

# Solving Ethical Dilemmas in Patient Care



# Speakers



**Robert W. Liles, J.D., M.B.A., M.S.**

Managing Member  
Liles Parker PLLC

Mr. Liles has worked in regulatory compliance as a Federal prosecutor and as defense counsel, for more than 25 years. This has provided a unique perspective on the challenges faced by clients in highly regulated industries such as health care, banking and finance.

Office: (202) 298-8750

Email: [rliles@lilesparker.com](mailto:rliles@lilesparker.com)



**Tom Forsberg**

Licensed Administrator, Regional Director  
Senior PsychCare

A licensed administrator for more than 30 years, Tom has a wealth of knowledge about the inner-workings of nursing homes and the long-term care community. As a Regional Director, Tom still interacts with facility admin staff and leads educational sessions for Providers and NH staff.

Office: (210) 826-1830

Email: [tforsberg@spchealth.com](mailto:tforsberg@spchealth.com)

A man in a dark suit and white shirt is shown in profile, looking towards the right. He has his hand near his chin, suggesting deep thought or contemplation. The background is a blurred cityscape with buildings and a bright sky, possibly during sunrise or sunset. A blue horizontal bar is overlaid on the bottom right of the image, containing white text.

Ethics – the Principles of Conduct  
Governing an Individual or a Group

# Facilities Face Make Daily Decisions Requiring Ethical Judgement

- Competing interests of constraints versus patient need
- Resident wishes versus resident reality
- Demands of the family and family conflict over aspects of care
- Residents ability to make an informed decision
- State regulatory requirements
- Pressures from corporate to achieve goals

# Balancing Competing Demands

- Family Wishes
- Facility Services
- Regulations
- Corporate Goals
- State Laws

Personal Judgement of  
Patients Needs for  
Their Best Quality of  
Life

After Carefully Assessing - Resident Needs Come First

# Criminal Risks from Situational Ethics to Justify Self (Facility) Enrichments

"Lure of Easy Money for Underfunded Programs"

Pharmacy Service Contracts

Consultant Pharmacy Services

Marketing of Anti-Psychotic Drugs in Nursing Homes

Therapy Services

Sham "Grants" and "Educational Funding" from Pharmaceutical Companies

Fees Paid to Providers for Attending Meetings with Pharmaceutical Representatives

# National Nursing Home Initiative

DOJ is investigating cases where substandard care is being alleged

Trying to get and maintain adequate staff to meet Texas Regulations is hard for everyone right now

Regulations: Meet the minimum ratio of the patients/residents



# Review of Statutory Requirements

# Patient Self-Determination Act (PSDA)

42 CFR § 489.100-104

- Passed by U.S. Congress in 1990 after a series of cases involving the withdrawal of life-supporting care when the wishes of the patient regarding such care were unknown
- The PSDA amended the Social Security Act and made it a "Condition of Participation" in the Medicare and Medicaid programs that hospitals, nursing homes, home health agencies, hospice providers and HMOs provide information about advance health care directives to all adult patients upon admission to the health care facility.
- Patients *must* be given written notice of their decision-making rights and the policies about advance healthcare directives in their state. (See 42 CFR § 489.102).
- Facilities must document in a "prominent" location within the patient's medical record whether the patient has an advance directive (42 CFR §489.102a).
- Patient rights include:
  - The right to facilitate their own healthcare decisions.
  - The right to accept or refuse any medical treatment.
  - The right to make an advance healthcare directive.

# Advanced Directives in Texas

An Advance Directive is a set of instructions that outlines an individual's health care wishes. It can be used when a medical event occurs, and an individual isn't able to communicate his or her wishes. Unlike a Living Will, an Advance Directive isn't limited to terminal illness. It may also include medical events such as dementia, stroke or coma.

- *Advance Directives in Texas are governed by the Health and Safety Code.*

Title 2. Subtitle H. Subchapter A. §166.001 through §166.011. An Advance Directive means:

- A "Directive to Physicians and Family or Surrogates" (also known as a Living Will, as defined in Subchapter B. §166.031 through §166.053);
- An out-of-hospital DNR order. (as defined in Subchapter C. §166.081 through §166.102); or
- A "Medical Power of Attorney." (as defined in Subchapter D. §166.151 through §166.166).

# Advanced Directives in Texas

Who can sign an Advance Directive?

- In order to execute an Advance Directive, an individual must be “Competent.” A competent person must have the ability based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to a proposed treatment decision.

Can a Declarant sign an Advance Directive using a digital or electronic signature?

- Yes. As long as the digital or electronic signature meets the requirements set out in §166.011.

Can a health care provider require that an individual have an Advance Directive in place?

- No. A physician, health facility, health care provider, insurer, or health care service plan may not require a person to execute or issue an advance directive as a condition for obtaining insurance for health care services or receiving health care services. See §166.007.

# Advanced Directives in Texas

What are your obligations as a “health care provider”?

- A health care provider is required to maintain written policies regarding the implementation of Advance Directives. These policies must include a clear and precise statement of any procedure the health care provider is unwilling or unable to provide or withhold in accordance with an Advance Directive. See §166.004(b).

What notice are you required to give to an individual?

- A health care provider is required to provide written notice to an individual of its written policies regarding Advance Directives. This notice must be provided at the earlier of:
  - (1) The time the individual is admitted to receive services from the health care provider; or
  - (2) The time the health care provider begins providing care to the individual. See §166.004(c).

# Advanced Directives in Texas

*How can you provide notice if a person is incompetent or otherwise incapacitated and is unable to receive notice?*

- In this situation, a health care provider is required to provide the written notice, in order of preference, to:
  - (1) The individual's legal guardian;
  - (2) A person responsible for the health care decisions of the individual;
  - (3) The individual's spouse;
  - (4) The individual's adult child;
  - (5) The individual's parent; or
  - (6) The person admitting the individual. See §166.004(d).

# Texas Living Will - "Directive to Physicians"

*Under Texas regulations, "Directive to Physicians" (commonly referred to a "Living Will") is limited to "qualified patients" with certain conditions:*

- (1) *The term "Directive" is defined as an instruction to administer, withhold, or withdraw life-sustaining treatment in the event of a terminal or irreversible condition. See §166.031(1).*
- (2) *A "Qualified Patient" is a patient with a terminal or irreversible condition that has been diagnosed and certified in writing by the attending physician. See §166.031(2).*

*Who can execute a written Directive? A competent adult can execute a written directive at any time. The Declarant must sign the directive in the presence of two qualified witnesses (the witnesses must also sign the Directive). Alternatively, a Declarant may sign the Directive in front of a notary public and have it notarized.*

*A sample form titled "Directive to Physicians and Family or Surrogates" is set out under §166.033.*

# Texas Living Will - “Directive to Physicians”

*How should you proceed if a person has not executed a “Directive to Physicians” or is incompetent or incapable of communication? If an adult qualified patient has not executed or issued a directive and is incompetent or otherwise mentally or physically incapable of communication, the attending physician and the patient's legal guardian or an agent under a medical power of attorney may make a treatment decision that may include a decision to withhold or withdraw life-sustaining treatment from the patient. See §166.039(a).*

*What if the patient doesn't have a legal guardian? If a patient does not have a legal guardian or agent under a medical power of attorney, the attending physician and one person (from the categories below, in the priority listed), may make a treatment decision that may include a decision to withhold or withdraw life-sustaining treatment:*

- Patient's spouse;
- Patient's reasonably available adult children;
- Patient's parents; or
- Patient's nearest living relative. See §166.039(b).

*What if a person does not have a legal guardian or one of the relatives listed above is not available? A treatment decision made under Subsection (b) must be concurred in by another physician who is not involved in the treatment of the patient or who is a representative of an ethics or medical committee of the health care facility in which the person is a patient. See §166.039(e).*

# Problems with Advance Directives and Living Wills

Prior to the adoption of Electronic Medical Records (EMRs), it wasn't uncommon for the existence of an Advance Directive to be missed by treating physicians. This might lead to an inadvertent violation of its terms.

Family members may not be aware that a patient has executed an Advance Directive or Living Will and may instruct health care providers to provide life-prolonging treatment (in contradiction of the patient's wishes). Family members later often found copies of Advance Directives in a patient's Safe Deposit Box or other personal records.

"Oral" revocations of a Directive can get complicated. Under Texas Law, A declarant may revoke a Directive at any time without regard to the declarant's mental state or competency. See §166.007.

# Law Enforcement Initiatives Focused on Nursing Homes

- *National Nursing Home Initiative (Initiative)*. Started pre-COVID, the Initiative has targeted nursing homes around the country identified as “Problematic.” Targeted nursing homes include, but are not limited to those that:
  - (1) Consistently fail to provide adequate nursing staff to care for their residents;
  - (2) Fail to adhere to basic protocols of hygiene and infection control;
  - (3) Fail to provide their residents with enough food to eat so that they become emaciated and weak
  - (4) Withhold pain medication
  - (5) Use physical or chemical restraints to restrain or otherwise sedate their residents.
  - (6) Provide grossly substandard care also force vulnerable elderly residents who cannot leave the facilities to live in filthy and dangerous conditions where there are leaks in the roofs, mold is found growing and rodents found living in residents’ rooms.

# Law Enforcement Initiatives Focused on Nursing Homes

- *National Nursing Home Initiative (Initiative), Continued:*
- *Use of physical or chemical restraints to restrain or otherwise sedate their residents.* This issue was recently highlighted in a New York Times article dated September 12, 2021, titled "*Phony Diagnoses Hide Rates of Drugging at Nursing Homes.*"
- As the article detailed, a New York Times investigation found that some providers were improperly adding diagnoses of schizophrenia in order to justify the ordering of Haldol.
- As the article further details, based on Medicare data, the share of nursing home residents with a schizophrenia diagnosis has risen 70% since 2012.
- Federal prosecutors and state regulators are carefully assessing this issue.

# Law Enforcement Initiatives Focused on Nursing Homes

- Provisions of the False Claims Act? (31 U.S.C. § 3729-3733). Simply put, the Federal civil False Claims Act (FCA) imposes civil monetary penalties and damages on any person who *knowingly* submits, or causes to be submitted, a false claim to the government for payment.
  - The term "*knowingly*" does not merely mean "*actual knowledge*," the term also includes *reckless disregard and deliberate ignorance*.
- Statute of Limitations Under the False Claims Act. Generally, the False Claims Act has a six-year statute of limitations that can be tolled (under certain circumstances) up to a maximum of ten years from when the government knew, or reasonably should have known, that the violation occurred. 31 U.S.C. § 3731(b).
- Damages and Penalties under the False Claims Act. A person found to have violated this statute may be liable for both civil penalties and treble damages.
  - As of today, the minimum penalty that may be assessed *PER FALSE CLAIM* is \$11,803, and the maximum penalty is \$23,607.

# Law Enforcement Initiatives Focused on Nursing Homes

Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)). Under the Anti-Kickback Statute, it is a crime to *knowingly and willfully* solicit, receive, offer, or pay any remuneration in return for: (1) referring or arranging for services payable by any Federal or State health care program; or (2) purchasing, leasing, ordering or arranging for any goods, facilities or services that may be paid for in whole or in part by any Federal or State health care program 42 U.S.C. § 1320a-7b(b)(2012).

- Under § 6402(f)(2) of the Affordable Care Act:
- "A person need not have actual knowledge of this section or specific intent to commit a violation of this section." (emphasis added).
- This change is noteworthy. It effectively lessens the requirements needed for the government to bring a criminal case under the Anti-Kickback Statute.
- Penalties under the Anti-Kickback Statute:
  - Felony / 10 years in prison / \$100,000 criminal fine.
  - Exclusion from Federal health benefits programs.
  - May be pursued as violations of the civil False Claims Act.

# Law Enforcement Initiatives Focused on Nursing Homes

*Kentucky.* In this case, two nursing home chains and their principals were sued under the False Claims Act due to allegations of kickbacks from a pharmaceutical company promoting its anti-psychotic drug. The government further alleged that the pharmaceutical company regularly paid kickbacks to nursing homes by providing consultant pharmacist services at rates below the company's cost and below the fair market value of such services in order to induce the homes to refer their patients to their company for pharmacy services. The pharmaceutical manufacturer agreed to pay \$112 million under the False Claims Act.

*Texas.* In this case, a company providing rehabilitation services allegedly offered illegal inducements to skilled nursing facilities and physicians. The inducements took the form of nurse practitioners who worked at client nursing homes without charge or for a nominal, below fair market fee in order to induce or reward nursing homes for contracting with their company to provide rehabilitation therapy for their residents. The rehabilitation services company agreed to pay the government \$6.1 million.

*Missouri.* In this case, a company providing rehabilitation services allegedly provided unnecessary physical, speech and occupational therapy to nursing home residents who had a relatively high level of independence and who were residing in a skilled nursing facility primarily because of a psychiatric condition. The rehabilitation services company agreed to pay the government \$8.3 million.

# Steps You Can Take to Strengthen Your Compliance Efforts

## Gifts, Business Courtesies, and Kickbacks

### Kickbacks & Disguised Kickbacks and Bribes

- Be especially careful before your nursing home enters into a business arrangement with a laboratory, compounding pharmacy, DME company or other 3rd party health care provider or supplier.
- A continuing concern of the government involves lease arrangements with actual and / or potential referral sources.
- Take care when engaging a medical director for your organization. Have the contract vetted by a health lawyer. This is especially important if you receive referrals from this individual.
- Participating in a sham loan arrangement with an entity from whom you receive referrals.
- Acquiring or having a financial interest in an entity from whom you receive referrals.
- Giving any type of remuneration (something of value), such as a gift card, sporting event tickets or liquor, to a referral source.

# Questions?

---

THANK YOU

