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Gratitude, Musings and the Future

By: Nicholas Romanello



This is my final note as the Chair of the Health Law Section. Before I accept the best role in any organization – past chair, I wish to acknowledge those that make the health section such a dynamic resource and a look ahead to the future of the Section.

As the most unlikely chair in recent memory, I owe a great debt of gratitude to all of those who really make the section work. With that gratitude in mind, I must start with our Section Administrator, Willie Mae Shepherd. For those of you who may not yet know Willie Mae, she is the finest and most knowledgeable administrator we can hope for. The Section's leadership team of Greg Chaires, Everett Wilson, JoAnn Guerrero and Steven Grigas have all been extraordinary to work with. We are fortunate to be in the very capable hands of these fine attorneys for the foreseeable future. Finally to all of those who assumed leadership roles in our programs and publications – such as Grant Dearborn, Shannon Hartsfield, Jamie Gelfman, Myla Reizen, Kim Nowakowski, Lester Perling, Jodi Laurence, Barry Herrin, and Robert Pelaia – thank you all for your underappreciated work.

While there are many voluntary bar organizations that emphasize health-centric issues, the Health Law Section of the Florida Bar is uniquely positioned to assist attorneys at all stages of their career. Our YLD is a vibrant training ground for newly minted lawyers. The HLS' CLE programs and publications offer mid-career attorneys the opportunity to share

their subject matter proficiency with others in convenient formats and local forums. Finally, our more experienced attorneys are able to market their expertise through board certification. These distinct avenues all converge into networking occasions where mentors are found, ideas shared and valued professional relationships formed. The Health Law Section provides an excellent return on the \$30 annual membership fee.

Concluding a year that started with Hurricane Irma, I have been reflecting upon the future of our profession and, more specifically, the Health Law Section. Technology continues to radically disrupt the way professional service providers practice. The lines that used to separate professional and personal time have all but been erased. The concept of work-life balance has morphed into work-life integration. Millennial attorneys are now entering our ranks. Hyper connected, purposeful and ambitious they demand an egalitarian professional culture, 24/7/365 mentoring and collaboration and will challenge the aging Boomers and GenXers like never before. Likewise, the American healthcare market is in the midst of a revolution. Value-based payments schemes, market consolidation, consumerism and the continuing political battle over the Affordable Care Act welcome us into the new normal. How does the Health Law Section respond to such professional and market-based upheaval?

We must enhance the Section's value proposition. The ABA, AHLA, HCCA all operate in the same space as the Section does. Law firms of all sizes are increasing

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GRATITUDE, MUSINGS

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their educational and networking offerings. To remain competitive, we must meet the membership in ways that are meaningful to them. Our publications and programming should be convenient, affordable, digital and, of course, high quality. We should also create content that distinguishes us from others. With these principals in mind, I offer the following suggestions to our future leadership:

- **Double down on our focus of Florida law.** The Section's logo proclaims us to be "the resource for Florida health law". While so much of our work involves federal law and regulations, there is a vast array of state law issues that confront us regularly. From professional licensure and insurance regulation to Florida's heightened physician self-referral and privacy schemes – Florida remains prolific in its regulation of payors and providers. As the third largest state in the country, we continue to experience an inflow of those looking to service Floridians and use our state as a strategic launching pad to service those in the Caribbean and South America. Remaining Florida-centric in our focus provides value to our membership which, in turn, enhances their ability to assist clients.
- **Increase our use of social media platforms.** This year, we digitized our quarterly newsletter. As we are apt to do – we blasted out emails

to the membership with links to the newsletters. While a huge improvement over mailing out hard copies, I think we can leverage technology in order to disseminate our updates. Most of us are tethered to our smart phone 24/7/365. We should embrace this phenomenon and frequently post meaningful information that is helpful to membership on multiple social media platforms.

- **Consciously review our live programs.** The Section continues to sponsor outstanding programs. The FUNDamentals and Board Certification Review courses are amazingly comprehensive and our Lunch and Learn series provides timely content. In a state that spans two time zones, is it practical to emphasize live programming as frequently as we do? Given the disruption our profession and industry is experiencing is it not also time to consider a critical examination of our content offering? Three specific suggestions I offer include:
 - › Critically evaluate the Section's CLE offerings to determine whether they are aligned with the needs of our members.
 - › Engage new and unconventional speakers – regulators, board members, CEOs, VPMAs, Risk Managers and physicians who provide industry perspective and context to the services we perform.
 - › Consider shorter programs that leverage technology. The Section may be well served to survey membership to determine whether more web-based training,

asynchronous environments and virtual libraries are desired.

Embrace a partnership with the next generation of leadership Millennials are on the cusp of surpassing Baby Boomers as the nation's largest living adult generation, according to population projections from the U.S. Census Bureau. Rather than rolling our eyes and complaining that they are spoiled and narcissistic – let us embrace our younger more ethnically and racially diverse partners. On track to be the most educated generation on our county's history, the Millennials are technologically savvy and energetic. If we are truly committed to mentorship, let us provide them with the gift of our collective wisdom and get out of their way as they transform the Section to a more user friendly and relevant resource of Florida Health Lawyers.

To close, I wish to, again, thank those who make the Section work. The secret sauce of the Section's success remains the professionalism and collegiality of you - the membership. The opportunity to have shared in the leadership of this Section will remain a professional highlight that I will forever cherish.

Nicholas W. Romanello is the Senior Vice President, General Counsel for Health First, which is Florida's only fully integrated delivery network (IDN). The interpretations of law and opinions contained in this note are personal to the author and not those of Health First, its Board of Trustees or executive management and staff. He can be reached at 321-434-4356 and Nicholas.Romanello@health-first.org.

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From the Editor

Getting to Know Charmaine Chiu

In this column, Charmaine Chiu, a past Chair of The Florida Bar's Health Law Section (2015-2016), responded to questions from the editor, Shannon Hartsfield. Ms. Chiu is the Chair of the Healthcare Practice Team and serves on the Board of Directors at Smith Hulsey & Busey in Jacksonville.

What made you decide to become a health lawyer?

I grew up watching my father, a former Chair of the Department of Pediatrics at the University of Florida College of Medicine – Jacksonville, manage a rapidly growing department in academic medicine. Although the clinical aspects of medicine are always fascinating, it was the business aspects of healthcare that really caught my attention. My father constantly challenged himself to grow his department to better serve children; and I think I've carried his influence into my practice of health law, constantly challenging myself to grow the firm's Healthcare Practice Team to better serve clients.

It was also an introduction during my senior year of college to my friend and mentor, Jeanne E. Helton – another former Chair of The Florida Bar's Health Law Section (2008-2009) – that convinced me healthcare law would be a fulfilling career. This field is dynamic. It is an incredibly satisfying challenge to keep up with the changes in the field, and to counsel clients through the changes. Jeanne and I both share this perspective, and I think others on our Healthcare Practice Team do as well: when you drive past the new wing of a hospital and your firm worked on the transaction that brought it about; when you read in the paper of a new healthcare technology available in your community and your firm negotiated the equipment acquisition; or when a clinical specialist is recruited to the area and your firm advised a group practice through that process, it is rewarding to know that your work as counsel ultimately impacts patient care.

You are certified in Health Law by The Florida Bar, and serve on its Health Law Certification Committee. In your view, what are the reasons a health lawyer should seek to become certified, and what advice do you have for someone going through that process?

Certification is an excellent way to communicate to potential clients that you



are highly experienced in health law and capable of handling their issues. Certification requires multiple levels of peer review: those selected by the applicant initially and additional reviews sought by The Bar. This indicates to clients that a certified Health Law lawyer is respected by others who practice in the field for their knowledge and professionalism. For those considering certification, first ensure you have practiced enough years and covered sufficient ground such that others know your work. Then, start studying early! This is one of the most difficult certification examinations administered by The Florida Bar, and there is a reason why only 129 lawyers throughout Florida have attained board certification in health law.

If you were not an attorney, what career might you have chosen?

A question I have not considered, as I've been relatively happy for the twenty plus years since starting law school! I suppose I would have ended up on the other side of the table as a physician or healthcare administrator – a health law client.

How did you get to your position as Chair of the Florida Bar Health Law Section?

The Section has been an incredible way for me to get to know others in this field, and I cherish many of the friendships I've developed with those who served alongside me in the Section. The Section's Executive Council is truly a working governing body; there's nobody who sits on that body who does not contribute in a significant way to the Section's operations. I started out with small assignments, and eventually worked my way up to Chair of the Section's Continuing Legal Education Committee. After a number of years helping to organize CLE programs, I was nominated to join the Executive Council, and later appointed a Section officer. It was a rather long path, but service to the Section was and remains very rewarding.

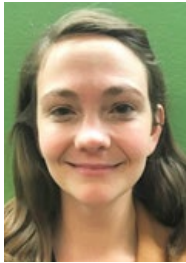
What advice do you have for attorneys who want to become health lawyers?

Practice with the best multidisciplinary health law team you can find. I have learned that "health law" does not simply encompass fraud and abuse, professional malpractice, or singular issues. Our healthcare clients run businesses. They have needs in employment law, real estate, tax exempt organizations, technology, and other areas – all of which raise very unique issues in the healthcare context – and which we need to be able to address expertly as counsel. This is very much the philosophy we had at Smith Hulsey & Busey in developing the Healthcare Practice Team. I think only by gaining exposure to these various areas of "health law" can one truly understand the needs of a healthcare client.

Shannon B. Hartsfield practices at Holland & Knight LLP. She is Board Certified in Health Law by the Florida Bar Board of Legal Specialization and Education.

Rolling Back Retroactive Medicaid Eligibility (RME)

By: Katy DeBriere and Miriam Harmatz



Under current federal Medicaid law, costs incurred during the three months prior to the month of application can be reimbursed if: 1) they are covered under the Florida Medicaid plan; and 2) the beneficiary would have been eligible for Medicaid at the time the expenses are incurred.¹ Florida's 2018 Legislature, however directed the Agency for Health Care Administration (AHCA) to seek federal approval

to change this provision for non-pregnant adults through an amendment to the 1115 waiver.² For those individuals, costs would only be covered from the first day of the month of application. The initial state comment period on this requested change to the law ended April 19, 2018. AHCA submitted the state's request to CMS on April 27th. Federal public comment period will remain open until June 5, 2018.

Multiple comment submissions asserted that this waiver request would interrupt and delay needed medical care, lead to worsened health outcomes, and increase medical debt and bankruptcies. Congress established RME to protect "persons who are eligible for Medicaid but do not apply for assistance until they have received care, either because they did not know about Medicaid eligibility requirements or because the sudden nature of their illness prevented their applying."³ Commenters argued that this change would undermine that protection. For example, adults with progressive diseases, like cancer, who previously attempted to apply for Medicaid based on disability and been denied, will have to "guess" the moment in time in which their disease had made them just disabled enough to qualify. Those who experience a catastrophic injury, rendering them unable to apply quickly for Medicaid, will be responsible for that period of time in which they incurred significant medical costs.

Florida's long term care system, which includes nursing home care, depends on retroactive Medicaid to provide services to those with debilitating age related conditions. Without a ninety-day RME period, long-term care providers may be unable to receive Medicaid reimbursement for care until a Medicaid application is filed and approved. Notably, 2010 US Census data shows that Florida's seniors represent 3.2 million residents and that number is only projected to grow. In light of that trend, reducing RME could delay needed care for Florida seniors covered by Medicaid.

While Section 1115 of the Social Security Act allows HHS to temporarily waive certain requirements of the Act to test new or "novel" experiments aimed at improving the Medicaid program, HHS can only waive requirements found within the provisions of 42 U.S.C. § 1396a.⁴ Importantly, RME, although referenced in §1396a of the Social Security Act, is separately defined" in §1396d(a).⁵ In other words, the RME period does not fall within the waiver authority of the Secretary because the provision lies outside of 1396a. It is also not clear that Florida's elimination of the ninety day RME period constitutes a 'novel approach' that would "improve medical assistance for low income people" thereby contravening the purpose of Section 1115.⁶ Thus, approval of Florida's RME waiver request may be subject to legal challenge.⁷

Katy DeBriere and Miriam Harmatz are Co-Executive Directors of the Florida Health Justice Project, which is focused on improving access to affordable health-care for Floridians.

Endnotes

- 1 42 U.S.C. § 1396a(a)(34); *see also*, 42 C.F.R. § 435.914, Fla. Admin. Code R. 65A-1.702(2)(9)
- 2 HB 5001: General Appropriations Act at 55, (March 16, 2018), <https://www.flsenate.gov/Session/Bill/2018/5001/?Tab=BillText>; Florida Managed Medical Assistance Waiver Public Notice Document at 5, AHCA (March 21 - April 19, 2018) http://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/1115_MMA_Public_Notice_Doc_LIP_Retroactive_Eligibility_2018-03.pdf. Under Section 1115 of the Social Security Act, states can submit a "waiver request" to the Secretary of HHS asking to waive some requirements of Medicaid in order to test novel approaches to improving medical assistance for low-income people. 42 U.S.C. § 1315a.
- 3 H.R. Rep. 92-231 (1972) reprinted in 1972 U.S.C.C. A.N. 4089,5099.
- 4 42 U.S.C. § 1315(a)(1).
- 5 The Medicaid Act defines "medical assistance" as a "payment of part or all of the cost of the following care and services or the care and services themselves, or both (if provided in or after the third month before the month in which the recipient makes application for assistance . . .)" (emphasis added). 42 U.S.C. § 1396d(a).
- 6 S. Rep. No. 87-1589 at 19-20.
- 7 *See Stewart v. Hargan*, 1:18-cv-152 (U.S.D.C. D.C. Cir., January 24, 2018) which challenges, in part, the state of Kentucky's attempt to eliminate retroactive Medicaid eligibility.

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Did You Know? The Florida Department of Corrections Health Care Privacy Law

By: Dorothy M. Burnsed



The Florida Department of Corrections is a covered entity for purposes of the Federal HIPAA Privacy Rule. Therefore, with respect to inmate protected health information, the Department is required to adhere to both Federal and Florida confidentiality laws. While limited record sharing is permitted by the Federal HIPAA Rule for various purposes, prior to July 1, 2017, Florida law was much more restrictive for the Department of Corrections and afforded inmates much greater privacy protections for their medical and mental health records. *See* § 945.10(1)(a), Fla. Stat. (2016) (making inmate medical, mental health, and substance abuse records maintained by the Florida Department of Corrections confidential); *see also* § 456.057, Fla. Stat. (2017). In fact, the Department was only allowed by Florida law to share inmate mental health, medical and substance abuse records in one circumstance—to the Department of Health and the county health department where an inmate plans to reside if he or she has tested positive for the presence of the antibody or antigen to human immunodeficiency virus infection. *See* § 945.10(2)(g), Fla. Stat. (2016). Thus, even though the Federal HIPAA Privacy Rule allowed for limited sharing of an inmate's protected health information, the Department was unable to share medical and mental health records of an inmate without a court order, subpoena, or inmate consent.

Inmate and offender protected health information may be contained in many Department of Corrections' records other than just an inmate's medical or mental health file. For example, inmate protected health information is often in classification records, housing records, inspector general reports, and inmate grievances. The inability to share inmate protected health information with other state agencies, state attorneys, and local law enforcement agencies without court involvement was challenging in

the correctional environment where time is often critical. Court orders and subpoenas to allow for disclosure of inmate health information for necessary law enforcement activities, investigative purposes, agency data and statistical functions, safer inmate transports, and continuity of care and services were time-consuming and burdensome for staff and courts. Additionally, relatives of deceased inmates had difficulty in obtaining access to medical and mental health records prior to the administration of an estate. This was frustrating for Department staff because there are many exemptions established in the HIPAA Privacy Rule that were not included in Florida law.

Some of these exemptions contained in HIPAA relate directly to the Florida correctional environment. *See e.g.* 45 C.F.R. § 164.512(k)(5). For example, the HIPAA Privacy Rule specifically created exceptions applicable to the correctional environment to permit correctional institutions that are covered entities to use and disclose inmate protected health information to provide health care to inmates, to protect the health and safety of an inmate or other inmates, to protect the health and safety of officers, employees or other persons present at a correctional institution, to protect the health and safety of the inmate and officers responsible for transporting inmates, for law enforcement on the premises of the correctional institution and for other purposes related to the maintenance of safety, security, and good order within the correctional institution. *See* 45 C.F.R. § 164.512(k)(5). In addition, HIPAA contains exemptions for valid law enforcement purposes and other health care operations between covered entities. However, Florida law lacked these exemptions and therefore, provided greater privacy of medical and mental health records. Thus, without the statutory amendment, the Department of Corrections was unable to avail itself of any of the record sharing permitted by the HIPAA Privacy Rule.

The 2017 amendments to section 945.10, Florida Statutes, are the first to directly bring exceptions contained

in HIPAA to Florida law. While exempting the Department of Corrections from some of the requirements contained in section 456.057, Florida Statutes, the new statute adopts some of the applicable HIPAA exemptions directly applicable to the correctional environment into Florida law and continues to balance inmate privacy rights afforded by the Florida Constitution against legitimate, compelling administrative access to protected health information that is necessary in the correctional setting. Section 945.10 contains enhanced procedural safeguards to prevent unauthorized access to inmate medical/mental health records and is narrowly-tailored to accomplish tasks specific to the correctional environment. The statute is consistent with the Federal HIPAA Privacy Rule and thus does not conflict with Federal law. Moreover, the statute contains administrative safeguards that are consistent with the individual inmates' Florida constitutional privacy interests. The new statute enhances governmental efficiency, promotes transparency between agencies to allow for authorized communication needs for legitimate law enforcement purposes, assists with continuity of medical and mental health services for inmates transitioning back into the community, and permits relatives of deceased inmates to timely access records of the deceased. § 945.10, Fla. Stat. (2017).

Dorothy M. Burnsed is the Deputy General Counsel at the Florida Department of Corrections and a 1999 graduate of Florida State University College of Law. Her legal practice focuses on health care law and correctional constitutional matters. Ms. Burnsed was involved in the legislative drafting for the amendments to section 945.10, F.S. Prior to joining the Department in 2003, Ms. Burnsed worked as an associate litigation attorney handling a wide-variety of cases for governmental and private clients involving civil rights defense, police liability defense, healthcare law, and employment law. She may be contacted at Dorothy.Burnsed@fdc.myflorida.com.

Assisted Living Facilities and Nursing Homes Prepare for Emergency Power Generators

By: Eddie Williams, III



On March 26, 2018, Florida Governor Rick Scott signed two bills into law that ratified Rule 59A-4.1265 and Rule 58A-5.036, which were adopted by the Agency for Health Care Administration (AHCA) and the Department of Elder Affairs (DOEA), respectively. The much debated rules, commonly referred to as the “Generator Rules,” require each nursing home and assisted living facility to acquire an alternative power source and fuel to ensure that ambient air temperatures at the facility will be maintained at or below 81 degrees Fahrenheit for a minimum of 96 hours in the event of the loss of primary electrical power.

As a result of the effects of Hurricane Irma in 2017, numerous residents died at a Hollywood, Florida nursing home allegedly due to the loss of power and increased temperatures inside the facility. In response to this tragic event, Governor Scott ordered AHCA and DOEA to issue emergency rules requiring nursing homes and assisted living facilities to install generators in order to protect residents in the event of a loss of power. Thereafter, the Governor directed AHCA and DOEA to begin the formal rulemaking process to adopt permanent administrative rules requiring assisted living facilities and nursing homes to have emergency generators.

Under the Generator Rules, the facilities were required to develop and submit a detailed plan as a supplement to their Comprehensive Emergency Management Plans to the respective local emergency management agency on or before April 25, 2018. Plans previously submitted and approved by the local agency require resubmission only if the facilities make changes to those approved plans. Once the plans are approved by the local emergency management

agency, the facility is required to submit proof of the approval to AHCA along with a consumer-friendly summary of the plan.

The detailed plans of the facilities must contain information regarding the alternate power source and the necessary fuel supply maintained at the facility. An assisted living facility with a licensed capacity of 16 beds or less must store 48 hours of fuel onsite. All nursing homes and assisted living facilities with a licensed capacity of 17 beds or more are required to store 72 hours of fuel onsite. Any facility located within an area where a state of emergency is declared that may impact primary power delivery is required to secure 96 hours of fuel during the period of the declared state of emergency. If local ordinances or other regulations limit the amount of onsite fuel storage at the facility, then the facility must develop a plan that includes the maximum onsite fuel storage allowable and a reliable method for obtaining the maximum additional fuel at least 24 hours prior to the depletion of onsite fuel. In addition to acquiring the alternate power source and fuel supply, an assisted living facility must also install and maintain a carbon monoxide alarm.

The facilities are required to have implemented their plan on or before June 1, 2018. The Generator Rules require AHCA to grant a facility an extension until January 1, 2019, upon a showing that issues beyond the facility’s control, such as delays in the construction, the delivery of equipment, or zoning or other regulatory approvals, will prevent the facility from meeting the June 1st compliance deadline. During the extension period, the facilities must have arrangements in place to locate residents in an area or areas where temperatures will be maintained at or below 81 degrees Fahrenheit for a minimum of 96 hours. If the facility is located within an evacuation zone, the facility must either evacuate the residents prior to the arrival of the event, or have an

alternate power source and 96 hours of fuel stored onsite within 24 hours of the issuance of a state of emergency for the area of the facility. If the facility is not located in an evacuation zone, the facility must either have an alternate power source onsite or have a contract in place for the delivery of such power source and fuel when requested. Within 24 hours of the issuance of a state of emergency for an event that may impact the facility’s electrical power, the facility must have the alternate power source and 96 hours of fuel stored onsite.

The facilities must notify AHCA if they elect to utilize the extension and keep the agency apprised of their progress to come into compliance with the Rules. Assisted living facilities must provide AHCA with quarterly updates, while nursing homes must provide the agency with monthly updates. If a facility will not be able to meet the January 1, 2019, extension deadline, the facility will have to submit a petition to AHCA to request a waiver pursuant to Section 120.542, Florida Statutes. The Generator Rules grant AHCA certain administrative remedies if a facility fails to comply with the Rules, including license revocation, suspension, and the imposition of administrative fines. Additional information regarding the Rules can be located on AHCA’s website, including emergency power plan rules Q&As, a sample format for emergency power plans, and a “consumer friendly” summary sample format.

Eddie Williams, III is a partner in Holland & Knight LLP’s Tallahassee office, and practices in the firm’s Business Law Section in the areas of healthcare regulation, state and local tax, as well as cybersecurity and privacy. Mr. Williams is experienced in assisting and advising clients with state and federal healthcare regulatory issues including compliance, HIPAA and data privacy.

Genetic Testing – Unintended Consequences?

By: Elizabeth Scarola



The advent of 23andMe, ancestryDNA, and other direct-to-consumer genetic testing products permit patients, from the comfort of their own homes and personal computers, to identify and assess their unique risk of developing disease. For less than \$200, these genetic testing companies claim to provide health insights. For example, 23andMe offers consumers “genetic health risk reports” that detect variants related to late-onset Alzheimer’s disease, Parkinson’s disease, alpha-1 antitrypsin deficiency, celiac disease, hereditary hemochromatosis, hereditary thrombophilia, and age-related macular degeneration. In March of 2018, the FDA authorized 23andMe to market its Personal Genome Service Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants).

According to the FDA, the test is the first direct-to-consumer FDA approved test to report on three specific BRCA1 and BRCA2 breast cancer gene mutations. In its approval, the FDA clarified that the test only detects three out of more than 1,000 known BRCA

mutations, meaning that a negative BRCA mutation result from 23andMe does not rule out the chance that consumers have a BRCA mutation.

Previously, genetic testing was made available only through the recommendation of a healthcare provider, and a healthcare provider was required to interpret the test results before passing them onto the individual. However, the FDA’s approval of 23andMe BRCA testing allows consumers to order and perform genetic tests without needing to interact with a healthcare professional, indicating the potential expansion of genetic testing services to other applications and raising concerns about consent, privacy, and confidentiality.

The month after the FDA approved 23andMe’s BRCA mutation testing, investigators in California utilized genetic data submitted through an online ancestry website to identify the Golden State Killer. According to reports, the detective’s use of DNA had previously led to the wrong suspect. The use of genetic data for law enforcement purposes raises concerns about the privacy and confidentiality of genetic data submitted to websites like 23andMe. Patients may be surprised that current HIPAA regulations do not apply to companies that are not “covered entities”

(health plans, health care clearinghouses, and most health care providers) or “business associates.” If de-identified data is used for research or other purposes, HIPAA does not apply to that information, either, so long as it cannot be traced back to the original patient. See 45 C.F.R. §§45 C.F.R. §§ 164.502(d)(2), 164.514(a) and (b). Further, there is no general legal prohibition on re-identification of individuals from their genetic data.

A spokeswoman for FamilyTreeDNA.com, which operates the website used by police to identify the Golden State Killer, reported that they had not been contacted by law enforcement to consent to the use of genetic data for such purposes. Company officials stated that “[w]hile [they] take ... customers’ privacy and confidentiality extremely seriously, [they] support ethically and legally justified uses of groundbreaking advancements of scientific research in genetics and genealogy.”

Elizabeth (“Beth”) Scarola is an Associate in the health care practice group of Carlton Fields. As a BRCA+ “previvor” and health care law enthusiast, Ms. Scarola is passionate about navigating the complexity of health care regulation and policy to promote the promise of precision medicine.

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The Essentials of EMTALA

By: Ben Asad Mirza



Today's Economic Pressures and the Uninsured

As the pressures to grow hospital top-line revenues mount, hospital senior teams and legal counsel are continually struggling to review and balance the insured patients versus uninsured patients. However, when it comes to treating uninsured patients under emergent conditions, every U.S. hospital must comply with the Emergency Medical Treatment and Active Labor Act (EMTALA) of 1986.

EMTALA and Its Potential Ramifications

EMTALA forbids hospitals from “dumping” patients out of the emergency departments. In other words, hospital emergency departments are forbidden from turning away a patient in the event of an emergency, regardless of whether the patient is insured or not, until the patient has been screened and stabilized. If the hospital is found to violate this federal statute, the hospital is subject to penalties of \$50,000 per violation (or \$25,000 in the case of hospitals with less than 100 beds). Similarly, the physician on call for the same emergency care is also subject to civil penalties up to \$50,000 per violation. Note that these violations apply to actions and inaction being carried out in a hospital environment. Florida has a similar statutory provisions for hospitals that provide emergency care. Under Section 395.1041, Florida Statutes, the potential for similar penalties exist, except the fines are \$10,000 per violation.

EMTALA Applies to Hospitals

According to 42 USC §1395dd(a), the following requirement is put upon hospitals with respect to screening patients:

In the case of a **hospital** that has a hospital emergency department, if any individual (whether or not eligible for benefits under this subchapter) comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition,

the hospital must provide for an **appropriate medical screening examination** within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an **emergency medical condition** ... exists. [bold emphasis added]

The word “emergency” is vague and leaves much to the discretion of the healthcare professional as to what is in fact deemed to be an “emergency.” The statute, subsection (e)(1), provides some level of clarification by defining “emergency medical condition” as follows:

The term “emergency medical condition” means—

- (A) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—
 - (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,
 - (ii) serious impairment to bodily functions, or
 - (iii) serious dysfunction of any bodily organ or part; or
- (B) with respect to a pregnant woman who is having contractions—
 - (i) that there is inadequate time to effect a safe transfer to another hospital before delivery, or
 - (ii) that transfer may pose a threat to the health or safety of the woman or the unborn child.

The requirements of EMTALA apply to hospital emergency departments, and their respective physicians, whether on-site or on call.

Requirements of EMTALA – Screening and Stabilizing the Patient

Under EMTALA, the hospital

emergency department must provide two things: 1) the appropriate medical screening to determine if an emergency exists, and 2) the stabilization of the patient. A hospital may not delay the provision of an appropriate medical screening examination in order to inquire about the individual's method of payment or insurance status. Once it is determined that the individual has an emergency medical condition, then the hospital must either 1) stabilize the medical condition, or 2) transfer the individual to another medical facility. After a hospital informs the individual the risks and benefits of the medical examination and treatment, if the patient refuses to consent to medical treatment, then the hospital should document the refusal, and when possible obtain the individual's written refusal for such examination and treatment.

Requirements of EMTALA – Transfer of Patient

If a patient in an emergency medical condition has not been stabilized, the hospital may not transfer the individual unless: 1) after being informed, the patient (or his or her representative) requests in writing to be transferred to another facility, 2) a physician signs the certification that the medical benefits reasonably expected at another medical facility outweigh the increased risks to the individual (or unborn child). If the physician is not physically present at the time of transfer, a qualified medical person may sign off on the certification only if after a physician has consulted with the patient, and has reached the same determination as the certification and subsequently countersigns the certification.

The federal statute requires the patient to be “stabilized” such “that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility.” Moreover, a transfer is appropriate if: a) the transferring hospital provides the medical treatment within its capacity, b) if the receiving facility has the space and the qualified personnel and agreed to accept the transfer, c) the transferring hospital sends the receiving facility all the medical records related to

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the emergency condition, and d) the transfer was effected though qualified personnel and transportation equipment, including life support measures.

Nondiscrimination and Whistleblower Protections

Hospital administrators must understand that “a participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units . . .) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.” This means that one hospital may be able to “push” a patient into another hospital provided that the capabilities requirements are in alignment with the statute. The hospital also may not penalize or take adverse actions against a medical person or physician or an employee because they refuse to authorize the transfer of an individual who has not been stabilized or they report an EMTALA violation.

Tips for Preventing EMTALA Violations

In light of EMTALA’s stringent requirements and significant penalties, hospitals and physicians should proceed with caution. George D. Prozgar, the author of a book entitled *Legal Aspects of Health Care Administration*, suggests ten “must do’s” for preventing EMTALA problems:

1. Treat all patients regardless of ability to pay.
2. Communicate with patient and their family to ensure that a complete and accurate picture has been obtained regarding the patient’s condition.
3. Provide an appropriate examination of the patient based on the symptoms the patient conveys. This is highly imperative.
4. Have the caregivers at the emergency department maintain clear and effective communication with each other, since each will obtain a piece of information that is unique to their role with the patient.
5. When appropriate, require consultations with professionals from various specialties.
6. Establish and implement an on-call

list for specialists, including maintaining call logs.

7. Obtain patient consent for performing procedures.
8. Ensure that the medical equipment has the appropriate preventative maintenance.
9. Make the appropriate arrangements when required to transfer the patient and document in the medical record information regarding the necessity to transfer; patient consent; procedures to obtain the certification for transfer; and obtain consent from the transferring facility to transfer the patient.
10. Maintain clear lines of communication between the transferring hospital and the receiving facility.

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