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INSIDE:

Message from the Chair

by Cynthia Mikos, Esq., Allen Dell, Tampa, FL*

Dear Reader:

The Health Law Section is pleased to present its Fall 2011 Newsletter. The Section's newsletter is one of the ways the Section communicates with its diverse membership about current developments in Florida health law in support of the Section's mission.

The mission of The Florida Bar Health Law Section is to serve as a forum for members to interact and develop expertise in health law and to provide education and resources emphasizing health law issues in Florida. One of the Section's 2011-2012 goals is to produce two or three newsletters between July 2011 and June 2012. This is our first volume of the Bar year. In furtherance of this mission, I am asking you to share expertise in your precise practice area with other section members by submitting one article in the next six months to our member editor, Tom Clark, a board certified health lawyer with the firm of Henderson Franklin Starnes & Holt, P.A. in Ft. Myers. Tom and his team will be happy to assist you to take advantage of this opportunity to educate your colleagues on Florida health law while promoting your professional practice.

Many of you reach out informally to other health lawyers who you consider to hold specialized knowledge in a particular part of health law. Other people may call you when they have a question about a topic that you routinely handle for your clients. Take a few minutes out

See "Chair's Message" page 3

Health Care Executives at Risk Under the Responsible Corporate Officer Doctrine

By Lester J. Perling, Esq., Broad and Cassel, Fort Lauderdale, FL*

On December 13, 2010, a federal judge upheld an order excluding three Purdue Pharma executives from participating in Medicare, Medicaid and all other federal health care programs for 12 years. The exclusion followed the officers' guilty pleas to misdemeanor violations involving the misbranding of Oxycontin entered as part of a global settlement of the government's investigation of Purdue-Frederick Company, a subsidiary of Purdue Pharma. Significantly, the executives' liability was founded solely on the "responsible corporate officer" doctrine.

The responsible corporate officer doctrine provides that an individual may be charged with a crime for violating the law simply by virtue of his or her position within a company. Under the doctrine, a person may be found guilty if he had, "by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct," an act in violation of the law, but failed to do so. *United States v. Park*, 421 U.S. 658, 673–74 (1975).

In *United States v. Dotterweich*, 320 U.S. 277 (1943), a case brought under the Food, Drug,

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and Cosmetics Act, a drug company as well as its president were prosecuted for shipping misbranded and adulterated drugs. Although the company was ultimately acquitted, a jury convicted the company's president. The Supreme Court recognized that the president had no personal knowledge of the wrongful acts of the company, but nevertheless reasoned that it was "in the interests of the larger good" to place "the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger," in this case, the company president. *Id.* at 281.

The notion of public danger is the basis for all responsible corporate officer doctrine prosecutions. The doctrine's use has been limited to cases that involve either regulatory or public safety crimes lacking a *mens rea* element. Specifically, the responsible corporate officer doctrine in criminal cases may only be invoked in a case that involves a strict-liability offense and where the corporate officer shared responsibility in a business enterprise that resulted in a public danger. Courts have recognized an affirmative defense in these cases. The defense of impossibility allows a defendant to show that it would have been impossible to prevent the regulatory violations. Defendants who claim impossibility argue that despite exercising extreme care, it was impossible for them to stop the violation.

The Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") has begun focusing on incorporating the responsible corporate officer doctrine into its existing authority to exclude individuals from participating in federal health care programs. HHS was given its discretionary exclusion authority under the Social Security Act and delegated it to the OIG. When an individual, or entity, is excluded from federal health care program participation, the programs are prohibited from paying for any medical items or services provided, ordered, or prescribed by that excluded person. Additionally, if claims are submitted, the submitting individual or entity may be subject to civil money penalties imposed by the OIG.

Over the years, HHS' exclusion authority has been expanded to exclude both entities owned or operated by individuals convicted of a federal health care program crime, and the individuals themselves. Congress expanded HHS' exclusion authority to apply to any individual having an ownership or control interest in a sanctioned entity that knew or should have known about the underlying actions that were the basis for the entity's sanction or an officer or managing employee in a sanctioned entity.

Recently, the OIG announced its dedication to holding owners, officers, and managing employees personally accountable for corporate wrongdoing. In October, 2010, the OIG published guidance on the imposition of exclusions under Section 1128(b)(15) of the Social Security Act and established the criteria and factors to be considered when determining the exclusion of a health care company's owner, officer, or managing employee. These factors are: the circumstances of the misconduct and seriousness of the offense; the individual's role in the sanctioned entity; the individual's actions in response to the entity's misconduct; and information about the entity, including whether it has previously been convicted of a crime or found liable, or resolved civil or administrative charges with a federal or state enforcement authority, and the size and structure of the entity and its subsidiaries.

The OIG has the authority to exclude the owner of a sanctioned company if he or she knew or should have known about the conduct constituting the basis of the sanction. If there is evidence to show that an owner knew or should have known about the conduct, the OIG will operate under a presumption in favor of exclusion, which may be overcome if OIG finds that significant mitigating factors weigh against exclusion. Similarly, knowledge is not required with respect to officers

Editor's Note

by Thomas P. Clark, Esq., Fort Myers, Florida

Welcome to the latest edition of the Florida Bar Health Law Section e-newsletter. This edition contains five articles covering the following topics: (a) Health Care Executives at Risk Under the Responsible Corporate Officer Doctrine; (b) New Laws on Controlled Substances Prescribing Will Impact Many Physicians; (c) Quality Initiatives Will Promote Physician-Hospital Alignment; (d) Beyond Medical Advance Directives: Implementing the POLST (Physician Orders for Life-Sustaining Treatment) Paradigm in Florida; and (e) Florida's Power of Attorney Act.

On behalf of the Health Law Section, I would like to thank the staff at the Florida Bar for their assistance with this edition. I also would like to thank the authors who submitted articles for publication. Without their help and support it would not be possible to continue the newsletter.

If you are interested in submitting articles for publication, please submit them to me at thomas.clark@henlaw.com. I look forward to working with you.

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and managing employees. Instead, where there is evidence that an officer or managing employee knew or should have known about the conduct, there will be a presumption in favor of exclusion.

On October 29, 2010, Marc Samuel Hermelin, a major shareholder and former chairman of the board of K-V Pharmaceutical ("K-V"), was excluded from participating in federal health care programs. The basis for Hermelin's exclusion was a guilty plea by Ethex Corporation, a wholly owned subsidiary of K-V, to criminal charges. The OIG, K-V, and Hermelin executed a separate settlement agreement which stated that Hermelin would withdraw from company management and divest his ownership interest in K-V. The settlement agreement also explained that if K-V or Hermelin did not comply with the terms governing his withdrawal, the OIG could exclude K-V based on Hermelin's prior exclusion. This was the first time that an executive of a pharmaceutical company was excluded under the Section 1128(b)(15) authority, but as demonstrated by the subsequent exclusions of the Perdue Pharma executives, the OIG intends to exercise its exclusion authority more forcefully than in previous years.

On March 2, 2011, Inspector General Dan Levinson, testified before Congress that

> some hospital systems, pharmaceutical manufacturers and other providers play such a critical role in the care-delivery system that they may believe that OIG would never exclude them and thereby risk compromising the welfare of our beneficiaries. We are concerned that these providers may consider engaging in fraud schemes, and paying civil penalties and criminal fines if caught, as a cost of doing business. As long as the profit from the fraud outweighs those costs, abusive corporate behavior is likely to continue....One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk. To that end, in 2008, we excluded three executive officers of the pharmaceutical company Purdue Frederick based on their convictions for misbranding the painkiller OxyContin. Each of the executives was convicted based on his status as a responsible corporate officer.

Additionally, the OIG has confirmed that it is possible, under strict liability, to exclude officers and managing employees for conduct that may be far removed from their individual oversight, even if they could not reasonably be expected to know of this conduct. Attorneys should apprise their clients in the health care industry of these changes to ensure they are aware of OIG's increased exclusion of executives. Because exclusion reaches to individuals within a company, and the acts of those individuals could potentially be attributed to the company itself, corporate executives face significant compliance responsibilities. Companies must take precautions to institute corporate compliance procedures in anticipation of the liability risks stemming from OIG's application of the responsible corporate officer doctrine. Likewise, health care executives should exercise diligence in performing their job responsibilities in order to avoid future exclusion from participating in federal health care programs. Specifically, health care organizations should implement comprehensive and effective compliance policies and procedures equipped with internal monitoring systems. Strict penalties for compliance violations should be published to all employees and enforced against all violators.

Inspector General Levinson's testimony reveals that the OIG intends to use its exclusion authority to combat health care fraud, which could include violations of the Anti-Kickback law or the Stark law. Thus, any executive, general counsel, or compliance officer who is responsible for the company's compliance efforts must be proactive in compliance efforts. The exclusion of Purdue-Frederick's Chief Executive Officer, Chief Medical Officer and General Counsel demonstrates that the OIG will examine the individual's duties and responsibilities, the actions and omissions of the individual, and the extent, whether directly or indirectly, to which the company's wrongdoing is attributable to that individual's action or failure to act. It is unclear whether the OIG's exclusion authority would reach those employees, including compliance officers, who are powerless to prevent or correct violations. It would seem that a compliance officer who fulfills his responsibilities with respect to the establishment or operation of a compliance program has fulfilled his corporate responsibilities. Nevertheless, what is clear is that "individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud," will be sought after by the OIG and excluded from participation in the federal health care programs. Counsel should ensure their clients are familiar with U.S. Sentencing Guidelines for Compliance Programs and possible vulnerability to exclusion from the federal health care programs.

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CHAIR'S MESSAGE, *from page 1*

of your busy day to identify one discrete Florida health law subject area with which you are familiar due to recent research or practice specialization. Then, seriously consider contributing a newsletter article on that topic or case, and calendar it as a task with a due date in the next few months. Newsletter articles can be brief, no law review research or detailed footnotes required. Not only are you supporting your colleagues when you share expertise, but you are gaining knowledge from the others who share theirs. The increased knowledge of the entire section benefits all of us in our daily practice. In these turbulent times for health law, we need reliable resources for timely insights on Florida law.

The Section is exploring relationships with Florida law schools that have expressed an interest in having their law students assist in newsletter article editing or other tasks. As the relationships form, we will update you on how law students might help practicing attorneys get published.

I look forward to working with you in the next few months as the Health Law Section continues its growth. Thank you for your membership, readership and support.

Cynthia A. Mikos
Chair, Health Law Section

New Laws on Controlled Substances Prescribing Will Impact Many Physicians

It's not just the "pill mills" that have to pay attention

By Ann M. Bittinger, Attorney, The Bittinger Law Firm, Jacksonville, FL*; and Kayce Clark, summer law clerk, The Bittinger Law Firm, Jacksonville, FL*

On Friday June 03, 2011, Governor Rick Scott signed HB 7095, called the "Pill Mill Bill." Other than one provision that was delayed by order of the Department of Health and a provision requiring profile updates by 2012, the bill became law effective July 1, 2011. This law attempts to crack down on the state's prescription drug abuse problem by strengthening the laws governing the conditions in which controlled substances can be prescribed.

According to some, the legislation came all too late. In the past years Florida has risen as one of the leading states in prescription drug abuse. According to CapitolSoup.com, the death toll due to overdoses in the state has risen to 7 deaths per day.[1] National media outlets such as CNN and Time have print or broadcast news documentaries showing the influx of individuals driving down I-75 (dubbed the "Oxy Express") from Kentucky and Tennessee to get cheap controlled substances from physicians in Florida and returning to sell them on the streets in Tennessee and Kentucky.[2] In an attempt to bring this problem to a halt, state legislature has taken a hard line; a line that healthcare professionals all over the state need to be mindful of, as they impact all clinical settings, not just licensed Pain Management Clinics. The law sets out several processes that will allow law enforcement to keep a closer eye on the controlled substances being prescribed and distributed within the state. It imposes new criminal and administrative penalties for doctors who over-prescribe narcotics such as Oxycodone.

Who Is Affected?

The new law changes and adds to some sections of Chapters 456, 458 (medical doctors), and 459 (osteopaths) Florida Statutes – not just the pain-management clinics section (found in Section 458.3265, Florida Statutes). The law states that beginning in January 1, 2012, a licensed physician who prescribes any controlled substance, or causes a controlled substance to be prescribed or dispensed, for the treatment of chronic nonmalignant pain must register online as a prescribing practitioner (on the Practitioner Profile).[3]

If a physician is found to prescribe or dispense a controlled substance in a manner that violates the standards of practice in Chapters 458 and 459, the physician shall be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count, according to the new law.

Impact on Individual Physicians

Now a new section 456.44(3), Florida Statutes, entitled "Standards of Practice," requires that before a prescription is written for a controlled substance, the physician must complete a detailed medical history and the patient medical record must document the nature and intensity of the pain as well as any underlying reasons for the need of pain medication. The physician must also write up an individualized treatment plan for each patient, stating objectives to determine treatment success and any planned modification in treatment. Additionally, each patient receiving a prescription for a controlled substance must be seen by the physician at regular intervals, no greater than 3 months apart. If, during those meetings, the physician sees that the treatment goals are not being achieved, the physician must then reconsider the continuation of the treatment. During these meetings the physician will be required to not only reevaluate treatment, but also must discuss with the patient issues of drug addiction and risks of using controlled substances. The physician will also be required to present the patient with a controlled substance agreement outlining patient responsibility in areas such as the number and frequency of refills, patient compliance with drug therapy and treatment and the patient's agreement to be treated by a single physician for chronic non-malignant pain.

There is an exception to the Standards of Practice for board certified anesthesiologists, physiatrists, or neurologists, or for any board-certified specialist who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. The exception also extends to any board certified specialist that has successfully completed a pain management fellowship approved by either Accreditation Counsel for Graduate Medical Education ("ACGME") or American Osteopathic Association ("AOA"), or any board certified physician specializing in pain management and has been approved by the American Board of Medical specialties.[4]

The new bill will also impact the way in which physicians write the actual prescription for controlled substances. A written prescription for any controlled substance must have the quantity of the drug in both textual and numerical format, must be "dated with the abbreviated month written out on the face of the prescription, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed. . ."[5]

Additionally, doctors will now be required to join a mandatory buyback program under the Governor's declaration of public health emergency. The buyback program will require doctors to return all controlled substances that are not used to the distributors. The expectation is that if physician offices do not "hang on" to these substances and are required to follow more strict tracking programs that the chances of substances falling into the wrong hands will diminish. This process will be strengthened when the new database, which has been delayed for nearly two years, finally goes into effect in the very near future.

Impact on Pain Management Clinics

Interestingly, the law provided greater clarification of what it means to operate

a pain management clinic, and the result has been that some practices that were previously registered as pain management clinics may no longer have to be registered. The new law contains a new exception from the registration requirement for a clinic that is wholly owned and operated by one or more board-certified medical specialists who have also completed fellowships in pain medicine or who are also board-certified in pain medicine and perform interventional pain procedures of the type routinely billed using surgical codes.[6] It contains a similar exception for clinics wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, or neurologists.[7]

Pain management clinics will have to follow additional requirements in order to be given a license to do business. Under the bill a "pain clinic" is defined as any facility that advertises in any way for any type of pain management service or where in any given month a majority of patients are prescribed opioids, benzodiazepines, barbiturates or carisoprodol.[8] Originally, the law stated that all "clinics" which advertise and employ any physician who is "primarily engaged in the treatment of pain" would fall under the heightened restrictions, but in the new law that language was removed.

Prior to the new law's enactment, there was question under the prior version of the pain management clinic law about whether a physician in a pain management clinic could delegate the exam, history and physical to a physician assistant or nurse practitioner. An addition to sections 458.3265(2) and 459.0137(2)(c), Florida Statutes makes clear now that the "physician, *a physician assistant or an advanced registered nurse practitioner* (italicized language is new) must perform a physical examination of a patient on the same day that the physician prescribes a controlled substance to a patient. . . ."

In addition to the previously-existing requirement that all pain-management clinics register with the state, all facilities must now have a publicly listed telephone number, an open reception area and private treatment rooms.[9] This new subsection 458.3265(2)(f) (and 459.0137(2)(f) for osteopaths) also requires pain management clinics to have disaster plans, one employee on the premises during patient care hours who is certified in Basic Life Support, quality assurance requirements, and data collection and reporting processes. The pain management clinic must report adverse incidents and report to the Board of Medicine, in writing, on a quarterly basis, the following data: the number of new and repeat patients seen and treated at the clinic who are prescribed controlled substances for the treatment of chronic, nonmalignant pain, the number of patients discharged due to drug abuse, the number of patients discharged due to drug diversion and the number of patients treated at the pain clinic whose domicile is located somewhere other than Florida.

Conclusion

When he signed the bill, Governor Scott stated: "I am proud to sign this bill which cracks down on the criminal abuse of prescription drugs. This legislation will save lives in our state and it marks the beginning of the end of Florida's infamous role as the nation's Pill Mill Capital." One thing is clear: there will be much work for Florida health law attorneys to assist their clients in understanding and complying with this new law.

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***Kayce Clark** is a 2L at Florida Coastal School of Law.*

Endnotes:

1 *Attorney General Bondi Applauds Governor Scott for Signing Anti-Pill Mill Bill*, June 3, 2011, http://capitalsoup.com/2011/06/03/attorney-general-bondi-applauds-governor-scott-for-signing-anti-pill-mill-bill/.

2 See, e.g., "Invasion of the Pill Mills in South Florida," Time.com, April 13, 2010.

3 Section 456.44(2), Florida Statutes, is the registration requirement for any physician licensed under Chapter 458, 459, 461 or 466, Florida Statutes, who prescribes "any controlled substance" for the "treatment of chronic nonmalignant pain."

4 It is somewhat unclear what "this subsection" refers to in section 456.44(3), Florida Statutes. This writer assumes that it applies only to the Standards of Practice subsection (Subsection (3)), not to Subsection 2 ("Registration"). Thus, registration under Subsection 2 may be required, but compliance with the Standards of Practice in subsection 3 may not be required for the physicians meeting the exception.

5 Section 456.42(2), Florida Statutes. The requirement of using the counterfeit-proof pad was suspended July 7 for 60 days. See *http://www.miamimed.com/news_updates_details.php?DOH-Emergency-Order---suspends-requirement-to-use-counterfeit-proof-prescription-pads-for-60days-242.* Approved vendor list is found at *http://www.doh.state.fl.us/mqa/info_approved_vendors.pdf.*

6 Section 458.3265(2)(h), Florida Statutes.

7 Section 458.3265(2)(g), Florida Statutes.

8 Section 458.3265(1)(b), Florida Statutes.

9 Section 458.3265(2)(f), Florida Statutes.

Quality Initiatives Will Promote Physician-Hospital Alignment

But employment isn't the only option

By Ann Bittinger, Esq., The Bittinger Law Firm, Jacksonville, FL*

As the Medicare payment system evolves from a pay-for-encounter system to a pay-for-quality system, physicians and hospitals must align further in order to survive and prosper. Most of the payment programs target hospitals, as opposed to physicians, for incentive payments for quality. Hospitals have quickly realized, though, that in order to design and implement effective protocols and processes to track and report quality to the Centers for Medicare and Medicaid Services ("CMS"), they must have physicians leading their design and implementation efforts. Based upon this realization, and coupled with various demographic, reimbursement and economic factors, many hospitals have reacted by buying practices and employing physicians en masse. The purpose of this article is to identify some of the incentive programs and to outline ways hospitals and physicians may be able to compliantly align in this current environment, other than by way of employment.

Background

Clearly most hospitals have had quality programs for many years. The tracking of reporting quality measures, such as in the programs described below, however, presents hospitals with greater challenges than in the past. Well-designed protocols must be followed and specific data tracked and reported in order to earn and collect quality incentive payments from CMS. As the early stages of reform have occurred, it is apparent that hospitals must focus medical staff members to participate in quality tracking and reporting efforts. Clearly physicians are concerned about quality. But they are also strapped for time and energy. Many physicians do not want to take time away from patients to attend meetings to promote hospitals' quality initiatives. Payment by the hospitals to physicians helps promote participation. Any payment between referral sources must, however, be structured correctly in order to comply with the Stark Law and Federal Anti-Kickback Statute.

CMS Quality Initiatives

1. ACOs

The Shared Savings Program established under PPACA (Patient Protection and Affordable Care Act) laid out proposed criteria for which an Accountable Care Organization could be formed. Hospitals and physicians are encouraged to form and join ACOs, according to CMS, because CMS will allow ACOs to participate in (i.e., get back a share of) any savings that they can cause CMS. In other words, put very simply, if the ACO demonstrates to CMS that it saved CMS money then CMS will give some of that money back to the ACO.

PPACA stated that ACOs must have clearly defined processes in place for evidence and data based patient care, report all quality care measures to CMS directly, and meet the required patient care criteria put in place by CMS. The quality measures, while described in the proposed regulation, are clearly statutorily-based. Under the Shared Savings Program, ACOs would use the first three years of data to determine a benchmark from which to move forward. With the data in place, the ACO could then be eligible to receive back a portion of the savings they generated.

The quality measure indicators are found in Table 1 to the April 2011 proposed ACO rules: "Proposed Measures or Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings" (CMS-1345-P) (available on the CMS website).[1]

2. Innovation Center

November 16, 2010: The Centers for Medicare & Medicaid Services (CMS) formally established the new Center for Medicare and Medicaid Innovation (Innovation Center). Created by the Affordable Care Act, the Innovation Center will examine new ways of delivering health care and paying health care providers that can save money for Medicare and Medicaid while improving the quality of care. CMS also announced the launch of new demonstration projects that will support efforts to better coordinate care and improve health outcomes for patients.

Demonstration Project

Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan, and Minnesota will participate in the Multi-Payer Advanced Primary Care Practice Demonstration that will ultimately include up to approximately 1,200 medical homes serving up to one million Medicare beneficiaries. The aim of the project is to evaluate the effectiveness of physicians across the care system working in a more integrated fashion and receiving more coordinated payment from Medicare, Medicaid, and private health plans.

Community Health Centers

The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration will test the effectiveness of doctors and other health professionals working in teams to treat low-income patients at community health centers. The demonstration will be conducted by the Innovation Center in up to 500 FQHCs and provide patient-centered, coordinated care to up to 195,000 people with Medicare.

Medicaid

A new State plan option under which patients enrolled in Medicaid with at least two chronic conditions can designate a provider as a "health home" that would help coordinate treatments for the patient. States that implement this option will receive enhanced financial resources from the Federal government to support "health homes" in their Medicaid programs.

3. PQRI

Probably the most well-known of

all the quality initiatives, the Physician Quality Reporting System ("PQRI") is a voluntary reporting program in which eligible professionals (and beginning in 2010, group practices) report data on quality measures to CMS. For 2010 and prior years, those who qualify can earn a PQRI incentive payment based on a percentage of the eligible professional's total estimated allowed Medicare Part B charges for covered professional services furnished during a specified reporting period. There are 153 quality measures and 7 measures groups in the 2010 PQRI program. For a complete listing, see: *www.cms.hhs.gov/pqri.* To be eligible for the bonus payment, a participant must report on at least three quality measures for at least 80 percent of the cases in which the measure was reportable. For some, this is a heavy burden.

Last year's (2011) Physician Fee Schedule, released June 25, 2010, included many initiatives and changed PQRI slightly. Providers who do not satisfactorily report via PQRI will have to pay a penalty. For 2011, physicians may earn an incentive payment of 1 percent of their estimated total allowed charges. Also in 2011, physicians who successfully report to PQRI are eligible to earn an additional 0.5 bonus if they participate in a Board Certification Maintenance or Certification program.

4. Readmissions Reduction Program

This program aims to decrease excess readmissions. Starting October 1, 2012, it will focus on AMI, heart failure and pneumonia readmissions. Starting in 2013, it will focus on COPD, coronary artery bypass graft, transluminal coronary angioplasty, percutaneous and other vascular procedures.

5. Hospital Value Based Purchasing

Starting October 1, 2012, hospitals must report outcomes on acute myocardial infarction, heart failure, pneumonia, certain surgeries, certain hospital-acquired infections. This program addresses efficiency measures, including measures of "Medicare spending per beneficiary," Hospital Acquired Conditions and Never Events.

Interestingly, a study by VHA Inc. published in June 2010 found that 75% of all hospitals will suffer loses if changes aren't made before VBP commences (results available on VHA Inc. website). The benefits for making the changes and reporting are significant though. By October 2012, hospitals that meet or exceed certain performance standards for a minimum of five measures will be eligible for higher Medicare payments from a pooled hospital-derived fund. The procedures/conditions: AMI, heart failure, pneumonia, certain surgeries and certain hospital-derived infections. The VBP program can track only those measures that have been included on the Hospital Compare website for at least one year prior to the beginning of the performance period and specified under the Hospital IQR (Inpatient Quality Reporting) Program.

On January 7, 2011, CMS issued a proposed rule for implementing the VBP program. 76 Fed. Reg. 2454 (Jan. 13, 2011). The rule proposes measures for 2013 and 2014, and includes "achievement performance standards" and the "improvement performance standards." The following regulation-proposed fiscal year 2013 measures illustrate the detail required in each measure:

Acute Myocardial Infarction:

- Aspirin prescribed at discharge
- Fibrinolytic therapy received within 30 minutes of hospital arrival
- Primary PCI received within 90 minutes of hospital arrival

Heart Failure:

- Discharge instructions
- Evaluation of LVS function
- ACEI or ARB for LVSD

Pneumonia

- Pneumococcal vaccination
- Blood cultures performed in the emergency department prior to initial antibiotic received in hospital
- Initial antibiotic selection for CAP in immunocompetent patient
- Influenza vaccination

Healthcare associated infections:

- Prophylactic antibiotic received within one hour prior to surgical incision
- Prophylactic antibiotic selection for surgical patients
- Prophylactic antibiotics discontinued within 24 hours after surgery end time
- Cardiac surgery patients with controlled 6 am post-operative serum glucose

Surgeries:

- Surgery patients on a beta blocker prior to arrival that received a beta blocker during the perioperative period
- Surgery patients with recommended venous thromboembolism prophylaxis ordered
- Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hours prior to surgery and 24 hours after.

6. Physician Compare

CMS started on December 30, 2010 a new "Physician Compare" component to the CMS Healthcare Provider Directory. It is a consumer-targeted program. According to CMS, it is intended to help Medicare and non-Medicare patients and their families find and assess the quality of providers. PQRS data will also be reported here.

Compliance

A detailed explanation of the Stark Law (and exceptions) and the Federal Anti-Kickback Statute (and safe harbors) is outside the scope of this article. Attorneys with a general understanding of the limited conditions in which hospitals can pay physicians may find solace in the following Stark Law commentary when analyzing issues of hospital payments to physicians for quality:

> "*..[A]s we discussed in Phase II, compensation related to patient satisfaction goals or other quality measures unrelated to the volume or value of business generated by the referring physician and unrelated to reducing or limiting services would be permitted under the personal service arrangements exception, provided that all the requirements of the exception are satisfied (for example, compensation to reward physicians for providing appropriate preventive care services where the arrangement is structured to satisfy the requirements of the exception. (69 FR 16091)."*

72 Federal Register 51046 (Sept 5, 2007). The Stark Law personal service arrangements exception at 42 U.S.C. § 1395nn(e)(3) provides, in general, that the Stark Law is not implicated in relationships in which one party pays another party for the provision of services if the following conditions are met: (a) the arrangement is set out in writing, signed by the parties, and specifies the services covered by

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the arrangement; (b) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity; (c) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement; (d) the term of the arrangement is for at least 1 year; (e) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and (f) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law.

Similarly, the Federal Anti-Kickback Statute regulations at 42 C.F.R § 1001.952(d) contain a safe harbor for personal services and management contracts. To qualify for this safe harbor, all of the following seven standards must be met: (a) the agency agreement is set out in writing and signed by the parties; (b) the agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent; (c) if the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals; (d) the term of the agreement is for not less than one year; (e) the aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; (f) the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and (g) the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services. For purposes of this safe harbor, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

Compensation related to quality outcomes (as opposed to compensation for time spent developing quality protocols and tracking or teaching quality) raises a compliance concern, however, because this type of compensation arrangement fails to meet the "aggregate compensation set in advance" requirement of the anti-kickback statute safe harbor. Sometimes attorneys, therefore, rely on the Stark Law fair market value or indirect compensation arrangements exceptions. To meet either exception, fair market value must be established with respect to any compensation arrangement (e.g., any base compensation or bonus compensation arrangement).

Types of Alignment Models

Neither CMS nor the Office of Inspector General of the Department of Health and Human Services have specifically blessed any of the following types of arrangements specifically addressing quality initiatives. However, the following types of arrangements are very similar to other types of agreements for relationships that have been long-established in the healthcare industry. The new idea is to twist those arrangements slightly to make quality programs or quality tracking and achievement the core service provided.

1. Service Line Management Agreement

In this type of arrangement, the hospital contracts with either a physician group or individual physicians to manage their service line (i.e., cardiology, OB, etc.) in the hospital. A main duty is quality improvement tracking and reporting, although the physicians/group also provide typical management services. This could be structured with a base fee for the typical administrative/management services (committee work, developing protocols, advising on equipment purchases and strategic planning), plus a bonus for reaching quality goals. Goals should be pre-determined and objectively measurable. They might include turnaround time, patient satisfaction, use of standardized protocols, supplies and equipment or other parameters and goals set by the government.

2. Medical Directorship with Quality Criteria

This arrangement is a typical medical director agreement, with a strong emphasis on quality program development and implementation. The idea is that each specialty within the hospital has unique challenges in measuring, tracking and reporting quality. Outcomes measures may work for some specialties, but not others, for

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example. The Medical Director for Quality in the departments or specialties would be charged with developing the actual protocols and processes to be measured, training colleagues on them and actually supervising the tracking process. This arrangement puts administrative quality issues in the hands of the medical direcctor. The medical director would track his time spent on this work and would submit an invoice to the hospital for his hourly rate, much like a typical medical directorship arrangement.

3. Hospital Based PSA with Quality Criteria

Another option may be a professional services agreement between the hospital and a physician or group, with an emphasis on quality. This arrangement is much like the medical directorship, but without the "medical director" title. This type of structure may allow the hospital to make payments, pursuant to a number of different PSAs, to a number of different physicians who might work together on a hospital-wide quality implementation program. It may also be the best fit for hospital-based physicians and situations in which one group is the exclusive provider of a service. The exclusive contract for the service can be tied to quality indicators.

4. Call Coverage Agreement with Quality Criteria

In this arrangement, the call coverage agreement also includes criteria for quality. Quality protocol development and quality compliance are added as duties to the call coverage agreement.

5. Quality Improvement PSA

The physician gets payments based not on referrals to the hospital (which would be illegal) but on quality results or improvements. It could be thought of as similar to gain sharing, but for services promoting and/or achieving quality. In structuring this arrangement (as well as the others) attention could be given to possible payments for results for the following: (a) turnaround time, (b) patient satisfaction, (c) reduction in cost per case, and (d) use of standardized supplies and equipment.

CMS has not clearly blessed any of these arrangements, so counsel should proceed with caution when considering the implementation of payment for quality. Counsel should be mindful of what can't be counted and compensated (referrals). Changes in volume in response to the implementation of a quality program could be indicative of a program that pays for something other than quality. Evidence of increased utilization could also be problematic. If the hospital reduces services to Medicare beneficiaries as CMS's pay-for-performance models become implemented, that too could give rise to legal issues.

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Endnote:

1 On October 20, 2011, the U.S. Department of Health and Human Services, issued final rules for accountable care organizations for subsequent publication in the Federal Register on November 2, 2011 (to be codified at 42 C.F.R,Part 425).

Beyond Medical Advance Directives:
Implementing the POLST (Physician Orders for Life-Sustaining Treatment) Paradigm in Florida

By Marshall B. Kapp, Director, Florida State University Center for Innovative Collaboration in Medicine & Law, Tallahassee, FL*

Every state, including Florida, has enacted laws intended to help critically ill medical patients maintain a degree of personal autonomy or self-determination regarding decisions about the initiation, continuation, withholding, or withdrawal of various medical interventions, even at a time when the patient no longer has sufficient present cognitive or emotional capacity to rationally make and communicate his or her own choices.[1] Florida Statutes Chapter 765 establishes a mechanism for currently decisionally capable adults to execute health care advance directives in the form of designating a health care surrogate or agent, making a living will instructing on future desired treatment, or providing a post-mortem anatomical gift such as an organ for transplantation. Florida Statutes Chapter 709 authorizes a capable adult to execute a durable power of attorney, which is the functional equivalent of creating a health care surrogate. Florida Statutes § 401.45(3)[2] empowers a physician to write a Do Not Resuscitate Order (DNRO) on the Department of Health Yellow form, with the concurrence of the patient or surrogate, for a critically ill patient who is not anticipated to recover from a cardiac arrest.

However, experience with advance directives over the last couple of decades has led to the identification of several significant problems.[3] The most salient of these problems include: the reluctance of many people to use the available legal tools in a timely fashion; the paucity of practical guidance, or the confusing guidance, provided by advance directive forms for patients filling them out and medical professionals trying to apply them in clinical scenarios; patients' care goals and preferences often changing over time; the frequent ignorance of the surrogate or health care agent regarding the real care preferences of the patient; the fact that, even when providers know that an advance directive exists (and such knowledge cannot always be assumed), the advance directive frequently does not significantly alter the patient's course of treatment[4] or may even exacerbate the clinical situation.[5]

Growing frustration with the inherent limitations of existing instruments for promoting the prospective autonomy of critically ill patients who may become decisionally incapacitated has led many attorneys,[6] health care providers, and commentators to advocate as the next step in the evolution of health care advance planning law and policy[7] the use of POLST (Physician Orders for Life-Sustaining Treatment)[8] forms. Unlike a traditional advance directive executed by a patient while still decisionally capable, POLST entails a medical order written by a physician (and with the concurrence of the patient or surrogate) instructing other health care providers such as emergency medical squads about the treatment of a critically ill patient under specific factual situations. Approximately a dozen states have formally implemented the POLST Paradigm, with national coordination efforts being administered through the Center for Ethics in Health Care at the Oregon Health & Science University.[9] Many more states are in the process of developing their own versions of POLST.[10]

There is an array of legal impediments in the various states to successful adoption and fulfillment of the POLST paradigm.[11] In Florida, an informal working group of interested attorneys, health care and human services providers, professional associations, and academics has come together under the coordinating umbrella of the Florida State University Center for Innovative Collaboration in Medicine & Law to identify and explore possible strategies for pushing forward acceptance and implementation of the POLST Paradigm in this jurisdiction.[12] In the coming months, this group will need to grapple with a myriad of legally tinged strategic choices about how best to achieve the objectives of POLST.

Needed Legal Changes?

The initial set of strategic issues asks about what changes, if any, in current Florida law are necessary to authorize and/or encourage attending physicians to write POLSTs for appropriate patients and to authorize and/or encourage other health care professionals to respect and implement those POLSTs. One potential route (involving the most complex and controversial political ramifications)[13] would be to propose legislative enactment of new, explicit statutory language. Such statutory language could be integrated into Chapter 765, as was unsuccessfully attempted with House Bill 1017 during the 2006 legislative session,[14] creating a new and different type of advance directive; alternatively, the legislature could be asked to amend Fla. Stat. § 401.45 to authorize physicians' orders pertaining to the withholding of specified other kinds of medical interventions besides cardiopulmonary resuscitation (CPR). Either as an alternative strategy to legislation or as a supplement implementing the statutory change, explicit regulatory modifications could be sought to clarify the POLST-related rights and responsibilities of affected parties.[15] This approach would necessitate identifying which state agency(ies) would have relevant jurisdiction and ways to assure inter-agency coordination and cooperation in the administration of POLST oversight.

A third potential strategy would bypass legislation and regulation in favor of action predicated on clinical consensus. This approach would entail obtaining explicit agreement from the relevant state agencies that current state statutes and regulations already permit physicians to write, patients and surrogates to agree to, and other health care providers to implement POLSTs, with the emphasis of change agents being placed on professional and public education rather than on trying to amend the law. The clinical consensus strategy would rely mainly on the "Preservation of existing rights" clause found in Florida's advance directive statute:

The provisions of this chapter [765] are

cumulative to the existing law regarding an individual's right to consent, or refuse to consent, to medical treatment and do not impair any existing rights or responsibilities which a health care provider, a patient, including a minor, competent or incompetent person, or a patient's family may have under the common law, Federal Constitution, State Constitution, or statutes of this state.[16]

The argument would be that current common and constitutional law already protects the liberty rights of patients to make contemporaneous and prospective medical decisions and to secure the assistance of their physicians in effectuating those liberty rights by, for example, documenting a POLST instructing other health care providers on behalf of the patient.

Drafting and Policy Issues

Assuming that either a statutory or regulatory change strategy is pursued to promote the POLST Paradigm in Florida, a myriad of policy questions will need to be addressed in the legislative or rule-making drafting stage. In looking for guidance elsewhere, there is a wide divergence among other states regarding how they have resolved these questions.[17]

For instance, decisions will need to be made about the specific content of the adopted POLST form and whether that content should be incorporated into statute or regulation or only described in broad terms. Typical POLST forms in use elsewhere contain separate sections dealing with: CPR attempts; medical interventions (full treatment versus comfort measures only); use of antibiotics; administration of artificially administered nutrition and hydration; reason for the orders (documenting the physician's conversations with the patient and/or surrogate); and signatures. A Florida POLST form might comport or deviate from this particular structure. If a new statute or regulation does incorporate specific POLST form content, a question arises whether the explicitly approved form must be used by the physician in order for the POLST to be considered valid or, alternatively, whether a somewhat deviating but comparable form would be legally acceptable.

A further legal and policy drafting question is whether to require health care providers to offer the POLST option to patients. If so, which specific providers would be covered? Should the requirement encompass all patients or only certain categories? What timing requirements (e.g., at the time of admission to a health care institution, as now specified in the Patient Self-Determination Act),[18] if any, should be delineated? What is the penalty for provider non-compliance? Another, likely very politically contentious, issue relates to who, beside physicians, should be granted the legal power to write POLSTs. Should this authority be extended, for example, to nurses or physicians' assistants?[19]

A different strategic conundrum concerns the extent of the authority that a new statute or regulation ought to grant surrogates to consent to a POLST on behalf of a patient who lacks enough present cognitive and emotional capacity to decide and speak personally about medical treatment concerns. The desire to facilitate the writing of POLSTs, even when concurrence must come from a surrogate instead of the patient, must be balanced against the need to protect decisionally compromised patients from surrogates who, unfortunately,[20] may not be worthy of such trust.

One of the largest impediments to successful POLST implementation elsewhere has been health care providers' anxieties about the risk of possible lawsuits brought against them by disgruntled family members.[21] Overcoming that vastly exaggerated but strongly and sincerely held apprehension will be vital to achieving successful POLST implementation. Thus, the good faith legal immunity provisions necessarily built into any new statutes and/or regulations must be drafted carefully, balancing encouragement of provider compliance with POLSTs against the need for some form of accountability for the actors involved. On a related note, should provider compliance with a valid POLST be mandated? If so, what is the proper range of sanctions for a failure to comply with the mandate?

Other operational issues also need to be resolved in the legislative or regulatory drafting stage. May a provider rely, in withholding certain kinds of treatment, on copies or faxes of the POLST document? Must those copies or faxes be printed on paper of a particular color and/or size so as to be identifiable readily? Alternatively, must the original document be available? If there is a material conflict between the physician's instructions in a patient's POLST and that patient's own earlier written advance directive, which document governs? What about POLST forms with some sections not completed? In the absence of a totally completed POLST form, should there be a presumption that maximum aggressive medical intervention must be rendered? Finally (although this enumeration of issues does not purport to be comprehensive), there is the matter of portability of the POLST as a patient travels between different jurisdictions. Should Florida legislation or regulation state that Florida providers may (or must) recognize and implement POLSTs validly executed in other jurisdictions, in return for reciprocal respect for Florida-drafted POLSTs by the other jurisdictions?

Storing and Retrieving POLST Forms

Let us assume that the working group is successful in achieving legal recognition in Florida of the POLST Paradigm, educating physicians (and any other authorized health care providers) to discuss POLST possibilities with patients and their surrogates and to write a POLST when appropriate and agreed to, and convincing health care providers to implement their patients' valid POLSTs if and when the forms can be found in a timely manner and the designated circumstances have materialized. At that point, an additional set of legally tinged policy and practice issues would emerge concerning the storage and retrieval of POLST forms so that they are readily available when needed.

One obvious, straightforward way to handle the storage and retrieval issue is the proverbial "form under the refrigerator magnet" method, with its equally obvious problem of inaccessibility of the document if an emergency situation involving the patient occurs outside of the patient's home. To avoid that frequent, foreseeable operational shortcoming, other options must be considered.

As physicians, hospitals, and other health care facilities move steadily in their documentation from paper toward electronic medical records, it is desirable that a patient's electronic medical record include the POLST, if one exists. Doing so, though, will implicate all of the potential legal issues that might apply to electronic medical records generally.[22]

In addition to encouraging the incorporation of POLST forms into individual patients' electronic medical records, the Florida working group

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eventually will need to consider establishing, either through legislative and/or regulatory recognition (and an accompanying appropriation of public funds) or through some type of voluntary arrangement, the creation of a central registry to facilitate both immediate form retrieval and quantitative research on the effectiveness of the POLST mechanism. Several other states are at various stages of planning or implementing such central registries, and a taxonomy of associated legal issues has already begun to emerge.

Most fundamentally, should submission of every written POLST form to the central registry be required? Who (the physician, the patient, and/or others) would be mandated to submit? If submission were not required, then who (if anyone) would be permitted to submit a POLST to the registry? What immunity from criminal and civil liability or other legal protections for POLST submitters should be embedded in statute or regulation? What penalties, if any, should be imposed on mandated submitters who fail to comply with submission requirements? Who should be granted access to the data compiled within the POLST registry, and under what conditions? What specific procedures should be imposed to assure that the registry complies with the confidentiality and data security requirements of the Health Insurance Portability and Accountability Act (HIPAA)[23] and state law[24] regarding personal health information?

Additional challenges arising in the development and implementation of a POLST registry mechanism would include quality control processes for maximizing the accuracy (i.e., the correct form for the correct patient) and timeliness of information entered into and stored within the registry. Potential questions pertaining to the civil liability of individuals and/or entities negligently entering data into or maintaining a registry need to be anticipated and dealt with proactively; these questions would involve, for instance, determining who would have standing to sue, defining the applicable standards of care, and delineating damages for breach of duty.

Policy Issues for Health Care Institutions

Besides the sort of public policy issues outlined above that may need to be addressed through the development of legislation and/or regulation, moving forward in promoting the POLST Paradigm to enhance patient autonomy and improve the quality of medical treatment for the critically ill will require individual health care providers (most notably, hospitals, nursing homes, rehabilitation facilities, and assisted living facilities) to confront several interrelated internal policy questions, ideally in a proactive stance. Specifically, despite a statutory or regulatory overlay, each institutional health care provider will likely retain substantial discretion about how POLSTs written by physicians for patients they serve are to be reconciled and integrated with existing institutional bylaws and protocols regarding the treatment of critically ill persons.

For example, will the institutional provider presently caring for a particular patient recognize and act upon a POLST signed by a physician who earlier cared for that patient in the community or in another institutional provider, but who does not have active admitting and treating privileges within the current provider? Conversely, will the provider limit its recognition of POLSTs to those that are written by physicians who are members of that provider's medical staff? In a connected vein, even if state law were to permit non-physicians to write POLSTs in consultation with patients or their surrogates, would any particular institutional health care provider elect to recognize and implement a POLST written by a non-physician?

Conclusion

Evidence has been produced in other jurisdictions that the POLST Paradigm is an effective way to move beyond the limitations of the advance medical directives approach to enhancing the self-determination of individual patients and improve the quality of available medical care during times of critical illness. Florida has been categorized as a "developing" POLST state, and robust, earnest discussion—as briefly summarized here—has begun to take

place about the contours and details of competing legal, public policy, and institutional strategies for propelling this jurisdiction forward. This challenge presents an opportunity for productive interprofessional collaboration in which the contributions of legal expertise to the delivery of excellent medical care will be essential.

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Endnotes

1 Fla. Stat. § 765. 102 (legislative findings and intent).

2 Implemented by Fla. Admin. Code r. 64B8-9.016.

3 See *Dorothy D. Nachman, Living Wills: Is It Time to Pull the Plug?* 18 J. Elder L. 289 (2011).

4 See Charles P. Sabatino, *The Evolution of Health Care Advance Planning Law and Policy,* 88 Milbank Q. 211, 221-224 (2010); Keith E. Sonderling, *POLST: A Cure for the Common Advance Directive—It's Just What the Doctor Ordered,* 33 Nova L. Rev. 451, 470-476 (2009).

5 Lesley S. Castillo, Brie A. Williams, Sarah M. Hooper *et al., Lost in Translation: The Unintended Consequences of Advance Directive Law on Clinical Care,* 154 Annals Intern. Med. 121 (2011).

6 See, *e.g., Kathryn Tucker, Elder Law: Counseling Clients Who Are Terminally Ill,* 37 Wm. Mitchell L. Rev. 117 (2010).

7 *See Sabatino, supra* Note 4.

8 Some states vary the terminology slightly. For example, some states call their POLST-equivalent a MOLST (Medical Order for Life Sustaining Treatment), POST (Physician Order for Scope of Treatment), MOST (Medical Order for Scope of Treatment), or COLST (Clinical Order for Life-Sustaining Treatment).

9 *http://www.ohsu.edu/polst.*

10 Charles P. Sabatino & Naomi Karp, *Improving Advance Illness Care: The Evolution of State POLST Programs.* Washington, DC: AARP Public Policy Institute, No. 2011-01 (2011).

11 Susan E. Hickman, Charles P. Sabatino, Alvin H. Moss, & Jessica Wehrle Nester, *The POLST (Physician Orders for Life-Sustaining Treatment) Paradigm to Improve End-of-Life Care: Potential State Legal Barriers to Implementation,* 36 J. L., Med. & Ethics 119 (2008).

12 *http://med.fsu.edu/index.cfm?page=InnovativeCollaboration/activities.*

13 *See generally* Kenneth Goodman, *Ethics Schmethics: The Schiavo Case and the Culture Wars,* 61 U. Miami. L. Rev. 863 (2007).

14 House Bill 1017, 2006 Leg. Reg. Sess. (Fla. 2006) (identical to S. 2572, 2006 Leg. Reg. Sess. (Fla. 2006)).

15 *See generally* Kathy L. Cerminara & Seth M. Bogin, *A Paper About a Piece of Paper: Regulatory Action as the Most Effective Way to Promote Use of Physician Orders for Life-Sustaining Treatment,* 29 J. Legal Med. 479 (2008).

16 Fla. Stat. § 765.106.

17 *See* Sabatino & Karp, *supra* Note 10.

18 Pub. L. 101-508, Title IV, §§ 4206, 4751 (1990).

19 Cf. Julia Johnson, *Whether States Should Create Prescription Power for Psychologists,* 33 L. & Psychol. Rev. 167 (2009).

20 *See, e.g.,* Joseph A. Rosenberg, *Regrettably Unfair: Brooke Aster and Other Elderly in New York,* 30 Pace L. Rev. 1004 (2010).

21 Regarding providers' anxieties about their own legal risks, *see generally* Robert A. Burt, *Doctors vs. Lawyers: The Perils of Perfectionism,* 53 St. Louis U. L. Rev. 1177 (2009).

22 *See, e.g.,* Blake Carter, *Electronic Medical Records: A Prescription for Increased Medical Malpractice Liability?* 13 Vand. J. Ent. & Tech. L. 385 (2011); Mark A. Hall, *Property, Privacy, and the Pursuit of Interconnected Electronic Medical Records,* 95 Iowa L. Rev. 631 (2010); Sharona Hoffman, *E-Health Hazards: Provider Liability and Electronic Health Record Systems,* 24 Berkeley tech. L.J. 1523 (2009).

23 Pub. L. 104-191 (1996), codified at 42 U.S.C. § 1301 et seq.; 42 C.F.R. Part 160 and Part 164, Subparts A and E.

24 Fla. Sta. § 456.057 (7), (8), & (11).

2011 - 2012 Health Law Section Events

Administrative Trials at the Division ofAdministrative Hearings
"Eat & Educate" Webinar
December 6, 2011, 12:00 noon – 1:00 p.m. EST

Health Law Executive Council Meeting
January 26, 2012
Renaissance Hotel International Plaza, Tampa

Representing the Physician 2012
January 27, 2012
Renaissance Hotel International Plaza, Tampa
[Course # 1314]

Health Law Certification Review 2012
March 9-10, 2012, Orlando
[Course #1328]

Health Law Executive Council Meeting
(@ The Florida Bar's Annual Convention)
June 21, 2012
Gaylord Palms Resort & Convention Center Kissimmee / Orlando

Florida's New Power of Attorney Act

By Richard N. Sherrill, Esq., Clark, Partington, Hart, Larry, Bond & Stackhouse, Pensacola, FL*

Background

Florida powers of attorney ("POA") are governed by chapter 709, *Florida Statutes*. That chapter has been substantially re-written by the Florida legislature this year as the Florida Power of Attorney Act, to provide greater structure and guidance for practitioners, the person giving the power of attorney (the "principal"), the person who is authorized to act on behalf of the principal (the "agent"), and financial institutions and others who may be presented with a power of attorney and requested to rely on it ("third parties"). Sections 709.2101 through 709.2402, *Florida Statutes*, will soon provide additional structure, requirements, and comfort to all involved in the drafting, execution and use of powers of attorney in Florida. Following is an overview of many of the key features of the new Florida Power of Attorney Act.

The effective date of this sweeping new legislation, which is Florida Session Law Service Chapter 2011-210, is October 1, 2011. After that date, the formalities, execution, use and acceptance or rejection for any document will be governed by the new power of attorney act (the "new POA Act"). Valid power of attorney documents created prior to October 1, 2011 are not affected by the new POA Act, nor are military powers of attorney (the form and use of which are governed by federal law). Out-of-state powers of attorney which do not conform with the new POA Act may be relied upon and used if the form of the document complies with applicable state law of the state where executed at such time of execution.

Formalities of POA

All powers of attorney must now be executed with the formalities of a deed: signed by the principal in the presence of two witnesses and a notary. As with a deed (but not a will), the notary can serve as one of the witnesses. Moreover, with all acknowledgments, the notary cannot be too-closely-related to the principal. Further, although there is no prohibition against a person named in the document from being a witness, it is often the case that any such person makes a poor witness due to potential interest in the subject of the document. For a power of attorney to be made to last beyond the principal's incapacity (subject to temporary or permanent suspension, discussed below), the instrument must be made "durable," by stating that "This durable power of attorney is not terminated by subsequent incapacity of the principal except as provided in chapter 709, Florida Statutes." If the instrument does not say so, then the mere incapacity (without the necessity of any judicial determination) of the principal suspends the authority given under the instrument. Copy of a POA under the new POA Act is as valid as the original unless the instrument provides otherwise.

No "Springing" Power of Attorney

Florida law previously provided that the effectiveness of a power of attorney could be made contingent upon the happening of some event — typically incapacity of the principal. The new POA Act now prohibits this, and all POAs are now exercisable upon execution. A power of attorney instrument can however, be made successive — a back-up agent is named if the primary agent dies, resigns or is incapacitated. In that sense, a POA can still be made contingent, but not in the more typical historic case where the principal wanted to maintain exclusive ability to act on his/her own behalf until he/she could not do so, then and only then could the agent act on behalf of the principal. This often presented a problem of proof of incapacity, and reliance on that proof to third parties, and is now outlawed.

Co-/Successor Agents

Multiple, as well as successive, agents may be named. The default rule for co-agents is that each may act independently, unless otherwise indicated in the document. Where joint action is required, one among the agents may be delegated authority to act on behalf of all. A successive agent can be named to act, but only after the primary agent is no longer acting. This successive agent is only authorized to act upon the death, resignation, incapacity of the primary agent. While a successive agent has no duty to review the actions of the prior agent, if the successor agent knows of a breach of fiduciary obligation by the primary agent, the successor agent must take reasonable action to protect the principal's interest.

Acceptance of Fiduciary Position

An agent named under a power of attorney accepts his/her fiduciary position by acting in such fiduciary position, or by taking any other act that indicates acceptance — such as a written acceptance. An agent is a fiduciary, and is held to the highest standards of trust.

Authority of Agent

A POA may no longer broadly and sweepingly authorize an agent to perform all acts which the principal could perform. Instead, authority to act must now be specifically granted. Specifically granted authority may be carried out by the agent without court approval. Examples of items that may be specifically granted include without limitation handling stock, dealing with/conveying/mortgaging real property including (if so provided) the principal's homestead, make health care decisions on behalf of the principal, and banking matters. These items may no longer be generally granted in the instrument under the new POA Act.

"Super-Powers"

Other functions which the agent may be authorized to perform require the principal to sign or initial next to each such authority, as follows: settle/amend/revoke a trust, make a permitted gift, re-arrange survivorship or beneficiary designation, deal with the principal's rights under an annuity, and disclaim property. For each of these authorities, the instrument must expressly authorize the agent to perform, and the principal must initial/sign next to each such authority.

Gifting Authority

Unless the instrument overrides this, the default rule is that an agent who is specifically authorized to make gifts may only gift up to the annual exclusion amount (and may be authorized to gift-split with

the spouse of the principal). Gifting is now statutorily subject to increased scrutiny. Gifts must be consistent with the agent's overall estate plan and not inconsistent with prior gifting history. Moreover, obligations of record-keeping imposed on the agent serve to minimize abuse by agent with access to the principal's assets in the name of authorized gifting.

Duties of the Agent

The agent is a fiduciary. The new statutes set out the duty to act in good faith; requirement to act consistent with the principal's best interests; preserving the principal's estate plan; the requirement to act personally on behalf of the principal (rather than delegating the fiduciary position); act loyally on behalf of the principal; avoiding conflict of interests with the agent's personal and financial matters; and with the care, competence and diligence equal to the circumstances and using the skills and abilities which the agent possesses. An agent acting in good faith who meets his/her duties as a fiduciary is not liable for decline in value of the principal's assets. The principal may knowingly and willfully provide in the instrument that the agent acting in good faith be held harmless. Failure to act in good faith in the principal's best interests may subject the agent to liability to restore the principal's assets and pay fees and costs associated with the breach.

Protection of Third Parties for Accepting POA

Properly executed effective POA of a living principal used in good faith for the benefit of the principal must be honored by third parties. A third party must accept the authority of an agent who presents the POA (or a copy unless the instrument provides otherwise) within a reasonable time (generally 4 business days), or else refuse in a reasoned writing to accept the instrument. No substitute preferred form of the third party can be required in place of an otherwise valid POA. A third party who is reluctant to rely on the POA may ask for a written opinion of counsel, at the principal's expense, which assures the third party that the instrument is valid and effective. A third party may also require an agent to execute an affidavit setting out the effectiveness of the POA — essentially that the principal is alive, the authority to act has not been terminated, and that the proposed act is authorized under the instrument.

Compensation

A qualified agent is entitled to reasonable compensation under the circumstances. Qualified agent is defined as someone who is sufficiently-closely related to the principal, is qualified to serve as corporate trustee, Florida attorney or CPA, or any other unrelated Florida resident "non-professional" agent (meaning never served as agent for more than three principals at the same time). An agent is generally entitled to reimbursement for expenses incurred on behalf of the principal.

Termination of Authority

The authority to act under a POA terminates at the latest when either the principal or agent dies. A power of attorney that is not made durable terminates upon the incapacity of the principal. A durable POA terminates upon the adjudication of incapacity of the principal — even a durable POA — unless the court determines that the instrument remains effective thereafter. Revocation by the principal terminates the authority, as does resignation by the agent. If the purpose of the authority is accomplished or the instrument expires by its terms, the authority under the POA terminates. Importantly, filing of a proceeding for dissolution or annulment of marriage, or for legal separation, terminates the authority of a spouse under POA unless the instrument provides otherwise.

Notice

An agent is entitled to actual written notice of the termination of the authority under the POA. Delivery of the notice may be made by a commercially reliable service (USPS, FedEx, hand delivery, fax or email, e.g.). An agent resigns by giving written notice to the principal and any successor or co-agent.

Conclusion

The execution, use and reliance on powers of attorney has been provided tremendous new structure. The effective date of the new laws is October 1, 2011, and previously executed instruments and military powers of attorney are exempt. The new POA Act has formalized many of the best practices that have been in use, and also addresses many opportunities of confusion, abuse and inefficiency that have been attributed to powers of attorney in Florida until now. Importantly, a power of attorney may no longer generally grant authority but instead must now specifically — and in some cases, be initialed by the principal — list the authority of the agent under the instrument; the authority given to a spouse is revoked upon filing divorce, separation or annulment proceedings; and the instrument must be executed with the formalities of a deed and is effective upon execution. There are many other important incidents of powers of attorney in this state resulting from the new Florida Power of Attorney Act.

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