

# **Case Western Reserve University** School of Law Scholarly Commons

**Faculty Publications** 

2019

## Healing the Healers: Legal Remedies for Physician Burnout

Sharona Hoffman

Case Western University School of Law, sharona.hoffman@case.edu

Follow this and additional works at: https://scholarlycommons.law.case.edu/faculty\_publications



Part of the Health Law and Policy Commons

## **Repository Citation**

Hoffman, Sharona, "Healing the Healers: Legal Remedies for Physician Burnout" (2019). Faculty Publications. 2099.

https://scholarlycommons.law.case.edu/faculty\_publications/2099

This Article is brought to you for free and open access by Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Faculty Publications by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

## Healing the Healers: Legal Remedies for Physician Burnout

#### Sharona Hoffman\*

#### ABSTRACT

A career as a doctor was long considered to be among the best professional paths that one could pursue. But medicine may no longer be the sought-after career that it once was. All too often, doctors, struggling with the demands of electronic health record systems and a myriad of administrative and regulatory responsibilities, find that they fail to derive much joy from their work and become victims of burnout. Physician burnout is an acute concern in the medical community, with forty-four percent of doctors reporting that they suffer from it. Physician burnout is a public health threat. Doctors who are profoundly distressed cannot provide their patients with the highest quality of care.

Thus far, physician burnout has received little if any notice in the legal literature. This Article argues that the problem deserves and requires legal attention. First, health care regulations relating to health information technology, insurance, and many other matters are partly responsible for physician burnout and must be streamlined. As a prime example, electronic health record systems are now heavily regulated, but rather than improving the quality and usability of products, the regulations needlessly overburden clinicians. Second, the government traditionally oversees and protects the health and well-being of the American workforce. This is especially true for safety-critical jobs, such as those in the transportation industry. Likewise, physicians should be understood to be doing safety-critical work because patients put their lives in clinicians' hands. This Article, therefore, aims to fill a void in the literature by analyzing physician burnout through a legal lens and by developing recommendations for legal interventions to address the problem.

\_

<sup>\*</sup> Edgar A. Hahn Professor of Law and Professor of Bioethics, Co-Director of Law-Medicine Center, Case Western Reserve University School of Law; B.A., Wellesley College; J.D., Harvard Law School; LL.M. in Health Law, University of Houston; S.J.D. in Health Law, Case Western Reserve University. I thank Jessica Berg, Henry Bloom, Stacia Dearmin, Maxwell Mehlman, Andy Podgurski, and Joseph White for their very helpful comments on prior drafts. I especially thank Melissa Vogley for her dedicated and highly competent research assistance.

Intro	DUCTION	59
I. PHY	SICIAN BURNOUT: THE NATURE OF THE PROBLEM	62
A. P	HYSICIAN BURNOUT	62
B. T	HE CONSEQUENCES OF BURNOUT	<u>67</u> 66
1.	PHYSICIAN WELL-BEING	67
2.	QUALITY OF CARE	68
3.	WORKFORCE ATTRITION	69
C. T	HE CAUSES OF BURNOUT	71
II. Eli	ECTRONIC HEALTH RECORD SYSTEMS AND PHYSICIAN BURNO	OUT 73
A. E	LECTRONIC HEALTH RECORD SYSTEMS	73
B. T	HE LINK BETWEEN EHR SYSTEMS AND BURNOUT	76
	HE REGULATORY BURDEN: MEANINGFUL USE, MACRA, AND TIFICATION	<u>79</u> 80
1.	THE MEANINGFUL USE REGULATIONS AND MACRA	80
2.	EHR CERTIFICATION	85
III. In	ABILITY TO SPEND ADEQUATE TIME WITH PATIENTS	<u>87</u> 88
A.	TIME ALLOTTED FOR PATIENT VISITS	88
В.	REASONS FOR SHORT VISIT TIMES	<u>89</u> 90
1.	ADMINISTRATIVE WORK	<u>89</u> 90
2.	FINANCIAL PRESSURES	91
3.	LOSS OF CLINICAL AUTONOMY	92
C.	PHYSICIANS' EFFORTS TO INCREASE TIME WITH PATIENTS	93
1.	SCRIBES	93
2.	DIRECT PRIMARY CARE AND CONCIERGE MEDICINE	95
IV. W	HY BURNOUT IS A LEGAL ISSUE	99
V. RECOMMENDATIONS		
A.	STREAMLINING EHR-RELATED REGULATIONS	101
B.	EXPANDING USABILITY TESTING IN THE EHR CERTIFICATION	103

VI. CO	ONCLUSION	<u>112</u> 113
STU	DY	<u>110</u> <del>111</del>
E.	ADDRESSING PATIENT VISIT LENGTH: A NEED FOR FURTHER	
D.	PROMOTING MEASURES PROVEN TO EASE BURNOUT	110
C.	MEASURING AND REPORTING PHYSICIAN WELLNESS	<u>107</u> 108
YALE	JOURNAL OF HEALTH POLICY, LAW, AND ETHICS	18:2 (2018)

#### Introduction

In a 2018 article in *The New York Times Magazine*, Dr. Abraham Verghese wrote of a "disease" from which an increasing number of his colleagues are suffering.<sup>1</sup> He describes a young colleague who is experiencing "existential despair" at a time that should be "the honeymoon of a career." The "disease" is commonly known as physician burnout.

Dr. Verghese explains the problem as follows:

My young colleague slumping in the chair in my office survived the student years, then three years of internship and residency and is now a full-time practitioner and teacher. The despair I hear comes from being the highest-paid clerical worker in the hospital: For every one hour we spend cumulatively with patients, studies have shown, we spend nearly two hours on our primitive Electronic Health Records, or "E.H.R.s," and another hour or two during sacred personal time. But we are to blame. We let this happen to our trainees, to ourselves.<sup>3</sup>

A career as a doctor has been long considered to be among the best professional paths that one could pursue.<sup>4</sup> Many parents have fervently hoped that one day they would be able to say "my son/daughter the doctor," and many students have dedicated themselves tirelessly to their studies so that they could enter medical school and ultimately enjoy the many rewards of being a physician.

But medicine may no longer be the appealing career that it once was.<sup>5</sup> All too often, in light of financial, technological, regulatory, and other pressures, doctors find that they fail to derive much joy from their work and become victims of burnout.<sup>6</sup> Physician burnout has become an acute concern in the medical

<sup>1.</sup> Abraham Verghese, *How Tech Can Turn Doctors into Clerical Workers*, N.Y. TIMES MAG. (May 16, 2018), https://www.nytimes.com/interactive/2018/05/16/magazine/health-issue-what-welose-with-data-driven-medicine.html.

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

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

<sup>4.</sup> Eric S. Williams et al., *Understanding Physicians' Intentions to Withdraw from Practice: The Role of Job Satisfaction, Job Stress, Mental and Physical Health*, 35 HEALTH CARE MGMT. Rev. 105, 106 (2010).

<sup>5.</sup> *Id.* at 106.

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

community. It has been called an epidemic, pandemic, and public health crisis. 8

Thus far, however, it has received little if any attention in the legal literature. This gap is surprising because health care regulations relating to EHRs, insurance, and many other matters are partly responsible for physician burnout. Physicians consistently report being overwhelmed by the demands of the labyrinth of American health care laws and regulations with which they must comply. As a prime example, electronic health record (EHR) systems are now heavily regulated, but rather than improving the quality and usability of products, the regulations needlessly overburden clinicians. This Article, therefore, aims to begin to fill this void and to analyze physician burnout through a legal lens.

Burnout is a syndrome that is characterized by emotional exhaustion, depersonalization, and dissatisfaction with one's work accomplishments. <sup>12</sup> According to a recent study, in 2017, forty-four percent of U.S. doctors identified as suffering from at least one symptom of burnout, while the burnout rate was only twenty-eight percent in the general working population. <sup>13</sup>

A profoundly unhappy health care workforce is unlikely to provide the highest quality of care <sup>14</sup> and at times may provide poor care that endangers patient welfare. It can also exacerbate the already worrisome problem of health care provider

<sup>7.</sup> Lotte N. Dyrbye et al., Burnout Among Health Care Professionals: A Call to Explore and Address This Underrecognized Threat to Safe, High-Quality Care, NAT'L ACAD. MED. (July 5, 2017), https://nam.edu/burnout-among-health-care-professionals-a-call-to-explore-and-address-this-underrecognized-threat-to-safe-high-quality-care/; Victor J. Dzau et al., To Care Is Human—Collectively Confronting the Clinician-Burnout Crisis, 378 New Eng. J. MED. 312, 312 (2018).

<sup>8.</sup> Lauren DeCaporale-Ryan et al., *The Undiagnosed Pandemic: Burnout and Depression Within the Surgical Community*, 54 CURRENT PROBS. SURGERY 453, 454 (2017); Uta Guo et al., *Electronic Health Record Innovations: Helping Physicians—One Less Click at a Time*, 46 HEALTH INFO. MGMT. J. 140, 140 (2017) ("Physician burnout is becoming an epidemic, given the pressures of being productive, an imperfect electronic health record (EHR) system, and limited face-to-face time with patients."); John Noseworthy et al., *Physician Burnout Is a Public Health Crisis: A Message to Our Fellow Health Care CEOs*, HEALTH AFFS. BLOG (Mar. 28, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170328.059397/full/.

<sup>9.</sup> See infra Parts II.C and III.B.1.

<sup>10.</sup> See infra Parts II.C and III.B.1.

<sup>11.</sup> See infra note 147151 and accompanying text for definition of usability.

<sup>12.</sup> Colin P. West et al., *Physician Burnout: Contributors, Consequences and Solutions*, 283 J. INTERNAL MED. 516, 516 (2018).

<sup>13.</sup> Tait D. Shanafelt et al., Changes in Burnout and Satisfaction with Work-Life Integration in Physicians and the General US Working Population Between 2011 and 2017, \_\_\_ MAYO CLINIC PROC. 1, 7, 8 (forthcoming 2019), available at <a href="https://www.mayoclinicproceedings.org/article/S0025-6196(18)30938-8/pdf">https://www.mayoclinicproceedings.org/article/S0025-6196(18)30938-8/pdf</a>. An assessment of 4893 physician respondents revealed a 43.9% burnout rate. *Id.* at 7. A comparison of 3971 nonretired physicians aged 29 to 65 to 5198 employed nonphysician in the same age group revealed burnout rates of 39.8% and 28.1%, respectively. *Id.* at 8-10.

<sup>14.</sup> Tait D. Shanafelt & John H. Noseworthy, Executive Leadership and Physician Well-being: Nine Organizational Strategies to Promote Engagement and Reduce Burnout, 92 MAYO CLINIC PROC. 129, 130 (2017).

shortages.<sup>15</sup> Many doctors have reduced their hours in order to alleviate work pressures, retired early, or abandoned clinical practice for jobs in medical education, administration, or industry.<sup>16</sup> Medical students, perceiving clinicians' distress, may avoid fields with high burnout rates, such as general internal and emergency medicine, or may choose not to be clinical caregivers altogether.<sup>17</sup> Burnout, therefore is a public health threat that policy-makers cannot ignore.

A variety of medical organizations have undertaken initiatives to study and formulate recommendations to alleviate physician burnout.<sup>18</sup> One might assume that the task of solving the burnout problem should be left to the health care industry.

In truth, however, the welfare of physicians and their patients is very much a legal concern as well. Policy-makers have enacted extensive regulations to govern safety-critical jobs such as positions of responsibility in the transportation industry, and these focus in part on the well-being of workers. For example, a federal regulation provides that "[n]o pilot of an airplane that has a crew of two pilots may be on duty for more than 16 hours during any 24 consecutive hours."

Likewise, doctors perform safety-critical work when they treat their patients. Doctors routinely make life and death decisions about their patients. It is often within their power to cure sick individuals but also to injure them or end their lives through medical errors. Consequently, it is both sensible and necessary for the law to be employed to minimize burnout and enhance physician well-being.

Unfortunately, there is no single legal intervention that can solve the physician burnout problem. The article suggests a variety of changes that will constitute

<sup>15.</sup> Sarah Mann, *Research Shows Shortage of More than 100,000 Doctors by 2030*, ASS'N AM. MED. COLLS. (Mar. 14, 2017), https://news.aamc.org/medical-education/article/new-aamc-research-reaffirms-looming-physician-shor/ (discussing provider shortages).

<sup>16.</sup> Mark Linzer et al., *The End of the 15–20 Minute Primary Care Visit*, 30 J. GEN. INTERNAL MED. 1584, 1584 (2015); Janis M. Miyasaki et al., *Qualitative Study of Burnout, Career Satisfaction, and Well-Being Among US Neurologists in 2016*, 89 Neurology 1730, 1736 (2017); Sandra Gittlen, *Survey Snapshot: Fixing Burnout Through Physician Input*, NEJM CATALYST (Dec. 15, 2016), https://catalyst.nejm.org/survey-fixing-burnout-physician-input/. *See also infra* notes 91-97 and accompanying text.

<sup>17.</sup> Linzer et al., supra note 16, at 1584. See also infra notes 43, 85-86 and accompanying text.

<sup>18.</sup> See, e.g., Task Force on Physician Stress and Burnout, Executive Summary Highlights of Survey Findings Fall 2016, MED. Soc'y St. N. Y. (Mar. 31, 2017), https://www.mssny.org/Documents/HOD/2017/2017resolutions/Task%20Force/Task%20Force%2 0-%20Physician%20Stress%20and%20Burnout%20Executive%20Summary%203-31-17%20.pdf; Alexi A. Wright & Ingrid T. Katz, Beyond Burnout—Redesigning Care to Restore Meaning and Sanity for Physicians, 378 New Eng. J. Med. 309, 311 (2018) (discussing an initiative by the University of Colorado health system's Department of Family Medicine to institute a team-based model called APEX, standing for ambulatory process excellence).

<sup>19.</sup> See, e.g., 14 C.F.R. § 91.1062 (2018) (discussing duty periods and rest requirements for flight attendants). See also infra Part IV.

<sup>20. 14</sup> C.F.R. § 121.505(b) (2018).

building blocks for addressing the physician burnout phenomenon.

The remainder of the Article proceeds as follows. Part I describes the physician burnout problem, including its nature, consequences, and causes. Part II analyzes the impact of electronic health record systems on physician burnout. It focuses on the shortcomings of the technology itself as well as on the burdens that various EHR-related regulations impose. The Article argues that rather than facilitating EHR system use and supporting physicians, the regulations worsen clinicians' work conditions and exacerbate burnout. It also critiques the certification requirements for EHR products and highlights their failure to incorporate adequate usability testing. Part III discusses an additional but interrelated source of burnout: physicians' frustration at having to rush through appointments and their inability to spend adequate time with patients. Their time is constrained both by crushing administrative burdens and by pressure to generate income. This Part also details self-help measures to which physicians have turned, namely, employing scribes to handle EHR data entry and establishing innovative direct primary care practices. Part IV develops the argument that the law is an appropriate and necessary tool for remedying the physician burnout problem. Part V proposes a series of legal interventions. These include streamlining regulatory requirements, expanding usability testing for purposes of EHR certification, enabling purchasers to conduct acceptance testing,<sup>21</sup> assessing and reporting physician wellness indicators as quality measures, supporting providers' own initiatives to ease burnout, and conducting further research to better understand the problem and identify effective solutions. Part VI concludes.

#### I. PHYSICIAN BURNOUT: THE NATURE OF THE PROBLEM

## A. Physician Burnout

Burnout can be defined as "a syndrome characterized by emotional exhaustion and depersonalization (which includes negativity, cynicism, and the inability to express empathy or grief), a feeling of reduced personal accomplishment, loss of work fulfillment, and reduced effectiveness."<sup>22</sup>

Burnout in the health care professions is commonly measured using the Maslach Burnout Inventory (MBI).<sup>23</sup> The MBI is designed to evaluate the frequency and intensity of burnout among members of the helping professions by

<sup>21.</sup> See infra notes 374379-380385 and accompanying text.

<sup>22.</sup> Dzau et al., supra note 7, at 312.

<sup>23.</sup> Shanafelt et al., *supra* note 13, at 3 (stating that the MBI is considered "the standard tool for measuring burnout"); *Validated Instruments to Assess Work-Related Dimensions of Well-Being*, NAT'L ACAD. MED. (2018), https://nam.edu/valid-reliable-survey-instruments-measure-burnout-well-work-related-dimensions/#purpose (asserting that "[t]he Maslach Burnout Inventory is the gold standard for research purposes.").

focusing on three phenomena: 1) emotional exhaustion, 2) a sense of diminished personal accomplishment, and 3) depersonalization.<sup>24</sup> It contains twenty-two items, each of which is rated twice: once for frequency (on a seven-point scale ranging from never to every day) and once for intensity (using an eight-point scale ranging from none to major).<sup>25</sup>

Several analysts have criticized the MBI and deemed it a flawed instrument.<sup>26</sup> They assert that it suffers from a number of shortcomings, including that its cutoff scores are arbitrary and that it ignores factors such as childcare pressures, having a supportive partner, and financial worries.<sup>27</sup> They also note that the MBI was developed initially to measure burnout among social service professionals and posit that it is unclear that it is an effective tool when assessing physicians.<sup>28</sup>

Moreover, some experts question the distinction between burnout and depression and posit that in reality burnout is a depressive disorder.<sup>29</sup> Arguably, the term "burnout" is preferred simply because it is less stigmatizing than "depression." In response, defenders of the burnout concept assert that burnout is "job-related and situation-specific," whereas clinical depressive conditions are "more general and context-free."<sup>30</sup> This controversy need not be resolved here. Whether it is called burnout or depression, it is clear that physicians are suffering work-related, adverse mental health consequences. Because the majority of the literature has embraced the term "burnout," I will continue to use it in this Article.

<sup>24.</sup> Edward F. Iwanicki & Richard L. Schwab, *A Cross Validation Study of the Maslach Burnout Inventory*, 41 EDUC. & PSYCHOL. MEASUREMENT 1167, 1168 (1981).

<sup>25.</sup> Id.; Yvonne Gold, The Factorial Validity of the Maslach Burnout Inventory in a Sample of California Elementary and Junior High School Classroom Teachers, 44 Educ. & Psychol. Measurement 1009, 1010 (1984).

<sup>26.</sup> See Jodie Eckleberry-Hunt et al., The Problems with Burnout Research, 93 ACAD. MED. 367, 367-68 (2018); Thomas L. Schwenk & Katherine J. Gold, Physician Burnout—A Serious Symptom, But of What?, 320 JAMA 1109, 1110 (2018) ("The MBI needs further validation among physicians, particularly the interplay between the 3 domains used to assess burnout.").

<sup>27.</sup> Eckleberry-Hunt et al., *supra* note 26, at 367-68; Raquel Marie Schears, *Defining Physician Burnout, and Differentiating between Burnout and Depression-II*, 92 MAYO CLINIC PROC. 1455, 1456 (2017).

<sup>28.</sup> Schwenk & Gold, supra note 26, at 1110.

<sup>29.</sup> *Id.* ("Clinical depressive disorders have more solid grounding, methods of measurement, pathophysiological foundation, and empirically proven approaches to treatment of varying levels of severity"); Kirsi Ahola et al., *Relationship Between Burnout and Depressive Symptoms: A Study Using the Person-Centered Approach*, 1 BURNOUT RES. 29, 29 (2014) (discussing "the conceptual similarity between burnout and depressive symptoms in the work context"); Renzo Bianchi & Irvin Sam Schonfeld, *Defining Physician Burnout, and Differentiating Between Burnout and Depression-1*, 92 MAYO CLINIC PROC. 1455, 1455 (2017) (asserting that "we think that a critical step is to understand burnout as a depressive condition" (emphasis omitted)); Irvin Sam Schonfeld & Renzo Bianchi, *Burnout and Depression: Two Entities or One?*, 72 J. CLINICAL PSYCHOL. 22, 22, 31-32 (2016) ("The state of burnout is likely to be a form of depression.").

<sup>30.</sup> Edward R. Melnick et al., *In Reply—Defining Physician Burnout, and Differentiating between Burnout and Depression*, 92 MAYO CLINIC PROC. 1456, 1457 (2017) (emphasis omitted).

I will use the term "depression" when discussing that condition specifically.

By all accounts, a startling number of physicians report symptoms of burnout. Dr. Tait Shanafelt, who has studied physician burnout for many years, found that in 2017, forty-four percent of physicians in the United States suffered from one or more symptoms of professional burnout.<sup>31</sup> He notes that burnout spiked in 2014, when it reached over fifty-four percent, and is now in the vicinity of its 2011 level.<sup>32</sup> However, the percentage of physicians suffering from depression consistently increased from 38.2% in 2011 to 39.8% in 2014 to 41.7% in 2017.<sup>33</sup> According to the study, during these years, the rate of burnout in the general working population in the United States remained steady at approximately twenty-eight percent.<sup>34</sup>

Other studies have confirmed the pervasiveness of physician burnout. In a 2015 survey, forty-six percent of physicians indicated that they suffered from burnout.<sup>35</sup> The Medical Society of the State of New York (MSSNY) conducted a survey in 2016 and concluded that fifty-seven percent of New York physicians are burned-out.<sup>36</sup> Moreover, only fifty-eight percent of New York physicians would choose to be doctors if they were currently selecting a career path.<sup>37</sup> The 2016 Physicians Foundation survey concluded that among 17,236 respondents, fifty-four percent had "somewhat or very negative" morale, forty-nine percent "often or always" felt burned-out, and forty-nine percent would counsel their children against pursuing a career in medicine.<sup>38</sup> A 2018 study of U.S. resident physicians

<sup>31.</sup> Shanafelt et al., supra note 13, at 7.

<sup>32.</sup> *Id.* (stating that the 2011 burnout rate was 45.5%). It is noteworthy that the 2017 study was smaller than its predecessor, involving 4893 respondents compared to 6767 in 2014 and 7227 in 2011. *Id.* The 2017 study had a 17.1% response rate compared to the 2014 study's 19.2% response rate. *See* Tait D. Shanafelt et al., *Changes in Burnout and Satisfaction with Work-Life Balance in Physicians and the General US Working Population Between 2011 and 2014*, 90 MAYO CLINIC PROC. 1600, 1600 (2015). Dr. Shanafelt explains that the positive change in burnout rates between 2014 and 2017 may be attributable to several factors. Physicians may have adjusted to using EHR systems, the unhappiest doctors may have left practice or reduced their hours to alleviate stress, and some employers have instituted effective wellness initiatives. Shanafelt et al., *supra* note 13, at 11.

<sup>&</sup>lt;sup>33</sup> Shanafelt et al., *supra* note 13, at 7.

<sup>34.</sup> *Id.* at 8. See also, Tait Shanafelt et al., Burnout and Satisfaction with Work-Life Balance Among US Physicians Relative to the General US Population, 172 ARCHIVES INTERNAL MED. 1377, 1377 (2012) ("Burnout is more common among physicians than among other US workers."). But see William B. Weeks, Physician Burnout-Overdiagnosis and Unproven Interventions, 178 JAMA INTERNAL MED. 576, 576 (2018) (questioning the results of the 2014 study because of its low response rate of 19.2%).

<sup>35.</sup> Carol Peckham, *Physician Burnout: It Just Keeps Getting Worse*, MEDSCAPE 1 (Jan. 26, 2015), https://www.medscape.com/viewarticle/838437 (reporting that the self-reported burnout rate was just under forty percent in 2013 and increased to forty-six percent in 2015).

<sup>36.</sup> Task Force on Physician Stress and Burnout, supra note 18.

<sup>37.</sup> Id.

<sup>38. 2016</sup> Survey of America's Physicians: Practice Patterns and Perspectives, 2016 PHYSICIANS FOUND. BIANN. PHYSICIAN SURV. 1, 7 (2016), https://physiciansfoundation.org/wp-

concluded that even these freshly-minted doctors suffer from burnout at a rate of 48.8%, which is often accompanied by "career choice regret." <sup>39</sup>

A recent large-scale international study may inform how we weigh the above conclusions. The systematic review examined 182 studies from forty-five countries that involved 109,628 physicians. <sup>40</sup> It found "remarkable variability in published prevalence estimates of burnout, with estimates of overall burnout ranging from 0% to 80.5%." It attributed this broad range to significant differences in the ways burnout was defined and measured in the studies. <sup>42</sup> Consequently, the review could reach no definitive conclusion about burnout prevalence among physicians globally. This finding may raise questions about the burnout figures cited in U.S.-focused studies as well.

The degree of physician burnout varies by specialty and demographics. Those in high-stress fields such as emergency medicine, general internal medicine, general surgery, and neurology, are at higher risk of burnout than those in dermatology, pathology, anesthesiology, or occupational medicine. <sup>43</sup> In addition, female physicians and those under fifty-five years old are more vulnerable to burnout. <sup>44</sup> To illustrate, according to the MSSNY study, sixty-three percent of female doctors in New York identified as experiencing burnout compared to fifty-three percent of male physicians. <sup>45</sup> Furthermore, peak burnout in New York was evident ten to nineteen years after the completion of training. <sup>46</sup> A different study involving 422 family physicians and general internists found that women physicians reported burnout nearly twice as often as did their male counterparts. <sup>47</sup>

The burnout phenomenon has spread to other health care providers as well.

content/uploads/2017/12/Biennial Physician Survey 2016.pdf.

<sup>39.</sup> Liselotte N. Dyrbye et al., Association of Clinical Specialty with Symptoms of Burnout and Career Choice Regret among U.S. Resident Physicians, 320 JAMA 1114, 1119 (2018).

<sup>40.</sup> Lisa S. Rotenstein et al., *Prevalence of Burnout among Physicians: A Systematic Review*, 320 JAMA 1131, 1143 (2018).

<sup>41</sup> *Id* 

<sup>42.</sup> Id. at 1143-44 (finding "142 unique definitions" of burnout).

<sup>43.</sup> Dyrbye et al., *supra* note 7; Dyrbye et al., *supra* note 39, at 1119, 1129; Shanafelt et al., *supra* note 13, at 7; John Squiers et al., *Physician Burnout: Are We Treating the Symptoms Instead of the Disease?* 104 Annals Thoracic Surgery 1117, 1118 (2017).

<sup>44.</sup> Dyrbye et al., *supra* note 7; Mark Linzer & Eileen Harwood, *Gendered Expectations: Do They Contribute to High Burnout Among Female Physicians?*, 33 J. GEN. INTERNAL MED. 963, 963 (2018) (arguing that "gender differences in patient panels and gendered expectations of female physicians may contribute to the high rate of burnout among female clinicians, as well as to the many female physicians working part-time to reduce stress in their work lives"); West et al., *supra* note 12, at 516.

<sup>45.</sup> Task Force on Physician Stress and Burnout, supra note 18.

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

<sup>47.</sup> Joseph Rabatin et al., *Predictors and Outcomes of Burnout in Primary Care Physicians*, 7 J. PRIMARY CARE & COMMUNITY HEALTH 41, 42 (2016) (reporting, however, that there were "no differences in burnout by age").

One study found that one-third of oncology physician assistants report burnout.<sup>48</sup> A different study identified burnout as a serious problem among rural physician assistants.<sup>49</sup> Studies of nurses have revealed alarming rates of burnout as well.<sup>50</sup> One investigation concluded that burnout disproportionately affects nurses in neonatal intensive care units.<sup>51</sup> Another found high burnout rates among nurses working in hospitals and nursing homes, reaching thirty-four and thirty-seven percent respectively.<sup>52</sup>

The United States is not the only country exposed to physician burnout. By many accounts, it is prevalent internationally.<sup>53</sup> For example, there are urgent calls to address physician burnout in Canada,<sup>54</sup> the United Kingdom,<sup>55</sup> Israel,<sup>56</sup> and even Finland.<sup>57</sup>

<sup>48.</sup> Eric Daniel Tetzlaff et al., National Study of Burnout and Career Satisfaction Among Physician Assistants in Oncology: Implications for Team-Based Care, 14 J. Oncology Prac. e11, e11 (2018).

<sup>49.</sup> Marc A. Benson et al. *Burnout in Rural Physician Assistants: An Initial Study*, 27 J. Physician Assistant Educ. 81, 81 (2016).

<sup>50.</sup> Dyrbye et al., *supra* note 7.

<sup>51.</sup> Daniel S. Tawfik et al., Factors Associated with Provider Burnout in the NICU, 139 PEDIATRICS e20164134 (2017).

<sup>52.</sup> Matthew D. McHugh et al., Nurses' Widespread Job Dissatisfaction, Burnout, and Frustration with Health Benefits Signal Problems for Patient Care, 30 HEALTH AFFS. 202, 204-5 (2011).

<sup>53.</sup> Kamran Azam et al., Causes and Adverse Impact of Physician Burnout: A Systematic Review, 27 J. C. Physicians & Surgeons Pak. 495 (2017) (reviewing studies conducted in the United States, Australia, Taiwan, Pakistan, Malaysia, Yemen, Iran, China, Hong Kong, Denmark, Japan, Germany, France, and Italy); Carolyn S. Dewa et al., The Relationship Between Physician Burnout and Quality of Healthcare in Terms of Safety and Acceptability: A Systematic Review, 7 BMJ OPEN e015141(2017) (reviewing studies of physician burnout published in the United States, Germany Greece, Israel, Japan, China and Taiwan); Andrew Leung Luk & Adrian Fai To Yau, Experiences of Public Doctors on Managing Work Difficulties and Maintaining Professional Enthusiasm in Acute General Hospitals: A Qualitative Study, 6 FRONTIERS PUB. HEALTH. 19, 19 (2018) ("Overseas studies suggest that 10-20% of doctors are depressed, 30-45% have burnout, and many report dissatisfaction with work-life balance."); West et al., supra note 12, at 516.

<sup>54.</sup> Lauren Vogel, *CMA Must Address Physician Burnout, Pharmacare, Say Doctors*, 189 CAN. MED. ASS'N J. e1171, e1171 (2017) ("Doctors called for urgent action on physician burnout and universal pharmacare at the Canadian Medical Association (CMA) General Council meeting in Quebec City.").

<sup>55.</sup> Udemezue O. Imo, Burnout and Psychiatric Morbidity Among Doctors in the UK: A Systematic Literature Review of Prevalence and Associated Factors, 41 B.J. PSYCH. BULL. 197, 197, 201 (2017).

<sup>56.</sup> Alan H. Rosenstein, *Addressing Physician Stress, Burnout, and Compassion Fatigue: The Time Has Come*, 2 ISR. J. HEALTH POL'Y RES. 32, 32 (2013) (discussing a study that "highlights the growing problem of stress, burnout, and loss of compassion in our physician population").

<sup>57.</sup> Tarja Heponiemi et al., Finnish Physicians' Stress Related to Information Systems Keeps Increasing: A Longitudinal Three-Wave Survey Study, 17 BMC MED. INFO. DECISION MAKING. 147, 148 (2017); Tarja Heponiemi et al., Predictors of Physicians' Stress Related to Information Systems: A Nine-Year Follow-Up Survey Study, 18 BMC HEALTH SERVS. RES. 284, 284 (2018).

Although the scope of the problem is global, this Article is limited to addressing professional burnout in the United States. While I do not wish to minimize the severity of the phenomenon among other health care professionals, I focus primarily on physicians in this piece.

## B. The Consequences of Burnout

Burnout has far-reaching effects on physicians and patients. These fall generally into three categories: diminished physician well-being, poor quality of care, and workforce attrition.

## 1. Physician Well-Being

Burnout takes a heavy toll on physicians' mental health. As noted above, it is characterized by emotional exhaustion, negativity, cynicism, and a sense of lack of accomplishment and job fulfillment. Not surprisingly, therefore, assuming that it is distinct from depression, the can lead to depression. In addition, physicians with high burnout scores suffer from insomnia and poor sleep quality at significantly higher rates than colleagues with lower levels of burnout. Burnout victims are also vulnerable to marital problems, substance abuse, and even suicide. Approximately four hundred physicians commit suicide each year in the United States. Experts have noted that "[o]f all occupations and professions, the medical profession consistently hovers near the top of occupations with the highest risk of death by suicide."

An even larger number experience suicidal ideation, that is, thoughts of suicide with or without a plan to end one's life.<sup>65</sup> In a study of 7905 surgeons, 501

<sup>58.</sup> See supra note 22 and accompanying text.

<sup>59.</sup> See supra notes 29-30 and accompanying text.

<sup>60.</sup> DeCaporale-Ryan et al., *supra* note 8, at 454 (noting that burnout is "a condition that is widely believed to lead and contribute to depression"); Bruce Sigsbee & James L. Bernat, *Physician Burnout: A Neurologic Crisis*, 83 Neurology 2302 (2014); Walter Wurm et al., *Depression-Burnout Overlap in Physicians*, 11 PLoS ONE e0149913 (2016) (demonstrating "the overlap of burnout and major depression in terms of symptoms" and questioning the traditional, "three-dimensional concept of burnout").

<sup>61.</sup> Antonio Vela-Bueno et al., Insomnia and Sleep Quality among Primary Care Physicians with

Low and High Burnout Levels, 64 J. PSYCHOSOMATIC RES. 435, 439 (2008)

<sup>62.</sup> DeCaporale-Ryan et al., supra note 8, at 454.

<sup>63.</sup> *Id.*; *see also* Louise B. Andrew, *Physician Suicide*, MEDSCAPE (June 17, 2017), https://emedicine.medscape.com/article/806779-overview (estimating that every day a physician commits suicide in the United States).

<sup>64.</sup> See Andrew, supra note 63; see also Pauline Anderson, Physicians Experience Highest Suicide Rate of Any Profession, MEDSCAPE (May 7, 2018), https://www.medscape.com/viewarticle/896257.

<sup>65.</sup> Robert I. Simon, Passive Suicidal Ideation: Still a High-Risk Clinical Scenario, 13

or 6.4% reported suicidal ideation during the prior twelve months. Suicidal ideation was 1.5 to 3.0 times more common among surgeons who were forty-five and older than among their counterparts in the general population.<sup>66</sup>

## 2. Quality of Care

There is substantial agreement that physician burnout adversely affects care quality and patient safety. <sup>67</sup> In a variety of studies, physicians self-reported that burnout caused them to make treatment mistakes. <sup>68</sup> One national study of surgeons involved 7905 participants. <sup>69</sup> Seven hundred of them (8.9%) reported that they had made what they consider to be a major medical error in the last three months. <sup>70</sup> The researchers noted that "each one point increase in depersonalization, emotional exhaustion, and mental QOL [quality of life] score was associated with a 5% to 11% higher likelihood of reporting a recent major medical error." <sup>71</sup> Medical residents who identify as suffering from burnout similarly perceive that they provide a lower quality of care to patients. <sup>72</sup> A study of emergency physicians, who work in one of the most stressful environments, also assessed themselves as providing "suboptimal care" when suffering from burnout. <sup>73</sup> Researchers acknowledge, however, the possibility that the causal relationship is reversed and that making medical mistakes is what causes physicians to feel burned-out rather

CURRENT PSYCHIATRY 13, 13 (2014).

<sup>66.</sup> Tait Shanafelt et al., Special Report: Suicidal Ideation among American Surgeons, 146 AMA Archives Surgery 54, 55 (2011).

<sup>67.</sup> See, e.g., Tait Shanafelt & Lotte Dyrbye, Oncologist Burnout: Causes, Consequences, and Responses, 30 J. CLINICAL ONCOLOGY 1235, 1237 (2012) (asserting that a "strong association between burnout and medical errors among practicing physicians has... been documented."); Shanafelt & Noseworthy, supra note 14, at 130; Jean E. Wallace, Jane B. Lemaire & William A. Ghali, Physician Wellness: A Missing Quality Indicator, 374 LANCET 1714, 1716-18 (2009). But see Joseph Rabatin et al., Predictors and Outcomes of Burnout in Primary Care Physicians, 7 J. PRIMARY CARE & COMMUNITY HEALTH 41, 41-42 (2016) (using 2002-03 data and concluding that "[p]hysicians reporting burnout at baseline and 12 months were not more likely to err or to provide lower-quality care than physicians who reported burnout once or never").

<sup>68.</sup> See, e.g., Tait D. Shanafelt et al., Burnout and Medical Errors among American Surgeons, 251 Annals Surgery 995, 997 (2010); Eric S. Williams et al., The Relationship of Organizational Culture, Stress, Satisfaction, and Burnout with Physician-Reported Error and Suboptimal Patient Care: Results from the MEMO Study, 32 HEALTH CARE MGMT. REV. 203, 206 (2007).

<sup>69.</sup> Shanafelt et al., *supra* note 68, at 997.

<sup>70.</sup> *Id.* at 995 (defining medical error as "a commission or omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences").

<sup>71.</sup> Id. at 997.

<sup>72.</sup> Tait D. Shanafelt et al., Burnout and Self-Reported Patient Care in an Internal Medicine Residency Program, 136 Annals Internal Med. 358, 358 (2002); Colin P. West et al., Association of Perceived Medical Errors with Resident Distress and Empathy, 296 JAMA 1071, 1071 (2006).

<sup>73.</sup> Dave W. Lu et al., *Impact of Burnout on Self-Reported Patient Care Among Emergency Physicians*, 16 W. J. EMERGENCY MED. 996, 999 (2015).

than vice versa.74

Several studies have attempted to develop objective evidence of a link between burnout and adverse health care outcomes. For example, one investigation focused on 178 pairs of patients who had been hospitalized in the prior year and their physicians. It concluded that the depersonalization aspect of physician burnout was associated with lower patient satisfaction and longer recovery time after hospital discharge. A meta-analysis of eighty-two studies including 210,669 health care providers found "small to medium-sized relationships between burnout and both decreased quality of care and decreased [patient] safety."

A few studies have found that errors are associated with depression but not with burnout that has not progressed to depression. One study focused on 123 residents in three U.S. children's hospitals, twenty-four of whom met the criteria for depression and ninety-two of whom met the criteria for burnout.<sup>78</sup> It found that residents with depression made 6.2 times as many drug errors per resident month as those without depression.<sup>79</sup> However, burnout alone did not appear to be associated with a higher rate of medication errors.<sup>80</sup> Likewise, a study of thirty-one intensive care units in France found that medical errors were associated with clinicians' depression but not burnout.<sup>81</sup>

## 3. Workforce Attrition

Physician burnout endangers patients not only through possible medical errors but also by contributing to already significant deficits in the physician workforce. By some accounts, physician shortages may reach crisis proportions in the near future. Reach according to the Association of American Medical Colleges, by 2030, the

<sup>74.</sup> Shanafelt et al., *supra* note 68, at 997 (conceding that the authors were "unable to determine whether distress causes errors or errors cause distress").

<sup>75.</sup> Jonathon R. B. Halbesleben & Cheryl Rathert, *Linking Physician Burnout and Patient Outcomes: Exploring the Dyadic Relationship Between Physicians and Patients*, 33 HEALTH CARE MGMT. REV. 29, 29 (2008).

<sup>76.</sup> *Id.* at 33-34. *See also* Renée A. Scheepers et al., *A Systematic Review of the Impact of Physicians' Occupational Well-Being on the Quality of Patient Care*, 22 INT'L. J. BEHAV. MED. 683, 696 (2015) (finding "that physicians' occupational well-being could positively contribute to patient satisfaction and the quality of interpersonal aspects of care").

<sup>77.</sup> Michelle P. Salyers et al., *The Relationship Between Professional Burnout and Quality and Safety in Healthcare: A Meta-Analysis*, 32 J. GEN. INTERNAL MED. 475, 479 (2017).

<sup>78.</sup> Amy M. Fahrenkopf et al., Rates of Medication Errors Among Depressed and Burnt out Residents: Prospective Cohort Study, 336 BMJ 488, 488 (2008).

<sup>79.</sup> Id.

<sup>80.</sup> Id.

<sup>81.</sup> Maite Garrouste-Orgeas et al., *The Iatroref Study: Medical Errors Are Associated with Symptoms of Depression in ICU Staff but Not Burnout or Safety Culture*, 41 INTENSIVE CARE MED. 273, 273 (2015).

<sup>82.</sup> See Aaron E. Carroll, A Doctor Shortage? Let's Take a Closer Look, N.Y. TIMES, Nov. 7,

United States will experience a shortage of between 42,600 and 121,300 doctors.<sup>83</sup> In the area of primary care, it predicts a shortfall of between 14,800 and 49,300 by 2030.<sup>84</sup>

It is already difficult to recruit medical students to the fields of internal medicine and primary care because students perceive these to be high-stress jobs. 85 Students observe physicians who are burned-out and opt for other specialties. 86

This trend is extremely troubling because competent primary care is often vital to maintaining good health. Primary care physicians practice general medicine and are able to diagnose and treat a multitude of conditions as well as prevent illnesses through vaccinations, screening, consistent monitoring, and other preventive interventions. Ideally, primary care physicians maintain thorough familiarity with their patients' health conditions and oversee all of their care. While specialists treat particular conditions in isolation, primary care physicians can ensure that a patient's care does not become fragmented and is well-coordinated.

Furthermore, because of the growing pressures of medical practice, some physicians are reducing their work hours or retiring early. 91 For example, a study

<sup>2016,</sup> https://www.nytimes.com/2016/11/08/upshot/a-doctor-shortage-lets-take-a-closer-look.html (explaining both the view that the country will soon experience a dire physician shortage and the argument that "there's no shortage at all—just a poor distribution of the doctors we have").

<sup>83.</sup> Association of American Medical Colleges, *New Research Shows Increasing Physician Shortages in Both Primary and Specialty Care*, AAMCNEWS PRESS RELEASE (April 11, 2018), https://news.aamc.org/press-releases/article/workforce\_report\_shortage\_04112018/; TIM DALL ET AL., THE COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS FROM 2016 TO 2030, 3 (2018).

<sup>84.</sup> Association of American Medical Colleges, *supra* note 83.

<sup>85.</sup> Mark Linzer et al., 10 Bold Steps to Prevent Burnout in General Internal Medicine, 29 J. GEN. INTERNAL MED. 18, 18 (2014) ("Recruitment of medical students into general internal medicine is worrisomely low, and may relate in part to the perceived stressfulness of a primary care career."); Linzer et al., supra note 16, at 1584.

<sup>86.</sup> Linzer et al., *supra* note 16, at 1584 ("Students observe harried primary care providers and choose alternative career paths."); Colin P. West & Karen E. Hauer, *Reducing Burnout in Primary Care: A Step toward Solutions*, 30 J. GEN. INTERNAL MED. 1056, 1056 (2015) ("Students demonstrate little interest in primary care careers, and even those who choose primary care training programs often depart for other specialty areas along the way.").

<sup>87.</sup> West & Hauer, *supra* note 86, at 1056 (asserting that "[p]rimary care is the cornerstone of high-quality health care systems across the world").

<sup>88.</sup> *The Importance of a Primary Care Provider*, MAYO CLINIC HEALTH SYS. (April 7, 2015), https://mayoclinichealthsystem.org/hometown-health/speaking-of-health/the-importance-of-a-primary-care-provider.

<sup>89.</sup> Id.

<sup>90.</sup> See Sharona Hoffman, Aging with a Plan: How a Little Thought Today Can Vastly Improve Your Tomorrow 73-5 (2015).

<sup>91.</sup> Thomas Bodenheimer et al., *Continuity and Access in the Era of Part-Time Practice*, 16 ANNALS FAM. MED. 359, 359 (2018) ("In 2011, 22% of male physicians and 44% of female physicians worked less than full time, up from 7% and 29% in 2005."); Miyasaki et al., *supra* note

at the Mayo Clinic found that the percentage of its physicians working less than full-time increased from 13.5 to 16.0 between 2008 and 2014.<sup>92</sup> These numbers correlated with burnout rates.<sup>93</sup> Women in particular often choose to work part-time.<sup>94</sup>

Many who have not already taken action to alleviate burnout assert that they plan to do so in the future. A 2008 study involving 7615 surgeons who were members of the American College of Surgeons found that approximately forty percent of participants experienced burnout and thirty-two percent reported "at least a moderate likelihood" that they would leave their current practice within the next two years. Among the latter, 58.5% indicated they planned to stop being surgeons and pursue other work. An analysis of data from the 2016 Physicians Foundation Survey revealed that only fifty-two percent of respondents planned to continue as they are in the next one to three years, and all others planned to take steps to improve their quality of life, such as reducing their hours, seeking a non-clinical health care job, or retiring.

As the American population ages, the demand for physicians will only grow. 98 Professional burnout may be a significant hindrance to meeting this critical need.

## C. The Causes of Burnout

What are the primary reasons for burnout among physicians in the United States? The literature identifies many causes.

In 2015, Medscape conducted a survey of physicians and inquired about burnout causes.<sup>99</sup> Physicians were asked to rank the causes on a scale of one to seven.<sup>100</sup> In order of importance, along with their average scores, they were as follows:

- Too many bureaucratic tasks (4.74)
- Too many hours at work (3.99)

<sup>16,</sup> at 1736.

<sup>92.</sup> Tait D. Shanafelt et al., Longitudinal Study Evaluating the Association Between Physician Burnout and Changes in Professional Work Effort, 91 MAYO CLINIC PROC. 422, 426 (2016).

<sup>93.</sup> Id. at 422, 426-27.

<sup>94.</sup> *Id.* at 426; Linzer & Harwood, *supra* note 44, at 963.

<sup>95.</sup> Tait D. Shanafelt et al., Why Do Surgeons Consider Leaving Practice?, 212 J. Am. C. SURGEONS 421, 421 (2011).

<sup>96.</sup> *Id*.

<sup>97. 2016</sup> Survey of America's Physicians: Practice Patterns and Perspectives, supra note 38, at 7.

<sup>98.</sup> Dyrbye et al., *supra* note 7 (discussing the need to provide "care for an aging population with high rates of chronic disease and co-morbidities").

<sup>99.</sup> Peckham, supra note 35.

<sup>100.</sup> Id.

- Insufficient income (3.71)
- Increasing computerization (3.68)
- The impact of the Affordable Care Act (3.65)
- Feeling like just a cog in a wheel (3.54)
- Too many difficult patients (3.37)
- Too many patient appointments in a day (3.34)
- Inability to provide patients with a high level of quality care (3.22)
- Lack of professional fulfillment (3.05)
- Difficult colleagues or staff (2.90)
- Inability to keep up with current research (2.85)
- Compassion fatigue (2.80)
- Difficult employer (2.80)<sup>101</sup>

The MSSNY 2016 survey found the following drivers of burnout, listed in order of prevalence. <sup>102</sup> The percentage of respondents who identified the stressor as a factor in burnout is indicated in parentheses.

- Length and degree of documentation requirements (65.99%)
- Extension of work into home life (e-mail, record completion, phone calls) (58.27%)
  - Prior authorizations for medications/procedures/admissions (54.74%)
  - Dealing with difficult patients (51.89%)
  - EMR functionality problems (51.05%)
  - CMS/State/Federal laws and regulations (44.33%)
  - Lack of voice in being able to decide what good care is (40.39%)
  - Hospital/Insurer imposed Quality Metrics (38.87%)
  - Dealing with difficult colleagues (31.49%)
  - Requirement for increased CME [Continuing Medical Education]/maintenance of certification (31.49%)<sup>103</sup>

A 2014 survey conducted by the Wisconsin Medical Society listed three factors as the primary causes of dissatisfaction and burnout among physicians: decrease in direct patient care, EHRs, and poor work-life balance. <sup>104</sup> Other experts emphasize that the cumbersome and time-consuming administrative tasks that contemporary physicians face are a root cause of burnout. <sup>105</sup>

<sup>101.</sup> Id.

<sup>102.</sup> Taskforce on Physician Stress and Burnout, supra note 18.

<sup>103.</sup> Id.

<sup>104.</sup> Michele Coleman et al., Factors Affecting Physician Satisfaction and Wisconsin Medical Society Strategies to Drive Change, 114 WMJ 135, 137-39 (2015).

<sup>105.</sup> Tait D. Shanafelt et al., *Addressing Physician Burnout: The Way Forward*, 317 JAMA 901, 901 (2017) ("Unlike many industries in which advances in technology have improved efficiency,

Two interrelated sources of burnout emerge as repeated themes in the literature. First is the transition to EHRs and associated clerical burdens, and second is inadequate time for face-to-face interactions with patients. Each of these could potentially be addressed through regulation, and thus, the remainder of this Article will focus on these two drivers of physician burnout.

#### II. ELECTRONIC HEALTH RECORD SYSTEMS AND PHYSICIAN BURNOUT

The EHR system has become the "virtual patient" that many believe demands more time than human patients. <sup>106</sup> This Part explains what EHR systems are and describes their benefits and shortcomings. It also analyzes the link between EHR systems and physician burnout. Finally, it describes and critiques the web of EHR-related regulations that are arguably key contributors to burnout. These include the Meaningful Use regulations, the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, <sup>107</sup> and EHR certification requirements.

## A. Electronic Health Record Systems

In 2004, President George W. Bush identified the transition from traditional paper records to EHRs as a priority for the federal government. President Bush set a goal of having all Americans' health records computerized within ten years and established the Office of the National Coordinator for Health Information Technology (ONC) within the U.S. Department of Health and Human Services to promote and oversee this process. The transition accelerated under the Obama administration. The Health Information Technology for Economic and Clinical Health (HITECH) Act, 110 part of the Obama stimulus plan, provided financial incentives for meaningful use of certified EHRs. 111 Today the vast majority of

EHRs appear to have increased clerical burden for physicians and can distract some physicians from meaningful interactions with patients."); Squiers et al., *supra* note 43, at 1120 (stating that the authors "believe that one important mismatch is obvious to most practicing physicians—the increasing demands of medical bureaucracy that is at odds with and distracts from their primary passions of medical practice (e.g. patient care, research, and teaching)").

<sup>106.</sup> Miyasaki et al., supra note 16, at 1736.

<sup>107.</sup> Pub. L. No. 114-10, 129 Stat. 87 (2015) (codified as amended in scattered sections of 16, 26, and 42 U.S.C.).

<sup>108.</sup> Joseph Conn, 10 Years after the Revolution: Health IT Coordinators Look Back at the Nation's Progress, Modern Healthcare (Apr. 5, 2014), http://www.modernhealthcare.com/article/20140405/MAGAZINE/304059980.

<sup>109.</sup> Id.

<sup>110.</sup> Pub. L. No. 111-5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

<sup>111.</sup> David Blumenthal & Marilyn Tavenner, *The 'Meaningful Use' Regulation for Electronic Health Records*, 363 New Eng. J. Med. 501, 501 (2010); Sharona Hoffman & Andy Podgurski, *Meaningful Use and Certification of Health Information Technology: What About Safety?*, 39 J.L.

practices have adopted EHR systems.<sup>112</sup> As of 2016, over ninety-five percent of hospitals eligible to participate in the HITECH incentive program and over sixty percent of all office-based physicians are using EHR systems in compliance with the program.<sup>113</sup> Many more physicians have EHRs but have not fulfilled all of the incentive program's requirements.<sup>114</sup>

The Institute of Medicine, the Robert Wood Johnson Foundation, and other experts<sup>115</sup> identified eight "core EHR functionalities" that could make them more useful and versatile than paper records:

Clinical documentation and health information display: EHR systems record and display a wealth of information such as diagnostic test results, allergies, medication lists, diagnoses, demographics, clinicians' notes, advance directives, and more.

Results management: EHRs enable clinicians to search the record for details such as a patient's laboratory test results and prior treatments, thus enhancing their access to needed information.

Computerized provider order entry and management (CPOE): Health care providers can order prescriptions, diagnostic tests, treatments, and referrals to other physicians electronically.

Clinical decision support: This is a potentially life-saving feature that generates alerts and reminders for clinicians. Examples are warnings about drug interactions or side effects, guidance regarding appropriate medication dosage, and prompts relating to preventive and wellness care.

MED. & ETHICS (SUPP. ISSUE 1), 77, 77 (2011).

<sup>112.</sup> Hospital Progress to Meaningful Use, Off. Nat'l Coordinator for Health Info. Tech. (2016) https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-Progress-to-Meaningful-Use-by-size-practice-setting-area-type.php; Office-based Health Care Professional Participation in the CMS EHR Incentive Programs, Off. Nat'l Coordinator for Health Info. Tech. (2016), https://dashboard.healthit.gov/quickstats/pages/FIG-Health-Care-Professionals-EHR-Incentive-Programs.php.

<sup>113.</sup> See supra note 112.

<sup>114.</sup> National Center for Health Statistics, *Electronic Medical Records/Electronic Health Records (EMRs/EHRs)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 31, 2017, https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm (indicating that 86.9% of office-based physicians use some type of EHR system).

<sup>115.</sup> Institute of Medicine, Key Capabilities of an Electronic Health Record System 7-11 (2003); Timothy G. Ferris, et al., *A Framework for Measuring the Effects of Health Information Technology on Health Care Quality, in* Health Information Technology in the United States: Where We Stand 178-79 (David Blumenthal et al. eds., Robert Wood Johnson Foundation, 2008).

Electronic communication and connectivity: EHR systems enable medical team members to communicate online with each other, with other providers whom they might consult, and with patients. More communication can enhance the patient's treatment experience and results.

Patient support: EHR systems can facilitate patient education and access to health records. Some systems offer patients a personal health record, which is "[a]n electronic application through which individuals can access, manage and share their health information . . . in a private, secure, and confidential environment." The systems also may remind patients to pursue preventive and follow-up care.

Administrative processes: Additional components include electronic scheduling systems, insurance eligibility verification, billing, and claims processing. Clinicians can further use computerized tools to identify individuals who are potential candidates for clinical trials, who are taking drugs subject to recalls, or who are eligible for chronic disease management programs. EHR systems can also facilitate quality assessment, quality improvement, public health, and other initiatives.

Reporting and population health management: Health care providers can collect clinical data to meet government, private, and institutional reporting requirements.<sup>117</sup>

EHR systems advocates have touted the many benefits that they can yield. These include enhancing the quality of care, improving patient safety, saving costs, and facilitating medical research and public health initiatives. 118 A key advantage is that EHRs eliminate the problem of illegible handwriting in physician notes and prescriptions. 119

Nevertheless, many physicians complain bitterly that contemporary EHR systems and the regulations that govern them generate cumbersome and time-

<sup>116.</sup> Paul C. Tang et al., Personal Health Records: Definitions, Benefits, and Strategies for Overcoming Barriers to Adoption, 13 J. Am. MED. INFORMATICS ASS'N 121, 122 (2006).

<sup>117.</sup> INSTITUTE OF MEDICINE, *supra* note 115, at 7-11; INSTITUTE OF MEDICINE, HEALTH IT AND PATIENT SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE 38-44 (2012); Ferris, et al., *supra* note 115, at 78-79.

<sup>118.</sup> Sharona Hoffman, Electronic Health Records and Medical Big Data: Law and Policy 15-23 (2016).

<sup>119.</sup> George A. Gellert et al., *Should US Doctors Embrace Electronic Health Records*?, 356 BMJ j242, j242 (2017).

consuming work. Consequently, many believe that EHR systems are a significant cause of burnout. 120

## B. The Link between EHR Systems and Burnout

Contemporary physicians spend as much as fifty percent of their total work time on documentation. According to one study, for each hour that doctors spend face-to-face with patients, they spend up to two hours on documentation. Moreover, physicians spend one to two hours outside the office each day on computer work. This phenomenon has spawned a new term popular among health care providers: "pajama time." A leading expert, Dr. Robert Wachter, has explained that "EHRs contribute to burnout by turning physicians into unhappy data-entry clerks."

A study of EHR system use at a community hospital concluded that even in the emergency room, physicians spent forty-four percent of their time on EHR work, which far exceeded the amount of time they devoted to direct patient care (twenty-eight percent). The EHR work required an average of four hundred mouse clicks per hour and thus 4000 clicks in a ten-hour shift. 127

Of course, before the advent of EHR systems, physicians were also required

<sup>120.</sup> N. Lance Downing et al., *Physician Burnout in the Electronic Health Record Era: Are We Ignoring the Real Cause?*, 169 ANNALS INTERNAL MED. 50, 50 (2018) (arguing that "there is a growing sense within the medical community that the EHR is driving professional dissatisfaction and burnout"); Jesse Ehrenfeld & Jonathan Wanderer, *Technology as Friend or Foe? Do Electronic Health Records Increase Burnout?*, 31 CURRENT OP. ANAESTHESIOLOGY. 357, 357 (2018) (asserting that "there is growing concern about the adverse consequences of [EHR] use on physician satisfaction and burnout").

<sup>121.</sup> Alexander K. Ommaya et al., Care-Centered Clinical Documentation in the Digital Environment: Solutions to Alleviate Burnout, NAT'L ACAD. MED. DISCUSSION PAPER, (Jan. 29, 2018), https://nam.edu/care-centered-clinical-documentation-digital-environment-solutions-alleviate-burnout/ ("Recent studies have shown that physicians spend as much as 50 percent of their time completing clinical documentation."); Christine Sinsky et al., Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties, 165 ANNALS INTERNAL MED. 753, 755 (2016) (finding that "[d]uring the office day, physicians spent 27.0% of their total time on direct clinical face time with patients and 49.2% of their time on EHR and desk work").

<sup>122.</sup> Sinsky et al., supra note 121, at 757. But see Ming Tai-Seale et al., Electronic Health Record Logs Indicate That Physicians Split Time Evenly Between Seeing Patients and Desktop Medicine, 36 HEALTH AFFS. 655, 655 (2017) (studying 471 primary care physicians and finding that "the physicians logged an average of 3.08 hours on office visits and 3.17 hours on desktop medicine each day").

<sup>123.</sup> Sinsky et al., *supra* note 121, at 756-57.

<sup>124.</sup> Ommaya et al., supra note 121.

<sup>125.</sup> Roger Collier, *Electronic Health Records Contributing to Physician Burnout*, 189 CMAJ E1405, E1405 (2017).

<sup>126.</sup> Robert G. Hill Jr. et al., 4000 Clicks: A Productivity Analysis of Electronic Medical Records in a Community Hospital ED, 31 Am. J. EMERGENCY Med. 1591, 1592 (2013). 127. Id.

to document their diagnoses and treatments thoroughly and to comply with health care regulatory requirements. <sup>128</sup> However, by many accounts, computerization has exacerbated rather than alleviated the onus of these tasks. <sup>129</sup>

The explanation for this perplexing change lies in the design and functionality of contemporary EHR systems. EHR products often have user interfaces<sup>130</sup> that are not intuitive and are difficult to navigate.<sup>131</sup> Fixed templates restrict physicians' ability to enter information in sensible and natural ways, and patient charts are plagued by information overload.<sup>132</sup> In the era of paper records, physicians could dictate notes or jot down notes at their own discretion, but now they spend up to six times longer on computer tasks.<sup>133</sup>

Another inefficiency arises from excessive alerts and reminders, also called clinical decision support.<sup>134</sup> Electronic alerts and reminders can save lives, and they are a welcome addition to the health care toolkit. However, in practice, they

<sup>128.</sup> See Ommaya et al., supra note 121 (discussing clinical documentation and coding requirements).

<sup>129.</sup> Tait D. Shanafelt et al., Relationship Between Clerical Burden and Characteristics of the Electronic Environment with Physician Burnout and Professional Satisfaction, 91 MAYO CLINIC PROC. 836, 846 (2016) (noting that in their current form, EHRs have "a variety of unintended negative consequences that reduce efficiency, increase clerical burden, and increase the risk of burnout for physicians").

<sup>130.</sup> The user interface is the "application that allows users to enter data into a computer and that presents data to the user." EDWARD H. SHORTLIFFE & JAMES J. CIMINO, BIOMEDICAL INFORMATICS: COMPUTER APPLICATIONS IN HEALTH CARE AND BIOMEDICINE 997 (2006).

<sup>131.</sup> Id. See also, Saif Khairat et al., Focus Section on Health IT Usability: Perceived Burden of EHRs on Physicians at Different Stages of Their Career, 9 APPLIED CLINICAL INFORMATICS 336, 344 (2018) (observing fourteen emergency physicians and concluding that "the factors causing high EHR frustrations are: (1) remembering menu and button names and commands use; (2) performing tasks that are not straightforward; (3) system speed; and (4) system reliability" and that more senior physicians experience more frustrations than younger doctors).

<sup>132.</sup> HOFFMAN, supra note 118, at 29-32.

<sup>133.</sup> Paul Dechant, How Does the EHR Drive Burnout? Let's Count the Ways, KEVINMD.COM (August 13, 2017), https://www.kevinmd.com/blog/2017/08/ehr-drive-burnout-lets-count-ways.html; Sun Young Park et al., The Effects of EMR Deployment on Doctors' Work Practices: A Qualitative Study in the Emergency Department of a Teaching Hospital, 81 INT'L J. MED. INFORMATICS 204, 204 (2012) (concluding that implementation of an EHR system increased "documentation time four to five fold"); Lise Poissant et al., The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review, 12 J. Am. MED. INFORMATICS ASS'N 505, 508 (2005) (finding that CPOE increased physicians' work time between 98.1% and 328.6%).

<sup>134.</sup> Megan E. Gregory et al., *Electronic Health Record Alert-Related Workload as a Predictor of Burnout in Primary Care Providers*, 8 APPLIED CLINICAL INFORMATICS 686, 688, 693 (2017) (finding that primary care physicians' subjective perception that they had inadequate time to manage EHR alerts contributed to burnout); Tina Shah et al., *Impact of a National QI Programme on Reducing Electronic Health Record Notifications to Clinicians*, BMJ QUALITY & SAFETY 1, 1 (2018).

can exacerbate burnout. A study of the primary care physicians working for the Department of Veteran Affairs revealed that seventy percent felt they could not effectively manage the number of alerts they received. 135 Moreover, thirty percent indicated that during the prior year, they had missed patient test results because of alert burden and consequently delayed patient care. 136 Another research project concluded that primary care physicians received a mean of 56.4 alerts with new information per day and spent an average of forty-nine minutes per day processing these alerts. 137 All too many alerts are boilerplate notifications that relate to trivial drug risks that are not of clinical significance or matters that do not apply to the patient in question. 138 According to one study, it takes over 331 alerts to prevent one adverse drug event, and just ten percent of notifications account for seventyeight percent of cost savings from preventable errors. 139 While alerts are worthwhile if they avert even one critical medical mistake and expense reduction is always appreciated, physicians commonly complain of "alert fatigue" and long for improved clinical decision support that would issue only serious warnings that could meaningfully enhance care. 140

Yet another source of information overload is the EHR's copy and paste feature. <sup>141</sup> The ability to copy narrative from a prior visit and paste it into new visit notes is designed to save clinicians time. <sup>142</sup> Ironically, however, this feature may waste a great deal of time because it can make the medical record repetitive and excessively voluminous. <sup>143</sup> Because of such "note bloat," reviewing a patient's record prior to a visit or locating particular details within it can become a slow and arduous task. <sup>144</sup> Moreover, if the copied information is not carefully edited and updated, the new visit notes could be erroneous and mislead or confuse physicians. <sup>145</sup> For example, in one reported case, the EHR of a patient who suffered

<sup>135.</sup> Hardeep Singh et al., *Primary Care Practitioners' Views on Test Result Management in EHR-Enabled Health Systems: A National Survey*, 20 J. Am. MED. INFORMATICS ASS'N 727, 731 (2013).

<sup>136</sup> Id

<sup>137.</sup> Daniel R. Murphy et al., Notifications Received by Primary Care Practitioners in Electronic Health Records: A Taxonomy and Time Analysis, 125 Am. J. MED. 209.e1, 209.e5 (2012). 138. HOFFMAN, supra note 118, at 28-29.

<sup>139.</sup> Saul N. Weingart et al., An Empirical Model to Estimate the Potential Impact of Medication Safety Alerts on Patient Safety, Health Care Utilization, and Cost in Ambulatory Care, 169 ARCHIVES INTERNAL Med. 1465, 1465 (2009).

<sup>140.</sup> NICK ZAGORSKI, *ARE TODAY'S EHR ALERTS PUTTING CLINICIANS, PATIENTS AT RISK?*, PSYCH. News, July 19, 2017, https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2017.5b23.

<sup>141.</sup> Ommaya et al., supra note 121.

<sup>142.</sup> HOFFMAN, supra note 118, at 25.

<sup>143.</sup> Ommaya et al., *supra* note 121 (indicating that because of the practice of copying and pasting, "the EHR has become a bloated repository of repetitive and redundant information").

<sup>144.</sup> *Id.* (stating that "clinical notes have become bloated and difficult to read," which forces clinicians "to go through a process of foraging to uncover important elements" of the record).

<sup>145.</sup> Sue Bowman, Impact of Electronic Health Record Systems on Information Integrity:

surgical complications and was hospitalized for many weeks indicated each day that this was "post-op day No. 2" because the note was repeatedly copied but never edited.<sup>146</sup>

Many clinicians have also complained generally about EHR system usability. Usability is a term that refers to "the extent to which a product can be used by specified users to achieve specified goals with *effectiveness*, *efficiency*, and *satisfaction* in a specified context of use." Contemporary EHR systems suffer from a number of inadequacies that make them difficult to operate. For example, physicians find that they are difficult to navigate, display information poorly, do not enable users to search easily for data, disrupt the natural workflow of health care operations, and do not enable clinicians to use language effectively to tell the patient's story. Experimentation with different user interface configurations has confirmed that optimized configuration can reduce physicians' task load, shorten the time it takes to complete tasks, and even lower error rates. A few suggestions concerning features that enhance EHR usability are offered in Part V.B below.

EHR systems contribute to physician burnout not only because of the technology itself, but also because of the regulations that govern them. EHR regulations are analyzed in the next section.

## C. The Regulatory Burden: Meaningful Use, MACRA, and Certification

In 2009, in an effort to dramatically advance EHR systems' adoption, Congress enacted the HITECH Act. <sup>150</sup> The law established an incentive program by which qualified health care providers could receive incentive payments for becoming meaningful users of certified EHR systems. <sup>151</sup> Health care providers could receive incentive payments from Medicare through 2016 and from Medicaid

Quality and Safety Implications, 10 Persp. Health Info. Mgmt. 1, 4 (2013).

<sup>146.</sup> Kevin B. O'Reilly, *EHRs: 'Sloppy and Paste' Endures Despite Patient Safety Risk*, AM. MED. NEWS, Feb. 4, 2013, http://www.amednews.com/article/20130204/profession/130209993/2/.

<sup>147.</sup> Tom Tullis & Bill Albert, Measuring the User Experience: Collecting, Analyzing, and Presenting Usability Metics 4 (2008).

<sup>148.</sup> *Id.* at 808-11; HOFFMAN, *supra* note 118, at 29-30 (discussing EHR systems' inflexibility and lack of customization); Ommaya et al., *supra* note 121, at 4 ("The patient's story is . . . lost in the fog of self-populated content that adds pages but little purpose to the notes.").

<sup>149.</sup> Adil Ahmed et al., *The Effect of Two Different Electronic Health Record User Interfaces on Intensive Care Provider Task Load, Errors of Cognition, and Performance*, 39 CRITICAL CARE MED. 1626, 1627, 1633 (2011) (reporting on the design of a novel user interface that displayed "a subset of high-value data").

<sup>150.</sup> Pub. L. No. 111-5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

<sup>151.</sup> Blumenthal & Tavenner, *supra* note 111, at 501; Hoffman & Podgurski, *supra* note 111, at 77. Providers could receive up to \$44,000 through Medicare or \$63,750 through Medicaid, depending on eligibility.

until 2021.<sup>152</sup> The program is now named the Promoting Interoperability (PI) Program.<sup>153</sup> In order to implement the HITECH Act, the Centers for Medicare and Medicaid Services (CMS) issued a series of regulations that establish the standards for meaningful use and EHR system certification. Meaningful Use standards have also been incorporated into a second law, MACRA.<sup>154</sup> This section addresses the regulations that are relevant to physician burnout and analyzes their pitfalls.

## 1. The Meaningful Use Regulations and MACRA

The Meaningful Use regulations and MACRA require physicians to perform a variety of functions using their EHR systems. Both have been criticized by commentators as overly burdensome and needlessly causing physicians distress. Both are analyzed below.

## a. The Meaningful Use Regulations

The Meaningful Use regulations aim to ensure that clinicians put EHR systems to good use and employ them to improve health outcomes.<sup>155</sup> They were rolled out in three stages, with the intention of allowing health care providers to adjust their practices gradually in order to fully utilize EHR systems.<sup>156</sup> Stage 3 Meaningful Use regulations became effective in 2017.<sup>157</sup> They establish eight objectives for professionals and hospitals that are eligible for incentives:

- 1) Protect patient health information
- 2) Generate and transmit prescriptions electronically
- 3) Implement clinical decision support
- 4) Use computerized provider order entry
- 5) Provide patients with electronic access to health information
- 6) Coordinate care through patient engagement
- 7) Engage in health information exchange

<sup>152.</sup> HOFFMAN, *supra* note 118, at 39-40. Eligible professionals had to select participation in either the Medicare or Medicaid program, but eligible hospitals could participate in both simultaneously. 42 C.F.R. §§ 495.60(e), 495.310(c), 495.310(g) (2018).

 $<sup>153.\ \</sup>textit{Medicare and Medicaid Promoting Interoperability Program Basics}, CTRS.\ FOR\ MEDICARE \& \ MEDICAID\ SERVS.\ (May\ 9,\ 2018), \ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Basics.html.}$ 

<sup>154.</sup> Pub. L. No. 114-10, 129 Stat. 87 (2015) (codified as amended in scattered sections of 16, 26, and 42 U.S.C.).

<sup>155.</sup> Centers for Disease Control and Prevention, *Meaningful Use* (Jan. 18, 2017), https://www.cdc.gov/ehrmeaningfuluse/introduction.html.

<sup>156.</sup> HOFFMAN, *supra* note 118, at 42.

<sup>157.</sup> Id.

## 8) Report data to public health authorities or clinical data registries 158

Health care providers participating in the PI program must also submit clinical quality measure (CQM) data to the Centers for Medicare and Medicaid Services. <sup>159</sup> CQMs focus on six primary domains:

- Patient and Family Engagement
- Patient Safety
- Care Coordination
- Population/Public Health
- Efficient Use of Healthcare Resources
- Clinical Process/Effectiveness<sup>160</sup>

Examples of CQMs are the "[p]ercentage of women 50-74 years of age who had a mammogram to screen for breast cancer" and the "[p]ercentage of patients 65 years of age and older who have ever received a pneumococcal vaccine." In 2018, eligible professionals receiving Medicaid EHR incentive payments must report six out of fifty-three CQMs. 163

#### b. MACRA

Physicians seeking Medicare payments must learn to comply with a new law

<sup>158. 42</sup> C.F.R. § 495.22(e) (2018); Eligible Hospital and Critical Access Hospital Medicaid EHR Incentive Program Stage 3 Objectives and Measures Table of Contents, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 2017), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/TableofContents EH Medicaid Stage3. pdf; Eligible Professional Medicaid EHR Incentive Program Stage 3 Objectives and Measures Table of Contents, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/ TableofContents EP Medicaid Stage3.pdf; Stage 3 Program Requirements for Providers Attesting to their State's Medicaid Promoting Interoperability (PI) Programs, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 25, 2018), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage3Medicaid Require.html.

<sup>159.</sup> Clinical Quality Measures Basics, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 8, 2018), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html.

<sup>160.</sup> Id.

<sup>161.</sup> Breast Cancer Screening, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 14, 2018), https://ecqi.healthit.gov/ecqm/measures/cms125v7.

<sup>162.</sup> Pneumococcal Vaccination Status for Older Adults, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 14, 2018), https://ecqi.healthit.gov/ecqm/measures/cms127v7.

<sup>163.</sup> Program for 2018 Reporting, CTRS. FOR MEDICARE & MEDICAID SERVS. (March 26, 2018), https://ecqi.healthit.gov/ecqms/ecqm-news/cms-clarifies-ecqm-requirements-eligible-professionals-eps-under-medicaid-electronic.

as well, MACRA, which went into effect in 2017.<sup>164</sup> MACRA, in relevant part, aims to decrease clinicians' administrative burdens by consolidating three quality reporting programs for Medicare purposes: 1) the Physician Quality Reporting System, 2) the Value-based Payment Modifier, and 3) Meaningful Use. It also adds a new performance category, however, called improvement activities.<sup>165</sup> MACRA does not apply to hospitals and does not affect the Medicaid Promoting Interoperability program.<sup>166</sup>

Under MACRA, physicians who wish to be paid by Medicare must participate in either the Merit-Based Incentive Payment System (MIPS) or an Advanced Alternative Payment Model (AAPM). MIPS creates a scoring system with a range from zero to one hundred and adjusts payment based on performance in four categories: quality, cost of care, promoting interoperability, and improvement activities. Based on their scores, physicians will receive positive, negative, or no Medicare payment adjustments. Thus, clinicians must scrupulously track and report the required data in compliance with complex and sometimes abstruse instructions in order to maximize Medicare payments and avoid penalties.

While most health care providers are subject to MIPS, some participate in an

<sup>164.</sup> Pub. L. No. 114-10, 129 Stat. 87 (2015) (codified as amended in scattered sections of 16, 26, and 42 U.S.C.); Virgil Dickson, *Physician Offices, Hospitals Still Trying to Prepare for MACRA's Reimbursement Changes*, Modern Healthcare (Aug. 26, 2017), http://www.modernhealthcare.com/article/20170826/NEWS/170829947.

<sup>165.</sup> Frequently Asked Questions: Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), AM. ACAD. FAM. PHYSICIANS (Jan. 2018), https://www.aafp.org/practice-management/payment/medicare-payment/macra-101/faq.html.

<sup>166. 42</sup> U.S.C. § 1395w-4(q) (Supp. 2016); 42 C.F.R. § 414.1310 (2018); HOFFMAN, *supra* note 118, at 46.

<sup>167.</sup> MACRA Basics Merit-based Incentive Payment System (MIPS), AM. ACAD. FAM. Physicians (Jan. 25, 2018), https://www.aafp.org/practice-management/payment/medicare-payment/mips.html. The regulations establish an exclusion for those meeting the "low volume threshold" of two hundred or fewer Medicare Part B beneficiaries or \$90,000 or less in billing for Part B covered services. See 42 C.F.R. §§ 414.1305, 414.1310(b) (2018).

<sup>168.</sup> In 2018 the categories were weighted as follows: quality – 50%, cost – 10%, promoting interoperability – 25%, and improvement activities – 15%. 42 U.S.C. § 1395w-4(q)(2)(A), (5) (Supp. 2016); 42 C.F.R. § 414.1380(c) (2018); *MACRA Basics Merit-based Incentive Payment System (MIPS)*, supra note 167171. In 2018 there were 275 available quality measures, and participants had to submit six that were relevant to their practice. See Quality Payment Program, CTRS. FOR MEDICARE & MEDICAID SERVS. (2018), https://qpp.cms.gov/mips/explore-measures/quality-measures?py=2018#measures.

<sup>169. 42</sup> U.S.C. § 1395w-4(q)(6) (Supp. 2016); 42 C.F.R. § 414.1405 (2018); MACRA Basics Merit-based Incentive Payment System (MIPS), supra note 167171.

<sup>170. 42</sup> U.S.C. § 1395w-4(q)(4)(B) (Supp. 2016); 42 C.F.R. § 414.1325 (2018); MACRA Basics Merit-based Incentive Payment System (MIPS), supra note 167171.

AAPM<sup>171</sup> and are exempt from MIPS.<sup>172</sup> Nevertheless, AAPM participants must still measure cost and quality and use certified EHR technology.<sup>173</sup>

#### c. Critique

If the foregoing sections were difficult for readers to follow, the regulations are all the more overwhelming for physicians who must comply with them. Undoubtedly, it is prudent to regulate EHR systems and track quality of care, and doing so should in principle promote improved health outcomes.<sup>174</sup> However, critics posit that the current reporting requirements are excessively arduous, repetitive, and inflexible and thus exacerbate burnout.<sup>175</sup>

John D. Halamka and Micky Tripathi, both renowned EHR experts, co-authored a commentary on the HITECH era in the *New England Journal of Medicine* in 2017.<sup>176</sup> They lamented that "confusing layers of regulations" caused the loss of the "hearts and minds of clinicians." To illustrate, they argued that "quality measurement added data collection requirements that had a substantial

<sup>171.</sup> The Centers for Medicare and Medicaid Services define an alternative payment model (APM) as "a payment approach, developed in partnership with the clinician community, that provides added incentives to clinicians to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population." *Quality Payment Program* 8, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 26, 2016), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf.

<sup>172. 42</sup> C.F.R. § 414.1310(b)(1)(ii) (2018); Answering Your FAQs about MIPS, MACRA AND APMS: The New Quality Payment Program Explained, MINGLE ANALYTICS (2018), https://mingleanalytics.com/confused-macra-mips-apms-explained-plain-english/; Quality Payment Program, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 26, 2016), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf. A subset of APMs are Advanced APMs.

<sup>173. 42</sup> U.S.C. § 1395l(z) (Supp. 2016); 42 C.F.R. § 414.1415 (2018).

<sup>174.</sup> See Sharona Hoffman & Andy Podgurski, Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems, 22 HARV. J.L. & TECH. 103 (2008); Quality Measure and Quality Improvement, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 24, 2017), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement-html (explaining that the aim of quality measures "is to optimize health outcomes by improving quality and transforming the health care system").

<sup>175.</sup> Shari M. Erickson et al., Putting Patients First by Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physicians, 166 Annals Internal Med. 659, app. (2017); Richard A. Young et al., The Challenges of Measuring, Improving, and Reporting Quality in Primary Care, 15 Annals Fam. Med. 175, 175 (2017); Sara Health, What Clinical Quality Measures Mean to Healthcare Providers, EHR Intelligence (July 1, 2016), https://ehrintelligence.com/features/what-clinical-quality-measures-mean-to-healthcare-providers.

<sup>176.</sup> John D. Halamka & Micky Tripathi, *The HITECH Era in Retrospect*, 377 New Eng. J. Med 907 (2017).

<sup>177.</sup> Id. at 907.

negative effect on usability with little return." Another author complained that the Meaningful Use regulations disrupt workflow because they require doctors to perform EHR tasks that non-physicians could otherwise handle. Likewise, the Medicare Payment Advisory Commission has asserted that MIPS is very complex and burdensome. 180

In his well-regarded book, *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age*, <sup>181</sup> Professor Robert Wachter critiqued the Stage 2 Meaningful Use regulations that preceded Stage 3. He posited that many of the mandates "depended on a clinical ecosystem and health care culture that did not yet exist." <sup>182</sup> For example, they required that more than five percent of patients "view, download, and transmit" their electronic health information to third parties. <sup>183</sup> Thus, physicians had to invest time in encouraging patients to engage in activities in which they may have no interest and from which they may not benefit.

In addition, the regulations required hospitals to transmit discharge summaries electronically to other facilities, <sup>184</sup> but they did not mandate that these summaries be useful to recipients. Consequently, some hospitals were spending time arbitrarily sending discharge summaries to other facilities for no good reason other than to "check a box on . . . [their] Stage 2 scorecard."<sup>185</sup>

As a third example, Dr. Wachter cited the requirement that doctors be prompted by their EHRs to provide educational materials to ten percent of their patients. <sup>186</sup> Doctors who routinely gave their patients information sheets about

<sup>178.</sup> Id

<sup>179.</sup> See supra note Error! Bookmark not defined. 136 and accompanying text.

<sup>180.</sup> Shannon Firth, MIPS Takes a Beating at MedPAC—Medicare Advisory Panel Says It Needs to Go, MEDPAGE TODAY (Oct. 5, 2017), https://www.medpagetoday.com/publichealthpolicy/medicare/68362.

<sup>181.</sup> ROBERT WACHTER, THE DIGITAL DOCTOR: HOPE, HYPE, AND HARM AT THE DAWN OF MEDICINE'S COMPUTER AGE (McGraw Hill Education, 2015).

<sup>182.</sup> Id. at 209.

<sup>183. 42</sup> C.F.R. § 495.20(j)(10)(ii)(B) (2018). Stage 3 retains this requirement. See 42 C.F.R. § 495.22(e)(8)(i)(A)(2)(ii) (2018). MIPS has a similar requirement. See Quality Payment Program, CTRS. FOR MEDICARE & MEDICAID SERVS. (2018), https://qpp.cms.gov/mips/explore-measures/quality-measures?py=2018#measures (requiring that at least one patient be "provided timely access to view online, download, and transmit his or her health information").

<sup>184. 42</sup> C.F.R. § 495.20(l)(11) (2018). Stage 3 retains this requirement. See 42 C.F.R. § 495.22(e)(5) (2018). MIPS has a related requirement. See Quality Payment Program, supra note 183187 (requiring that "[f]or at least one transition of care or referral received or . . . [encounter with a new patient], the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document").

<sup>185.</sup> WACHTER, *supra* note <u>181</u><del>185</del>, at 209.

<sup>186. 42</sup> C.F.R. § 495.20(j)(12)(ii) (2018). Stage 3 retains this requirement. See 42 C.F.R. § 495.22(e)(6) (2018). MIPS has a similar requirement. See Quality Payment Program, supra note 183187 (requiring that clinicians "use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient").

their conditions were not deemed in compliance. They had to find a way to have their EHR system *prompt* them to do so. According to the author, the regulations were so problematic that some clinicians referred to them as "Meaningless Abuse." <sup>187</sup>

## 2. EHR Certification

EHR certification regulations are designed to establish oversight and quality control for EHR products. Unfortunately, they fall short of ensuring optimal usability of EHR systems. Consequently, many clinicians feel that rather than diminishing their administrative burdens, computerization has caused these burdens to become even heavier. 189

## a. Regulatory Requirements

Health care providers that wish to participate in the incentive program must operate certified EHR systems.<sup>190</sup> ONC, a division of the U.S. Department of Health and Human Services, oversees the Health IT Certification Program.<sup>191</sup> Ideally, certification should ensure that a product is safe and user-friendly and that it facilitates clinicians' clerical tasks to the extent possible. However, that is not the primary focus of this certification process.<sup>192</sup>

The certification regulations focus on enabling EHR system users to fulfill the Meaningful Use objectives.<sup>193</sup> To illustrate, one certification criterion is that the EHR system enable users to "electronically record, change, and access" medication, laboratory, and radiology or imaging orders.<sup>194</sup>

Another regulatory provision requires that "[u]ser-centered design processes must be applied to each capability an EHR technology includes." User-centered design (UCD) prioritizes the cognitive and information needs of users. Although UCD evaluates the design and development process and focuses on the product's

<sup>187.</sup> WACHTER, supra note 181185, at 209-210. See also, G. Talley Holman et al., Meaningful Use's Benefits and Burdens for US Family Physicians, 25 J. Am. Med. Informatics Ass'n 694, 694 (2018) (stating that MACRA adopted the Meaningful Use (MU) criteria and that "[f]or many physicians, MU created a significant practice burden without clear benefits to patient care").

<sup>188. 45</sup> C.F.R. § 170.300, .314-.315, .545-.550, .555-.557 (2018).

<sup>189.</sup> See supra Part II.B.

<sup>190. 42</sup> U.S.C. § 1395w-4(o)(2) (Supp. 2016).

<sup>191.</sup> About the ONC Health IT Certification Program, HEALTHIT.GOV (Feb. 21, 2018), https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program.

<sup>192.</sup> HOFFMAN, supra note 118, at 46-49, 50-54.

<sup>193. 45</sup> C.F.R. § 170.315 (2018).

<sup>194. 45</sup> C.F.R. § 170.315(a)(1) (2018).

<sup>195. 45</sup> C.F.R. § 170.315(g)(3) (2018).

<sup>196.</sup> Raj M. Ratwani et al., Electronic Health Record Vendor Adherence to Usability Certification Requirements and Testing Standards, 314 JAMA 1070, 1070 (2015).

anticipated users, <sup>197</sup> it does not specify precise methods for the design process and does not evaluate the product itself.

Vendors who wish to obtain certification must attest to implementing a UCD process and must conduct and report the results of usability testing on eight specified EHR functions. <sup>198</sup> Vendors can develop their own UCD process or adopt well-respected processes, such as those published by the International Organization for Standardization or the National Institute of Standards and Technology. <sup>199</sup>

In order to conduct usability testing, vendors recruit participants to engage in representative tasks relating to the eight EHR capabilities.<sup>200</sup> Vendors then measure the amount of time it takes to complete the task, the number and types of errors found, and subjective user satisfaction with the way the EHR system operated.<sup>201</sup> According to ONC, vendors should include at least fifteen participants, and reports are made public once the EHR product is certified.<sup>202</sup>

## b. Usability Testing Critique

The certification process focuses only on a narrow set of technical meaningful use requirements in a controlled laboratory setting, and vendors are given testing scenarios in advance.<sup>203</sup> Thus, testing does not examine the product's capabilities in wide-ranging and diverse circumstances, such as those that exist in the real world.<sup>204</sup>

Moreover, vendors maintain a great deal of discretion with respect to usability

<sup>197.</sup> User-Centered Design Basics, USABILITY.GOV (Apr. 3, 2017), https://www.usability.gov/what-and-why/user-centered-design.html.

<sup>198.</sup> Raj M. Ratwani et al., Electronic Health Record Usability: Analysis of the User-Centered Design Processes of Eleven Electronic Health Record Vendors, 22 J. Am. MED. INFORMATICS ASS'N 1179, 1179 (2015). See also 45 C.F.R. § 170.314—315 (2018); Understanding Certified Health IT, OFF. NAT'L COORDINATOR FOR HEALTH INFO. TECH. (2015), https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf. The eight capabilities encompass clinical processes, care coordination, clinical quality measurement, privacy and security, patient engagement public health, health IT design and performance, and electronic exchange of information.

<sup>199.</sup> Ratwani et al., *supra* note 196201, at 1070.

<sup>200.</sup> *Id.* at 1181; Robert M. Schumacher & Svetlana Z. Lowry, National Institute of Standards and Technology, Customized Common Industry Format Template for Electronic Health Record Usability Testing 10 (2010), http://www.nist.gov/itl/hit/upload/LowryNISTIR-

<sup>7742</sup>Customized\_CIF\_Template\_for\_EHR\_Usability\_Testing\_Publicationl\_Version-doc.pdf.

<sup>201.</sup> SCHUMACHER & LOWRY, *supra* note <u>200</u>205, at 18-19.

<sup>202.</sup> Ratwani, et al., *supra* note <u>196200</u>, at 1070.

<sup>203.</sup> A. Jay Holmgren et al., Are All Certified EHRs Created Equal? Assessing the Relationship Between EHR Vendor and Hospital Meaningful Use Performance, 25 J. Am. MED. INFORMATICS. ASS'N 654, 659 (2018).

<sup>204.</sup> Id.

and invest varying amounts of resources in it.<sup>205</sup> According to one study, the quality of vendors' UCD processes ranges from well-developed to basic to misconceived.<sup>206</sup> A second study led by the same investigator found "a lack of adherence to ONC certification requirements and usability testing standards among several widely used EHR products that were certified as having met these requirements."<sup>207</sup>

The American Medical Association and MedStar Health's National Center for Human Factors in Healthcare have criticized the usability process for its "narrow focus on only eight capabilities among the dozens required by the ONC for the Meaningful Use (MU) program and to the absence of best practices in the certification process." They assert that many vendors do not implement best practices and are nevertheless certified by ONC. 209

Consequently, researchers cite persistent problems in the areas of data entry, alerts, interoperability of different systems, visual displays, availability of information, automation, default settings, workflow disruptions, electronic ordering, test results management, and more. EHR systems remain plagued by poor usability and excessive "click burden." These deficiencies not only contribute to physician burnout, but also may lead to medical errors and endanger patients. <sup>212</sup>

#### III. INABILITY TO SPEND ADEQUATE TIME WITH PATIENTS

One of the consequences of the very heavy administrative burdens with which physicians are saddled is that they spend relatively little time interacting face-to-face with patients. Thus, many lament that they cannot do what they love to do most as members of the healing profession. <sup>213</sup> Physicians are forced to rush through examining patients, listening to them, thoughtfully considering the reasons for

<sup>205.</sup> *Id.* at 655 ("Vendors... make different decisions about system architecture, user interface design, and functionality, which carry important implications for how they are implemented and used.").

<sup>206.</sup> Ratwani et al., *supra* note <u>198</u>202, at 1180.

<sup>207.</sup> Ratwani et al., *supra* note <u>196</u>200, at 1071.

<sup>208.</sup> National Center for Human Factors in Healthcare, *EHR User-Centered Design Evaluation Framework*, MEDSTAR HEALTH, https://www.medicalhumanfactors.net/ehr-vendor-framework/.

<sup>210.</sup> Jessica L. Howe et al., *Electronic Health Record Usability Issues and Potential Contribution to Patient Harm*, 319 JAMA 1276, 1277 (2018); Zahabi et al., *supra* note <u>147</u>451, at 808-811.

<sup>211.</sup> Guo et al., *supra* note 8, at 140.

<sup>212.</sup> Howe et al., *supra* note <u>210215</u>, at 1277; Kathryn M. Kellogg et al., *EHR Usability: Get It Right from the Start*, 51 BIOMEDICAL INSTRUMENTATION & TECH. 197, 197 (2017).

<sup>213.</sup> Larissa R. Thomas et al., *Charter on Physician Well-being*, 319 JAMA 1541, 1541 (2018) (asserting that "[a]uthentic, humanistic interactions with patients and colleagues enhance physician well-being").

their concerns, explaining diagnoses and treatments, and answering questions.<sup>214</sup> These time pressures contribute to physicians' dissatisfaction and burnout.<sup>215</sup> This section analyzes the length of time allotted for patient visits, the causes of short patient visits, and two self-help measures that physicians are using to increase the time they have with patients.

## A. Time Allotted for Patient Visits

The average primary care visit is fifteen to twenty minutes.<sup>216</sup> While relatively simple medical problems can be addressed in a few minutes, many cannot.<sup>217</sup> Experts note that because of our aging population, an increasing number of patients have multiple chronic ailments and complex needs.<sup>218</sup> The time allotted, therefore, is frequently inadequate to the task. Some experts posit that effective primary care visits often require thirty minutes or more.<sup>219</sup>

Medscape conducted its 2018 Physician Compensation Report by electronically surveying 20,329 physicians in twenty-nine specialties. The survey included a question about the number of minutes doctors generally spent with patients during visits. They responded as follows:

- Five percent spent fewer than five minutes per visit;
- Twenty-two percent spent between nine and twelve minutes per visit;
- Twenty-nine percent spent between thirteen and sixteen minutes per visit;
- Thirty-three percent spent between seventeen and twenty-four minutes per visit;

<sup>214.</sup> Thomas L. Schwenk, *Physician Well-being and the Regenerative Power of Caring*, 319 JAMA 1543, 1543 (2018) (bemoaning "the loss of the opportunity and ability for physicians to care in the current health care system").

<sup>215.</sup> Virginia Adams O'Connell et al., *Physician Burnout: The Effect of Time Allotted for a Patient Visit on Physician Burnout Among OB/GYN Physicians*, 24 J. MED. PRAC. MGMT. 300, 300 (2009) ("A factor associated with the likelihood of reporting burnout is lack of control over the pace of work, and one aspect of pace of work is the length of patient visits.").

<sup>216.</sup> Linzer et al., *supra* note 1617, at 1584; Peter Pronovost, *How the 15-Minute Doctor's Appointment Hurts Health Care*, WALL St. J. (Apr. 15, 2016), https://blogs.wsj.com/experts/2016/04/15/how-the-15-minute-doctors-appointment-hurts-health-care/.

<sup>217.</sup> Pronovost, *supra* note <u>216</u><del>221</del>.

<sup>218.</sup> Linzer et al., *supra* note 16, at 1584; Michael Stein, *When Medical Care is Delivered in 15-Minute Doses, There's Not Much Time for Caring*, WASH. POST, Nov. 13, 2015, https://www.washingtonpost.com/opinions/when-medical-care-is-delivered-in-15-minute-doses-theres-not-much-time-for-caring/2015/11/13/85ddba3a-818f-11e5-a7ca-6ab6ec20f839\_story.html.

<sup>219.</sup> Linzer et al., *supra* note 1616, at 1585.

<sup>220.</sup> Leslie Kane, *Medscape Physician Compensation Report 2018*, MEDSCAPE, https://www.medscape.com/slideshow/2018-compensation-overview-6009667.

<sup>221.</sup> Id. at 32.

• Eleven percent spent twenty-five minutes or longer per visit. 222

The 2016 Physicians Foundation survey revealed that only fourteen percent of doctors felt they have the time necessary to provide the highest quality of care. <sup>223</sup> Furthermore, eighty percent reported being overextended or at capacity and lacking time to see any additional patients. <sup>224</sup>

Even highly specialized physicians who care for complex patients are rushed for time. A study of neurologists found that they suffered burnout partly because of reduced time with patients and consequently diminished enjoyment of their work.<sup>225</sup>

It is important to recognize that patient visits that are too short have adverse consequences not only for physicians who are more likely to suffer burnout, but also for patients. Time pressures can lead to poor patient care. Providers may take abbreviated patient histories, conduct superficial physical exams, and order unnecessary tests because they do not have time to be more thoughtful about what course to pursue. Thus, spending more time with patients could not only increase physicians' career satisfaction but could also enhance patient welfare, improve treatment outcomes, and save the health care system money.

## B. Reasons for Short Visit Times

Physicians face an accumulation of demands and responsibilities that take time away from patient appointments. This section will focus on two areas: administrative work and financial pressures.

#### 1. Administrative Work

The work of operating EHR systems and complying with associated regulations, discussed extensively above, is no small factor in limiting the time that

<sup>222.</sup> Id.

<sup>223. 2016</sup> Survey of America's Physicians: Practice Patterns and Perspectives, supra note 38, at 7.

<sup>224.</sup> Id.

<sup>225.</sup> Miyasaki et al., supra note 16, at 1736.

<sup>226.</sup> Linzer et al., *supra* note 16, at 1584.

<sup>227.</sup> *Id.* (positing that physicians do not have time to develop a deep understanding of patients' conditions or to consider psychosocial determinants of health, and these shortcomings can "translate to decreased patient satisfaction, excess emergency room usage and non-adherence to treatment plans").

<sup>228.</sup> See Kim Tingley, Trying to Put a Value on the Doctor-Patient Relationship, N.Y. TIMES MAG. May 16, 2018, at 43, https://www.nytimes.com/interactive/2018/05/16/magazine/health-issue-reinvention-of-primary-care-delivery.html (recounting that a primary care practice that spent more time with patients was able to reduce hospitalizations by twenty percent).

doctors can devote to face-to-face patient care.<sup>229</sup> However, it is not the only culprit.

Physicians grapple with a myriad of additional administrative demands arising from regulatory mandates and other obligations. For example, as noted above, MACRA includes numerous reporting requirements, many of which are unrelated to EHR systems.<sup>230</sup> Physicians must also interact with public health authorities and submit certain data to them, such as information about communicable diseases.<sup>231</sup>

Health care payers and regulators require clinicians to report a multitude of quality and performance measures. The National Quality Measures Clearinghouse lists over 2500 performance measures. CMS alone uses as many as 1700 measures with which providers may have to be familiar. Performance measures have faced increasing criticism in recent years. One survey found that only twenty-seven percent of physicians felt that contemporary measures were "moderately or very representative of the quality of care" they provide. Another assessed the validity of eighty-six of the 271 measures in MIPS's Quality Payment Program and determined that only thirty-two were valid, whereas thirty were invalid, and twenty-four were of uncertain validity. 235

Obtaining insurance payments from either private or public insurance payers is a work-intensive and time-consuming endeavor.<sup>236</sup> In addition to reporting quality measures, health care providers must be prepared to handle eligibility verification, billing, prior authorization, appeals of coverage denials, referrals, and much more.<sup>237</sup> Billing requires expertise with respect to Evaluation/Management Codes, International Classification of Diseases Tenth Revision (ICD-10), Relative Value Units, and the Geographic Practice Cost Index, among other matters.<sup>238</sup>

<sup>229.</sup> See supra Part II.

<sup>230.</sup> See *supra* notes <u>164168-170174</u> and accompanying text.

<sup>231.</sup> Communicable Disease Reporting, N.Y. STATE DEP'T HEALTH (Feb. 2015), https://www.health.ny.gov/professionals/diseases/reporting/communicable/ ("Reporting of suspected or confirmed communicable diseases is mandated under the New York State Sanitary Code.").

<sup>232.</sup> Catherine H. MacLean et al., *Time Out—Charting a Path for Improving Performance Measurement*, 378 New Eng. J. Med. 1757, 1757 (2018).

<sup>233.</sup> Gail Wilensky, *The Need to Simplify Measuring Quality in Health Care*, 319 JAMA 2369, 2370 (2018) (stating that MIPS is very burdensome and "would cost about \$1.3 billion to implement").

<sup>234.</sup> Lawrence P. Casalino et al., US Physician Practices Spend More than \$15.4 Billion Annually to Report Quality Measures, 35 HEALTH AFFS. 401, 402 (2016).

<sup>235.</sup> MacLean et al., *supra* note <u>232237</u>, at 1757-58.

<sup>236.</sup> Erickson et al., supra note 175179, at app.

<sup>237.</sup> Id.

<sup>238.</sup> Centers for Medicare and Medicaid Services, How to Use the Searchable Medicare Physician Fee Schedule (MPFS) 4, 8 (2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-

MLN/MLNProducts/Downloads/How to MPFS Booklet ICN901344.pdf; What Is ICD-10?, Am.

Another source of administrative tasks is board certification, evaluation, and accreditation by professional entities such as the American Board of Internal Medicine,<sup>239</sup> the Joint Commission,<sup>240</sup> the National Committee for Quality Assurance,<sup>241</sup> and others. Interacting with vendors and suppliers and ordering medical equipment likewise can entail considerable administrative hassles.<sup>242</sup>

#### 2. Financial Pressures

Financial pressures abound as well. Medicare established the relative value unit (RVU) payment model in the early 1990s.<sup>243</sup> RVUs are calculated based on the physician's work, the expenses of the medical practice, and the cost of medical malpractice insurance.<sup>244</sup> To illustrate, in 2014, an intermediate office visit was assigned 3.01 RVUs, a diagnostic colonoscopy 11.03 RVUs, and a total hip replacement 38.94 RVUs.<sup>245</sup>

In order to enhance their total RVUs, health systems began to pressure physicians to increase the number of patients they saw and meet daily visit targets. The reimbursement system incentivizes all clinicians to do more in order to be paid more." Even salaried physicians working for well-established medical centers face powerful financial inducements. The majority receive "productivity bonuses." In some cases, their salaries are directly tied to RVUs, or they suffer wage deductions if their RVUs are too low. 249

ACAD. PROF. CODERS (2018), https://www.aapc.com/icd-10/icd-10.aspx.

<sup>239.</sup> Certification by the American Board of Internal Medicine (ABIM), AM. BD. INTERNAL MED., https://www.abim.org/about/mission.aspx ("Certification by the American Board of Internal Medicine (ABIM) has stood for the highest standard in internal medicine and its 20 subspecialties.").

<sup>240.</sup> What is Certification?, JOINT COMM'N, https://www.jointcommission.org/certification/certification\_main.aspx ("Certification is earned by programs or services that may be based within or associated with a health care organization.").

<sup>241.</sup> About NCQA, NAT'L COMM. FOR QUALITY ASSURANCE, https://www.ncqa.org/about-ncqa/ ("Since 2008, our mission has brought us closer to where care is delivered: We've grown to measure the quality of medical providers and practices.").

<sup>242.</sup> Erickson et al., *supra* note 175<del>179</del>, at app.

<sup>243.</sup> Linzer et al., *supra* note 16, at 1584.

<sup>244.</sup> The Basics: Relative Value Units (RVUs), NAT'L HEALTH POL'Y F. (Jan. 12, 2015), at 1, https://www.nhpf.org/library/the-basics/Basics RVUs 01-12-15.pdf.

<sup>245.</sup> *Id.* at 2.

<sup>246.</sup> Linzer et al. *supra* note 16, at 1584-85.

<sup>247.</sup> Robert Fifer, *Health Care Economics: The Real Source of Reimbursement Problems*, AM. SPEECH-LANGUAGE-HEARING ASS'N (July 2016), https://www.asha.org/Articles/Health-Care-Economics-The-Real-Source-of-Reimbursement-Problems/.

<sup>248.</sup> ELISABETH ROSENTHAL, AN AMERICAN SICKNESS: HOW HEALTHCARE BECAME BIG BUSINESS AND HOW YOU CAN TAKE IT BACK 37 (2017); Dhruv Khullar et al., *How 10 Leading Health Systems Pay Their Doctors*, 3 HEALTHCARE 60, (2015) (finding that of ten leading health systems, five "use productivity-adjusted salaries").

<sup>249.</sup> ROSENTHAL, *supra* note <u>248253</u>, at 37.

Medical employers routinely hire consultants and health care advisory firms in an effort to increase revenues.<sup>250</sup> Today, few physicians work independently. Over seventy-five percent of doctors were employed by large health care organizations in 2014,<sup>251</sup> and forty-two percent were employed by hospitals as of 2016.<sup>252</sup> A majority of physicians thus work in environments that are likely influenced by fiscal consultants and the income-maximizing pressures they create.

#### 3. Loss of Clinical Autonomy

A related concern is that physicians employed by large organizations often feel that they are deprived of clinical autonomy. The 2016 Physicians Foundation survey found that loss of autonomy was the second most commonly cited reason for job dissatisfaction, behind only regulatory and paperwork burdens (listed by 58.3% and 31.8% of respondents, respectively). Remarkably, a 2018 study concluded that physicians in practices with five or fewer doctors in New York City had only a 13.5% burnout rate. The researchers attributed the very low burnout rate to the independence that physicians in small practices enjoy. Among other benefits, such autonomy allows doctors to spend more time with patients and form deeper relationships with them.

Because of administrative and financial pressures, most contemporary physicians are said to "have one eye on the patient and one eye on the clock." This phenomenon takes a toll both on patients and doctors who often feel profoundly disappointed with a career that they assumed would enable them to focus first and foremost on caring for their patients.

<sup>250.</sup> *Id.* at 35 (stating that Deloitte is ranked the top health care consulting firm and enjoyed record revenues of \$34.2 billion in 2014).

<sup>251.</sup> Shanafelt et al., supra note 32, at 1608.

<sup>252.</sup> Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012-2016, PHYSICIAN ADVOC. INST., (Mar. 2018), http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/2016-PAI-Physician-Employment-Study-Final.pdf.

<sup>253. 2016</sup> Survey of America's Physicians: Practice Patterns and Perspectives, supra note 38, at 13.

<sup>254.</sup> Batel Blechter et al., Correlates of Burnout in Small Independent Primary Care Practices in an Urban Setting, 31 J. Am. BD. FAM. MED. 529, 529 (2018) (involving "235 providers practicing in 174 small independent primary care practices in New York City").

<sup>255.</sup> Id. at 531-32.

<sup>256.</sup> Id. at 532.

<sup>257.</sup> Roni Caryn Rabin, *15-Minute Doctor Visits Take a Toll on Patient-Physician Relationships*, PBS NEWS HOUR (Apr. 21, 2014, 10:52 AM), https://www.pbs.org/newshour/health/need-15-minutes-doctors-time.

### C. Physicians' Efforts to Increase Time with Patients

Some doctors have taken matters into their own hands. They have crafted partial solutions to alleviate some of the burdens contributing to physician burnout. This section will analyze two approaches: 1) scribes and 2) direct primary care.

#### 1. Scribes

Scribes are professionals who shadow physicians and do the work of EHR data entry while the doctors interact with patients. Employing a scribe can significantly reduce the time the doctor must spend on documentation. Doctors employed close to 17,000 scribes in 2016, and the number is expected to grow to 100,000 by 2020. At least twenty-two companies supply scribes and provide them with pre-employment training. Scribes are often pre-medical college students or graduates. Scribes are often pre-medical college students or graduates.

Not all physicians are equally enthusiastic about scribes.<sup>264</sup> Some doctors and patients may be concerned about privacy because scribes learn sensitive information about patients and must be trusted to maintain confidentiality.<sup>265</sup> In addition, incompetent or careless scribes could introduce errors into EHRs.<sup>266</sup> Perhaps most importantly, scribes require salaries and thus could reduce the income of medical practices.<sup>267</sup> According to Salary.com, medical scribe salaries

<sup>258.</sup> Katie Hafner, *A Busy Doctor's Right Hand, Ever Ready to Type*, N.Y. TIMES, Jan. 12, 2014, https://www.nytimes.com/2014/01/14/health/a-busy-doctors-right-hand-ever-ready-to-type.html.

<sup>259.</sup> *Id.*; Vinod E. Nambudiri et al., *Medical Scribes in an Academic Dermatology Practice*, 154 JAMA DERMATOLOGY 101, 103 (2018).

<sup>260.</sup> Melissa Bailey, *The Pay is Low, the Typing Nonstop, but the Medical Scribe Business is Booming*, STAT (April 25, 2016), https://www.statnews.com/2016/04/25/scribes-emergency-room/.

<sup>261.</sup> Meg Bryant, *Why More Providers Are Seeing Value in Medical Scribes*, HEALTHCAREDIVE (Apr. 13, 2017), https://www.healthcaredive.com/news/why-more-providers-are-seeing-value-in-medical-scribes/440472/; Derek Klein, *Medical Scribes: A Physician's Secret Weapon*, MERRITT HAWKINS (Mar. 6, 2018), https://www.merritthawkins.com/news-and-insights/blog/healthcare-news-and-trends/medical-scribes-a-physicians-secret-weapon/.

<sup>262.</sup> George A. Gellert et al., *The Rise of the Medical Scribe Industry: Implications for the Advancement of Electronic Health Records*, 313 JAMA 1315, 1315 (2015). *See, e.g., Who We Are*, SCRIBEAMERICA (Aug. 2018), https://www.scribeamerica.com/who\_we\_are.html (stating that ScribeAmerica is "the nation's most frequently used medical scribe company with more than 15,000 employees in 50 states providing professional services for over 2,000 clients").

<sup>263.</sup> Bailey, *supra* note <u>260265</u>; *Scribe Resources FAQ*, SCRIBEAMERICA, https://www.scribeamerica.com/faqs.html#a15.

<sup>264.</sup> Gellert et al., *supra* note <u>262</u><del>267</del>, at 1316.

<sup>265.</sup> HOFFMAN, *supra* note 118, at 102.

<sup>266.</sup> Robert Pranaat et al., *Use of Simulation Based on an Electronic Health Records Environment to Evaluate the Structure and Accuracy of Notes Generated by Medical Scribes: Proof-of-Concept Study*, 5 JMIR MED. INFORMATICS e30 (2017) (finding that "there was a wide inter- and intrascribe variation in accuracy for each section of the notes with ranges from 50% to 76%").

<sup>267.</sup> Id.

ranged from \$27,637 to \$36,498 in 2018, with an average of \$33,162.<sup>268</sup>

Scribe advocates have responses to all of these objections. Studies show that patients are generally comfortable with scribes in the examination room.<sup>269</sup> Moreover, when data is entered by time-strapped clinicians in often chaotic circumstances, EHRs can easily become replete with errors.<sup>270</sup> Scribes whose sole or primary job is to enter data may actually increase EHR accuracy.<sup>271</sup> Finally, according to some experts, scribes enhance rather than diminish income for medical practices. When physicians are freed of some of their documentation duties, they have time to see more patients. The added income can compensate for scribes' modest wages or even exceed them.<sup>272</sup> To illustrate, one study of a cardiology clinic in Minnesota found that physicians who used scribes were ten percent more productive than those without scribes. <sup>273</sup> As a result, use of scribes increased the clinic's annual revenue by \$1,372,694 at a cost of only \$98,588.<sup>274</sup> A second study concluded that two full- time scribes would increase the earnings of a small office of seven family physicians by \$168,600 per year at an annual cost of only \$79,500.<sup>275</sup> Overall, many physicians have found that scribes significantly improve their work quality and, consequently, job satisfaction.<sup>276</sup> Note, however, that if hiring scribes translates into pressure to schedule a larger number of patient appointments and does not create opportunities to devote more time to each patient,

<sup>268.</sup> Salary for Medical Scribe in the United States, SALARY.COM, https://www1.salary.com/Medical-Scribe-Salary.html.

<sup>269.</sup> Nambudiri et al., *supra* note 259264, at 103 ("Scribes were well received by patients, with few refusals and unchanged overall patient satisfaction scores."); Chen Yan et al., *Physician, Scribe, and Patient Perspectives on Clinical Scribes in Primary Care*, 31 J. GEN. INTERNAL MED. 990, 990 (2016) ("Most patients were comfortable with the scribe's presence and perceived increased attention from their physicians.").

<sup>270.</sup> HOFFMAN, *supra* note 118, at 23-27.

<sup>271.</sup> Risha Gidwani et al., Impact of Scribes on Physician Satisfaction, Patient Satisfaction, and Charting Efficiency: A Randomized Controlled Trial, 15 ANNALS FAM. MED. 427, 430 (2017) (finding that "[s]cribes improved physician-perceived chart quality and chart accuracy"); Yan et al., supra note 269274, at 994 (stating that "clinical scribe notes were more up-to-date, thorough, useful, and comprehensible").

<sup>272.</sup> Nambudiri et al., *supra* note <u>259</u>264, at 103 (finding that revenue increases "more than offset the cost of the scribes").

<sup>273.</sup> Alan J. Bank & Ryan M. Gage, *Annual Impact of Scribes on Physician Productivity and Revenue in a Cardiology Clinic*, 7 CLINICOECONOMICS & OUTCOMES RES. 489, 489 (2015).

<sup>275.</sup> Stephen T. Earls et al., Can Scribes Boost FPs' Efficiency and Job Satisfaction?, 66 J. FAMILY PRAC. 206, 206 (2017). See also Heather A. Heaton et al., Effect of Scribes on Patient Throughput, Revenue, and Patient and Provider Satisfaction: A Systematic Review and Meta-Analysis, 34 Am. J. Emergency Med. 2018, 2027 (2016) (concluding that "[t]here might be a benefit on increase revenue value units" and that "[t]here is a small increase in the number of patients per hour seen when using scribes").

<sup>276.</sup> Gidwani, *supra* note 271276, at 430 ("When working with a scribe, physicians were much more satisfied with how their clinic went, the length of time they spent face-to-face with patients, and the time they spent charting."); Hafner, *supra* note 258263.

burnout rates are unlikely to improve.

Some physicians delegate clerical tasks to others without using professional scribes. <sup>277</sup> Various organizations have health coaches, medical assistants, or nurses that help with documentation and other tasks. <sup>278</sup> Others have "flow managers" that guide physicians' activities with the aim of improving efficiency and saving time. <sup>279</sup> Many experts emphasize the importance of teamwork and its potential to improve physician well-being. <sup>280</sup> In a team model, certain work can be delegated to non-physicians such as nurse practitioners so that doctors can spend more time with patients, doing the work they enjoy most and do best. <sup>281</sup> However, expanding staff to include new team members can also complicate the work environment and require additional coordination, and thus may generate stress and even costs. This section has focused on scribes because their job in particular is to alleviate the burdens of EHR data entry.

## 2. Direct Primary Care and Concierge Medicine

A more radical approach to freeing up time for patient care is to devise new medical practice settings that remove some of the shackles that encumber contemporary physicians. Direct primary care (DPC) is a model that is being adopted by a growing number of clinicians. <sup>282</sup> As of early 2018, there were at least 770 DPC offices operating in forty-eight states. <sup>283</sup>

DPC physicians provide all of their patients' primary care for a monthly fee that commonly ranges between twenty-five and eighty-five dollars.<sup>284</sup> Consequently, DPC has been described as a "subscription" or "retainer" form of

<sup>277.</sup> Scott A. Shipman & Christine A. Sinsky, Expanding Primary Care Capacity by Reducing Waste and Improving the Efficiency of Care, 32 HEALTH AFFS. 1990, 1993 (2013).

<sup>278.</sup> Id.

<sup>279.</sup> Id.

<sup>280.</sup> Annalena Welp & Tanja Manser, *Integrating Teamwork, Clinician Occupational Wellbeing and Patient Safety – Development of a Conceptual Framework Based on a Systematic Review*, 16 BMC HEALTH SERVS. RES. 281, 319 (2016); Wright & Katz, *supra* note 18, at 311.

<sup>281.</sup> Sophia Arabadjis & Erin E. Sullivan, *How One California Medical Group Is Decreasing Physician Burnout*, HARV. BUS. REV. June 7, 2017, https://hbr.org/2017/06/how-one-medical-group-is-decreasing-physician-burnout; Rachel Willard-Grace et al., *Panel Management, Team Culture, and Worklife Experience*, 33 FAM., SYS. & HEALTH 231, 232, 237 (2015).

<sup>282.</sup> Philip Eskew, In Defense of Direct Primary Care, 23 FAM. PRAC. MGMT., 12, 12 (2016).

<sup>283.</sup> Rita Rubin, *Is Direct Primary Care a Game Changer*?, 319 JAMA 2064, 2064 (2018) (stating that the Direct Primary Care Coalition, a lobbying group, has 770 members in 48 states). *See also* Lydia Ramsey, *A New Kind of Doctor's Office that Doesn't Take Insurance and Charges a Monthly Fee Is 'Popping up Everywhere'—and that Could Change How We Think about Healthcare*, Bus. Insider, Mar. 18, 2018, http://www.businessinsider.com/direct-primary-care-no-insurance-healthcare-2018-3 (stating that there are 790 DPC practices).

<sup>284.</sup> Charlotte Huff, *Direct Primary Care: Concierge Care for the Masses*, 34 HEALTH AFFS. 2016, 2016 (2015).

practice.<sup>285</sup> A key advantage from the physicians' perspective is that DPC practices generally do not bill insurers and rely instead on the income they receive directly from patients.<sup>286</sup> Thus, DPC doctors are liberated from the considerable hassles of billing private insurers, Medicare, or Medicaid and are spared the expense of hiring staff to do this administrative work. Note, however, that DPC patients still need health insurance to cover non-primary care services, such as visits to specialists or treatment in hospitals.<sup>287</sup>

Because they have low overhead costs and a predictable income that is not dependent on the vicissitudes of insurance coverage, DPC physicians feel they can afford to treat fewer patients and spend much more time with them. DPC physicians generally accept six hundred to eight hundred patients rather than the typical patient panel of 2000 to 2500 that family physicians ordinarily have. PC Consequently, DPC doctors pride themselves on their availability and responsiveness to patients. As a result, they often derive greater career satisfaction than those in traditional practice settings.

A well-known DPC practice is Atlas MD, located in Wichita, Kansas.<sup>292</sup> On its website, Atlas MD states that each of its physicians attends to only five-hundred patients and that the practice offers "[s]ame-day scheduling with little to no waits and extended visits of an hour or more, if you'd like."<sup>293</sup> Among the benefits it furnishes are house calls, when needed, and round-the-clock accessibility to physicians.<sup>294</sup> Atlas MD has a tiered fee schedule as follows:

- Adults 20-44 years old, \$50/month;
- Adults 45-64 years old, \$75/month;

<sup>285.</sup> Glenn E. Chappell, Health Care's Other "Big Deal": Direct Primary Care Regulation in Contemporary American Health Law, 66 DUKE L.J. 1331, 1331 (2017); Robert Doherty, Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices: A Policy Position Paper from the American College of Physicians, 163 Annals Internal Med. 949, 950 (2015).

<sup>286.</sup> Eskew *supra* note <u>282287</u>, at 12; Kyle Rowe et al., *Direct Primary Care in 2015: A Survey with Selected Comparisons to 2005 Survey Data*, 10 KAN. J. MED. 3, 6 (2017) (finding that between 2005 and 2015 the rate of insurance billing significantly diminished).

<sup>287.</sup> Eli Y. Adashi et al., *Direct Primary Care: One Step Forward, Two Steps Back*, 320 JAMA 637, 637 (2018); Edmond S. Weisbart, *Is Direct Primary Care the Solution to Our Health Care Crisis*?, 23 FAM. PRAC. MGMT. 10, 10-11 (2016); Ramsey, *supra* note 283288.

<sup>288.</sup> FAQ on Direct Primary Care, AM. ACAD. FAM. PHYSICIANS, https://www.aafp.org/practice-management/payment/dpc/faq.html.

<sup>289.</sup> Id.

<sup>290.</sup> Id.

<sup>291.</sup> *Id*.

<sup>292.</sup> About Us, ATLAS MD, https://atlas.md/wichita/about-us/.

<sup>293.</sup> Id.

<sup>294.</sup> Benefits, ATLAS MD, https://atlas.md/wichita/benefits/.

Adults 65+ years old, \$100/month.<sup>295</sup>

Atlas MD has also developed a "Direct Care Curriculum," offering advice to physicians interested in establishing their own DPC practices. <sup>296</sup>

An alternative to DPC is concierge medicine. Concierge practices are more common than DPC offices, numbering as high as 12,000 in 2014.<sup>297</sup> Like doctors with DPC practices, concierge physicians charge patients monthly fees and maintain a relatively small patient panel, which enhances their job satisfaction.<sup>298</sup> However, concierge practices generally continue to bill insurers for their services and thus must grapple with the regulatory and administrative burdens associated with that activity.<sup>299</sup> They also charge much higher monthly fees—according to one source \$183 per month on average in 2015.<sup>300</sup> Consequently DPC has been called "concierge care for the masses."<sup>301</sup>

The DPC/concierge medicine model is not without critics. For the sake of clarity and brevity, I will address only DPC in the remainder of this section, but many of the arguments apply to the higher-end concierge practices as well.

One concern relates to DPC practices' lack of participation in Medicare and Medicaid. Because they need not comply with Medicare and Medicaid regulations and their associated reporting requirements, these practices may be less accountable than other providers.<sup>302</sup>

Because DPC physicians see fewer patients per day than others, some are concerned that a proliferation of these practices will reduce overall access to care and worsen physician shortages.<sup>303</sup> Potentially, the DPC phenomenon could exacerbate health disparities. This is because it might be unavailable to disadvantaged individuals who cannot pay monthly fees or do not live near a DPC

<sup>295.</sup> Monthly Membership Fees, ATLAS MD, https://atlas.md/wichita/our-fees/.

<sup>296.</sup> Atlas.md Direct Care Curriculum, ATLAS MD, https://atlas.md/dpc-curriculum/topics/view/140/.

<sup>297.</sup> James E. Dalen & Joseph S. Alpert, *Concierge Medicine Is Here and Growing!!*, 130 Am. J. MED. 880, 880 (2017).

<sup>298.</sup> HOFFMAN, supra note 90, at 75.

<sup>299.</sup> Huff, supra note 284289, at 2016; Direct Primary Care vs. Concierge Medicine: Which is Right for You?, Am. Acad. Fam. Physicians Ins. Program (Mar. 21, 2016), http://www.aafpins.com/2016/03/direct-primary-care-vs-concierge-medicine-which-is-right-for-you/; Nick Hernandez, Concierge Medicine vs. Direct Primary Care, Physicians Prac. (Jan. 28, 2015), http://www.physicianspractice.com/fee-schedule-survey/concierge-medicine-vs-direct-primary-care.

<sup>300.</sup> Michael Laff, Researchers Study What 'Direct Primary Care' Really Means, AM. ACAD. FAM. PHYSICIANS (Nov. 10, 2015, 8:43 AM), https://www.aafp.org/news/practice-professional-issues/20151110dpcterms.html.

<sup>301.</sup> Huff, *supra* note <u>284289</u>, at 2016.

<sup>302.</sup> Eli Y. Adashi et al., *supra* note <u>287</u><del>292</del>, at 637-38.

<sup>303.</sup> Doherty, *supra* note  $\underline{285290}$ , at 950 (noting concerns that DPC may impede access for patients who cannot afford the monthly fees); Weisbart, *supra* note  $\underline{287292}$ , at 10.

office, and the trend could absorb many doctors who would otherwise see larger numbers of patients in traditional practices.<sup>304</sup> DPC practices may also be tempted to turn away sicker patients who would require frequent appointments and complex care.<sup>305</sup>

On the other hand, for those without insurance, paying modest monthly fees for comprehensive primary care may be an affordable and prudent approach. 306 The alternative for uninsured patients is paying out-of-pocket for treatment, often after having neglected their health problems and facing a medical crisis that requires a costly visit to a hospital emergency room. 307 Some practices have made particular efforts to be accessible to lower-income patients. For example, they may offer financially stressed patients discounted fees or even fee waivers. 309

In addition, advocates argue that concern that the DPC phenomenon will contribute to physician shortages is misplaced.<sup>310</sup> The growing availability of urgent care centers and retail clinics means that patients can receive medical attention for certain conditions when they need it even if they cannot immediately see their primary care physician, and some prefer the convenience of such facilities.<sup>311</sup> Thus, some patients may seek appointments with primary care physicians less frequently. In fact, the emergence of DPC practices could arguably diminish shortages if it keeps some doctors in practice when they would otherwise leave the profession.<sup>312</sup>

According to the Direct Primary Care Coalition, twenty-five states have passed legislation addressing DPC. 313 The laws generally define DPC as a medical

<sup>304.</sup> Doherty, *supra* note <u>285290</u>, at 950 (noting that DPC physicians have been found to have a disproportionately low number of Hispanic and African American patients and that this may be because the practices often choose to be located in wealthier communities).

<sup>305.</sup> Eli Y. Adashi et al., *supra* note 287<del>292</del>, at 637.

<sup>306.</sup> Doherty, *supra* note <u>285</u><del>290</del>, at 950.

<sup>307.</sup> Robin M. Weinick et al., *Many Emergency Department Visits Could Be Managed at Urgent Care Centers and Retail Clinics*, 29 HEALTH AFFS. 1630, 1632 (2010) ("[A]pproximately 17 percent of visits to emergency departments were made by patients who were uninsured, compared with approximately 26 percent of visits to retail clinics.").

<sup>308.</sup> Doherty, *supra* note <u>285</u><del>290</del>, at 950.

<sup>309.</sup> Charlotte Huff, *New Practice Model Evolves: 'Direct Care'*, APC INTERNIST, Jan. 2015, https://acpinternist.org/archives/2015/01/practice.htm ("One option is to carve out a portion of each panel for low-income scholarship or charity care patients who can't afford the fee").

<sup>310.</sup> Reed Abelson & Julie Creswell, *The Disappearing Doctor: How Mega-Mergers Are Changing the Business of Medical Care*, N.Y. TIMES, Apr. 7, 2018, https://www.nytimes.com/2018/04/07/health/health-care-mergers-doctors.html (noting that visits to primary care physicians declined by eighteen percent during the years 2012-2016, though visits to specialists increased in number).

<sup>311.</sup> *Id.* (stating that patients are "flocking to retail clinics and urgent care centers," of which approximately 12,000 exist in the United States).

<sup>312.</sup> David Von Drehle, Medicine Gets Personal, TIME, Dec. 29, 2014–Jan. 5, 2015, p. 49, 54.

<sup>313. 2018</sup> DPC Laws Passed in 25 States, DIRECT PRIMARY CARE COALITION, https://www.dpcare.org/state-level-progress-and-issues.

service that is not governed by state insurance regulations, and some establish certain patient protections.<sup>314</sup> For example, the Oregon statute prohibits discrimination based on "race, religion, gender, sexual identity, sexual preference or health status" and requires DPC practices to make various disclosures to patients.<sup>315</sup>

At the federal level, the Primary Care Enhancement Act was introduced in Congress in 2017.<sup>316</sup> It would allow patients to use health savings accounts<sup>317</sup> to pay DPC retainer fees, a practice that is currently illegal under Internal Revenue Service rules.<sup>318</sup> If passed, such a law would make DPC practices more appealing to patients with such accounts and likely would promote DPC growth.

#### IV. WHY BURNOUT IS A LEGAL ISSUE

Physician burnout is a serious problem for the medical community.<sup>319</sup> However, it is also a threat to the welfare of the public at large. Demoralized physicians who are prone to error or who reduce their hours or abandon the profession altogether will leave considerable medical needs unmet.<sup>320</sup>

Physician wellness is an area that is ripe for legal intervention. The health and safety of workers, including health care providers, is traditionally a matter that is subject to government regulation.<sup>321</sup> The Fair Labor Standards Act,<sup>322</sup> the Occupational Safety and Health Act,<sup>323</sup> a variety of anti-discrimination laws, and many other statutes protect American employees.<sup>324</sup>

Safety-critical jobs are of particular concern to regulators. Federal regulations recognize that professionals who are responsible for public safety, such as transportation workers, must be well-rested when they are fulfilling job duties. Thus, regulations limit the work hours of air traffic controllers, <sup>325</sup> pilots, <sup>326</sup> flight

315. OR. REV. STAT. § 735.500 (2017).

<sup>314.</sup> *Id*.

<sup>316.</sup> H.R. 365, 115th Congress (2017).

<sup>317.</sup> A health savings account (HSA) is an account available to consumers with high deductible health plans that allows them to save pre-tax money to pay for qualified medical expenses such as deductibles, copayments, and coinsurance. Because individuals are not taxed on these funds, the HSA can lower their overall health costs. *Health Savings Account (HSA)*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/health-savings-account-hsa/.

<sup>318.</sup> H.R. 365, 115th Congress (2017); Ramsey, *supra* note 283288.

<sup>319.</sup> See supra Part I.

<sup>320.</sup> Id.

<sup>321.</sup> See Workplace Safety and Health, U.S. DEP'T LAB., https://www.dol.gov/general/topic/safety-health.

<sup>322. 29</sup> U.S.C. §§ 201-219 (2010).

<sup>323. 29</sup> U.S.C. §§ 651-78 (2010).

<sup>324.</sup> Laws and Guidance, EEOC, https://www.eeoc.gov/laws/index.cfm.

<sup>325.</sup> See 14 C.F.R. § 65.47 (2018).

<sup>326.</sup> See 14 C.F.R. §121.503 (2018).

attendants,<sup>327</sup> train employees,<sup>328</sup> merchant marine officers,<sup>329</sup> nuclear power reactor employees,<sup>330</sup> and others.<sup>331</sup> Likewise, the states have enacted legislation to ensure adequate rest for transportation workers, police officers, and firefighters, among others.<sup>332</sup>

It is no stretch to posit that physicians are safety-critical workers as well. Missed diagnoses and careless treatments can surely injure or even kill patients. Thus, the mental health and well-being of doctors should be within reach of the law.

Regulators have already recognized the need to limit the fatigue and stress of some health care providers. For example, state regulations limit the nurse to patient ratios in hospitals and other health care facilities.<sup>333</sup> Congress has also considered a federal bill entitled "The Nurse Staffing Standards for Hospital Patient Safety and Quality Care Act of 2017."<sup>334</sup> The bill would mandate specific minimum nurse-to-patient ratios, depending on the hospital unit, and would require hospitals to post notices regarding ratios and record actual ratios for each shift and unit.<sup>335</sup>

To the relief of many young doctors, the Accreditation Council for Graduate Medical Education<sup>336</sup> capped the number of hours that medical residents can work at eighty per week, with limited exceptions.<sup>337</sup> Moreover, residents are restricted to twenty-four consecutive hours per shift, with an additional four hours allowed to manage care transitions.<sup>338</sup> Yet, no law, regulation, or certification standard is

<sup>327.</sup> See 14 C.F.R. § 91.1062 (2018).

<sup>328.</sup> See 49 C.F.R. § 228.405 (2018).

<sup>329. 46</sup> C.F.R. § 15.1111 (2018).

<sup>330. 10</sup> C.F.R. § 26.205 (2018).

<sup>331.</sup> See, e.g., 49 U.S.C.  $\S$  21104 (2010) (railroad signal employees); 49 U.S.C.  $\S$  21105 (2010) (railroad dispatching service employees).

<sup>332.</sup> See, e.g., ALA. CODE § 32-9A-6 (1975) (limiting hours for commercial vehicle drivers); ARK. CODE ANN. § 14-53-105 (1973) (relating to municipal firefighters); N.J. REV. STAT. § 34:10-3 (2018) (establishing 12-hour maximum days for employees operating street railroads and elevated railroads); WIS. STAT. § 62.13(2e), (7M), (7n), (11), (11a) (2018) (limiting hours and mandating rest periods for police and fire department employees).

<sup>333.</sup> Nurse Staffing, AM. NURSES ASS'N (Dec. 2015), https://www.nursingworld.org/practice-policy/advocacy/state/nurse-staffing/. See, e.g., CAL. CODE REGS. tit. 22, § 70217 (2018) (addressing nurse to patient ratios in general acute care hospitals); DEL. CODE ANN. tit. 16, § 1162 (2018) (establishing minimum staffing levels for residential health facilities); ILL. ADMIN. CODE tit. 77, § 1110.220(b)(5)(a)(ii) (2018) (establishing minimum nurse to patient ratios for open heart surgery patients in intensive care units).

<sup>334.</sup> H.R. 2392, 115th Cong. (2017); S. 1063, 115th Cong. (2017).

<sup>335.</sup> See supra note <u>334339</u>.

<sup>336.</sup> This is an independent, not-for-profit organization. *About Us*, ACCREDITATION COUNCIL FOR GRADUATE MED. EDUC., http://www.acgme.org/About-Us/Overview.

<sup>337.</sup> ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION, THE ACGME 2011 DUTY HOUR STANDARD: ENHANCING QUALITY OF CARE, SUPERVISION AND RESIDENT PROFESSIONAL DEVELOPMENT 29-30 (2011), https://www.acgme.org/Portals/0/PDFs/jgme-monograph[1].pdf.

<sup>338.</sup> Id. at 31-35; Luke Gale, ACGME Approves 24-Hour Shifts for First-Year Residents,

designed to curb the demands placed on physicians who have completed their training and to ensure that their workload is manageable.

A second justification for legal intervention is that cumbersome regulations are partly responsible for physician burnout. As discussed extensively above, these regulations relate to EHR systems, insurance, quality measures, and other matters, and physicians complain bitterly about the regulations' impact on their workdays and job satisfaction. Consequently, it would be reasonable to focus on the maze of regulations that govern physicians to identify possible modifications that would alleviate physician burnout.

#### V. RECOMMENDATIONS

There is no sweeping reform that will constitute a panacea for physician burnout. At best, a number of modifications can be made that will incrementally yield improvement. This Part recommends the following changes: streamlining EHR-related regulations, expanding usability testing, measuring and reporting physician wellness, promoting mechanisms that are proven to ease burnout, and engaging in further study of the problem.

### A. Streamlining EHR-related Regulations

As they modify and develop the regulatory landscape, health care regulators should concentrate on relieving physicians' workload pressures. Contemporary physicians must navigate a thicket of regulatory requirements and dedicate a vast amount of time to responding to the demands of Meaningful Use regulations, quality measures, MACRA, and more.<sup>340</sup>

Legislators have not turned a blind eye to this problem. As noted above, MACRA consolidated three separate quality programs with the hope of diminishing clinicians' administrative workload, though some argue that it is doomed to fail in this regard.<sup>341</sup>

Section 4001 of the 21st Century Cures Act requires the Department of Health and Human Services to develop a strategy and recommendations for reducing administrative burdens related to EHR use.<sup>342</sup> ONC and CMS, which are units within the Department, have stated that they are committed to fulfilling this

HEALTHCARE DIVE, March 10, 2017, https://www.healthcaredive.com/news/acgme-approves-24-hour-shifts-for-first-year-residents/437891/.

<sup>339.</sup> See supra Parts II.C. & III.B.1.

<sup>340.</sup> See supra Parts II.C. & III.B.1.

<sup>341.</sup> Wilensky, supra note  $\underline{233238}$ , at 2369. See also supra notes  $\underline{164168}$ - $\underline{166170}$  and accompanying text.

<sup>342.</sup> Pub. L. No. 114-255, 130 Stat. 1033 (2016) (codified as amended at 42 U.S.C. § 300jj note (Supp. 2016) (Assisting Doctors and Hospitals in Improving Quality of Care for Patients)).

mandate.<sup>343</sup> To that end, they plan to revise evaluation and management (E&M) codes, which are used to document the nature and severity of patients' ailments for insurance billing purposes.<sup>344</sup> The current E&M coding guidelines were created in 1995 and 1997, and many physicians consider them to be outdated and vexing.<sup>345</sup>

ONC and CMS further hope to implement a "meaningful use overhaul," with three specific goals:

- Making the program more flexible and less burdensome;
- Emphasizing measures that require the exchange of health information between providers and patients;
- Incentivizing providers to make it easier for patients to obtain their medical records electronically.<sup>346</sup>

The first objective, which is responsive to burnout concerns, is consistent with suggestions formulated by well-regarded experts. John Halamka and Micky Tripathy have suggested that the Meaningful Use regulations and MIPS be "dramatically simplified to focus on interoperability and a streamlined set of outcome-oriented quality measures." Interoperability refers to EHR systems' capacity to communicate with one another, exchange information, and operate seamlessly and in a coordinated fashion across organizations. While the architects of the EHR incentive program envisioned a fully interoperable National Health Information Network, current technology has fallen far short of enabling widespread interoperability. The suggestion of the enabling widespread interoperability.

Health economist Gail Wilensky has asserted that health care quality measures must be dramatically revised and simplified.<sup>350</sup> Likewise, the American College of Physicians issued a position paper in which it made several recommendations for reducing clinicians' administrative tasks.<sup>351</sup> It emphasized the need for all stakeholders, including public and private payers, professional societies, health

<sup>343.</sup> Greg Slabodkin, *ONC, CMS Set Their Sights on Reducing EHR Clinical Burden*, HEALTH DATA MGMT. (Mar. 8, 2018, 6:11 AM), https://www.healthdatamanagement.com/news/onc-cms-set-their-sights-on-reducing-ehr-clinical-burden.

<sup>344</sup> *Id* 

<sup>345.</sup> Id.; Richard A. Young et al., Family Physicians' Opinions on the Primary Care Documentation, Coding, and Billing System: A Qualitative Study from the Residency Research Network of Texas, 46 FAM. MED. 378, 382-83 (2014).

<sup>346.</sup> Mary Butler, *CMS Announces Overhauls to Meaningful Use in Proposed Rule*, J. AHIMA (Apr. 25, 2018), http://journal.ahima.org/2018/04/25/cms-announces-overhauls-to-meaningful-use-in-proposed-rule/.

<sup>347.</sup> Halamka & Tripathi, *supra* note <u>176</u><del>180</del>, at 908.

<sup>348.</sup> SHORTLIFFE & CIMINO, *supra* note 130, at 952.

<sup>349.</sup> HOFFMAN, *supra* note 118, at 36-37.

<sup>350.</sup> Wilensky, *supra* note <u>233</u>238, at 2369-70.

<sup>351.</sup> Erickson et al., *supra* note <u>175</u><del>179</del>, at 660-61.

care providers, patients, and EHR vendors to collaborate to determine how best to streamline administrative tasks.<sup>352</sup>

CMS has recently proposed removal of some quality measures, a step that is welcomed by many health care providers.<sup>353</sup> As of this writing, the government has not detailed its plans or made final decisions about how it will simplify and trim its regulatory requirements.<sup>354</sup>

Developing a comprehensive blueprint for regulatory reform is beyond the scope of this Article. Instead, I offer a limited set of recommendations below. At the same time, it is essential that HHS remain steadfast in its commitment to the task of reducing administrative burdens and seek extensive input from all stakeholders. HHS must eliminate regulatory duplication and require only measures that will appreciably yield benefits to patients or public health. Doing so is vital for the well-being of the American health care workforce and therefore of the public at large.

# B. Expanding Usability Testing in the EHR Certification Process and Requiring Acceptance Testing

Despite the general plea for streamlining articulated above, a few regulatory gaps must be filled in order to combat physician burnout. The first is in the area of certification and thus would target vendors rather than clinicians. EHR certification regulations should emphasize usability to a much greater extent. <sup>356</sup> As noted above, current product testing prior to certification is minimal and is executed with varying degrees of thoroughness. <sup>357</sup>

Thus, pre-certification usability testing should be significantly expanded. To the extent possible, it is important to assess how EHR products perform in real-world settings. What difficulties do users encounter? How can EHR systems be made more efficient and user-friendly? The certification regulations should specify the methodology by which products will be evaluated, including the types of system failures and adverse events that clinician-testers will consider, how testers will detect, report, and confirm those failures, and what failure and adverse event

<sup>352.</sup> Id.

<sup>353.</sup> CMS Proposes Changes to Empower Patients and Reduce Administrative Burden, CTRS. **MEDICARE** & MEDICAID SERVS. 24, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releasesitems/2018-04-24.html; Erin Dietsche, Goodbye, Meaningful Use. CMS Renames Program "Promoting Interoperability", MEDCITY News 2018, (Apr. 25, https://medcitynews.com/2018/04/meaningful-use-cms/;

<sup>354.</sup> CMS Proposes Changes to Empower Patient and Reduce Administrative Burden, supra note 353358; Dietsche, supra note 353358.

<sup>355.</sup> See Shanafelt et al., supra note 105, at 901.

<sup>356.</sup> See supra Part II.C.2.

<sup>357.</sup> See supra Part II.C.2.b.

rates are acceptable (since rates of zero are not realistic). 358

To that end, certification should include much more extensive EHR system usability testing through simulated clinical workloads. Testing should employ real-world scenarios that vendors do not receive in advance.<sup>359</sup> Such simulations do not require a product's installation in a medical facility, but rather, they test various functions using fictional patient data.<sup>360</sup> Authorized Certification Bodies<sup>361</sup> should recruit clinician-testers and pay them, perhaps from a fund to which vendors seeking product approval contribute. Clinician-testers would be assigned to authorized testing laboratories<sup>362</sup> and then to individual products' testing processes.

Testing should be based on national usability standards developed by well-respected professional organizations such as the National Institute for Standards and Technology. Usability should be measured using appropriate usability metrics. Usability metrics measure user experience in an observable, quantifiable way, assessing a product's effectiveness or efficiency, or the user's satisfaction with respect to particular tasks. 365

Experts have noted that a variety of features can improve EHR system usability. As John Glaser, Senior Vice President, Population Health of Cerner Corporation, explains:

Context-aware software can whittle down choices to a manageable number so that users don't have to scroll through dozens of options every time they need to enter an order. Advanced data visualization can help users focus on the most important information and correctly interpret that information.

Natural language processing is already making amazing progress at interpreting free text and pulling out individual data elements. It can potentially liberate clinicians from clicks and pull-down menus entirely. Combined with advanced voice recognition, it could even save them from typing.<sup>366</sup>

<sup>358.</sup> HOFFMAN, *supra* note 118, at 50-52.

<sup>359.</sup> *Id.*, at 51; WACHTER, *supra* note 181185, at 269; Holmgren, *supra* note 203208, at 659.

<sup>360.</sup> HOFFMAN, *supra* note 118, at 51.

<sup>361.</sup> See HOFFMAN, supra note 118, 47-49 (explaining the certification process); Certification Process, HEALTHIT.GOV (June 27, 2018), https://www.healthit.gov/topic/certification-ehrs/certification-process.

<sup>362.</sup> See HOFFMAN, supra note 118, 47-49; ONC – Authorized Testing Laboratories (ONC-ATLs), HEALTHIT.GOV (Sept. 25, 2017), https://www.healthit.gov/topic/certification/onc-authorized-testing-laboratories-onc-atls.

<sup>363.</sup> John Glaser, Cerner's John Glaser: How to Finally Fix the EHR Usability Problem, HEALTHCAREITNEWS (Aug. 9, 2017, 11:09 AM), https://www.healthcareitnews.com/blog/cerners-john-glaser-how-finally-fix-ehr-usability-problem; NAT'L INST. FOR STANDARDS & TECH., https://www.nist.gov/.

<sup>364.</sup> TULLIS & ALBERT, *supra* note <u>147</u><del>151</del>, at 7-8.

<sup>365.</sup> Id.

<sup>366.</sup> Glaser, *supra* note <u>363</u>368.

Other features that have been found to improve usability include color-coding abnormal test results and physician alerts in the EHR to reduce inappropriate test ordering.<sup>367</sup> Certification must ensure that vendors are incorporating updated, proven technology to reduce physicians' clerical burdens.<sup>368</sup>

However, simulated EHR usage is by nature based on specific assumptions about users and their environments. A limited number of simulations cannot take into account the very diverse population of EHR system users that have very different levels of computer skills and capabilities. Thus, they cannot anticipate all of the difficulties, obstacles, and mistakes that could arise in real health care facilities. As the American Medical Association and other experts observed, EHR systems "deployed in dynamic clinical settings do not always mirror the laboratory testing environment of the ONC Certification Program." 370

Not all usability problems are attributable to flawed design or production. Some are caused by health care organizations' attempts to customize products to fit their own needs.<sup>371</sup> Customization can be a serious contributor to usability problems, and health care organizations should be sure to employ highly skilled information technology specialists to prevent glitches and resolve them when they arise. But many problems are inherent to products as they are originally configured.<sup>372</sup>

In an ideal world, effective usability testing would include clinical safety testing of EHR systems in their natural environments.<sup>373</sup> Facilities would be asked to volunteer to be testing sites and have staff members use new EHR products over time in order to identify usability defects. Facilities could choose this undertaking if they are interested in the product and then would be rewarded with discounts if the EHR system is approved and they decide to purchase it. In addition, they could adopt the EHR system only to a limited extent and have just some clinicians use it in order to minimize disruption to the practice.

Admittedly, however, such clinical testing would pose significant challenges. First, it would require greater government oversight and more testing personnel.

<sup>367.</sup> Guo et al., *supra* note 8, at 140-41.

<sup>368.</sup> Kellogg et al., *supra* note <u>212217</u>, at 197 (stating that user-centered design must put "the cognitive needs of the clinician at the forefront of development, with a better understanding of the cognitive support that clinicians will need").

<sup>369.</sup> HOFFMAN, *supra* note 118, at 51.

<sup>370.</sup> Letter from American Medical Association et al., to Karen B. DeSalvo, Nat'l Coordinator for Health Info. Tech., U.S. Dep't Health & Human Servs. (Jan. 21, 2015) at 3, http://www.aafp.org/dam/AAFP/documents/advocacy/health\_it/emr/LT-ONC-EHRCertification-012115.pdf.

<sup>371.</sup> Sharona Hoffman & Andy Podgurski, Meaningful Use and Certification of Health Information Technology: What about Safety? 39 J.L. Med. & Ethics 77, 79 (2011).

<sup>372.</sup> HOFFMAN, supra note 118, at 23-35 (discussing EHR system shortcomings).

<sup>373.</sup> See id. at 50-52 (recommending clinical safety testing).

Second, it would place demands on health care providers. For testing purposes, some would have to implement EHR systems that are not yet certified and that they may find to be a poor fit. Usability assessments, therefore, could exacerbate burnout at testing facilities in the short-term. Third, any incentive, such as price discounts, could create conflicts of interest. Facilities that find a new EHR system to be satisfactory may be motivated to report data that are excessively positive in order to ensure product certification and obtain discounts. Consequently, it is unrealistic to expect that the proposed clinical usability testing would be mandated in the near future.

In the alternative, CMS regulations should require that vendors allow customers to engage in acceptance testing. Acceptance testing is common in the software arena and is the final phase of testing, performed after a product is delivered and installed.<sup>374</sup> It is designed to verify that users can accomplish their work using the system and that all of the customer's requirements have been met.<sup>375</sup> It often reveals flaws that were not apparent from simulated test data.<sup>376</sup> Vendor contracts specify the terms of acceptance testing. <sup>377</sup> If the customer does not accept the product pursuant to the contract terms, it may provide the vendor additional time to remedy defects or may reject the product and obtain specified remedies such as refunds of any money already paid.<sup>378</sup> Contracts thus should provide that final payment is not due until the buyer has performed acceptance testing and accepted the product.<sup>379</sup>

Acceptance testing would place little if any burden on health care providers. It is performed after a health care organization has selected an EHR system and signed a contract for its purchase.<sup>380</sup> Without it, clinicians would simply have to adopt the system and begin using it despite any flaws. Acceptance testing will furnish an opportunity to demand that the vendor eliminate defects or to reject

<sup>374.</sup> IAN SOMMERVILLE, SOFTWARE ENGINEERING 80 (8th ed. 2007); Linda Ray, *The Difference Between Acceptance Testing & Qualification Testing*, CHRON (Nov. 21, 2017), https://smallbusiness.chron.com/difference-between-acceptance-testing-qualification-testing-39049.html.

<sup>375.</sup> ROB CIMPERMAN, UAT DEFINED: A GUIDE TO PRACTICAL USER ACCEPTANCE TESTING 8 (2006),

http://proquest.safaribooksonline.com/book/software-engineering-and-development/software-testing/0321498143.

<sup>376.</sup> SOMMERVILLE, *supra* note <u>374</u>379, at 80.

<sup>377.</sup> Jon L. Roberts, *Work Made for Hire: The Fiction, the Reality and the Impact Upon Software Development*, 1 HARV. J.L. & TECH. 97, 123 (1988). For more information about software contracts, *see generally* AMERICAN LAW INSTITUTE, PRINCIPLES OF THE LAW OF SOFTWARE CONTRACTS (2015).

<sup>378.</sup> Michael J. Dunne, Eight Significant Points in Technology Outsourcing and Remote Hosting Contracts, 255 N.J. LAW., Dec. 2008, at 19, 21.

<sup>379.</sup> Stephen M. Goldberg, What the Customer Can Do About Software Disabling Devices (with Sample Clauses), 45 PRAC. LAW., Apr. 1999, at 71, 77.

<sup>380.</sup> See supra note 356 and accompanying text.

severely problematic products before they are fully implemented and all members of the workforce undergo training to use them.

Finalizing EHR system implementation without thorough usability testing is akin to selling drugs that have not been responsibly tested in clinical trials involving actual patients.<sup>381</sup> After investing substantial money, time, and effort in purchasing and implementing an EHR system, providers may be very reluctant to switch to a different product even if their existing system has significant flaws.<sup>382</sup> Yet, EHR systems manage many aspects of patient care and have the potential to cause clinicians great misery.<sup>383</sup> EHR systems also have serious safety implications for patients because documentation mistakes, inappropriate prompts, defective CPOE, and other aspects of the technology can lead to serious treatment errors.<sup>384</sup> Consequently, it is critical that every certification process include comprehensive usability testing. In addition, it is important to allow buyers to conduct acceptance testing before finalizing their purchases. Ensuring that EHR systems rate highly in the usability area and facilitate rather than hinder clinicians' administrative work could go far towards alleviating physician burnout.

# C. Measuring and Reporting Physician Wellness

In addition to expanded usability testing, federal regulations should require the inclusion of physician wellness among the quality measures that are reported to CMS. Thus, MACRA and the Meaningful Use regulations should be revised to incorporate a physician wellness measure. Physicians should be required to complete the MBI or an equivalent assessment tool annually. This would not be an excessively burdensome task because it takes only ten to fifteen minutes to complete the MBI. Clinicians should then upload the results directly to a website

<sup>381.</sup> See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm.

<sup>382.</sup> The Challenges of Switching EHRs, MED. ECON. (Oct. 25, 2016), http://www.medicaleconomics.com/medical-economics-blog/challenges-switching-ehrs (stating that "while 60% of ambulatory EHR system users either dislike their system or are neutral about it, and nearly half say they wouldn't recommend it to a colleague, only 15% of respondents say they're considering switching to another system in the next year"). But see, Switching EHRs Becoming Norm in Healthcare, MED. ECON., (Oct. 25, 2017), http://www.medicaleconomics.com/med-ec-blog/switching-ehrs-becoming-norm-healthcare (stating that 62% of respondents indicated they had switched EHR systems during their career and that while half did so because of a change in employment, the other half did so because of dissatisfaction with the system they were using).

<sup>383.</sup> See supra Part II.B.

<sup>384.</sup> HOFFMAN, *supra* note 118, at 23-35 (discussing EHR system shortcomings); *supra* note 117 and accompanying text (discussing EHR system features).

<sup>385.</sup> See supra Part II.C.1.

<sup>386.</sup> See supra notes 23-25 and accompanying text.

<sup>387.</sup> Vibeke Hansen & Afaf Girgis, Can a Single Question Effectively Screen for Burnout in

provided by CMS. Direct submission will prevent health care employers from having an opportunity to manipulate outcomes in order to avoid negative financial consequences. Health care organizations should receive summary reports from CMS regarding burnout in their workforces. If CMS becomes concerned that clinicians are manipulating their MBI responses in order to protect their employers, it could require employers to submit annual data regarding the number of workers who left, switched to a part-time schedule, or retired early. Such data may serve as an additional indicator of the level of burnout in the workplace and be used to determine whether testing outcomes appear reliable.

CMS could then include physician burnout in its reimbursement calculus so that organizations with a burnout rate that exceeds a stated level would be subject to pay adjustments.<sup>388</sup> CMS may need to adjust the allowable burnout rate for particular practice settings, such as high-stress specialties<sup>389</sup> or resource-poor facilities in underserved areas. Small practices (to be defined by CMS) would be exempt from the reporting requirement because every physician would have an outsize influence on the overall burnout rate. Nonetheless, they should be encouraged to measure physician wellness and act to mitigate burnout.

Experts have noted that health care systems traditionally embrace the triple aim of enhancing patient experience, improving population health, and reducing costs, but they posit that a fourth aim should be added: cultivating providers' wellness. <sup>390</sup> Without workforce wellness, it is impossible to achieve the first three goals. <sup>391</sup>

The adverse consequences of physician burnout are well-recognized.<sup>392</sup> It can erode physicians' mental health, reduce productivity, diminish the quality of care, and lead to workforce attrition.<sup>393</sup> Burnout should be of concern to all health care providers because it can be associated with outcomes such as lower patient satisfaction, longer recovery time after hospital discharge, and even malpractice suits arising from medical errors.<sup>394</sup>

Furthermore, promoting physician wellness is a professional ethical

Australian Cancer Care Workers?, 10 BMC HEALTH SERVICES RES. 341, 341 (2010)

<sup>388.</sup> See supra notes 168<del>172</del>-169<del>173</del> and accompanying text.

<sup>389.</sup> See supra note 43 and accompanying text (discussing high-stress and lower-stress specialties).

<sup>390.</sup> Thomas Bodenheimer & Christine Sinsky, From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider, 12 Annals Fam. Med. 573, 575 (2014); Christine A. Sinsky, Dissatisfaction Among Wisconsin Physicians Is Part of Serious National Trend, 114 WMJ 132, 133 (2015).

<sup>391.</sup> Bodenheimer & Sinsky, *supra* note <u>390</u>395, at 575.

<sup>392.</sup> See supra Part I.B.

<sup>393.</sup> Tait Shanafelt et al., *The Business Case for Investing in Physician Well-being*, 177 JAMA INT'L MED. 1826, 1827-28 (2017); Wallace et al., *supra* note 67, at 1714-19; *supra* Part I.B.

<sup>394.</sup> See Dzau et al., supra note 7, at 312; Halbesleben and Rathert, supra note 75, at 34.

obligation.<sup>395</sup> The American Medical Association Code of Medical Ethics Opinion 9.3.1 establishes that "physicians have a responsibility to maintain their health and wellness" and "an obligation to ensure that colleagues are able to provide safe and effective care, which includes promoting health and wellness among physicians."<sup>396</sup>

CMS pay adjustments would constitute a meaningful incentive for health care organizations to attend to clinician wellness. Concern for patient welfare and business interests should do so as well. Reporting and tracking of physician wellness is worthwhile because entities can implement a variety of interventions.<sup>397</sup> Educational programs regarding mindfulness and stress management and small group discussions have proven useful.<sup>398</sup> Likewise, support through teamwork or the hiring of scribes is helpful.<sup>399</sup> Professional organizations have begun to develop additional tools to help health care providers combat burnout.<sup>400</sup> Indeed, Dr. Tate Shanafelt credits such initiatives with helping to reduce burnout rates between 2014 and 2017.<sup>401</sup> Collecting and storing burnout data from across the nation would also enable researchers to study the phenomenon in greater depth and better evaluate the efficacy of different interventions.

This Article proposes that CMS consider reported wellness measures in calculating reimbursement rates. However, these measures would be of even greater benefit to regulated health care entities themselves because they could use the information as a springboard for addressing the problem of burnout. 402 Without

<sup>395.</sup> Rosandra Walker & Harold Pine, *Physician Wellness Is an Ethical and Public Health Issue*, 158 OTOLARYNGOLOGY—HEAD & NECK SURGERY 970, 970 (2018).

<sup>396.</sup> COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS 377-78 (2016), https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-9.pdf.

<sup>397.</sup> Noseworthy et al., *supra* note 8 (discussing the importance of measuring physician well-being and taking action to address it).

<sup>398.</sup> Shanafelt et al., supra note 105, at 902.

<sup>399.</sup> Bodenheimer & Sinsky, *supra* note <u>390</u>395, at 575; Wright & Katz, *supra* note 18, at 311. *See also supra* Part III.C.1.

<sup>400.</sup> See Dzau et al, *supra* note 7, at 313 (discussing a National Academy of Medicine collaborative that is creating an online "knowledge hub" that will serve as a "repository for available data, models, and toolkits"); Mark Linzer et al., *Preventing Physician Burnout*, STEPSFORWARD (June 2017),

https://www.stepsforward.org/Static/images/modules/15/downloadable/Preventing\_Physician\_Burn out.pdf (presenting a module designed to help providers eliminate burnout and adopt wellness approaches in their practices); Stephen Swensen et al., *Physician-Organization Collaboration Reduces Physician Burnout and Promotes Engagement: The Mayo Clinic Experience*, 61 J. HEALTHCARE MGMT. 105, 108-20 (2016) (describing the Listen-Act-Develop model for reducing burnout).

Shanafelt et al., *supra* note 13, at 11.

<sup>402.</sup> Linzer et al., *supra* note 85, at 18 ("Any system that does not measure, monitor and optimize clinician well-being and sustainability is at risk."); Shanafelt & Noseworthy *supra* note 14, at 133-42 (emphasizing the importance of measuring physician well-being and offering nine

specific data about burnout in their own work environment, health care organizations may not be motivated to implement interventions.

# D. Promoting Measures Proven to Ease Burnout

Health care regulations and laws should support and promote approaches that have proven successful in mitigating physician burnout. These include employing scribes and shifting to a direct primary care model.<sup>403</sup>

For example, Medicare could provide bonus points for MIPS scoring purposes to practices that hire scribes. 404 Medicare already provides bonus points in a variety of circumstances. It awards a five-point bonus for small practices with fewer than fifteen clinicians and up to five bonus points for treating complex patients. 405 Such a bonus would encourage providers to implement this self-help measure and may ultimately help pay for scribes' wages. If other workplace interventions prove particularly successful, Medicare could provide bonus points for implementation of those as well. 406

Congress should support direct primary care practices by passing the Primary Care Enhancement Act that would allow patients to use health savings accounts to pay DPC retainer fees. 407 This benefit would help some patients cover the out-of-pocket costs of DPC and would thus provide important financial support for DPC practitioners. The law could include a sunset provision. Thus, if Congress determined that DPC was exacerbating physician shortages, 408 it could choose not to renew the legislation at the end of the sunset period.

Policy-makers should use their considerable power to aid physicians in adopting mechanisms to combat burnout. If physicians feel empowered to promote their own wellness, they are much more likely to remain content and productive members of the clinical medicine profession.<sup>409</sup>

# E. Addressing Patient Visit Length: A Need for Further Study

It is known that longer patient visits improve physicians' job satisfaction as well as treatment outcomes. 410 It is therefore tempting to propose legal limits on

institutional strategies to improve it).

<sup>403.</sup> See supra Parts III.C.1 & III.C.2.

<sup>404.</sup> See supra notes 167171-169173 and accompanying text (describing MIPS).

<sup>405.</sup> MACRA Basics: Merit-based Incentive Payment System (MIPS), supra note 167171.

<sup>406.</sup> See supra note 400405 and accompanying text.

<sup>407.</sup> H.R. 365, 115th Cong. (2017); Ramsey, *supra* note <u>283288</u>; *supra* notes <u>316321</u>-<u>318323</u> and accompanying text.

<sup>408.</sup> See supra notes 303308-305310 and accompanying text.

<sup>409.</sup> See supra Part III.C.

<sup>410.</sup> Linzer et al., *supra* note 85, at 19 (urging that health care organizations lengthen patient visits in order to combat burnout); Tingley, *supra* note 228233, at 43 (stating that having doctors

the number of patients physicians can see each day.

Other jurisdictions have considered or implemented such proposals. In 2015, the Alberta Medical Association suggested that general physicians see no more than six patients per hour (a number that seems alarmingly high). British Columbia doctors are subject to a fifty-patient daily cap, after which they get paid only half of their fee until they reach sixty-five patients, after which they are paid nothing (also very high limits). In June 2018, the British Medical Association passed a motion calling for a "sensible cap" on the workload of general practitioners. In June 2018, the British Medical Association passed a motion calling for a "sensible cap" on the workload of general practitioners.

American scholars have also suggested workload limitations. For example, one study of primary care physicians found that "visit rates above 3 to 4 per hour are associated with suboptimal visit content." Similarly, experts have urged that it is irresponsible for primary care physicians to see more than twenty-five to thirty patients per day. For hospitalists, the suggested number has been lower, perhaps fifteen to eighteen per day. Its

Nevertheless, it would be inappropriate to formulate a legal mandate with absolute visit caps based on currently available evidence. The number of patients a physician can effectively treat in a day depends on a multitude of factors. These include the specialty, patients' complexity, physician's efficiency and work habits, the amount of work that is delegated to other team members, and more.<sup>417</sup> We do

spend more time with patients can reduce hospitalizations and save the health care system money); supra Part III.A.

<sup>411.</sup> Emily Mertz, *Alberta Medical Association Proposes Capping Number of Patients Doctors See*, GLOBAL NEWS, (Nov. 13, 2015, 4:51 PM) https://globalnews.ca/news/2337609/alberta-medical-association-proposes-capping-number-of-patients-doctors-see/.

<sup>412.</sup> Get Rid of Daily Patient Cap, Says B.C. Walk-in Clinic Founder, CBC News (Jan. 20, 2017, 2:08 PM), http://www.cbc.ca/news/canada/british-columbia/get-rid-of-daily-patient-cap-says-b-c-walk-in-clinic-founder-1.3945412.

<sup>413.</sup> Jenny Cook, *BMA Demands GP Workload Cap to Protect Patients and Doctors*, GP (June 26, 2018), https://www.gponline.com/bma-demands-gp-workload-cap-protect-patients-doctors/article/1486038. *See also*, Laurence Buckman & Michael Griffiths, *Should GPs' Daily Number of Consultations Be Capped?*, 361 BMJ k1947 (2018) (debating both sides of the argument).

<sup>414.</sup> David C. Dugdale et al., *Time and the Patient–Physician Relationship*, 14 J. GEN. INTERNAL MED. (Supp. 1) S34, S36 (1999). *See also*, Eric S. Williams & Asheley Cockrell Skinner, *Outcomes of Physician Job Satisfaction: A Narrative Review, Implications, and Directions for Future Research*, 28 HEALTH CARE MGMT. REV. 119, 134 (2003) (citing the Dugdale study and calling on managers to work with physicians to "develop realistic practice policies for physician productivity").

<sup>415.</sup> See Luis Collar, How Many Patients Can a Doctor Safely See a Day?, KEVINMD (Dec. 31, 2013), https://www.kevinmd.com/blog/2013/12/patients-doctor-safely-day.html.

<sup>416.</sup> James Allen, *How Many Patients Should a Hospitalist See a Day?*, HOSP. MED. DIR. (Aug. 13, 2016), https://hospitalmedicaldirector.com/how-many-patients-should-a-hospitalist-see-a-day/; Steven M. Harris, *Appropriate Patient Census: Hospital Medicine's Holy Grail*, THE HOSPITALIST (Jan. 2012), https://www.the-hospitalist.org/hospitalist/article/125455/appropriate-patient-census-hospital-medicines-holy-grail.

<sup>417.</sup> See Allen, supra note 416420 (listing a large number of variables that should be considered

not know what the workload tipping point is that causes physicians to suffer burnout. Nor have we verified the extent to which burnout or consequent depression causes medical errors. Many published studies have focused on physicians' own perception of performing sub-optimally rather than on objective measure of poor outcomes. American physicians would likely find a cap objectionable because it would deprive them of discretion and could harm patients. A patient who is seriously ill may not be able to access her doctor if the clinician has already scheduled the allotted number of appointments for the day.

Thus, researchers should continue to study burnout to determine its consequences and identify effective preventive mechanisms. Such causal inference studies are complex and must adjust for numerous variables that can impact physicians' performance.<sup>421</sup> If researchers develop a sound rationale for capping the number of patients seen per day (or per hour or week) in particular specialties, those caps could be established by law. Caps would need to take into account the nature of the patient visit and allow for exceptions in emergency situations. For example, one British proposal suggested that family doctors have twenty-five to thirty-five appointments per day if they were for routine care (e.g. sore throats or blood pressure checks) but see only fifteen patients per day if the individuals had complex problems.<sup>422</sup>

In the meantime, other proposed interventions, such as streamlining regulatory requirements, improving EHR usability, and encouraging the use of scribes, 423 should diminish the demands of clerical work and leave physicians with opportunities to lengthen patient visits. Health care organizations must refrain from requiring that doctors fill freed-up time with extra appointments. Regulatory improvements must enable physicians to enjoy greater job satisfaction by spending more time with patients. They should not generate even more crowded appointment schedules and thus fuel the fires of physician burnout.

#### VI. CONCLUSION

The American health care system suffers from numerous fractures and

in determining hospitalists' patient loads).

<sup>418.</sup> See supra Part I.B.2.

<sup>419.</sup> See Buckman & Griffiths, supra note 413417.

<sup>420.</sup> Id.

<sup>421.</sup> HOFFMAN, *supra* note 118, at 157-60 (discussing data analysis challenges); Sharona Hoffman & Andy Podgurski, *The Use and Misuse of Biomedical Data: Is Bigger Really Better?* 39 Am. J.L. & MED. 497, 521-25, 532-36 (2013) (discussing the challenges of bias and causal inference and causal inference techniques); *supra* note 417421 and accompanying text.

<sup>422.</sup> Brian Goldman, Should Number of Appointments by Family Doctors Be Capped? Medical Community Weighs in, CBC RADIO (May 14, 2018), http://www.cbc.ca/radio/whitecoat/blog/doctors-are-run-off-their-feet-1.4661676.

<sup>423.</sup> See supra Parts V.A, V.B, and V.D.

failures. 424 Physician burnout is a core problem, which is as serious as any. 425 Quality health care cannot be delivered without dedicated physicians who are happy with their work. 426

Health care professionals widely bemoan their existing professional circumstances. Physician and author Siddhartha Mukherjee critiques "the form-filling, diagnosis-coding, button-pushing culture of modern medicine." Dr. Thomas Schwenk writes in *JAMA* that the "caring relationship has been lost for many physicians in the current system of fragmented, rushed, dysfunctional, digitized, corporatized, and costly medical care – a system that prizes efficiency over relationships, profits over common good, and volume over value." Philip Miller asks in *Health Affairs*: "The question is, Will medicine remain a calling with patient care at its heart or become a mere occupation, characterized by bureaucracy and a focus on the bottom line?" <sup>429</sup>

Physician well-being is a worthy cause that deserves the attention of both the medical community and policy-makers. Because public health is at stake, the law can no longer ignore the reality of physician burnout. Its power must be harnessed to launch a multi-faceted effort to combat the problem. Initiatives should include streamlining regulatory requirements, emphasizing usability in the process of EHR certification, measuring and reporting physician wellness indicators, supporting the use of scribes and direct primary care, and conducting further research to better understand burnout and identify additional solutions.<sup>430</sup>

Policy-makers must work to restore the appeal of the medical profession and retain the physician workforce. The health of the nation is at stake.

<sup>424.</sup> See, e.g., Jonathan Bush, Four Ways to Heal Our Broken Healthcare System, FORBES (June 14, 2016, 6:30 AM), https://www.forbes.com/sites/realspin/2016/06/14/four-ways-heal-healthcare-system/.

<sup>425.</sup> Bodenheimer & Sinsky, *supra* note <u>390395</u>, at 573-75; Wallace et al., *supra* note 67, at 1714.

<sup>426.</sup> See supra Part I.B.2.

<sup>427.</sup> Siddhartha Mukherjee, For Doctors, Delving Deeper as a Way to Avoid Burnout, N.Y. TIMES (Oct. 10, 2018), https://www.nytimes.com/2018/10/10/magazine/for-doctors-delving-deeper-as-a-way-to-avoid-burnout.html.

<sup>428.</sup> Schwenk, *supra* note <u>214219</u>, at 1543.

<sup>429.</sup> Phillip Miller, *The Medical Profession's Future: A Struggle between Caring for Patients and Bottom-Line Pressures*, 35 HEALTH AFFS. 407, 409 (2016).

<sup>430.</sup> See supra Part V.