rural hospitals, including less pre-hospital stroke care, less experience dealing with stroke victims in an emergency room, and reservations among smaller emergency room doctors about using recombinant tissue plasminogen activator (rtPA).<sup>37</sup> The use of rtPA, “a thrombolytic drug made using recombinant DNA technology,”<sup>38</sup> is valuable because “it can sometimes dissolve blood clots that cause ischemic strokes.”<sup>39</sup>

In an attempt to eliminate this disparity, several ideas have been proposed, such as improving “prompt recognition of stroke symptoms by patients and their caregivers, rapid notification of emergency services personnel, and a similar rapid response and transport by paramedics.”<sup>40</sup> Another way to help rural hospitals

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<sup>36</sup> Joubert et al., *supra* note 8, at 1922.

<sup>37</sup> Leira et al., *supra* note 8, at 888-89.

<sup>38</sup> EverydayHealth.com, Glossary of Stroke Terms, <http://www.everydayhealth.com/senior-health/stroke/glossary-of-stroke-terms.aspx> (last visited Feb. 5, 2010).

<sup>39</sup> *Id.*

<sup>40</sup> Leira et al., *supra* note 8, at 888.

includes teaching rural doctors how to use rtPA, since most rural hospitals have the capability to use the technology.<sup>41</sup>

Additionally, one of the most practical and easy to implement ideas is the use of telemedicine. Telemedicine can provide reliable and objective information by allowing a real time examination, through video, audio, and neuro-imaging, which allows a patient to be treated locally with the assistance of a tertiary care physician.<sup>42</sup> Telemedicine may be the only option for remote areas where transferring a patient by ambulance or hospital is not an option.<sup>43</sup> While the quality of care for strokes at rural hospitals may not be up to par with urban hospitals, there are many viable options that would allow rural hospitals to improve their care by working with urban hospitals.

### III. IMPORTANCE OF RURAL HOSPITALS ON THEIR COMMUNITIES AND THEIR CHALLENGES

Rural hospitals have struggled financially for a variety of reasons, which has affected the surrounding communities. The federal government finally decided to help rural hospitals by providing additional funding.<sup>44</sup> This extra funding has allowed rural hospitals to use new strategies to close any gaps in quality of care when compared with urban hospitals.

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<sup>41</sup> *Id.* at 889.

<sup>42</sup> *Id.*

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

<sup>44</sup> *See generally*, Balanced Budget Act of 1997, Pub. L. No.105-33, 111 Stat. 251 (1997) [hereinafter BBA of 1997]; Medicare, Medicaid, and Schip Balanced Budget Refinement Act of 1999, Pub L. No. 106-113, 113 Stat. 1501 (1999) [hereinafter BBRA of 1999].

*A. Economic Impacts and Difficulties Surrounding Rural Hospitals*

Rural hospitals are prone to having small operating margins, which causes them to diversify their services to provide care to their communities.<sup>45</sup> Due to the low volume of patients, rural hospitals are very dependent on each service that they provide to remain economically viable.<sup>46</sup> Rural hospitals are not only important for medical care, but they also provide 10% to 15% of all jobs in many rural counties, and “if the secondary benefits of those jobs are included, the health sector then accounts for 15% to 20% of all jobs.”<sup>47</sup> Rural hospitals also help local economies by bringing in outside dollars, stimulating local purchasing, and attracting industry and retirees to an area.<sup>48</sup> Thus, rural communities need hospitals not only for medical care, but to help boost the rural economy,<sup>49</sup> which is a compelling reason to help rural hospitals operate with a profit.

A main issue affecting rural hospitals’ financial struggle is the low volume of patients, but very little can be done to alleviate this problem. The next major difficulty is the disparities in payers of patient care since “a greater percentage of rural residents [18%] are Medicare beneficiaries, compared to urban residents [15%].”<sup>50</sup> 39% of rural hospital inpatient revenue comes from Medicare payments, and in some areas it can reach as high as 80%.<sup>51</sup> This is a problem

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<sup>45</sup> Testimony of Fox, *supra* note 1. (diversification of rural hospital services include: 100% provide outpatient services; 59% operate home health agencies; 72% provide either a home health agency, a skilled nursing facility, or both; 21% operate an outpatient center, a skilled nursing facility, and a home health agency).

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

<sup>47</sup> *Id.*

<sup>48</sup> George Holmes et al., *The Effect of Rural Hospital Closures on Community Economic Health*, 41 HEALTH SERV. RESEARCH 467, 467 (2006).

<sup>49</sup> *Id.* at 467-68.

<sup>50</sup> Testimony of Fox, *supra* note 1.

<sup>51</sup> *Id.*

because “total Medicare payment per beneficiary is nearly \$1,000 less for rural beneficiaries than for urban beneficiaries.”<sup>52</sup> The lower Medicare payments, in turn, caused a “rapid succession of [rural] hospital closures throughout the 1980s and 1990s [which] helped stimulate legislation, such as the creation of Critical Access Hospitals”<sup>53</sup> and the BBA of 1997.<sup>54</sup> Both acts were designed to ensure the economic stability of rural hospitals by providing more funding which could also improve the quality of care.

### *B. Economic Reforms to Help Rural Hospitals*

The BBA of 1997 was designed to cut Medicaid costs in order to balance governmental spending, but also provided additional funding for Medicare.<sup>55</sup> In 1999, President Clinton wanted to add more provisions to the BBA so that rural hospitals would have a better chance of qualifying for higher urban payments, which was accomplished by lowering the average wage for employees necessary to qualify for the higher reimbursement rates.<sup>56</sup> This plan was designed to increase payments to low-volume rural hospitals,<sup>57</sup> which would, in theory, allow them to achieve greater economic stability.

Other reforms proposed to the BBA of 1997 by President Clinton included helping rural hospitals adjust to new outpatient prospective payments systems,

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<sup>52</sup> *Id.*

<sup>53</sup> Holmes et al., *supra* note 46, at 468.

<sup>54</sup> BBA of 1997, *supra* note 43.

<sup>55</sup> See generally Andy Schneider, *Overview of Medicaid Provisions in the Balanced Budget Act of 1997*, P.L. 105-33, CTR. ON BUDGET & POL’Y PRIORITIES. (Sept. 8, 1997), <http://www.cbpp.org/cms/index.cfm?fa=view&id=2138>. (noting that the Medicaid cuts are projected to save the government \$61.4 million over ten years, while Medicare will cover increases in premiums from \$43.80 to \$105.40 in those same ten years.)

<sup>56</sup> Testimony of Berenson, *supra* note 1.

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

making additional funds available to rural hospitals, and giving rural hospitals larger rate increases between 2003 and 2009.<sup>58</sup> There was also a provision to provide more relief to “home health agencies.” A home health agency is defined as “[a] public or private agency that specializes in providing skilled nursing services, home health aides, and other therapeutic services, such as physical therapy, in the home.”<sup>59</sup> Home health agencies are often associated with rural hospitals by “extend[ing] the time for agencies to repay overpayment without interest from one year to three years.”<sup>60</sup> The BBA also helped rural hospitals through a reform in Medicare payment systems by: (1) allowing very small “critical access” hospitals to be reimbursed for the money spent on each patient;<sup>61</sup> (2) reinstating the Medicare dependent hospital” designation;<sup>62</sup> (3) “permanently grandfathering special ‘rural referral center’ status;”<sup>63</sup> (4) “allowing more rural hospitals to obtain special ‘disproportionate share’ payments,” which hospitals serving higher volumes of low income patients receive; and (5) “authorizing payment for telemedicine.”<sup>64</sup> The telemedicine provision was especially important as a way to close the gap in quality of care between rural and urban

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<sup>58</sup> *Id.*

<sup>59</sup> ANN BOOKMAN ET AL., FAMILY CAREGIVER HANDBOOK: FINDING ELDER CARE RESOURCES IN MASSACHUSETTS (2007), available at <http://web.mit.edu/workplacecenter/hndbk/sec7.html#H>.

<sup>60</sup> Testimony of Berenson, *supra* note 1.

<sup>61</sup> *See id.* (stating that Medicare usually reimburses hospitals based on the average expected cost for specific diagnoses).

<sup>62</sup> *Id.* (noting that Medicare dependent hospitals provide “higher reimbursement for rural facilities with less than 100 beds serving large numbers of Medicare beneficiaries”).

<sup>63</sup> *Id.* (stating that Rural referral centers are considered hospitals with 275 or more beds that serve large numbers of patients that live more than 25 miles away from the hospital or other referred hospital).

<sup>64</sup> *Id.* (noting that Telemedicine is a medical consultation completed over the phone or computer for patients living in rural areas).

hospitals for strokes.<sup>65</sup> It is unclear whether these provisions will help close the minimal gaps left in quality of care between rural and urban hospitals or help relieve the economic stress that is placed on rural hospitals, but these moves are a step in the right direction.

#### IV. CONCLUSION

Rural hospitals were historically perceived to have a lower quality of care than urban hospitals; however, when variables that can create significantly disparate research outcomes, such as patient characteristics and transfer rates of patients, are controlled for in comparative studies, the quality of care for certain procedures such as myocardial infarctions and Cesarean sections was similar for rural and urban hospitals.<sup>66</sup> Even though perceived disparities in care were usually not statistically significant, rural hospitals have still struggled to shed their image of providing a lower quality of care.

Although differences in quality of care have been found to be more pronounced for strokes, many new ideas have been proposed and implemented to close the gap and help rural hospitals perform at the same level as urban hospitals. Many of these proposals call for urban hospitals to provide education and assistance to rural hospitals.<sup>67</sup> Accordingly, through a sharing of ideas and education, the disparities will disappear and acknowledgement of the perceived deficiency in rural hospital care will disappear as well.

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<sup>65</sup> See *supra* notes 42-43 and accompanying text (describing the role of telemedicine in decreasing disparities between rural and urban hospitals).

<sup>66</sup> See *supra* notes 13-35 and accompanying text (dispelling myths that rural hospitals provide lower qualities of care with respect to myocardial infarctions and Cesarean sections).

<sup>67</sup> See *supra* notes 55-635 and accompanying text (discussing the BBA's economic proposals for reform).

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***Increasing the Quality of Care During Times of Disaster***

*Margaret L. Begalle\**

I. INTRODUCTION

A number of recent disasters in the United States highlight the importance of being prepared in the medical community when responding to disaster events. Natural disasters, terrorist attacks, and epidemics, all have the potential to put an enormous strain on the healthcare system. Given the devastation these types of events are capable of producing, the overall quality of healthcare is likely to decrease in response to a disaster event. In the wake of a disaster, resources are scarce or even non-existent, sources of communication may be limited, and physicians and other healthcare professionals are working under stressful conditions for which they have not received adequate training.

Although the public may be more forgiving of healthcare providers in times of crisis, a certain level of quality is still expected. If the level of care provided by the medical community in response to a disaster fails to meet the public's expectations, there can be significant legal implications. For example, the events at Memorial Medical Center in New Orleans following Hurricane

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Katrina in September 2005, demonstrates the potential legal ramifications when physicians and other healthcare professionals are not adequately prepared to deal with disaster events.

Irrespective of the legal consequences, studies show that a large percentage of healthcare professionals are willing to provide medical care in response to a disaster; however, most believe they are not properly prepared to do so.<sup>1</sup> Thus, the issue is: how do we ensure that the highest possible quality of care is provided in response to a disaster event? The answer lies in providing increased training and education to healthcare professionals on how to better respond in advance of any disaster event. Such preparation and training may include performing simulated disaster exercises and drills, and requiring periodic attendance at educational and training seminars on disaster response and preparedness.<sup>2</sup>

This article addresses some of the events that followed Hurricane Katrina and the legal issues faced by healthcare professionals when they provide care in response to a disaster. While various laws exist for protecting healthcare professionals who provide medical care in response to a disaster, the legal landscape is patchy at best. Although not an easy task, the medical community can work to mitigate the potential legal concerns by preparing physicians and

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<sup>1</sup> THE COUNCIL ON MED. EDUC., EDUCATION IN DISASTER MEDICINE AND PUBLIC HEALTH PREPAREDNESS DURING MEDICAL SCHOOL AND RESIDENCY TRAINING 6 (2009), available at <http://www.ama-assn.org/ama1/pub/upload/mm/377/cme-report-15a-09.pdf> [hereinafter EDUCATION IN DISASTER MEDICINE].

<sup>2</sup> See Nikunj K. Chokshi et al., *Disaster Management Among Pediatric Surgeons: Preparedness, Training and Involvement*, 3 AM. J. DISASTER MED. 5, 8 (2008); see also Sten Lennquist, *Education and Training in Disaster Medicine*, 94 SCANDINAVIAN J. SURG. 300, 302 (2005), available at <http://www.fimnet.fi/sjs/articles/SJS42005-300.pdf>.

other healthcare providers to provide the best quality of care possible under the circumstances. This article discusses how the medical community can mitigate liability concerns by proactively preparing to provide care during disaster events, such as natural disasters, terrorist attacks, and epidemics. Through more focused training and education, the healthcare community can significantly increase the quality of care provided in response to disaster events.

## II. THE EVENTS AT MEMORIAL MEDICAL CENTER

The story of what happened at Memorial Medical Center (Memorial) following Hurricane Katrina demonstrates the complications and potential liabilities that can arise when physicians and other healthcare professionals are inadequately prepared to provide healthcare during disasters, and the need for better disaster preparedness. In the aftermath of Hurricane Katrina, Memorial experienced more fatalities than any other hospital of comparable size.<sup>3</sup> A handful of the deaths that occurred at Memorial led to a subsequent investigation and allegations of murder against Dr. Anna Pou, a cancer surgeon at Memorial, and two nurses who provided care to patients in the days following the storm.<sup>4</sup>

When Hurricane Katrina hit New Orleans in the early hours of Monday, August 29, 2005, more than 2,000 people took shelter from the storm at Memorial, including more than 200 patients.<sup>5</sup> By Thursday, September 1, after losing all power, working with limited resources and under horrendous

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<sup>3</sup> Sheri Fink, *Strained by Katrina, a Hospital Faced Deadly Choices*, N.Y. TIMES, Aug. 30, 2009, at MM28, available at <http://www.nytimes.com/2009/08/30/magazine/30doctors.html?pagewanted=print>.

<sup>4</sup> *Id.*; Kevin B. O'Reilly, *Grand Jury Clears Dr. Pou; Medicine Wants to Protect Future Disaster Responders*, AMNEWS, Aug. 13, 2007, <http://www.ama-assn.org/amednews/2007/08/13/prl20813.htm>.

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

conditions, and receiving only sporadic help from the outside, Memorial physicians decided to give certain patients a combination of morphine and midazolam, a sedative.<sup>6</sup> According to Dr. Pou, who took the lead in administering the drugs, the intention “was only to ‘help the patients that were having pain and sedate the patients who were anxious.’”<sup>7</sup> All of the patients that received the morphine and midazolam cocktail, however, died at Memorial.<sup>8</sup>

For nearly two years following Hurricane Katrina, Dr. Pou fought to clear her name of any criminal wrongdoing, arguing that she only acted in the best interests of her patients under horrendous conditions.<sup>9</sup> In July 2007, a grand jury refused to indict Dr. Pou on nine murder counts stemming from the events that occurred at Memorial following Hurricane Katrina; however, Dr. Pou continues to face civil liability.<sup>10</sup> Since the events following Hurricane Katrina, Dr. Pou has noted that more focus must be placed on the issues that were brought to light during Hurricane Katrina, including “inadequate preparation and a systems failure at every level.”<sup>11</sup> Dr. Pou believes that in order to properly respond to disasters, civilian physicians should receive training similar to that given to military physicians, including disaster and battlefield triage and military evacuation protocols.<sup>12</sup> In addition, Dr. Pou emphasizes that hospitals should implement and

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<sup>6</sup> *Id.*; see also Susan Okie, M.D., *Dr. Pou and the Hurricane – Implications for Patient Care During Disasters*, 358 NEW ENG. J. MED. 1, 1 (2008).

<sup>7</sup> Fink, *supra* note 3.

<sup>8</sup> *Id.*

<sup>9</sup> See O'Reilly, *supra* note 4.

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

<sup>11</sup> Anna Maria Pou, M.D., *Hurricane Katrina and Disaster Preparedness*, 358 NEW ENG. J. MED. 1524, 1524 (2008).

<sup>12</sup> *Id.*

test comprehensive disaster plans that are capable of being followed in a time of crisis.<sup>13</sup>

### III. LIABILITY CONCERNS MAY LIMIT THE CARE PROVIDED DURING DISASTERS

The story of Dr. Pou demonstrates the extreme liability issues healthcare providers may face when they choose to provide care in response to disaster events. Physicians and other healthcare professionals may find themselves facing civil and criminal penalties arising from “claims of medical malpractice, discrimination, invasions of privacy, or violations of other state and federal statutes.”<sup>14</sup> Such concerns over liability have the potential to deter healthcare professionals from providing much needed care in disaster situations. A 2006 survey by the American Public Health Association reported that “[a]lmost [70%] of [clinicians] answered that immunity from civil lawsuits would be an important (35.6%) or essential (33.8%) factor when considering whether to volunteer in an emergency.”<sup>15</sup>

Various state and federal statutes exist for limiting the liability for healthcare professionals in disaster situations; however, the liability protections are often described as “patchwork” in terms of when they apply and whom they protect.<sup>16</sup> In response to a declared emergency “an array of state and federal

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

<sup>14</sup> INST. OF MED., GUIDANCE FOR ESTABLISHING CRISIS STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS: A LETTER REPORT 48 (2009) [hereinafter IOM REPORT]; *see also* Sharona Hoffman, *Responders' Responsibility: Liability and Immunity in Public Health Emergencies*, 96 GEO. L.J. 1913, 1925-37 (2008) (noting that in addition to negligence, physicians and healthcare professionals may also face potential liability for privacy and confidentiality violations, constitutional claims, and violations of various other federal and state statutes).

<sup>15</sup> Hoffman, *supra* note 14, at 1917.

<sup>16</sup> *See id.* at 1950; *see also* IOM REPORT, *supra* note 14, at 49.

liability protections exist for providers—particularly volunteers and government entities and officials acting in their official duties—who act in good faith and without willful misconduct, gross negligence, or recklessness.”<sup>17</sup> Paid healthcare providers, however, are largely unprotected from liability under state and federal statutes.<sup>18</sup> Yet, as the likely first responders, paid healthcare professionals are the most vulnerable to liability in disaster situations.<sup>19</sup> Thus, the “existing patchwork of liability protections can complicate planning and response efforts and deter emergency response participation.”<sup>20</sup>

Federal, state, and even many local governments are working on ways to address and deal with liability issues in disaster situations. In the wake of Hurricane Katrina and the subsequent charges levied against Dr. Pou, Louisiana passed a number of statutes addressing the liability of healthcare professionals in times of disaster.<sup>21</sup> In addition, the Institute of Medicine recently convened a “committee to develop guidance that state and local public health officials and health-sector agencies and institutions can use to establish and implement standards of care that should apply in disaster situations—both naturally occurring and manmade—under scarce resource conditions.”<sup>22</sup> The apparent goal of these statutes and the Institute of Medicine report is for the legal system to acknowledge the need for modified medical standards during disaster events by

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<sup>17</sup> IOM REPORT, *supra* note 14, at 48.

<sup>18</sup> Hoffman, *supra* note 14, at 1953.

<sup>19</sup> *Id.*

<sup>20</sup> IOM REPORT, *supra* note 14, at 49.

<sup>21</sup> See S. 301, 2008 Reg. Sess. (La. 2008); S. 330, 2008 Reg. Sess. (La. 2008); see also Tammy Worth, *Disaster Legislation Shields Healthcare Workers in Louisiana*, 108 AM. J. NURSING 20, 20 (2008), available at <http://www.nursingcenter.com/pdf.asp?AID=818847>.

<sup>22</sup> IOM REPORT, *supra* note 14, at 1.

allowing for altered legal standards of care during such events.<sup>23</sup> Efforts to protect healthcare professionals providing care in times of disaster are only just beginning in most states. Thus, the medical community must do its own part to try to limit liability concerns by focusing on improving the quality of care provided in the wake of a disaster.

#### IV. HEALTHCARE PROFESSIONALS ARE INADEQUATELY PREPARED TO HANDLE DISASTER EVENTS

Currently, most healthcare professionals are inadequately prepared to deal with disaster events. The American Medical Association (AMA) and even the federal government have attempted over the years to encourage, and in some cases even fund, disaster medicine and public health preparedness, education, and training. For example, in 2003, the AMA began working on a “national education and training initiative called the National Disaster Life Support Program (NDLS) to provide physicians, medical students, other health professionals, and other emergency responders with a fundamental understanding and working knowledge of their integrated roles and responsibilities in disaster management and response efforts.”<sup>24</sup> Despite these efforts, reports continue to show that the current medical school curriculum related to disaster medicine and public health preparedness is insufficient.<sup>25</sup>

The disaster preparedness curriculum in medical schools and in other healthcare programs is spotty, and most recent medical school graduates are

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<sup>23</sup> See *id.* at 46-50; see also Worth, *supra* note 21.

<sup>24</sup> EDUCATION IN DISASTER MEDICINE, *supra* note 1, at 3-4.

<sup>25</sup> See *id.* at 6; see also Christopher T. Born, M.D. et al., *Disasters and Mass Casualties: I. General Principles of Response and Management*, 15 J. AM. ACAD. ORTHOPAEDIC SURGEONS 388, 388 (2007) (“There is no provision in medical school or during residency training in the unique demands and approaches required for the medical care of mass casualties.”).

wholly unprepared to deal with disaster situations on the scale of the September 11 terrorist attacks or Hurricane Katrina.<sup>26</sup> In a recent survey, almost half of the medical school students surveyed stated that they are inadequately prepared during medical school to respond to disaster events.<sup>27</sup> In another survey, 96% of medical students stated they were willing to provide care during a disaster event, yet only 17% of those students actually believed they received the appropriate training and education during medical school to do so.<sup>28</sup>

Based on the events at Memorial in the wake of Hurricane Katrina, it is safe to say that not only are medical students unprepared to deal with disaster events, but so too are experienced healthcare professionals. “Disaster planning in most hospitals is rudimentary at best and is frequently geared to the minimal passing requirement standards as determined by the . . . government and the Joint Commission on Accreditation of Healthcare Organizations.”<sup>29</sup> For example, a critical component to managing and providing healthcare during a disaster is triage, which is “the prioritizing of patients according to injury severity and the need for immediate care.”<sup>30</sup> Yet, most healthcare professionals have neither triage experience nor are they otherwise trained to perform patient triage.<sup>31</sup> In one survey of pediatric surgeons, 77% of respondents stated they would respond in a disaster, but only 24% “felt ‘definitely’ prepared to respond.”<sup>32</sup>

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<sup>26</sup> EDUCATION IN DISASTER MEDICINE, *supra* note 1, at 6.

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

<sup>28</sup> *Id.*

<sup>29</sup> Born et al., *supra* note 25, at 388-89.

<sup>30</sup> *Id.* at 389.

<sup>31</sup> *Id.*

<sup>32</sup> Chokshi et al., *supra* note 2, at 5, 8 (a high percentage of respondents also stated that they needed more training in the area of disaster response and management).

V. HOW TO IMPROVE THE QUALITY OF CARE PROVIDED  
DURING DISASTER EVENTS

In general, healthcare professionals with prior disaster response experience, prior military service experience, or are in a leadership role in their everyday job, are more prepared for disaster events.<sup>33</sup> Thus, in order to improve the quality of care provided in response to a disaster event, it is necessary for healthcare professionals to receive more extensive and focused training and education in the area of disaster response.

Training and education are crucial steps in preparing healthcare professionals to respond to disaster events.<sup>34</sup> Education in the form of attendance at conferences and seminars focusing on disaster response and management can be an effective tool.<sup>35</sup> Individuals who attended national disaster training meetings felt three times more prepared than those healthcare professionals who had not participated in such training.<sup>36</sup> Thus, more participation in such programs can be beneficial in preparing healthcare professionals for disasters.<sup>37</sup>

Because large-scale disasters are uncommon, real world experience with disaster response is limited. Training in the form of simulated disaster drills and exercises is critical in teaching healthcare professionals how to respond properly during disaster events.<sup>38</sup> Such training “must be based on simulated situations,

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<sup>33</sup> *Id.* at 8.

<sup>34</sup> Born et al., *supra* note 25, at 395 (“Commitment in the form of education, training, and interdisciplinary communication . . . is the key to an effective medical response.”).

<sup>35</sup> See Chokshi et al., *supra* note 2, at 8.

<sup>36</sup> *Id.*

<sup>37</sup> See *id.* (noting that only 14% percent of respondents had attended national disaster training programs).

<sup>38</sup> Lennquist, *supra* note 2, at 302.

employing a wide array of mock casualties, simulators and educational tools.”<sup>39</sup>

It is necessary that the simulation be as close to a real life disaster event as possible in order to be effective.<sup>40</sup> Thus, for example, the exercises should include a realistic consumption of time, resources, personnel, and supplies as would be present in an actual disaster.<sup>41</sup>

At a minimum, training should include procedures for the coordination of staff, resources and supplies, patient triage, palliative care, and evacuation procedures.<sup>42</sup> It is logical that proper coordination and training of healthcare professionals will inform those involved of the role they will play during a disaster event, and limit the amount of chaos that is likely to be present during such an event. Coordination of resources and supplies will also help physicians and staff to work more effectively and efficiently and allocate limited resources to those patients in need.<sup>43</sup> As noted, such coordination should not simply be planned and communicated to healthcare professionals, but also practiced in a realistic setting. Without training, “or with erratic and insufficient training, the possibility of achieving an optimal outcome with regard to survival and health in major accidents and disasters is significantly reduced.”<sup>44</sup>

Finally, disaster response training must be evaluated to maximize its effectiveness. Healthcare professionals participating in such training need to

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<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at 302-303; *see also* Chokshi et al., *supra* note 2, at 8 (noting that a fairly high percentage of physicians with previous simulated disaster training feel “ill-prepared,” but still twice as likely to feel prepared compared with professionals with no simulated disaster training).

<sup>41</sup> Lennquist, *supra* note 2, at 302-303.

<sup>42</sup> *See* IOM Report, *supra* note 14, at 58-59.

<sup>43</sup> *Id.* at 68.

<sup>44</sup> Lennquist, *supra* note 2, at 300.

understand the consequences of the decisions they make when providing care in disaster situations in order to learn the proper response.<sup>45</sup> In all fields of medicine, constructive evaluation is critical to developing proper skills and techniques.<sup>46</sup> Requiring constructive and thorough evaluation in disaster response training will help prepare healthcare professionals for the realistic possibility that during a disaster, with limited resources, some consequences are not preventable regardless of the time and effort put forth.

One suggested example of how to conduct such training and evaluation is through the use of charts and illustrations attached to mock patients.<sup>47</sup> The charts allow the instructor to continuously indicate changes to the patient's condition according to the interventions and procedures, or lack thereof that have been performed by the trainees.<sup>48</sup> This is accomplished by moving the markers on the chart to reflect any changes to the patient's condition based on the trainee's course of treatment.<sup>49</sup> If there is a failure to treat or inappropriate treatment is given to the patient, the changes to the patient's condition will be charted to illustrate the patient's deteriorating condition, which may eventually result in death.<sup>50</sup> Thus, for example, a patient presenting "with internal bleeding and clinical signs of shock, if left untreated, should not remain in the same circulatory condition but instead show progressive circulatory impairment and finally die."<sup>51</sup>

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<sup>45</sup> *Id.* at 303.

<sup>46</sup> *Id.* at 306.

<sup>47</sup> *Id.* at 303.

<sup>48</sup> *Id.* at 303-04.

<sup>49</sup> Lennquist, *supra* note 2, at 304.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 303.

If death occurs in that situation, the instructor may flag it as a preventable death.<sup>52</sup>

By working through the possible consequences of their decisions, the trainees will become better decisions makers when providing care in response to disaster events.<sup>53</sup>

## VI. CONCLUSION

Recent events, such as terrorist attacks, natural disasters, and epidemics, highlight the need for more extensive preparation by healthcare professionals to be able to provide high quality healthcare in response to disaster events. Research shows that most healthcare professionals feel unprepared to deal with disasters due to lack of education and training focused on disaster response. Given the potential liability issues that can arise when care is provided in the wake of a disaster, it is prudent for healthcare professionals to focus on disaster response and preparedness. The medical community can take steps to try to decrease the potential liability concerns by placing more emphasis on training and education, including requiring attendance by healthcare professionals at seminars and participation in simulated disaster drills and exercises. Such training and education will give healthcare professionals the tools necessary in order to effectively and efficiently respond in the event of a disaster, and thereby allowing such professionals to provide the best care possible under difficult circumstances.

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<sup>52</sup> *See id.*

<sup>53</sup> *Id.*

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***A Plea to End Medical Imperialism:  
Efforts to End Physicians' Moral Interference  
with Quality of Care***

*Melanie Younger*<sup>\*</sup>

I. INTRODUCTION

“The door to ‘value-driven medicine’ is a door to a Pandora’s box of idiosyncratic, bigoted, discriminatory medicine.”<sup>1</sup> A physician’s moral qualms can steer them away from being able to provide quality care to their patient. In essence, a physician is providing “bigoted, discriminatory medicine”<sup>2</sup> if they only provide treatments that are consistent with their own moral values. Morals typically consist of a set of beliefs or code of conduct that people follow based on their culture, religion, philosophy,<sup>3</sup> or on an interpretation of what is good or right.

Part II of this article will address how moral qualms can affect a physician’s fiduciary duty to his patient and how this can lead to a diminished quality of care. A physician’s personal moral beliefs and professional duties can

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<sup>1</sup> Julian Savulescu, *Conscientious Objection in Medicine*, 332 BRIT. MED. J. 294, 297 (2006).

<sup>2</sup> *Id.*

<sup>3</sup> Bernard Gert, *The Definition of Morality*, in THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., 2008), available at <http://plato.stanford.edu/entries/morality-definition/>.

often be conflicting, leading to a discriminatory outcome if they are unable to provide treatment, such as certain sensitive services.<sup>4</sup> Sensitive services include treatments that some physicians might consider to be against their morals, including family planning, abortion, infertility treatment, or end of life support.<sup>5</sup> When the word “treatment” is used in this article, it could be a sensitive service, but arguably it also could be any treatment with which a physician has a moral objection. The term “sensitive service” is used in this article to refer to a particular treatment that is more likely to suffer from considerable physician moral objection, such as abortion.

Informed consent, notice and referral, and decrease in trust in physicians are the three concerns patients may have if physicians’ morals negatively interfere with quality of care. Part II of this article will focus on informed consent. Informed consent is an important concern because of the physician’s duty to the patient.<sup>6</sup> If the physician does not uphold their duty and allow their morals to interfere, the quality of care is in jeopardy since the physician may be unable to provide informed consent, thereby leading to a situation where the patient does not have the requisite knowledge to make an informed decision.

Part III will discuss notice. Notice is another concern because a patient could have no knowledge of the physician’s moral qualms, which could possibly delay the patient’s access to treatment. This section will also discuss the referral of patients from a physician with moral qualms to one without. The concern is

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<sup>4</sup> Comm. on Ethics, *ACOG Committee Opinion No. 385: The Limits of Conscientious Refusal in Reproductive Medicine*, 110 OBSTETRICS & GYNECOLOGY 1203, 4 (2007).

<sup>5</sup> Katherine A. White, *Crisis of Conscience: Reconciling Religious Health Care Providers’ Beliefs and Patients’ Rights*, 51 STAN. L. REV. 1703, 1703 (1999).

<sup>6</sup> *Doe v. Noe*, 690 N.E.2d 1012, 1018 (Ill. App. Ct. 1997).

that some patients may have no knowledge of alternative physicians. Part IV will then discuss the decrease of trust in physicians by patients. Patients will not trust their physicians if they are unsure whether physicians' morals are interfering with providing treatment, which could lead to a breakdown of the physician-patient relationship and a decrease in quality of care. Finally, part V will offer policy recommendations that suggest ways to overcome physicians' moral qualms to improve quality of care.

## II. HOW PHYSICIANS' MORAL QUALMS NEGATIVELY AFFECT PATIENT QUALITY

A study by "Religion, Conscience, and Controversial Practice," shows that physicians who do not believe they are obligated to disclose information about medically available treatments that they consider objectionable may care for more than forty million Americans.<sup>7</sup> Despite the fact that physicians have these beliefs, they also have a duty or responsibility to conform to a certain standard of care for the safety of another against an unreasonable risk of harm.<sup>8</sup> In addition, physicians are bound by a fiduciary duty to protect their patients' health, especially in situations where patients' health interests conflict with physicians' self-interest.<sup>9</sup> A physician's refusal of treatment constitutes an imposition on the patient who does not share the physician's belief, thereby undermining patient autonomy and threatening a violation of the physician's fiduciary duty.<sup>10</sup>

A physician's ability to refuse to administer treatment because of a moral

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<sup>7</sup> Farr A. Curlin et al., *Religion, Conscience, and Controversial Clinical Practice*, 356 NEW ENG. J. MED. 593, 599 (2007).

<sup>8</sup> *Doe*, 690 N.E.2d at 1018.

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

<sup>10</sup> Comm. on Ethics, *supra* note 4, at 3.

or religious objection goes against the constitutionally guaranteed right to freedom of religion, which was to prevent the privilege of religion over non-religion.<sup>11</sup> Physicians with a moral objection are given a special right to refuse a legal obligation while physicians without moral qualms remain compelled to comply.<sup>12</sup> When physicians' morals conflict with their duty to their patient, a decrease in quality of care can result because the physician is unable to properly provide informed consent, notice, or referral services to the patient.<sup>13</sup> Consequently, this would result in a decrease in trust in physicians if physicians let their moral qualms cloud their legal and ethical responsibilities to their patient. Thus, when weighing the individual rights of patients, versus the rights of physicians and their ability to impose their moral views, patients' rights must always tip the scale in the furtherance of providing quality care, among other reasons.

### III. INFORMED CONSENT

Physicians' inability to cast aside moral values may make it difficult for them to provide proper informed consent to patients, thereby negatively affecting quality of care. Although in the United States there is no established legal right to health care, patients do have the right to self-determination, which is the ability to determine one's own fate without external compulsion.<sup>14</sup> The notion of self-determination can be traced to the principles of individual liberty from the

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<sup>11</sup> CATHERINE WEISS ET AL., *ACLU REPRODUCTIVE FREEDOM PROJECT, RELIGIOUS REFUSALS AND REPRODUCTIVE RIGHTS* 7 (2002).

<sup>12</sup> *Id.*

<sup>13</sup> *Comm. on Ethics, supra* note 4, at 3.

<sup>14</sup> Merriam-Webster Online Dictionary, *Self-determination*, <http://www.merriam-webster.com/dictionary/self-determination> (last visited Apr. 16, 2010).

American Revolution<sup>15</sup> and was supported by both statutes and common law.<sup>16</sup> At the core of self-determination is the right to make an informed decision: “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”<sup>17</sup> The doctrine of informed consent employs a patient’s right of self-determination.<sup>18</sup> Informed consent is when a physician provides a clear explanation of the risks and benefits of proposed treatments, alternative treatments, and the consequences of not undergoing treatment.<sup>19</sup> Informed consent is important because it ensures that a patient is neither misled nor coerced in making important health decisions. It is a key element in enabling a patient’s autonomy or ability to make a decision.

If, however, a physician allows his moral values to conflict with his ability to provide informed consent to his patients, the patients may not receive the risks, benefits, and alternatives available, thereby infringing on their autonomous ability to choose the best treatment and decrease their quality of care. A physician may neglect to mention the best prospective treatment to a patient because of the physician’s moral qualms. This could result in the patient not receiving the best treatment available, as well as having no knowledge of other treatment options.

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<sup>15</sup> Eric Brahm, *Self-Determination Procedures*, BEYOND INTRACTABILITY, Sept. 2005, [http://www.beyondintractability.org/essay/self\\_determination/](http://www.beyondintractability.org/essay/self_determination/).

<sup>16</sup> Patricia L. Selby, *On Whose Conscience? Patient Rights Disappear Under Broad Protective Measures for Conscientious Objectors in Health Care*, 83 U. DET. MERCY L. REV. 507, 510 (2006).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 511.

## IV. NOTICE AND REFERRAL

Currently, in situations where physicians have religious or moral objections to certain treatments, they have a duty to notify patients and refer them to another physician who can adequately administer the treatment.<sup>20</sup> A physician must also notify a patient of any inability to perform treatment due to moral qualms so that a patient can seek another physician, if desired. Due to a physician not being forthright about his moral qualms and providing notice to the patient, a patient may be unable to access another physician, albeit one who provides quality treatment, resulting in a decrease in quality of care.

The study by “Religion, Conscience, and Controversial Practice,” noted that “nearly 100 million Americans—may be cared for by physicians who do not believe they have an obligation to refer the patient to another provider for such treatments.”<sup>21</sup> Referrals provide patients with the ability to seek treatment from another practitioner if their initial practitioner is unable to perform treatment due to conflicting moral values. For example, “[o]ne physician may be unwilling to perform an abortion but willing to refer, while another may be unwilling to refer, believing that doing so would make him or her complicit in an immoral act.”<sup>22</sup>

Even if a physician is willing to refer patients, referrals, in general, can result in an inefficient delivery of health care. When referred, the patient must visit another physician whose quality of care may be different from their initial

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<sup>20</sup> Julie Cantor, *Conscientious Objection Gone Awry — Restoring Selfless Professionalism in Medicine*, 360 NEW ENG. J. MED. 1484, 1485 (2009).

<sup>21</sup> Curlin et al., *supra* note 7, at 597.

<sup>22</sup> Robert D. Orr, *Doctors Weigh Morals, Ethics in Decisions on Refusing Services*, ETHICS F., July 13, 2009, <http://www.ama-assn.org/amednews/2009/07/13/prca0713.htm> (reply to the scenario: Do physicians have the right to refuse to offer types of care that conflict with their beliefs?).

physician,<sup>23</sup> which may require the patient to produce any necessary medical documentation and undergo any additional diagnostics and testing requested by the new physician. In some cases, the quality of care may be subpar, resulting in a decrease in the quality of care to the patient.

Additionally, referrals result in a discontinuity of care, and could increase the risk to a patient's health if the treatment is not timely. Referrals may also result in an inequitable situation where a disenfranchised patient, living in a resource poor area with few physicians, would have a much harder time accessing a physician who would be able to adequately perform a sensitive treatment.<sup>24</sup> Thus, referrals can inevitably negatively impact patient quality of care, which is inextricably linked to the physician's conflicting morals. Due to this possible negative impact in quality of care, physicians should have no right to impose their moral views on patients. Instead, the individual rights of the patient should trump the rights of the physician in furtherance of quality health care.

#### V. DECREASE OF TRUST IN PHYSICIANS

According to the American Medical Association Code of Ethics, the physician-patient relationship based on trust engenders physicians' ethical responsibility to place patients' welfare above their own self-interest and to advocate for their patients' welfare.<sup>25</sup> Therefore, if physicians place their own interest above a patient's welfare, it taints their ethical responsibility and destroys the physician-patient relationship. "Patients need assurance that the standard of

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<sup>23</sup> Savulescu, *supra* note 1, at 295.

<sup>24</sup> Comm. on Ethics, *supra* note 4, at 5.

<sup>25</sup> AM. MED. ASS'N, *Opinions on the Patient-Physician Relationship 10.015*, in CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS, 2008-2009 341, 348 (2001).

care is unwavering...and that they will not be presented with half-truths and shades of gray when life and health are in the balance.”<sup>26</sup> To allow a physician’s moral values to trump the rights of a patient’s would debase the medical profession because society would no longer be able to trust their physicians.

Patients rely on physicians for expertise, “to be the neutral arbiters of medical care.”<sup>27</sup> If patients cannot rely on physicians, the trust-based system that is essential for proper functioning of the healthcare delivery system will be in disrepair, leading to decreases in the quality of care. Patients participating in this dysfunctional healthcare delivery system may feel too distrustful when seeking a physician to the point where they may rather take their health care into their own hands. The final result could be a collapse in the healthcare delivery system due to the initial lack of trust of physicians’ moral values. This would cause society to seek an alternative form of organizing health care: one that does not require a reliance on physicians<sup>28</sup> or one that mandates its physicians not to put his/her moral values above a patient’s rights. Therefore, we cannot allow physicians to abuse the public’s trust by asserting an unfettered right to moral values and possessing monopolistic power over the health of the public.<sup>29</sup>

## VI. POLICY RECOMMENDATIONS

Apart from providing informed consent, prior notice, and referrals, physicians should employ other policy recommendations so that patients’ rights, as well as the quality of healthcare, are preserved. First, if physicians are not

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<sup>26</sup> Cantor, *supra* note 20.

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

<sup>28</sup> Orr, *supra* note 22.

<sup>29</sup> R. Alta Charo, *The Celestial Fire of Conscience — Refusing to Deliver Medical Care*, 352 NEW ENG J. MED. 2471, 2473 (2005).

prepared to offer beneficial care to a patient because it conflicts with their morals, perhaps they should choose another profession.<sup>30</sup> “As the gatekeepers to medicine, physicians and other health care providers have an obligation to choose specialties that are not moral minefields for them.”<sup>31</sup> At minimum, medical students should keep their ethical objections in mind when choosing a specialty.

In addition, ethics training should be a necessary component to every medical school’s curriculum in order to aid medical students in dealing with moral dilemmas that will inevitably arise during their practice. A study, with an objective to assess the perspectives of medical students after taking ethics training, found that ethics training was beneficial in assisting medical students with managing ethical conflicts.<sup>32</sup> The medical students, whose goals for taking medical ethics included improving patient quality, stated that medical school alone does not prepare them for ethical dilemmas, giving rise to the need for more medical school education reform.<sup>33</sup> Though many medical schools are responding by offering medical ethics classes,<sup>34</sup> all medical schools should have a substantive ethics curriculum requirement for their students in order to prepare students on managing ethical conflicts.

Access to a wide variety of practitioners is imperative in resource poor areas so that patients with little resources do not have to be at the mercy of

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<sup>30</sup> Savulescu, *supra* note 1, at 294.

<sup>31</sup> Cantor, *supra* note 20.

<sup>32</sup> Laura Weiss Roberts et al., *The Positive Role of Professionalism and Ethics Training in Medical Education: A Comparison of Medical Student and Resident Perspectives*, 28 ACAD. PSYCHIATRY 170, 171 (2004).

<sup>33</sup> *Id.* at 180.

<sup>34</sup> *Id.* at 179.

physicians who neglect to provide referrals.<sup>35</sup> Instead, they would be able to find and obtain treatment in the vicinity of the initial physician since they may be unable to travel longer distances due to financial impediments.<sup>36</sup> Thus, a heightened duty should be imposed on providers with moral objections practicing in poor resource areas to make sure they are in close proximity to providers that do not share the same views.<sup>37</sup> This increases the likelihood that referral logistics will be in place so that patients have access to sensitive services which may conflict with a physician's morals.<sup>38</sup> If this is not possible, the physician with the moral objection should practice in a more metropolitan setting, due to an increased likelihood of there being a wider variety of physicians willing to perform the treatment.

Physicians must also be held accountable if they compromise the delivery of medical services to patients on moral or religious grounds.<sup>39</sup> This could be in the form of sanctions or a removal of their license.<sup>40</sup> Most importantly, a physician's cultural conquest and medical imperialism should not be allowed to prevail, but instead, the right to self-determination and the preservation of the health of our society should govern.

## VII. CONCLUSION

The imposition of a physician's religious or moral doctrines on patients who do not share the same beliefs is inexcusable, especially when it negatively

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<sup>35</sup> Comm. on Ethics, *supra* note 4, at 5.

<sup>36</sup> *Id.*, at 4.

<sup>37</sup> *Id.*, at 5.

<sup>38</sup> *Id.*

<sup>39</sup> Savulescu, *supra* note 1, at 296.

<sup>40</sup> *Id.*

affects the health of the patient. Since all people have moral and religious values, it would be impossible to regulate regardless of whether it would be infringing on the constitutionally protected freedom of religion. There are some ways, however, to prevent friction between physicians' morals and patient autonomy. For example, mandatory ethics training and testing in medical school is necessary for physicians to manage moral dilemmas. But, why would physicians go into a certain field if they know they will have to perform certain treatments? Why would physicians choose to have their religious and moral values continually challenged?

Ethical dilemmas are so pervasive in the practice of medicine that it is almost impossible to escape them.<sup>41</sup> Even if a physician does not have a problem performing sensitive services at the inception of their practice, they may develop a moral objection over the course of their practice. Although physicians' moral values should be respected, when physicians take their oath to practice medicine ethically upon graduation of medical school, society trusts and expects them to take their obligations seriously.<sup>42</sup> Respect for physicians' religious and moral values should not come at the expense of the patients' health. A physician's conscience is not something that patients should have to bear.<sup>43</sup> "Whatever your religious and moral beliefs are, you really have to look at what is legal and what is

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<sup>41</sup> Nancy Valko, *Are Pro-Life Healthcare Providers Becoming an Endangered Species?*, VOICES, Pentecost 2003, <http://www.wf-f.org/03-2-Healthcare.html>.

<sup>42</sup> Orr, *supra* note 22.

<sup>43</sup> Cantor, *supra* note 20.

good medicine. If it is legal and good medicine, then you shouldn't deny a patient medical care."<sup>44</sup>

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<sup>44</sup> Telephone Interview with Dr. Leonard Lawson, Obstetrician & Gynecologist, Female Health Care Assocs. (Mar. 31, 2010).

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***The Potential and Pitfalls of the Physician  
Quality Reporting Initiative***

*Amanda Byrne*<sup>\*</sup>

I. INTRODUCTION

The mounting inertia for more pay-for-performance healthcare models provokes an obvious, but perplexing, question: how do we measure performance? Health and Human Services began responding to this question in 2001 when then-Secretary, Tommy Thompson, launched a Quality Initiative to determine how well healthcare providers performed and reported certain quality measures.<sup>1</sup> Not only did providers see how they compared to their peers, but patient-consumers were also able to access this information to make informed decisions when choosing a provider.<sup>2</sup> Then, in 2003, hospitals were given financial incentive to follow Medicare reporting measures for quality care through the Medicare Modernization Act.<sup>3</sup> The well-regarded opinion that public reporting is a good

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<sup>1</sup> Sandra J. Tanenbaum, *Pay for Performance in Medicare: Evidentiary Irony and the Politics of Value*, 34 J. HEALTH POL. POL'Y. & L. 717, 720 (2009).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

strategy to measure and improve quality performance led to similar incentives.<sup>4</sup>

Public reporting holds the provider accountable by recording the steps taken to provide quality care while providing recognition for doing so, thereby yielding financial incentives, patient influx, or both.<sup>5</sup>

This article will address one such reporting system, the Physicians Quality Reporting Initiative (PQRI). The PQRI follows from a line of “Quality Initiatives” and has incorporated some of the successful aspects of other programs. The article will explain how the PQRI works as well as the successes and shortcomings reported thus far. Despite many mixed reviews about the program, many are hopeful that it will improve the quality of care provided by our healthcare system in the coming years.

## II. THE BEGINNING OF THE PQRI

Authorized under the Tax Relief and Health Care Act of 2006, Centers for Medicaid and Medicare Services (CMS) followed Health and Human Services’ lead in 2007 by creating the PQRI.<sup>6</sup> The PQRI is a payment incentive system for healthcare providers to receive financial benefits for meeting certain quality care thresholds, also known as benchmarks, when treating Medicare patients.<sup>7</sup> When first launched, physicians earned up to a 1.5% bonus payment on their allowed

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

<sup>5</sup> *Id.*

<sup>6</sup> Timothy Cahill, *The 2007 Physician Quality Reporting Initiative: Will it be a Significant Step in the Move Toward Pay-for-Performance*, 19(7) THE ABA HEALTH LAW SEC.: THE HEALTH LAW. 1, 1 (2007).

<sup>7</sup> Brett Elliott, *To Participate or Not in the Physician Quality Reporting Initiative (PQRI); That is the Question*, 79(5) DEL. MED. J. 197, 197 (2007).

Medicare charges by reporting on up to seventy-four different quality measures.<sup>8</sup> In 2010, the bonus increased to 2%,<sup>9</sup> and the number of quality measures expanded to 179.<sup>10</sup> It is important to note that, despite the name, the PQRI applies to a broad range of healthcare providers, including physicians, dentists, chiropractors, registered dietitians, clinical social workers, and other allied health professionals.<sup>11</sup> The quality care benchmarks are established by an array of medical agencies, such as the American Medical Association and the Physician Consortium for Performance Improvement, along with input from other organizations regarding benchmarks particular to their specialty.<sup>12</sup>

CMS instituted the PQRI after the relative success of its Hospital Quality Incentive Demonstration program, in which 270 hospitals reported on quality measures in five clinical areas from 2003 to 2006.<sup>13</sup> CMS provided bonuses to the top performers and reduced payments to the lowest performers.<sup>14</sup> Even though the data available for analysis was somewhat limited, CMS did report a 6.6% improvement rate in overall quality of care.<sup>15</sup> However, not all of CMS's past quality initiatives were successful. The PQRI came in the wake of CMS's Physician Voluntary Reporting Program in 2006, which was not as successful as

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<sup>8</sup> Latanya Sweeney, *The Medical Billing Framework as the Backbone of the National Health Information Infrastructure 2* (Carnegie Mellon Univ., Working Paper No. 1001, 2009), available at <http://advancehit.org/publications/p1001/AdvanceHIT1001.pdf>.

<sup>9</sup> Ctrs. for Medicare & Medicaid Servs., Physician Quality Reporting Initiative: Overview, [http://www.cms.hhs.gov/pqri/01\\_Overview.asp](http://www.cms.hhs.gov/pqri/01_Overview.asp) (last visited Feb. 26, 2010) [hereinafter *Physician Quality Reporting*].

<sup>10</sup> CTRS. FOR MEDICARE & MEDICAID SERVS., 2010 PQRI MEASURES LIST 1 (2009), available at [http://www.cms.hhs.gov/PQRI/Downloads/2010\\_PQRI\\_MeasuresList\\_111309.pdf](http://www.cms.hhs.gov/PQRI/Downloads/2010_PQRI_MeasuresList_111309.pdf) [hereinafter MEASURES LIST].

<sup>11</sup> Elliott, *supra* note 7, at 197.

<sup>12</sup> *Id.* at 197-98.

<sup>13</sup> Tanenbaum, *supra* note 1, at 721.

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

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

anticipated.<sup>16</sup> This program, unlike the PQRI, did not have many participants for two main reasons: lack of financial incentive and burdensome reporting methods.<sup>17</sup>

CMS learned from their missteps in past programs and made PQRI relatively easy to follow and provided financial incentives as well. Every quality measure requires a specific clinical action that may be related to prevention, management of chronic care condition, management of acute episodes of care, resources utilization, or care coordination.<sup>18</sup> An example of a quality measure is the percentage of patients who are age sixty-five or older and were screened over the past year for future fall risks.<sup>19</sup> Each measure also has a reporting frequency requirement. In other words, certain measures may only need to be recorded one time, whereas other measures may need to be recorded for each test of certain conditions.<sup>20</sup> For instance, the previous example of screening for future fall risks in seniors must be recorded once a year.<sup>21</sup>

### III. FEATURES OF THE PQRI

The PQRI provided performance modifying measures for the inescapable exceptions to the rules set out above.<sup>22</sup> There may be reasons when a clinical action required by the rules may not be taken. For instance, the patient could have already received the needed care from another healthcare provider or there

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<sup>16</sup> Cahill, *supra* note 6, at 1.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 3.

<sup>19</sup> *Id.*

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

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

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

could be a potential adverse drug interaction.<sup>23</sup> In addition to medical reasons for not following PQRI protocol, the provider may also report when a patient declines prescribed care for social, economic, religious, or other personal reasons.<sup>24</sup> This is an important feature of the PQRI because it applies real world circumstances to potentially static laws. Through these performance modifying measures, physicians are not penalized for non-compliant patients or patients who require care that does not coincide with the traditional treatment methods and preventative care established by the PQRI.<sup>25</sup>

Typically, not all 179 quality measures will apply to every healthcare provider given the breadth of health conditions the PQRI covers, which include conditions ranging from diabetes to prostate cancer to cataracts.<sup>26</sup> Therefore, all eligible providers select which measures are relevant to their practice and prepare reports for their applicable Medicare patients.<sup>27</sup> For instance, if no more than three quality measures apply to an eligible provider, the PQRI mandates that each measure be reported in 80% of the cases in which the measure could have been reported.<sup>28</sup> If more than three quality measures apply to a provider, 80% of the relevant cases still must still be reported in at least three of the measures.<sup>29</sup>

The percentage is derived from a numerator, the clinical action required by the measure and quantified by a quality data code, and a denominator, the pool of eligible patients that would benefit from the action, associated with each quality

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> Elliott, *supra* note 7, at 198.

<sup>26</sup> MEASURES LIST, *supra* note 10.

<sup>27</sup> Cahill, *supra* note 6, at 3.

<sup>28</sup> *Id.* at 4.

<sup>29</sup> *Id.*

measure.<sup>30</sup> The percentage is finally calculated by analyzing the numerators and denominators and comparing when a measure was actually reported to when the measure could have been reported.<sup>31</sup> Once it is determined that the eligible provider successfully reported 80% of Medicare cases for the requisite quality measures, the provider is eligible for a bonus payment of 2% on the allowed charges for all covered Medicare services, not just services affiliated with the reported quality measures.<sup>32</sup> The bonus amount is subject to a cap that is determined at the end of the PQRI reporting cycle.<sup>33</sup> The PQRI is completely voluntary, and eligible providers only need to submit their quality data codes to be considered for the Medicare bonus payment.<sup>34</sup>

#### IV. POTENTIALS AND PITFALLS

While this approach is logical, it presents some logistical difficulties. Such difficulties are particularly pronounced in group practices electing to participate in the PQRI because CMS pays the bonuses to the holder of the group Tax Identification Number (TIN) as required by § 1848(m)(3)(C)(iii) of the Social Security Act.<sup>35</sup> A group practice holds the TIN, thus making individual providers in the group ineligible for receiving separate bonuses through the PQRI.<sup>36</sup> Thus, the CMS reporting measure bonuses will be aggregated to the group as opposed to

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<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Physician Quality Reporting*, *supra* note 9.

<sup>33</sup> Cahill, *supra* note 6, at 4.

<sup>34</sup> Elliot, *supra* note 7, at 202.

<sup>35</sup> Ctrs. for Medicare & Medicaid Servs., Physician Quality Reporting Initiative: Group Practice Reporting Option, [http://www.cms.hhs.gov/PQRI/22\\_Group\\_Practice\\_Reporting\\_Option.asp#TopOfPage](http://www.cms.hhs.gov/PQRI/22_Group_Practice_Reporting_Option.asp#TopOfPage) (last visited Feb. 26, 2010).

<sup>36</sup> *Id.*

the individual providers.<sup>37</sup> Since all of the PQRI data is aggregated for group practice,<sup>38</sup> the decision of whether or not to even participate may be a source of contention among group practitioners.

Furthermore, the manner in which the pool of eligible patients is derived presents difficulties for practices that do not have electronic medical records (EMR). In fact, although 40% of physicians utilize EMRs in their offices in 2008 and 2009, only 7% were considered fully functional.<sup>39</sup> Some EMR systems may only provide demographic information,<sup>40</sup> which is not sufficient to report on PQRI quality measures.<sup>41</sup> For instance, in the example of screening patients age sixty-five and older for future fall risks, most practices that utilize a limited EMR system could generate a list of those patients based on demographic information. But since the PQRI only applies to Medicare patients, such systems are insufficient as they merely generate a large patient pool that must still be sifted through to find Medicare patients. Some physicians argue that reporting tasks are manageable by simply adding the quality code to Medicare claims that healthcare providers already use in everyday practice.<sup>42</sup> While this would be an improvement over sifting through individual patient's charts, it would still be an

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> Marianne Kolbasuk McGee, *Many Doctors Already Using E-Medical Records*, INFORMATIONWEEK, Jan. 13, 2010, <http://www.informationweek.com/story/showArticle.jhtml?articleID=222300536>.

<sup>40</sup> *Id.*

<sup>41</sup> Stinson Paul, *The PQRI Catch-22: The CMS 1.5 Percent Reimbursement May Incentivize IT Adoption, but Will It Do so Equally, and Is It Enough?*, ALLBUSINESS, Oct. 1, 2007, <http://www.allbusiness.com/insurance/health-insurance-government-health-medicare/5504694-1.html>.

<sup>42</sup> Elliott, *supra* note 7, at 203.

arduous task to go through all Medicare claims to determine whether or not a condition was reported and whether or not it should have been reported.

Another reporting option available to providers is the use of an independent, PQRI-approved registry.<sup>43</sup> These registries compile information from participating providers and generate quality measure results that they then submit to CMS.<sup>44</sup> An organization may qualify as a registry if it meets several requirements promulgated by CMS; including at least twenty-five participants, not owned or managed by an individual locally-owned single-specialty group, and the ability to collect all the data necessary to calculate compliance of the PQRI benchmarks.<sup>45</sup>

In addition to reporting difficulties, the results of the quality measures are difficult to quantify. Not only does the PQRI focus only on Medicare patients, but also, the quality benchmarks focus only on process indicators as opposed to outcome indicators.<sup>46</sup> This protocol means that, although the ordered tests and referrals are factored into quality measures, the result of treatment and patient follow-up is not incorporated.<sup>47</sup> While this method seems insufficient, objective outcome indicators are difficult to measure. For example, at what point does a physician reach the benchmark for treating a patient with a terminal illness? Is it after a patient's life is extended for several months after diagnosis? Several

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<sup>43</sup> CTRS. FOR MEDICARE & MEDICAID SERVS., REGISTRY REQUIREMENTS FOR SUBMISSION OF 2010 PQRI DATA ON BEHALF OF ELIGIBLE PROFESSIONALS 1 (2009), *available at* [http://www.cms.hhs.gov/PQRI/Downloads/2010RegistryRequirementsFinal\\_1\(2\).pdf](http://www.cms.hhs.gov/PQRI/Downloads/2010RegistryRequirementsFinal_1(2).pdf).

<sup>44</sup> *Id.*

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

<sup>46</sup> Elliott, *supra* note 7, at 198.

<sup>47</sup> *Id.*

years? Should the quality of life factor into the benchmark, and how can it be measured?

Moreover, the absence of outcome benchmarks safeguards healthcare providers against non-compliant patients.<sup>48</sup> Rightly, physicians should not be penalized for a lack of patient follow-up; however, at the same time, physicians should be held accountable for failing to follow-up with their patients. The healthcare agencies involved in the PQRI need to determine the appropriate follow-up measure for physicians, such as a phone call to discuss test results or a postcard reminding the patient to schedule a follow-up appointment.

#### V. CONCLUSION

Moving forward, it is important for the PQRI to continue its tradition of receiving input from the medical community in formulating new requirements and recommendations. According to Dr. David Cutler, one of President Obama's health advisors, "if a [payment] system is just imposed on doctors. . . it will be a disaster."<sup>49</sup> Cutler emphasizes that there is a need for physicians to buy-in for healthcare reforms to succeed.<sup>50</sup> In contrast, the current payment system penalizes physicians for spending extra time with patients, but the system would benefit from incorporating widely accepted quality measures with input from practicing physicians.<sup>51</sup> Hopefully, the historical input of health agencies into the

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<sup>48</sup> *Id.*

<sup>49</sup> Mark Crane, *Obama Chief Health Advisor Pushes Pay for Performance if Doctors Like Standards*, MEDPAGE TODAY, Mar. 14, 2008, <http://www.medpagetoday.com/Washington-Watch/Washington-Watch/8743>.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

PQRI quality measures will encourage the implementation of quality measures that healthcare providers will support and incorporate into their everyday practice.

The PQRI, like other healthcare reform models, is far from perfect. The current CMS Fee Schedule tends to reward providers for the quantity of patients' physicians and the resources consumed, rather than the quality of the visit or the value of such services to the patient.<sup>52</sup> While the PQRI seeks to improve the quality of care, it has limited applications and must be studied in context. The biggest drawback is that the PQRI only applies to Medicare patients. As this demographic grows exponentially in the coming decades, the PQRI may prevent an accurate assessment of quality measure reporting for the entire patient population.

Another shortcoming is that the PQRI only reports on process indicators and not the actual outcomes of treatment.<sup>53</sup> While outcome indicators are difficult to quantify, it is important to assure that patients are benefiting from these quality measures. The lack of reporting on the patients' health status challenges the effectiveness of the model and its benefit to the general population. Also, most healthcare providers do not have the necessary EMR technology available to utilize easier reporting methods.

When the PQRI was first instituted, the acting CMS Administrator, Leslie V. Norwalk, Esq., stated:

[T]he Medicare program needs to compensate physicians appropriately for the services they provide to people with Medicare. But how the program pays also matters. We think the early work on the PQRI program is one of those reforms

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<sup>52</sup> Cahill, *supra* note 6, at 1, 3.

<sup>53</sup> Elliott, *supra* note 7, at 198.

that could help lead us to a point where we can promote better quality care and more efficient care.<sup>54</sup>

Norwalk's optimistic outlook is shared by many in the healthcare community. Many benchmarks remain to be met with PQRI; namely, whether there was an actual improvement in patients' health due to these quality measures and what the implication is for the general population. Once all of the PQRI benchmarks are met, and with the increasing use of EMR to assist in reporting, the PQRI has the potential be to an effective model for the entire U.S. healthcare system.

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<sup>54</sup> Cahill, *supra* note 6, at 5-6.

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### *The PROMETHEUS Model: Bringing Healthcare into the Next Decade*

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#### I. INTRODUCTION

The United States' current healthcare system has long been structured to emphasize the quantity of health care over the quality of health care.<sup>1</sup> Such a focus of quantity is evident in the fee-for-service structure, where providers are paid a specified amount for each service provided.<sup>2</sup> This structure gives doctors and other health providers' incentive to order extra tests and procedures that may be unnecessary to improve the outcome of the patient.<sup>3</sup> Thus, fee-for-service payments motivate healthcare providers to give more care, but not necessarily better, care.<sup>4</sup> President Obama recently stated that the current structure "is a

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<sup>1</sup> The Editors, *Doctors' Pay, a Key to Health Care Reform*, N.Y. TIMES, June 18, 2009, available at <http://roomfordebate.blogs.nytimes.com/2009/06/18/better-medical-care-for-less/> [hereinafter *Doctors'*].

<sup>2</sup> Alice G. Gosfield, *A New Payment Model for Quality: Why Quality Now?*, 22 AM. J. MED. QUALITY 145, 145 (2007).

<sup>3</sup> *Id.*

<sup>4</sup> François de Brantes et al., *Building a Bridge from Fragmentation to Accountability: The PROMETHEUS Payment Model*, 361 NEW ENG. J. MED. 1033, 1033 (2009).

model that has taken the pursuit of medicine from a profession — a calling — to a business.”<sup>5</sup>

To break this trend of quantity-based care, several payment models have emerged to encourage quality care. A pay-for-performance structure is increasingly being used by healthcare providers, which improves quality by basing providers’ payment incentives on their ability to reduce cost for the patient while still providing quality care.<sup>6</sup> This pay-for-performance model, however, offers little compensation to doctors and physicians compared to the current fee-for-service system.<sup>7</sup> As an alternative, the PROMETHEUS Payment model establishes its own method by focusing first on the patient’s clinical needs.<sup>8</sup> PROMETHEUS stands for: **P**rovider payment **R**eform for **O**utcomes **M**argins **E**vidence **T**ransparency **H**assle-reduction **E**xcellence **U**nderstandability and **S**ustainability.<sup>9</sup>

The PROMETHEUS method sets itself apart from current health care models by focusing on scientific research and the resources required to treat a condition to calculate the base cost to the patient.<sup>10</sup> On top of the base rate, the PROMETHEUS method individualizes the cost of care by factoring in the

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<sup>5</sup> *Doctors’*, *supra* note 1.

<sup>6</sup> Gosfield, *supra* note 2, at 145.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 146.

<sup>9</sup> ALICE G. GOSFIELD, J.D., MAKING PROMETHEUS PAYMENT RATES REAL: YA’ GOTTA START SOMEWHERE 2 (2008), <http://www.prometheuspayers.org/publications/pdf/MakingItReal-Final.pdf>.

<sup>10</sup> Robert Wood Johnson Found., *PROMETHEUS Payment Set to Test New Method of Paying Providers For High-Quality Health Care*, <http://www.rwjf.org/qualityequality/product.jsp?id=30231> (last visited Mar. 22, 2009).

patient's health and pre-existing conditions.<sup>11</sup> The system is voluntary, and may be implemented across a variety of health care setups – from large integrated systems to small private physician groups.<sup>12</sup> Additionally, the PROMETHEUS method recognizes that a new healthcare payment system can only succeed if disparate parties work together.<sup>13</sup> The PROMETHEUS method is a payment system that is based on the adherence to guidelines and patient outcomes, which requires strong coordination among a care team, comprised of doctors, dietitians, pharmacists, specialty doctors, and other professional involved in the patients treatment.<sup>14</sup>

This article will focus on the applicability of the PROMETHEUS method including: the structure of the PROMETHEUS method and how it works,<sup>15</sup> the benefits of using the PROMETHEUS method,<sup>16</sup> and whether the PROMETHEUS method can be feasibly implemented into our current healthcare system.<sup>17</sup>

## II. WHAT IS THE PROMETHEUS PAYMENT METHOD AND HOW DOES IT WORK?

The name, PROMETHEUS, speaks of the model's core values and echoes what it stands for in the progress of healthcare.<sup>18</sup> The PROMETHEUS Payment model rewards doctors and hospitals for providing high-quality care.<sup>19</sup> However,

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<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

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

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

<sup>15</sup> *See infra* Part II.

<sup>16</sup> *See infra* Part III.

<sup>17</sup> *See infra* Part IV.

<sup>18</sup> GOSFIELD, *supra* note 9, at 2.

<sup>19</sup> The Commonwealth Fund, *What does Rockford, Illinois have to Teach the Country about Health Care?*, PURCHASING HIGH PERFORMANCE, Nov. 3, 2009, <http://www.commonwealthfund.org>

unlike many of the pay-for-performance models, the rewards are not contingent on delivering good outcomes, but rather on preventing negative outcomes.<sup>20</sup>

In practice, the basic theory of the PROMETHEUS method is to pay the correct sum to the health care provider for the proper procedures and tests.<sup>21</sup> The results of the tests and procedures are to be used in accordance with the best scientific research to treat the condition or illness, as outlined in a good clinical practice guideline (CPG).<sup>22</sup> A panel of medical experts develop and establish an evidence-informed case rate (ECR) for a particular illness or condition,<sup>23</sup> which is modeled from the CPG, taking into account all of the providers who will interact with the patient during the delivery of CPG-based care.<sup>24</sup> ECRs are then adjusted for the severity of the individual's condition and other factors.<sup>25</sup> However, ECRs exist for only seventeen conditions where national clinical guidelines or expert opinions have already been established.<sup>26</sup>

To calculate a patient's ECR, the expert panel follows three steps.<sup>27</sup> First, the expert panel alters the ECR price to replicate the patient's current health.<sup>28</sup> Second, they add an ECR negotiated fee schedule, establishing a payment plan for the patient to pay the provider.<sup>29</sup> Third, they build in additional funds for

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.org/Content/Newsletters/Purchasing-High-Performance/2009/November-3-2009/Case-Studies/What-Does-Rockford-Illinois-Have-to-Teach-the-Country-about-Health-Care.aspx.

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

<sup>21</sup> Alice G. Gosfield, J.D., *PROMETHEUS Payment: Better Quality and a Better Business Case*, 4 J. NAT'L COMPREHENSIVE CANCER NETWORK 968, 968 (2006).

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

<sup>23</sup> The Commonwealth Fund, *supra* note 19.

<sup>24</sup> GOSFIELD, *supra* note 9.

<sup>25</sup> The Commonwealth Fund, *supra* note 19.

<sup>26</sup> *Id.*

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

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

potentially avoidable complications on top of the patient's ECR.<sup>30</sup> At a specified time, incentives are paid to healthcare providers based on whether mistakes occurred and whether they followed good clinical protocol.<sup>31</sup> A provider must score high in both avoidable PACs and following good clinical protocol get the full incentive;<sup>32</sup> otherwise the remainder of the quality funds is withheld and reserved as a bonus for outstanding medical performances by other providers.<sup>33</sup> Although the model seems complex, the underlying principle for hospitals and providers is simple: to make more money by avoiding mistakes. The research suggests that significantly higher margins will be realized for high-quality providers under PROMETHEUS than under any other system.<sup>34</sup>

### III. WHY USE THE PROMETHEUS PAYMENT METHOD?

The main reason for using the PROMETHEUS method is to reduce the cost to the patient without sacrificing quality. Potentially avoidable complications (PACs) are common in the United States. For every dollar lost to PACs, implementing the PROMETHEUS method could help save up to forty cents.<sup>35</sup> Additionally, PACs account for 22% of all private healthcare expenditures in the United States and up to 80% of the costs for conditions that require intensive

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<sup>30</sup> *Id.* (“For example, a patient with chronic obstructive pulmonary disease might have a total calculated ECR of \$15,000, which includes a \$2,000 allowance for potentially avoidable complications. For doctors and hospitals that avoid making a mistake while treating that patient, the \$2,000 is pure profit. These incentives are withheld until the end of the year when claims and care can be analyzed in aggregate.”).

<sup>31</sup> The Commonwealth Fund, *supra* note 19.

<sup>32</sup> *Id.*

<sup>33</sup> Gosfield, *supra* note 21, at 969.

<sup>34</sup> The Commonwealth Fund, *supra* note 19.

<sup>35</sup> ROBERT WOOD JOHNSON FOUND., WHAT IS PROMETHEUS PAYMENT? AN EVIDENCE-INFORMED MODEL FOR PAYMENT REFORM 2 (2009), <http://www.rwjf.org/files/research/prometheusmodeljune09.pdf>.

management, such as congestive heart failure.<sup>36</sup> Finally, research estimates that with the broad application of the PROMETHEUS model of bundled payments for ECRs, national healthcare spending could be reduced by 5.4% between 2010 and 2019.<sup>37</sup> Overall, the PROMETHEUS model could reduce the country's healthcare bill by more than \$700 billion over ten years.<sup>38</sup>

#### IV. WILL THE PROMETHEUS PAYMENT METHOD WORK IN PRACTICE?

The PROMETHEUS Payment method is a promising approach to fix the United States healthcare crisis, but the underlying issue is whether it can be implemented into our healthcare scheme. The Office of the Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) suggest that a healthcare plan must include quality measures, incentive payments, and patient notification and care to be effective and provide high quality care.<sup>39</sup>

##### A. *Quality Measures*

According to the CMS and OIG, quality measures should be clearly and separately identified to provide high-quality care.<sup>40</sup> The measure of quality of care using the PROMETHEUS model depends on avoiding PACs, and the PROMETHEUS method takes measures to reduce PACs and the costs associated with them.<sup>41</sup> Doctors, patients, and other healthcare providers are aware of the

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<sup>36</sup> Brantes, *supra* note 4, at 1034.

<sup>37</sup> Peter S. Hussey et al., *Controlling U.S. Health Care Spending - Separating Promising from Unpromising Approaches*, 361 NEW ENG. J. MED. 2109, 2110 (2009).

<sup>38</sup> Brantes, *supra* note 4, at 1034.

<sup>39</sup> Jen Johnson, *Do You Know the Fair Market Value of Quality?* [http://www.hfma.org/hfm/2009archives/month10/HFM1009CvrSty\\_Johnson.htm](http://www.hfma.org/hfm/2009archives/month10/HFM1009CvrSty_Johnson.htm) (last visited Feb. 25, 2010).

<sup>40</sup> *Id.*

<sup>41</sup> Brantes, *supra* note 4, at 1033.

PACs because they are identified on the ECR of each patient.<sup>42</sup> Moreover, to better determine the accountability of PACs, the costs attributable to patient-related factors are separated from those attributable to the providers' actions.<sup>43</sup>

The CMS and OIG also point out that quality measures should be verifiable and sustained by medical evidence.<sup>44</sup> The PACs used in the PROMETHEUS method are tracked and accounted for separately.<sup>45</sup> Additionally, the ECR, which establishes a base rate for the treatment of each illness or condition, is also supported by medical evidence.<sup>46</sup> An expert panel establishes the ERC, modeling it after the CPG, which is made in accordance with all scientific data to treat the condition or illness.<sup>47</sup> This scientific approach is limited, however, because ECRs only exist for seventeen conditions.<sup>48</sup>

Finally, the CMS and OIG conclude that quality measures should consider the patient's race, ethnicity, and medical history.<sup>49</sup> The PROMETHEUS method takes into account the patient's population by establishing an individualized base for the ECRs.<sup>50</sup> The PROMETHEUS method does this through evidence-based guidelines that include adjustments for each patient's severity of disease and medical history.<sup>51</sup> Although limited to seventeen conditions, the PROMETHEUS

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<sup>42</sup> The Commonwealth Fund, *supra* note 19.

<sup>43</sup> Brantes, *supra* note 4, at 1034.

<sup>44</sup> Johnson, *supra* note 39.

<sup>45</sup> Brantes, *supra* note 4, at 1034.

<sup>46</sup> The Commonwealth Fund, *supra* note 19.

<sup>47</sup> Gosfield, *supra* note 21, at 969; The Commonwealth Fund, *supra* note 19.

<sup>48</sup> The Commonwealth Fund, *supra* note 19.

<sup>49</sup> Johnson, *supra* note 39.

<sup>50</sup> François de Brantes, *Pay for Performance and Beyond: A Recipe for Improving Healthcare*, in THE QUALITY CONUNDRUM: PRACTICAL APPROACHES FOR ENHANCING PATIENT CARE 110, 112 (2006).

<sup>51</sup> *Id.*

method is individualized to those practices with empirical research backing up their conclusions.<sup>52</sup>

### *B. Incentives Payments*

The CMS and OIG also provide suggestions pertaining to incentives and payments for future healthcare plans.<sup>53</sup> The CMS and OIG state that incentive payments should target national benchmarks and consider a hospital's historical baseline data.<sup>54</sup> The pricing of medical services using the PROMETHEUS method is packaged into ECRs for a particular illness or condition, and CPGs are factored into ERCs to establish the price of care for patients, establishing the benchmark for cost of care for a patient.<sup>55</sup> The ECRs and CPGs, as explained in the section above, use the scientific data collected by an expert panel to establish the cost of the treatment for the illness or condition.<sup>56</sup>

While the research does not indicate whether a hospital's historic baseline is factored into the pricing, the PROMETHEUS method is more patient-specific, since it takes into account the severity of an individual's condition into the overall cost, and therefore, incentive payment.<sup>57</sup> The PROMETHEUS method incorporates CMS and OIG's guidelines of targeting national benchmarks by using researched data indicating the cost of care for an illness or condition. Additionally, the PROMETHEUS method goes a step beyond the recommendations by tailoring each incentive payment to the individual patient.

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<sup>52</sup> See GOSFIELD, *supra* note 9, at 8-13.

<sup>53</sup> Johnson, *supra* note 39.

<sup>54</sup> *Id.*

<sup>55</sup> Gosfield, *supra* note 21, at 969; The Commonwealth Fund, *supra* note 19.

<sup>56</sup> The Commonwealth Fund, *supra* note 19.

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

Additionally, CMS and the OIG suggest that incentive payments should be based on fair market value and there should be thresholds where no payment exists.<sup>58</sup> The PROMETHEUS method does not follow the recommendations of the CMS and OIG to use fair market value for payment.<sup>59</sup> Instead, the PROMETHEUS method relies on empirical research to set the base price.<sup>60</sup> However, practice groups that are paid for managing chronic conditions using the PROMETHEUS model have considerable opportunities to maximize the profits that come from avoiding costly hospitalizations.<sup>61</sup> On the other hand, the PROMETHEUS method imposes a cap on the amount of payment a practitioner can receive.<sup>62</sup> The maximum payment a practitioner can receive is the ECR plus the amount allocated to PACs, if all PACs are avoided.<sup>63</sup> Therefore, if the ECR is \$10,000, the PACs equal \$2,000, and the practitioner has no cost associated with PACs, then the highest bonus that the practitioner could receive is the \$2,000 of PACs, with an overall payment of \$12,000.

### *C. Patient Care and Notification*

Finally, the CMS and OIG support that patients should be notified of the payment method and the method should be offered to all available providers.<sup>64</sup> Even if not already included in the setup of the model, providers notifying their patients of the use of the PROMETHEUS method would not alter the current setup and could be easily added to the PROMETHEUS method. Additionally, the

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<sup>58</sup> Johnson, *supra* note 39.

<sup>59</sup> See GOSFIELD, *supra* note 9, at 8-13.

<sup>60</sup> *Id.*

<sup>61</sup> Brantes, *supra* note 4, at 1035.

<sup>62</sup> The Commonwealth Fund, *supra* note 19.

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

<sup>64</sup> Johnson, *supra* note 39.

PROMETHEUS method is designed to be implemented in a variety of different healthcare setups from large integrated delivery networks to individual practitioners.<sup>65</sup> Since the PROMETHEUS method is designed to be implemented into numerous healthcare structures and can provide payment incentives for physician specialties, hospitals, and other healthcare providers,<sup>66</sup> the PROMETHEUS model is available and appealing to all providers. The PROMETHEUS method reaches most of the standards set by the CMS and OIG; therefore, under the PROMETHEUS method, this payment model has the potential to be a successful healthcare model.

#### V. CONCLUSION

Pay-for-performance models are transitional at best and are only a step in the right direction from the “one size fits all” quality approach of most healthcare payments.<sup>67</sup> National institutions have even recognized the need for a new payment system as a pivotal thrust to bring healthcare into the twenty-first century.<sup>68</sup> Pilot projects, like the one tested in Rockford, Illinois, demonstrate the positive future of the PROMETHEUS model.<sup>69</sup> Because the PROMETHEUS model was shown to be attractive with a low-risk start-up, patients, doctors, and other healthcare providers can see the benefit of the model. The model’s apparent conformity with the standards set by groups such as the CMS and OIG only further establishes the potential success of the PROMETHEUS model. At a minimum, the PROMETHEUS model suggests that it can effectively improve the

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<sup>65</sup> Brantes, *supra* note 50, at 112.

<sup>66</sup> *Id.*

<sup>67</sup> Gosfield, *supra* note 21, at 968.

<sup>68</sup> *Id.*

<sup>69</sup> See The Commonwealth Fund, *supra* note 19.

United States' current disassociated delivery system to a respected healthcare system in which teamwork and the drive for quality are the norm.<sup>70</sup>

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<sup>70</sup> Brantes, *supra* note 4, at 1035.

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***Carrot Before Stick:  
Utilizing a Business Case for Quality of Care Initiatives***

*Joseph T. Van Leer*<sup>\*</sup>

I. INTRODUCTION

The United States healthcare system must improve quality of care for patients.<sup>1</sup> Although medical professionals must provide their patients with a certain level of quality, the system cannot sustain merely meeting minimum standards any longer. We must exceed them. Thus, the government and private payors must incentivize greater quality of care.

Evidence-based medicine, better measurement, and transparency comprise the core of the quality initiatives movement.<sup>2</sup> Unfortunately, these initiatives are not penetrating the healthcare sector fast enough.<sup>3</sup> The absence of a “business case” for quality enhancement interventions (QEI) explains the lack of penetration.<sup>4</sup> A business case enables organizations to justify QEIs by realizing a

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<sup>1</sup> INST. OF MED., TO ERR IS HUMAN, BUILDING A SAFER HEALTH SYSTEM (Nat’l Acad. Press 2000) [hereinafter TO ERR IS HUMAN]; INST. OF MED., CROSSING THE QUALITY CHASM (Nat’l Acad. Press 2001) [hereinafter CROSSING THE QUALITY CHASM].

<sup>2</sup> HEALTH L. HANDBOOK § 5:2 (2006).

<sup>3</sup> DAVID BLUMENTHAL & TIMOTHY FERRIS, THE BUSINESS CASE FOR QUALITY: ENDING BUSINESS AS USUAL IN AMERICAN HEALTH CARE 1 (Commonwealth Fund 2004).

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

financial return on investment (ROI) within a reasonable timeframe.<sup>5</sup> Although punishing providers most assuredly grabs their attention, a business case acts as the carrot, as opposed to the stick, by giving a business incentive to implement QEIs.<sup>6</sup> Rising costs and shrinking margins may be the impetus necessary for implementing QEIs that result in a positive ROI throughout the country.<sup>7</sup> Misaligned financial incentives are partly responsible for this problem.<sup>8</sup> For instance, a fee-for-service payment system rewards redundant medical care.<sup>9</sup> Therefore, quality improvements under a fee-for-service paradigm could actually reduce revenue and account for a negative ROI.<sup>10</sup>

What happens when a hospital successfully implements a QEI? Chances are that the quality of treatment will improve, translating into shorter lengths of hospital stays for patients.<sup>11</sup> Although there will certainly be a cost savings for the community and patients, under a fee-for-service system, the hospital will likely see a loss in revenue even with cost reductions.<sup>12</sup> Many healthcare

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<sup>5</sup> Sheila Leatherman et al., *The Business Case For Quality: Case Studies And An Analysis*, 22 HEALTH AFF. 17, 18 (2003).

<sup>6</sup> See *id.* (using ROI as financial incentives); *contra* Ctrs. for Medicare & Medicaid Servs., *Eliminating Serious, Preventable, and Costly Medical Errors – Never Events*, <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=1863&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date> (last visited Apr. 15, 2010) [hereinafter CMS Never Events].

<sup>7</sup> Nicole Lurie et al., *Challenges To Using A Business Case for Addressing Health Disparities*, 27 HEALTH AFF. 334, 335 (2008).

<sup>8</sup> Leatherman et al., *supra* note 5, at 17; Some experts say that existing payment mechanisms may actually thwart quality. ALICE G. GOSFIELD & JAMES L. REINERTSEN, *DOING WELL BY DOING GOOD: IMPROVING THE BUSINESS CASE FOR QUALITY* 12 (2003), available at [http://www.ufta.com/PDF/uft-a\\_White\\_Paper\\_060103.PDF](http://www.ufta.com/PDF/uft-a_White_Paper_060103.PDF)

<sup>9</sup> GOSFIELD & REINERTSEN, *supra* note 8, at 13.

<sup>10</sup> See, e.g., ARTEMIS MARCH, *THE BUSINESS CASE FOR CLINICAL PATHWAYS AND OUTCOMES MANAGEMENT: A CASE STUDY OF CHILDREN'S HOSPITAL AND HEALTH CENTER OF SAN DIEGO* 30 (Commonwealth Fund 2003).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

administrators face this problem today.<sup>13</sup> We need to change healthcare policy to align financial and quality interests; however, patients cannot afford to wait any longer.<sup>14</sup> Through proper targeting, hospitals can develop a positive (or near positive) ROI to alleviate many of the financial constraints.<sup>15</sup> By pinpointing QEIs at the 20% of patients which generate 80% of costs, a provider is likely to see a positive ROI by avoiding unrecoverable costs.<sup>16</sup>

Without a positive ROI, it is unlikely that widespread quality enhancement will occur. In order to demonstrate this, Part II of this article will outline current quality of care initiatives.<sup>17</sup> Next, Part III discusses how to develop a business case for quality of care.<sup>18</sup> Finally, Part IV analyzes the potential barriers to the business case.<sup>19</sup>

## II. UNDERSTANDING CURRENT QUALITY OF CARE INITIATIVES

Many in healthcare feel frustrated, concerned, and distrustful about the plethora of initiatives utilized to incentivize quality.<sup>20</sup> These initiatives spawned the creation of a whole industry to facilitate these efforts.<sup>21</sup> Healthcare quality reporting began in the early 1970's as part of a "shopper's guide" to Philadelphia hospitals.<sup>22</sup> This trend continued and has increased substantially in recent years,

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<sup>13</sup> William J. Ward, Jr. et al., *Building the Business Case for Clinical Quality*, 60 HEALTHCARE FIN. MGMT. 92, 92 (2006).

<sup>14</sup> MARCH, *supra* note 10, at 45.

<sup>15</sup> *Id.* at 32.

<sup>16</sup> GOSFIELD & REINERTSEN, *supra* note 8, at 26.

<sup>17</sup> *See infra* Part II.

<sup>18</sup> *See infra* Part III.

<sup>19</sup> *See infra* Part IV.

<sup>20</sup> HEALTH L. HANDBOOK, *supra* note 2, at § 5:1.

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

<sup>22</sup> Kristin Madison, *The Law and Policy of Health Care Quality Reporting*, 31 CAMPBELL L. REV. 215, 216 (2009).

largely due to the publication of *To Err is Human*<sup>23</sup> and *Crossing the Quality Chasm*,<sup>24</sup> which raised awareness about the healthcare system's quality shortcomings. Currently, the Agency for Healthcare Research and Quality and the Centers for Medicare and Medicaid Services (CMS) have partnered together to improve the quality, safety, and effectiveness of healthcare for all Americans.<sup>25</sup> Of course, there are many other private and public organizations involved in the attempt to find a panacea for quality.

Better measurement and transparency underpin the initiatives designed to improve quality in healthcare.<sup>26</sup> In theory, publicizing more information about healthcare performance will improve quality by making providers, and the entire system, accountable for performance.<sup>27</sup> Traditionally, the Joint Commission on Accreditation of Health Care Organizations led the push for greater hospital quality.<sup>28</sup> In 2003, CMS launched the National Voluntary Hospital Reporting Initiative<sup>29</sup> and offered financial incentives to report quality and safety data.<sup>30</sup> The Joint Commission, CMS, and the National Quality Forum promulgated the first quality metrics.<sup>31</sup> Current measure types include: efficiency, structure,

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<sup>23</sup> TO ERR IS HUMAN, *supra* note 1.

<sup>24</sup> CROSSING THE QUALITY CHASM, *supra* note 1.

<sup>25</sup> Carolyn M. Clancy, M.D., Dir. of the Agency for Healthcare Research & Quality, Testimony on Health Care Quality Initiatives (Mar. 18, 2004), *available at* <http://www.ahrq.gov/news/qttest319.htm>.

<sup>26</sup> HEALTH L. HANDBOOK, *supra* note 2.

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

<sup>28</sup> Tracy E. Miller & Valerie L. Gutmann, *Changing Expectations for Board Oversight of Healthcare Quality: The Emerging Paradigm*, 2 J. HEALTH & LIFE SCI. L. 31, 35 (2009).

<sup>29</sup> See Cts. for Medicare & Medicaid Servs., Hospital Quality Initiatives: Reporting Hospital Quality Data for Annual Payment Update, [http://www.cms.hhs.gov/HospitalQualityInits/08\\_HospitalRHQDAPU.asp](http://www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp) (last visited Apr. 15, 2010).

<sup>30</sup> Miller & Gutmann, *supra* note 28, at 40.

<sup>31</sup> 2 HEALTH L. PRAC. GUIDE § 31:85 (2009).

process, intermediate outcome, outcome, and patient centeredness.<sup>32</sup> Essentially, these mechanisms strive to improve quality through many different programs, such as bonus payments, regulatory mandates, market-driven effects, and even morality.<sup>33</sup> Because of the significant expense often associated with QEIs, organizations must understand how enhanced quality will affect their financial performance.

Quality-based payments, known as “Value Based Purchasing”, such as pay-for-performance (P4P), account for a large part of quality incentives.<sup>34</sup> Various forms of P4P, which reward hospitals and physicians for better performance, litter reimbursement schemes in modern medicine.<sup>35</sup> From a business perspective, however, the real concern is being paid less.<sup>36</sup> For example, CMS’ “never event program” simply refuses to reimburse hospitals for a number of events listed on the National Quality Forum’s “never events list.”<sup>37</sup> These events are unambiguous, preventable, serious, and adverse, including surgery on the wrong body part, leaving an object in the patient’s body, and the use of contaminated drugs.<sup>38</sup> This initiative sparked similar programs from private

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<sup>32</sup> See CTRS. FOR MEDICARE & MEDICAID SERVS., ROADMAP FOR QUALITY 3 (2009), available at [http://www.cms.hhs.gov/QualityInitiativesGenInfo/downloads/QualityMeasurementRoadmap\\_OE\\_A1-16\\_508.pdf](http://www.cms.hhs.gov/QualityInitiativesGenInfo/downloads/QualityMeasurementRoadmap_OE_A1-16_508.pdf) (explaining measure types).

<sup>33</sup> HEALTH L. HANDBOOK § 1:1 (2008).

<sup>34</sup> Catherine A. Martin & Tamara R. Tenney, *Preparing for Quality-Based Payments: Trends & Legal Barriers to Successful Implementation*, 2 J. HEALTH & LIFE SCI. L. 1, 6 (2009).

<sup>35</sup> Anne B. Claiborne et al., *Legal Impediments To Implementing Value-Based Purchasing In Healthcare*, 35 AM. J.L. & MED. 442, 450 (2009).

<sup>36</sup> Linda Wilson, *The Cost of Errors*, MODERN HEALTHCARE, Jun. 2, 2008, at 8.

<sup>37</sup> CMS Never Events, *supra* note 6.

<sup>38</sup> *Id.*

insurers, such as Aetna and Wellpoint.<sup>39</sup> Although its full effect is unclear, many believe that linking quality and payment will reduce unnecessary cost.<sup>40</sup> In fact, a Thomson Reuters study estimated that hospitals stand to lose \$23,772 annually, as a result of “never events.”<sup>41</sup> Although these financial penalties may incentivize quality improvement, organizations seemingly need greater incentive. A business case acts as a solution to the problem.

### III. MAKING A BUSINESS CASE FOR QUALITY

There are many definitions of the “business case for quality.” The most appropriate is likely the one set forth in an article written by Sheila Leatherman, which propelled “business case” research.<sup>42</sup> According to Leatherman, a “business case” exists if the organization receives a financial ROI from its QEI within a reasonable time frame, and if the QEI leads to a positive, indirect effect on the organization.<sup>43</sup> This could manifest itself through efficiency, market share, or even morale.<sup>44</sup>

Leatherman limits her definition primarily to direct financial considerations, but there are often indirect factors that may make a QEI argument more persuasive.<sup>45</sup> Additionally, it rules out other factors like economic and

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<sup>39</sup> CAL. ASS’N OF HEALTH PLANS, “NEVER EVENTS”: MEDICARE AND HEALTH PLAN’S POLICIES ON PROVIDING PAYMENT FOR SERIOUS AND PREVENTABLE HOSPITAL ERRORS 3(2008), available at [http://www.calhealthplans.org/documents/DH03\\_NeverEventsPoliciesProvidingPmt.pdf](http://www.calhealthplans.org/documents/DH03_NeverEventsPoliciesProvidingPmt.pdf).

<sup>40</sup> Martin & Tenney, *supra* note 34.

<sup>41</sup> Wilson, *supra* note 36.

<sup>42</sup> Leatherman et al., *supra* note 5.

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

<sup>44</sup> *Id.*

<sup>45</sup> See MICHAEL BAILIT & MARY BETH DYER, BEYOND BANKABLE DOLLARS: ESTABLISHING A BUSINESS CASE FOR IMPROVING HEALTH CARE 6 (Commonwealth Fund 2004), available at <http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2004/Sep/Beyond-Bankable-Dollars--Establishing-a-Business-Case-for-Improving-Health-Care.aspx>.

social benefits.<sup>46</sup> For example, a patient may benefit as a result of a QEI, either in cost, quality, or both; however, a provider may see increased costs and less revenue as a result of better care.<sup>47</sup> This could be the result of misaligned financial incentives, a lengthy ROI, or even an implementation problem, such as motivating physicians.<sup>48</sup> Although less tangible motives, like philanthropy, are certainly laudable, providers surely need greater incentive to jumpstart private quality enhancements. Nevertheless, by utilizing direct and indirect financial considerations, organizations may be able to make a business case for quality.<sup>49</sup>

#### A. Internal Financial Incentives

Overwhelmingly, Leatherman's analysis showed a loss for nearly every provider that conducted a QEI.<sup>50</sup> On the other hand, individual patients and society fared well in general.<sup>51</sup> Perverse payment incentives were largely responsible for this outcome.<sup>52</sup> For example, the Henry Ford Health System implemented a lipid clinic that was designed to improve the monitoring of statin therapy and the management of patients with high serum cholesterol levels.<sup>53</sup> The clinic demonstrated clear gains, however, they could not justify expanding the clinic beyond their capitated health plan because it would result in a displaced ROI.<sup>54</sup> The costs averted would likely accrue for another stakeholder because the

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<sup>46</sup> Leatherman et al., *supra* note 5, at 19.

<sup>47</sup> *See, e.g., id.* at 24.

<sup>48</sup> BAILIT & DYER, *supra* note 45, at 3-4.

<sup>49</sup> MARCH, *supra* note 10, at 34.

<sup>50</sup> Leatherman et al., *supra* note 5, at 24.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 27.

<sup>53</sup> *Id.* at 20.

<sup>54</sup> *Id.*

patients would move on to another healthcare provider.<sup>55</sup> Although the Health System in this case was unable to fully maximize its quality and cost impact, organizations can utilize ROI analysis to target different population subsets in order to determine which will generate the greatest ROI.<sup>56</sup>

Although central to developing a business case, placing too much focus on financial incentives may actually reduce quality and ostracize physicians.<sup>57</sup> Alternatively, improving quality through evidence-based medicine may develop better care, and consequently, save money.<sup>58</sup> In 1995, the Children's Hospital and Health Center of San Diego developed a program instituting clinical pathways that were "designed to increase the likelihood of positive outcomes based upon the effective and efficient use of utilizing evidence, best practices, and clinical expertise."<sup>59</sup> From fiscal years 1995 to 2001, the Children's Hospital generated an estimated \$5.4 million in cumulative direct cost savings.<sup>60</sup> As expected, however, misaligned incentives led to losses in terms of direct financials.<sup>61</sup> This was a direct result of payment on a *per diem* basis, where reductions in patient's hospital stay meant forfeiting millions of dollars in revenue annually.<sup>62</sup> Accordingly, these savings accrued to the payor rather than to the provider.<sup>63</sup> Interestingly enough, experts contend that such a program may be more

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<sup>55</sup> *Id.* at 20-21.

<sup>56</sup> ALLISON HAMBLIN & CHAD SHEARER, MAXIMIZING QUALITY AND VALUE IN MEDICAID: USING RETURN ON INVESTMENT FORECASTING TO SUPPORT EFFECTIVE POLICYMAKING 3 (Commonwealth Fund 2009), available at <http://commonwealthfund.org/Content/Publications/Issue-Briefs/2009/Apr/Maximizing-Quality-and-Value-in-Medicaid.aspx>.

<sup>57</sup> See MARCH, *supra* note 10, at 5.

<sup>58</sup> *Id.* at 6.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 28.

<sup>61</sup> *Id.* at 30.

<sup>62</sup> *Id.*

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

successful, in terms of a direct business case, if it were instituted at an adult hospital.<sup>64</sup> This is largely because Medicare reimbursement is on a *per discharge* basis where a reduction in the length of a patient's hospital stay results in a financial gain.<sup>65</sup> Accordingly, if a similar program targeted a group that would result in aligned financials, it could surely result in a true business case. Nevertheless, although the Children's Hospital could not show a direct ROI, many external sources proved beneficial for the organization by resulting in an overall positive ROI.<sup>66</sup>

### *B. External Financial Incentives*

Outside of the internal bankable dollars lie potential outside sources of increased revenue. Certainly, P4P programs are growing rapidly,<sup>67</sup> but some providers are seeing a form of P4P through gain-sharing with payors.<sup>68</sup> Additionally, reduced malpractice costs can result in a large indirect ROI that providers cannot ignore.<sup>69</sup> Also, quality improvement may streamline processes which increase capacity, and revenue.<sup>70</sup> Lastly, and potentially the most important, is an increase in market share.<sup>71</sup>

In addition to direct benefits, a successful QEI may improve an organization's image and reputation and, as a corollary, increase market share and

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<sup>64</sup> *Id.* at 32.

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

<sup>66</sup> *Id.* at 34.

<sup>67</sup> HEALTH L. HANDBOOK, *supra* note 33.

<sup>68</sup> MARCH, *supra* note 10, at 36.

<sup>69</sup> Wilson, *supra* note 36.

<sup>70</sup> MARCH, *supra* note 10, at 34.

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

patient volume.<sup>72</sup> This could also potentially attract and retain high-quality staff.<sup>73</sup> A competitive market may be essential to parlay these changes into increased market share, but there is something to be said for successfully implementing a QEI in a less competitive market.<sup>74</sup> As Leatherman and her colleagues noted, providers will be unable to realize indirect benefits unless consumers are able to perceive quality differences.<sup>75</sup> In doing so, providers must use data presentation approaches that reduce the complexity and burden that consumers face in evaluating quality reports.<sup>76</sup>

Through the use of a well-developed QEI and, as a result, increased capacity, the Children's Hospital was able to attract unprecedented levels of business without a large capital outlay.<sup>77</sup> To illustrate, Children's Emergency Department, originally built to serve 25,000 children in 1984, actually served 55,000 in 2000.<sup>78</sup> Additionally, the increase in market share and improved public image led to better relationships with private payers.<sup>79</sup> Finally, a large part of the Children's Hospital's success was due to better information technology through computerized physician order entry.<sup>80</sup> This led to savings from avoided harm, which reduces litigation, additional treatment, and disciplinary costs.<sup>81</sup> In sum,

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<sup>72</sup> BAILIT & DYER, *supra* note 45.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 2.

<sup>75</sup> Leatherman et al., *supra* note 5, at 25.

<sup>76</sup> Judith H. Hibbard et al., *It Isn't Just about Choice: The Potential of a Public Performance Report to Affect the Public Image of Hospitals*, 62 MED. CARE RESEARCH & REV. 358, 360 (2005).

<sup>77</sup> MARCH, *supra* note 10, at 34.

<sup>78</sup> *Id.* at 35.

<sup>79</sup> *Id.* at 35-36.

<sup>80</sup> *Id.* at 38-39.

<sup>81</sup> *Id.* at 42.

organizations can develop a comprehensive business case through proper targeting and the use of external benefits. Nevertheless, potential barriers exist.

#### IV. POTENTIAL BARRIERS

A provider can implement endless change, but without the willing collaboration of physicians, most, if not all, initiatives are destined to fail.<sup>82</sup> This includes health plans because many of Health Effectiveness Data and Information Set measures that monitor quality reflect physician services.<sup>83</sup> Although non-financial methods can enable hospital-physician collaboration, it seems that various gain-sharing arrangements provide increased cooperation.<sup>84</sup> Gain-sharing is a type of incentive arrangement where hospitals and physicians share in the reduction of the hospital's patient care costs based on standardized changes in patterns.<sup>85</sup>

Unfortunately, many barriers to implementing gainsharing programs exist. Fraud and abuse laws constrict most plans that would sufficiently incentivize physicians.<sup>86</sup> For example, the Civil Monetary Penalties Statute prohibits remuneration, directly or indirectly, to a physician to reduce or limit services provided to CMS patients.<sup>87</sup> Alternatively, exceptions under the Stark Law for physicians through the bona fide employment and personal services exceptions

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<sup>82</sup> See HEALTH L. HANDBOOK, *supra* note 2, at § 5:4.

<sup>83</sup> See *id.*

<sup>84</sup> Claiborne et al., *supra* note 35, at 485.

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

<sup>86</sup> See HEALTH LAW HANDBOOK, *supra* note 2, at § 5:4; See also Richard S. Saver, *Squandering the Gain: Gainsharing & the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145, 150 (2003).

<sup>87</sup> 42 U.S.C. § 1320a-7a(b) (2006).

may apply.<sup>88</sup> It appears, however, that CMS may be making changes to the Stark law by instituting a specific exception for gain-sharing or “incentive” programs which will require compliance with the specific guidelines.<sup>89</sup> Finally, the Anti-Kickback Statute may be an impediment, as no specific exception for gain-sharing arrangements exists.<sup>90</sup> Of course, these issues require considerably more legal analysis, and are most assuredly fact-intensive inquiries. Nevertheless, organizations must be aware of potential legal land-mines.

#### V. CONCLUSION

It remains clear that quality initiatives are, by no means, easy to accomplish. On the other hand, there are a plethora of potential incentives for providers to engage in quality enhancement. A large amount of literature focuses on P4P as one way to incentivize better care; however, it seems insufficient by itself. Thus, it is essential to develop a business case. Although most business case studies focus on direct financial ROI, by expanding the scope, providers can justify interventions through greater market share, lower malpractice costs, and moral leadership. On the policy side, changes that align financial incentives with quality targets will vastly increase private action. Until then, organizations should attempt to implement new programs by partnering with physicians and payors to develop financially cognizable interventions.

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<sup>88</sup> Claiborne et al., *supra* note 35, at 487.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.* at 489.

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***The Defensive Medicine Debate:  
Driven by Special Interests***

*Jill Fairchild\**

I. INTRODUCTION

Tort reform is a contentious issue within the larger U.S. debate on healthcare reform that has received surprisingly little media attention. The first medical malpractice crisis erupted in the mid-1970s, which was marked by exorbitant malpractice insurance premiums and caught the attention of Congress.<sup>1</sup> Since the early 2000s, however, medical malpractice rates have stabilized,<sup>2</sup> which lessened the tort reform discussion to a small piece of the healthcare reform overhaul rather than an independent issue.<sup>3</sup> Nonetheless, the current tort reform discussion, specifically in relation to defensive medicine practices, has created a lot of tension in the current debate.<sup>4</sup>

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<sup>1</sup> Bernadette Fernandez et al., *Medical Malpractice Insurance and Health Reform*, CONG. RESEARCH SERV., Oct. 19, 2009, at 1.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 2.

<sup>4</sup> Amer Kaissi, *What is Defensive Medicine and Why Should We Care?*, HEALTHCARE HACKS, Oct. 30, 2009, <http://healthcarehacks.com/what-is-defensive-medicine-and-why-should-we-care-0>.

In President Obama's June 2009 address to the American Medical Association's House of Delegates, President Obama acknowledged doctors' concerns, not by advocating for caps on medical malpractice, but rather by advocating for solutions to curtail the use of defensive medicine by doctors.<sup>5</sup> President Obama stated a real issue is that "some doctors may feel the need to order more tests and treatments to avoid being legally vulnerable."<sup>6</sup> He added, "That's a real issue."<sup>7</sup>

Before this issue can be resolved, however, many questions need to be answered, including the true costs of defensive medicine, the frequency in which doctors practice defensive medicine, and the reasons why doctors practice defensive medicine. This article will provide an overview of defensive medicine practices and examine the debate from the perspectives of doctors, trial lawyers, and patients. It will conclude by briefly discussing possible interim solutions to the healthcare debate until overall tort reform is passed, which proponents argue will decrease the use of defensive medicine.

## II. WHAT IS DEFENSIVE MEDICINE & WHAT ARE ITS CONSEQUENCES?

Beginning with the first medical malpractice crisis in the 1970s, defensive medicine practices have been purported as a result of malpractice legislation.<sup>8</sup> Defensive medicine is considered "a deviation from sound medical practice,

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<sup>5</sup> President Barak Obama, Obama Addresses Physicians at AMA Meeting (June 15, 2009), available at [http://www.ama-assn.org/ama/pub/about\\_ama/our-people/house-delegates/2009-annual-meeting/speeches/president-obama-speech.shtml](http://www.ama-assn.org/ama/pub/about_ama/our-people/house-delegates/2009-annual-meeting/speeches/president-obama-speech.shtml) (transcript and video available from the American Medical Association).

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

<sup>7</sup> *Id.*

<sup>8</sup> Colleen Smith, Defensive Medicine: The Effects of Medical Malpractice Tort Law on Physician Behavior 1 (Jan. 28, 2009), available at <http://hdl.handle.net/1961/4817> (unpublished honor's program Capstone project, on file with American University Archives).

induced primarily by threat of liability.”<sup>9</sup> There are two types of defensive medicine: assurance and avoidance behaviors.<sup>10</sup> Assurance behavior is viewed as positive defensive medicine because it may not negatively affect the patient’s health, but doctors may perform extra tests or services in order to avoid medical liability suits.<sup>11</sup> Avoidance behavior is considered negative defensive medicine because it reflects doctors’ efforts to avoid legal liability by refusing to see high-risk patients or by refusing to perform high-risk operations.<sup>12</sup>

The National Bureau of Economic Research conducted a study on the costs of defensive medicine in 1996.<sup>13</sup> It analyzed the effects of malpractice liability reforms by using data from Medicare beneficiaries who were treated for serious heart diseases.<sup>14</sup> Researchers Daniel Kessler and Mark McClellan contend that “defensive medicine is a potentially serious social problem: if fear of liability drives health care providers to administer treatments that do not have worthwhile medical benefits, then the current liability system may generate inefficiencies many times greater than the costs of compensating malpractice claimants.”<sup>15</sup> In other words, it is not the cost of compensating patients through the medical malpractice system that drives up costs, but rather it is physician behavior, specifically the practice of administering treatments with minimal

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<sup>9</sup> Johnny Benjamin, *Healthcare Reform and Defensive Medicine*, HUFFINGTON POST, July 23, 2009, [http://www.huffingtonpost.com/johnny-benjamin/healthcare-reform-and-def\\_b\\_243537.html](http://www.huffingtonpost.com/johnny-benjamin/healthcare-reform-and-def_b_243537.html).

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

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Daniel P. Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine?*, 111(2) Q. J. ECON. 353, 353-390 (1996).

<sup>14</sup> *Id.* at 353.

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

expected medical benefit that drives up costs.<sup>16</sup> McClellan and Kessler's analysis indicates reforms which directly limit provider liability, such as caps on awards to patients, could reduce hospital expenditures by 5% to 9% within three to five years of adoption by reducing the practice of defensive medicine.<sup>17</sup>

Recently, in 2008, the Massachusetts Medical Society (MMS) also conducted a study on its members' use of defensive medicine.<sup>18</sup> The study revealed that 83% of those doctors surveyed practiced defensive medicine,<sup>19</sup> with an average of between 18% and 28% of tests, procedures, referrals, consultations, and 13% of hospitalizations ordered for defensive reasons.<sup>20</sup> MMS estimated that these practices cost the state of Massachusetts a minimum of \$1.4 billion per year.<sup>21</sup> MMS contends that the consequences of defensive medicine go beyond the unnecessary toll on healthcare spending; defensive medicine practices reduce access to care for high-risk patients and, often times, the tests involving radiation can be unsafe for patients.<sup>22</sup>

The MMS and the McClellan/Kessler studies are distinguishable in that they each studied different aspects of defensive medicine. MMS studied the frequency and the costs of defensive medicine, which is considered the first study of its kind, while the McClellan/Kessler report focused on the impact of defensive

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<sup>16</sup> *Id.* at 354.

<sup>17</sup> *Id.* at 386.

<sup>18</sup> See MASS. MED. SOC'Y, INVESTIGATION OF DEFENSIVE MEDICINE IN MASSACHUSETTS (2008), available at [http://www.ncrponline.org/PDFs/Mass\\_Med\\_Soc.pdf](http://www.ncrponline.org/PDFs/Mass_Med_Soc.pdf) [hereinafter MMS].

<sup>19</sup> *Id.* at 3.

<sup>20</sup> *Id.* at 4.

<sup>21</sup> *Id.* at 7.

<sup>22</sup> Richard Gulla, *MMS Urges Special Study of Defensive Medicine*, MASS. MED. SOC'Y, June 23, 2009, <http://www.massmed.org/AM/Template.cfm?Section=Home6&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=30633>.

medicine on medical malpractice costs.<sup>23</sup> Medical malpractice costs are estimated at \$30 billion per year, or about 1% of national healthcare spending.<sup>24</sup> The estimate on the costs of defensive medicine is difficult to ascertain. The estimates are between \$100 billion to \$300 billion, or 3% to 10% of overall healthcare costs.<sup>25</sup>

As evidence of the difficulties of putting a price tag on defensive medicine, doctors' and lawyers' estimates vary drastically. Doctors estimate that defensive medicine and malpractice insurance premiums cost upwards of 10% of health care spending, while lawyers estimate costs at less than 0.5%.<sup>26</sup> Different specialties, geographic locations, and insurance carriers also contribute to the varying estimates of malpractice premiums.<sup>27</sup> The Congressional Budget Office, while acknowledging that studies have shown evidence of defensive medicine, maintains that it is still difficult to ascertain a true measure of the costs of defensive medicine. Further, the Congressional Budget Office points out that even provider groups acknowledge that defensive medicine is difficult to measure.<sup>28</sup>

### III. COMPETING SPECIAL INTERESTS

A closer look at obstetricians will lend insight into the prevalence of the practice of defensive medicine. Some researchers and doctors have been able to

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<sup>23</sup> See generally MMS, *supra* note 18; see also Kessler & McClellan, *supra* note 13.

<sup>24</sup> Kaissi, *supra* note 5.

<sup>25</sup> *Id.*

<sup>26</sup> The Henry J. Kaiser Family Found., *Doctors Scrutinize Defensive Medicine, Surgeons Oppose Senate Reform Bill*, KAISER HEALTH NEWS, Nov. 6, 2009, [www.medicalnewstoday.com/articles/170077.php](http://www.medicalnewstoday.com/articles/170077.php) [hereinafter Kaiser].

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

<sup>28</sup> Fernandez et al., *supra* note 1, at 4.

connect cesarean sections with defensive medicine. For example, according to Dr. Elizabeth A. Platz, from the Medical University of South Carolina in Charleston, “states classified as having a medical liability crisis or crisis brewing by ACOG (American College of Obstetricians and Gynecologists) have significantly higher rates of cesarean delivery, and this may reflect a pattern of defensive medicine in response to the liability climate.”<sup>29</sup> Currently, cesarean rates are as high as 30% of total births in the United States compared to only 4.5% of births in 1965.<sup>30</sup> Obstetricians may be quicker today to perform cesarean sections at any sign of complications from a fear of litigation and the high price of malpractice awards in these types of suits.<sup>31</sup> Other doctors concur with the obstetricians’ position that it is the fear of litigation driving the practice of defensive medicine.<sup>32</sup> Doctors, however, also say that it is difficult to ascertain which decisions are driven solely by fear of litigation because doctors also want to provide patients with comprehensive exams and treatments.<sup>33</sup>

Another group with a special interest in the defensive medicine argument is trial lawyers. Considering that trial lawyers represent patients in medical malpractice suits, it is not surprising that the trial lawyers’ position on tort reform has historically been in stark contrast to that of doctors; their stance on defensive medicine is no exception. Trial lawyers point to medical errors, contending that

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<sup>29</sup> Richard Hyer, *ACOG 2009: Liability Fears May be Linked to Rise in Cesarean Rates*, MEDSCAPE MED. NEWS, May 12, 2009, <http://www.medscape.com/viewarticle/702712>.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> Kristina Goodnough, *Study Shows Defensive Medicine Widespread*, ADVANCE, Feb. 23, 2009, at 1, 4, available at <http://advance.uconn.edu/pdf/090223.pdf>.

<sup>33</sup> Dionne Searcey & Jacob Goldstein, *Tangible and Unseen Health-Care Costs*, WALL ST. J., Sept. 3, 2009, at A13, available at <http://online.wsj.com/article/SB125193312967181349.html>.

“one way to slash the exorbitant cost of health care would be to cut down on errors doctors make so that fewer cases wind up in the legal system.”<sup>34</sup> In other words, “bad medicine, not lawsuits is to blame.”<sup>35</sup> The organization Americans for Insurance Reform believes that “only a very small portion of health care costs result from defensive medicine.”<sup>36</sup>

Finally, the most important perspective of all is the patient’s perspective. Kevin Pho, a primary care doctor based in Nashua, New Hampshire, who also manages a medical blog,<sup>37</sup> discusses the risks associated with more tests and posits that a doctor must have a willing patient.<sup>38</sup> A patient must “know that more tests might not always be better medicine.”<sup>39</sup> Further, “before undergoing a scan or procedure, [the patient should] understand why it is being ordered.”<sup>40</sup> Interestingly, it is not always the doctor who is practicing defensive medicine, but it is the patient who is asking for a certain test, and doctors comply by practicing assurance medicine.<sup>41</sup> It is this very assurance behavior that may change the standard of care that patients expect, as well as accessibility to medical

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<sup>34</sup> Ashby Jones, *Is Practicing Defensive Medicine Needlessly Costly?*, WALL ST. J., Sept. 3, 2009, <http://blogs.wsj.com/law/2009/09/03/is-practicing-defensive-medicine-needlessly-costly/tab/article>.

<sup>35</sup> Kaiser, *supra* note 26.

<sup>36</sup> Ams. for Ins. Reform, *The Defensive Medicine Myth*, <http://www.insurance-reform.org/issues/MedMalDefensiveFactSheet2009F.html> (last visited Apr. 16, 2010).

<sup>37</sup> Searcey & Goldstein, *supra* note 33.

<sup>38</sup> See generally Kevin Pho, *Wasted Medical Dollars*, USA TODAY, Apr. 23, 2008, <http://blogs.usatoday.com/oped/2008/04/wasted-medical.html>. (Patients often equate defensive medicine with more thorough care).

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> Marloes A. van Bokhoven et al., *Influence of Watchful Waiting on Satisfaction and Anxiety Among Patients Seeking Care for Unexplained Complaints*, 7 ANNALS FAM. MED. 112, 113 (2009).

information through the internet or other forms of media that may also change their expectations of care.<sup>42</sup>

#### IV. POSSIBLE SOLUTIONS

Historically, Democrats generally side with the trial lawyers, who oppose tort reform, while Republicans advocate for tort reform.<sup>43</sup> Placing this debate in the current political context is important to understand why tort reform is only a small component of the healthcare overhaul. Additionally, with an overview of the defensive medicine debate, it is clear that no one solution will appease all groups. But, the White House has included in the current bill a \$25 million allocation for states to implement patient safety and medical liability programs.<sup>44</sup> The extent of these programs is yet to be determined.

The special interest groups have their own ideas of what could be the best interim solution until the political stars align and tort reform is passed. For instance, the American Medical Association advocates for safe harbor legislation, which would protect doctors from being sued for failing to order a test if the doctor has followed established guidelines that indicate a test is unnecessary.<sup>45</sup> Yet, another solution approved this summer by the House Committee on Energy and Commerce requires malpractice attorneys representing patients to get a certificate of merit.<sup>46</sup> This certificate of merit would be issued by a medical

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<sup>42</sup> Stuart L. Weinstein, *The Cost of Defensive Medicine*, AAOS NOW, Nov. 2008, at 1, 3, available at [http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page\\_url=http://www.aaos.org/news/aaosnow/nov08/managing7.asp](http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page_url=http://www.aaos.org/news/aaosnow/nov08/managing7.asp).

<sup>43</sup> Kaiser, *supra* note 26.

<sup>44</sup> Patricia Zengerle, *Update 2 - W. House Sets \$25 Mln for Medical Liability Project*, REUTERS, Sept. 17, 2009, <http://www.reuters.com/article/idUSN1720347020090917>.

<sup>45</sup> Jones, *supra* note 34.

<sup>46</sup> Searcey & Goldstein, *supra* note 33.

professional certifying that procedures in a case failed to meet certain minimum standards.<sup>47</sup> Another solution, supported by the MMS, is the creation of a task force to investigate issues related to the practice of defensive medicine.<sup>48</sup> This task force could investigate the frequency of defensive medicine and the cost of defensive medicine in each state. Any of these solutions would be a step forward to better understanding the effects of defensive medicine on patient quality of care.

#### V. CONCLUSION

President Obama's call to the American Medical Association House of Delegates to acknowledge and address the use of defensive medicine is not only an important call to doctors, but also to lawyers, patients, and Congress. It is clear that each of the groups have a special interest in either accepting or rejecting the prevalence of defensive medicine practice. Congress should bear these biases in mind when considering the different arguments on the true costs of defensive medicine, the frequency in which doctors practice defensive medicine, and the reasons why doctors practice defensive medicine.

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<sup>47</sup> *Id.*

<sup>48</sup> Massachusetts Medical Society, *supra* note 18.

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### *The Effect of Medical Malpractice*

*Jonathan Thomas*<sup>\*</sup>

#### I. INTRODUCTION: WHAT IS MEDICAL MALPRACTICE

“Every year, medical malpractice is a serious problem for thousands of people across the country.”<sup>1</sup> Medical malpractice claims arise when a healthcare professional fails to provide a patient the standard quality of care, thus resulting in an injury or harm to the patient.<sup>2</sup> Medical malpractice can take place in any and every healthcare facility by any type of medical personnel, including internists, surgeons, nurses, and support staff.<sup>3</sup>

As a leading personal injury firm in Chicago, Power Rogers & Smith explains:

When we go to a doctor or a hospital, we hope that we will receive the best possible care at the hands of the medical profession. Unfortunately, that is not always the case. Many people are gravely injured or even die as a result of these mistakes. Healthcare providers, including doctors, chiropractors, dentists, nurses, and hospitals need to be held accountable for the pain and suffering that they create after performing negligence.<sup>4</sup>

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<sup>1</sup> Amy Nutt, *Negative Effects of Medical Malpractice*, EZINE ARTICLES, May 7, 2009, <http://ezinearticles.com/?Negative-Effects-of-Medical-Malpractice&id=2317877>.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> Power Rogers & Smith, *Chicago Medical Malpractice Law*, <http://prslaw.com/whatWeDo/Chicago-Medical-Malpractice-Law/> (last visited Feb. 21, 2010).

Moreover, an article published in the *Journal of the American Medical Association* noted that every year in the United States almost 12,000 patient deaths occur due to unnecessary surgery, 7,000 deaths were caused by medication errors in hospitals, and 20,000 deaths resulted from other errors in hospitals.<sup>5</sup> The *Journal of the American Association for Justice* stated that a decade ago as many as 98,000 people died every year from preventable medical errors, costing the nation an estimated \$29 billion dollars.<sup>6</sup>

Medical malpractice can negatively affect all aspects of an injured patient's life, from physical and emotional damages to serious financial hardships. Results such as loss of work, permanent disability, loss of quality of life, and loss of future wages are a few examples of the possible negative impacts.<sup>7</sup> Furthermore, when death is the result of medical negligence, "the surviving dependents or beneficiaries may be entitled to monetary damages in order to help pay for medical costs and other expenses incurred by the family of the victim."<sup>8</sup>

Medical malpractice is not an easy subject to address, as the impact seems to cover almost all spectrums of the economy. Medical malpractice affects both patients and physicians severely. Thus, it is crucial to examine the effects of medical malpractice claims against physicians. This article aims at examining the impact that medical malpractice claims have on physicians and quality of care.

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<sup>5</sup> Nutt, *supra* note 1.

<sup>6</sup> Am. Ass'n for Justice, Preventable Medical Errors – The Sixth Biggest Killer in America, <http://www.justice.org/cps/rde/xchg/justice/hs.xsl/8677.htm> (last visited Feb. 21, 2010).

<sup>7</sup> Nutt, *supra* note 1.

<sup>8</sup> *Id.*

## II. THE EFFECT OF MEDICAL MALPRACTICE ON PHYSICIANS

The litigious nature of American society is influencing the field of medicine. An overwhelming majority of practicing physicians believe that their concerns regarding medical malpractice liability impair their ability to provide quality care, cause them to order unnecessary tests, and make unnecessary referrals. This belief is shared by many nurses and hospital administrators. Furthermore, a large majority of physicians, nurses, and hospital administrators believe that these extra tests, referrals, and procedures significantly contribute to healthcare costs.<sup>9</sup> There have been numerous studies conducted to examine these beliefs, and the results are striking.

For instance, Harris Interactive for Common Good, a newly formed bipartisan coalition, conducted a nationwide survey in March 2002.<sup>10</sup> This survey included interviews from 300 physicians, 100 hospital-based nurses, and 100 hospital administrators.<sup>11</sup> Overall, the survey revealed that a large number of physicians have a fear of malpractice liability that causes them to provide unnecessary care.<sup>12</sup> Specifically, 79% of physicians said they ordered unnecessary tests, and 74% said they made unnecessary referrals.<sup>13</sup>

Additionally, about 54% of physicians knew other doctors who were reluctant to help an injured person while off-duty because of a fear of liability.<sup>14</sup> Of those 54%, 34% of those physicians knew of a specific situation where a

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<sup>9</sup> See HARRISINTERACTIVE, COMMON GOOD FEAR OF LITIGATION STUDY: THE IMPACT ON MEDICINE 8-9 (2002).

<sup>10</sup> *Id.* at 6.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 8.

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

<sup>14</sup> *Id.* at 18.

doctor did not volunteer to help.<sup>15</sup> Moreover, 76% of physicians reported that their concerns about malpractice litigation hurt their own ability to provide quality patient care.<sup>16</sup> A majority of physicians, hospital administrators, and nurses believe that unnecessary or excessive care was sometimes provided because of the fear of medical liability, and many believe this happened "very often."<sup>17</sup>

Other alarming statistics found from the Harris study include the fact that half of all physicians believe that their ability to provide quality medical care to patients has substantially decreased in the past five years.<sup>18</sup> More than three-fourths of physicians believe that the concern about malpractice has harmed their ability to provide quality care in recent years.<sup>19</sup> Also, nearly one-third of physicians reported that they were selective of specialties based upon a fear of higher legal exposure.<sup>20</sup> Finally, the survey uncovered the belief that the extra tests, referrals, and procedures resulting from the fear of liability contributed in a significant way to healthcare costs.<sup>21</sup>

The statistical information from the Harris Interactive for Common Good study contains an over-arching theme: healthcare providers are fearful of lawsuits being brought against them.<sup>22</sup> Some researchers suggest that the fear of malpractice does not improve medical care; rather, it forces doctors to take a more defensive approach in treating patients by providing unnecessary or excessive

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

<sup>16</sup> *Id.* at 23.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 8.

<sup>19</sup> *Id.*

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

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

<sup>22</sup> *Id.* at 8.

care.<sup>23</sup> Such unnecessary or excessive care given by physicians may include: ordering more tests than necessary; increasing referrals of patients to specialists; suggesting invasive procedures, such as biopsies, to confirm diagnoses more often than what is medically needed; and prescribing more medications, such as antibiotics.<sup>24</sup> Conducting additional tests and taking otherwise unnecessary measures help to establish a solid record of care may be good for defending a malpractice case, but are significant factors in making healthcare more time-consuming and expensive.<sup>25</sup>

Legal action can result in other costs, including mental distress, lost time from work, and a damaged reputation.<sup>26</sup> Medical malpractice lawsuits can impose more than just a financial burden upon physicians. There is significant research showing that coping with a medical malpractice suit can weigh heavily on a physician. No one wishes an ill outcome on a patient,<sup>27</sup> and physicians are especially challenged when there is an unexpected outcome, such as an unanticipated death, followed by a charge of malpractice.<sup>28</sup> In this situation, a physician may feel overwhelmed and out of control.<sup>29</sup> Often physicians take the accusation of malpractice personally,<sup>30</sup> and some are prone to symptoms of

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<sup>23</sup> *Id.*; Am. Bar Ass'n, *What Is Medical Malpractice?*, ABA FAMILY LEGAL GUIDE, 2004, <http://public.findlaw.com/abafg/flg-17-3b-1.html>.

<sup>24</sup> HARRISINTERACTIVE, *supra* note 9, at 19.

<sup>25</sup> Am. Bar Ass'n, *supra* note 23.

<sup>26</sup> CONG. BUDGET OFFICE, MEDICAL MALPRACTICE TORT LIMITS AND HEALTHCARE SPENDING 1 (2006) [hereinafter CBO].

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

<sup>28</sup> Sara C. Charles, *Coping with a Medical Malpractice Suit*, 174 WEST J. MED. 55, 55-58 (2001).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 56.

depression, adjustment disorder, the onset of a physical illness, alcoholism, or drug misuse.<sup>31</sup>

### III. MEDICAL MALPRACTICE INSURANCE PREMIUMS

Nearly all health care providers, such as physicians and hospitals, purchase insurance that covers expenses related to medical malpractice claims including payments to claimants and legal expenses. The most common physician policies provide \$1 million of coverage per incident and \$3 million of coverage per year.<sup>32</sup> Today the primary sellers of physician medical malpractice insurance are the physician-owned and/or operated insurance companies that, according to the Physician Insurers Association of America, insure approximately 60% of all physicians in private practice in the United States.<sup>33</sup>

Medical malpractice insurance premiums have a great impact on a physician's career. With increasing malpractice premiums, physicians may make alterations in their practices.<sup>34</sup> For instance, physicians may relocate because some geographic areas have increased premiums for certain specialties.<sup>35</sup> These areas may see a decrease in that type of specialty in the long run because young physicians are dissuaded from practicing in that market area.<sup>36</sup> For many of these physicians, they do not look at the increase in malpractice insurance as a lack of

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<sup>31</sup> *Id.* at 55.

<sup>32</sup> U.S. GEN. ACCOUNTING OFFICE, MEDICAL MALPRACTICE INSURANCE: MULTIPLE FACTORS HAVE CONTRIBUTED TO INCREASED PREMIUM RATES 6 (2003).

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

<sup>34</sup> FRANK A. SLOAN & LINDSEY M. CHEPKE, MEDICAL MALPRACTICE 56 (2008).

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

income, but instead, identify it as a probability of personal liability.<sup>37</sup>

Former president George W. Bush attributed the high cost of personal health services throughout the United States to extensive litigation and the high cost of medical malpractice insurance.<sup>38</sup> Moreover, a recent study showed that in Florida, and increasingly around the country, many physicians are choosing to retire early or to practice in specific specialties because of the rising cost of medical malpractice insurance.<sup>39</sup> The Executive Summary of the report of the Governor's Select Task Force on Healthcare Professional Liability Insurance from Florida states that "[t]he concern over litigation and the cost and lack of medical malpractice insurance have caused doctors to discontinue high-risk procedures, turn away high-risk patients, close practices, and move out of state. In some communities, doctors have ceased delivering babies and discontinued hospital care."<sup>40</sup> Because of the effect of medical malpractice on physicians, something must be done to find a solution.

#### IV. SOLUTIONS TO MEDICAL MALPRACTICE

There are potential solutions to minimize the effects of medical malpractice lawsuits. The Congressional Budget Office previously considered the effects of limits on tort claims for medical malpractice at the state level.<sup>41</sup> The Congressional Budget Office concluded that limits on claims reduced both malpractice awards and malpractice insurance premiums.<sup>42</sup> The study predicted

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<sup>37</sup> *Id.* at 57.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> CBO, *supra* note 26.

<sup>42</sup> *Id.*

that the lower malpractice premiums would reduce providers' costs.<sup>43</sup> However, the study realized that the analysis was inconsistent and dependent upon the particular relationships and specifications tested.<sup>44</sup>

Recently, there has been debate that some sort of tort reform or cap on medical malpractice damages would decrease overall healthcare costs. In an effort to control the rising costs of medical malpractice insurance, there has been a recent effort to impose limitations on medical malpractice lawsuits.<sup>45</sup> Many states have implemented restrictions on tort claims for medical malpractice, and Congress has considered various proposals to establish nationwide limits similar to those already imposed by many states.<sup>46</sup> The American Medical Association and medical malpractice insurers say that a limit on damages awarded for pain and suffering in medical malpractice lawsuits will benefit doctors, insurers, and patients throughout the country.<sup>47</sup> The belief is that by controlling the costs of these lawsuits, the cost of medical malpractice insurance is likely to decrease both for the physicians and insurance companies.<sup>48</sup> In former President Bush's support of placing caps on lawsuits, he believed that:

If one of the goals of a good healthcare system is for it to be affordable and accessible, and if lawsuits are running up the cost of medicine and/or driving docs out of business because the practicing of medicine is too expensive, we've got to do something about it.<sup>49</sup>

While this may be true, the impact of putting caps on pain and suffering are not seen overnight. The impact of a cap can take years to have an effect on

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

<sup>44</sup> *Id.*

<sup>45</sup> Joseph B. Treaster, *Malpractice Insurance: No Clear or Easy Answers*, N.Y. TIMES, Mar. 5, 2003, at C.

<sup>46</sup> CBO, *supra* note 26.

<sup>47</sup> Treaster, *supra* note 45.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

physicians and patients.<sup>50</sup> Caps can only do so much for the overall impact on medical costs; however, there must also be a drop in medical malpractice premiums.<sup>51</sup>

## V. CONCLUSION

Physicians believe that medical malpractice premiums have increased exponentially during the last decade, which has resulted in a decreased pool of qualified physicians available to consumers seeking quality care. A number of older physicians are feeling forced out of practice as a result of rising medical malpractice premiums. Some physicians find themselves torn between providing their patients with quality care while feeling unable to do so because of exorbitant premiums. Thus, patients are left with fewer and fewer options when seeking out quality medical care. As discussed above, in some areas, patients are left with no convenient options. In addition, physicians are faced with the belief that they must stop providing certain services to patients. Even when physicians do provide patients with services, many times they provide additional unnecessary tests because of their fear of litigation.

It is clear that the practice of medicine and delivery of medical care by all healthcare providers is significantly influenced by the fear of malpractice claims.<sup>52</sup> Physicians believe that with the adverse consequences, including financial liability and the fear of litigation, there is a need for change in order to allow for better, more efficient healthcare in the future. If no changes are made,

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<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> HARRISINTERACTIVE, *supra* note 9, at 11.

physicians will continue to leave the practice of medicine and leave certain areas of this country underrepresented by certain medical specialties.

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***Using Medical Liability Tort Reform to  
Improve Patient Care***

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I. THE NEED FOR MEDICAL LIABILITY REFORM

Since the health care reform has passed, patient safety and access to care will continue to have issues affecting many people.<sup>1</sup> Patients are forced to wait longer and travel farther to see a doctor as physicians change their practice patterns due to the lack of affordable and available medical liability insurance.<sup>2</sup> Doctors have responded to rising liability insurance rates by giving up high-risk practices, limiting their practice to minimal litigation risk areas, or moving to states that enforces caps on liability.<sup>3</sup> Patients, in turn, are experiencing greater difficulties in seeing specialists.<sup>4</sup>

This article argues that states should continue to cap malpractice damage awards as a way of improving quality of care by managing the rising cost of

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<sup>1</sup> Stuart L. Weinstein, *Medical Liability Reform Crisis 2008*, 467 CLINICAL RISK & JUD. REASONING 392, 392 (2009).

<sup>2</sup> *Id.*

<sup>3</sup> U.S. Dep't of Health & Human Servs., *Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs By Fixing Our Medical Liability System 1*, (2002), <http://aspe.hh.gov/daltcp/reports/litrefm.pdf> [hereinafter CONFRONTING THE HEALTH CARE CRISIS].

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

health care. Part II discusses how our malpractice system decreases patient care when doctors practice defensive medicine. Furthermore, Part II encourages states to enact damages caps, which have demonstrably reduced the number of doctors practicing defensive medicine. Part III describes how the threat of litigation undermines efforts to improve care arguing that capping lower liability rates will assist hospitals and practice groups to divert funds to improve health care services. Finally, Part IV discusses how caps have improved access and quality of care, and how caps have ensured that each stakeholder of the healthcare system, including hospitals, physicians, nurses, and insurers, remain focused on improving patient care. Although caps are not a permanent solution, implementing caps is the best solution available under our current medical liability paradigm.

## II. THE VOLATILE MALPRACTICE ENVIRONMENT ENCOURAGES PHYSICIANS TO PRACTICE DEFENSIVE MEDICINE

Unlike other forms of insurance, such as automobile insurance, a physician's past performance does not affect how much medical liability insurance a private physician must acquire.<sup>5</sup> Generally, insurance companies charge premiums based on a physician's specialty and do not take into account the competence, skill, and quality of services provided by the physician.<sup>6</sup> To improve health care by compensating the injured, the fear of litigation has induced physicians to practice "defensive medicine." Defensive medicine is a

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<sup>5</sup> Lee Harris, *Tort Reform as Carrot-and-Stick*, 46 HARV. J. ON LEGIS. 163, 178 (2009) ("Bad doctors are not penalized by insurance companies, which do not normally take into account previous performance when assessing medical malpractice insurance rates.").

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

deviation from sound medical practice because doctors “alter their clinical behavior [due to] the threat of malpractice liability.”<sup>7</sup>

Defensive medicine creates important implications for the cost, access, and quality of care for patients.<sup>8</sup> When doctors practice defensive medicine, they provide substandard care to their patients.<sup>9</sup> Instead of focusing on the care the patient needs, physicians will provide care they think will help them avoid frivolous lawsuits.<sup>10</sup> Practice areas where defensive medicine is particularly prevalent include: emergency medicine, obstetrics/gynecology, neurosurgery, general surgery, orthopedic surgery, and radiology.<sup>11</sup>

One type of defensive behavior in which physicians engage in is known as “assurance behavior,” which is when a physician refers a patient to a specialist to show that the legal standard of care has been met.<sup>12</sup> Another type of assurance behavior is where a doctor supplements patient care with additional testing or treatments with little or no marginal health care value.<sup>13</sup> Doctors will also order unnecessary procedures to bolster their own confidence or create a trail of evidence that showed they had either confirmed or excluded certain diseases.<sup>14</sup> Each unnecessary test and treatment creates a potential risk to the patient, which

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<sup>7</sup> David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 J. AM. MED. ASS'N 2609, 2609 (2005) (discussing how physicians practice “defensive medicine,” which is induced by the threat of liability).

<sup>8</sup> *Id.* at 2610 (“during a more volatile period in liability insurance markets, physicians’ uncertainty about the costs and availability of coverage may induce a wider array of defensive practices, affecting not only the cost of health care, but also its accessibility and quality”).

<sup>9</sup> See Michelle M. Mello et al., *Caring for Patients in a Malpractice Crisis: Physician Satisfaction and Quality of Care*, 23 HEALTH AFFS. 41, 51 (2004) (discussing how physicians’ defensive behavior may result in the form of lower quality and availability of health services).

<sup>10</sup> CONFRONTING THE HEALTH CARE CRISIS, *supra* note 3, at 4.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 2609.

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

<sup>14</sup> *Id.* at 2616.

jeopardizes the patient's safety.<sup>15</sup> In addition, false-positive results associated with low-yield diagnostic testing occur more often with additional tests.<sup>16</sup> When ambiguous test results occur, the quality of care is compromised because patients undergo emotional distress when subjected to additional invasive or hazardous procedures.<sup>17</sup>

Ever increasing malpractice insurance premiums also induce physicians to practice avoidance behavior.<sup>18</sup> Physicians have attempted to limit the risk of litigation by reducing care, such as refusing to treat patients with complicated health conditions or eliminating high-risk procedures.<sup>19</sup> Physicians with high premiums avoid high-risk procedures, move to states with damage award caps, and either retire early or stop practicing medicine altogether.<sup>20</sup> All these circumstances negatively affect patient treatment because patients are required to travel farther and wait longer to be seen by a specialist.<sup>21</sup> When doctors leave a clinical practice or relocate, they disrupt the continuity of care of their patients and compromise access to health services in underserved regions.<sup>22</sup>

Studies have shown that states that have implemented damage caps have helped reduce the frequency and severity of malpractice claims, premiums, and

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<sup>15</sup> Michael Rowe, *Medical Malpractice: What Remedy?*, 262 OECD OBSERVER 17, 18 J (2007), (calling more tests, prescribing more drugs, and sending patients to specialists are costly measures with little benefit and involve risks for patients); *see also* Studdert et al., *supra* note 7, at 2612 (prescribing more medications and suggesting invasive procedures that were unwarranted in their professional judgment).

<sup>16</sup> *See* Studdert et al., *supra* note 7, at 2616.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 2609.

<sup>19</sup> *Id.* at 2609, 2613.

<sup>20</sup> Mello et al., *supra* note 9, at 43-44 (discussing how physicians react to rising liability rates and practice defensive medicine).

<sup>21</sup> Donald J. Palmisano, *Health Care in Crisis: The Need for Medical Liability Reform*, 5 YALE J. HEALTH POL'Y L. & ETHICS 370, 375, 382 (2005) (discussing indirect effects on patients).

<sup>22</sup> *See* Mello et al., *supra* note 18, at 43-44.

health care expenditures because physicians engage in less defensive medicine.<sup>23</sup>

Physicians practicing in states with caps have lower perceptions of malpractice risks compared to physicians practicing in states without caps.<sup>24</sup> Damage caps help insurance carriers lower their premiums<sup>25</sup> and, as a result, more doctors can afford liability insurance.<sup>26</sup> Not only does this increase the supply of health care by increasing the number of physicians in a geographical area, but when doctors can pay their premiums, they are less likely to practice defensive medicine.<sup>27</sup>

Indeed, studies show that caps are responsible for a small but statistically significant increase in the supply of physicians.<sup>28</sup> The number of physicians in rural counties is about three percent higher in a state with caps versus states without caps.<sup>29</sup> As a result, states that enact caps can improve the quality and access to care for patients.

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<sup>23</sup> Fred J. Hellinger, *The Impact of State Laws Limiting Malpractice Damage Awards on Health Care Expenditures*, 96 AM. J. PUB. HEALTH 1375, 1375 (2006) (discussing how tort reform directly limit payments, reduce the frequency, and severity of malpractice claims).

<sup>24</sup> See John F. Dick III et al., *Predictors of Radiologists' Perceived Risk of Malpractice Lawsuits in Breast Imaging*, 192 AM. J. ROGENTOLOGY 327, 332 (2009) (radiologists from Colorado might have lower perceptions of malpractice risk compared to other U.S. radiologists because Colorado has malpractice caps).

<sup>25</sup> Hellinger, *supra* note 21, at 1377 (states with malpractice payment caps had premiums that were 17.1 % lower than states without caps).

<sup>26</sup> Weinstein, *supra* note 1, at 396 ("caps have been proven to keep premiums down").

<sup>27</sup> See Studdert et al., *supra* note 7, at 2616 (finding that physicians practiced defensive medicine to qualify for less expensive medical insurance).

<sup>28</sup> Michelle M. Mello, *Medical Malpractice: Impact of the Crisis and Effect of State Tort Reforms*, 11 (2006) (concluding that "caps are associated with a small increase in physician supply").

<sup>29</sup> Carol K. Kane et al., *The Impact of Liability Pressure and Caps on Damages on the HealthCare Market: An Update of Recent Literature*, POLICY RES. PERSP. 1, 3 (2007) (describing the positive impact of caps).

III. MALPRACTICE LITIGATION IMPAIRS THE ABILITY TO  
IMPROVE PATIENT CARE

Not only do rising liability premiums and the inability to obtain coverage influence the location of practice and what practice areas physician choose,<sup>30</sup> but they also affect the amount of time a physician can spend treating a patient.<sup>31</sup> Improving patient care requires preventing medical errors, but the fear of litigation discourages doctors and hospital staff from discussing their mistakes.<sup>32</sup> Physicians do not want their medical authority undermined; and as a result, they refrain from getting involved with another doctor's patient, even at the expense of increasing the risk of medical error.<sup>33</sup>

Fear of litigation has negatively affected the quality of care that physicians provide their patients and is detrimental to the patient-physician relationship as well.<sup>34</sup> First, fear of litigation incentivizes physicians to waste valuable and scarce hospital resources.<sup>35</sup> For example, obstetrics and breast cancer detection are high-liability fields where the quality of care is diminished when specialists order costly and wasteful imaging studies.<sup>36</sup> Second, physicians cannot provide the best quality of care and services to their patients when malpractice concerns

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<sup>30</sup> See Kesser et al., *Impact of Malpractice Reforms on the Supply of Physician Services*, 293 J. AM. MED. ASS'N at 2618, 2618 (2005) (malpractice climate influences what specialty a physician enters into and the location).

<sup>31</sup> See Mello et al., *supra* note 9, at 50.

<sup>32</sup> See CONFRONTING THE HEALTH CARE CRISIS, *supra* note 3, at 6.

<sup>33</sup> Jonathan Todres, *Toward Healing and Restoration for All: Reframing Medical Malpractice Reform*, 39 CONN. L. REV. 668, 691 (2006) (discussing doctors' reluctance to admit and talk openly about mistakes).

<sup>34</sup> Mello et al., *supra* note 9, at 48.

<sup>35</sup> See e.g., Studdert et al., *supra* note 7, at 2613 (high-risk specialists reported performing extensive tests and ordering unnecessary tests).

<sup>36</sup> *Id.* at 2617.

preclude them from having an open and truthful patient-physician relationship.<sup>37</sup>

Because a physician views each patient as a potential lawsuit, the physician prescribes the care that he or she thinks will meet the legal standard rather than discussing the different treatment options with the patient.<sup>38</sup>

Not only does excessive litigation impede the efforts to improve care, but also forces everyone to pay higher premiums as well as increases out-of-pocket expenses.<sup>39</sup> Many practices and hospitals have taken steps, such as creating “volume” practices, to reduce overhead costs associated with liability insurance.<sup>40</sup> Practices and hospitals have reduced their clinical and administrative staff to help pay for liability insurance premiums.<sup>41</sup> Simply stated, to generate revenue doctors must either increase their fees or treat more patients. Many times, however, Medicare, Medicaid, and other managed healthcare plans prevent doctors from raising their fees.<sup>42</sup> As a result, doctors are forced to treat more patients to generate enough revenue.<sup>43</sup> Physicians who have full patient loads have a difficulty treating additional patients without compromising patient care.<sup>44</sup>

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<sup>37</sup> See Mello et al., *supra* note 18, at 48-49 (liability pressures affect the quality of care by impinging upon the physician-patient relationship).

<sup>38</sup> *Id.* at 44 (the physician-patient relationship suffers because the physician does not trust the patient and does not speak freely due to the fear of malpractice); see also Studdert et al., *supra* note 7, at 2609.

<sup>39</sup> David A. Hyman et al., *Speak Not of Error*, HEALTH & MED. 52, 54 (2005) (discussing how the tort system does not adequately compensate patients, increases costs and error rate).

<sup>40</sup> See Mello et al., *supra* note 18, at 50.

<sup>41</sup> *Id.* at 50-51.

<sup>42</sup> James A. Comodeca et al., *Killing the Golden Goose By Evaluating Medical Care Through the Retroscope: Tort Reform From the Defense Perspective*, 31 U. DAYTON L. REV. 207, 220 (2006).

<sup>43</sup> Mello et al., *supra* note 18, at 50 (discussing how liability pressures affect the quality of care by impinging upon the physician-patient relationship).

<sup>44</sup> *Id.* (“The first victim is going to be quality of care, in terms of how many patients you seen an hour, the amount of time you give them.”).

Finally, practices and hospitals must sacrifice improving patient safety and modernizing treatment facilities to pay high liability costs.<sup>45</sup>

Indeed, health services have been reduced in response to the rising medical malpractice costs. Even trauma centers are not immune from the downward spiral of quality of care caused by the threat of litigation and increased malpractice insurance premiums.<sup>46</sup> In 2003, two neurosurgeons from Joliet, Illinois were forced to stop practicing brain surgery.<sup>47</sup> As a result, the only two hospitals in Joliet could no longer treat head trauma cases.<sup>48</sup> The hospitals were forced, therefore, to stabilize and transport their patients with serious head injuries to the nearest trauma center, which was forty-five minutes away.<sup>49</sup> Forcing a patient with serious head injuries to wait forty-five minutes to receive medical treatment is not only unreasonable, but clearly shows that tort reform is necessary. Our current malpractice system creates barriers that not only limits a patient's access, but also diminishes the quality of care.<sup>50</sup>

High malpractice costs have forced free clinics to shut down; thus, leaving many Americans vulnerable without access to quality care.<sup>51</sup> Because many doctors cannot afford their high liability insurance, they are unable to volunteer their time in free clinics.<sup>52</sup> Clinics are forced to spend the little funding they have to obtain malpractice insurance and, thus, less money is left to provide services

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<sup>45</sup> *Id.* at 51

<sup>46</sup> Comodeca et al., *supra* note 40, at 220-21 (almost half of the American hospitals have reported reduced coverage in their emergency department).

<sup>47</sup> *Id.* at 221.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> See CONFRONTING THE HEALTH CARE CRISIS, *supra* note 3, at 2.

<sup>51</sup> *Id.* at 4.

<sup>52</sup> *Id.*

for low-income patients.<sup>53</sup> Free clinics have a difficult time providing health care services due to the lack of volunteer physicians.<sup>54</sup>

Hospitals, doctors, and nurses are reluctant to report errors and problems and to participate in joint efforts to improve patient care.<sup>55</sup> Our adversarial legal system discourages open and honest communications because doctors fear that any admission of fault will be used against them in court.<sup>56</sup> To reduce litigation, physicians must be assured that any admissions of error will not be used against them and thus, future mistakes can be prevented.<sup>57</sup> Unless our healthcare paradigm provides doctors protection from liability, mistakes will continue to occur and injure patients.

#### IV. DAMAGE CAPS ARE THE MOST EFFECTIVE TORT REFORM AVAILABLE

In comparison to other tort reform measures, legislation that limits damage awards has proven to be effective in controlling liability costs, reducing medical costs to consumers, and increasing access to health care.<sup>58</sup> Statute of limitations is a law that “establish[es] a time limit for [a plaintiff to sue] in a [medical-malpractice] case, based on the date when the [plaintiff’s] claimed accrued (as when the injury occurred or was discovered).”<sup>59</sup> Many states have shortened their statute of limitations to encourage plaintiffs to take prompt legal action and

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<sup>53</sup> *Id.*

<sup>54</sup> *See id.*

<sup>55</sup> *Id.* at 1.

<sup>56</sup> Bryan A. Liang et al., *Medical Liability Insurance and Damage Caps: Getting Beyond Band Aids to Substantive Systems Treatment to Improve Quality and Safety in Healthcare*, 30 AM. J.L. & MED. 501, 503 (2004) (discussing how reducing medical errors will reduce medical malpractice).

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

<sup>58</sup> *See id.* at 502.

<sup>59</sup> BLACK’S LAW DICTIONARY 1450-51 (8<sup>th</sup> ed. 1999).

discourage frivolous lawsuits; however, this measure fails to improve patient compensation.<sup>60</sup> In fact, statute of limitations does not ensure that only meritorious cases proceed and the tolling period varies from state to state.<sup>61</sup> Limiting contingency fees may reduce the number of frivolous lawsuits; but this remedy does not efficiently compensate the injured patient, does not facilitate harm reduction, and does not address the emotional needs of the patient.<sup>62</sup>

Alternative dispute resolution (ADR) is another remedy used to permit parties to “control” how they want to resolve the malpractice conflict by allowing parties to select the arbitrator as well as reduce the trauma of litigation, reduce costs, and provide an efficient resolution.<sup>63</sup> Nevertheless, ADR presents a less restrictive forum compared to the traditional legal system.<sup>64</sup> Furthermore, ADR alleviates the procedural restraints and procedural rules that would be enforced in court.<sup>65</sup> Critics of ADR question whether patients really fully understand all the terms of the mandatory arbitration contract.<sup>66</sup> Similar to ADR, mediation is a more informal environment for parties to resolve their dispute; however, the threat of litigation exists if a resolution cannot be reached.<sup>67</sup>

Although damage caps are not a permanent solution, this type of reform has proven to be effective and is the best solution available under our current

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<sup>60</sup> Todres, *supra* note 33, at 695.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 696.

<sup>63</sup> *Id.* at 697.

<sup>64</sup> *Id.*

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

<sup>66</sup> *Id.* at 699.

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

healthcare system.<sup>68</sup> To help alleviate costs for practice groups, hospitals and clinics, states should further implement damage caps. Studies show that states with caps have per capita health expenditure costs three percent lower than states without caps.<sup>69</sup> States without caps should enact laws to cap the total damage awarded or limit the noneconomic component to deter frivolous lawsuits, but still permits meritorious claims to proceed.<sup>70</sup> Consequently, insurance companies would be able to lower their liability rates because caps make it possible for insurers to more accurately predict exposure to malpractice damages.<sup>71</sup> In some states, damage caps have helped insurance companies to reduce their rates and, thus, allowing physicians to continue to practice and provide continuous care to patients in that particular state.<sup>72</sup>

## V. CONCLUSION

Legislation that limits damage awards has proven to be effective in controlling liability costs, reducing medical costs to consumers, and increasing access to health care for individuals.<sup>73</sup> Research studies show that these laws have a successful track record to help lower losses or indemnity amounts, lower premiums, and increase the supply of physicians.<sup>74</sup> As such, states should implement damage caps to help improve the quality of care and medical services

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<sup>68</sup> Liang et al., *supra* note 56, at 502.

<sup>69</sup> Hellinger, *supra* note 23, at 1379.

<sup>70</sup> See Troyen A. Brennan et al., *Medical Malpractice*, 350 NEW ENG. J. MED. 283, 288 (2004) (discussing how caps on damages make the most lucrative lawsuits worth less, indirectly limit the contingency fee, and ensure that fewer cases hold the promise of a favorable return on investment for a plaintiff's attorney).

<sup>71</sup> *See id.*

<sup>72</sup> Liang et al., *supra* note 56, at 502.

<sup>73</sup> Hellinger, *supra* note 23, at 1375.

<sup>74</sup> *Id.*; see also MELLO, *supra* note 28, at 11.

to its citizens. Although damage caps are not the perfect solution, this is a tort reform that has proven to be effective to helping several states reduce their health care costs and stabilize access to care by providing incentives for physicians to continue practicing within the state.<sup>75</sup>

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<sup>75</sup> Liang et al., *supra* note 56, at 502.