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INSIDE:

Telemedicine: The Emerging Healthcare and Legal Landscape

By: Caitlein J. Jammo, Esq., Clearwater; with guidance from Michael T. Cronin, Esq., Clearwater

I. Introduction - What is telemedicine

Telemedicine cannot be pigeonholed into one strict definition. Merriam Webster's dictionary defines "telemedicine" as "the practice of medicine when the doctor and patient are widely separated using two-way voice and visual communication (as by satellite or computer)."[1] Scholars have defined it as "the use of electronic communications and information technologies to provide or support clinical care at a distance."[2] No matter how you cut it, telemedicine allows a patient to seek and receive medical care—regardless of his/her location—through technology as simple as a phone call to technology as advanced as machines that transmit pulse oximetry and respiratory flow data across the world.[3] Having a humble beginning in the Netherlands in the early 1900's, telemedicine has flourished since the late 1980's due to improved technology, decreased costs associated with the use of this technology, and the continuation of "intransigent problem in healthcare delivery" that telemedicine can address.[4] While the technology associated with telemedicine has vastly improved, the legislature has been far more sluggish. However, in recent times, Florida has started taking large steps towards creating a healthcare system that includes telemedicine—up to now, culminating in Proposed Rule 64B8-9.0141, which sets out to articulate the standards for telemedicine practice in Florida.

II. Benefits

The benefits of telemedicine are wide-ranging. Telemedicine provides a direct connection for patients to interface with doctors regardless of location. Other benefits include providing care to a great variety of underserved patients including citizens of rural areas[5] and military personnel,[6] reducing travel time for child-abuse victims,[7] increasing healthcare access to women with high-risk pregnancies,[8] reducing healthcare costs,[9] and improving supervisory care for diabetic patients.[10]

III. Issues

Physicians utilizing telemedicine must be cognizant of issues that arise with telemedicine's use. Along with the advent of telemedicine and its benefits, follow complications that physicians need to address. However, physicians should not shy away from telemedicine on account of issues such as malpractice differences, Medicare reimbursement, and HIPAA/privacy concerns, but rather, physicians should be aware of their presence in order to best be prepared. Going forward, as more cases arise, courts will be able to address and clarify these issues in the legal context.

MEDICAL MALPRACTICE

The malpractice issues facing traditional medical physicians are not the same as those facing telehealth physicians. It is clear that telehealth physicians have a duty to treat patients with care, but the question arises as to what extent the duty of care is the same in the telemedicine context as it is in the traditional healthcare context? The answer is that a physician owes the same duty regardless if he/she is providing care in the same room or remotely. The specifics as to how a telehealth physician fulfills his/her duty of care and how this differs practically from a traditional physician-patient relationship have yet to be established by the courts.[11] Additionally, courts have yet to establish the procedural aspects of telemedicine, so whether and how a physician becomes subject to personal jurisdiction and which law applies is still unclear. To date, the malpractice cases in the telemedicine context have generally arisen from physicians prescribing medications over the internet—not from physicians providing negligent care via telemedicine. Physicians should also

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Sunshine is on the Horizon: Evaluating the Sunshine Act from Reporter and Reported Points of View

By: Mark Bajalia, Esq., Jacksonville and Samantha Prokop, Esq., Akron, OH

In recent presentations to attendees at healthcare educational seminars, we have been asking the question, "How many of you know about the Sunshine Act?" Often, the response we receive is, "Isn't that what allows me to request documents from the government, and hasn't it been around for years?"

The Sunshine Act[1] ("Act") is one of the lesser known provisions contained in the Patient Protection and Affordable Care Act. Under the Act, pharmaceutical and medical device manufacturers and group purchasing organizations ("GPOs") must disclose to the government most transfers of value made to physicians and teaching hospitals. In addition, they must also report ownership interests/investment interests of physicians or their immediate family members in these companies. This information will then be published on the publicly accessible Centers for Medicare and Medicaid Services ("CMS") Open Payments website, which also has a mobile application.

This public reporting provision has left manufacturers and GPOs scrambling to find mechanisms to comply, left physicians concerned that their financial information is now available for the world to see, and led many hospitals to issue an outright ban on physicians having financial relationships with reporting entities. This article summarizes the basic provisions of the Act and the impact of the Act from these various perspectives. This article also offers some practical solutions to compliance and reporting concerns.

The Reporters – Manufacturers and GPOs

All of the obligations under the Act fall solely on manufacturers and GPOs. Manufacturers must report all transfers of value to covered recipients (physicians/teaching hospitals) and all physician (or immediate family member) ownership or investment interests. GPOs must report all physician (or immediate family member) ownership or investment interests and any transfers of value to physician owners or investors. Reporting entities were to begin collecting data on August 1, 2013, and must report the data to CMS by March 31, 2014.

A manufacturer is "[a]n entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients" or any entity under common ownership with such an entity. A group purchasing organization ("GPO") is any entity that "[p]urchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.[2] CMS interprets this definition to include organizations that purchase pharmaceuticals for resale, including physician-owned distributors.[3]

Manufacturers and GPOs have to report a broad range of transfers of value, including consulting fees, compensation for speaking, compensation for presenting continuing medical education, honoraria, gifts, entertainment, travel and lodging, food and beverage, research, charitable contributions, rental or facility fees, distribution, and licensing or royalty fees.[4] They must also report names, addresses, National Provider Identifier ("NPI") numbers, and specialties of recipients.

Certain payments and transfers of value are excluded from reporting. Reporting entities do not have to report transfers of value to physician employees, indirect transfers when the entity does not know the identity of the recipient, payments of less than $10 unless the aggregate payment amount in a year is greater than $100,[5] discounts, patient educational materials, product samples, and distributions from publicly traded securities,[6] among others.

Although reporting is fairly straightforward, there are a few nuances. For example, the Act has special rules for research payments, CME, and food and beverage.[7] If they have not done so already, manufacturers and GPOs will need to develop policies and procedures for collecting and reporting data. They should also be intimately familiar with the law and its requirements. Reporting entities should also review marketing practices and procedures. Once data is reported, physicians and teaching hospitals reported will have an opportunity to review and dispute the data. Thus, reporting entities should have a mechanism for processing and resolving data disputes.

A good practice may be to provide the data to the physician or teaching hospital for review prior to reporting. We also recommend that these reporting entities take the lead in educating physicians and teaching hospitals about their reporting procedures to help alleviate any questions or concerns with reporting.

Entities that are required to report

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Reproductive Technology Law in Florida

By: Jessica Hoffman, Jacksonville

Florida's ART scene is booming. Consequently, there are many reasons why attorneys and medical professionals practicing in this state should be familiarwith a modern ART—AssistedReproductive Technology.

Assisted Reproductive Technology (ART) is the term describing the various medical procedures available to people who cannot otherwise conceive a genetic child.[1]The medical advancements making this possible are nothing short of a miracle to some. However, as the rate of advancements in infertility procedures become more rapid, the laws to regulate this new technology are evolving at a much slower rate. As a result, there are many new issues involving the legal status, rights, and duties of intended parents, donors, carriers, and even physicians.

Emerging ART Issues

The last reported study of infertile couples reported 7.5 million affected—meaning approximately 1 in 8 couples suffer from infertility.[2]This statistic reflects only married, heterosexual couples and does not consider other parties using ART. Therefore, the number of ART recipients professionals encounter is probably higher. The problem is many people who use ARTare unlikely to discuss their experience with their own families, much less voluntarily disclose it to their attorneys and doctors.

Since ART touches many areas of law and ethics, practitioners must foresee its impact on less obvious circumstances. For example, the most litigated ART issues include the disposition of stored genetic material (after divorce or death).[3]Likewise, simple estate planning becomes tricky with the existence of stored genetic material, such as embryos.[4]A recent move to pierce the anonymity of sperm and egg donors further complicates matters of probate.[5]Also, consider thata single embryo can be tied to many individuals including sperm and egg donors, a carrier, carrier's husband, and two intended parents. This creates problems for the fertility doctors who must then determine which party they owe a duty.

Professionals in seemingly unrelated fields may also face ART's ethical dilemmas. Consider a woman who donated her eggs while in college only to have a genetic disease emerge decades later. If her records mention the donation, does her general physician owe a duty to warn children created from the egg donation as a foreseeable third-party?[6]What if a child created from that donation seeks the woman's medical records to help with his own diagnosis, is the genetic relationship enough to expand the physician's duty?[7]

These emerging issues make it clear that attorneys and medical professionals in all fields could benefit from a working knowledge of ART.

Why People Come to Florida For ART

Florida is one of only 15 states with statutes permitting surrogacy.[8]Some states use case law to address ART disputes, but the majority of states have neither. Many countries either prohibit surrogacy or employ tight restrictions. When all statutory requirements are met, Florida's ART statute favors intended parents. Therefore, would-be parents from all over the world come to Florida to create their families using the well-established procedures set forth in section 742of the Florida Statutes.

ABCs of ART

Infertility is a disease of the reproductive system and is generally defined as being unable to achieve pregnancy after a year of unprotected intercourse.[9] Medically infertile couples are generally referred to a fertility specialist after one year (earlier if the intended mother is over 35). The following are common ART procedures practiced in Florida and descriptions of the parties involved:

Procedures

Intrauterine Insemination (also known as artificial insemination) is the oldest form of ART and involves inserting spouse or donor sperm into a woman's womb.

In vitro fertilization (IVF) involves an egg (provided by either the intended mother or egg donor) which is fertilized outside of the body in a culture dish. The resulting embryos are implanted in the womb of the intended mother or a carrier. Eggs not immediately implanted are cryopreserved for future use, donated (to other couples or medical research), or destroyed.[10] Florida further dissects the term embryo into "preembryo" describing the fertilized cells until the "appearance of the embryonic axis".[11]

In Florida, when both the husband and wife consent in writing to intrauterine insemination or in vitro fertilization, they are irrebuttably presumed to be the parents of the resulting child (except in cases of gestational surrogacy).[12]

Preembryo and Gamete Donation

Gamete refers to egg or sperm that has the potential to combine and form an embryo.[13] Embryos are the successful result of combining gamete and have the potential to be born into a live human being.[14] Both gamete and embryos may be donated. Florida allows for reasonable compensation for donating gamete or preembryos, and the donors presumably relinquish parental and inheritance rights as well as all obligations to the resulting child.[15]However, the statute does not specify details of compensation or method for terminating rights, leaving room for ART issues to occur.[16] When both the husband and wife consent in writing to the use of donor gamete or preembryos, they are irrebuttably presumed to be the parents of the resulting child (except in cases of gestational surrogacy).[17]

Surrogacy

Although the terminology in this area varies, generally, surrogacy involves a woman who contracts to become pregnant and gives birth to a child for another person or couple. Floridahas agestational surrogacy statute requiring a valid contract where the parties are at least 18 years of age, the commissioning coupleis legally married, and alicensed physician declares the intended mother infertile(or a pregnancy would endanger the intended mother or child).[18]The statute requires a genetic relationship between the child and at least one of the intended parents.[19] Hence, a married, heterosexual couple suffering from medically diagnosed infertility will find the law in Florida ideal.

Unmarried couples, same-sex couples, and single persons wanting to participate in a surrogacy arrangement, can follow a similar path using thePreplanned Adoption Arrangement in Florida's Adoption statutes.[20]

Parties to a Surrogacy Arrangement

Intended Parents (also called commissioning couple) are the people (or person) who want to raise the child. Intended parents enter into a reproductive arrangement with doctors, attorneys,

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Limitations on the Ability of Public Hospitals to Enter into Long Term Lease Obligations

By: Nicholas W. Romanello, Palm Springs and Mitchell Bottey, Tallahassee

While continuing to adapt to the "new normal" economic environment, healthcare-related transactions are on an upward trajectory. The Patient Protection and Affordable Care Act ("ACA") provideshospitals and health systems with opportunities to expand their services by way of the tried and true (joint ventures) as well as the model de jour (forming Provider Service Networks and/or Affordable Care Organizations). However, Florida's current political environment is forcing hospitals to reassess their strategic plans.Specifically, Florida's inability to act on the two main prongs of the ACA (health insurance exchanges and Medicaid expansion) creates a high level of uncertainty for many hospitals trying to navigate the current economic landscape. Consequently, this uncertainty demands that hospitals remain flexible in their business planning.

In order to remain flexible during these evolving times, hospitals commonly enter into leases for both space and equipment. Leasing equipment, such as diagnostic imaging equipment,canprovide a hospital with several advantages, including a reduction in acquisition costs, ability to easily upgrade as well as tax deductions. In order to maximize these advantages, hospitals may consider a capital lease. There are distinct differences betweenthe accounting methods used incapital and operating leases. A capital lease, which is similar to a term loan or a conditional sales contract, is normally used to finance the purchase of capital equipment. A capital lease is defined as a lease that meets at least one of the following four criteria:

1. The lease life exceeds 75% of the life of the asset.
2. There is a transfer of ownership to the lessee at the end of the lease term.
3. There is an option to purchase the asset at a bargain price at the end of the lease term.
4. The present value of the lease payments, discounted at an appropriate discount rate, exceeds 90% of the fair market value of the asset[1].

While private sector health systems are free to enter into lease agreements subject only to their financial position, public hospitals face legal prohibitions against some lease arrangements. This note provides health law practitioners with guidance as to the constraints that public sector health systems face when leasing space and/or equipment. Additionally, a proposed workaround, whichcircumvents the constraints public hospitals face is offered.

Florida's Public Hospitals

With more than 9000 beds, Florida's twenty-ninepublic hospitals[2] range from the small and rural to the large and urban. Florida's public hospitals serve the most vulnerable populations and are often referred to as "safety net facilities". These safety net facilities operate under extraordinary financial pressure, in part, because they treat a disproportionate number of uninsured patients. Reductions in state Medicaid payments coupled with Florida's failure to expand Medicaid consistent with levels outlined in the ACAhave caused Florida's safety net providers to face severe financial constraints.

According to the Florida Department of Economic Opportunity, Florida has more than seventy-five special taxing districts ("Districts") whose mission is limited to the administration of hospitals, health facilities, or health care. While some of these Districts are significant actors in the health care delivery system, others play smaller roles in their communities. Large or small, these Districts share the common element of being a unit of local government. As units of local government, these Districts' must manage their hospitals in accordance with public procurement and finance laws.

The legislation that createspublic hospital districts generally authorizes the hospital to acquire by lease any property it deems necessary to carry out the purpose of the legislation[3]. However, a public hospital's authority to enter into a lease is subject to the Florida Constitution, which prohibits local governments from pledging its ad valorem tax revenues for obligations exceeding twelve months, unless approved by referendum[4]. Thus, while Florida law generally empowers public hospitals to enter into lease agreements, Florida's Constitution constrains that authority by mandating a referendum for public entities wishing to pledge tax revenue beyond twelve months. These equally valid principals have the cumulative effect of complicating a public hospital's business planning and practices.

Further complicating matters for public hospitals is Florida's prohibition against a special taxing district from paying any amount, unless specifically appropriated in their annual budget. Section 189.418(3), Florida Statutes (2012), states, in part, "[t]he governing body of each special district shall adopt a budget by resolution each fiscal year. The total amount available from taxation and other sources, including amounts carried over from prior fiscal years, must equal the total of appropriations for expenditures and reserves. The adopted budget must regulate expenditures of the special district, ***and it is unlawful for any officer of a special district to expend or contract for expenditures in any fiscal year except in pursuance of budgeted appropriations***."[5]Notwithstanding any contractual provision to the contrary, state law governs and controls all lease agreements to which the public hospitals and health care systems are parties.

Public hospitals with low operating margins need a strategy, which allows them to enter into long-term leases without pledging ad valorem revenue in excess of twelve months.

Workaround

Faced with an complex framework within which to lease space or equipment, public hospitals require a viable, practical, workaround to comply with state law while providing them with flexibility to appropriately enter into some long term business planning.

In order for a local government to enter a multi-year lease without a referendum, it may wish to consider using a non-appropriations clause. As set forth more fully below, a non-appropriations clausegenerally provides that if in any given year the local government fails to appropriate funds to make the lease

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LIMITATIONS

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payments, the lease terminates. Like many units of local government, public hospitalscould usethisclausein theirlong-term leases.

Historically, public hospitals and health systems negotiate appropriations terms and conditions into proposed lease agreements thatrecognize state law. With respect to lease agreements, thestandard language may take the following form:

> APPROPRIATIONS: Termination of this Agreement shall not affect any rights, obligations, and liabilities of the parties arising out of transactions, which occurred prior to termination. Notwithstanding the foregoing, the parties acknowledge and agree that *[the Public Hospital, Inc.]* is a subsidiary *of [the Local Hospital District]* andis a political subdivision of the state of Florida, subject to the terms of *[Local Hospital District's Enabling Legislation]* and as such, this Agreement (and all Exhibits hereto) are subject to budgeting and appropriation by the *[Public Hospital District]* of funds sufficient to pay the costs associated herewith in any fiscal year of the *[Public Hospital District]*. Notwithstanding anything in this Agreement to the contrary, in the event that no funds are appropriated or budgeted by the *[Public Hospital District's]* governing board in any fiscal year to pay the costs associated with the District's obligations under this Agreement, or in the event the funds budgeted or appropriated are, or are estimated by the District to be, insufficient to pay the costs associated with the District's obligations hereunder in any fiscal period, then the District will notify*[Lessor]* of such occurrence and either the District or *[Lessor]* may terminate this Agreement by notifying the other in writing, which notice shall specify a date of termination no earlier than twenty-four (24) hours after giving of such notice. Termination in accordance with the preceding sentence shall be without penalty or expense to *the [Public Hospital District]* of any kind.

The use of this non-appropriations clause provides public hospitals with the ability to enter into a capital lease without pledging ad valorem revenue beyond a single fiscal year. Not surprisingly, potential vendors may initially recoil against such language. The non-appropriations clause, on its face, limits the public hospital's exposure on a long-term lease to a single year. While technically accurate, it would be imprudent to invoke such a clause lest a public hospital risk its credit rating. An experienced health law attorney knowledgeable in public finance should be able to assist to bridge the gap between public hospital and vendor.

Conclusion

The American health care system is in the midst of perhaps one of its most fluid and uncertain times. Florida's failure to establish a state health insurance exchange and expand Medicaid increases this uncertainty. This uncertainty most acutely affects Florida's safety net hospitals who already labor under competing laws regarding their ability to enter into long term leases. In order to remaincompetitive, Florida's public hospitals must find a way to enter into long-term leases without violating the Florida Constitution's prohibition against pledging ad valorem revenue in excess of twelve months. The use of a non-appropriations clause as described in this note may be a suitable strategy for those public hospitals that cannot finance long terms leases through operating revenue.

Authors:

Nicholas W. Romanello *is the General Counsel and Chief Legal Officer of the Health Care District of Palm Beach County which provides health coverage for low-income residents, a nationally acclaimed trauma system, clinics with a dedicated nurse in more than 170 public schools, a pharmacy network, a long-term skilled nursing and a rehabilitation center, a network of federally qualified health centers and acute care hospital services at Lakeside Medical Center, the county's only public hospital. The interpretations of law and opinions contained in this note are personal to the author and not those of the Health Care District of Palm Beach County, its Board of Commissioners or executive management and staff. He can be reached at 561.659.1270 and nromanel@hcdpbc.org.*

Mitchell Bottey is a third year law student at the Florida State University, College of Law. He can be reached at mab07g@my.fsu.edu

Endnotes

1. Accounting for Leases, Statement of Fin. Accounting Standards No. 13 (Fin. Accounting Standards Bd. 1976).
2. *Facts &* Stats, Florida Hospital Association, http://www.fha.org/reports-and-resources/facts-and-stats.aspx (last visited Sept. 29, 2013).
3. *See generally* H.B. 427, 2003 Reg. Sess. (Fla. 2003); S.B. 3202, 2004 Reg. Sess. (Fla. 2004); H.B. 1245, 2006 Reg. Sess. (Fla. 2006); H.B. 113, 2003 Reg. Sess. (Fla. 2003).
4. 4 Fla. Const. art. VII § 12(a).
5. Fla. Stat. § 189.418(3) (2012) (emphasis added).

and a carrier (and the carrier's spouse, if applicable).

Carrier (often referred to as a surrogate). This is a woman who agrees to become pregnant with a child, give birth to him, and then turn him over to the intended parents. There are two types of carriers: traditional and gestational.

A traditional carrier is a woman who may or may not use ART procedures to become pregnant. She uses her own egg, thus, she is genetically related to the child. Parties entering into a traditional carrier arrangement follow the procedures set forth in Florida's Adoption statute under a Preplanned Adoption Arrangement.[21]Here, the carrier (and spouse, if applicable) consent to termination of parental rights and adoption before the carrier becomes pregnant. However, since she is genetically related to the child, the carrier may revoke her consent within forty-eight hours after birth.[22]

A gestational carrier is a woman who uses ART procedures to become pregnant and who is not genetically related to the child. Parties entering into a gestational carrier arrangement get to take advantage of Florida's progressive and strong gestational surrogacy statutes. If the requirements of the statute are followed, the carrier has no parental rights to the child.[23] Therefore, there is no need to terminate parental rights or to adopt. Instead, the intended parents will petition for a hearing three days after the birth of their child.A judge will then check compliance with the statute and that there is a genetic link to the child before issuing a final order declaring the intended parents as the legal parents.[24]

Conclusion

For centuries, becoming a parent was straightforward. Would-be parents had two options: sexual intercourse or adoption. Only in the last few decades can people who never thought it possible to conceive a genetic child now become parents.Assisted Reproductive Technology brings the legal and medical fields together to paint these hopeful parents a new family portrait. But to create a true masterpiece, we must also be aware of the issues ART presents so we can protect those new families and the professionals who assist them.

Author:
Jessica Hoffman works in Jacksonville, FL for the Law Offices of Robert T. Terenzio. She is an active member of the American Bar Association Committee on Assisted Reproductive Technologies and mother to a daughter born via a gestation carrier.

Endnotes

1. American Bar Association Model Act Governing Assisted Reproductive Technology § 102(1)-(2) (2008). (ART procedures include, but are not limited to: intrauterine insemination, in-vitro fertilization, embryo transfers, egg donation, and embryo donation.).
2. Anjani Chandra, Gladys M. Martinez, William D. Mosher, et al., Fertility, Family Planning, and Reproductive Health of U.S. Women: Data from the 2002 National Survey of Family Growth, 23 Vital & Health Statistics 25, 105, 108, 316 (2005).
3. See generally,Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992) (where the court uses a balancing test weighing the interests of the father who did not wish to procreate against the interest of the mother who wanted to donate the embryos.) andKass v. Kass, 696 N.E.2d 174, 180 (N.Y. 1998) (originally using family law to settle a dispute over frozen embryos, but on appeal the court used contract law ruling that prior written agreements outlining the wishes of the progenitors are enforceable).
4. Fla. Stat. § 742.17 (a posthumously conceived child is only considered a child of a decedent when decedent provided for a child in a will). See also Stephen v. Comm'r of Soc. Sec., 386 F. Supp. 2d 1257 (M.D. Fla. 2005) (where a posthumously conceived child was denied Social Security benefits because the genetic father did not leave a will).
5. Problems occur when donors are known to the intended mother or she is single. See,Lauren Gill, Who's Your Daddy? Defining Paternity Rights in the Context of Free, Private Sperm Donation, 54 Wm. & Mary L. Rev. 1715, 1727 (2013); Case about child support belonging to child, parent cannot contract it away.
6. Tarasoff v. Regents of the University of California, 551 P.2d 334 (Cal. 1976). (expanded a medical professional's duty to warn foreseeable third parties known to be at risk, even when the third party is not a patient).
7. Susan M. Denbo, What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives?, 43AM.BUS.L.J. 561, 580–86 (2006) (discussing the genetic disease being exception to the doctor-patient privilege).
8. FL, IL, NH, NV, TX, UT, VA, WA have statues permitting gestational surrogacy. AR, CT, IA, ND, NM, TN, WV have statutes which address the types of surrogacy prohibited. See,Diane S. Hinson & Maureen McBrien, Surrogacy Across America,Family Advocate, Vol. 34. No. 2, 35 (Fall 2011).
9. American Society for Reproductive Medicine, Frequently Asked Questions About Infertility, available at http://www.asrm.org/Patients/faqs.html.
10. Charles P. Kindregan, Jr. & Maureen McBrien, Assisted Reproductive Technology, 122, American Bar Association, (2nd ed. 2011).
11. Fla. Stat. § 742.12(12) (2010).
12. Id. § 742.11(1).
13. ART Model Act § 102(13) (2008).
14. Id. § 102(10) (defining embryos a "a cell or group of cells ...that has the potential to develop into a live born human being...").
15. Fla. Stat. § 742.14 (2010).
16. See,79 So. 3d 787, 787 (Fla. Dist. Ct. App. 2011) (where the court held that the statute violated a constitutionally protected parental right and granted parental rights to both the biological mother and her lesbian partner).
17. Id. § 742.11(2).
18. Id. § 742.15.
19. Id. § 742.13 (2).
20. Fla. Stat. § 63.213(6)(h) (2012).
21. Id.
22. Id.§ 63.213(2)(a).
23. Id. § 742.16 (7).
24. Id. § 742.16 (6).

be aware that depending on the state, medical malpractice insurance may not protect them. In fact, most malpractice insurance only protects against face-to-face interactions with the patient and patient interactions in the state in which the physician is licensed.[12] Some states force insurance companies to protect physicians for medical care provided outside the state, while other states do not require this type of coverage.[13] To protect themselves, physicians have begun to request written assurances from their insurers stipulating that they will be protected for their remote caregiving, while some other physicians are getting policies that are solely for remote healthcare.[14]

MEDICARE REIMBURSEMENT

Medical providers should also consider the fact that Medicare does not always fully reimburse patient care that occurs remotely. Medicare will only reimburse expenses for telemedicine if the patient is in a Health Professional Shortage area or if the patient is outside of a Metropolitan Statistical Area. Both of these terms are defined by the HRSA and the Census Bureau.[15] Further, the patient cannot be in his/her own home at the time of the consultation—rather the patient must be in a medical facility, which includes the physician's office.[16] Finally, Medicare will not reimburse expenses for face-to-face consultations and will not reimburse expenses for store-and-forward services (except in Alaska and Hawaii), such as when a patient gets an x-ray which is stored and forwarded to the physician for his/her review.[17] On the other hand, Medicare will reimburse services performed by physicians, nurse practitioners, physician assistants, nurse midwives, clinical nurse specialists, clinical psychologists, clinical social workers, and nutritional professionals.[18]

PRIVACY/HIPAA

Telehealth physicians are required to protect electronic patient records in the same manner physicians traditionally have had to protect paper files. However, the protection of patient privacy is slightly more difficult with the amount of patient data needed to adequately provide telemedicine and the possible hacking risks associated with this data.[19] "Telemedicine, at least at present, will require a technical staff to run the system that is completely independent from the medical team."[20] Further because of the large amount of information being transferred electronically, there is the potential for hackers to obtain this information.[21] In order to protect patient privacy and comply HIPAA, physicians must set up and follow strict protocols to ensure patient privacy. .[22]

IV. Florida

LICENSING

Anyone who wishes to practice medicine in the state of Florida must obtain a Florida medical license. This differs from some states which allow physicians to obtain limited or restricted licenses to practice remotely in the state.[23] While Florida has a statute that permits the Board of Medicine to issue restricted licenses to up to 100 persons annually,[24] this power has not be extended to a limited or special license that allows doctors to work remotely with patients in Florida (i.e. telemedicine).[25]

While any doctor wishing to practice generally in Florida must obtain a license, there are a few statutory exceptions.[26] These exceptions include "consultation services,"[27] "care provided to the military,"[28] "emergency care,"[29] "domestic administration of recognized family remedies,"[30] "religious practices,"[31] and the "selling and fitting of artificial body parts".[32] Further, this license requirement does not apply to "duly licensed health care practitioners acting within their scope of practice authorized by statute."[33]

REGULATIONS

Being duly licensed in Florida, however, is not the final hurdle to being able to practice telemedicine in Florida. The Florida Administrative Code creates requirements that practicing doctors must meet in order to practice remotely. First, the code prohibits prescribing medications solely based on an electronic questionnaire.[34] In order to practice remotely,[35] three requirements must be met: (1) there must be a documented patient evaluation; (2) the doctor and the patient must have a discussion about the risks and benefits of treatment as well as different treatment options; and (3) the doctor must maintain contemporaneous medical records.[36] However, these requirements need not always be met. For instance, these requirements need not be met in emergency situations or when a doctor "has an ongoing relationship with the patient." In the latter situation, the doctor is permitted to supervise the continued treatment of the patient remotely.

LEGISLATION

No Florida statute currently addresses telemedicine directly.[37] Bills have been proposed that directly address telemedicine, but the only one to pass was House Bill 2125 in 1999, which created

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a telemedicine task force. The goal of this task force has been to "protect the health and safety of all patients in this state receiving services by means of such technology and to ensure the accountability of the health care professions with respect to unsafe and incompetent practitioners using such technology to provide health care services to patients in this state."[38]

Since the creation of this task force, other bills have been proposed to no avail.[39] Most recently, Senator Arthenia Joyner proposed Senate Bill 70 in early August of this year. [40] This bill would include a provision that would prevent health insurers from requiring doctor-patient face-to-face visits if remote examination is feasible.[41] The bill states that for the purpose of insurance coverage, remote examinations will be equivalent to in-person visits.[42] The bill is expected to be considered during the 2014 legislative session and would take effect in January 2015.[43]

As previously mentioned, Rule 64B8-9.0141 has been proposed to be the standards utilized in telemedicine. It incorporates the same standard of care as with face-to-face medicine but then goes further to require that care providers ensure the accuracy of their technology used for telemedicine.[44] However, the Rule is quite clear that "the standard of care. . .shall remain the same regardless of whether a Florida licensed physician or physician assistant provides health care services in person or by telemedicine."[45] If accepted this rule defines telemedicine as "services [that] are provided through the use of medical information exchanged from one site to another via electronic communications."[46] It allows the patient-physician relationship to be entirely remote—including the initial consultation—but it draws the line and prohibits telemedicine to be solely via telephone, e-mail, text messages, fax, or U.S. Mail.[47] Further, a rather important provision in the Rule is that is prohibits the prescription of controlled substances through telemedicine.[48] However, as with other rules and regulations, this Rule will not prohibit telemedicine care in an emergency situation.[49]

V. LOOKING FORWARD

Telemedicine will only see increased prevalence and importance in our global society. Going forward, we will see telemedicine become more a part of our everyday lives. Applications on phones that examine medical data are rather common—such as the smart phone application that heart-attack patients are using to monitor and attempt to prevent future heart attacks.[50] Further telemedicine centers are becoming more common—such as the University of Florida's Diabetes Center of Excellence which uses telemedicine to provide care to children with diabetes who do not reside within the area.[51] While the advancements in technology continue to soar, the need for healthcare in certain areas remains the same, so looking forward, telemedicine will continue to find increased prevalence in today and tomorrow's society.

Caitlein J. Jammo, Esq. Associate, *Johnson, Pope, Bokor, Ruppel & Burns, LLP* Clearwater;
with guidance from Michael T. Cronin, Esq. Partner, *Johnson, Pope, Bokor, Ruppel & Burns, LLP* Clearwater; and
With special thanks to Tom Meehan, a pioneer in the marketing of telemedicine services, who was the inspiration of this Article.

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are subject to fines of up to $10,000 for each failure to report or $100,000 for each knowing failure to report a payment, transfer of value, or ownership or investment interest.[8] There are still some gray areas as to reporting requirements. For example, if two physicians are immediate family members and one has an ownership interest in a manufacturer, how is this reported? CMS has indicated that duplicate reports need not be made, but does not address this specific situation. Overall, it is not entirely clear how the Act will play out, but reporting entities seem to be taking these new requirements in stride.

The Subjects – Physicians and Teaching Hospitals

Physicians and teaching hospitals[9] do not have any reporting obligations under the Act. However, information about them will be reported and published. As such, we recommend that reporting entities educate physicians and teaching hospitals about the reporting entities' obligations to report and the process for doing so.

Physicians: Where Are the Safe Harbors?

On the one hand, reporting transfers of value to physicians is nothing new. Large pharmaceutical companies such as Pfizer, Eli Lilly, and AstraZeneca either have had to or must currently publicly post all transfers of value to physicians pursuant to Corporate Integrity Agreements with the Office of Inspector General of the U.S. Department of Health and Human Services. For example, due to a 2009 Corporate Integrity Agreement, Eli Lilly posts all transfers of value to physicians on its website. The site was last updated in June of this year, and the list is 1,728 pages with 25 names on each page. In total, the most recent report lists over 43,000 physician names.

On the other hand, reporting of investment amounts and value of interests is a new concept to physicians. While several professional organizations have encouraged physicians to disclose such financial relationships to patients, physicians have often been able to keep relationships with manufacturers or distributors secret. Furthermore, they have not traditionally been required to disclose the actual value of their relationships.

Often, when physicians learn about the Act, they are concerned with privacy of their financial information. Another concern is that the information will be used against them in litigation. A common question is whether there are any exceptions to reporting that would help protect this information that many physicians deem confidential. Unfortunately, the language of the Act is broad, and there are few exceptions.

There is an exception to reporting where the reporting entity does not know the identity of the covered recipient.[10] Despite this, reporting entities may not act in deliberate ignorance of the facts identifying the covered recipient.[11] Some

continued, next page

physicians may inquire whether they can "carve-out," federal health program business in order to avoid reporting. It is important to note that the Act's reporting requirements apply to all physicians, regardless of whether they participate in Medicare, Medicaid, or any other federal health care program.[12]

In calming physician fears, the first issue to point out is the unlikely event that a patient will even view the website. Furthermore, it is unlikely that a patient will be deterred from seeking treatment from a physician due to the physician's financial relationship with a reporting entity. Because there are so many reports it will become readily apparent that this is not an unusual or infrequent event. Nevertheless, physicians may want to take a proactive approach and draft a notice to clients about why he/she has a financial interest in a company. Even CMS has recognized "that collaboration among physicians, teaching hospitals, and industry manufacturers contributes to the design and delivery of life-saving drugs and devices."[13]

Further, physicians should not be overly concerned about the implication of the Act on litigation. First, this information was, and still is, likely available through discovery even without the reporting requirements. Additionally, these issues often arise in the context of over-utilization and unnecessary procedures that ultimately result in harm to the patient. Most physicians do not have to be concerned with this issue.

Finally, CMS is developing a notification process for physicians about whom reports have been made. It is a good practice for physicians to ask reporting entities for an opportunity to review data prior to submission and also to review submissions to ensure accuracy and correct any errors before the information is publically reported.

Hospitals: Not in My Hospital!

Many hospitals across the country have already received media inquiries about the Act. Reports under the Act have the potential of subjecting hospitals and their physicians to public scrutiny. Some hospitals are responding by implementing strict policies prohibiting medical staff physicians from having any reportable ownership interests or accepting any reportable transfers of value. Others are considering strategies to monitor physician relationships.

For hospitals, allowing physicians to retain their autonomy, while monitoring potential conflict of interest concerns is a balancing act. An outright prohibition on physicians having financial relationships with reporting entities may encourage some physicians to take their business elsewhere. Another approach is for hospitals to create conflict of interest committees to evaluate these relationships and guard against undue influence. Furthermore, hospitals are encouraged to review financial relationships with manufacturers and GPOs as well as reports made about themselves and their physicians. CMS has indicated that they should request to view data prior to submission to CMS in order to ensure accuracy of data.

Relation to Fraud and Abuse

Although reputation is important, ultimately, it may not be consumers that these physicians and hospitals should be worried about. Although CMS has been very clear that a report on the Open Payments website does not signify wrongdoing, undoubtedly, the OIG will mine through the massive amounts of data reported under the Act. This will likely lead to an increased number of fraud and abuse investigations. Thus, it is important for manufacturers, GPOs, hospitals, and physicians alike to review data and make every effort to ensure its accuracy.

In addition, with this increased transparency, it is more important than ever that financial arrangements involving physicians and hospitals are structured appropriately and in accordance with all laws and regulations. Providers should also ensure they have implemented robust compliance plans and training to mitigate against potential fraud and abuse penalties. Although the Sunshine Act may not have brightened many peoples' day, it is an attempt to encourage the transparency that many healthcare professional organizations have promoted and encouraged for years. As such, it is important to ensure that your clients are aware of their reporting obligations and develop strategies to deal with the potential adverse impact of reporting.

Authors:
Mark Bajalia, Esq.
Brennan, Manna & Diamond, PL
800 W. Monroe Street
Jacksonville, FL 32202
(904) 366-7302
mbajalia@bmdpl.com
Samantha Prokop, Esq.
Angela Cox
Brennan, Manna & Diamond, LLC
75 E. Market St.
Akron, OH 44308
(330) 253-3766; slprokop@bmdllc.com
(330) 374-7475; acox@bmdllc.com

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3. 78 Fed. Reg. 9,458, 9,493 (Feb. 8, 2013).
4. *See* 42 C.F.R. § 403.904(e)(2)(i)-(xvii).
5. These are the values for 2013. The amount will be calculated each year in accordance with 42 C.F.R. § 403.904(i)(2)(ii).
6. 42 C.F.R. § 403.904(i).
7. For research payments, see § 403.906(f). For CME, see 42 C.F.R. § 403.906(g). For food and beverage, see 42 C.F.R. § 403.906(h).
8. 42 C.F.R. § 403.912(a)-(b).
9. A teaching hospital is "any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the [Social Security] Act during the last calendar year for which such information is available." 42 C.F.R. § 403.902. CMS will post a list of teaching hospitals on its website approximately 90 days prior to each reporting period.
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