The Impact of Regulatory Requirements on Patient Experience:

Changing the Current Course to Combat Noncompliance and Adverse Outcomes

Exploratory Paper

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Introduction

Voltaire is quoted as saying, “The art of medicine consists of amusing the patient while nature cures the disease,” which may have been true in the 18th century however, as time progresses we are now faced with how to adapt technology, law, and the science of medicine to provide exceptional quality healthcare in a meaningful and resource efficient manner.

Very early in American history, the United States Supreme Court ruled in the case of Dent vs. West Virginia where M.H. Dent, a physician was indicted for practicing medicine in violation of state law. The West Virginia State Board of Health refused a medical license to Dent, a graduate of an Ohio medical college who had an established practice. The Board determined that Dent’s six years of practice did not qualify under the licensure act's grandfather clause and that he was not a graduate of a “reputable school”. The unanimous Supreme Court decision rejected Dent's claim and Justice Field affirmed, “Every one may have occasion to consult [the physician], but comparatively few can judge the qualifications of learning and skill which he possesses. Reliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications.” The court held that the statute was a valid exercise of the state's police power to regulate the medical profession. (USSC Dent v. West Virginia 1889)

With this decision, the Supreme Court authenticated regulation for professional licensure, holding that the uninformed consumer did not have the ability to understand or identify skilled or experienced medical providers and therefore required the regulatory intervention to protect the public.

As technology and access to treatment information, increase medical professionals struggle to balance patient choice and the standard of care anticipated by regulatory bodies and payors. An article in the Pepperdine Law Review puts forth the supposition that regulation adds another layer to health care, which puts the fiduciary responsibility of the provider in potential conflict with expectations of the patient and the requirements of regulatory bodies (Marsh 2015). This is supported by earlier articles including one in the Alabama Law Review that sums up the theory that any proposed health care reform must take into account the prevailing influencers of healthcare law, inclusive of marketing, public opinion, technology and legal policy (Satz 2008).

Originally the physician made the medical determination and provided a course of treatment without intervention of insurance or government, but payor and government interests have shifted that focus and placed the medical provider as an activist for the patient against the real or perceived limitations on medical resources. According to most courts, the provider has the fiduciary responsibility to be the formal advocate for their patient in health care which supports the perception of the provider's role in healthcare activism (Matthew 2011).

Health care providers, through licensure and educational reform, have control over entry into medicine and the ability to self-regulate through peer review and credentialing nonetheless, federal regulation based on quality and billing has added significant layers of administrative complexity to the practice of medicine. In addition, the creation and execution of healthcare regulation is not a simple formula applied in a uniform fashion across all specialties and settings necessitating the need for nonclinical experts to facilitate meeting all applicable regulatory requirements and thus influencing

clinical decision-making (Madison 2007). Multiple agencies determine the regulatory framework and may have coinciding commonalities or incongruent differences that apply the same or similar principles with varying degrees of consequence. As healthcare reform progresses, change will need to lead to a "reorientation of healthcare quality regulation" to focus on the value and quality of health care services provided rather than to concentrate on stationary regulation that lacks the flexibility to take into account technology and cultural change (Madison 2007).

Patient safety and health care quality moved to the forefront of the health care reform debate as medical horror stories surface on mainstream and social media as highlighted by government scrutiny and by the myriad of newspaper reports and litigation currently going through the courts (Liang 2015). Also spurring the movement was the rising cost of health services juxtaposed against the desire of patients and their families to limit the financial impact of medical procedures. In the eyes of patients and providers, there is an overwhelming belief that physicians have a patient-centered obligation for care. This duty compels the medical professional to educate and provide information regarding all available treatments and to advocate on behalf of the patient when there are limits that restrict the patient's access to care (Mantel 2015). The struggle between providing patients all existing options and concentrating on either best practice or mandated policies creates an ethical dilemma for providers. Many proposed reforms focus on basic health care services and cost containment without allowing for prevention services or other innovative growth that would shift the dynamic from reactive to proactive medicine (Sage 1999).

Systems based on regulatory structure to frame medical decision-making do not take into account the variability of the individual, the resources available, the financial or geographic restraints, and healthcare literacy of both the provider and patient (Agrawal 2001). To add to the issue, regulatory requirements that rely on audits are subjective and dependent on provider documentation or other post encounter information. To change behaviors in medically complex conditions or treatments cannot be standardized rather the work must be organized in a fashion that allows for discrete accountability in both patient and provider (Agrawal 2001).

All involved parties have acknowledged that some regulatory requirements and standards provide value and may be critical to guarantee the delivery of safe, high-quality care. However the redundancy of many requirements due to multiple agencies or laws creates either low value or contradictory systems. Regulatory requirements to ensure quality in healthcare delivery that negatively influence patient experience need to change the current course of noncompliance and adverse outcomes.

Purpose

The purpose of this paper is to explore the scope and impact of regulatory requirements on patient care and quality outcomes. The American Hospital Association distributed an Executive Summary in 2017 looking at the regulatory burden on health systems which succinctly discussed many of the issues that organizations face today (AHA 2017). This paper takes that research one step further to examine how we got to current state, the barriers to change, and potential paths to transformation required of our

current healthcare environment to impact quality of care while streamlining the regulatory burden on healthcare systems.

Historical Context of Quality Reform and Federal Regulations

President Roosevelt first suggested the idea of comprehensive health care coverage almost 100 years ago. The Constitution does not recognize health care as a right however there has been a long-standing desire by the public for accessible healthcare that more formally manifested with the introduction of the Medicare and Medicaid programs in 1965. As federal and state governments assumed financial responsibility for the delivery of health care, complementary regulatory administrations were quickly created for the purpose of standardization. However in the view of the healthcare consumer, as shown in a 1970 survey, three out of four people viewed the U.S. health care system as quickly circling the drain (Pratt 2011). A solution in the form of the 1974 Employee Retirement Income Security Act (ERISA), shifted regulation from state to federal responsibility. Among other things, ERISA regulates benefits provided through insurance and thus creates regulation for health plan coverage that preempts state requirements (Kinney 1999). The issue with ERISA is that the interpretations of the details in the act are open to a myriad of interpretations and thus make enforcement difficult and costly to administer.

To give reform efforts more teeth Congress revitalized the Civil False Claims Act (FCA) in 1986. FCA started as a Civil War-era statute prohibiting the "knowing submission of false or fraudulent claims to the federal government." As an enhancement to prevent financial arrangements that influence physician referral patterns, both the Stark

Law and the Anti-Kickback Statute (AKS) were enacted in 1989 and 1972 respectively. The intent of the statutes was dual focused on cost containment and prevention of over-utilization in the context of inhibiting fraud and abuse, however, both laws created significant hurdles to the implementation of progressive value based reform models that incentivize value and care coordination. Value based models tied provider compensation with high quality outcomes and reduced costs to the payors. In 2015, the Department of Health and Human Services (HHS) determined a goal of 90% of payments models should be value based by 2018 (HHS.GOV). The biggest issue with this goal was the lack of clear, attainable metrics and the cooperation of patients to participate in care. To add to the mix, some providers realized that they could work the system to avoid performance penalties by ending the patient provider relationship or limiting specific demographics treated in the practice.

The lack of clarity of the statutes prevented the formation of an integrated health care system due to potential vulnerability to federal fraud and abuse concerns. In addition, Stark Law prohibits a physician from referring a Medicare patient for medical treatment or service to an entity for designated health services (DSH) if the provider or his/her immediate family member has a financial relationship with the DSH entity, unless the relationship satisfies a Stark Law exception. AKS is a criminal statute that makes it illegal for any person or entity to provide or receive anything of value to influence, or in exchange for, the referral of patients covered by federal health care programs. Regardless of the changes made, confidence was still low, as shown in a 1990 poll reported in the CMS website, where ninety percent stated that the U.S. health care system required a reorganization in some form to control rising costs (CMS.GOV).

Cost containment has been a goal in almost all reform efforts as the cost of care increases dramatically each year. Congress enacted the Sustainable Growth Rate (SGR) as part of the Balanced Budget Act of 1997, which was passed to balance the budget by 2002. SGR is a methodology utilized by the Centers for Medicare & Medicaid Services (CMS), to control Medicare costs through physician payments without regard to quality, volume, or intensity of services. Flaws in the SGR methodology encouraged overutilization and decreased patient access mostly blamed on inadequate payments. Due to dissatisfaction from both Congress and physicians, the SGR was repealed in 2015. Despite its repeal, the SGR and fee-for-service arrangements still impact current compensation and reimbursement models which in turn have slowed the implementation of quality reform (Trotter 2013).

Since 2010, the care debate has fixated on enacting laws requiring the purchase of health care insurance throughout a variety of health care markets. Health care law was again transformed in 2010 with the passage of The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act (HCERA). Per CMS.org, the intent of enacted reforms was to empower the healthcare consumer by allowing choice to help control cost (CMS.GOV). PPACA had significant potential for containing the costs of health care however it did not significantly reform any part of the regulations that created the current fragmented health care system it operated within. Instead, the legislation created numerous new entities and requirements central to the success and longevity of the health reform itself (Cunix 2013). Twenty-six states challenged the constitutionality of PPACA with the case going to the Supreme Court to determine the appropriate role of federal and state government in health care. The basis

for challenging PPACA was that Congress did not have the constitutional authority to promote the Act. This Supreme Court decision is considered one of the most significant in history in line with Bush v. Gore and Brown v. the Board of Education because it limits the ability of Congress to regulate commerce when set against the individual mandate that required the purchase of insurance or payment of a penalty (Richm 2013).

Additional proposed regulatory reforms have been introduced over time and most have the same recommendations to incentivize positive outcomes, reduce inefficiencies, and coordinate legislative bodies to promote increased communication and lower cost. While the intent is virtuous the vague clutter of contract and social welfare regulations hinders the ability to provide care while regulatory and quality expectations will remain fragmented and convoluted.

Regulations made to correct abuse

In 1999, the Institute of Medicine (IOM) published, “To Err is Human: Building a Safer Health System," which stressed the abundance of medical errors impacting patient safety. To respond to the information provided by the IOM report, the Quality Interagency Coordination Task Force (QuIC) was developed “to ensure that all Federal agencies that purchase, provide, study, or regulate health care services are working in a coordinated way toward the common goal of improving the quality of care” (AHRQ.GOV 2018). With limited success, the QuIC developed strategies to identify patient safety issues and to reduce the number of errors by 50 percent over the next 5 years. QuIC actively provided quality indicators and other patient safety tools for health care organizations and some advancements in care were realized. Using 2011-2014 data,

QuIC efforts indicated improvement; a 2.8% decrease in the percentage of hospitals classified as worse than average and a 2.1% increase of hospitals classified as better than average for patient quality and mortality outcomes but not to the scale that was intended by the implementation of the taskforce.

In 2015 President Obama signed into law the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA focused on reimbursement associated with quality indicators, value to the patient and payor, and clinical outcomes, as opposed to simple fee for service which had been the main model to date. MACRA was the newest proposed methodology that changed the way healthcare dollars flowed from the payor to the healthcare provider by requiring the provider accept the risk for part of the difference between actual total costs and exceeded budgeted costs. MACRA's new payment models incentivized providers for delivering coordinated and cost controlled quality outcomes (DiVarco 2019).

The American Hospital Association released an executive summary that assessed the regulatory burden on health systems through legal requirements. These conditions of participation governed the federal health care programs leading to underdeveloped guidance and conflicting requirements for quality and cost measures. In 2016 alone almost 24,000 pages of hospital and post-acute care related federal regulations were published. The administrative cost for health care providers related to regulatory compliance was close to $39 billion (AMA 2017). Nonetheless most health systems have decided that the organizational spend was preferable to the potential civil penalties, exclusion, and even imprisonment for violation of the myriad laws and regulations that apply. Among healthcare providers there is a growing concern that the magnitude of the

FCA's penalties could force settlements for cases that represent deceptive allegations stemming from good faith interpretations of ambiguous regulations (Krause 2001).

Regulation reform's influence of current state

Health systems, hospitals, and post-acute care providers (PAC) must comply with 629 separate regulatory requirements that include 341 hospital-related requirements and 288 PAC-related quality requirements (AHA 2017). There are four main agencies that have the greatest impact on regulatory requirements: the Centers for Medicare & Medicaid Services (CMS), the Office of Inspector General (OIG), the Office for Civil Rights (OCR) and the Office of the National Coordinator for Health Information Technology (ONC). To put this into perspective, according to the American Hospital Association data, a community hospital with around 161 beds will spend nearly $7.6 million annually on administrative compliance activities to maintain compliance with the current and potential regulations (AHA 2017).

In the same argument that there is an unnecessary burden for information on the healthcare system, there is also the idea that there is a significant information gap related to pricing and quality information. To bridge the division between cost and quality data, agencies must come together to provide an overarching governing body specifically developed to mandate, document, and publish patient safety improvement data and outcomes. The conclusion in most of the literature is that many proposed or current regulatory reforms fail to specify the form of the quality program, how to measure performance, or prescribed actions to take when low performers are identified (Grout 2013).

Healthcare financial crisis

Economists and health care experts agree that the unrelenting increase in health care costs are the single biggest threat to the national economy. The power of the insurance lobby and multilayered state and federal government bodies have stifled the majority of health care reform efforts. Historically countries, including the United States, have made significant reforms to health care policy during times of financial crisis. The creation of legislation in response to the economic recession increased time sensitive pressure for regulation without allowing for a full evaluation of the potential penalties for all impacted parties. The New England Journal of Medicine reviewed the Affordable Care Act and provided a running commentary that no one had the time to review the thousands of pages that made up the pivotal health care reform and in the same vein there were also very few people who could understand or get meaningful metrics from the bulky legislation (NEJM.ORG).

During the passage of PPACA the argument was that meaningful reform would curtail health care spending threatening the economic stability of the country. One powerful argument used against PPACA was the very public discussion of the "death panels" which put a name to the fear that health care rationing would be the result of any health care reform.

Opinions on both sides agreed that health care fraud was leading to a significant amount of waste and abuse of available health care dollars. In the Journal of the American Medical Association, a report was published that indicated that physicians had "exaggerated the severity of a patient's condition, adjusted a billing diagnosis, or

fabricated patients symptoms" to ensure treatment is covered (Price 2009). In response to the perceived abuse of the system many regulations have been implemented resulting in increased organizational costs to track and report applicable data.

The administrative costs of the claims review process as a piece of both quality review and cost containment put an additional burden on an already overwhelmed system. In addition, as the preauthorization process becomes mandatory for an increasing number of procedures, labs, medicines, and treatments the access to timely care decreases. With the significant influence of the most recent financial crisis meaningful quality reform struggled with the impact of both economic fluctuations and outdated or reactive regulation (Kaal 2013).

Litigation and healthcare law trends

Over time legal cases have shaped regulatory reform by holding providers and organizations accountable for the quality of care provided. Notable cases include Darling v. Charleston County Memorial Hospital 1965 and Johnson v. Misericordia Community Hospital 1981, revolve around the failure of the organization and credentialing body to use reasonable care when allowing a physician privileges in the hospital. While the cases focus on negligent credentialing, the court referred to comprehensive responsibility of the provider or organization to audit the competency of the care provided. In addition to these cases, there have been many others that have spurred the quality movement based on the theory that the organization or provider owes a duty of care to the patient (Koch 2009).

Federal agencies including the Department of Justice (DOJ) and the Office of Inspector General (OIG) along with state Attorneys General have utilized CMS billing data to pursue cases against providers and organizations citing substandard quality of care as an abuse of the FCA guidelines. Where this becomes sticky is that in order to prosecute under the FCA, it must be determined that the claim itself was fraudulent. When an organization or provider submits a claim there is a concurrent certification that the claim is compliant with all CMS expressed or implied statutes and regulations. Implied certification is difficult to defend and has not been accepted by all state or federal authorities. In addition, the FCA statute indicates that there does not need to be proof that there was specific intent to submit fraudulent claims (FCA 31 USCS).

Malpractice reform initiatives and defensive medicine

Medical malpractice reform initiatives truly started gaining traction in the 1970s. In the years between 1970 and 2001, only five states did not pass some type of medical malpractice reform. In general, reform efforts center on decreasing the costs associated with medical malpractice litigation and therefore a reduction of health care spending (Lieber 2013). Defensive medicine comes into play when providers order testing or procedures they otherwise would not have ordered to protect themselves from potential litigation or conversely limits the scope of their practice. The current malpractice system creates pressure on providers to order medical services and the cumulative cost inflates health care spending (King 2011).

Until recently, the provider's peers judged the quality of care a provider rendered through credentialing and other processes. According to an article by Karen Jordan

published in the Arizona State Law Journal, providers are judged on the technical quality defined as "the application of medical science and technology in a manner that maximizes its benefits to health without correspondingly increasing its risks" (Jordan 1995). Basically the inefficiencies created by fragmented regulatory requirements decrease communication among health care providers while increasing administrative costs.

As managed care increases the requirements for authorizing treatments, providers have a perceived fiduciary duty to advocate for their patients to get treatment approval. In the case of *Neade v. Portes,* the Illinois Supreme Court ruled on a case that was brought by a patient's spouse who alleged that her husband died of medical malpractice when his physician failed to order testing because of potential compensation and also failed to disclose the financial arrangement. The court refused to recognize breach of fiduciary claims against physicians and held the fiduciary claim separate from the medical malpractice claim of the case.

Most of this part of the reform process focused on including caps on monetary damages and legal fees, revisions of liability rules, and adjustments to the statutes of limitations. Though there have been many schemes, a noteworthy example is from the 1993 Presidential Task Force on National Health Care Reform proposal which failed because it did not include specific strategies to overcome issues associated with malpractice replacements like alternative dispute resolution and it did not emphasize quality indicators as a locus of malpractice tort reform. New areas of thought propose full-scale change instead of traditional tort litigation yet, these proposals have not gotten far in the political arena (MacCourt 2009).

Evaluation of global healthcare systems

As Americans face rising health care costs there are almost 700,000 citizens a year that recognize the value provided by health care tourism, not necessarily based on quality, but more focused on affordability. Conversely, since the market is driven by consumer choice, potentially the quality of care and cost to the patient are also positively influenced by market forces (Chou 2016).

Numerous studies have shown that other industrialized nations have a lower cost of care, lower infant mortality, and higher life expectancy than the United States due to the disparity of healthcare access and utilization. This does not mean that the rising cost of health care is not a concern, for example in the countries that belong to the Organization for Economic Cooperation and Development (OECD), the average health expenditure has risen from 7.1% in 1990 to 8.8% in 2003 (Rich 2003). The European Union states have a managed health care system that identifies health care as a basic right for its citizens and stresses universal coverage and access to necessary care.

To achieve this the government plays a critical role in governing funding through cost controls and rationing along with continuous reform efforts to keep legal guidance contemporary. The United States hodge podge of insurance coverage resembles many successful systems but fails to provide complete coverage or consistent systems due to the convoluted implementation. The Canadian system of national coverage is like Medicare, coverage for select groups like veterans resembles Britain, and employer sponsored plans are like Germany, France and Japan. For example, the German health

care system is based on the concept of solidarity where each individual's ability to pay is based on earned income while access to care and coverage is for the entire population.

The biggest difference between the United States and others is the attitude, which from an American perspective is more aligned with regulation from the government while others, like the Swedish system is cooperation oriented and relies on the provider and consumer driven market to drive quality. Therefore, while many of these programs are successful for the individual country it represents, the fragmented regulation has created a program that struggles in the United States (Stauch 2011). Furthermore other countries like Britain subscribe to a more strict form of cost containment in practices that limit the availability or access to treatments or procedures. Overall Britain spends less money and has longer life expectancies, lower infant mortality, and more acute care beds in hospitals than in the United States (Cunix 2013).

Antitrust statutes that impact competition

The population of the United States has traditionally been opposed to a universal health care system, like Canada's single payer system, instead preferring the choice of a market-based system. The mainstream American consumer desires reform that provides first-rate coverage yet does not adversely affect their ability to make independent decisions regarding their health care or increase costs. As reimbursements decline and regulatory oversight increases, there is also a concern that competition in the market will focus on the cost and pricing of health care weakening quality initiatives and innovation. Antitrust laws can both hinder and help competitive transformation of health care depending on the application of the law to the current context.

Anti-trust law, through Stark and AKS, are intended to allow the health care provider and consumer choice by limiting collusion between health care organizations. Reforming antitrust regulation to allow for vertical integration of systems, in theory, would then determine the point at which the service will be provided based on quality, which will influence cost. However, because personal bias and managed care both play a role in dictating choice, there is not a true competition determined by market forces. Therefore, the competitive advantage in the market should lead to fair prices and quality outcomes through selective credentialing and contractual relationships that dictate quality management of health care networks to provide superior care.

In addition, there are opportunities within the anti-trust laws to develop proactive reforms that will promote competition. ACOs are an example of how, if antitrust laws were changed to reflect the unique nature of medicine, the ability to provide quality, coordinated care would increase due to the synchronization of communication and services among health care providers.

Reducing regulation to streamline quality care

Quality of care can be a subjective measurement that is difficult for organizations to quantify in a meaningful, actionable way. The heavy reliance on documentation as a form of regulatory oversight puts the onus on providers and organizations to both have the tools and understanding to meet the requirements. Both federal and state laws have created extensive regulations on insurance, health care providers and medical treatments that have increased administrative costs without showing a requisite benefit to quality.

The current state of health care reform has created fragmentation in health law and statues without a unified decision making body focused on quality patient outcomes. Evidence supports a collaborative, best practice focused approach that includes all key players who understand the clinical needs and can objectively balance that against the financial restraints (Satz 2015). Currently the bulk of case and statutory law does not give credence to peer review standards but rather emphasizes the enforcement of mechanical processes as a metric of quality. From a healthcare perspective, peer review characterizes the organization's resolve to ensure quality standards (Noah 1998).

Healthcare literacy to promote accountability and compliance

Health care literacy as defined by the government on the Health.gov website that a patient's ability "to obtain, process, and understand health information needed to make informed health decisions" (Health.gov). Successful health care literacy movements are examples for how patients, as consumers, can be included in their care to generate healthier outcomes at lower cost. The theory is that when patients embrace the right care at the right time and partner with their care providers to understand their treatment options then the trifecta of access, quality, and cost reduction can occur (Clark 2011).

Health literacy is dependent on an individual's proficiency for accessing and understanding information as it relates to health care data. Factors including English literacy skills, cultural influence, and socioeconomic status all affect the ability of the patient to acquire the necessary health information to make informed health care decisions. Along the same argument, the provider's ability to communicate successfully also determines the patient's understanding of the issues influencing their health care

highlighted by cases like Truman v. Thomas or Canterbury v. Spence. In these case examples there is an underlying understanding that while the medical provider is required to competently treat the patient there is also a duty to communicate the true gravity and scope of the clinical issue and present choices in a way that the patient will understand and be able to make informed decisions. The driver behind this is that 88 percent of the population has difficulty understanding some level of health information (Trudeau 2016). Regardless of the outcomes, these cases and others are brought forward because there was a perceived failure on the part of the medical provider either to disclose the risk or to explain it in a way that the patient understood the risks of either having or not having the procedure.

The most inclusive proposal to date regarding health care literacy was the National Health Literacy Act of 2007, which died before being signed into law. As a result, regulatory oversight is still inconsistent in purpose and expectation so, while it is a laudable objective, a rigorous effort to standardize information for clinical accurateness is required to overcome the difficulty measuring the success of the initiatives. While current efforts are moving in the right direction, this restructuring needs to support reorganizing regulatory responsibilities and streamline requirements to include protection against lawsuits when the provider actively, and in good faith, engages the patient in shared decision-making.

Other Considerations Impacting Change Initiatives

As discussed in the Harvard Medical Practice Study (HMPS), the risk of being sued positively influences the quality of health care. The study goes on to explore the

theory that as quality improves providers often see a drop in revenue indicating that there is no "business case for quality." The reasoning is that targeting reform efforts to the collection of providers and treatments most responsible for the problem is an effective utilization of resources. While HMPS results are somewhat inconclusive, it does support the theory that malpractice cases do not impede efforts to protect patients. HMPS did validate that once a provider has had the potential of a lawsuit it "made [doctors] twice as likely to take more time in explaining the risks of treatment to their patients." Thus, HMPS advocates that regulatory policy does influence the prevention of harm to patients and therefore is an effective tool in providing quality healthcare (Hyman 2004).

Political agenda driving quality and payment standards

As health care has evolved the state's role in health related programs has increased to the point where the relationship between state and federal agencies can be challenging. Under federalism, the states have the "Constitutional prerogative" to create and enforce health care reform. States have responsibility for facilitation of Medicaid programs and have the nimbleness on a local level to handle the particular needs of that patient and health care provider population. On the same note, states compete for money and most states lack the resources to independently fund comprehensive programs without federal tax dollars (Kinney 1999).

A proposed reform that could benefit all parties is MACRA. MACRA eliminates the fee-for-service model and instead links payment to specific performance metrics and shares the risk with the providers. MACRA's intention is to incentivize efficiencies of scale and coordination with hospitals and health systems to provide information streams

and reduce hospital readmissions and other negative outcomes. The benefit of MACRA beyond improved quality and cost is the idea that providers will practice medicine in a more patient centric, less cost driven manner and patients will have care tailored to their needs as opposed to being a quota to meet. Focusing on quality as part of a patient-centered system potentially could reduce federal spend and reduce physician burn out. Interestingly enough, federal agencies whose motivation is on health care cost containment and quality outcomes struggle to find support in the political arena and MACRA has lost forward momentum due to a lack in the attainability of quality metrics and data.

Capitalism as an enforcer of quality reform

Per CMS in 2016 spending on health care related services grew 4.3 percent, reaching $3.3 trillion, translating into 17.9 percent of the United States Gross Domestic Product (Ginsberg 2012). By contrast, other first world countries spend significantly less with generally better outcomes. This divergence in cost and quality highlight opportunities to improve the health care delivery and payment systems that dictate adherence to pre-determined mandates without consideration to medical decision-making or patient preference. Supporters of universal healthcare coverage desire access to high quality, affordable care however, performance data indicates that legislated coverage potentially drives less utilization of care due to high deductibles and other barriers. Regulation through inflexible licensing or limitations on scope affects the quantity, type, and facilities where care is available thus decreasing resources and driving demand and cost.

Market forces that focus on quality improvement activities compel organizations and providers to develop new skill sets and drive progressive innovation. Managed networks that compete against one another compel participants to conform to the quality and efficiency standards that become the expectation. Transparency in performance data increases the strength of market forces to give emphasis to arrangements that incentivize providers to deliver superior quality care by requiring measurable improvements in outcomes. In general, existing compensation arrangements pay providers on a production basis, which fails to account for all the work required in patient care that generates little or no revenue. In theory, competition will also reduce the costs of producing value for the health care consumer by capping pricing (Carnahan 2006).

One way to encourage competition and quality is through value-based purchasing which utilizes performance data to determine quality and incentivize high performers. Value based purchasing runs into a roadblock when set against antitrust law due to information sharing to determine cost savings and quality opportunities. Antitrust laws view quality as a consequence of an economic transaction whereas health care providers typically prioritize quality and patient care in absolute terms with ability to pay as a secondary consideration.

In 1974, during the case of *Goldfarb v. Virginia State Bar,* the Supreme Court rejected the claim that health care should be entitled to antitrust exemptions under the "learned profession" exclusion. The subsequent years have not changed the antitrust argument, which creates an environment where providers are reluctant to share quality related data for fear of a lawsuit. Accountable Care Organizations (ACOs), through vertical integration systems and accountability from health care providers, have the

potential to streamline the process through legal agreements and provider incentives (Rowe 2012). A vertically integrated system needs the flexibility to operate in different delivery systems and on both state and federal levels. Thus, the legal incentive for change must come in a change of antitrust laws to enable innovation and collaboration between health care providers.

Medical Malpractice influence on clinical decision-making

Medical malpractice is defined as the failure to do "what a reasonable provider in the same specialty would have done under the same or similar circumstances". However, every medical event is different due to the variations in training, circumstance, resources, information, and most importantly, the human being presenting with the issue. To that end, some regulation is created based on bias and expectations of behavior without true data to support those assumptions. This has resulted in forty years of legislative reforms to the medical liability system that have not significantly reduced avoidable injury for a variety of reasons. Medical errors can be difficult to ascertain because outcomes are variable by patient. Excellent care can have negative outcomes while poor decision-making can sometimes generate good results.

Reduction in the quality of care can come from one of two main areas. First, traditional risk management encouraged medical providers to avoid discussing errors or to apologize for a potential mistake therefore discouraging discussion on quality opportunities. The argument against optional incident reporting is the questionable value of incomplete data and thus the ability to truly affect quality improvement efforts. Second, the fragmentation of care due to lack of communication between services and

providers, while not intentionally deliberate, creates poor quality and in turn poor health outcomes for patients. In 2003, a coordination of care study found that only 55% of the time did patients receive the appropriate level of care as determined by diagnosis and health status.

To supplement the legislative initiatives, provider incentive programs were developed to address the failures of the system to improve health outcomes by positively motivating provider behaviors to increase patient compliance of plans of care. In 1996, the American Medical Association Council on Ethical and Judicial Affairs issued Opinion 8.13 that affirmed financial incentives to be permissible if promoting cost efficient care and not for promoting the withholding of medically necessary treatment. Yet legal standards that allow providers to castoff noncompliant patients remove the accountability for the patient's well-being and weaken the incentive to take the actions necessary to reduce the barriers of providing complete care. Studies have shown that breaks in continuity of care, for example when a patient is fired from a practice, leads to higher costs and poorer health outcomes. Incentive pay is also problematic in that it relies on compliance to specific guidelines as a driver for quality as opposed to promoting innovation and resourcefulness in care.

Avoidance behaviors that shape consumer choice

Defensive medicine occurs when a provider orders unnecessary services to safeguard against medical malpractice liability rather than promote patient care. In fee-for-service, this practice benefited the health care provider but also drove up costs significantly.

Health care providers bounce between the patient demand for services and the financial limitations of today's fiscal environment.

Evolving compensation models link reimbursement to patient outcomes and health care costs. Provider payment connected to overzealous quality or data reporting that can negatively impact reimbursement has the effect of reducing access for patient populations that sometimes need it the most. Providers also have publically reported data available online that also influences their willingness to take on patients that could potentially negatively impact the provider's reputation and limit their ability to contract with insurance and other organizations. CMS already provides for some financial reimbursement based on quality outcomes. By creating attainable quality measure and standards and reducing the perceived risk of litigation, true quality metrics and data could be attainable.

Conclusion

The call for meaningful regulatory reform is driven by economic and human factors that are sometimes at odds due to the very personal nature of health care. The process is very dynamic and will continue to change as the political and financial players change over time. Just managing the provisions of care through legal requirements does not address the larger issue of how the law fragments the coordination of care. The current policies and legislation have been layered over time thus unraveling this burden will take time and specific efforts to address each piece. Our current disjointed regulatory system causes to an unstainable administrative burden on health care providers

and organizations which in turn increases cost, reduces efficiencies, and does not have the desired impact on quality outcomes.

The solution is evidence-based reform with healthcare focused technology and meaningful and actionable information for patients, providers and regulators. Producing low-cost, high quality health care protected from medical malpractice liability by standardizing quality measures is the ultimate goal. A vertically integrated system that encompasses the entire scope of health care delivery from the provider, facility, and payment perspective is required to bring together the currently fragmented structure. The utilization of initiatives like ACOs, MACRA, health literacy programs and other potential government reform could incentivize the desired outcome only if the administrative burden and potential liability issues are reduced to a level that is manageable by even the small health care provider offices. These types of arrangements would also help control costs due to the amalgamation of more than a single health care source and the spread of overhead costs including compliance and risk. Health care reform must focus on meaningful consistent change that facilitates the right care at the right time based on clinically proven data. Health care transformation will need to start at the state level with regulatory and finance reform as part of an integrated delivery system that protects and facilitates provider and organizational efforts to advance quality care.

Reference List and Research Methodology

The intent of this paper was to explore the facts, legal actions, and opinions around the regulatory impact on health care. To prepare for this article a thorough review of contemporary legal and healthcare journals was completed to both truly understand and speak to the prevailing opinions and issues. The historical timeline provided is important to highlight how one process or issue built upon another to get to current state. It is important to note that there are many additional issues and proposed solutions not explored in this paper due to constraints on the amount or quality of the supporting information.

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