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Known by some as the 2010 Patient Protection and Affordable Care Act, others by the often sardonic alias “Obamacare,” and most recently highlighted through contentious “repeal and replace” rhetoric, health care reform has reemerged as a hot topic of discussion in households across the country. Those affected by this issue include anyone who (1) is currently sick or has been sick in the past, (2) has a friend or family member that is dealing or has dealt with an illness, or (3) is or knows someone who may one day receive that plastic bracelet bestowing the title of “hospital patient.” Basically, this refers to every American. And yet, so great is the divisiveness on how best to manage health care in the modern age, the Affordable Care Act (ACA) now finds itself in a paralytic state as advocates and critics tangle over the vast complexities at its core. The only commonality is the recognition that there is no simple solution.

Is Health Care Really So Complicated?

Complex by necessity, America’s current health care system may appear elaborate, ridiculous or even labyrinthine in turns, and changing even the smallest fraction involves delving deep into the belly of the beast. For example, Medicare disproportionate share hospital (DSH) adjustment provisions rely upon a statutory formula to calculate DSH patient percentage which is equal to the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid by not Medicare Part A. With this in mind, even the health care layman is quick to realize that, in labeling DSH adjustments (DSH Patient Percent = (Medicare SSI Days / Total Medicare Days) + Medicaid, Non-Medicare Days / Total Patient Days), one is forced to learn the equivalent of a new language.

Terminology is not the only factor to consider when addressing the intricacies of America’s health care structure. Seemingly counterintuitive at times, inherent within more recent axioms of Medicare is the qualitative shift used to determine the ways in which programs function and succeed. The Hospital Value-Based Purchasing Program (HVBP) rewards (or penalizes)
acute care hospitals with incentive payments (or reductions) by as much as two percent, based upon the quality of care the hospital delivers, rather than simply the quantity of services it provides. To do so, the HVBP uses the hospital quality data reporting infrastructure that was developed for the Hospital Inpatient Quality Reporting Program. When evaluating certain new measures introduced in 2017, such as elective delivery prior to 39 complete weeks’ gestation, clostridium difficile infection and methicillin-resistant staphylococcus aureus, some may consider such an approach absurd.

Another consideration is the Medicare Hospital Readmissions Reduction Program’s (HRRP) requirement that CMS reduce payments to inpatient prospective payment system hospitals with excess readmissions by calculating the readmission adjustment factor with the following formula:

\[
\text{Excess readmission ratio} = \frac{\text{risk-adjusted predicted readmissions}}{\text{risk-adjusted expected readmissions}}.
\]

Aggregate payments for excess readmissions = \([\text{sum of base operating DRG payments for AMI} \times (\text{excess readmission ratio for AMI-1})] + [\text{sum of base operating DRG payments for HF} \times (\text{excess readmission ratio for HF-1})] + [\text{sum of base operating DRG payments for PN} \times (\text{excess readmission ratio for PN-1})] + [\text{sum of base operating DRG payments for COPD} \times (\text{excess readmission ratio for COPD-1})] + [\text{sum of base operating payments for THA/TKA} \times (\text{excess readmission ratio for THA/TKA-1})]\].

It is not unreasonable to view this as a potentially tortuous, not to mention torturous, endeavor.

Further, equally elaborate examples include (1) the calculation and updating of diagnosis-related groups (DRGs) in the Medicare Hospital Prospective Payment System (HPPS), (2) the Hospital Quality Assurance Fee Program, (3) payment limitations imposed by the Omnibus Budget Reconciliation Act (OBRA), (4) the medical loss ratio imposed upon health insurance issuers, (5) qualified health plans with the minimum essential coverage to satisfy the individual mandate, (6) business relationships that violate the Federal Anti-Kickback Statutes or Stark Laws, (7) safe harbors that protect providers from violating the Federal Anti-Kickback Statutes or Stark Laws, and (8, the fact that a covered entity still faces substantial penalties for accidentally disclosing the identities of its patients, regardless of malady, even as internet pirates abscond with patient health information belonging to millions of Americans.

When contemplating the complexity of our nation’s health care system, one must also consider the subject under care. Anatomically, modern Homo sapiens has nearly 80 organs, ten of which are important enough to consider “vital,” more than 200 bones (approximately 70 fewer than newborn members of the species), 60,000 miles of blood vessels, loses close to 300 million cells each day and can produce a cough that clocks in at 60 miles per hour. The tenth revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) and its 70,000 codes serve as the indispensable bridge between the physical care received and payment issued on behalf of those...
who live in the United States.

To further confuse the issue, matters of the mind rely upon an entirely different cadre of information (the Diagnostic and Statistical Manual of Mental Disorders (fifth edition) (DSM V)) for treatment and funding, even though its connection to the body is inextricable. As a result, much of the regulatory infrastructure overseeing mental health exists outside of the ACA, and in recent years Congress has pushed to establish “mental health parity” to protect patients from insurance benefit discrepancies when it comes to issues of soma and psyche.

While the estimated 100 trillion synapses in the human brain designed to orchestrate the ways in which our body communicates internally may offer some explanation as to why federal and state lawmakers cannot agree upon a national health care system devoid of partisan politics, the mysterious and extraordinary axon is not to blame for the complexity of either the ACA or its putative replacement. At best, such a parallel can only serve to illuminate the codependence at the heart of the system within which doctors and patients must daily interact.

**What Happens Next?**

Thankfully, complexity is not the sole basis by which the United States determines the propriety of its health care system. Friend or foe of Medicare, Medicaid, and all related programs up to and including Obamacare and the American Health Care Act, the time has come to ignore causation and instead surrender to the reality of our health care system as it exists today. To successfully do so, efforts to improve our health care structure would be well advised to disregard political agendas, especially since a system responsible for the health of an entire nation rarely has the opportunity to start anew.

The idea that the nation’s leaders on the right believed a mere 123 pages of legislation could replace not just the 906-page outline defining the ACA but also the tens of thousands of regulatory clarifications promulgated by the federal government over the past seven years is just as preposterous as the thought process of those leaders on the left who feared the American Health Care Act might actually survive. This particular partisan battle has not been about the intellectual acumen of those embroiled in such debates, but rather blame rests with ordinary hubris on both sides, the same enemy that has been toppling Gods and nations as far back as classical antiquity. Whether medically or legislatively speaking, there is little room for pride in the realms of modern health care.
Charting the evolution of Medicare over the past 52 years underscores a need to approach changes in health care methodically and with patience. Even the ACA, championed as the instrument of reform in 2010, was built upon the foundations of a predated system. History is often overlooked as a necessary ingredient in constructing a better health care system, and the American political process can sometimes mask its presence. Still, the keys needed to unlock the complexities of today’s health care conundrum lie in our nation’s past as much as in its future. The cumulative wisdom provided by hindsight is a far more powerful tool for advancing the health of a nation than the momentary success of any single political party or elected official. Until then, Congress will probably ignore until it escalates into something it can understand.

* * *

* * *
“Necessity is not an established fact, but an interpretation.” – Friedrich Nietzsche

Evolution or Devolution?

In a constant state of flux, the American health care system has struggled to exist in the present since the introduction of Medicare in 1965. Both in terms of medical care and its delivery, our nation’s health care system must continually evolve if it is to keep up with advances in science, technology and the treatment of disease, as well as the way we access these advances. As a result, each generation’s health care must balance providing that which has come to be expected with the need to expand coverage and modern methods of care. As a nation, we depend upon those in highest office to monitor such changes, adding provisions where applicable and paring down what is no longer practical. Much of the divided nation fears that come January 20, 2017, Barack Obama’s legacy, the Affordable Care Act, may find itself vulnerable to a single stroke of the pen, potentially leaving millions of Americans without meaningful access to medical care. Others will celebrate as Donald John Trump accepts the role of 45th President of the United States. The only immediate certainty for modern American health care is that both sides will continue to argue whether the Affordable Care Act is a frivolous luxury or a social necessity.

These prophecies of domestic medical Armageddon espoused by many Americans as inauguration day approaches are certainly nothing new. Over the past 60 years, health care propaganda has often shown a dramatic flair, foretelling its own impending demise. In 1954, an article in Fortune Magazine associated advances in medicine with the end of the physician as the nation once knew. In 1986, an article in Health Affairs suggested that changes in health care could shutter as many as 1,000 hospitals before 1990.

In 1987, during a period in which Medicare transitioned from a cost-based to a prospective payment system, the Sacramento Bee criticized the media for its description of American medicine as being on the verge of decay, and the House subcommittee blamed the DRG system for placing the elderly at great risk. More recently, just 13 months after President Barack Obama signed the Affordable Care Act into law, the New York Times enumerated the inefficiencies of American health care, within which patients seemingly grew sicker, treatments became purportedly more complex, and overall health fell into a state of decline, while the the army of our nation’s doctors behaved less like their benevolent
Santa Monica based television equivalent, Marcus Welby, M.D., and more like disgruntled automotive technicians facing frightening futures in Flint, Michigan. When dealing with issues of health, change is always disconcerting.

**No Status Quo in 2017**

In 2007, a leader from the same political party that now threatens to repeal the Affordable Care Act tried with some success to make the term “Obamacare” pejorative in its early days. Ten years later, politically-driven fear over the end of “Obamacare” has stirred the nation into a frenzy over the supposed 30 million newly uninsured living in soon-to-be bankrupt state health care systems. History shows that the resilience of health care in the United States should not be underestimated even in its purported darkest hours, as the system combines institution with entitlement in its effort to remain accessible to everyone, though geographic disparities in quality continue to expand.

While the provision of health care is not technically a Constitutional right, certain elements at the heart of our current system have earned honorary status. The elimination of preexisting conditions, drastic modifications to arbitrary limits in coverage, premium parities and coverage for children/young adults up to the age of 26 are just a few of the modern-day tenets that local, state and federal politicians dare not challenge. That said, the estimated annual $190 billion price tag on lost earnings due to issues brought about by mental health challenges alone illustrates the extent to which America’s health care system is bleeding, both in terms of funding and its ability to offer care where needed. For the one in five Americans experiencing any type of mental illness, including the six percent of the population living with a severe mental illness and the two out of three who avoid treatment due to cost, mental health parity laws may just be the answer. Eliminating the Affordable Care Act and the sturdy anchor it brought to the 2008 Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, not to mention the added billions of dollars in funding it currently directs toward states, may actually make it ok to not be ok.

With the benefit of nearly seven years of historical hindsight, it appears that some aspects of the Affordable Care Act work better than others. The complexities added to the Medicare program, for example, prove both impressive and daunting. Unfortunately, between the Hospital Value-Based Purchasing Program, the Hospital Readmission Reduction Program, the Physician Merit-Based Incentive Payment System, electronic health records and most of HIPAA, health care in its 2017 iteration is no easy pill to swallow. In the midst of such confusion, it may be time for the Federal Government to reconsider the scope of its push toward performance-based reimbursement over its cost-based counterpart. Likewise, even with the crippling effects of fraud, abuse and waste on the national health care
budget, some of the Stark laws and Federal Anti-kickback statutes that seek to minimize these losses have been known to cause dizzy spells to rival a severe case of vertigo.

In its present form, the Affordable Care Act leaves very little room for financial vicissitudes, and the loss of substantial funding could ultimately have the same effect as repeal. Exactly how the executive and legislative branches will utilize this proverbial trump card remains to be seen, but if nothing else, the economic fragility woven into the framework of health care reform should serve as a deterrent against rapid change. Even the concept of “repeal and replace,” a reasonable solution to most problems, brings with it nearly 50,000 pages in statutory and regulatory challenges. Simply put, there are no sustainable overnight solutions.

The Obama administration had almost eight years to craft today’s health care reform. At best, the ones who fight for repeal have but two years to replace it. Left without a viable alternative at mid-term or by the next Presidential election, the United States could grant a 73-year old Hillary Clinton her rematch against the President elect. Provided, of course, neither gets sick from the stress of campaigning in a nation whose health care system is flirting with chaos.

* * *
SUPREME COURT DECISION ADDS MORE CONFUSION TO FALSE CLAIMS ACT
July 2016

“The darkest places in hell are reserved for those who maintain their neutrality
in times of moral crisis.” — Dante Alighieri

As modern medicine continues its attempts to bridge the gap between body and mind to provide more comprehensive care for patients, so too must the Federal Government address this gray area while endeavoring to regulate care for those less tangible medical issues of the mind. The already elaborate labyrinth known as the Medicare Act has recently grown even more chaotic under the recent Supreme Court decision Universal Health Services, Inc. v. United States (ex rel. Escobar), which further blurs the line between false and fraudulent claims.

Teenage Medicaid beneficiary Yarushka Rivera sought guidance at Arbour Counseling Services in Lawrence, Massachusetts. The facility diagnosed Rivera as bipolar, although the Arbour “Ph.D.” rendering this opinion failed to disclose that her degree was from an unaccredited Internet-based college, or that Massachusetts had rejected her application for licensure as a psychologist. Twenty-three other Arbour “clinicians” also lacked the purported mental health professional licensures Arbour professed to represent. Not surprisingly, the service’s “prescribing psychiatrist” was in fact a registered nurse who lacked the credentials to do so. Arbour also misrepresented various payment codes, such as “family” or “individual” therapy, and it was discovered to have lied in its attempt to garner National Provider Identification (NPI) numbers for its non-practitioners. Needless to say, Rivera’s mother Carmen Correa and stepfather Julio Escobar were not pleased upon learning of the facility’s transgressions from an Arbour counselor five years into Rivera’s treatment.

As a result, Universal Health faced allegations that it defrauded Medicaid by submitting reimbursement claims through Arbour, which is owned and operated by a Universal Health subsidiary. The complaint alleged Universal Health submitted claims that made representations about the specific services Rivera received, but failed to disclose the myriad regulatory violations pertaining to requisite staff qualifications and licensing. The complaint further contended that these representations of Arbour professionals rendering services on behalf of Rivera triggered false claims liability. By submitting claims for payment using codes corresponding to specific counseling services, Universal Health effectively led Medicaid to believe that it had provided specific types of treatment. According to the complaint, Universal Health’s misrepresentations were so integral to reimbursement under Medicaid that had the program known otherwise, payment would surely have been denied.
Universal Health prevailed at the District Court level, but lost before the First Circuit Court of Appeal. The First Circuit held that every submission of a Medicaid claim implicitly represents compliance with germane Medicaid regulations, and moreover, failure to disclose a violation of a precondition of payment makes that submission “false or fraudulent.” The First Circuit concluded that Medicaid regulations provided proof that absolute integrity is a condition precedent to payment. More specifically, the court held that these regulations obligated treatment facilities to supervise staff properly as a condition of payment.

Even so, the United States Supreme Court thought otherwise, and on June 16, 2016, issued the much-anticipated decision in *Universal Health Services, Inc. v. United States (ex rel. Escobar).* The Supreme Court held that submission of such claims may be actionable to the extent they do more than merely demand payment from Medicaid. Representations that state only half-truths, according to the Supreme Court, may just be considered a false claim.

Dating back to the American Civil War, the False Claims Act (FCA) has over time become the “primary litigative tool for combating fraud” for both federal and state governments. At its core, the FCA imposes liability on anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” Since the passage of Medicare in 1965, the FCA has grown exponentially in its attempt to control fraud and abuse, while curtailing waste. With the first wave of reform occurring just seven years after the birth of Medicare (The Social Security Amendments of 1972), the FCA evolved quickly, growing under the strength of such further regulations as the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 (Congress expanded the scope of prohibited conduct under Medicare to include practically any remuneration for a physician from the referral of a Medicare or Medicaid beneficiary), the Omnibus Reconciliation Act of 1980 (Congress added a knowledge qualifier so enforcement could focus on providers who “knowingly and willfully” violated the tenets of Medicare and Medicaid), the Civil Monetary Penalties Law of 1981, the Medicare and Medicaid Patient and Program Protection Act of 1987 (Congress enlisted the aid of the Office of Inspector General to clarify which types of provider arrangements were inappropriate), the Ethics in Patient Referral Act of 1989 (the first of three “Stark” laws), the Omnibus Budget Reconciliation Act of 1993 (Stark II) and the 2007 modifications to Stark II (informally known as Stark III), The Fraud Enforcement and Recovery Act of 2009 (which expanded the reverse false claim provision significantly so that it now prohibits “knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay” the United States, and finally the Affordable Care Act (which established a new requirement for “Reporting and Returning of Overpayments”).
With the Escobar decision, the Supreme Court has added to this confusion, noting that FCA liability for failing to disclose violations of legal requirements does not necessarily depend upon whether such requirements were expressly designated as conditions of payment. Rather, what matters to the Supreme Court is not the label the government attaches to any particular requirement, but rather whether or not the defendant knowingly violated a requirement that he or she understood to be material in the decision to make payment. Moreover, when evaluating the FCA’s materiality requirement, the government’s decision to expressly identify any particular provision as a condition of payment may be relevant, but not necessarily dispositive.

According to the Supreme Court, if the government pays a particular claim in full despite any knowledge that certain requirements were violated, such information is considered strong evidence against any finding that such requirements were material. In reversing the First Circuit’s expansive view that any statutory, regulatory or contractual violation is material if a defendant knows Medicaid could refuse payment were it aware of the violation, the Supreme Court failed to provide dispositive criteria by which a submission for payment may violate the FCA.

At issue in Escobar is the “implied false certification theory” of the FCA. According to this theory, when a defendant submits a claim there is an implied certification of compliance with all conditions of payment. Should that claim fail to disclose a defendant’s violation of some material statutory, regulatory or contractual requirement, pursuant to the implied false certification theory the defendant has made a misrepresentation that renders such claim “false or fraudulent.” This theory can attach when a defendant submits claims that make specific representations about goods or services provided, but still fails to disclose known noncompliance with a statutory, regulatory or contractual requirement. Liability does not necessarily turn upon whether those requirements were expressly designated as conditions of payment, but there can be liability for violating requirements even if there is no express condition of payment. However, in the opinion of the Supreme Court, not every violation of this sort gives rise to FCA liability.

Ultimately, what appears to matter most is whether the defendant knowingly violated a requirement that is understood to be material to a decision by which the government makes payment. This is the degree to which materiality must be dissected under the implied false certification theory. While still nebulous at best, the implied certification theory may be a basis for liability when two conditions are met: (1) a claim does not simply request payment, but it also makes specific representations about the goods or services provided; and (2) the provider submitting the claim fails to disclose noncompliance with material statutory, regulatory or contractual requirements. This is what the Supreme Court referred to as actionable “half-truths,” or “representations that state the truth only so far as it goes, while omitting critical qualifying information.” While the Supreme Court failed to impose a limit on this
liability, it did hold that not every undisclosed violation of an express condition of payment automatically results in liability, nor is the relevancy of a condition of payment dispositive of the material inquiry.

Mental health and substance use disorder parity, an idea President Kennedy first championed in 1963 for federal employees, remains the primary objective today. The 1996 Mental Health Parity Act required comparable annual and lifetime dollar limits on mental health and medical coverage for large employer-sponsored health plans, and the 2008 Mental Health Parity and Addiction Equity Act expanded protection to additional financial requirements. In 2010 the Affordable Care Act included mental health care as an “essential health benefit,” and recently the Federal Government released regulations for parity in Medicaid, Children’s Health Insurance Programs and Tricare. Today, an estimated 170 million Americans have insurance coverage for issues pertaining to mental health.

Understanding the laws governing the delivery of mental health care in modern America can be complicated, as compliance regulations have come nearly as far as the science of its treatment in the 126 years since German scientist Friederich Golz surgically removed the temporal lobes of dogs to make canines calmer, thus heralding the miracle of the lobotomy. Today’s federal and state lawmakers continue their Sisyphean struggle to regulate care of the psyche, though their rock just got larger through the Supreme Court’s decision to toss the puzzling issues of fraud and abuse into this already unbalanced mix.

* * *
“We must be willing to let go of the life we planned so as to have the life that is waiting for us.”
– Joseph Campbell

Every era relies on the intuition of a talented few in its search for scientific breakthroughs. Herodotus rejected the notion the Earth was flat, and in particular its description on the Shield of Achilles in Homer’s Iliad. Some 29 centuries later, science has reduced the labors of Homer to little more than myth, though philosophy still honors the epic, from its very first word (“μῆνῐν” or “wrath”) to its lesson addressing the value of balancing excessive pride with the fear of anonymity. Similarly, advances in technology have greatly benefited medicine in recent generations, as doctors increasingly approach diseases of the body from a tangible perspective. However, the treatment of diseases of the mind continues to be far more speculative in nature, serving to highlight the chasm between these two seemingly similar but ultimately disparate fields. This in turn presents a complex issue for both medical practitioner and mental health provider.

While modern medicine can envision scientific methods in its attempt to re-engineer poliomyelitis to treat glioblastoma multiforme, it struggles to cure, let alone truly understand, other attacks on the brain such as depression, posttraumatic stress disorder and addiction. Family members and friends of those fortunate enough to survive this deadly and most common form of brain cancer have little need to understand the importance of the fluorescent dye used during surgery or the necessity of anticonvulsants and corticosteroids. And yet, for the husband or wife watching a spouse suffer through depression or other mental illness, there is no standard prescription to assuage the inevitable feelings of helplessness, and no symptomatic treatment for the comorbidities known as blame, guilt and anger.

Conventional medicine’s struggle to connect matters of the body and mind often ignores matters of the psyche, hiding instead behind a façade of therapeutic and holistic approaches to treatment that references some type of somatic therapy. Even when science has linked certain conditions at least in part with past behavior, such as lung cancer or pancreatitis, the objectivity of the diagnosis renders any subjective reasoning nearly obsolete. Friends and family waiting for a patient to wake from a segmentectomy, lobectomy or pneumonectomy rarely cast aspersions in the direction of the operating room, placing fate squarely in the hands of the surgeon. And yet, someone suffering from depression or addiction is more likely to be called upon to produce positive results. Patients suffering from diseases of the mind that are equally physiological are often forced to endure platitudes such as “what’s
wrong?” or “smile,” much like the recovering addict who must often shoulder insults or vilification from loved ones. Likewise, the moral code to honor the inextricable connection between sleep and healing for post-surgical patients often goes missing in homes afflicted by mental illness, as the disease is considered to be of the mind alone.

Medicine has yet to find the exact location where matters of the mind and body intersect, and for today’s health care practitioner this can create problems in terms of granting equal treatment and coverage. Unlike the traditional practice of medicine, which allows for specialization among its providers, the inclusion of mental health care professionals seeks to endow the totality of care with an umbrella suitable for covering all patients, regardless of type of illness. To be sure, an appendectomy is standard procedure for those suffering from appendicitis, and coronary artery bypass surgery does wonders to restore normal blood flow to the heart. However, the inability of the mental health care physician to diagnose based upon similar tangibles does not mean the disease is unconnected to the body, and as a result the diagnosis often calls upon a greater emphasis on instinct. Not everyone suffering from depression is suicidal, not everyone with mania is an artist, not every addict has lost his or her moral compass, and not every patient presenting with posttraumatic stress disorder has been a victim of war or sexual abuse.

To ensure that both factions receive equal coverage under the law, the Federal Government has been searching as well for a link between body and mind, although its efforts appear more like the construction of a bridge between New York and London than a direct plan to combine disciplines. Nevertheless, the 2008 Mental Health Parity and Addiction Act (MHPAEA), as amended by the Affordable Care Act, now enters its sixth year in its attempt to prohibit financial requirements and treatment limitations for mental health and substance abuse benefits in group health plans from being more restrictive than those placed on medical and surgical benefits, recognizing the equality of illness within the two differing factions. Even the Emergency Medical Treatment and Labor Act (EMTALA), the seminal law protecting all patients who present in an emergency department from disparate treatment due to insurance or financial status, extends the stabilization obligation to mental health as well.

More recently, in February 2016 the Federal Government updated the 1987 regulations that for the past 25 years had governed the confidentiality of substance use disorder patient records. The 38-page installment in the Federal Register bolsters the protection of substance abuse records to persuade such afflicted individuals to seek needed treatment rather than fear potential negative consequences such as loss of employment, housing or child custody, not to mention discrimination by medical professionals, insurers and law enforcement.
Parity and protection alone, however, are but bandages on the system’s infirmities, from the perspective of both the medical and health care provider. Some of the key components needed to find this elusive location where body and mind intertwine cannot as yet be measured tangibly, though modern technology laudably continues to forge ahead in its attempt to deconstruct and therefore further understand the brain. Only when such progressive tools are combined with intuition and wisdom can a great physician capable of such a breakthrough be born, and only then will body and mind find some semblance of balance, both under the knife and under the law.

* * *
The issue of confidentiality when applied to modern American healthcare is fraught with differing objectives, creating myriad complications as the needs of each attempt to merge together in their search for common ground and compromise. To arrive at a sense of clarity, we must look to those exceptions that define the fundamental system of rules at the heart of our nation’s health care structure, as the conflicting areas to be found within shed light on the vulnerabilities of the concept as a whole. The demands of federal statutes aside, gray areas abound, since attorneys can breach the duty of confidentiality in response to threats against life or to prevent substantial bodily harm, physicians must answer to certain matters of public health before protecting the secrets of the patient, and spouses can freely tell all when it comes to the actions of their partner, even if the words between them remain protected.

In direct opposition to the fundamental tenet for which it now stands, the introduction of the 1996 Health Insurance Portability and Accountability Act (“HIPAA”) did not originally include privacy legislation, but was modified in November 1999 to address patient concerns. Some 52,000 public comments and another year later, the U.S. Department of Health and Human Services (“HHS”) issued final regulations known as the HIPAA Privacy Rule. HHS again modified the Privacy Rule in March 2002, and after 11,000 more public comments, issued its directive in August 2002. Since that date, HHS has been nothing short of prolific, releasing HIPAA’s Security Rule governing “e-PHI” in February 2003, HIPAA’s Enforcement Rule in 2006, the Breach Notification Rule as well as HITECH (the Health Information Technology for Economic and Clinical Health Act) Enforcement Rule in 2009, and the updated Administrative Simplification Rule in 2013, among others. Now in 2016, whether providers are ready or not, the Office of Civil Rights (“OCR”), the federal agency responsible for policing patient privacy, announced it will commence wide-scale audits to ensure and enforce HIPAA and HITECH compliance.

The absence of consistent or even cogent public policy behind HIPAA makes this body of law frustrating to patients and providers both. While the desire to foster open and frank communication marks the foundation for protecting confidential discussions between priest and penitent or taxpayer and tax return preparer, HIPAA fails to distinguish between confidentiality and commonality. Instead, HIPAA protects those who fail to protect themselves. Though an attorney and client may renounce their right to privilege by speaking in a crowded elevator, the protections of HIPAA remain sacrosanct to any
patient in that same elevator who speaks aloud about an upcoming appendectomy or a recent bout with a sexually transmitted disease. That said, these expansive HIPAA safeguards prove helpless in response to a data breach, at least with respect to the estimated 112 million health care records compromised in 2015. This highlights the fact that HIPAA’s foremost goal is in some ways flawed at its very core.

To best understand what exactly we are trying to protect, we must ask ourselves why we have encased patient health information (“PHI”) in such an impenetrably regulated fortress. By its very nature, matters of the body are commonplace in health care, and the system seeks to streamline itself by reducing various ailments to 14,400 ICD-10 codes. Within any one condition, however, there may exist layers of confidentiality, useless to the diagnosis and irrelevant to treatment. As a result, that which happens outside the scope of medical oversight during treatment is of no concern to HIPAA, irrespective of any need for confidentiality.

HIPAA imposes draconian punishments on the medical provider who speaks out of turn concerning a simple broken bone, though the cause of the fracture remains bare and exposed, equally, for the accidental slip and fall or deliberate battery. This defines the type of complexity HIPAA cannot reconcile, even after 20 years of presiding over health care. To counteract such disparity, HIPAA regulations must be broad enough to absorb these distinctions, a solution to which is markedly inflexible.

Such emphasis on inflexibility often gives rise to failure, as was the case with the Berlin Wall, Prohibition and punishment for preexisting health care conditions. If modern medicine offers any lesson on how to address HIPAA’s shortcomings, we should attack the cancer of the act’s imperfections from the inside out, rather than blasting a circumference far beyond its borders. Another strong indication that HIPAA may have been doomed from the start is the frequency of data breaches, which are increasing at such a rate there may soon be no PHI left to protect. Before HIPAA takes its next evolutionary step, modern medicine must ask itself if it is worse to fail in the attempt to protect that which is held sacred by law or ignore the transgressions occurring below the surface that so desperately need to be targeted.

To heal the body it may also be necessary to treat the mind, but HIPAA only protects both when medicine recognizes one as a comorbidity of the other. When this is not the case, all of HIPAA’s power slices the treatment in half, at least in terms of confidentiality. What remains of the act’s reach is therefore totally ineffective in light of it’s ultimate intent. At the crossroads where HIPAA now stands, a decision must be made whether to let HIPAA kill health care through its preordained powerlessness, or whether HIPAA itself must be laid to rest.

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HEALTH CARE IS NOT ONE WORD OR ONE PERSON
February 2016

“The truth is rarely pure and never simple.” — Oscar Wilde

With the passing of Justice Antonin Scalia, the Supreme Court has lost a brilliant legal scholar and formidable protector of the U.S. Constitution. Scalia both earned respect and instilled fear during his 30-year tenure supervising America’s political climate. While his legacy ought to take precedence during this time of mourning, widespread panic over the future of health care reform threatens to overshadow the passing of Scalia the individual in favor of highlighting the ways in which his unexpected death may advance partisan agendas.

History has shown that a single justice can have a dramatic effect on the formation and defense of policy. In 1896, Justice John Marshall Harlan disagreed with those Supreme Court justices who believed that the Constitution allowed “equal but separate” public transportation accommodations for black and white citizens. His solitary dissent in *Plessy v. Ferguson* argued otherwise, stating that the Constitution did not create a “superior, dominant, ruling class of citizens” in the United States, and that the Constitution was itself color-blind. Fifty-eight years later, a unified Supreme Court made history with *Brown v. Board of Education of Topeka* in holding that “separate but equal” had no place in public education.

In 1963, eight of the nine Supreme Court justices stopped a practice in public schools of reading from the Bible or reciting the Lord’s Prayer. Justice Potter Stewart, however, believed otherwise in *School District of Abington Township v. Schempp* and argued that religion and government “necessarily interact in countless ways.”

In 1988, while seven Supreme Court justices reversed a federal court order of contempt against Theodore Olson, Edward Schmults and Carol Dinkins in *Morrison v. Olson*, Scalia disagreed, and in his dissent summarized the precise nature of the lawsuit, a matter of power, in particular the “allocation of power among Congress, the President, and the courts” in such a way as to protect the foundation of the Constitution.

To be sure, Scalia was known to chastise Congress, declaring that the Supreme Court has no free-floating power to save the legislative branch “from its drafting errors.” His passing begs the question as to whether one federal jurist has the power to decide the fate of the Patient Protection and Affordable Care Act. Plurality decisions and swing votes notwithstanding, it is the institution of the Supreme Court...
itself and not any one justice that has presided over issues of federal law and other matters of original jurisdiction since 1789. Supreme Court eras referenced by the chief justice at the time represent a reflection of the court’s composition during such tenure, beginning with the Marshall court (1801-1335), and more recently with the Warren court (1953-1969), the Burger court (1969-1986) and the Roberts court (since 2005). It remains to be seen whether it shall be the 44th or 45th president of the U.S. to select a replacement for Scalia, as does the fortitude of the process by which Congress advances or stalls the confirmation of a new Supreme Court justice.

Regardless of the leanings of Scalia’s replacement, what happens down the street from 1 First Street, Northeast will not uproot health care reform as it enters its seventh year. The Affordable Care Act is neither fleeting nor finished, but has instead become the foundation for health care in the United States. No one person, president, senator or justice, can single handedly defeat the only health care system ever known to the 4 million students currently enrolled in the first grade of elementary school. Justice Antonin Scalia may be missed, but the institution of the U.S. Supreme Court shall continue to prevail as the preeminent moral compass for this country.

* * *
“And though she’s not really ill | There’s a little yellow pill | She goes running for the shelter of a mother’s little helper | And it helps her on her way, gets her through her busy day.”
— Sir Michael Philip Jagger and Keith Richards

To date, there exists no thermometer to measure vacillations in a person’s mental health, which is a good thing for febriphobics, and generally speaking, neither acetaminophen nor ibuprofen can cure mental illness, especially if the diagnosis is pharmacophobia. Unlike a fractured bone or sinus infection, ailments of the mind tend to be subjective and therefore more difficult to gauge. Just as a diagnosis of schizophrenia relies on a spectrum, psychotic examples range from hallucinations to speech impediments (even for glossophobics), and bipolar affective disorder by definition alternates between periods of elevated mood and depression. While the tenth revision of the medical classification system known as the International Statistical Classification of Diseases and Related Health Problems (ICD-10) contains more than 14,400 different physical health concerns, the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), still hovers around a paltry 300 disorders from which to choose.

We Know What We Do Not Know

The dearth of clearly identifiable mental disorders is a disheartening factor for the 3.1% of American adults who have presented with serious psychological distress within the past 30 days, or the 1.5 million hospital inpatients discharged with psychosis as the primary diagnosis, the average length of stay for whom was 7.2 days (and this not fast enough for those inpatients with nosocomephobia). Add to such dismal figures some 63.3 million visits to doctors (not including iatrophobics), as well as emergency departments or other outpatient clinics, and top off the numbers by including the 41,149 suicides that took place in 2013 (which equates to 13 deaths by suicide for every 100,000 people), one does not need a PsyD to identify a serious problem.

Even when the risks have certain clarity, like the general population’s 1% at-risk status for schizophrenia, which jumps to 10% for those with a schizophrenic parent or sibling, or 50-60% with schizophrenic identical twin, the inability to test for, or even definitively diagnose such a malady sounds insane. And while medical conditions such as Ebola and Dementia continue to make headlines as being incurable, the prognosis of sufferers from Kluver-Bucy (presenting as memory loss and the eating of inappropriate objects) and Diogenes (the hoarding of random items and pets, though not by disposophobics)
remains equally dismal.

Parity Does Not Mean Clarity or Evenhanded Implementation

Notwithstanding the disparity between identifying and treating mental health and medical concerns, the 2008 Mental Health Parity and Addiction Equity Act (MHPAEA) focused on preventing health insurance agencies from imposing unequal benefit limitations upon the two. While MHPAEA had certain limitations in its initial application across health plans, the Affordable Care Act effectively eliminated any imperfections in parity. Today, a qualified health plan must include at least ten essential health benefits, although certain states require more. California, for example, mandates “chemical dependency services” must be consistent with MHPAEA, including inpatient detoxification, outpatient evaluation and treatment for chemical dependency, transitional residential recovery services or chemical dependency treatment in a residential recovery setting.

For those not quite ready to accept the changes to the mental health industry brought about by health care reform, it may be of some consolation to know that the traditional AA program now extends anonymity to those suffering from online gaming (OLGA), cluttering (CLA), underearners (UA), workaholics (WA) and spenders (SA), to name but a few. With more Californians now dying from drug overdoses than car accidents, perhaps an AA-appropriate elective should replace driver’s education in each high school curriculum (with at least one exception for amaxophobics and possibly both for didaskaleinophobics).

Funding a public system for mental health in California is in many ways as complicated as diagnosing the diseases themselves. With monies from the state, counties, the federal government through Medicaid, Substance Abuse and Mental Health Services Administration block grants, CHIP programs, and the one percent income tax from Proposition 63 (the Mental Health Services Act), one of California’s greatest challenges is to protect the integrity of these funds for the intended beneficiaries. Unfortunately, even the combined strength of MHPAEA and the Affordable Care Act cannot fully stop the payer system synapses from misfiring. Medicaid still has sizeable gaps for adults (21 to 64) seeking mental health coverage, and the payer mix for mental health and addiction treatment in particular is about as functional as a patient diagnosed with dissociative identity disorder. Left untreated, the cost of substance abuse to society is close to $900 billion (factoring in a combination of lost productivity, increased health care costs, and the burden on the criminal justice system, as well as the further cost to victims of related crimes).
The Challenge to Provide Treatment

In antiquity, the Oracle of Delphi or “Pythia” delivered information in the form of prophecies after inhaling oleander vapors rising from the limestone at Mount Parnassus in central Greece. These seemingly epileptic advisors counseled some of ancient Greece’s best and brightest, although even Hunter S. Thompson understood how helpless and irresponsible a person in the “depths of an ether binge” could be. As mental health disorders continue to steal center stage (except for those with topophobia), treatment options remain confusing to more than just decidophobics. Likewise, the ranks of mental health practitioners tasked with doling out diagnoses can be equally disparate, including primary care physicians, psychiatrists, psychopharmacologists, mental health nurse practitioners, psychologists, social workers, members of the clergy and counselors.

While psychotherapy and prescription medication have made great progress in the past 20 years, the list of cognitive therapy treatments still ranges from rational-based (rational emotive and rational behavior therapy as well as rational living therapy) to dialectic behavior therapy. Today disfavored by many health care professionals (and avoided by electrophobics), certain patients still undergo shock or electroconvulsive therapy. Newer brain stimulation options include transcranial magnetic stimulation, vagus nerve stimulation and deep brain stimulation, among others. Residential treatment centers provide an important alternative to psychiatric hospitalization, especially when such facilities extend treatment to an actual curriculum complete with the promotion of life skills and general functionality in an environment similar to that which may have contributed to the original condition at issue.

Though many of the treatments listed above are voluntary, sometimes personal choice is not an option. Involuntary psychiatric holds lasting three days (Section 5150 of the California Welfare and Institutions Code), 14 days (Section 5250) or 30 days (Section 5270) may be used with a person suspected of being a danger to him or herself or others due to his or her mental illness. While able medical and mental health practitioners shepherd patients through such treatments, each temporal extension of an involuntary hold includes ways in which the patient can seek emancipation. To be sure, mental illness is a condition, not a crime, and while there is no right to a jury trial, a writ of habeas corpus may still apply. In much the same way as mental illness is diagnosed and treated, the law of involuntary holds that was designed to protect society can be unpredictable at best.
HIPAA: SOCIETY’S MODERN DAY PROHIBITION
May 2015

“Secrets, silent, stony sit in the dark palaces of both our hearts: secrets weary of their tyranny: tyrants willing to be dethroned.” – James Joyce, Ulysses

Codified in American Law through Article Three of the United States Constitution and evolving through changing times by way of the Sixth and Fourteenth Amendments, the right to trial by jury remains a sacrosanct keystone of our nation’s legal system. Even so, there exists a degree of delicacy with which the judicial system evaluates the facts of any given case, and all involved must remain mindful that at times pertinent information may not be available for consideration. Significant violations of judicial filtering may result in the end of deliberations, known more abrasively as a “mistrial.”

The judicial system understands all too well that information cannot be honestly disregarded or ignored once heard, and does its best to account for the imperfections of the human mind. To enforce the Constitutional tenets of trust and truth upon which the faith of a jury must rest, today’s health care providers find themselves held to a unique standard of scrutiny when dealing with issues of privacy.

Recently, the greatest challenge to health care in America has been to find ways in which to safeguard the confidentiality of patient health information, also known as protected health information (PHI). In the past several years, the United States has spent billions of dollars to safeguard the gamut of health information, from broken bones to heart surgery to mental illness, all of which are protected by federal and state law from public disclosure. The potential punishment for failure to respect and uphold patient confidentiality by those charged with its safekeeping strikes terror in those who may even unwittingly cause public disclosure.

The Federal Office of Civil Rights (OCR) oversees complaints relating to the 1996 Health Insurance Portability and Accountability Act (HIPAA), and more specifically those 109,722 HIPAA-related complaints registered between April 2003 and February 1, 2015. Of these potential HIPAA infractions, approximately 70% did not fall within OCR jurisdiction or the OCR determined no violation had occurred. But in some 40,000 cases investigated by the OCR, 30% found no violation, while 70% required some corrective action usually in reference to impermissible uses and disclosures of PHI, failure to keep PHI safe, lack of patient access to PHI, or disclosure of more information than was reasonably necessary. Private practices and acute care hospitals were among the worst offenders.
When it comes to PHI, the law of our nation insists that every patient is entitled to absolute confidentiality. While the penalties for transgressions in confidentiality may differ due to a number of factors, health care’s version of the proverbial mistrial is known collectively as a “data breach.” In matters of health care records, however, not all data breaches are created equal, and perhaps more important, not all victims of a data breach are aware of the misuse of their information. Nevertheless, HIPAA’s influence in this respect has changed the very infrastructure of health care, as it protects the disclosure of a broken finger as equally as a diagnosis of iatrophobia. It is important to note that, like stricken testimony or illegally obtained evidence, when sensitive medical information is divulged, the knowledge of its existence cannot be reversed.

As the new program flexed its muscles, it was no surprise that 2013 saw 6,381 more HIPAA complaints than 2004, resulting in a 51% increase over the decade. At times the complaints and resulting fines make sense, as when someone stumbled across the patient health information of a deceased partner, launching an investigation that ended in a $4.8 million fine against New York and Presbyterian Hospital and Columbia University. The fact that the transgression was caused by an errant physician deactivating a personal computer server on a system network did little to mitigate the record-breaking penalty levied against these two institutions. In the view of HIPAA, a breach is a breach.

Sometimes the penalty is appropriate, though it may not seem fair. One such example occurred when CBS purchased a photocopier from Affinity Health Plan, Inc. Before releasing the machine, Affinity forgot to delete the stored patient health information of up to 344,579 individuals. The resultant fine was $1,215,780.

There are also instances when a data breach determination is the right decision, even if the facts are somewhat at odds with the law. When a thief stole an unencrypted desktop computer from Sutter Health containing the patient information of over 4 million patients, one of the largest class actions to date followed. In 2014 the California Court of Appeal dismissed the 13 class action lawsuits seeking over $4 billion in damages because Sutter Health did not intend to disclose the compromised information, and the court ruled that loss of the unencrypted computer alone was “not a breach of confidentiality.” When the California Supreme Court rejected this review, the health system’s 50,000 employees, 5,000 physicians and 5,000 volunteer partners, not to mention the 197,264 patients discharged from Sutter Health in 2013, breathed a collective sigh of relief. While it would be tragic if a casual theft were to cause the insolvency of such a thriving system, California may never know what came of the 4 million missing patient records.
The right to an individual’s privacy is by no means specific to the health care industry, but financial transgressions highlight the difficulty of protecting data in the modern age. While not necessarily a health record breach, Target’s 2013 debacle affected 40 million credit and debit card accounts and exposed the data of 70 million customers. In 2012 Global Payments, Inc. reported the compromise of 1.4 million card accounts. Five million Tricare military beneficiaries took issue in 2011 when computer backup tapes with personal data on military service members went missing from the care of a Tricare-contractor. Finally, the February 2015 disclosure of a breach at Anthem involved as many as 80 million current and former Anthem members. With this in mind, perhaps the United States should take a different stand when it comes to HIPAA. With over 320 million residents to care for, we must ask ourselves how many mistrials and how many bells set into motion that cannot be unrung it will take before HIPAA proves itself unworthy of the task at hand? Only time will determine the future of HIPAA, though history tells us that the folly of prohibition lasted 13 years.

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“Nothing recedes like progress.” — Edward Estlin (e.e.) Cummings

Though cutting-edge technology serves as the foundation for modern American healthcare, an accurate measure of progress must consider the occasional conflict between society and science. Even as yesterday’s medical miracles give way to what are now considered “state of the art” practices, it is the duty of health care providers to remain mindful of both sides of the equation, balancing the capabilities of today’s technologies with the needs of today’s patient. If society and science are not in sync, patient care will suffer, and sometimes we can only advance healthcare through old-fashioned methods. For example, radiology information systems (RIS) and picture archiving and communication systems (PACS) collaborate to deliver dynamic and brilliant medical images to any healthcare provider around the globe with access to a desktop computer or mobile device. And yet, if these technologically advanced tools of the trade fail to employ the appropriate methods of encryption as they transmit digital health information to a doctor’s iPad as he or she vacations on the island of Tristan da Cunha, or worse, send this sensitive information to the hard drive of any one of the island’s 297 permanent residents living in the recesses of the Atlantic Ocean, a data breach occurs. This is no small matter for the hospital of today, and could easily result in a series of fines that could force the shutting of its doors for a single infraction.

Likewise, the modern technique of delivering medication placed inside microscopic bubbles of fluorocarbon gas injected into a patient’s bloodstream, set to dispense a strong narcotic upon the release of a high-energy ultrasound pulse, does little to protect the attending physician from the misplaced wrath of a patient in a hypnagogic state, that period just before falling asleep. This is the state of health care today, where the miracles of modern technology are forced to work their magic by providing what all patients want most – quality health care – in the last place anyone wants to be – a hospital. Bringing innovation to the forefront of healthcare can at times be as challenging as drawing the number six while making clockwise circles with one’s legs. In matters of life and death, however, healthcare is all too familiar with the need to overcome adversity, and innovation will always fight to find its place so that the system can flourish.
Remember the Basics in Advancing Health Care

A 640-slice computed tomography (CT) scanner can digitally capture an image of the human heart in less time than it takes that heart to beat, while also aiding in the evaluation of strokes, pulmonary embolisms, abdominal illness and sinus headaches. In the hands of an inept clinician, however, the results of this $2.5 million technological masterpiece can be just as unhelpful as the once lauded but now discredited pneumoencephalography study, an antiquated medical procedure which involved draining cerebrospinal fluid, replacing it with oxygen or helium and then filming the results by x-ray. Not surprisingly, Sir William Osler, a founding professor of Johns Hopkins Hospital who was also known as the “Father of Modern Medicine, pioneered the notion that a complete medical diagnosis must also include a thorough physical examination. Although Osler died 95 years ago, his legacy has endured and remains inextricably connected to the use of any 640-slice CT scanner.

Remember the Patient

Naturally, the idea of robotic surgery can leave certain patients unnerved, especially if the doctor behind the computer terminal is wearing an Atari hoody. And yet, when viewed in the proper context, the medical advantages of robotic surgery in certain common procedures, such as gallbladder removal, hysterectomy, kidney transplants and hip replacement, still outweigh the aversion experienced by some when facing high-functioning, if inanimate, healthcare providers.

Whether viewed as a legitimate response to an unnatural trend or a glorified form of pupaphobia (fear of puppets), meaningful discussion with the patient before employing robotic surgery is yet another fundamental aspect of the physician/patient relationship. While there are many ways to capture a patient’s written consent before attempting such modern surgical procedures, only through one-to-one communication can such a directive be meaningful.

The same analogy applies to a physician’s bedside manner. To be sure, the quantity of patient health information existing on a doctor’s iPad can be astounding, and if used correctly should ultimately lead to better diagnoses based upon clinical results. But no matter how impressive the capabilities of the iPad mini 3 may be, it cannot take the place of the provider delegated to that hospital bed. Such technology can, however, remind the clinician that making regular eye contact with the patient during an examination goes a long way toward establishing trust and creating a much-needed bond between patient and provider.
Remember to Budget

When it comes to healthcare, new equipment does not come cheaply, and the costs for most technological advances do not end with acquisition. Radiological modalities, for example, require service agreements and an integrated process by which information can be shared, stored and most importantly, viewed. Sometimes the price tag of such accouterments exceeds the cost of the acquisition itself, and proper institutional budgeting must accommodate both.

Remember to Integrate

Efficiency is the key to survival for the modern healthcare provider, and this is particularly true of hospitals. A hospital’s revenue cycle must depend upon an accurate and expedient calculation of the sum of all clinical departments. As the push toward electronic health records and meaningful use dominates today’s healthcare news, the question of how well pharmacy charges reconcile with nursing documentation and clinical laboratory results impacts any hospital’s ability to bill and collect faster. Any deployment of hospital-wide technological advances must be tempered by a commonality of systems, which presents an obvious challenge for any hospital looking to provide automated pharmacy services, a PACs system and a way for an attending physician to peruse a patient’s vital statistics in “real time” from any location.

Remember to Train and Educate

Perhaps the most advanced radiological modality on television made its debut circa 1966, on the original Star Trek series. With his twenty-third century bedside manner and degree from University of Mississippi, Dr. Leonard H. “Bones” McCoy’s tool of choice was the tricorder, a handheld device used to diagnose disease and collect information about a patient’s body. An invaluable medical device for any qualified physician, the necessity for proper training and education on its use underscored the reason that Bones alone was capable of using the tricorder for the medical purposes it provided.

As health care research and development push forward, each new innovation requires proper training and education for the clinician who uses it. Training courses in PACs administration can take up to a week and cost an institution more than $5,000 for each pair of employees. It may take another week and further $10,000 to learn how to use a 640-slice CT Scanner. For those interested in familiarizing themselves with the operation of a sophisticated robotic platform designed to make surgeons better and scars smaller, there are more than 1,000 hours of procedure videos to support education on the da Vinci Surgical System.
Remember that Innovation Itself Grows Outdated

Any hospital able to afford the 3 Tesla Digital magnetic resonance imaging ("MRI") scanner for digital broadband MRI imaging, a CyberKnife for robotic radiosurgery, digital subtraction angiography equipment or even a shockwave lithotripter should not get too comfortable with its conquering of the health care tech market. Much as Apple personal computers from 1984 have evolved from the Macintosh 128k to the 3.7GHz processor, 15GB 1600MHZ memory of today’s MacBook Pro, medical technology and innovation evolve at an astounding rate. Although computed tomography successfully scanned the human brain a decade before Apple’s first Macintosh, the difference between a 1-slice and 640-slice CT Scanner is beyond comparison. In the medical specialty of cardiology, some experts believe that a 64-slice scanner sufficiently captures the image of an entire heart, while critics state that a faster scanner such as a 320-slice or 640-slice is imperative, so that the entire heart can be imaged within a single heartbeat. If given a lineup of images from modalities of sufficient difference (16, 64 and 256 slice, for example), most radiologists can immediately identify the fastest scan, though even within certain thresholds, a high definition 64-slice CT produces images up to 100 times faster than the standard 64-slice CT.

At the same time, a physician’s approach to diagnosis is just as important as the technology with which results can be achieved. A positron emission tomography ("PET") scan identifies anomalies in the human body by tracing an injection of fluorodeoxyglucose. A radiologist may work closely with an oncologist as the pair searches for tumor metastasis, the success of which depends as much on the physicians as on the accuracy of this radioactive modality.

It may seem unfortunate that the greatest scientific achievements are still beholden to the ordinary doctor, nurse or technician working in a local hospital at any given time. The relationship between entity and individual, and more specifically between hospitals and physicians, can be erratic and/or symbiotic on any given day. To be sure, most doctors prefer an institution with a strong commitment to capital innovation, and in the area of health care technology this proclivity is even more pronounced. At the same time, if CT modalities could speak, they may wish to have a word or two with the professionals tasked to review and interpret the results. For health care to excel, the whole must truly be greater than the sum of its parts, and for this reason health care’s version of the idiom “keeping up with the Joneses” must include not only the ability to afford innovation, but also to maintain it and train the appropriate staff to utilize the new technology. The challenge to ensure that today’s practitioners integrate with innovation may ultimately determine the fate of tomorrow’s health care.

* * *
Lower Oconee Community Hospital in southern Georgia closed its doors this month, eliminating 25 hospital beds and up to 100 hospital jobs. This was the fourth Georgia hospital to fold in two years and the eighth rural hospital in the state to close since 2000. Although Lower Oconee's shutdown may not have registered much media coverage, those in search of medical attention in Glenwood, Ga., should be mindful that the closest hospital is now 30 miles away. As reference, Santa Ana is 30 miles from Los Angeles. When faced with a medical emergency, no one fancies a long road trip.

Whether viewed as the fallout of modern healthcare’s transition from cost-based to performance-driven measures or simply as collateral damage from the effects of partisan politics, the growing trend of hospital closures in the United States has failed to command the attention it deserves. Across the nation, both rural and urban areas are struggling daily to maintain the necessary infrastructure to provide support for residents. The loss of even the smallest facility places additional strain on the already tenuous existence of neighboring institutions.

To make matters worse, access to prompt medical care is not the only thing compromised when a local hospital shuts down. In many instances, the neighborhood hospital, especially in rural areas, serves as the backbone of the community, providing employment around the clock, acting as an institution for community gatherings and, in some cases, offering the area’s only convenient restaurant and banking options.

The role of the American hospital has evolved, and only in the last century has it come to be regarded as the centerpiece of our nation’s healthcare delivery system. Before modern advances in technology and medical science, and before the influence of President Franklin D. Roosevelt’s New Deal, a hospital was considered a place where the poor and destitute could turn when there was neither friend nor family to provide care. By contrast, today’s medical facilities are the foundation of our healthcare system, where modern medicine and miracles intersect and high-quality care is readily accessible.

For then-Rep. Gabrielle Giffords of Arizona, that evolution in the role of hospitals may have saved her life. She was taken to and treated at the University Medical Center in Tucson less than an hour after suffering a gunshot wound to the head in January 2011. Had the congresswoman been speaking in a place like Glenwood, Ga., today, it is doubtful she would have survived the 30-mile transport to the nearest hospital.
Federal laws have created the functional equivalent of a constitutional right to emergency medical treatment at nearly every hospital across the country, extending even to those outside the protections granted by citizenship. Popular culture, too, has established the idea that only a hospital can properly address a medical emergency, because in matters of life and death, a hospital is symbolic of hope. No ambulance company or helicopter transport can fill that role in a town that has lost its hospital.

For healthcare reform to mature unimpeded, the debates surrounding the Affordable Care Act require concentrated, nonpartisan attention. And for reform to succeed, we also need hospitals to flourish, especially in places with few options.

Every hospital has a story to tell. Lower Oconee Community Hospital will not keep the nation’s attention for long, but its absence and that of other hospitals that close will certainly leave profound voids throughout their communities. Rather than ignore these continuing cracks in the foundation of our evolving healthcare system, there is much to be learned from these now-defunct facilities. We would do well to address the underlying problems behind the closures.

As any medical practitioner will tell you, it is wiser to treat the cause today than alleviate the symptoms tomorrow.

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HEALTH CARE’S ADVENTURES IN WONDERLAND:
PROVIDER AGREEMENTS FOR ELECTRONIC HEALTH RECORDS

By Craig B. Garner\(^1\) and Jessica Weizenbluth\(^2\)

“Now, here, you see, it takes all the running you can do, to keep in the same place. If you want to get somewhere else, you must run at least twice as fast as that!”\(^3\)

I. INTRODUCTION

Today’s health care provides its own spin on the word “complex,”\(^5\) while at the same time forging possible paths to what may be “unwinnable” scenarios.\(^6\) For the modern physician,\(^7\) the universe within which he or she exists requires updated definitions for words such as “complex” and “challenging,” especially as that “perfect storm”\(^8\) also known as health care reform continues to age. Somewhere in between the 2015 Physician Quality Reporting System (“PQRS”),\(^9\) the Physician Value Based Payment Modifying Policies (“VBP”)\(^10\) and tenth revision of the International Statistical Classification of Diseases and Related Health Problems (also known as ICD-10),\(^11\) physicians find themselves still struggling to adopt electronic health records (“EHR”) in practice.\(^12\)

As technology continues to evolve, there remains a general landscape with which those in the health care field must familiarize themselves. Even from this challenging vantage point, providers still have opportunities to bolster their position and practice their craft as they continue down the digital path and adopt an EHR system for which the Federal Government established incentive payments.\(^13\)

II. WHAT COULD GO WRONG?

In 2004 President George W. Bush announced his administration’s objective for “development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care.”\(^14\) In fact, President Bush predicted that by 2014 there would be “an interoperable electronic health record for each U.S. resident.”\(^15\) Needless to say, President
Bush’s goal is still a work in progress. Still, a decade later, 2015 has been a busy year for federal regulations on EHR incentive programs and meaningful use for EPs, all of which occurred concurrently with the downward payment adjustments under the Medicare EHR Incentive Program, updates to the certification criteria, as well as the Health IT Certification Program by the Office of the National Coordinator (“ONC”), and the solidification of the fate of the Merit-Based Incentive Payment System (“MIPS”) for EPs long into the future.

Today, the Federal Government has outlined four specific goals in its attempt to apply the “effective use of information and technology to help the nation achieve high-quality care at lower costs, a healthy population, and engaged individuals.” These goals include: (1) the advancement of person-centered and self-managed health; (2) the transformation of health care delivery and community health; (3) the fostering of research, scientific knowledge and innovation; and (4) the enhancement of the nation’s health IT infrastructure. A laudable objective notwithstanding, EHR implementation nevertheless has met with certain challenges along the way.

These so-called challenges present for certain Providers as larger obstacles to implementation. On the front line of health care reform, physicians must lead the EHR charge, even as they face the greatest risk individually without many opportunities to align independently. Even though many consider EHR to be cost prohibitive, the Federal Government addressed implementation, in part, when it encouraged physician and hospital alignment to further EHR. The track on which EHR exists appears to be incapable of derailment, but Providers would be remiss to think that the contractual agreements that create a vehicle with which they can join the convoy, contain the entire gamut of necessary rails. Rather, each Provider should examine the path ahead, paying careful attention to key terms that may prove the difference between digital success and demise.

III. SOME IMPORTANT TERMS TO CONSIDER

W61.33XA: Pecked by a chicken, initial encounter

When transitioning from paper to digital in any medical practice, Providers must familiarize themselves with basic field-related terminology, as well as gain a general understanding of the pending technological acquisition, not to mention what the potential developer/partner provides and what it demands in return. To be sure, such information is far more useful before signing an agreement than after execution. Not understanding some of the more salient terms and conditions of an agreement to acquire an EHR system, especially terms unique to this new digital frontier, can compromise a Provider’s medical practice, and have the potential to create vulnerabilities in the delivery of patient care as set forth...
below, if unfavorable terms were to evolve into medical risks. This section provides a general overview of key terms, the knowledge of which all Providers should be mindful.

A. Indemnification

1. Indemnification as a Moving Target

In many contractual relationships, the notion of indemnification serves as the cornerstone for protection. In an EHR contract, the party charged with technology development (the “Developer”) must offer the EHR software to the health care provider (the “Provider”) with certain necessary services, and the Provider agrees to pay the cost (alone or with one or more third parties). Bound and isolated by the agreement, success is typically, dependent upon the actions and omissions of the Developer and Provider. Indemnification language in Developer contracts is critical, especially when third party claims loom in the distance. The degree to which one party must indemnify the other for transgressions, set forth in contractual indemnity provisions, can be the difference between success and failure. Other times, however, an agreement may be altogether silent on indemnification.

When drafting an indemnity clause, the Developer may insist the provider bear liability for any third party claims that arise from the EHR technology software. Providers should be reluctant to accept such liability, especially for technology outside the scope of the Provider’s expertise and control. Reasonable parties generally accept responsibility for the risk of reasonable culpability, but not much more. Developers will insist the Providers indemnify for all personal injury or death claims, at least to the extent such a claim includes third parties like Developers. Unless the harm to patient care resulted from an unlikely issue on the part of the Developers, such potential liability is not unreasonable for Providers to keep. Other claims, such as privacy violations, may not be as objective for purposes of allocating culpability. While this is a fundamental tenet of the system, there is often a fine line between a technical malfunction and “user error.” If possible, it is best to approach indemnification through mutuality, so that each party is responsible for its own acts and omissions.

2. Indemnification (Intellectual Property)

When Providers and Developers contract, it would be nice to assume that all necessary software licenses and legal rights are in order, to accommodate the transaction. There are instances when a Developer intentionally, unintentionally or recklessly fails to obtain certain legal rights and, as a result, the third party who holds exclusive or superior ownership rights to the intellectual property, takes issue. Under California law, the owner of a patent or copyright for intellectual property has the right to
sue anyone who uses the intellectual property without having first obtained the necessary rights. Indemnity can be as broad as a contract provides or even implied through its absence in an agreement, or in equity. Insurance, too, is prudent in an agreement, and those between Provider and Developer are no exception.

B. Confidentiality and Non-Disclosure Agreements

Both Provider and Developer may insist on certain confidentiality requirements before, during, and possibly even after the existence of a contract between them. Developer contracts may define “confidential information” too broadly, and such scope is almost always prudent to measure. To be sure, the Developer may include provisions restricting disclosure of the technology to third parties, not to mention the consequences for failing to comply such as the right to terminate the agreement upon a confidentiality breach.

Too broad of a definition, however, could prevent a Provider from entering into meaningful negotiations, especially if a confidentiality agreement creates restrictions on disclosure to trusted advisors. Restrictions that prevent sharing certain information with other Providers could compromise certain networks if the sharing of such information proves important yet prohibited. In the field of health care, confidentiality is almost always important, but even privacy has certain limitations. Providers should be mindful not to become unnecessarily bound, especially when it comes to conducting business. At the same time, Providers should insist on protecting sensitive practice information, thereby making it critical that the confidentiality agreement is mutual. If this creates a source of contention with the Developer, it may signal yet again the importance of finding a different developer.

There are also exceptions to confidentiality obligations, despite the language in an agreement. One such instance includes disclosure mandated by law. Certain situations, however, may not create a legal obligation to disclose, but there may exist other reasons for why a party desires to volunteer information at the center of a confidentiality agreement, so appropriate language in a confidentiality agreement can still preserve the integrity of a Provider’s practice, as well as his or her reputation. Only by understanding the terms for a confidentiality agreement, can a Provider make certain, sensitive disclosures with confidence.

C. A Storm is Coming

The path toward EHR has not always been without skeptics. While modern medicine may accept the importance of creating a digital record of each and every patient experience, the resulting disruption is not overlooked. “One of the under-told
stories from the digitizing of patient records is the burden computerized documentation places on doctors. They are being tasked with greater data entry, and less with analysis and care. This goes beyond anecdotes. To be sure, technology today creates new opportunities for Providers that simply did not exist in the past, not to mention the possibility of delivering superior medical care due to the accessibility of the information at hand. Notwithstanding, some architects of the proverbial cloud, including Amazon, Google and Microsoft, fail to embrace this technology in the way that federal and state laws mandate health care’s acquiescence. Only time will tell, however, if the cloud is ready for health care and its EHR requirements.

D. Warranties and Disclaimers

A warranty is an express or implied assurance from one party that what it promises in the contract will in fact be provided to the other party. An implied warranty is one that may be contractually binding, even if unstated, while an express warranty is set forth in the agreement. If parties prefer to avoid any implied warranties, a contract can always expressly disclaim them.

At times, Developer contracts may include an express warranty, but only as it relates to the Developer’s “then current” technology. Understanding a transaction’s “then current” status is challenging, yet critical for both sides. Providers should review the documentation to identify which provisions refer to and determine the technology needed at the time the parties enter into an agreement, at least to the extent the Provider desires an express warranty. As an extra measure of protection, a Provider may want to include language that protects against any adverse impact from future changes and technology, or states that these same changes down the road will not retroactively compromise the express warranty in place. Rather than predicting future technology, however, a sound practice should be the inclusion of all material specifications, initial Developer proposals and Provider needs, leaving nothing to chance outside the four corners of the final agreement.

1. Meaningful Use Warranty

“Meaningful Use” is part of the foundation for most agreements between Developer and Provider. Standard terminology in Developer contracts designed to identify Provider eligibility for participation in Medicare and Medicaid EHR Meaningful Use Incentive Programs should always include an express warranty covering meaningful use certification for the present, as well as the necessary and appropriate future modifications required by federal law. If a Developer is not willing to expressly warrant for

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meaningful use, Providers must determine the Developer’s status for certifying the same. Providers should be cautious when a Developer expressly certifies Meaningful Use at the time the parties enter into an agreement but refuses to make any representations for the future. With no future warranties, a change in the Developer’s system that results in a loss of certification, or perhaps even the loss of the Developer, will create sizable challenges for any Provider. Planning for such an event can be even more complicated, especially if the Developer cannot provide price information on the cost to comply with that which is unknown.

2. Integration Clauses

“Terms set forth in a writing intended by the parties as a final expression of their agreement with respect to the terms included therein may not be contradicted by evidence of a prior agreement or of a contemporaneous oral agreement.” This standard integration clause language, common in most agreements, “vitiates” any and all promises and representations made before the parties agreed to contract.

Irrespective of what was discussed in the past, the inclusion of similar language effectively ensures that the agreement is all that really matters from this point forward. While this applies to the “four corners” of the agreement between Provider and Developer, Providers should always make sure the acquisition is comprehensive enough to address all facets of EHR and that it communicates directly with the surrounding digital landscape from where the Provider is expected to make Meaningful Use of its EHR. Anything less than such a demand may defeat the very purpose for the software.

E. Limitation of Liability

Y92.253: Opera house as the occurrence of external cause

A limitation of liability clause is a provision that limits the financial risk a company faces in the event of a lawsuit usually by placing limits on the amount of potential damages a company may be required to pay. In an EHR contract, Providers should be reluctant to limit the liability for the Developer, either with monetary caps on payout obligations or by excluding consequential and other special damages so that the Developer is only liable for direct damages.

Before signing any agreement, Providers should determine if the Developer has set a maximum dollar amount for liability. If there is maximum dollar threshold, Providers should analyze how this amount could impact business under different scenarios. Rather than limiting liability based on a dollar amount,
Providers may consider liability limitations in terms of possible categories of damages, although it is difficult to waive liability for direct damages (arising from costs incurred as a result of a party's breach). A Developer typically will seek to avoid liability for consequential damages, which are damages that result on account of the breach, such as lost profits or damage to reputation.

### F. Termination and Wind Down

*R46.1: Bizarre personal appearance*

It is never too soon for a Provider to think about the end, or at least the end of an agreement with a Developer. Continuous access to patient records is critical for almost all practices, and equally important is the language in an agreement addressing a possible transfer of information from one EHR system to another. It is also important that the operative business associate addendum includes a provision that ensures the return or destruction of all protected health information. While Providers would be prudent to demand the return of their own information, at a minimum they must ensure there is no compromise on the integrity of that information.

One of HIPAA's original tenets was portability, at least for the patient’s health records. Patient health information quickly evolved into “PHI” and “the meaning ascribed to it in the regulations concerning the confidentiality of individually identifiable health information promulgated by the Secretary of Health and Human Services” pursuant to HIPAA. After HITECH, the idea of portability merged with data portability, the purpose of which includes the following:

Data portability. Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

(ii) Immunizations. The standard specified in § 170.207(e)(2);

(iii) Cognitive status;

(iv) Functional status; and

(v) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information.

(vi) Inpatient setting only. Discharge instructions.
Providers are like shepherds, only guarding medical records instead of sheep. With an appropriate BAA in place between Providers and Developers, the collection of the medical records at the conclusion of the agreement should resemble the return or destroy language in most BAAs. It is important that Providers preserve the default provisions of a BAA in agreements with Developers, and even more important that the Developers comply.

The standard by which Developers must maintain an EHR system for purposes of certification is always evolving, yet the standards remain strong. Until January 13, 2016, the patient summary record must meet the following standards:


After January 13, 2016, the standards include a fourth requirement:


No matter how the relationship between Provider and Developer may end, it does not modify the EHR-related obligations on the part of the Provider. Even as the standards evolve, Provider compliance is not optional. As important as termination and wind down may be for the Provider, it is only a transition. The ease with which a Provider can move from one Developer to another depends on the Developer agreement, not to mention the condition of the Provider’s information upon retrieval from the system, assuming the information the Provider can retrieve exists in a usable format.
denial by a Developer, of course, creates an entirely added level of complexity for the Provider, although strict adherence to federal law in drafting business associate agreements should prevent such an unpleasant result. Ultimately, Providers must retrieve patient information in an accessible format upon termination of the agreement. “Portability” (another term from “HIPAA”) remains critical. Knowing in advance the cost and timing for such a transition is also an important item to negotiate before entering into an agreement with a Developer. and Providers should always be mindful that business stability upon termination is critical.

G. Dispute Resolution

Z63.1: Problems in relationship with in-laws

The dispute resolution provisions within an EHR contract are integral to avoid any disruption in patient care and business operations. To determine the best option for Providers, consider what is available, and how implementation would occur. Providers should be mindful that during a dispute the need to maintain an EHR system most likely remains. The costs of replacement or disruption of services, however, may be more challenging and expensive than the dispute itself. Fortunately, alternative dispute resolution, and arbitration in particular, may be just as difficult to avoid as the underlying disagreement. Providers should not ignore the additional benefits to mediation, especially when the dispute involves sensitive business information or even PHI.

H. The Take Away is that EHR is Not Going Away

In passing California Senate Bill 945 in 2010, Medi-Cal can distribute one billion four hundred million dollars ($1,400,000,000) to Medi-Cal providers over the next 10 years for EHR support purposes. The federal and state commitments to wide scale implementation of EHR are unmistakably clear, but ultimate success depends upon the ways in which Providers and Developers interact to accomplish these objectives. Health care is a business, and for Providers to successfully participate in EHR implementation, they must focus on all salient provisions of any Developer agreement.
IV. HITECH WITHOUT THE EHR BUBBLE

A. There Is Always Room to Improve

Notwithstanding the importance of Provider success when it comes to EHR implementation, each and every Provider path intersects with HITECH and the privacy obligations set forth in HIPAA. The success of health care reform depends in large part on innovation, including the replacement of paper medical records with EHRs. Still, the Federal Government still recommends the same degree of vigilance as before. In this January 2014 study, the Office of the Inspector General (“OIG”) for the United States Department of Health and Human Services (“DHHS”) noted:

[C]ertain EHR technology features may be used to make true authorship of the medical record and distort information to inflate health care claims. The transition from paper records to EHRs may present new vulnerabilities and require the Centers for Medicare & Medicaid Services (“CMS”) and its contractors to adjust their techniques for identifying improper payments and investigating fraud.

More recently, the OIG urged the federal Office of Civil Rights to strengthen its oversight of the ways in which covered entities comply with the privacy standards under HIPAA as well as OCR’s follow up on reported breaches of patient health information.

B. When Things Go Wrong?

Even the best-made plans for EHR do not always work, the result from which can be a “data breach.”

<table>
<thead>
<tr>
<th>Violation</th>
<th>Minimum Penalty</th>
<th>Maximum Penalty</th>
<th>Annual Maximum Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entity did not know (even with reasonable diligence)</td>
<td>$100 per violation</td>
<td>$50,000 per violation</td>
<td>$1.5 million</td>
</tr>
<tr>
<td>Reasonable cause, not willful neglect</td>
<td>$1,000</td>
<td>$50,000</td>
<td>$1.5 million</td>
</tr>
<tr>
<td>Willful neglect, but corrected within 30 days</td>
<td>$10,000</td>
<td>$50,000</td>
<td>$1.5 million</td>
</tr>
<tr>
<td>Willful neglect, not corrected</td>
<td>$50,000</td>
<td>None</td>
<td>$1.5 million</td>
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</tbody>
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Monetary penalties notwithstanding, HIPAA and HITECH obligate Providers to mitigate the damage caused by privacy transgressions, including the use or disclosure of protected health information (“PHI”). Federal law also requires the Provider to give notice to each individual whose unsecured PHI has been disclosed due to a breach, or there is a reasonable belief of a disclosure. California’s Confidentiality of Medical Information Act (“CMIA”) also requires notification within 15 business days from identifying the breach.

V. CONCLUSION

In the past several years, the United States has spent billions of dollars to safeguard the gamut of health information, from broken bones to heart surgery to mental illness, all of which are protected by federal and state law from public disclosure. The OCR handled 109,722 HIPAA-related complaints registered between April 2003 and February 1, 2015. Private practices and acute care hospitals were among the worst offenders. When it comes to PHI and EHR, the law of our nation affords each and every patient is with strict confidentiality. The influence of HIPAA and HITECH on health care has changed its very infrastructure, protecting the disclosure of a broken finger equally as a diagnosis of iatrophobia.

Without Provider participation and cooperation, however, HIPAA and HITECH mean nothing. Failure by any Provider to follow the strict requirements of HIPAA and HITECH may result in loss of license, significant financial penalties, or both. To be sure, Providers have financial incentives to comply with HIPAA and HITECH, including Meaningful Use. To avoid penalties and enjoy the financial incentives of statutes and regulations relating to EHR, there will be a Developer agreement along the way, into which Providers must enter. Providers should be mindful that such agreements, although necessary, can be treacherous, and Providers must pay careful attention to all terms included therein, especially since HIPAA and HITECH are rather unforgiving.

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3. Lewis Carroll, THROUGH THE LOOKING GLASS AND WHAT ALICE FOUND THERE at 16 (Macmillan 1871).

4. This is one example from the tenth revision of the International Statistical Classification of Diseases and Related Health Problems (also known as ICD-10). See infra n.11.


6. History, science and the arts provide the discerning individual with numerous examples of unwinnable scenarios:  In Colonial America, an accused witch faced the “water test” to determine guilt or innocence. See generally Matthew Hopkins, THE DISCOVERY OF WITCHES (1647). After landing in a body of water, if the individual could float, the town concluded the now-proven witch forwent baptism after contracting with the devil. If she could not float, however, her innocence was celebrated post mortem. Id. “Morton’s fork” (a term originating with John Morton, Archbishop of Canterbury, in the late 15th century) refers to contradictory arguments leading to the same unpleasant result. See, e.g., United States v. Winters, 782 F.3d 289, 299 n.5 (6th Cir. 2015). One such example is the Scylla and Charybdis, both unpleasant results when traveling by water between mainland Italy and Sicily circa 800 B.C.E. See, e.g., Homer, THE ODYSSEY at Book 12 (Robert Fagles trans., Penguin Books 1996) (“Deadly Charybdis – can’t I possibly cut and run from her and still fight Scylla off when Scylla strikes my men?”). Even Star Trek’s “Kobayashi Maru” provides a modern twist to this time-tested dilemma. See, Janet D. Stemwedel, The Philosophy of Star Trek: The Kobayashi Maru, No-Win Scenarios, And Ethical Leadership, FORBES MAGAZINE (Aug. 23, 2015), available at http://www.forbes.com/sites/janetstemwedel/2015/08/23/the-philosophy-of-star-trek-the-kobayashi-maru-no-win-scenarios-and-ethical-leadership/. And of course there is Zugzwang, that moment in chess when the next move will unavoidably make things worse. Lasker’s CHESS MAGAZINE, at 105 (Feb. 1905).

7. In addition to physicians, “[t]he term ‘health care provider’ includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center . . . renal dialysis facility, blood center, ambulatory surgical center . . . emergency medical services provider, federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory . . . a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe . . . a rural health clinic . . . a therapist . . . and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the [HHS Secretary].” 42 U.S.C. § 300jj(3).

8. See, e.g., William M. Thackeray, Vanity Fair: A Novel Without a Hero, Ch. 8 (Punch Magazine 1847-48).


the Medi-Cal Electronic Health Records Incentive Program for the purposes of providing federal incentive payments to Medi-Cal providers for the implementation and use of electronic health records systems.

The term "qualified electronic health record means an electronic record of health-related information on an individual that—(¶) (A) includes patient demographic and clinical health information, such as medical history and problem lists; and (¶) (B) has the capacity—

(i) to provide clinical decision support;
(ii) to support physician order entry;
(iii) to capture and query information relevant to health care quality; and
(iv) to exchange electronic health information with, and integrate such information from other sources." 42 U.S.C. § 300jj (13).


15. See Michael J. Daray, Esq., Negotiating Electronic Health Record Technology Agreements, 22 No. 2 HEALTH LAWYER 53 (Dec. 2009). By 2009, an estimated 30 to 70% of EHR deployments failed. Id.

16. See 80 Fed. Reg. 62762, 62765 (Oct. 16, 2015) (final rule) ("The Stage 1 final rule established the foundation for the Medicare and Medicaid EHR Incentive Programs by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of their health information. [¶] [Stage 2] focused on the . . . exchange of essential health data among health care providers and patients to improve care coordination [and] finalized a set of clinical quality measures (CQMs) that all providers participating in any stage of the program" must report to CMS. Stage 3 built on the groundwork of both earlier stages, and "focuses on the advanced use of EHR technology to promote improved patient outcomes and health information exchange." See also 80 Fed. Reg. 20346 (Apr. 15, 2015) (proposed rule).

17. See 80 Fed. Reg. 62602, 62603-62604 (Oct. 16, 2016) (final rule) (making the ONC Health IT Certification Program more accessible to other types of health IT and not just EHR, including the technology of health information service providers ("HISPs") and health information exchanges ("HIEs") so that they can "receive appropriate attribution and not be referenced by a certificate with 'EHR' included in it").


20. Id. at p. 9.


24. See, e.g., E.L. White, Inc. v. City of Huntington Beach, 21 Cal. 3d 497, 510 (1978) (noting that indemnity has been defined as "the obligation resting on one party to make good a loss or damage another has incurred.").

26. See, e.g., Cal. Civ. Code § 3529 (“That which ought to have been done is to be regarded as done, in favor of him to whom, and against him from whom, performance is due.”).


28. See, e.g., Myers Bldg. Indus., Ltd. v. Interface Tech., Inc., 13 Cal. App. 4th 949, 968 (“An indemnity agreement is to be interpreted according to the language and contents of the contract as well as the intention of the parties as indicated by the contract.”).

29. But see Miller v. Ellis, 103 Cal. App. 4th 373, 380 (2002) (holding equitable indemnification is not automatically available, but rather at times is a decision for the Court to make).


31. See, e.g., Myers Bldg. Indus., Ltd. v. Interface Tech., Inc., 13 Cal. App. 4th 949, 968 (“An indemnity agreement is to be interpreted according to the language and contents of the contract as well as the intention of the parties as indicated by the contract.”).

32. But see Miller v. Ellis, 103 Cal. App. 4th 373, 380 (2002) (holding equitable indemnification is not automatically available, but rather at times is a decision for the Court to make).


36. See e.g., Buss v. Superior Ct., 16 Cal. 4th 35, 45-46 (1997) (The insurer’s duty to indemnify runs to claims that are actually covered, in light of the facts proved. . . . By definition, it entails the payment of money in order to resolve liability.”).


43. The importance of a business associate addendum should not be forgotten for “any health care provider who transmits any health information in electronic form in connection with a transaction.” 45 C.F.R. § 164.104. The logistical requirements, however, are not always simple and can involve a multitude of variables, all of which create challenges on their own. See 45 C.F.R. § 164.530.
44. “It is a widely accepted myth that medicine requires complex, highly specialized information technology (IT) systems. This myth continues to justify soaring IT costs, burdensome physician workloads, and stagnation in innovation – while doctors become increasingly bound to documentation and communication products that are functionally decades behind those they use in their ‘civilian’ life.” Kenneth D. Mandl, M.D., M.P.H., and Isaac S. Kohane, M.D., Ph.D., Escaping the EHR Trap – The Future of Health IT, 366:24 N. ENG. J. MED. 2240 (June 14, 2012).


46. Id.; see also Mark W. Friedberg, Peggy G. Chan, et al., Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy at p. xvi (2013 Rand Corporation, sponsored by the American Medical Association), available at http://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR439/RAND_RR439.pdf:

“EHRs had important effects on physician professional satisfaction, both positive and negative. In the practices we studied, physicians approved of EHRs in concept, describing better ability to remotely access patient information and improvements in quality of care. Physicians, practice leaders, and other staff also noted the potential of EHRs to further improve both patient care and professional satisfaction in the future, as EHR technology—especially user interfaces and health information exchange—improves. However, for many physicians, the current state of EHR technology significantly worsened professional satisfaction in multiple ways. Poor EHR usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less fulfilling work content, inability to exchange health information between EHR products, and degradation of clinical documentation were prominent sources of professional dissatisfaction. Some of these problems were more prominent among senior physicians and those lacking scribes, transcriptionists, and other staff to support data entry or manage information flow. Physicians across the full range of specialties and practice models described other problems, including but not limited to frustrations with receiving template-generated notes (i.e., degradation of clinical documentation). In addition, EHRs have been more expensive than anticipated for some practices, threatening practice financial sustainability.”

47. See, e.g., “Cloud Computing: An Overview Standard Medicine Information Resources & Technology, available at https://med.stanford.edu/irt/security/cloud.html (“Before cloud storage existed, in order to provide storage to users an organization would need to: purchase the storage; create a data center where the storage would reside; run servers that would utilize the storage; and employ server administrators, storage experts and data center operators. Today, an organization or even an individual can have the equivalent of a data center’s infrastructure, just by using a cloud-based service. It can potentially save thousands of dollars and man-hours, and might even be completely free while being available 24/7. But there are security issues that must be addressed before these services can be verified as truly secure, including data ownership, data separation, data protection, and backup.”).

48. See, e.g., Robert McMillan, Cloud-Computing Kingpins Slow to Adapt to Own Movement, WALL ST. J. (Aug. 4, 2015), available at http://www.wsj.com/articles/cloud-computing-kingpins-slow-to-adapt-to-own-movement-1438731775 (“This market, combined with some other cloud services, has grown from $10.5 billion in 2013 to $19.9 billion this year. . . . It is projected to be worth $26.5 billion in 2016.”).


51. See, e.g., Cal. Com. Code § 2314 (implied warranty; merchantability; usage of trade); Cal. Com. Code § 2315 (implied warranty; fitness for a particular purpose).
52. See, e.g., Cal. Com. Code § 2313 (express warranties by affirmation, promise, description, sample).

53. See, e.g., Cal. Com. Code § 2316 (exclusion or modification of warranties); Delta Air Lines, Inc. v. Douglas Aircraft Co., 238 Cal. App. 2d 95, 101 (1965) (“The statutory implied warranties of quality can, of course, be disclaimed by the seller, provided the buyer has knowledge or is chargeable with notice of the disclaimer before the bargain is complete.”). But see generally International Knights of Wine, Inc. v. Ball Corp., 110 Cal. App. 3d 1001 (1980) (claims for fraud, negligent misrepresentation or strict liability may still exist after a disclaimed warranty).


55. See supra n. 53.

56. See, e.g., Amtower v. Photon Dynamics, Inc., 158 Cal. App. 4th 1582, 1609 (2008) (“The purpose of an integration clause is to preclude the introduction of evidence which varies or contradicts the terms of the written instruments. [citations omitted] It does not function to meld the documents it mentions.”); cf. supra n. 59.

57. See 45 C.F.R. § 170.314 (certification criteria for Complete EHRs or EHR Modules effective January 14, 2016).

58. See id.

59. This can be done by accessing the following Website maintained by the Office of the National Coordinator for Health Information Technology: http://oncchpl.force.com/ehrcert. For more information about the Office of the National Coordinator for Health Information Technology, see 42 U.S.C.A. § 300jj-11.

60. See, e.g., In re Manville Forest Products Corp., 209 F.3d 125, 129 (2nd Cir. 2000).


65. See, e.g., 22 C.C.R. § 72534.

66. 45 C.F.R. § 164.504(e)(2)(ii)(J); see also 42 C.F.R. 164.502(a)(3): (“Business associates: Permitted uses and disclosures. A business associate may use or disclose protected health information only as permitted or required by its business associate contract or other arrangement pursuant to § 164.504(e) or as required by law. The business associate may not use or disclose protected health information in a manner that would violate the requirements of this subpart, if done by the covered entity, except for the purposes specified under § 164.504(e)(2)(i)(A) or (B) if such uses or disclosures are permitted by its contract or other arrangement.”).


69. 45 C.F.R. § 170.314(b)(7).

69. See supra n. 66.


72. As part of CMS’ conditions of participation for hospitals, the medical records for each inpatient and outpatient must be “accurately written, promptly completely, properly filed and retained, and accessible.” 42 C.F.R. § 482.24(b) (emphasis added); see also Cal. Health & Safety Code § 1250.05(d)(“All general acute care hospitals . . . shall develop and implement policies and procedures to ensure that relevant portions of patient’s medical records can be made available within a reasonable period of time . . .”).

73. Historically the focus of courts in part was determination of constructive possession or actual control. See, e.g., Ashton v. Burke, 83 B.R. 716, 724 (D.N.D. 1988).


75. See 42 C.F.R. § 164.504(e)(2)(ii)(J) (“At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form. . . .”); but see Medassets Net Revenue Systems, LLC v. Downey Regional Medical Center, 2014 WL 1607633, *13 (C.D. Cal. 2014) (“But HIPPA [sic] does not create an independent duty. Rather, § 164.504(e) sets forth assurances that covered entities must include in a written contract.”).


78. Id.

79. See Cal. Civ. Proc. Code § 1281 (validity of enforcement of arbitration provisions); Cal. Civ. Proc. Code § 1141.11(a) (“[A]ll nonexempt unlimited civil cases shall be submitted to arbitration under this chapter if the amount in controversy, in the opinion of the court, will not exceed fifty thousand dollars ($50,000) for each plaintiff”); but see Cal. Civ. Proc. Code § 1775.4 (the court cannot force parties into mediation where the action was ordered into arbitration pursuant to Section 1141.11(a), nor can a mediation pursuant to Section 1775.3 be forced into arbitration).


82. Id. These funds are made available through the American Recovery and Reinvestment Act of 2009, § 4201 (Pub. L. 111-5).


85. Id. at 1. Two examples noted by the OIG include federal guidance on electronic signatures in EHRs and audit logs to authenticate the medical records supporting a claim. Id. at p 13.

86. HHS has designated the OCR as the primary agency to enforce the Privacy Rule. See, e.g., Protection & Advocacy System, Inc. v. Freudenthal, 412 F. Supp. 2d 1211, 1217 (D. Wyo. 2006). OCR oversees complaints relating to HIPAA, and more specifically those 109,722 HIPAA-related complaints registered between April 2003 and February 1, 2015. Of these potential HIPAA infractions, approximately 70% did not fall within OCR jurisdiction or the OCR determined no violation had occurred. But in some 40,000 cases investigated by the OCR, 30% found no violation, while 70% required some corrective action, usually in reference to impermissible uses and disclosures of PHI, failure to keep PHI safe, lack of patient access to PHI, or disclosure of more information than was reasonably necessary. Private practices and acute care hospitals were among the worst offenders. See generally Craig B. Garner, HIPAA -- Society’s Modern Day Prohibition (Ca. Healthcare News, May 2015), available at http://www.cahcnews.com/newsletters/ca-cgarner-0615.pdf.

87. See generally Office of Inspector Gen., OEI-09-10-00510, OCR Should Strengthen Its Oversight of Covered Entities’ Compliance with the HIPAA Privacy Standards at 11-12 (Sept. 2015) (recommending that OCR (1) strengthen its oversight of covered entities compliance with the Privacy Rule; (2) improve its investigation process; (3) fully implement a permanent audit program; (4) carefully track corrective action; (5) identify previous investigations against providers; and (6) continue to educate covered entities about OCR and the privacy standards.

88. Office of Inspector Gen., OEI-09-10-00511, OCR Should Strengthen its Follow up of Breaches of Patient Health Information Reported by Covered Entities at 13-14 (Sept. 2015) (recommending that OCR (1) maintain information regarding small breaches in a searchable format; (2) maintain complete documentation of corrective actions; (3) expand outreach and education efforts; and (4) check for prior breaches by covered entity).

89. For purposes of HIPAA, of concern are data breaches where information is not just lost but also used or abused. See, e.g., In re Science Applications International Corp. (SAIC) Backup Tape Data Theft Litigation, 45 F. Supp. 3d 14, 20 (D.D.C. 2014). The idea of a data breach, however, is not always objective. For example, identify theft is “the unauthorized use of another person’s personal identifying information to obtain credit, goods, services, money, or property.” See Cal. Civ. Code § 1798.92(b). PHI is individually identifiable health information maintained by a covered entity, such as a hospital. See 45 C.F.R. § 160.103. The perpetrator of identity theft can also be the “owner” of PHI, even if admitted to a hospital under the name of the victim. The perpetrator should not be confused, however with the victim of identify theft, or “a person who had his or her personal identifying information used without authorization by another to obtain credit, goods, services, money, or property, and did not use or possess the credit, goods, services, money, or property obtained by the identity theft, and filed a police report in this regard pursuant to Section 530.5 of the Penal Code.” Cal. Civ. Code § 1798.92(d). Should a data breach occur using the name of the victim, or is it really a violation under federal or state law?

90. For a list of all federal civil money penalties, see 45 C.F.R. § 160.404. For additional information about California penalties, see generally Cal. Civ. Code § 56.101; but see Sutter Health v. Superior Court, 227 Cal. App. 4th 1546, 1564 (holding that the loss of an unencrypted computer alone was “not a breach of confidentiality” when a thief stole an unencrypted desktop computer from Sutter Health containing the personal information of over 4 million patients).

91. “Reasonable diligence refers to the business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances.” 45 C.F.R. § 160.401.
92. "Reasonable cause means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect." *Id.*

93. "Willful neglect refers to conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated" *Id.*

94. 45 C.F.R. § 164.308(a)(6); 45 C.F.R. § 164.530(f).

95. 42 U.S.C. § 17932(a). If only a handful of individuals are affected, notice should be mail or other comparable communication. 45 C.F.R. § 164.404. If a breach involves more than 500 individuals, notification must be made through the media outlets in the area, see 45 C.F.R. 164.406(a), as well as to the Secretary for HHS. 45 C.F.R. § 164.408.


98. See supra n. 86; see also http://www.hhs.gov/ocr/privacy/hipaa/enforcement/index.html.


100. See, e.g., 15 C.C.R. § 3361(c)("Recognizing that mental health care often involves revealing deeply personal and private matters, all mental health care shall be provided in such a manner as to maintain the dignity of the inmate. Professional relationships shall be conducted with proper privacy, with due regard to the professional to take necessary and appropriate action to prevent harm to the patient or to others.").

101. See 45 C.F.R. § 160.103 ("Protected health information means individually identifiable health information: (1) Exempt as provided in paragraph (2) of this definition [educational records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232.g], that is: (i) transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium."). In matters of health care records, however, not all records, nor data breaches, are created equal. But see 15 C.C.R. § 3361(c)("Recognizing that mental health care often involves revealing deeply personal and private matters, all mental health care shall be provided in such a manner as to maintain the dignity of the inmate. Professional relationships shall be conducted with proper privacy, with due regard to the professional to take necessary and appropriate action to prevent harm to the patient or to others.").

102. See 42 U.S.C. §§ 1320-d(5)(a)(1) through 1320-d(6)(a)(2); *Diment v. Cushing*, 2007 WL 2344981, *2* (D.C.W.D. Va. 2007) ("HIPAA imposes civil and criminal penalties on a person who knowingly and illegally obtains or discloses 'individually identifiable health information' from or to another person.").

103. See, e.g., 42 C.F.R. § 495.104 (incentive payments to eligible hospitals); 42 C.F.R. § 496.102 (incentive payments to eligible professionals).

104. See, e.g., 45 C.F.R. § 164.502; THROUGH THE LOOKING GLASS, *supra*, n. 3 at 223 ("It's too late to correct it," said the Red Queen: 'when you've once said a thing, that fixes it, and you must take the consequences.'").
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