

## Written Statement of Katharine Van Tassel

Chairman Castro and other esteemed members of the Commission, thank you for inviting me to submit this written statement on the very important issue of the effectiveness of the Emergency Medical Treatment and Labor Act in preventing the practice of "patient dumping." Patient dumping refers to the situation where hospitals, states and/or localities prematurely discharge or transfer certain patients in need of emergency care, typically uninsured, mentally disabled, and minority individuals.

My name is Katharine Van Tassel. I am a Professor of Law at the University of Akron School of Law where I am also the Director of the Public Health Law & Science Center and the Health Law Program. One of my main areas of research involves the legal standards that are used to measure healthcare quality, cost, and equal access. My Statement is directed to two of the four topics that the Commission has asked the panel of academics to speak upon: (1) "what policies are in place to detect potential violations of the law"; and, (2) "whether hospital policies governed by the Act should be revised to ensure the protection of patient's rights."<sup>1</sup> For your convenience, this Statement starts with an overview of its basic points in a two-page question and answer format.

### I. STATEMENT SUMMARY - Questions and Answers

**A. *Why is EMTALA ineffective in stopping patient dumping?*** The effectiveness of EMTALA is seriously undermined by its reliance on custom-based treatment choices in its measurement of equal access to emergency care. The customary-care model of medical practice can create serious inequalities in emergency treatment, facilitates the overuse of summary judgment to dismiss EMTALA cases, and can allow room for bias and stereotypes in emergency treatment choices.

1. ***What is custom-based care?*** As a general matter, "customary care" is the type of care that is typically given by other healthcare providers under comparable circumstances. Customary care is subjective and is based on the predilections of particular physicians based upon tradition, opinion, personal clinical experience (or other rules of thumb) and not on objective, scientific evidence.

2. ***What is evidence-based care?*** The evidence-based model of medical practice is grounded in empirical data generated by clinical outcomes and effectiveness research which suggests the optimum treatment for a rapidly growing number of clinical conditions. This empirical data is used to create clinical practice guidelines (CPGs) which reflect the well-considered opinions of expert panels, based upon reviews of the best available data, as to how healthcare providers should approach certain clinical problems. Written protocols and checklists are then based on CPGs.

**B. *What are the problems associated with custom-based care?*** The customary-care model of medical practice can have a negative impact on healthcare quality, cost, and equal access—

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<sup>1</sup> Press Release, U.S. Commission on Civil Rights Announces Briefing on Patient Dumping by Hospitals: Enforcement of the Emergency Medical Treatment Act (January 28, 2014), [http://www.usccr.gov/press/2014/Patient-Dumping-Briefing\\_PR.pdf](http://www.usccr.gov/press/2014/Patient-Dumping-Briefing_PR.pdf).

including unequal treatment in the form of misuse, underuse and overuse—all of which can cause actual harm with no counterbalancing benefit.

**C. *What are the solutions to the problems caused by custom-based care?*** The problems with custom-based care have led to a new, national push to move the United States to a modern, evidence-based model of medical practice through major changes in government-provided healthcare, including the numerous, multi-billion dollar programs created by the Affordable Care Act, as well as changes in the VA Hospital System and Medicare.

**D. *What are the roadblocks to the adoption of evidence-based care?*** The three major, national systems for improving healthcare quality that have long-existed in the United States—the state medical malpractice system, the state licensure system, and the private hospital peer review system—appear to be undermining the federal efforts to encourage the adoption of evidence-based medical practice by adhering to the use of customary care as the exclusive proxy for quality of care. Thus, these systems are acting instrumentally to encourage the perpetuation of custom-based practices.

**E. *How does custom-based care undermine EMTALA enforcement?*** EMTALA contributes to the roadblock to the transition toward evidence-based medical practice by requiring that physicians use the same emergency care that they use for patients with similar symptoms. The same care is likely to be based upon the customary-care model of medical practice as this is the normative form of medical practice in the United States. EMTALA is seriously undermined by its reliance on customary-care treatment choices when measuring equal access. The customary-care model of medical practice can create serious inequalities in treatment, allow room for bias and stereotypes in treatment choices, and create an overuse of summary judgment to dismiss EMTALA cases.

**F. *How can EMTALA be modified to increase its effectiveness?*** EMTALA should be modified to harmonize with other federal systems in place to improve quality, cost, and equal access through the requirement of written protocols for emergency department care. At the same time, CMS regulations should be modified to require that these written protocols be based on evidence-based standards, called clinical practice guidelines (CPGs). These simple steps will allow CMS and EMTALA to work in tandem to significantly improve EMTALA's effectiveness by making violations more easily ascertainable, encouraging hospitals to self-regulate, and substantially improving the quality of, and equal access to, emergency care for all individuals. Adoption of a systems reform approach moves disparity reduction efforts from the sole domain of EMTALA and the civil rights arena and into an alternative, but co-existing and complimentary, world of healthcare quality regulation. A major benefit of this solution is the ability to use actual data to both continuously track, and create interventions to resolve, actual disparities in emergency care suffered by those with disabilities and the uninsured.

**G. *How is this suggested solution forward thinking?*** The simple changes this Statement proposes will remove the current barriers to important innovations in the delivery of healthcare based on the growing scientific understanding of how genetics, epigenetics, and the microbiome contribute to chronic disease. Of note, in the near future, **equal** care will mean **different care** for each individual based on each individual's unique genetic, epigenetic, and microbiome profile.

## II. INTRODUCTION

The Emergency Medical Treatment and Active Labor Act (EMTALA) is a federal statute designed to ensure equal access to emergency treatment and to halt the practice of "patient dumping." Patient dumping is a situation where some patients— typically uninsured, disabled, and minority individuals—receive inferior medical care or are denied treatment altogether. EMTALA requires hospitals to medically screen every person who comes to the emergency room requesting medical treatment to assess whether that person suffers from an emergency medical condition.<sup>2</sup> If an emergency medical condition is found, the hospital must treat and stabilize that person.<sup>3</sup> The courts have interpreted EMTALA to apply a standard of equality that is met if a hospital provides the same screening and stabilization that would have been performed for other patients with similar symptoms at that particular hospital.<sup>4</sup>

Unfortunately, the practice of patient dumping appears to be continuing.<sup>5</sup> The most recent case in the news is the haunting story of a psychiatric hospital in Las Vegas that purportedly discharged patients too early and bussed them out of state.<sup>6</sup> Starting in 2008, the facility allegedly bused nearly 1,500 patients out of state over several years. According to one major class action lawsuit filed in 2013, patients apparently were given a small amount of food and

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<sup>2</sup> Jeffrey C. Moffat, *THE EMTALA ANSWER BOOK*, 2014 EDITION, xiii (2014).

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

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

<sup>5</sup> Sara Rosenbaum et al., *Case Studies at Denver Health: 'Patient Dumping' in the Emergency Department Despite EMTALA, The Law That Banned It*, 31 *HEALTH AFFAIRS* 1749 (2012) (reporting on five case studies and concluding that inappropriate discharges and transfers are continuing). *See also*, Nathan S. Richards, *Judicial Resolution of EMTALA Screening Claims at Summary Judgment*, 87 *N.Y.U. L. Rev.* 591, 592-93 (2012), *citing*, for example, Heather Rosen et al., *Downwardly Mobile: The Accidental Cost of Being Uninsured*, 144 *ARCHIVES SURGERY* 1006, 1006, 1010 (2009) (summarizing academic literature showing that "[u]ninsured patients currently face health-related disparities in screening, hospital admission, treatment, and outcomes," and conducting a study finding that, "even after admission to a hospital, trauma patients can have worse outcomes based on insurance status"); Anbesaw Wolde Selassie et al., *The Influence of Insurance, Race, and Gender on Emergency Department Disposition*, 10 *ACAD. EMERGENCY MED.* 1260, 1266 (2003) (performing multivariate logistic regression on emergency-department data and finding that, "after controlling for a patient's clinical condition ... , patients who were uninsured were consistently less likely to be admitted, regardless of the severity of the injury"); U.S. GOV'T ACCOUNTABILITY OFFICE, *EMERGENCY CARE: EMTALA IMPLEMENTATION AND ENFORCEMENT ISSUES* 3(2001)("Violations of EMTALA continue to occur, underscoring the need for effective education and enforcement."); Michael J. Frank, *Tailoring EMTALA To Better Protect the Indigent: The Supreme Court Precludes One Method of Salvaging a Statute Gone Awry*, 3 *DEPAUL J. HEALTH CARE L.* 195, 198 (2000) ("[P]atient dumping continues."); Lawrence Bluestone, Note, *Straddling the Line of Medical Malpractice: Why There Should Be a Private Cause of Action Against Physicians via EMTALA*, 28 *CARDOZO L. REV.* 2829, 2839 (2007) ("Patient dumping continues to happen in busy hospital emergency rooms, with dramatic and unsavory results to patients, normally minorities and normally poor.")

<sup>6</sup> American Civil Liberties Union of Nevada, *ACLU of Nevada Challenges 'Patient Dumping' by Rawson-Neal Psychiatric Hospital in Las Vegas*, available at <http://www.aclunv.org/news/aclu-nevada-challenges-patient-dumping-rawson-neal-vegas> (June 12, 2013) ("Over the last four years, Rawson-Neal Psychiatric Hospital in Law Vegas bused 1500 patients out of state to cities where the patient had no family, no friends or contacts, leaving the patient without arrangements for housing, hospitalization or follow-up care. Agencies investigating the violation of required discharge practices have deplored the patient dumping. The lawsuit, *Brown v. Rawson Neal*, was filed on June 11, 2013").

medication and told to dial 911 or find a shelter upon their arrival in their new city. According to this lawsuit, hospital officials did not reach out to make arrangements for patient care prior to putting these patients on buses bound for new locations.

This practice of patient dumping is of great concern to all patients, but particularly for those in our society who are the most vulnerable—children, many elders, and the disabled—as many of these individuals do not have the ability to engage in self-protection. The number of elders with mental disabilities will be growing as our population ages and our elders increasingly suffer from dementia and Alzheimer's,<sup>7</sup> among many other mental health conditions.

One of the root causes for the continued problem of patient dumping is likely to be how the courts have interpreted the vague standard that is being used under EMTALA to measure equal treatment. EMTALA requires that physicians use the same care that they use for patients with similar symptoms. The same care is likely to be based upon the customary-care model of medical practice as this is the normative form of medical practice in the United States. The customary care, or eminence-based, model of medical practice is based on physician preference and not on objective, scientific evidence. A wealth of empirical studies, described herein, detail the problems with, and negative impact of, the customary-care model of medical practice on healthcare quality, cost, and equal access—including unequal use, misuse, underuse, and overuse—all of which can cause actual harm.

The quality and cost problems with the customary-care model have led to a new, national push to move the United States to a modern, evidence-based model of medical practice through major changes in government provided healthcare, including the VA Hospital System, Medicare and numerous, multi-billion dollar programs created by the Patient Protection and Affordable Care Act of 2010 (ACA), also known as Obama Care. The evidence-based model of medical practice is grounded in empirical data generated by clinical outcomes and effectiveness research which suggests the optimum treatment for a rapidly growing number of clinical conditions. This use of empirical data generated through scientific methodology to make medical decisions shows great promise for enhancing quality of care while decreasing the cost of care.<sup>8</sup>

Unfortunately, the effectiveness of EMTALA is seriously undermined by its reliance on customary care treatment choices when measuring equal access. The customary-care model of medical practice can create serious inequalities in treatment, allow room for bias and stereotypes in treatment choices, and create an overuse of summary judgment to dismiss EMTALA cases.

The solution that this Statement recommends is focused on the adoption of systems reform, which moves disparity reduction efforts from the sole domain of EMTALA and the civil rights arena and into an alternative, but co-existing and complimentary, world of healthcare quality regulation. This solution calls for the implementation of written protocols and check lists for emergency-department care based on evidence-based standards, called clinical practice

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<sup>7</sup> James T. O'Reilly & Katharine Van Tassel, LITIGATING THE NURSING HOME CASE, 130(2014) ("Currently, approximately 5.3 million Americans of all ages have Alzheimer's disease. In 2030 approximately 7.7 million people will have Alzheimer's disease, and the number will increase to 16 million in 2050").

<sup>8</sup> Katharine Van Tassel, *Harmonizing the Affordable Care Act with the Three Main National Systems for Healthcare Quality Improvement: The Tort, Licensure, and Hospital Peer Review Hearing Systems*, 78 BROOKLYN L. REV. 883, 884 (2013) [hereinafter *Harmonizing the Affordable Care Act*].

guidelines (CPGs). This change can be made through just a few simple modifications to EMTALA and CMS regulations that will allow these two systems to work in tandem according to their different areas of expertise. This solution will harmonize EMTALA with the other federal systems that are working to move the US to an evidence-based model of medical care.

Written protocols can significantly improve EMTALA's effectiveness by making violations more easily ascertainable, decreasing the costs of litigation and encouraging hospitals to self-regulate. They also allow for more certainty in the steps that hospitals can take to limit potential liability under EMTALA. This Statement explains how these simple, but powerful, changes also avoid the creation of a federal malpractice cause of action by EMTALA. Finally, a major benefit of this systems reform solution is the use of actual data to both continuously track, and create interventions to resolve, actual disparities in emergency care.

Importantly, these simple changes will remove the current barriers to the adoption of significant innovations in the delivery of healthcare based on the growing scientific understanding of how genetics, epigenetics, and the microbiome contribute to chronic disease.

## II. FRAMING THE PROBLEM

### A. What is Custom-Based Care?<sup>9</sup>

As a general matter, “customary care” is the type of care that is typically given by other health care providers under comparable circumstances. Customary care is subjective and is based on the predilections of particular physicians based upon tradition, opinion, personal clinical experience (or other rules of thumb) and not on objective, scientific evidence.<sup>10</sup> The practice of providing customary care, also referred to by many as “eminence-based medicine,” is the normative practice in the United States.<sup>11</sup>

In contrast, the practice of modern medicine involves the use of evidence-based care. The evidence-based model of medical practice is centered on empirical data created by comparative effectiveness research and outcomes analysis. As this body of research grows, evidence-based treatment guidelines, called clinical practice guidelines (CPGs), are being developed using this empirical data. These CPGs can be used to recommend optimal treatments for a steadily increasing number of clinical disorders, including those relating to mental health conditions. CPGs reflect the “well considered opinions of expert panels, based upon reviews of the best

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<sup>9</sup> The material contained in this section is mainly excerpted from Katharine Van Tassel, *Using Clinical Practice Guidelines and Knowledge Translation Theory to Cure the Negative Impact of the National Hospital Peer Review Hearing System on Healthcare Quality, Cost, and Access*, 40 PEPPERDINE L. REV. 911, 937–38 (2013) [hereinafter *Using Clinical Practice Guidelines*] and *Harmonizing the Affordable Care Act*, *supra* note 8.

<sup>10</sup> See IOWA CONSORTIUM FOR SUBSTANCE ABUSE RESEARCH & EVALUATION, EVIDENCE-BASED PRACTICES: AN IMPLEMENTATION GUIDE FOR COMMUNITY-BASED SUBSTANCE ABUSE TREATMENT AGENCIES 3 (2003), available at <http://www.uiowa.edu/~iowapic/files/EBP%20Guide%20-%20Revised%205-03.pdf> (The Iowa Consortium for Substance Abuse Research and Evaluation is based at the University of Iowa).

<sup>11</sup> *Using Clinical Practice Guidelines*, *supra* note 9, at 938.

available data, as to how [health care providers] should approach certain clinical problems.”<sup>12</sup> This use of empirical data generated through scientific methodology to make medical decisions shows great promise for enhancing quality and equal access to care while decreasing the cost of care.

In other words, custom is what practitioners *do*, empirical evidence is evidence of what a practitioner *ought to be doing*.

### **B. What are the Problems Associated with Custom-Based Care?<sup>13</sup>**

Unfortunately, a steadily growing group of studies demonstrate that many customary treatment choices can have a negative impact on healthcare quality, equal access, and cost.<sup>14</sup> These problems with the customary care model of medical practice have, over time, become well documented by the Dartmouth Atlas Project.<sup>15</sup> Research conducted under the auspices of the Dartmouth Atlas Project<sup>16</sup> “uses very large claims databases from the Medicare program and other sources to define where Americans seek care, what kind of care they receive, and to determine whether increasing investments in health care resources and their use result in better health outcomes for Americans.”<sup>17</sup> In a special report issued by the Dartmouth Atlas Project, three different categories of customary care practices were identified that can have a significant, negative impact on healthcare quality, equal access, and cost: failure to provide necessary care, preference-sensitive care, and supply-sensitive care.<sup>18</sup> This Statement refers to these categories

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<sup>12</sup> Richard R. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CALIF. L. REV. 1483, 1506 (1989).

<sup>13</sup> The material contained in this section is mainly excerpted from *Using Clinical Practice Guidelines*, *supra* note 9, at 938-949.

<sup>14</sup> For a full and detailed discussion of a series of studies documenting the problem with the use of customary care standards to measure quality of care, *see id.* at 937-49.

<sup>15</sup> DARTMOUTH ATLAS OF HEALTH CARE, *Understanding the Efficiency and Effectiveness of the Health Care System*, <http://www.dartmouthatlas.org/> (last visited Apr. 2, 2013). The Dartmouth Atlas describes itself as follows:

For more than 20 years, the Dartmouth Atlas Project has documented glaring variations in how medical resources are distributed and used in the United States. The project uses Medicare data to provide information and analysis about national, regional, and local markets, as well as hospitals and their affiliated physicians. This research has helped policymakers, the media, health care analysts and others improve their understanding of our health care system and forms the foundation for many of the ongoing efforts to improve health and health systems across America.

*Id.*

<sup>16</sup> The Dartmouth Atlas Project is a “product of the Center for the Evaluative Clinical Sciences at Dartmouth Medical School.” Press Release, Geisel Sch. of Medicine at Dartmouth, *New Study Shows Need for a Major Overhaul of How United States Manages Chronic Illness* (May 16, 2006), [http://geiselmed.dartmouth.edu/news/2006\\_h1/16may2006\\_overhaul.shtml](http://geiselmed.dartmouth.edu/news/2006_h1/16may2006_overhaul.shtml).

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

<sup>18</sup> ELLIOT S. FISHER, DAVID C. GOODMAN & AMITABH CHANDRA, REGIONAL AND RACIAL VARIATION IN HEALTH CARE AMONG MEDICARE BENEFICIARIES: A BRIEF REPORT OF THE DARTMOUTH ATLAS PROJECT 24 (Kristen K. Bronner ed., 2008), [http://www.dartmouthatlas.org/downloads/reports/AF4Q\\_disparities\\_Dec2008.pdf](http://www.dartmouthatlas.org/downloads/reports/AF4Q_disparities_Dec2008.pdf).

of unequal use as underuse, overuse and misuse, all of which can cause actual harm without any counterbalancing benefit.

A large group of physicians adhere to customary practices of not providing critical treatments, even in the face of repeated, empirically sound studies that these treatments are of great benefit to their patients.<sup>19</sup> The failure to provide these treatments can, in many situations, expose patients to a significantly increased risk of death. These customary-care practices represent *underuse* of health care.<sup>20</sup> A major 2012 study suggests that underuse continues to be a major problem despite efforts to integrate CPGs into daily physician practice.<sup>21</sup> For example, physicians are failing to provide antithrombotic treatment in 28.1 percent of atrial fibrillation cases.<sup>22</sup> Prescribing antithrombotic drugs decreases the risk of stroke for these patients.<sup>23</sup> For patients with coronary heart disease, doctors are failing to provide aspirin 35.5 percent of the time, beta-blockers 44.8 percent of the time, and statins 41.4 percent of the time.<sup>24</sup> Aspirin can reduce the occurrence of vascular events, including myocardial infarction and death.<sup>25</sup> Beta-blockers can decrease all cause and cardiovascular mortality, cardiovascular hospitalizations, and the need for revascularization procedures.<sup>26</sup> Statins can reduce the risk of cardiovascular events.<sup>27</sup> Doctors also fail to prescribe beta-blockers in congestive heart failure patients 40.3 percent of the time<sup>28</sup> (beta-blockers ameliorate symptoms and greatly improve mortality<sup>29</sup>) and fail to prescribe statins for diabetes patients 63.8 percent of the time<sup>30</sup> (statins can decrease cardiovascular disease events by 19 percent to 55 percent—a major cause of mortality in diabetes

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<sup>19</sup> Minal S. Kale et al., *Trends in the Overuse of Ambulatory Health Care Services in the United States*, 173 JAMA: INTERNAL MED. 142, 142–43 (2013) (“underuse represents the failure to deliver healthcare for which the benefits outweigh the risks (e.g. use of an aspirin in residents with coronary disease); and misuse is the delivery of the wrong care (e.g. the use of an antibiotic other than nitrofurantoin, trimethoprim-sulfamethoxazole or quinolone is the incorrect treatment for uncomplicated urinary tract infections).”).

<sup>20</sup> Ashish K. Jha et al., *Care in U.S. Hospitals—the Hospital Quality Alliance Program*, 353 NEW ENG. J. MED. 265, 265 (2005) (uncovering the unfortunate failure of both physicians and hospitals to provide treatments that were essential for saving the lives of those who suffered from the most common causes of death, pneumonia, heart attack, and heart failure).

<sup>21</sup> Kale, *supra* note 19, at 142–43 (describing a study that suggests there has been little improvement on the part of individual physicians in this underuse problem in the seven years since the 2005 Jha study, *supra* note 20).

<sup>22</sup> *Id.* at 143.

<sup>23</sup> N. A. Mark Estes III et al., *ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults with Nonvalvular Atrial Fibrillation or Atrial Flutter*, 117 CIRCULATION 1101, 1104 (2008), <http://circ.ahajournals.org/content/117/8/1101.full> (“Atrial fibrillation is associated with an increased risk of stroke, heart failure, and all-cause mortality, especially in women.”).

<sup>24</sup> Kale, *supra* note 19, at 143.

<sup>25</sup> Am. Coll. of Cardiology et al., *Chronic Stable Coronary Artery Disease: Performance Measurement Set 55* (2005), <http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/cadminisetjune06.pdf>.

<sup>26</sup> *Id.* at 61.

<sup>27</sup> *Id.* at 29.

<sup>28</sup> Kale, *supra* note 19, at 143.

<sup>29</sup> William E. Chavey II, *The Importance of Beta Blockers in the Treatment of Heart Failure*, 62 AM. FAM. PHYSICIAN 2453–62 (2000), <http://www.aafp.org/afp/2000/1201/p2453.html>.

<sup>30</sup> Kale, *supra* note 19, at 143.

patients).<sup>31</sup> Adding to this surprising picture, physicians fail to prescribe ACE inhibitors in congestive heart failure patients 58.4 percent of the time. ACE inhibitors can, when prescribed in conjunction with standard treatment, slow heart failure progression in patients with mild symptoms, and can have a beneficial impact on mortality, morbidity, and quality of life.<sup>32</sup> Finally, physicians are failing to prescribe antiplatelets for stroke patients 51.3 percent of the time (the use of antiplatelets can significantly decrease the risk of secondary stroke, myocardial infarction, and death<sup>33</sup>) and are failing to prescribe drugs for the treatment of osteoporosis 54.9 percent of the time<sup>34</sup> (the use of pharmacologic treatments can “prevent fractures in women and men with osteoporosis or low bone density”).<sup>35</sup>

Preference-sensitive care and supply-sensitive care can result in *overuse* of health care. The overuse of health care that results from customary care practices is a major concern. Of the estimated \$700 billion wasted every year by the U.S. health care system, “over use, or the delivery of services for which the risks exceed the benefits, has been identified as a significant component, equaling roughly \$280 billion.”<sup>36</sup> Overall, “[r]esearch on appropriateness indicates that from one quarter to one third of medical services may be of no value to [patients].”<sup>37</sup> For example, 11.3 percent of screening EKGs, 25.3 percent of screening urine analyses, 7.0 percent of screening X-rays, and 37.9 percent of complete blood counts are unnecessarily ordered as part of a general medical exam.<sup>38</sup> Antibiotics are unnecessarily prescribed for upper respiratory tract infections 40.2 percent of the time, for acute bronchitis 58.8 percent of the time, and for asthma 6.8 percent of the time.<sup>39</sup>

Another category is *misuse* of medical care. With regard to misuse, scientific studies have identified numerous customary care practices that show little to no evidence of benefit, but which can actually put patients in danger of harm, that are still practiced on a daily basis. For example, in an initiative to change entrenched medical practices, 17 major medical specialty groups issued recommendations that physicians stop using 90 different unnecessary, but

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<sup>31</sup> John Buse, *Statin Treatment in Diabetes Mellitus*, 21 CLINICAL DIABETES 168 (2003) (“Since the 1970s, there have been substantial epidemiological data demonstrating that cardiovascular diseases (here defined as ischemic heart disease, stroke, and peripheral vascular disease) constitute the primary cause of morbidity and mortality in patients with diabetes. In fact, at least 60% and arguably 80% of people with diabetes will eventually succumb to cardiovascular disease (CVD).”).

<sup>32</sup> M. K. Davies et al., *ABC of Heart Failure: Management: Diuretics, ACE Inhibitors, and Nitrates*, 320 BRIT. MED. J. 428, 429 (2000).

<sup>33</sup> Dawn Meyer, *Antiplatelets and Stroke Outcomes: State of the Science*, 21 CRITICAL CARE NURSING CLINICS N. AM. 517–28 (2009).

<sup>34</sup> Kale, *supra* note 19, at 143.

<sup>35</sup> Amir Qaseem et al., *Pharmacologic Treatment of Low Bone Density or Osteoporosis to Prevent Fractures: a Clinical Practice Guideline from the American College of Physicians*, 149 ANNALS OF INTERNAL MED. 404, 405 (2008).

<sup>36</sup> Kale, *supra* note 19, 142–43, *citing*, THOMSON REUTERS, WHERE CAN \$700 BILLION IN WASTE BE CUT ANNUALLY FROM THE US HEALTH-CARE SYSTEM? (2009), <https://healthleadersmedia.com/content/241965.pdf>.

<sup>37</sup> See Barry R. Furrow et al., *Health Law* § 7-1, at 34 (5th ed. 2004) (citing Robert Brook & Kathleen Lohr, *Will We Need to Ration Effective Medical Care?*, 3 ISSUES IN SCI. & TECH., no. 1, at 68 (Fall 1986)).

<sup>38</sup> Kale, *supra* note 19, at E5.

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



frequently used, tests and procedures, many of which are harmful to patients.<sup>40</sup> This list of “don’ts” adds to a prior list of 45 recommendations made in “an educational initiative called Choosing Wisely, directed at both residents and physicians, under the auspices of the American Board of Internal Medicine Foundation and in partnership with Consumer Reports.”<sup>41</sup> For example, one of the many practice customs that involve the misuse of care that is on the Choosing Wisely list of “don’ts” is the American Geriatrics Society recommendation against the prescription of benzodiazepines or other sedative hypnotics in older adults as a first choice for insomnia, agitation, or delirium because the use of these medications doubles the risk of car accidents, falls, and hip fractures in older adults.<sup>42</sup>

This problem with the integration of evidence-based treatment choices into physician practice is a well-studied problem. Scores of studies have revealed that physicians are being exposed to evidence-based medicine in the form of CPGs on a regular basis—they go to seminars, listen, agree, then go back to practice and ignore the new information.<sup>43</sup> In a recent

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<sup>40</sup> Laurie Tarkan, *Doctor Groups Issue Lists of Overused Medical Tests*, N.Y. Times (Feb. 21, 2013, 12:52 PM), [http://well.blogs.nytimes.com/2013/02/21/doctor-groups-issue-list-of-overused-medical-tests/?\\_r=0](http://well.blogs.nytimes.com/2013/02/21/doctor-groups-issue-list-of-overused-medical-tests/?_r=0).

<sup>41</sup> Roni Caryn Rabin, *Doctor Panels Urge Fewer Routine Tests*, N.Y. Times (Apr. 4, 2012), [http://www.nytimes.com/2012/04/04/health/doctor-panels-urge-fewer-routine-tests.html?\\_r=0](http://www.nytimes.com/2012/04/04/health/doctor-panels-urge-fewer-routine-tests.html?_r=0); *see also* CHOOSING WISELY: LISTS, <http://www.choosingwisely.org/doctor-patient-lists/> (last visited on Mar. 16, 2013). An initiative of the ABIM Foundation, the website explains the Lists page as follows:

U.S. specialty societies representing more than 500,000 physicians developed lists of Five Things Physicians and Patients Should Question in recognition of the importance of physician and patient conversations to improve care and eliminate unnecessary tests and procedures. These lists represent specific, evidence-based recommendations physicians and patients should discuss to help make wise decisions about the most appropriate care based on their individual situation. Each list provides information on when tests and procedures may be appropriate, as well as the methodology used in its creation. In collaboration with the societies, Consumer Reports has created resources for consumers and physicians to engage in these important conversations about the overuse of medical tests and procedures that provide little benefit and in some cases harm.

<sup>42</sup> AM. GERIATRICS SOC’Y, *Five Things Physicians and Patients Should Question*, CHOOSING WISELY, <http://www.choosingwisely.org/doctor-patient-lists/american-geriatrics-society/> (last visited on Mar. 16, 2013).

<sup>43</sup> *See e.g.*, Lee A. Green et al., *Translation of Research into Practice: Why We Can’t “Just Do It,”* 18 J. Am. Brd. Family Prac. 541, 541(2005) (There is “widespread agreement that physicians and healthcare systems simply do not put new knowledge about how to improve our patients’ outcomes into practice nearly quickly enough. . . . For example, consider the guideline that “congestive heart failure patients should be evaluated for use of beta-blockers.” An expert physician may be aware of this recommendation and may wholeheartedly accept it as good practice, but may still fail to adopt it when they happen to see an elderly patient in the clinic who could benefit from beta-blockage. Knowledge of evidence can remain separate from, and not integrated into, the physician’s extensive database of procedures that guides their decision and actions. This makes the likelihood of recognizing that the new knowledge is appropriate and incorporating it into these well-rehearsed procedures very uncertain.”); Illaria Baiardini et al., *Why Do Doctors and Patients Not Follow Guidelines?*, 9 Current Opinion Allergy Clinical Immunology 228, 228 (2009) (“During the last few years, different studies and theories have tried to explain the reason why doctors and patients do not follow guidelines. . . . [A]lthough the efforts to develop and divulge evidenced-based guidelines, results of studies conducted in the United States and

New Yorker article, quality-of-care expert and Harvard Professor Atul Gawande noted that there is a disconcerting fifteen-year average lag time in the adoption by physicians of evidence-based practice choices.<sup>44</sup>

The number of studies that suggest that customary-care choices can lead to a physician providing the wrong treatment, or failing to provide a lifesaving treatment, are steadily growing. These studies demonstrate that using customary-care treatment choices may mean that a patient's condition may not only fail to improve, it may worsen through exposure to unnecessary risks of harm, including long-term disability and death. All together, these studies demonstrate that customary-care practices can have a significantly negative impact on healthcare quality, equal access, and cost.

### **C. What are the Solutions to the Problems with Custom-Based Care?<sup>45</sup>**

These quality and cost problems with the customary-care model have triggered a new, national push to move the United States to a modern, evidence-based model of medical practice through major changes in government-provided health care, including the numerous, multi-billion dollar programs created by the ACA, as well as changes in the VA Hospital System and Medicare.<sup>46</sup>

The evidence-based model of medical practice is grounded in empirical data generated by clinical outcomes and effectiveness research which suggests the optimum treatment for a rapidly growing number of clinical conditions. This use of empirical data generated through scientific methodology to make medical decisions shows great promise for enhancing quality of care and equal access to care while decreasing the cost of care.

Importantly, in conjunction with the American Recovery and Reinvestment Act of 2009, the ACA will be providing hundreds of millions of dollars of funding for research to develop evidence-based clinical practice guidelines that will be used to define the “best practices” that the

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the Netherlands suggest that most of the time, guidelines are not applied; about 30-40% of patients do not benefit from a cure program based on scientific evidence, whereas 20-25% of therapeutic choices may be unnecessary and sometimes even harmful.”); Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines?*, 282 JAMA 1458, 1458 (1999) (“Despite wide promulgation, clinical practice guidelines have had limited effect on changing physician behavior.”); Justin Timbie et al., *Five Reasons That Many Comparative Effectiveness Studies Fail to Change Patient Care and Clinical Practice*, 31 Health Aff. 2168, 2168 (2012) (“[D]ecades of experience suggest that translating evidence into changes in clinical practice is rarely rapid. . . .”); David A. Davis et al., *Translating Guidelines Into Practice: A Systematic Review of Theoretic Concepts, Practical Experience and Research Evidence in the Adopting of Clinical Practice Guidelines*, 15 Can. Med. Ass'n J. 408, 408 (1997) (“The evidence shows serious deficiencies in the adoption of CPGs in practice”). Physicians will be incentivized to adopt evidence-based treatment choices if EMTALA requires written protocols, CMS requires that these protocols are created based upon best practices grounded in CPGs and hospitals require documentation that protocols are followed or the reasons why they are not.

<sup>44</sup> Atul Gawande, *Big Med*, NEW YORKER (Aug. 12, 2012), [http://www.newyorker.com/reporting/2012/08/13/120813fa\\_fact\\_gawande](http://www.newyorker.com/reporting/2012/08/13/120813fa_fact_gawande)

<sup>45</sup> The material contained in this section is largely excerpted from *Harmonizing the Affordable Care Act*, *supra* note 8 and *Using Clinical Practice Guidelines*, *supra* note 9, at 938.

<sup>46</sup> For a more detailed overview of these programs, see *Harmonizing the Affordable Care Act*, *supra* note 8, at 899 to 906.

Act promotes. For example, under § 10303 of the ACA, these best practices will be used to create more of the same types of patient outcome measures that are already being utilized in Medicare. The ACA creates a new oversight entity, the Patient-Centered Outcomes Research (PCOR) Institute, to direct the Comparative Effectiveness Program that will create data banks comparing the effectiveness of two or more treatments. These databanks will provide much needed decision-making tools for both healthcare providers and consumers in light of the multiple medications and treatments that are marketed to deal with the same health condition.

Adding another layer to this push for the nation-wide adoption of evidence-based medical practice is the creation by the ACA of the Center for Quality Improvement and Patient Safety (“CQIPS”). This Center will develop tools to facilitate the adoption of best practices by healthcare providers. CQIPS will award grants and provide technical assistance to help providers adopt best practices. With the addition of this Center, the ACA now has a system for the development of best practices (the Agency for Healthcare Research and Quality), a system for publicizing these best practices (PCOR), and a system for integrating these best practices (CQIPS) into the everyday practices of hospitals and physicians.

Central to the ACA are the Health Benefit Exchanges and, in keeping with ACA’s theme of improving the quality and cost of care, these exchanges also work instrumentally to move the ball forward in these areas. To qualify to sell insurance to consumers through these exchanges, insurers must evaluate providers by the same quality benchmarks that are being used by CMS. As with the CMS reimbursements under Medicare, the higher the rating, the greater the private insurance reimbursement will be for health care services. Continuing the parallel, just like Medicare, the insurance companies must also publish the quality of care and patient satisfaction data that they gather.

Together, the quality improvement provisions under the ACA and CMS create a powerful regulatory engine that should work to move the United States from a system that follows the customary-care model of medical care to a modern, evidence-based system of medical care grounded in the use of best practices.

#### **D. What are the Roadblocks to the Adoption of Evidence-Based Care?<sup>47</sup>**

Unfortunately, the three major, national systems for improving healthcare quality that have long-existed in the United States—the state medical malpractice system, the state licensure system and the private hospital peer review system—appear to be undermining the federal efforts to encourage the adoption of evidence-based medical practice by adhering to the use of customary care as the exclusive proxy for quality of care. Thus, these systems are acting instrumentally to encourage the perpetuation of custom-based practices.

##### ***1. How can the customary-care rule applied in medical malpractice, licensure and peer review cases slow the change to evidence-based treatment choices?***

In order to meet the standard of care in a medical malpractice case, a health care provider must “possess and use the care, skill and knowledge ordinarily possessed and used under like

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<sup>47</sup> The material contained in this section is excerpted from *Harmonizing the Affordable Care Act*, *supra* note 8 and *Using Clinical Practice Guidelines*, *supra* note 9.

circumstances.<sup>48</sup> The scope of admissible evidence that may be used to define reasonable care in the majority of states is based on the dated “customary care rule.”<sup>49</sup> Importantly, if there is a conflict between customary and evidence-based care choices, physicians are likely to follow custom-based standards to avoid medical malpractice liability, in spite of the incentives contained in the ACA to change.<sup>50</sup>

Reflecting an understanding of the benefits of evidence-based treatment choices,<sup>51</sup> a minority of state tort systems have moved away from using customary care as the exclusive proxy for quality of care in medical malpractice actions. These tort systems are allowing the introduction of risk-benefit analysis grounded in empirical science as evidence of what is reasonable care.<sup>52</sup> A recent study<sup>53</sup> suggests that these tort systems are operating instrumentally to encourage health care professionals to transition away from custom-based to evidence-based medical practice.<sup>54</sup> A second study by this same author reinforces this conclusion.<sup>55</sup> These

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<sup>48</sup> *Burns v. Metz*, 513 N.W.2d 505, 509 (Neb. 1994); *Vergara v. Doan*, 593 N.E.2d 185, 188 (Ind. 1992) (judging the physician’s conduct by a “minimum standard of care for the particular practice”). For an excellent overview of medical malpractice law, see DAN B. DOBBS, *THE LAW OF TORTS* § 242, 631–34 (2000).

<sup>49</sup> See generally Philip G. Peters Jr., *The Role of the Jury in Modern Malpractice Law*, 87 Iowa L. Rev. 909 (2002) (discussing the merits of the role of custom as conclusive evidence of the standard of care in malpractice litigation and the movement by many states to use custom as only some evidence of the standard of care); Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 Wash. & Lee L. Rev. 163, 170 (2000).

<sup>50</sup> For an example of how this is likely to play out in an actual case, see *Harmonizing the Affordable Care Act*, *supra* note 8, at 909-13.

<sup>51</sup> In 1999, an Institute of Medicine report revealed the startling news that treatment errors in hospitals were the cause of up to 98,000 deaths annually. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000). In a recent update on this situation, a Consumer Reports investigation came to the conclusion that “[m]ore than 2.25 million Americans will probably die from medical harm this decade . . . . That’s like wiping out the entire populations of North Dakota, Rhode Island, and Vermont. It’s a manmade disaster.” *How Safe Is Your Hospital? Our New Ratings Find That Some Are Riskier than Others*, CONSUMER REPS. (Aug. 2012), <http://www.consumerreports.org/cro/magazine/2012/08/how-safe-is-your-hospital/index.htm>. The IOM report and the follow-up Consumer Reports investigation published over a decade later suggest that the three main systems in the United States tasked with improving the quality of patient care — the state medical malpractice and licensure systems and the private hospital peer review hearing system — are all failing at their missions. One reason may be the continued use of customary care as the exclusive proxy for quality of care. See *infra* notes 53-55 and accompanying text.

<sup>52</sup> See Peters, *supra* note 49. By virtue of applying their own state law, the state licensure systems of these states are likely to follow suit.

<sup>53</sup> A recent empirical study employing data kept by the National Hospital Discharge Surveys on treatment utilization rates from 1977 to 2005 showed that there was “a 30–50 percent reduction in the gap between state and national utilization rates of various treatments and diagnostic procedures [including obstetric, cardiac and diagnostic procedures] following the adoption of a rule requiring physicians to follow national, as opposed to local, standards.”<sup>53</sup> Professor Michael Frakes of the Cornell Law School, who is the author of the study, found that “custom-based liability standards may indeed encourage the perpetuation of customary practices and likewise discourage deviations from custom. . . .” Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules*, 103 AM. ECON. REV. 257, 257 (2013).

<sup>54</sup> The ACA has some provisions that may start to address the need for these states to adopt the use of evidence-based standards of care, but more is needed. For a proposal of how to harmonize the

studies suggest that one of the road blocks to the integration of evidence-based treatment choices into physician practice may be the concern of practitioners that the failure to make the customary treatment choice sanctioned by the medical malpractice, licensure, and peer review systems could lead to civil liability, licensure sanctions, and loss of hospital staff privileges.<sup>56</sup>

### **E. How does Custom-Based Care Undermine EMTALA Enforcement?**

EMTALA contributes to the roadblock to the transition toward evidence-based medical practice by requiring that physicians use the same care that they use for patients with similar symptoms. The same care is likely to be based upon the customary-care model of medical practice as this is the normative form of medical practice in the United States. Thus, as with the impact of the tort, licensure, and hospital peer review systems, if there is a conflict between customary and evidence-based care choices, physicians are likely to follow custom-based standards to avoid EMTALA liability on the part of the hospital, in spite of the incentives contained in the ACA to change.

Relying on custom-based medical practice, rather than written protocols based on CPGs, seriously undermines equality of treatment, allows for overuse of summary judgment in EMTALA cases, and allows for bias and stereotypes in treatment choices.

Lack of written protocols leaves room for physicians to use their subjective personal predilections (based on custom, other rules of thumb, or their individual clinical experience) to decide which of a presenting patient's symptoms are relevant and which can be ignored. Based on this subjectively selected constellation of symptoms, the physician again has room to use his or her personal predilections to decide which screening tools should be used to make up the appropriate medical screening.<sup>57</sup> As noted above, there are substantial discrepancies in physician decisions both between and within hospitals.<sup>58</sup> The studies referred to in this Statement, among

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Affordable Care Act with the three main national systems for healthcare quality improvement - the tort, licensure, and hospital peer review hearing systems, *see Harmonizing the Affordable Care Act, supra* note 8, at 919-927.

<sup>55</sup> Michael Frakes et al., *Does Medical Malpractice Law Improve Health Care Quality?*, SSRN, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2374599](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2374599) (January 14, 2014).

<sup>56</sup> For a complete discussion, see *Using Clinical Practice Guidelines, supra* note 9.

<sup>57</sup> It is the choice of symptoms to recognize that drives what screening process to use. The choice of one set of screening tools rather than others can be outcome determinative on the issue of whether an emergent condition exists.

<sup>58</sup> Richards, *supra* note 5, at 619, *citing*, MICHAEL L. MILLENSON, DEMANDING MEDICAL EXCELLENCE: DOCTORS AND ACCOUNTABILITY IN THE INFORMATION AGE 4 (1997) ("In the absence of reliable information, physicians' decisions fluctuate wildly," noting surprisingly large divergences in care both between and within hospitals, and arguing that implementation of quality measurement and written protocols of best practices could help to reduce inconsistencies). "

Millenson cites numerous examples of this throughout his book. *See id.* ("[W]hen family practitioners in Washington State were queried about treating a simple urinary tract infection in women, eighty-two physicians came up with an extraordinary 137 different strategies."); *id.* at 15-18 (discussing enormous inconsistencies in the treatment of pneumonia patients at eight hospitals in Maine, noting that the researchers in the study "looked in vain for any consistent pattern," and concluding that "[t]he results in this one small state showed just how deceptive the surface similarities of American medicine can be"); *id.* (noting similar disparities in methods of

many others, make it clear that "[w]ithout standardized instruction of some sort from a hospital, it is highly unlikely that screenings performed by different physicians could possibly be uniform."<sup>59</sup>

The reliance on customary practice choices also appears to be resulting in many EMTALA cases being dismissed by summary judgment.<sup>60</sup> The courts are granting summary judgment based upon hospital affidavits asserting that the medical screening provided was the same that other patients would have received with the same constellation of symptoms. The reality is that, in many cases, these affidavits are likely to be of little actual evidentiary value as different physicians treat patients with the same set of symptoms differently. The empirical evidence is clear that physicians' decisions fluctuate wildly absent evidence based on comparative effectiveness studies to guide treatment choice. Thus, "[a]n assessment of uniformity in screening examinations that defers to the perception and judgment of an individual physician in determining what constituted the hospital's standard protocol will inexorably excuse disparate care."<sup>61</sup> Because the courts are giving over probative value to these affidavits leading to dismissal of EMTALA cases, hospitals are likely to be avoiding the creation of written treatment protocols which could make summary judgment far less likely.<sup>62</sup>

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treating heart attack victims and remarking that one "possible explanation for the variation" was that "[t]he differences could result from physicians' 'practice styles' or 'preferences,' the polite terms the medical community uses to describe treatment that varies because doctors vary"); *id.* at 30 (noting dissimilarity among physicians deciding whether or not to remove a child's tonsils).

Richards, *supra* note 5, at 619, n. 162.

<sup>59</sup> Richards, *supra* note 5, at 619 (Millenson also describes "the experience of one hospital, which, when it attempted to 'write a protocol spelling out every detail of treatment' for acute respiratory distress syndrome, encountered substantial problems with physician variance: 'A treatment regimen that appeared on the surface to be orderly and scientific quickly dissolved into a series of individual 'rules of thumb' used by each physician", citing, M. Gregg Bloche, *Race and Discretion in American Medicine*, 1 YALE J. HEALTH POL'Y L. & ETHICS 95, 100 (2001) ("Most medical decisions do not rest firmly on empirical evidence. There are typically multiple diagnostic and therapeutic options, and wide variations in the incidence of many common medical and surgical procedures have been documented within small geographic areas and between individual practitioners.").

<sup>60</sup> Richards, *supra* note 5.

<sup>61</sup> *Id.* at 620.

<sup>62</sup> Richards, *supra* note 5, at 623, n. 174, explaining that "[a]lthough some hospitals have written guidelines for the processing of emergency department patients, such as standardized triage instructions or requirements for nurse monitoring, a survey of EMTALA opinions indicates that few hospitals have detailed protocols that guide physicians during screenings" and citing as examples the following: *Reynolds v. Maine General Health*, 218 F.3d 78, 83-84 (1st Cir. 2000) (discussing a basic policy that required the taking of "complete [medical] history"); *Cunningham v. Fredonia Reg'l Hosp.*, No. 95-3350, 1996 WL 584917, at \*2 (10th Cir. Oct. 11, 1996) (involving a policy that determined whether a nurse or a physician would screen a patient depending on the severity of the patient's chest pain); *Bode v. Parkview Health Sys., Inc.*, No. 1:07-CV-324, 2009 WL 790199, at \*2, \*4 (N.D. Ind. Mar. 23, 2009) (noting that the hospital had a written nursing policy requiring that "nurses ... take each patient's blood pressure," but making clear, in its affidavits, that "[i]t is within the medical judgment of the physician who performs the Medical Screening Examination to determine what history, examination and testing is needed in order to determine whether the patient has an Emergency Medical Condition"); *Fuentes Ortiz v. Mennonite Gen. Hosp.*, 106 F. Supp. 2d 327, 331 (D.P.R. 2000) (noting that, in response to an interrogatory question asking "whether on May 21st, 1998 you had established any policies or procedures for screening patients coming to your emergency room who display or complain of symptoms such as the

The absence of written protocols coupled with preference-based treatment choices allows for unconscious biases and stereotypes in screening, diagnosis and treatment choices.<sup>63</sup> These unconscious biases and stereotypes have been shown to influence physician judgments about patients' suitability for particular tests, procedures, and treatments.<sup>64</sup> This problem is more acute

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ones described by plaintiff in his complaint," the hospital administrator stated: "Patient is first screened in Triage .... Relative to the specific condition of the patient, no protocol exists, other than the applicable standard of care."); *see also* Timothy H. Bosler & Patrick M. Davis, *Is EMTALA a Defanged Cobra?*, 51 J. Mo. B. 165, 169 (1995) ("[M]any hospitals do not provide an established protocol for screening procedures related to even common serious medical conditions .... Based on our personal experience, many hospitals provide emergency room service through contract physicians and provide little, if any, written screening standards or protocols for the guidance of the individual employees or independent contractors to determine how they will screen a given patient presentation."). *Id.*

<sup>63</sup> Richards, *supra* note 5, at 623, n. 174 citing as examples Kevin A. Schulman et al., *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 NEW ENG. J. MED. 618, 623-25 (1999) (describing significant differences in doctor reactions to Black and White individuals reporting identical symptoms); Janice C. Blanchard et al., *Racial and Ethnic Disparities in Health: An Emergency Medicine Perspective*, 10 ACAD. EMERGENCY MED. 1289, 1289-93 (2003) (reviewing "existing research on disparities in the area of emergency medicine," noting, for example, that "[r]ecent data showed that nonwhites with acute cardiac ischemia were two times more likely to be sent home from the ED, and nonwhites with myocardial infarctions were over four times more likely to be missed," and contending that "[r]acial bias is an important factor that must be considered in explaining disparities"); Jordan J. Cohen, *Disparities in Health Care: An Overview*, 10 ACAD. EMERGENCY MED. 1155, 1156 (2003) (stating that the "evidence is incontrovertible" that "biases and stereotypes affect patient care"); Arnold M. Epstein & John Z. Ayanian, *Racial Disparities in Medical Care*, 344 NEW ENG. J. MED. 1471, 1471-72 (2001) (explaining that "[m]any studies have shown that black Americans are less likely than whites to receive a wide range of medical services, including potentially life-saving surgical procedures," and suggesting, as one contributing factor, that "both white and black physicians may have subtle biases that are based on other social factors and that influence their judgments about patients' suitability for procedures"); Diana J. Burgess et al., *Why Do Providers Contribute to Disparities and What Can Be Done About It?*, MEDSCAPE NEWS, Dec. 7, 2004, available at <http://www.medscape.com/viewarticle/494312> (collecting research on social cognition and provider decision making, and explaining that, although "[c]linicians are generally expected, and expect themselves, to view each patient objectively and impartially, ... these expectations are highly unrealistic. Providers, like all humans, are likely to unconsciously apply stereotypes when making sense of patients"); Kurt Samson, *Researchers Find Racial Disparities in Care for Epilepsy at Hospitals*, NEUROLOGY TODAY, Jan. 6, 2011, at 1 (reporting a finding that "blacks and Hispanics were less likely to receive neuroimaging or to be admitted to the hospital when seen in their tertiary care emergency department (ED) for an epileptic seizure").

<sup>64</sup> Richards, *supra* note 5, at 621, n. 167-171, citing, Anthony G. Greenwald & Linda Hamilton Krieger, *Implicit Bias: Scientific Foundations*, 94 CAL. L. REV. 945, 946, 961, 966-67 (2006) (explaining that "the science of implicit cognition suggests that actors do not always have conscious, intentional control over the processes of social perception, impression formation, and judgment that motivate their actions," asserting that "evidence that implicit attitudes produce discriminatory behavior is already substantial and will continue to accumulate," and concluding that "a substantial and actively accumulating body of research evidence establishes that implicit race bias is pervasive"); Kevin A. Schulman et al., *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 NEW ENG. J. MED. 618, 623-25 (1999) (finding similar disparities in physician decisions based on gender); RAYMOND S. DUFF & AUGUST B. HOLLINGSHEAD, *SICKNESS AND SOCIETY*, 84-85, 117-18 (1968) (reporting disparate treatment of patients on the basis of socioeconomic status by physicians, nurses, and hospital administrators); Selassie et al., *supra* note 5, at 1266 (finding that the

in the emergency room as studies have shown that physician fatigue, overload, and time pressure, common in emergency rooms, can decrease cognitive ability and exacerbate problems of stereotyping and bias.<sup>65</sup>

## F. How can EMTALA be Modified to Increase its Effectiveness?

The solution recommended in this Statement is focused on adoption of systems reform which is the "redesign of the underlying systems of care themselves in order to better serve all patients."<sup>66</sup> As explained by Professor Sydney Watson,

[i]n a monumental shift from old-style quality oversight, which focused on blaming individuals for errors, systems reform is a non-punitive, forward-looking approach to quality oversight. With the acknowledgment that "to err is human," it envisions quality improvement as an organizational responsibility. Advocates argue that more can be accomplished by raising the mean performance of all caregivers than by merely eliminating the worst performers. Quality improvement is seen as an ongoing process of evaluation, design adjustment, reevaluation, and further adjustment. The aim is not just to reduce errors but to deliver ever better care.<sup>67</sup>

Focusing on systems reform and continuous quality improvement<sup>68</sup> moves disparity reduction efforts from the sole domain of EMTALA and the civil rights arena and into an alternative, but coexisting and complimentary, world of healthcare quality regulation.<sup>69</sup> To

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uninsured were less likely to be admitted to a hospital, even after controlling for the patient's clinical condition); Scott Burris, *Dental Discrimination Against the HIV-Infected: Empirical Data, Law and Public Policy*, 13 YALE J. ON REG. 1, 35 (1996) (reporting discrimination against HIV-positive patients in the provision of dental care); see also *Howe v. Hull*, 874 F. Supp. 779, 786 (N.D. Ohio 1994) (denying a defendant hospital's summary judgment motion in an EMTALA case against a hospital that allegedly "did not wish to treat an AIDS patient"). For a general overview of legal scholarship dealing with unconscious discrimination, see Symposium, *Unconscious Discrimination Twenty Years Later: Application and Evolution*, 40 CONN. L. REV. 927 (2008).

<sup>65</sup> Diana J. Burgess et al., *Why Do Providers Contribute to Disparities and What Can Be Done About It?*, MEDSCAPE NEWS, Dec. 7, 2004, available at <http://www.medscape.com/viewarticle/494312> ("features of the health care setting that decrease cognitive capacity, such as fatigue, overload, and time pressure" exacerbate problems of "stereotyping and bias.").

<sup>66</sup> Sidney D. Watson, *Equity Measures and Systems Reform as Tools for Reducing Racial and Ethnic Disparities*, The Commonwealth Fund, v (2005). "Historically, civil rights law—specifically, Title VI of the 1964 Civil Rights Act—has provided the legal framework for redressing racial and ethnic disparities in health care, but civil rights litigation focuses on identifying blame. Plaintiffs in civil rights cases must prove that a health care provider either intentionally discriminated or used policies, practices, or procedures that had a statistically significant, adverse impact on minority patients. But disparity issues are complex and may be deeply embedded in providers' actions and patients' decisions, as well as in institutional policies and practices. Given this genesis, many disparities are unlikely to be suitable to the approach required by civil rights laws. The adoption of systems reform, which moves disparity-reduction efforts from the civil rights arena into the world of health care quality regulation, may ease this limitation." *Id.*

<sup>67</sup> *Id.* at 2-3 (citations omitted).

<sup>68</sup> *Using Clinical Practice Guidelines*, *supra* note 9 (proposing the use of a new system that relies upon the application of knowledge translation theory—along with continuous quality improvement—to integrate evidence-based treatment choices using clinical practice guidelines into physician practice).

<sup>69</sup> Watson, *supra* note 66, at 3.



institute this systems approach, EMTALA should be modified to harmonize with other federal systems in place to improve quality, cost, and equal access through the requirement of written protocols for emergency-department care. At the same time, CMS regulations should be modified to require that these written protocols be based on evidence-based standards, using CPGs. This two-part solution works across systems to ensure equal access to emergency care. This also integrates EMTALA with the continuous quality of care improvement movement that involves an "ongoing process of evaluation, design adjustment, reevaluation, and further adjustment."<sup>70</sup> This linkage recognizes that the unequal provision of emergency care caused by uncertainty, subconscious bias or stereotyping can be looked at as another variety of human error that can be prevented with a systems approach.

Making these changes requires two simple steps. First, EMTALA must be modified to require clearly written protocols and to create a rebuttable presumption of compliance if a hospital produces substantial evidence that it has conformed with its written screening and treatment protocols.<sup>71</sup> Second, CMS's *Conditions of Participation: Emergency Services*<sup>72</sup> must be modified to include regulations that require that "[t]he services provided or arranged by the facility must . . . meet professional standards of care. . . ." <sup>73</sup> As part of this modification, the *Interpretive Guidelines for the Conditions of Participation: Emergency Services* should read that "[p]rofessional standards of quality' means services that are provided according to accepted standards of clinical practice."<sup>74</sup> A statement should be provided that explains that "accepted standards of clinical practice" can include the use of standards published by a short list of sources, including professional organizations, licensing boards, clinical literature, current professional journals, or the clinical practice guidelines published by the Agency of Health Care

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

<sup>71</sup> As part of this provision, it should be noted that the failure to follow written protocols creates a rebuttable presumption of an EMTALA violation. This presumption can be rebutted by a showing that the physician's decision not to follow the written protocol was reasonable under the circumstances. Relying on the libertarian paternalism theory developed by Professors Cass Sunstein and Richard Thaler, this proposed system relies upon "gold standard" clinical practice guidelines as the default treatment choice, but then allows for individual physician choice in deviating from this default choice if it is reasonable to do so. This exception allows for the currently high level of scientific uncertainty that exists when it comes to many medical conditions, particularly in the realm of the treatment of outliers. As the practice of evidence-based medicine (population-based medicine, or the treatment of "norm") grows through the greater understanding of optimal treatment choices for the majority of people, and later transitions to personalized medicine based on the treatment of individuals according to their unique genetic profiles, this currently high degree of scientific uncertainty will steadily diminish over the next several decades, reducing the use of this exception.

<sup>72</sup> Ctrs. for Medicare & Medicaid Servs., State Operations Manual, Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases (as revised on July 16, 2010), available at [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_v\\_emerg.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf)

<sup>73</sup> This language is taken from the Ctrs. for Medicare & Medicaid Servs., State Operations Manual, CMS Pub. No. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, 42 C.F.R. § 483.20(k) (3) (as revised on July 1, 2011) (relating to Tag F281) [hereinafter CMS Survey Guidance].

<sup>74</sup> CMS Survey Guidance, 42 C.F.R. § 483.20(k) (3) (i) (as revised on July 1, 2011).

Policy and Research.<sup>75</sup> Importantly, the use of “customary care” should not be included on this short list of accepted standards of clinical practice.<sup>76</sup>

The result of these changes is that the courts applying EMTALA will be charged with determining if the hospital complied with its written emergency treatment protocols when treating the plaintiff, much as before. However, this reformulation requiring written protocols based on best practices allows the courts to make a concrete, more easily ascertainable and more substantively accurate assessment of whether the care provided to a particular patient conforms with hospital screening and treatment protocols for all patients. Separately, CMS will be tasked with ensuring that these written protocols further quality of care. This places the obligation to ensure quality of care with CMS which has both the expertise and the resources to do so. This dual-system solution also avoids the creation of a federal medical malpractice cause of action.

Finally, the use of written protocols allows for the use of outcomes analysis to track the results of the use of each particular protocol based upon mental and physical disabilities, race, ethnicity, and insurance status. This data collection based upon based upon mental and physical disabilities, race, ethnicity, and insurance status has become possible under the new data collection obligations created by the ACA. "The ACA requires that federally supported or conducted health programs collect their data in a form that is arrayed by race, ethnicity, sex, primary language, and disability status."<sup>77</sup> This data collection will allow for the ongoing process of continuing quality improvement to tailor these protocols on an ongoing basis to ensure that they are both furthering equal access and not inadvertently exacerbating disparities.<sup>78</sup> Thus, a major benefit of this systems reform solution is the use of actual data to both track, and create interventions to resolve, actual disparities in emergency care.

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

<sup>76</sup> For example, in the context of the care of pressure ulcers in long term care facilities, CMS has identified several organizations that have created CPGs that CMS finds acceptable. According to 42 C.F.R. § 483.25(c):

There are many recognized clinical resources regarding the prevention and management of pressure ulcers (including wound care, and complications such as infections and pain). Some of these resources include: [1] The Clinical Practice Guidelines from the Agency for Healthcare Research and Quality (AHRQ) [www.ahrq.gov](http://www.ahrq.gov) (Guideline No. 15: Treatment of Pressure Ulcers and Guideline No. 3: Pressure Ulcers in Adults: Prediction and Prevention) (AHRQ was previously known as the Agency for Health Care Policy and Research [AHCPR]); [2] The National Pressure Ulcer Advisory Panel (NPUAP) [www.npuap.org](http://www.npuap.org); [3] The American Medical Directors Association (AMDA) [www.amda.com](http://www.amda.com) (Clinical Practice Guidelines: Pressure Ulcers, 1996 and Pressure Ulcer Therapy Companion, 1999); [4] The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives site at [www.medqic.org](http://www.medqic.org); [5] The Wound, Ostomy, and Continence Nurses Society (WOCN) [www.wocn.org](http://www.wocn.org); and; [6] The American Geriatrics Society guideline “The Management of Persistent Pain in Older Persons,” [www.healthinaging.org](http://www.healthinaging.org).

CMS Survey Guidance, 42 C.F.R. § 483.25(c) (2006); see Ctrs. for Medicare & Medicaid Servs., State Operations Manual, CMS Pub. No. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities 111–32 (2011) (“Overview”).

<sup>77</sup> Furrow, *supra* note 37, at 623.

<sup>78</sup> Watson, *supra* note 66, at 2.

### III. CONCLUSION

This proposal allows CMS and EMTALA to work in tandem in a systems approach that has great potential for significantly improving EMTALA's effectiveness. This systems approach makes EMTALA violations more easily ascertainable, encourages hospitals to self-regulate and decreases the costs of litigation,. It also allows for more certainty in the steps that hospitals can take to avoid potential liability. Written protocols can also decrease transaction costs for courts by providing a more quantifiable standard for decision-making in the form of a rebuttable presumption of equality if the hospital can demonstrate that the care provided to the patient comported with its written protocols.

This solution also incentivizes physicians to adopt evidence-based treatment choices as EMTALA will require written protocols, CMS will require that these protocols are created based upon best practices grounded in CPGs and hospitals will require documentation that these protocols have been followed or the reasons why they were not. This proposed solution is forward thinking as it removes the barrier created by EMTALA to evidence-based emergency treatment while also facilitating the transition to personalized medical care based on genetics. This solution also opens the door to important innovations in healthcare delivery. For example, just on the horizon is the development of diagnostic software that will rely upon an individual's unique genetic and epigenetic profile and distinctive microbiome.<sup>79</sup> This type of innovation holds the promise of dramatically improving healthcare quality and equal access while decreasing costs. Of note, in the near future, **equal** care will mean **different** care for each individual based on each individual's unique genetic, epigenetic and microbiome profile.

I thank you for this opportunity to present these thoughts to the U.S. Commission on Civil Rights. I look forward to your questions and your comments on these suggestions for achieving the goal of equal access to emergency health care for all.

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<sup>79</sup> "The host of microorganisms inhabiting the human body, or microbiome, plays essential roles in both health and the pathogenesis and resolution of disease. Symbioses between humans and the microbiome influence broad aspects of human biology including nutrition, immune function, and even brain development. Altered microbial community profiles are associated with a variety of chronic diseases such as inflammatory bowel disease, allergic conditions, obesity, *and psychiatric and neurological disorders*. The microbiome influences therapeutic interventions: metabolism of drugs by both intestinal bacteria and enterocytes, leading to systemic absorption may provide valuable insights into pre-systemic drug metabolism, delivery, and toxicity. A better understanding of the metabolic pathways may aid in drug development and toxicity evaluation processes. The microbiome itself may be a target of, or tool for new therapeutic strategies for diseases as diverse as irritable bowel syndrome, and Parkinson's disease." The New York Academy of Science, *The Microbiome in Health, Disease, and Therapeutics: Bugs, Guts and Drugs*, <http://www.nyas.org/Events/Detail.aspx?cid=ee890695-4f54-4a59-930f-ae59bf7ec0d5> (last visited February 1, 2014) (emphasis added).