FHCA 2019 Annual Conference & Trade Show

CE Session #41 – Regulatory and Case Law Update
Wednesday, August 7 – 10:30 to 11:30 a.m.
Windermere X – Legal/Regulatory/Survey

Upon completion of this presentation, the learner will be able to:

- Identify regulatory changes
- Understand the objectives of the federal regulations as evidenced by the interpretive guidelines
- Ensure understanding of the policies and procedures employed by the surveyors to interpret certain regulations

Seminar Description:

This session will focus on regulatory changes (state and federal) in the last year, including changes in interpretive guidelines and policies and procedures as well as actual regulatory changes. A discussion of case law will be included.

Presenter Bio(s):

Karen Goldsmith currently serves as FHCA's Regulatory Counsel and previously served as the association's Legal Counsel since 1980. She is on the American Health Care Association's Legal Subcommittee and served as its Chair for three years. She is active in the American Health Lawyers Association and served as Chair of their long term care subgroup for two years. She has been published in several books produced by AHLA. She practices primarily in long term care.

Regulatory and Case Law Update

FHCA 2019 ANNUAL CONFERENCE & TRADE SHOW

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- CAVEATS:

This presentation is not legal advice but general legal and factual information

When **PROPOSED RULES** are discussed this refers to the Rules recently published by CMS for comment which are not in effect and may not be in effect by November 28 when Phase III kicks in. They may change before finalization. These are being given to the audience for information only.

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I. IDR vs IIDR

Informal Dispute Resolution:

>Is a federal requirement

>Does not include N tags but if N tag results from same facts as F tag AHCA typically changes both

>Involves telephone hearing

>Panel consists of 2-4 AHCA employees with knowledge of ROP's

>Area Office can have as many on phone as they want

>Each side tells its story

>Should submit written narrative – don't read – know your material

>Documentation supporting your position should be offered in a concise, easily readable manner and highlighted and tabbed to match your narrative

>If new issues raised by oral presentation, panel will let you submit additional documents

>Panel makes recommendation to Kim Smoak

>Kim makes decision subject to approval by CMS-Atlanta

>Presentation should be made by those most familiar with the underlying facts and center's processes

>Administrator typically part of the presentation

>Facility clinicians should speak about clinical issues

>There may be a role for outside experts or regional people

>Attorney may be present but cannot participate

>Opportunity to present information that you may not have had when survey conducted such as information supplied to you by a hospital or a vendor of product involved

Independent Informal Dispute Resolution:

>Preparation is much the same

>Panel is totally independent of survey team and AHCA

>Often no conference but all done with paper

- We have seen no clear difference between results of each
- Benefit of IIDR is that if you do not ask for IDR within timeframe of POC you may get second chance
- You cannot fight low level scope and severity – if low level tag have to argue facts of tag
- You sometimes get one or more examples removed which may have the effect of lowering scope and severity
- Good opportunity to learn what the surveyors were thinking when you were cited

- Results of IDR cannot be appealed
- Pending IDR or IIDR does not stop penalty clock

PROPOSED CHANGE IN REGULATION:

>Will require completion of IDR in 60 days which is what IIDR now requires. This has not been a problem in Florida.

>Results of surveys will not be uploaded until completion of IDR or IIDR

II. Hemp and CBD Oil

- CBD Oil has been around for years and sold at various locations
- It technically is a hemp product
- Technically it was an illegal substance under federal and state law
- Recently the federal government removed hemp as an illegal substance under the Farm Bill
- As of July 1, state law made hemp legal
- CBD oil is subject to regulations which have been published but not yet promulgated

- CBD Oil is derived from hemp, not the marijuana plant
- It is the non-psychoactive compound found in cannabis
- Hemp is used for over 25,000 manufactured items
- Until the law changed July 1, hemp was included in the statutory definition of cannabis as an illegal drug
- The regulations Florida passes must be approved by the federal government
- Growers will be highly regulated and required to be licensed

- Nikki Fried, Commissioner of Agriculture, is a strong proponent of hemp production and use so process should move quickly

- CBD Oil is found to:
  - Reduce seizures
  - Relieve pain
  - Relieve anxiety
  - Reduce depression

- In other states, research on CBD Oil has been conducted and the medicinal claims seem to be supported
- Anecdotal data is growing on the positive effects of CBD Oil

- Great grandmother arrested at local theme park for possession of CBD Oil - WHY?
  - It has not been regulated so there is concern that one is buying a marijuana product
  - No standards for quality and purity
  - No matter how much is used if it is processed properly and is pure it should not give anyone a high

- Issue unique to southern climates:
  - CBD Oil cannot contain more than 0.3% THC which is the component of marijuana that creates the euphoric state, high temperatures during growing can increase the level of THC so agricultural precautions are necessary

- Proposed regulations will address:
  - Hemp meant for ingestion must be obtained from a state-approved source
  - It must originate from a crop intended to be used in the food supply chain
  - Hemp meant for bodily application will be under the Florida Drug and Cosmetic Act
  - It must be stored and transported at low temperatures
  - It must be stored without exposure to light
  - THC must be less than 0.3%
  - Specific labeling required

III. Proposed revisions to the ROP's

- Published by CMS Thursday, July 18
- 60 days to file comments and concerns
- Feds then have time to review and act on comments and concerns
- No time limit
- When review completed rules with changes, if any, will be published as final
- Typically 30 day window for implementation
- May not be in effect before November 28 when Phase III goes into effect – should continue as you are

Most important proposed changes:

- Resident rights:
  - Center must provide primary care physician's name and contact information upon admission and when information changes or resident requests

- Grievances:
  - No discrimination or reprisal
  - Grievance is with respect to care and treatment as well as that not delivered
  - Behavior of staff
  - Behavior of other residents
  - Other concerns "[which] differ from general feedback from residents or their resident representative"
  - Right for center to make prompt efforts to resolution
  - Must give notice can file in writing or orally
  - Can file anonymously

- Notice of right to reasonable timeframe for resolution
- Notice of right to written decision
  - Includes pertinent information
  - Including but not limited to summary of findings or conclusions
  - Corrective action to be taken

Must maintain evidence for 18 months (now 3 years)

Remainder of rule will not change

- Admissions, Transfer and Discharge:
  - No longer would have to give notice to Ombudsman of emergency transfers to hospital when return is expected

REMEMBER THESE ARE PROPOSED – NOT IN EFFECT

- Pharmacy:
  - Permits orders beyond 14 days for psychotropic drugs if physician documents in medical records and states duration – FACILITY MUST HAVE POLICY
  - Policy must:
    - Take into account resident population
    - Use recognized standards of practice
    - Individual resident's need for psychotropic drugs
    - Resident's access to physician and other health care practitioners
    - Include standards re PRN review no less than frequency of required physician visits

- Documentation must include:
  - Diagnosis
  - Indications for use
  - Nursing documentation that supports the administration
  - Justification for prolonged use

Must make disclosures to resident or representative if prescribed an anti-psychotic

- Food and Nutrition
- If qualified dietitian or other clinically qualified nutrition professional is not employed full time must designate person as director of food and nutritional services who:

  * has at least 2 or more years experience in that position in a nursing facility

  * has completed course of study in food safety and management (rule includes certain subjects)

  * Need consultant

- Administration – facility assessment:
  - Must perform assessment to determine necessary resources to care for residents day-to-day and in emergency
  - Must use assessment to prepare policies and procedures
  - Must be reviewed and updated as necessary but at least every 2 years or when substantial change would require modification
  - Elements now in rule remain

- QAPI:
  - Must be ongoing, comprehensive and capable of addressing all aspects of care and services
  - Must have and implement written policies and procedures for feedback, data collection, monitoring which includes adverse event monitoring
  - Must take action to improve performance, implement, monitor and measure success and track performance to ensure improvements are realized and sustained

- Compliance and Ethics:
  - Program must be reasonably designed, implemented and enforced to be effective in preventing and detecting criminal, civil and administrative violations
  - Must promote quality of care
  - Required components for all facilities
    - Effective written standards, policies and procedures
    - Reasonably capable of reducing violations
    - Specific individuals within the organization with overall responsibility for program
    - Must be in high level positions
    - Sufficient resources and authority

- Due care to avoid giving substantial discretionary authority to individuals in organization who have propensity to engage in violations
- Effective communication with staff, contract service personnel and volunteers
- Includes mandatory training in accordance with role
- Monitoring and auditing systems
- Effective reporting system
- Consistent enforcement
- Discipline including for failure to report
- Steps to ensure a problem detected has an appropriate response

- Organizations with 5 or more facilities:
  - *Have a more formal program that includes established written policies defining standards and procedures to be followed by its employees*
  - *Develop a program…appropriate for the complexity of the organization….*

All facilities must have periodic review and revision

Remember these are proposed rules which are not yet effective

- Physical Environment:
  - Specific provision for fire safety if certified before July 5, 2016
  - Need sufficient space
  - Conduct regular inspection of bed frames, mattresses and bed rails
  - Ensure compatibility of bedrails, mattresses, and frames
  - No more than 4 residents in a room. *FOR FACILITIES THAT RECEIVE APPROVAL OF CONSTRUCTION PLANS BY STATE AND LOCAL AUTHORITIES OR ARE NEWLY CERTIFIED AND HAVE NEVER PREVIOUSLY BEEN A LTC FACILITY AFTER NOVEMBER, 28, 2016,BEDROOMS MUST ACCOMMODATE NO MORE THAN 2 PERSONS*

- Bathrooms must be near resident rooms if not within room
- For facilities as per the previous slide each room must have a bathroom with a commode and a sink

- IMPORTANT:

RULES ARE WRITTEN TO DELAY IMPLEMENTATION OF:

Certain part of QAPI

Compliance and Ethics

Training elements

For one year, however, until rules are adopted should proceed as if that will not occur.

- Other areas not discussed:
  - Bed rail changes
  - Nursing service data retention requirements
  - Behavioral health service changes
  - Infection control change regarding infectionist
  - Training changes

IV: Arbitration

Has been controversial

* Right to a jury trial is constitutional but can be waived so long as done voluntarily and knowingly

* Federal Arbitration Act promotes the use of arbitration in settling disputes

* Nursing facilities have been singled out as one area where arbitration should not be used

*Arbitration has many advantages including speedy resolution of issue, more realistic judgments and thus settlements

*Much less stressful on the parties

- States must comply with the federal arbitration requirements because of the Supremacy Clause
- State courts cannot pass a law that forbids arbitration
- State courts, however, to an extent, are free to interpret the content of the contract for arbitration in accordance with state law
- Several years ago CMS put forward a regulation that would eliminate the use of arbitration clauses in nursing home contracts
- That decision was challenged in court and held unconstitutional and the regulation was suspended

- Why is arbitration favored:
  - Faster
  - Cheaper
  - Arbitrators make more reasonable judgments than many juries
  - Juries are often not business people and do not make business judgments
  - Smaller panel of arbitrators

- Terms of an arbitration agreement are set out in the contract between the parties
- For nursing home contracts regulations play a role
- On July 18, 2019 CMS published its FINAL rule on arbitration agreements in nursing home contracts which did the following:
  - Facility must not require a resident or representative to sign a binding arbitration agreement as a condition of admission or continued stay
  - Must explicitly advised resident of this right
  - Agreement must be explained in a language and manner resident understands

- Resident or representative must acknowledge that he or she understands the agreement
- Agreement must provide for a neutral arbitrator agreed to by both parties
- Agreement must have a venue convenient to both parties
- Must have explicit right to rescind the Agreement within 30 calendar days of signing
- Must include the language re not condition or admission or continued stay
- *…may not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state or local officials, including but not limited to federal and state surveyors, other federal or state health department employees, and representatives of the* Ombudsman.

Rule requires that when a matter is resolved through arbitration, a copy of the signed agreement and the final decision must be retained for 5 years after the resolution and available for inspection by CMS or designee

- Except for administrative things such as keeping records and what must be in disclosure and acknowledgement this type of arbitration agreement is widely used in Florida

- State law has been used to overturn a number of arbitration agreements:
- In Mendez v Hampton Court, the Florida Supreme Court held that the agreement was not enforceable because the son did not have the authority to bind the father to an arbitration agreement

- If a competent resident signs an arbitration agreement that meets the federal and state law (contract) requirements it is most likely enforceable
- Agreements signed on behalf of the resident by third parties may or may not be enforceable depending on the factual circumstances and the source and depth of the legal authority of the third party

- Arbitration vs Mediation:
  - Mediation is a tool often used by the courts to settle disputes through agreement
  - Mediators are go-betweens who assist the parties in working out an agreement they can live with
  - Mediators must keep information shared by party confidential unless that party waives the right

- Arbitration is a decision made by one or more third parties
- Both parties tell their story
- The arbitrator's decision is binding and in some cases, not appealable
- Evidentiary rules are used but relaxed
- Arbitrators may encourage settlement but that is not their role
- Their role is to decide the case and set the amount of damages, if any

- Regulations and law cited herein should be reviewed by the reader and the reader should not rely on the presenter's interpretation.
- Rules set out herein are mostly in the adoption process and are not effective until adopted by CMS and implemented
- The part of the rules discussed herein is not the entire rule but only the part changed. Changes must be read in context with the entire rule.
- This document is not legal advice. Consult your center's attorney for specific legal advice.