Risk R

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Risk R_x Last Issue of Risk Rx

Announcement of a New Peer-Reviewed Journal

HEALTHCARE PROFESSIONAL LIABILITY Review

Risk Rx has had a long and distinguished run. Numerous published articles reviewed by experts in their respective fields were made available to all those served by SIP to increase their knowledge of opportunities to reduce risk of professional liability and to enhance patient safety. Although this is the last edition, Risk Rx will serve as a foundation for the next SIP publication initiative – *Healthcare Professional Liability Review.* We value the Risk Rx knowledge base created over the years, and all articles published by Risk Rx will remain available on our SIP website at <u>www.flbog.sip.</u> <u>edu</u>. A special thanks to Jan Rebstock who championed Risk Rx and to all Risk Rx article contributors and members of the Editorial Board.

Healthcare Professional Liability Review is coming.

These are exciting times for SIP. We are joining the realm of peer-reviewed publications with our first edition of *Healthcare Professional Liability Review* scheduled for February 2016. *Healthcare Professional Liability Review* serves as a scholarly, peer-reviewed, national and international information exchange for the analysis of contemporary professional liability challenges confronting healthcare, legal, and insurance professionals. *Healthcare Professional Liability Review* advances creative solutions with the objective of mitigating the adverse consequences of medical malpractice claims and litigation. It will seek articles relevant to its stated objective, with the focus on perceptive, discerning articles that positively impact the healthcare, legal, and insurance professions individually and collectively.

Healthcare Professional Liability Review articles are welcomed on an open submission basis at any time. If accepted for review and approved for publication, articles will be published in one of the two semiannual editions. All articles are submitted through the Open Journal System portal on the *Healthcare Professional Liability Review* website (healthcareprofessionalliabilityreview.org). The Editorial Board is composed of outstanding professionals in the fields of healthcare, law, and insurance. The members are seasoned practitioners and professionals who are devoted to the dissemination of quality information that enhances the professional liability knowledge and skill sets. We are pleased to retain some of the members of the Editorial Board who served on the Risk Rx board.

We encourage all of our Risk Rx readership to continue building their knowledge base by reading *Healthcare Professional Liability Review*, and we also encourage our readership to consider writing scholarly articles for publication in our new peer-reviewed journal. Specific instructions on submitting articles for consideration for publication will be broadcast to all Risk Rx readers in the near future.



Palliative Care:

A specialty that has come into its own

Sheri Kittelson, MD, Medical Director Palliative Care UF Health Department of Medicine Toni L. Glover, PhD, GNP-BC, Assistant Professor University of Florida College of Nursing Marie-Carmelle Elie, MD, Associate Professor University of Florida Emergency Medicine, Critical Care, Hospice and Palliative Medicine



Palliative care is a relatively new medical specialty rapidly expanding over the past decade. Since the year 2000,

the number of hospitals with inpatient palliative care teams has increased by nearly 148%, including 66% of all hospitals over 50 beds¹. Despite this rapid growth, there are not enough specialists in palliative care to meet the growing need and all providers could benefit from generalist training in palliative care principles (Quill, & Abernathy, 2013). Palliative comes from the Latin root "Palliere" which means "to cloak." The practice of palliative care represents the interdisciplinary care that aims to relieve suffering, improve quality of life, optimize function, and promote both autonomous and shared decision-making for patients (and their families) with serious illness. Care is holistic, addressing not only the medical illness but also the psychological, social, and spiritual dimensions of serious illness. For a person to feel well, all aspects of suffering must be addressed. While a cure may not always be tenable at the end stage of chronic disease or a terminal illness, the management of troublesome symptoms may relieve suffering and improve a patient's quality of life. This article serves to define palliative care, summarize the differences and similarities of palliative care and hospice, generalist vs. specialist care, prognostication, symptom management, advance care planning and the overall benefits of palliative care.

Palliative Care vs. Hospice:

The distinguishing and often misunderstood feature of palliative care is that it can occur in conjunction with life prolonging and curative therapy. In other words, all hospice care is palliative, but not all palliative care is hospice. For example, patients with cancer may receive surgery, chemotherapy, and radiation with the intent to cure, and still qualify

for and benefit from palliative care services. A landmark trial in the New England Journal of Medicine demonstrated "among patients with metastatic non-small-cell lung cancer, early palliative care led to significant improvements in both quality of life and mood. As compared with patients receiving standard care, patients receiving early palliative care had less aggressive care at the end of life but longer survival."² Hospice falls under the umbrella of palliative care, and referral is appropriate when patients have a terminal diagnosis and death is expected within 6 months. Patients and health care providers often need reassurance that a referral to hospice is not "giving up hope". Studies show patients receiving hospice care, when compared to hospitals, nursing homes, and traditional home care, have significantly improved symptoms (less pain, shortness of breath, fatigue), better quality of life, better caregiver spiritual and emotional support, and decreased complex grief among decedents associated with intensive care unit deaths.^{3,4} Hospice care actually results in a mean overall survival benefit of 29 days for many cancers and congestive heart failure (CHF), with a benefit of the reduced cost of hospital care.

(Similarities) Palliative Care and Hospice: interdisciplinary, holistic, patient and family focused, quality of life, communication, symptom management

(Differences) Palliative Care:	Hospice:
Chronic illness	Terminal illness
Can seek life-prolonging, curative treatment	Not seeking curative treatment
No eligibility criteria	Expected prognosis < 6 mon (if the illness runs its normal course)
Same Co-pay as other MD visits	Medicare – part A
Medicare – part B (same co-pay as other MD visits)	

Locations of Care:

The ultimate goal is to offer palliative care in any location in which a patient would need services.

- Hospital Inpatient Consultative Service
- Dedicated Hospital Inpatient Unit
- Emergency Department
- Outpatient Clinic, free standing or imbedded in specialty clinics such as Oncology or Geriatrics
- Home Care Visits

Meet the Team:

Palliative care is delivered utilizing an interdisciplinary model. A team may include physicians, advanced provider practitioners, and nurses in various medical specialties, as well as social workers, chaplains, mental health providers, and community members. While some members of the team may be palliative care specialists, others represent a group of multifaceted expertise who contribute to the overarching goals of optimizing palliation (Quill & Abernathy, 2013). Listed below are the distinctions between generalist and specialist palliative care.⁶

All Medical Providers:	Specialist Palliative Care:
Pain and symptoms	Manage refractory pain
Depression and anxiety	Manage complex psychological distress
Prognosis	Conflict resolution families/staff
Goals of treatment	Assist in cases of medical futility
Suffering	Ethics/Legal assistance
Proactive Advance Care Planning	Advance Care Planning and Code Status at the end of life

Consult Etiquette:

When a consultation is requested, providers exchange information about what is most important to accomplish during the visit from the standpoint of the referring clinician. This discussion with the referring clinician should include whether the patient and/or family are aware of the palliative consult, the content of previously discussed management and planning and whether matters of a sensitive nature are acceptable to discuss with the patient at the initial visit. Following a detailed assessment which includes a thorough chart review of the patient's history, symptoms, and examination; the provider should prepare to engage the patient and their family. An appropriate location should be identified to discuss desired goals for management. A private setting with minimal distraction is ideal and an invitation should be

made in advance to ensure all surrogate decision members are present. Consults are typically standardized within institutions and include: symptom management, prognosis, goals of care, advance care planning such as code status/completion of advance directives, psychosocial and spiritual support. Knowledge of aggressive pain and non-pain symptom management and its relationship to the social and practical needs of caregivers, and the relationship of spiritual and existential suffering is a necessary component of palliative care. Engaging other members of the patient's care team to gather additional treatment specific considerations and prognosis may be indicated. In complex cases, additional consultation by a specialist may prove necessary to facilitate care (e.g. heart transplant and/or heart pump assist devices from a cardiologist). Specialist-level skills include advance care planning, status of life sustaining therapies (ie code status), roles and responsibilities of surrogate decision-makers, ethical considerations, provider-patient shared decision making, legal requirements for use of controlled substances, pronouncing death, and request for autopsy and organ donation .

Symptom Management:

Patients with serious illness or in advanced stages if their co-morbidities eventually develop symptoms related to their disease. These symptoms can decrease quality of life for the patient and caregivers by impeding sleep, work, eating, self-care, mentation and participation in enjoyable activities. Patients and caregivers may have a poor understanding of the disease, unrealistic expectations of care, and low health literacy. Health care treatment can be fragmented with poor communication or resources to prepare patients and families for the end of life. This paradigm frequently ends in a systematic default to emergent and aggressive care in response to an overestimated legal risk, fear, or discomfort with death. ⁸ The result is non-beneficial care in elderly or terminal patients with serious illness including escalation of care at the end of life, including repeated and potentially preventable emergency room visits, hospital readmissions, burdensome treatments and interventions and death in the hospital intensive care unit. In some situations, these interventions only serve to prolong the dying process. This invasive trajectory can create unnecessary suffering of patients, caregivers, health care providers, and can threaten the stability of the healthcare system at large. When provided with prognosis and assessments of the risks and benefits of treatment, many patients chose to focus on care that preserves the quality of their life, even if the quantity of life may be limited. Studies show the majority of patients, families, and even health care providers want symptoms managed, to be informed of their prognosis, treated as a whole person, and to avoid artificial life support as death approaches.⁹ Palliative symptoms include pain and non-painful symptoms such as shortness of breath, nausea,

vomiting, constipation, anorexia, fatigue, insomnia, anxiety, depression, and delirium. Pain, and most other symptoms, are subjective. That is, individuals can experience the same painful stimulus or injury differently because of genetic variance underlying physiologic differences in pain perception and emotional, cultural or spiritual influence. Pharmacologic treatments can also include complementary and alternative medications, such as vitamins and herbs. Non-pharmacologic care includes arranging sessions with a mental health professional, physical/occupational/speech therapy, spiritual/ cultural advisor, meditation (or other forms of therapy that triggers the relaxation response such as repetitive prayer, guided imagery, Tai Chi, Yoga), arts in medicine, animals in medicine, diet, and exercise.

Prognostication:

Good communication and shared informed decision making is a cornerstone of palliative care. Ensuring that patients and families understand their diagnosis and prognosis is imperative, as this allows individuals to make informed decisions about the benefits and burdens of medical interventions. Prognosis is based not only on the disease, but on age, functional status, comorbidities, and psychosocial support. Physicians overestimate prognosis and the longer they have cared for a patient, the greater the overestimation (Christakis & Lamont, 2000). If care will not add to the quantity or quality of life, its benefit should be questioned. Based on cultural background and experience individuals develop a set of values that influences their choices in medical care. These values vary individually and are as unique as each patient. Values and priorities may change as the disease progresses. Palliative care specialists set aside personal values and listen openly to determine the patient-centered values and goals of care. A key role of palliative care is to help facilitate honoring a patient's treatment preferences. At times the palliative care team is called to assist in resolving conflicts in goals of care between patients and family, between patients and health care providers. Ethics consultation may be helpful when conflict arises and teams need to ensure all avenues legally, medically, ethically have been explored to honor a patient's autonomy. An example is a family is unable to make a decision for their loved one regarding life-prolonging versus comfort care. Physicians often assume patient's goal of care is life prolongation and the medical system defaults to aggressive care for all individuals, even if this would not result in an acceptable quality of life for an individual base their values. This comes from an underlying culture of medical training that illness and death represent a "failure".

What is your patient's goal of care?

- Life Prolongation: Desire to prolong life at all costs. An acceptable quality of life would include electing for placement of an artificial feeding tube and breathing tube if in a persistent vegetative state dependent on the caregivers for all personal care needs.
- **Comfort:** Desire not to accept treatment that would create unnecessary suffering. The burden of treatment does not outweigh the benefit. An example is a patient with advanced stage cancer forgoing experimental chemotherapy with toxic side effects and only a 10% chance of adding weeks to a patient's life.
- Function: Desire to live with a certain standard of functional ability. For example, a 85 year-old who lived independently presents with a debilitating stroke that has a 90% chance of being fatal and 10% chance of requiring placement of a feeding tube to eat, breathing tube to breathe, and 24-hour care in a nursing facility to never walk or eat again. The patient may opt for hospice care to allow a natural death as the burden of treatment would not add an acceptable benefit of quality time. When the family is tasked with the decision, they are asked to utilize substitute judgment; in other words, what would their loved one decide if they were able to make the choice themselves.

Advance Care Planning:

Advance care planning is the foundation of palliative care and a basic skill required by all healthcare providers. The goal is to move advance care planning upstream, to outpatient clinics. Advance care planning should be initiated earlier in the trajectory of chronic illness, when patients can express their wishes and communicate them to their loved ones. All providers need to create processes within their practice for engaging in these important conversations and understanding patients' wishes. Contrary to expectations, patients appreciate talking to their healthcare provider about advance care planning. Having the conversation in a non-emergency setting is much preferred to waiting until the patient's arrival at hospital emergency departments when the patient can no longer voice their wishes. The goal is to normalize advance care planning conversations and assist patients to carefully consider and document healthcare preferences prior to crisis situations. Completion of advance directives enables individuals to maintain their wishes for care, even during a period of incapacity, which can occur after unexpected illness, accident, or during the end of life. Completion of documents is typically not an isolated event, but a process over time to be revisited periodically and updated based on disease progression. Once advance directives are complete, there may be barriers in implementing them in

critical situations, including availability to treating physicians and institutions, vague and legalistic language, proxy availability and use of substituted judgment and honoring previously expressed wishes to make decisions according to what the patient would have wanted. As you can imagine, system wide approaches in addition to palliative care consultation are needed to successfully implement routine completion, collection, and storage of advance directives. The Physician's Order for Life Sustaining Treatment (POLST) is legally valid document in several other states to direct current treatments, created with the intention of addressing the issue of portability between inpatient and outpatient settings and between institutions specifically for patients with serious illnesses. It is legally valid in and out of the hospital and specific to the patient's treatment preferences. For more information and to be part of initiatives to implement the POLST in Florida, please visit its website listed below.

Quality Improvement:

Research, education, and policy making are included in the mission of academic palliative care. Recently published by the Institute of Medicine, and receiving national attention, is a report entitled Dying in America. The report outlines the importance of improving quality and honoring individual preferences near the end of life. "Health system managers, payers, and policy makers have a responsibility to ensure that end of life care is compassionate, affordable, sustainable, and of the best quality possible". A substantial body of evidence demonstrates that this type of care is within reach and provided by palliative care. In summary, palliative care is "associated with higher quality of life, including better understanding and communication, access to home care, emotional and spiritual support, well-being and dignity, care at the time of death, and lighter symptom burden. Some evidence suggests that, on average, palliative care and hospice patients may live longer than similar ill patients who do not receive such care" all for a cost savings to the system.

Summary of Benefits:

- **Primary: Patient:** Prevention/relief of pain and symptoms, attention to social, emotional, spiritual, practical needs. Clarify prognosis and goals of care, greater concordance between preference and care received. Improved interdisciplinary communication, and survival in lung cancer and pre-surgical frail patients.
- **Secondary: Caregivers:** Improved family and provider satisfaction, bereavement
- Tertiary: Institutions, Systems, and Payers: Early PC Consult=Better Quality Measures: ↓ Acute care hospitalizations/readmissions/ICU/Hospital Length of stay, ED/ Urgent care visits, death in acute care facilities, aggressive

care in final month of life (chemo last 14 days), costs. ↑ Hospice Utilization, Hospice LOS [3]

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Advance Directives: A Short Primer

By Cristina Palacio, Esq. Senior Associate General Counsel UF Health Shands

As health care providers expand the availability of hospice services and palliative care services to assist severely or terminally ill patients in transitioning to end-of-life care, there is a concurrent need to encourage and expand conversations on advance directives, the important role they play, and impact they can have not only on end-of-life care, but also on unexpected medical care episodes. The beginnings of a move to increase awareness can be seen in recent media attention on the importance of advance care planning.¹

Advanced care planning can be seen, simply, as a fundamental aspect of patient self-determination. As the United States Supreme Court Stated in 1891, "no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."² This fundamental right of self-determination (which includes the right to informed consent and to refuse treatment), developed first in common law and professional ethical standards, has since been codified into statutory law, both on the federal and state level. With respect to advance care planning in particular, the Patient Self Determination Act of 1990³, CMS Conditions of Participation⁴, Florida Statutes⁵, and the Joint Commission standards⁶ all require hospitals to inform patients of their right to formulate advance directives. Despite this strong regulatory support, studies continue to indicate that the number of adults (with and without serious illnesses) that have completed an advance directive remains relatively low. For example:

- Both the Centers for Disease Control and Prevention ("CDC") and the Agency for Healthcare Research and Quality ("AHRQ") report that, even among severely or terminally ill patients, fewer than 50 percent had an advance directive in their medical record.⁷
- A survey of nearly 1,700 California adults showed that 76% of those responding did not have a written advance directive (and less that 40% had heard of the term "advance directive.")⁸

Additionally, despite the fact that most states' laws strongly support respecting patient's wishes as expressed through their advance directives, implementation of supportive processes to assure that an individual's wishes are known, and that care



is provided in accordance with those wishes, continues to present a challenge. A study sponsored by the Robert Wood Johnson Foundation found that nearly a third of terminally ill participants did not want cardiopulmonary resuscitation (CPR), but less than half of their physicians knew of their preference.⁹ AHRQ has reported that between 65 and 76 percent of physicians whose patients had an advance directive were not aware that it existed.¹⁰

Fortunately, healthcare providers throughout the country - and of particular interest here in Florida - continue to discuss the importance of improving, and finding ways to increase, the public's knowledge about advance directives and end-of-life planning.¹¹ For example, the UF Health system recently convened a task force to improve dissemination of information regarding advance directive not only to hospital and clinic patients, but throughout the community. The Florida legislature recently considered legislation to recognize the Physician Order for Life-sustaining Treatment ("POLST"), currently endorsed in at least 13 states.¹² And CMS is considering reimbursing physicians for advance care planning, including the explanation and discussion of advance directives.¹³ All of these efforts recognize the fact that the best time and place for advance care planning is probably not upon admission to the hospital, the only currently 'legally' required time that such information be provided.

There is clear consensus that in order to assure that health care providers are delivering care in accordance with their patient's wishes we must improve the number of individuals with advance directives. Less discussed is that it is also

important to educate not only patients and potential patients (a.k.a. the public) regarding the different kinds, requirements, applications and limitations of each advance directive under the applicable law, but also health care providers. A 2012 article in the AMA's American Medical News reported that "[m]isunderstandings among physicians about living wills, advance directives and do-not-resuscitate orders are common.... A series of surveys by QuantiaMD, an online physician learning collaborative, found that nearly half of health professionals misunderstood the components of living wills. Ninety percent of those surveyed were physicians."14 Despite very detailed policies regarding advance directives, the legal department of UF Health Shands Hospital routinely receives questions regarding the implementation, effect and/or validity of different kinds of advance directives. Following is a brief summary of the most commonly recognized advance directives and the requirements for each under Florida law¹⁵ that I hope will provide Risk Rx readers a basic foundation for continuing education in this very important area:

Living Will

Originally designed by attorney Luis Kutner and the Euthanasia Society of America/Euthanasia Educational Council in 1967¹⁶, the Living Will is probably the best known 'advance directive.' Generally, a Living Will sets forth an individual's wishes regarding withholding and/or withdrawal of life-prolonging procedures in the event that s/he has lost the ability to express her/his wishes and is suffering from a terminal illness, end-stage condition, or persistent vegetative state.

How is it properly executed?¹⁷ A Living Will must be signed by a competent adult (the "principal") in the presence of two subscribing adult witnesses, at least one of whom cannot be the spouse or a blood relative of the principal. If the principal is physically unable to sign, one of the witnesses must sign for the principal at her/his direction and in her/his (and the other witness') presence.¹⁸

When does it become effective? A Living Will becomes effective only during an end-of- life situation. Before withholding/withdrawal¹⁹ of life-prolonging procedures can be done in accordance with a patient's Living Will, the patient's attending physician must determine that the patient is incapacitated, and s/he and another consulting physician must each determine and document that:

- 1. the patient is suffering from a terminal condition, end stage condition or persistent vegetative state, and
- 2. the patient is unlikely, within any reasonable medical probability, to regain capacity (and thereby be able to directly exercise his/her right to refuse treatment).

Florida law provides the following definitions for the above referenced conditions precedent to implementation of a Living Will: 20

- Terminal condition "a condition caused by injury, disease, or illness from which there is no reasonable medical probability of recovery and which, without treatment, can be expected to cause death."
- End-stage condition "an irreversible condition that is caused by injury, disease, or illness which has resulted in progressively severe and permanent deterioration, and which, to a reasonable degree of medical probability, treatment of the condition would be ineffective."
- Persistent vegetative state a permanent and irreversible condition of unconsciousness in which there is:
 - the absence of voluntary action or cognitive behavior of any kind [and]
 - an inability to communicate or interact purposefully with the environment.

A person may designate an individual – a 'surrogate'- to carry out their wishes as expressed in the Living Will, but does not have to; a Living Will stands on its own to represent the patient's wishes. Once the two physicians have made the requisite findings and documentation, a patient's wishes regarding which life-prolonging procedures s/he does or does not want in specific end-of-life circumstances can be implemented.

In the Florida statutory "suggested" Living Will²¹ form, a patient directs "that life-prolonging procedures be withheld or withdrawn when the application of such procedures would serve only to prolong artificially the process of dying, and that [s/he] be permitted to die naturally with only the administration of medication or the performance of any medical procedure deemed necessary to provide [her/him] with comfort care or to alleviate pain." While such general guidance helps, the more detail provided in a Living Will, the better guidance a health care provider and the patient's loved ones have to assure that the patient's exact wishes can be fulfilled. For example, the form available through UF Health hospitals and clinics prompts the patient to give more specific direction regarding artificial nutrition and hydration and cardiopulmonary resuscitation. It also encourages additional instructions regarding not only specific treatments desired (or not), but also "conditions that are important to making life acceptable to [the patient]" in order to "help your doctor know exactly what [the patient's] wishes are."

While a Living Will form may provide directions regarding a patient's preferences relating to CPR, it is important to distinguish a Do Not Resuscitate Order from a Living Will. QuantiaMD (cited by American Medical News above) performed a survey wherein it provided characteristics of a patient who had a living will and asked survey respondents to identify the patient's code status. "Of about 10,000 respondents, 44% incorrectly identified the patient as having a DNR, and 16% did not know the code status. About 41% correctly identified the patient's status as a full code."²² Similarly, The Realistic Interpretation of Advance Directives (TRIAD III) nationwide study reported in The Journal of Emergency Medicine concluded that most physicians misinterpret a living will as a DNR designation, and that the more sub- specialized the physician, the less understanding there is regarding the role and differences of each.²³

A Living Will may provide directions regarding the patient's desire to forego CPR, but in order to implement those wishes, a physician medical order must be entered. Regardless of the Living Will instructions, without the physician's Do Not Resuscitate Order, CPR must be initiated. Furthermore, prior to issuing a DNRO on an incapacitated patient that is based on a Living Will or an incapacitated patient's surrogate or proxy's request, a physician must document the conditions precedent to implementation of the Living Will discussed above. (N.B. - a DNRO may be entered on a capacitated patient's request without the existence of any of the three conditions required for a Living Will to take effect.) Moreover, a DNRO simply addresses the withholding of cardiopulmonary resuscitative efforts in the event of cardiac or respiratory arrest. It has no impact on any other care to be withheld or withdrawn from a patient.

Designation of a Health Care Surrogate

All too often discussions regarding Advance Directives focus primarily on Living Wills. While undoubtedly an important advanced care planning tool, it is by no means the only one, and perhaps not even the most important one. A Living Will is important for an end-of-life event, but there are many potential health care encounters that do not require a decision on the provision of life-prolonging procedures, but which require guidance from the patient – at a time when the patient cannot her/himself provide that direction. Clearly, written instructions for every contingency is impossible. For example, a healthy, active 65 year old patient who has a bad car accident receives emergent life-saving treatment, but once stabilized must remain in an induced coma while they recover, during which time several invasive procedures are required. How can one assure that one's preferences for care at such times are communicated and respected?

A Designation of a Health Care Surrogate ("HCS") permits a person to appoint a trusted individual with knowledge regarding her/his health preferences (and life philosophy) to speak for a patient during unanticipated episodes of care when a patient cannot speak for her/himself. Unless specifically restricted, a HCS can also make withholding/ withdrawal decisions for a person during end-of-life. Thus a well-informed HCS can provide more than a Living Will alone; that is they can help health care providers respect your wishes in more circumstances that the Living Will can alone, and potentially with more detail than usually provided in a Living Will.

"Of about 10,000 respondents, 44% incorrectly identified the patient as having a DNR, and 16% did not know the code status. About 41% correctly identified the patient's status as a full code."

- http://www.amednews.com/article/20121029/profession/310299941/4/

How is it properly executed? Like the Living Will, a Designated Health Care Surrogate must be signed by the principal in the presence of two subscribing adult witnesses. If the principal is physically unable to sign, s/he should direct one of the witnesses to sign on her/his behalf. As with a Living Will, only one witness may be a spouse or blood relative. Additionally, the HCS is prohibited from being a witness. A copy of the designation must be provided to the HCS. If the principal desires, s/he may name an alternate HCS on the same instrument in case the primary HCS is unable or unwilling to serve in that capacity when needed.²⁴ Whether written or oral, documentation used to designate the HCS should have contact information for the HCS (and alternate where appropriate). Unless limited by the principal in the designation, an HCS has the authority to: give, or refuse informed consent for medical care²⁵; make end of life decisions; apply for public benefits to help pay for the cost of the principal's care; consent admission or transfer of the principal to or from a health care facility; obtain all medical records needed to carry out her/his duty; authorize release of information and medical records to provide for the principal's health care.

When does it become effective? A Designation of Health Care Surrogate becomes effective at such time as the patient's attending/treating physician determines that the patient lacks capacity to make health care decisions regarding her/ his own health care, or to give informed consent for her/his care. Such incapacity must be documented in the patient's record before turning to the HCS for decisions regarding the patient's care. It remains effective until such time as the patient's attending/treating physician determines that the patient has regained capacity.²⁶

Health Care Durable Power of Attorney

A Health Care Durable Power of Attorney ("Health Care DPOA") serves the same purpose as the Designation of Health Care Surrogate – it appoints a person who will speak on behalf of the patient in the event of incapacity.

How is it properly executed? A Health Care DPOA must be executed with the same formality as any other power of attorney. Therefore, it requires not only two subscribing witnesses to the principal's signature, it also must be notarized.²⁷ Additionally, unlike a "regular" power of attorney, which is not valid if the principal is incapacitated, a 'durable power of attorney' must contain the following (or similar) words: "This durable power of attorney is not terminated by subsequent incapacity of the principal except as provided in chapter 709, Florida Statutes.³²⁸ Finally, the Health Care DPOA must specifically grant the power to make health care decisions to the agent.²⁹ Individuals who are DPOAs often mistakenly assume that they have the authority to make health care decisions: however, most DPOAs with which UF Health Shands Hospital is presented are limited to financial matters. Therefore, it is important for health care providers to carefully read the DPOA upon which a purported "health care" DPOA is relying to claim s/he has authority to speak for the patient. A bona fide Health Care DPOA has the same authority, unless otherwise stated or limited, as a Designated Health Care Surrogate.

When does it become effective? Like the HCS, a Health Care DPOA becomes effective upon a determination, and documentation, by the patient's attending/treating physician that s/he is incapacitated, and ends upon a finding that s/he has regained capacity.

Mental Health Advance Directive

A less commonly known, but potentially very valuable advance directive is the Mental Health Advance Directive. The Florida Department of Children and Families has designed a "Mental Health Advance Directive" that not only allows the patient to designate a mental health HCS, but also provides a patient with numerous prompts in order to provide very detailed direction on the kinds of treatments, medications, facilities, and physicians that s/he would or would not find acceptable, as well as directions regarding persons to whom information may be disclosed.

How is it properly executed? A Mental Health Advance Directive is executed in same manner as a Designated Health Care Surrogate form, requiring that the principal execute in the presence of two subscribing witnesses, neither of which is the named surrogate or alternate, and only one of which may be the spouse or blood relative of the principal.

When does it become effective? A Mental Health Advance Directive becomes effective if the principal has been admitted to a facility on an involuntary basis, and the treating physician has determined that the principal is incompetent to make his/her own treatment decisions, and remains effective until principal regains competency (or, if for some reason a court grants the authority to a Guardian Advocate).

Health Care Proxy

A Health Care "Proxy" is not an advance directive - it is what happens when an individual has NOT provided guidance - through a HCS or Health Care DPOA - on who should speak for her/him if s/he is incapacitated and requires healthcare. In a recent study, Yale researchers reviewed the records of more than 100,000 veterans who received care between 2003 and 2013 and found that 7% of the time the patient identified people outside their immediate family as their next of kin.³⁰ However, unless that person was specifically designated as a HCS or Health Care DPOA, Florida law, and most other state laws, would not have permitted that person to make health care decisions for the patient if an alternate decision-maker was needed. Under Florida law, if an incapacitated patient has not designated a surrogate, the person(s) who the hospital must turn to for decisions, in descending order of priority is/are:²¹

- 1. a court appointed guardian, if one already exists (but note, in the case of a need for mental health consents for an involuntary patient under the Baker Act, a court must appoint a Guardian Advocate if the patient has not designated an surrogate)
- 2. the patient's spouse
- **3.** an adult child of the patient, or if there is more than one, a majority
- 4. a parent of the patient
- 5. a sibling of the patient, or if there is more than one, a majority
- 6. an adult relative who has exhibited special care for the patient

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- 7. a close friend of the patient
- 8. a clinical social worker not affiliated with the provider

While this may be the patient's own preference order, it may not be. Part of the conversation health care providers should be having with their patients is to let them know who the law provides will make decisions for them in the event of an unanticipated health care crisis (including decisions regarding withholding/withdrawal of life-prolonging procedures) if the patient has not provided directions.





Under Florida law, an anatomical gift made by the decedent her/himself in advance is considered an "advance directive." A competent adult may arrange for the donation of all or part of her/his body through an organ and tissue donor card, a Living Will or other advance directive (in addition, s/he make such designation in a regular will, on a driver's license, or by registering online with a donor registry).³²

How is it properly executed? Like the Living Will or surrogate designation, the donor card or other advance directive regarding an anatomical gift must be signed by the principal in the presence of two subscribing witnesses.

When does it become effective? The donation becomes effective upon the principal's death, and is irrevocable at that time. The donation cannot be revoked, modified or denied by a family member, guardian, or a designated health care surrogate after the principal's death.³³

While the above listing discusses the more common forms of advance directives, a person may leave instructions regarding any aspect of health care that they wish; there is nothing in Florida law that limits the content of an advance directive to only end-of-life, mental health, or alternate decision-maker instructions. And while this article has focused on the options for advance care directives, it is important to remember that having advance directives is just part of addressing endof-life care or other unpredictable health care circumstances. Equally (if not more) important is having discussions with your physician(s) and family, so that they are aware of your thoughts on these important issues. CMS's recently proposed reimbursement codes for advance care planning is an important step in supporting the discussion with physicians; some insurance plans already provide reimbursement for the conversation. Providing reimbursement should help encourage physicians to initiate these discussions in an office setting, which is much better than waiting until a patient is admitted to a hospital, which is currently where most patients first encounter an advance directive form. The more we encourage advance care discussions and planning, and written directives which can be readily available, the more we can assure that we are providing care consistent with our patient's wishes when they are unable to express their wishes directly.

1 See e.g. End-of-life debate hinder "Right to Try" legislation, Lloyd Dunkelberger, Gainesville Sun April 6, 2015, 1b; Advance care planning is essential, Timothy C. Flynn and Randy Harmatz, Gainesville Sun April 13, 2015; Milan organizations to present workshop on living wills, advance care planning, The Milan News-Leader, April 13, 2015 http:// www.heritage.com/articles/2015/04/13/milan_news_leader/ news/doc5527ffa66f0c8651692126.prt, accessed 4/13/2015. 2 Union Pacific Railway Company v. Botsford, 141 U.S. 250, 251 (1891)

3 42 USC §1395cc (f)

4 42 CFR §482.13 (3)

5 F.S. §765.110

6 The Joint Commission Hospital Standards Manual , Standard RI.01.05.01

7 See e.g. Advance Care Planning; Ensuring your Wishes are Known and Honored If You Are unable to Speak for Yourself, http://www.cdc.gov/aging/pdf/advanced-care-planning-critical-issue-brief.pdf accessed 4/3/2014, and Kass-Bartelmes BL. U.S. Agency for Healthcare Research and Quality. Advance Care Planning: Preferences for Care at the End of Life in Research in Action Issue 12. March 2003. www.ahrq.gov/research/endliferia/endria.htm 8 76% of patients neglect end of-of-life care planning" by Kevin B. O'Reilly, Feb 27, 2012; http://www.amednews. com/article/20120227/profession/302279943/6/ accessed

3/31/2015

9 Supra note 6, CDC article pp2-3

10 See id at p.2

11 See e.g. Hospitals teach being 'conversation-ready' for endof-life care, by Kevin B. O'Reilly, April, 2013, http://www. amednews.com/article/20130415/profession/130419978/6/ accessed 3/31/2015

12 SB 1052

13 79 FR 219 at 67670-67671, November 13, 2014 14 Clearing up confusion on advance directives, by Alicia Gallegos, October 29, 2012; http://www.amednews.com/article/20121029/profession/310299941/4/ accessed 3/27/2015; see also "Triad III: Nationwide Assessment of Living Wills and Do Not Resuscitate Orders," F.L. Mirarchi, E. Costello,

J. Puller, T. Cooney, and N. Kottkamp in The Journal of Emergency Medicine, Vol. 42, No. 5 pp. 511-520, 2012, at 512: "Evidence from other institutions reveals that there are vast differences in the understanding of living wills among patients, family members, and physicians. Additionally, evidence suggests that the majority of those interpreting advance directives are poorly trained or untrained in the interpretation of these documents."

15 Note, however, that Florida law permits recognition of an advance directive that is valid in accordance with the laws of the state within which it was executed. F.S. §765.112 16 Personal note: The author worked at Euthanasia Educational Council the summer of 1977, sending Living Will forms to individuals in response to their requests. 17 Unless otherwise stated herein, Florida law recognizes both written and oral advance directives. While providing clear directions for proper execution of written advance directives, the law provides no concrete guidance on documentation requirements for 'oral' directives. While oral directives are probably rare, there are circumstances in which a patient provides clear instructions that can be interpreted (usually in hindsight) as an advance directives. Such instructions should be witnessed in the same manner required for a written Advance Directives (two witnesses in presence of principal when uttering the directive, with same persons excluded from being witnesses). In order to avoid conflict of interest, it would seem prudent to have at least one of the witnesses be a person who is not affiliated with the hospital. The witnesses' names and contact should be documented in the chart along with the instruction given by the patient. 18 F.S. §765.302

19 Under Florida law, there is no 'legal' distinction between withholding and withdrawal of life prolonging procedures. Nevertheless an individual may make a distinction when giving instructions regarding her/his personal preferences at end of life.

20 F.S. §765.101

21 F.S. §765.303

22 Supra note 13.

23 "Triad III: Nationwide Assessment of Living Wills and Do Not Resuscitate Orders," supra note 13. See also "Understanding Living Wills and DNR Orders" in Pennsylvania Patient Safety Advisory, Vol.5, No. 4, pp 111-117 December 2008: "Despite the prevalence of living wills and DNR orders, [Pennsylvania Patient Safety Reporting System] reports received between June 2004 and September 2008 have revealed that healthcare providers, as well as patients and families, may not understand the differences between living wills and DNR orders."

24 F.S.§765.202

25 Certain procedures require that the principal specifically have granted authority (abortion, sterilization, refusal of life-prolonging procedures if patient is pregnant with viable fetus, and non-FDA approved experimental treatment.)

26 F.S. \$765.204

27 F.S. §709.2105

28 F.S. §709.2104

29 F.S. §709.2201

30 Many Very Ill Patients Choose 'Next of Kin 'Who Aren't, Study Finds by Dennis Thompson, HealthDay News, April 2015, http://consumer.healthday.com/senior-citizen-information-31/misc-death-and-dying-news-172/many-veterans-choose-next-of-kin-who-aren-t-kin-study-says-698155. html%5B4/8/2015, accessed 4/8/2015, citing Andrew Cohen, M.D., D.Phil., postdoctoral fellow, Yale University School of Medicine, New Haven, Conn.; Jonathan Keyserling, senior vice president for health policy and in-house counsel, National Hospice and Palliative Care Association; April 7, 2015, Journal of the American Medical Association2015, http:// consumer.healthday.com/senior-citizen-infor

31 F.S. \$765.401 32 F.S. \$765.514 33 F.S. \$765.512

Starting a Medical Practice

Gregory A. Chaires, Esq. Chaires, Brooderson and Guerrero, P.L



Starting a new business is not for the faint of heart, but starting a new medical practice can certainly be a daunting task. The physician starting a practice needs to earn a living, many times pay off student and other loans, run a medical practice and provide quality care to his or her patients. It is essential that both new and more experienced physicians have a comprehensive understanding of the operational elements of a medical practice. Many consider obvious elements such as selecting the right location to avoid over saturation in the market, getting phones set up and the anticipated cost of staff. However, there are many other elements necessary to establishing a medical practice.

In addition to the challenges of just running a new business, the health care industry is one of the most regulated industries in the United States. There are federal laws, state laws, rules issued by oversight entities like the Florida Board of Medicine and Center for Medicare & Medicaid Services, there are billing reimbursement guidelines and contracts that must be followed. There are a variety of federal and state privacy and security laws such as HIPAA, the HITECH Act, and the recently enacted Florida Information Protection Act of 2014.

It would take several articles to cover all the issues and considerations for the formation and successful operation of a medical practice. This article will discuss some broad areas of consideration but it is recommended that you interact with professionals to assist you in the formation of the practice. In this age of the internet there are a host of resources available that provide basic background information on the various issues involved in starting up a medical practice, some of which we will discuss below. We have found the Medical Group Management Association Checklist for a new practice start-up (<u>http://www.mgma.com/Libraries/Assets/Practice%20Resources/Tools/Checklist-for-Starting-a-New-Medical-Practice.pdf</u>) a good resource for practitioners looking to start their own medical practice.

The important people to consider part of your advisory team are an accountant, health care attorney and management consultant. It is important that you not lull yourself into thinking that since you are highly intelligent and skilled at medicine, you can just "figure" out the formation and operation of a medical practice by reading an article or as you go along. While the various internet materials are available, all the decisions that you make have ramifications and must not be considered lightly. Thus, it is important to seek out those that can help you the most. When you have a heart problem, you generally do not take care of it yourself or go see a podiatrist. Your advisory team will be very helpful in your success and an experienced health care attorney is critically important.

Below are some broad areas of consideration in starting a medical practice or joining an existing medical practice.

I. Forming the practice and Entity Choice

It is critical to have an understanding of the various types of legal entities available (Corporation, LLC, partnership, etc.), and the liability and tax consequences associated with each entity choice. Depending upon your interest in capitalization, plans for future growth and the size of the entity, some entities may be more appropriate for your needs than others. It is also helpful to understand anti-trust and security law ramifications, as well as more general issues, such as registering and maintaining compliance with state regulations. Your governance documents are very important to ensure that your practice has a road map to operate. Questions regarding partnership, admission of new owners, termination of owners and employees, buy outs of owners are examples of issues that need to be considered and addressed in the governance documents of the practice. It is always important to have documents in place in advance. Consultation with an accountant as well as legal counsel who understands business, corporate law as well as health law, is very important from the outset.

II. Employees/ Employment Contracts

After forming the practice, one of the early issues is the hiring of employees and how that will be structured (and remember you, the physician owner, will be an employee as well). A physician owner must consider salaries, bonuses, annual increases, various fringe benefits and restrictive covenants, such as covenants not to compete (which are enforceable in Florida if properly drafted). Consideration needs to be given to the type of personnel necessary to operate your practice, contracting with other physicians and the compensation requirements and regulatory considerations for the use of physician extenders such as physician assistants and nurse practitioners.

III. Operation of the Practice

This broad category encompasses everything from staffing issues, billing services, adverse incident reports, subpoenas, compliance programs and lease arrangements to designating a HIPAA privacy and security officer, maintaining HIPAA and HITECH Act compliance policies and procedures, email policies, managed care contracting and credentialing with commercial and governmental payors, and call coverage. Many practitioners opt to have office policies and procedures for employees to assist in maintaining compliance and in effectuating termination policies, if necessary. Some providers outsource their billing to companies that specialize in these services. Some providers choose to participate with certain managed care networks. Risk management is always important as well and there are part-time risk managers that can assist in a practice.

IV. Additional considerations

You cannot forget the elemental issues like malpractice insurance coverage and asset protection. A physician is advised to weigh the costs and benefits of having coverage versus going "bare." Additionally, it is urged that physicians become educated about regulations on compensation, investment and financial relationships, such as the Stark Self-Referral Laws, federal and state anti-kickback laws, and Florida laws such as the Patient Self-Referral Act, the Anti-Kickback Statute and Fee Splitting laws, the Medical Practice Act, (Chapter 458), the Osteopathic Medical Practice Act, (Chapter 459), Florida Statutes, , as well as Florida's Patient Brokering Act, and the rules published by the Boards of Medicine or Osteopathic Medicine thereunder. There are three simple rules to keep in mind (1) if it sounds too good to be true it generally is, (2) there is rarely, if ever, anything for free in the business of medicine, and (3) if things of value flow in the direction of a referral source, there could be potentially significant concerns.

Finally, physicians must be sure to properly apply for and comply with Medicare and Medicaid guidelines, if they

wish to be a participating provider. This will entail being assigned a group number and a NPI number and complying with coding guidelines and requirements. Becoming familiar with the requirements for coding and ensuring excellent documentation will put you on the right track to minimizing an audit, which can be devastating to a practice (think compliance programs which every practice, no matter what size, should have). There is no substitute for adequate and accurate documentation whether it be a third party payer audit, a Department of Health investigation or a medical malpractice lawsuit.

We started off by discussing how starting a medical practice can be daunting, but it can also be very personally rewarding. There are resources out there that can help you make the decision if owning and operating your own medical practice is right for you. You need to know your market and have a marketing plan. You need to have a business plan and a pro forma so that you have a plan and strategic guidelines in which to operate your new practice. Most importantly, you must be patient as it can easily take nine months or so to get things fully operational. Editor: Jan Rebstock, RHIT, LHRM, CPHRM UF Self-Insurance Program

Editorial Board: Joseph J. Tepas, III, M.D. Professor Surgery and Pediatrics UF Health- Jacksonville

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Gregory A. Chaires, Esq. Board Certified in HealthCare Law Chaires, Brooderson & Guerrero, P.L. Altamonte Springs, FL 32701 www.chlawyers.com

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As I prepare to retire June 12, I want to take this opportunity to let you know in this final edition what a sincere pleasure it has been to bring you Risk Rx these many years.

Thank you editorial board, feature contributors, and readers for making this publication such a popular and practical resource for risk management and loss prevention issues.

> -Jan Rebstock, RHIT, LHRM, CPHRM Editor

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