Leading Age Tennessee
Annual Meeting
July 30, 2019

Successfully Navigating the Regulatory Landscape

A Former Surveyor's Perspective

William M Vaughan RN, BSN
Vice President, Education and Clinical Affairs
Remedi SeniorCare

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DISCLOSURE/CONTACT

- Remedi SeniorCare
- Advisor, ISMP LTC Newsletter

- william.vaughan@remedirx.com

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ISMP Institute for Safe Medication Practices
A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

"Welcome to the ISMP ***Long-Term Care Advise-ERR***, a medication safety newsletter designed specifically to meet the needs of administrators, nursing directors, and nurses who transcribe medication orders, administer medications, monitor the effects of medications on residents, and/or supervise those who carry out these important tasks."

http://www.ismp.org/Newsletters/longtermcare/default.aspx

Jan/Feb 2019

Death Associated with Unnecessary Continuation of Venous Thromboembolism (VTE) Prophylaxis After Hospital Discharge

Your Reports at Work: FDA tells pen injector needle manufacturers to improve patient instructions

Entire bottle of nitroglycerin given, again!

Don't "hold" onto that patch!

Unsafe practices abound!

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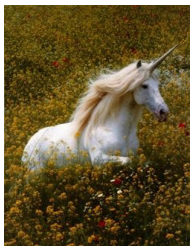
REGULATORY MYTHS VERSUS CLINICAL REALITIES



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WHY REGULATE NURSING HOMES ?

- State license
  - •protect the vulnerable
- Federal certification
  - •protect the $$$

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YOU MUST STRICTLY COMPLY WITH?

- Regulations
- Standard of care
- Guidance to surveyors
- Policies and procedures

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FEDERAL REGULATIONS … THE BOTTOM LINE

➢**Quality of Care**

- If possible, make me better …
- If that's not possible, keep me stable …
- If that's not possible, slow my decline …
- Don't make mistakes that hurt me

➢**Quality of Life**

- Keep "me" involved
- Let me say yes … and no
- You're my partner, not my parent
- Always treat me as a person, not a patient

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RESIDENT CHOICE / FACILITY RESPONSIBILITY WHERE IS THE LINE?

Surveyor Guidance – F 552 (care planning)

While Federal regulations affirm a resident's right to participate in care planning and to refuse treatment, the **regulations do not require the facility to provide specific medical interventions or treatments requested by the resident, family, and/or resident representative that the resident's physician deems inappropriate for the resident's medical condition.**

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RESIDENT CHOICE / FACILITY RESPONSIBILITY WHERE IS THE LINE?

Surveyor Guidance – F 689 (accidents)

… **regulations do not create the right for a resident, legal surrogate, or representative to demand the facility use specific medical interventions or treatments that the facility deems inappropriate**. The regulations hold the facility ultimately accountable for the resident's care and safety. Verbal consent or signed consent forms do not eliminate a facility's responsibility to protect a resident from an avoidable accident

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RESIDENT CHOICE / FACILITY RESPONSIBILITY WHERE IS THE LINE?

Resident Autonomy / Regulatory Requirements

F 758 (Psychotropic Drugs)

Residents who use psychotropic drugs receive **gradual dose reductions**, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs

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REGULATIONS

- Broadly written minimum standards
  - " … regulations establish the outcomes which facilities must achieve **but provide each facility with flexibility to select methods to achieve them** that are appropriate to its own circumstances and needs …" (Departmental Appeals Board, Decision # 2339, September 30, 2010)
- Flexibility varies
  - Pressure ulcers verses quarterly assessment

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" … BUT PROVIDE EACH FACILITY WITH FLEXIBILITY TO SELECT METHODS TO ACHIEVE THEM …"

- ➢Evidenced based / sound rationale
- ➢Comprehensive risk versus benefit analysis
- ➢Resident / decision maker involvement

❑ Example:
- "Delay" in hospitalization
- Administration of synthroid

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HOW DO SURVEYORS DETERMINE COMPLIANCE WITH SOMETHING LIKE THIS?

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

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STANDARD OF CARE

- No universally accepted definition
- "same degree of knowledge, skill, and ability as an ordinarily careful professional would exercise under similar circumstances."
  - Illinois Supreme Court
- "the average degree of skill, care, and diligence exercised by members of the same profession, practicing in the same or similar locality in light of the present state of medical and surgical science."
  - Black's Legal Dictionary

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GUIDANCE TO SURVEYORS

➢**Thomas Hamilton, S&C-08-10, January 18,2008**

- "In providing [new] interpretive guidance, CMS is careful not to prescribe new requirements. Instead, the focus is on relaying to surveyors information consistent with the regulations and accepted standards of care."
- " … surveyors must base all cited deficiencies on a violation of statutory and/or regulatory requirements, **rather than sections of the interpretive guidelines**."

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POLICIES AND PROCEDURES

- Failure to follow = federal deficiency?
- Can facilities develop P&P > regulations?
  - Examples:
    - Frequency of consultant pharmacist visits
    - Posting of deficiencies
- Exception: F 607
  - "The facility must develop **and implement** written policies and procedures that prohibit and prevent abuse …

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" … The ALJ noted that HCFA itself conceded that "failure by a facility to comply with a protocol is **not** a failure to comply with a participation requirement where the protocol does not comport with a professionally recognized standard of care and where the participation requirement does not direct a facility to follow each of its internal protocols …"

DATE: April 29, 1998
In the Case of:
Lake City Extended Care Center,
Petitioner,
- v. -
Health Care Financing Administration.
Civil Remedies CR494
App. Div. Docket No. A-98-13
Decision No. 1658

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What about this?

§ 483.75(i) Medical Director
(1) The facility must designate a physician to serve as medical director.
(2) The medical director is responsible for –
(i) **Implementation of resident care policies**; and
(ii) The coordination of medical care in the facility.

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MUST STRICTLY COMPLY WITH:

- Regulations 
- Standards of care 
- Guidance to surveyors * 
- Policies and procedures * 

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ARE SURVEYORS RESIDENT ADVOCATES?

- Surveyors tend to think this way, but …
- They should be objective and evidenced based
  - Not pro-resident or pro-facility
- Dangerous thinking
  - Facility staff always lie
  - Residents, families, complainants always tell the truth
- More like umpires calling balls/strikes
  - Either the regs were met or they weren't
- The surveyor "said" …..
- Thoughts on surveyor motivation

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STEPS TO SURVEY SUCCESS

- Pre-survey facility success
  - Problematic operations can't be "fixed" for the survey
  - QA activity can mitigate the damage
- Staff preparation
  - Leadership must set the appropriate tone
  - Consider mock surveys, med pass observations, etc.
  - Don't forget consultants, vendors, volunteers, etc.
- Resident/family preparation
  - Newsletter, signage, staff interaction

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STEPS TO SURVEY SUCCESS

- **Demonstrating compliance**
  - Documentation
  - Discussion
  - Disputing

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DOCUMENTATION

➢ *If it isn't written, it didn't happen*

- How about the converse, "*If it is written, it did happen*"
  - Food intake = 75%, normal BM x 1, slept soundly (resident died the evening prior to the writing of this note)
  - Turn and reposition q 2 hours signed off on TAR x 4 days (resident hospitalized the entire time)
  - Medications signed off as administered every day at 12 noon (resident out to dialysis qod)

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IF IT ISN'T WRITTEN, IT DIDN'T HAPPEN?

- Documentation is important, but one dimensional
- SOM replete with admonition to surveyors to talk (and listen) to the facility's staff, residents, families, ombudsman, etc.
- Use other sources of data (911 tape, ER record, autopsy report, controlled drug record)

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DISCUSSION

- View discussions with surveyors as a positive
- Reinforce this perspective with your staff
- Best answer to a surveyor's question:
  - *"Let me look into this and I will get back to you"*
- Expect to be quoted in the 2567
- Discussion is the best method to supplement "weak" documentation
  - **Never** sacrifice credibility

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THE VALUE OF A CONSULTANT'S PERSPECTIVE

- Subject matter expert
  - Standard of care
  - Knowledge on current / evolving research
  - Articulate risk/benefit analysis
- Viewed as not directly under the facility's control and therefore more "credible"
- Case example: consultant pharmacist

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DISPUTING (IDR / IIDR)

- Failing to challenge inaccurate deficiencies reinforces surveyor behavior
- State agency QAPI
- Past deficiencies → future enforcement
- 5 star rating
- Effective IDR
  - Fact pattern
  - Regulatory requirement
  - Standard of care

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CHALLENGING SURVEYORS → RETRIBUTION?

- Perception verses reality
- What is retribution?
  - Baseless deficiencies
  - Increase enforcement
  - Benefit of the doubt ***

- Keep complaints regarding surveyors and deficiency disputes separate
- The state agency wants to know about conflicts of interest, unprofessional behavior, threats, etc..
  - Try to quantify the issue
- It's how the challenge is performed that matters

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REGULATORY PEARLS

- The medical record is accurate until proven otherwise (weights, fluid intake, VS, etc..)
- A documented allergy is accurate until proven otherwise
- Dramatic weight change over a short period of time = fluid and must be promptly addressed
- The timeliness of many interventions is not defined in the regs but rather is based on the needs of the resident

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REGULATORY PEARLS

- Unless defined by facility policy, the use of terms such as “no heroics” and “comfort care only” is problematic
- CPR (providing/withholding) related deficiencies often involve sanctions
  - Poor outcome statistics
  - Informed consent?
  - Facility process

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CPR IN LTC
LONG ON EFFORT … SHORT ON RESULTS?

- CMS Memo (S&C: 14-01-NH): Cardiopulmonary Resuscitation (CPR) in Nursing Homes (10/18/13)
- ➢ Basic life support including CPR **must** be provided unless:
  - ➢ DNR order
  - ➢ Advance directive refusing CPR
  - ➢ Signs of clinical death present
    - ➢ Rigor mortis
    - ➢ Dependent lividity
    - ➢ Decapitation
    - ➢ Decomposition

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WHAT ABOUT .....

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REGULATORY PEARLS

- Failing to follow this geriatric principle puts the facility and resident at risk:

  "Any symptom in an elderly patient should be considered a drug side effect until proven otherwise." -- J. Gurwitz et al. Brown University Long-Term Care Quality Letter, 1995.

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REGULATORY PEARLS

- The best way to avoid being “second guessed” on clinical decisions is to document a thoughtful risk/benefit analysis (or at least be able to articulate it)
- Poor communication is the genesis for many deficiencies
  - Transitions in care
- Medications should be monitored for effectiveness as well as adverse reactions

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REGULATORY PEARLS

- Understand what immediate jeopardy is (and isn't):
  - Immediate Jeopardy is interpreted as a crisis situation in which the health and safety of individual(s) are at risk (see SOM §3010)
- Never alter a medical record to prevent a deficiency … credibility is everything and hard to regain
- When the facts are clear, consider agreeing with the surveyor … or at least remain silent

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REGULATORY PEARLS

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QUALITY ASSURANCE / PERFORMANCE IMPROVEMENT

- If the survey team has identified a current issue which will be cited at S/S level of E or above, or has identified substandard quality of care, the surveyor conducting the QAPI/QAA Review should consider if the facility's monitoring systems should also have identified the same issue.

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QUALITY ASSURANCE / PERFORMANCE IMPROVEMENT (QAPI) MULTIPLE REGULATIONS – EFFECTIVE NOVEMBER 28, 2019

PROCESS MANDATES

- **Collect** / analyze **data**
  - *High-risk, high-volume, and problem-prone issues such as medical errors and adverse events*
- **Determine** causes / contributing factors
- **Develop** / implement corrective action
- **Monitor data** to determine effectiveness

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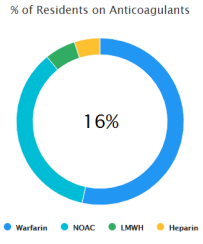

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Date Range
11/1/2017
to
11/30/2017
Anticoagulant Orders by Med Category
Warfarin
NOAC
LMWH
Heparin
0
10
20
30
40
50
60
Orders
Demo Facility 875
Anticoagulant Orders by Prescriber
Generic Prescriber 5924
Generic Prescriber 9477
Generic Prescriber 5968
Generic Prescriber 8926
Generic Prescriber 6472
Other Prescribers
0
10
20
30
40
50
Orders
Heparin
LMWH
NOAC
Warfarin
ALL ANTICOAGULANT MEDICATION DETAILS
Download Excel
Facility
Order Date
Resident
Medication
Category
NS/Room
Demo Facility 875
10/5/2017
Doe, Resident
Warfarin Sodium - 2.5MG - TABS
Warfarin
Nursing Station / SMP263
Demo Facility 875
1/5/2016
Doe, Resident
Rivaroxaban - 20MG - TABS
NOAC
Nursing Station / SMC223
ADMINISTER 1 TABLET BY MOUTH ONE TIME A DAY FOR AF CLOT PROPHYLAXIS
Route: ORAL
Not Profile Only
Prescriber: Generic Prescriber 6619

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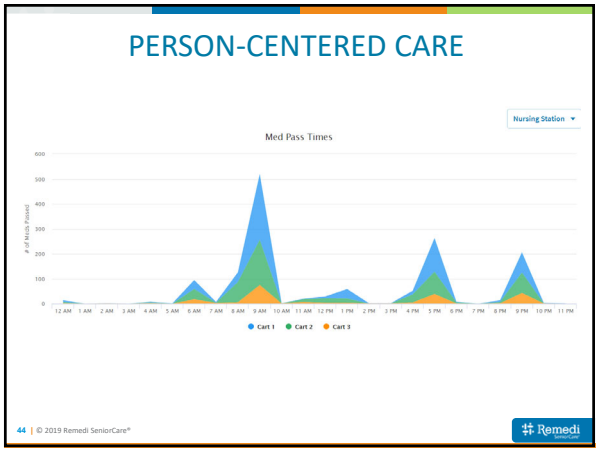
PERSON-CENTERED CARE
Nursing Station
Med Pass Times
600
500
400
300
200
100
0
# of Meds Passed
12 AM
1 AM
2 AM
3 AM
4 AM
5 AM
6 AM
7 AM
8 AM
9 AM
10 AM
11 AM
12 PM
1 PM
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Cart 2
Cart 3
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Compliance is best achieved by focusing your attention on residents … not on regulations
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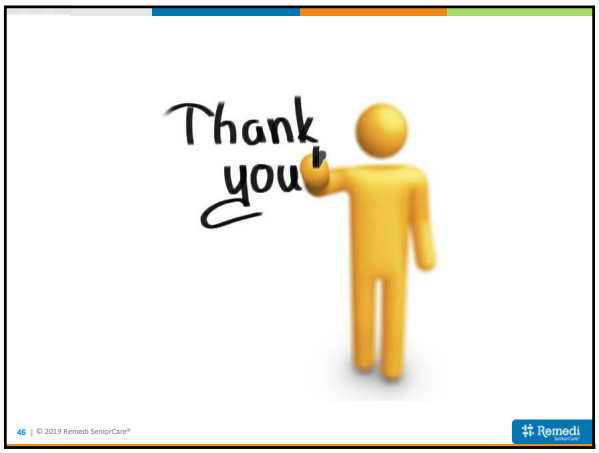

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