Current Legal and Regulatory Challenges in Long Term Care

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Janet Feldkamp

Janet focuses her practice in the area of health care law, including long-term care survey and certification, state and federal regulation, physician and nurse practice, and fraud and abuse involving hospitals, suppliers, insurers and physicians. She retains active licenses as a registered nurse and a nursing home administrator and has extensive health care experience.

Janet is a member of the editorial advisory board of Caring for the Ages, a monthly newspaper for long term care practitioners. She has been a frequent speaker, particularly in the area of long term care and is the co-author of The Law of Medical Practice in Ohio, Second Edition. She is also co-author of The Long Term Care Handbook: Regulatory, Operational and Financial Guideposts published by the American Health Lawyers Association.

Overview

• Survey & Enforcement
  – Recent releases
  – Trends
• HIPAA issues
• Compliance issues
• OIG Workplan 2013
• Tidbits
Survey & Enforcement

Nursing Facility Characteristics
- December 2012
- Nationwide
- Facilities 15,677
  - Multi-facilities 54.7% (2 or more)
  - Independent: 45.3%
  - Hospital-based: 6.2%
*American Health Care Association Statistics, December 2012

Ownership Type
- 69.2% for profit
- 25.0% nonprofit
- 5.8% government
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Facility Certification
- Includes only certified facilities, some facilities remain state licensed only
- Medicare only 5.0%
- Medicaid only 3.5%
  - (not permitted in some states)
- Medicare & Medicaid 91.5%

Direct Care Staffing
- Average full-time direct care staffing (35 hour week)
- Nationwide: Total direct care staff 65.83 FTE
  - RN 7.73
  - LPN 14.76
  - Aide 43.33
- Lowest total staffing: Iowa 38.82 FTE
- Lowest RN staffing: South Dakota 2.15 FTE

Average PPD
- Nationwide for direct care staff per patient per day
  - Highest state:
    - Alaska 6.30
  - Lowest state:
    - Illinois 3.16
Median Occupancy Rate

Nationwide:
• 82.9% certified bed occupancy

Highest state: District of Columbia:
• 96.2% certified bed occupancy

Lowest state: Oregon:
• 60.3% certified bed occupancy

OBRA Enforcement Rule

Isolated

1

Immediate Jeopardy (Fast Track)

• Temporary Manager
• Terminate Provider Agreement
• Civil Money Penalty
$3,050 - $10,000 per day
• Deny Payment for New Admissions
• Deny All Payment
• Directed PoC
• State Monitoring
• Directed Inservices

Pattern

2

Widespread

3

Abuse & Neglect

• Resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion. (42 CFR 483.13(b))

• “Neglect” means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (42 CFR 488.301)
Elder Justice Act

- Subtitle H (Section 6701 et seq.) of Patient Protection and Affordable Care Act (PPACA)
- Amends Title XX of the Social Security Act (42 U.S.C. § 1397 et seq.)
- Notification of Law Enforcement
  - Within 2 hours with serious injury or death
  - Within 24 hour others
- Allegation triggers requirement
  - Actual knowledge not required
  - Allegation only


- June 2011 CMS issued guidance
- S & C: 11-30-NH Issued June 17, 2011
- Provided some additional guidance to the State Agencies as well as providers

Elder Justice Provisions

- Substantial penalties
  - Fines
    - $200,000
    - $300,000 if failure to report exacerbates the harm to the victim or result in further harm
    - HHS to take into consideration financial burden on providers in underserved areas
  - Exclusion
    - Exclusion from Medicare/Medicaid participation for individuals for 2 years
Elder Justice Provisions

- Posting of requirements
  - Post sign
  - Employee may file complaint against the facility for violating reporting provisions
  - Must include how to file a complaint
  - Conspicuous location
- Policies and procedures
  - Review all policies and procedures related to abuse, neglect and exploitation
- Train employees
- No retaliation

Quality Alert: Handling Notification

- Have a routine process
- Late notification: damage control
- Reaching out for assistance
- Thorough investigation with excellent documentation

Nursing Home Quality Assurance and Performance Improvement (QAPI) Guide

- CMS S &C: 13-05-NH; December 14, 2012
  - Updates S & C: 11-22 from April 8, 2011
- Preview of QAPI Guide
- Core set of materials to be provided on CMS website
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QAPI
Data-driven, proactive approach to improve quality of life, care and services
5 strategic elements for a program:
1. design and scope
2. governance and leadership
3. feedback, data systems and monitoring
4. performance improvement projects
5. systematic analysis and systemic action

Fire Safety Requirements
- CMS S &C: 09-04; October 3, 2008
- 73 FR 47075 published August 13, 2008
- Effective date August 13, 2013
- Requires completed supervised automatic sprinkler system
- Required compliance

Immediate Jeopardy Trends
- Abuse and neglect
- Sexual abuse (by visitors & others)
- Falls, accident hazards, accident supervision
- Elopements
- Side rail entrapment and restraint issues
- CPR/DNR and other issues related to resuscitation
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Immediate Jeopardy Trends

- Change of condition and professional standards of nursing care
- Pressure ulcers
- Laboratory monitoring—anticoagulants and other medications requiring periodic levels
- Infection Control: c. diff.; others

Top 10 Citations: Nationwide

1. F441: Infection control
2. F371: Store, prepare and distribute food
3. F323: Accident hazards
4. F309: Quality of Care
5. F279: Care plan
6. F329: Unnecessary drugs
7. F431: Labeling of drugs and biologicals
8. F241: Dignity
9. F514: Clinical records
10. F281: Professional standards of nursing care

Top Citations on Complaint Surveys

- F323: Accident hazards
- F309: Quality of Care
- F225: Abuse
- F157: Notification of change
- F514: Clinical records

More likely to result in actual harm or above
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Citation Trends

Relatively Stable
- Citations per survey **6.1**
- Facilities in substantial compliance **10.3%**
- Substandard care surveys **3.0%**
- Immediate jeopardy surveys
  - 2011: **2.4%**
  - 2012: **2.2%**

Draft CMS Pilot Project CMPs

- Draft: CMS Pilot Project for Civil Money Penalty (CMP) calculation
  - To improve consistence of CMPs
  - CMP analytic tool
    - Choosing type of CMP (per instance v. per day)
    - CMPs for past noncompliance
    - Choosing CMP start dates
  - Not yet formally issued

Remedies

Region V: FY 2012
- Total amount of per day CMPs:
  - MI $7,756,430 (389) to MN $34,250 (2)
- Total amount of per instance CMPs:
  - OH $347,00 (97) to MI $57,000 (24)
- Denial of payment for new admissions
  - MI 44 to MN 8
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New Dining Standards

S & C: 13-13-NH
• Information only
• CMS issued March 1, 2013
• Forwarded interdisciplinary task force results
• Expanding diet options for older individuals
• Surveyor training video: 24 minutes
  – 10 categories of changes
  – “Individualization of care and careful monitoring after a diet changes are essential elements of any care plan”

Nursing Home Compare
Changes to Nursing Home Compare Website

- Added SFF designation
- Added link to click on for complaints by consumers
- Added sanction listing
- Quality Measures have returned

Nursing Home Compare

- www.medicare.gov/NursingHomeCompare
- Increasing information being added
- More transparency
  - Will be adding 3 standard surveys of Statements of Deficiencies (SODs) in April 2013
  - Won’t be adding Plans of Correction (POCs)
    - State required to have POCs available on web
    - Can request a copy from State Agency

Changes to Nursing Home Compare Website

- Added SFF designation
- Added link to click on for complaints by consumers (some states with hotlinks)
- Added sanction listing
  - CMPs
  - Ban on payment
  - Other sanctions
SFF Program

- Used for facilities with a track record of poor performance
- Used to prevent cyclical noncompliance
- Focus on quality of life and quality of care

CMS Issuances & Other Guidance

Use of Insulin Pens

- CMS S&C: 12-30-ALL
- Issued by CMS May 23, 2012
- Insulin pens are used for a single person
- One 2011 episode of required post exposure notification due to multiple person use
- Label pen with resident name
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**F309 Quality of Care**
- S & C: 12-48-NH
- Issued September 27, 2102
- Advance copy of the changes to F309 for Quality of Life
- Implemented November 30, 2012

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**F309 Quality of Care**
- End of Life
- Multiple pages addressing end of life
- Review the definitions
- Gives references to materials
- Care Planning focus
- Investigative protocol
- IU examples

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**F322 Tube Feeding**
- S & C: 12-46-NH
- Released September 27, 2012
- F322 tube feedings and collapsed F321 into F322
- Provided training materials
- Implemented November 30, 2012
F322 Tube Feeding

- Definitions continue to be important
- Regulations require the use of tube feeding to be unavoidable (42 CFR 483.25(g))
- Multiple pages with citation to many reference materials

CMS & Antipsychotic Drugs

- CMS announced the Partnership to Improve Dementia Care
  - Initiative to ensure reduction of antipsychotic medications
  - Goal reduce antipsychotic use by 15% in NF
  - 2010 CMS data shows >17% residents with daily doses
  - 40% of residents with dementia had some antipsychotics in 2010 without diagnosis of psychosis
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CMS & Antipsychotic Drugs

- QIS survey and antipsychotic medications
  - Included since 2007 (beginning)
  - Stage I includes measurement of use of benzodiazepines and antipsychotics
  - Antipsychotics with and without diagnosis of psychosis
  - Can trigger to enter Stage II

Antipsychotic Meds (Long stay)

OIG Report on Antipsychotics

- Issued July 2012
- OEI-07-08-00151
- Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs
- Study used resident records from 2007
S & C 12-39-NH

- Issued July 6, 2012
- Nursing Home Action Plan
- Section G: Inappropriate Use of Antipsychotic Medications in Nursing Homes
  - “Off label” use with dementia related behavioral and psychological symptoms

Antipsychotics

- SOM: not indicated for
  - wandering; poor self care; restlessness; impaired memory; mild anxiety; insomnia; unsociability; inattention or indifference to surroundings; fidgeting; nervousness; uncooperativeness; and certain verbal expressions or behaviors that do not represent a danger to the resident or others.

Antipsychotics: Nursing Home Compare

- Each facility has 2 Quality Measures reported related to antipsychotic medications
- % of short stay residents who newly received antipsychotic medication
  - MS average 3.5% (9th highest in the country)
  - National average 3.0%
Antipsychotics: Nursing Home Compare

- Long stay residents
  - % of long-stay resident who received an antipsychotic medication
  - National average 23.9%

Physician Delegation of Tasks

- S & C: 13-15-NH
- Issued March 8, 2013
- Replaces S & C: 04-08
- Clarification related to physician delegation
  - Added PAs to list of practitioners for certifications and recerts
  - Review difference between employed by SNF/NF and not employed by SNF/NF

Office of the Inspector General (OIG)
### OIG Work Plan for FY 2013

- Issued each year in October
- Many pages-2013 with 123 pages
- Pages related to nursing facilities
  - Adverse events in post acute care
  - Medicare payments and Quality of Care
  - State Agency verification of deficiency correction (new)

### OIG Work Plan for FY 2013

- Oversight of poorly performing nursing homes
- Use of atypical antipsychotic drugs (new)
- Questionable billing practices during non-Part A stays
- Hospitalizations of nursing home residents
- Oversight of the MDS submitted by long term care facilities (new)
- Nursing facilities and communicable disease care

### OIG Work Plan for FY 2013

- Many other areas that are important to long term care
  - Hospice
  - Home health
  - DME providers
  - Part B payments for prescription drugs
  - Part D payments for prescription drugs
## OIG Report

- Fraud and Abuse Annual Report FY 2012
- Issued February 2013
- FY 2012 Feds won or negotiated:
  - over $3.0 billion in health care fraud judgments and settlements
  - 1,131 new criminal health care fraud investigation
  - 826 defendants convicted
  - 3,131 persons and entities excluded from Medicare and Medicaid

## OIG Report (continued)

- US Attorneys with DOJ
  - Owner of 3 nursing homes sentenced to 20 years in prison
  - Medicare and Georgia Medicaid
  - “Worthless services” submitting claims for payment
  - Ordered to pay $6.7 million in restitution
- USAOs opened 885 new civil matters with 1,023 civil suits for health care fraud investigations pending

## OIG Report (continued)

- Fraud investigations
  - Civil
  - Criminal
  - Multiple agencies
  - Cooperative efforts including HEAT initiatives with task forces in 9 cities
OIG Report

- OEI-02-09-00200, November 11, 2012
- *Inappropriate Payments to SNFs Cost Medicare More than a Billion Dollars in 2009*
- Found \( \frac{1}{4} \) of all SNF claims were in error in 2009 ($1.5 billion)
- Most for ultrahigh therapy
- SNFs misreported information on the MDS for 47% of claims

OIG Recommendations

1. Increase and expand review of SNF claims
2. Use Fraud Prevention System to identify SNFs that are billing for higher paying RUGs
3. Monitoring compliance with therapy requirements
4. Change current method for determining appropriate therapy
5. Improve accuracy of MDS
6. Follow-up with SNFs that have incorrectly billed

OIG Enforcement Action

- OIG and state enforcement actions with press releases almost daily
  - [http://oig.hhs.gov/fraud/enforcement/criminal/](http://oig.hhs.gov/fraud/enforcement/criminal/)
- Increasing criminal actions
- Increasing civil actions
- Fraud elimination a focused goal
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OIG Action
• Tennessee Company Settles
  – $2.7 million settling charges of false claims
  – Unnecessary Medicare therapy
  – Enter into Corporate Integrity Agreement
  – “Whistle-blower”

OIG & Increased Use of Technology
• Semi-annual Report to Congress by OIG
  – Indicates that OIG is using advance data analytics to target fraudulent activities
• First half of FY 2012: recoveries of $1.2 billion
• Touting Medicare Fraud Strike Force:
  – Resulted in filing charges against 101 individuals or entities and $50.9 million in investigative receivables

Quality Alert: Handling Investigation
• Who?
• What?
• Why?
• Never underestimate the power, scope and information of the state or federal agency
• Reach out for assistance
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HIPAA Issues

What is HIPAA?

• HIPAA
  – Health Insurance Portability and Accountability Act of 1996 (Amended and revised)
• Recently, HITECH Amendments added fines, penalties and new requirements
• Newest amendments January 17, 2013
  – Final rule effective March 23, 2013
  – Compliance required September 23, 2013

Who is covered?

• HIPAA Privacy Rule covers health plans and health care providers that transmit any information in electronic form
• That covers the vast majority of health care providers and insurers in the country
• Includes “business associates”
• Each provider is responsible for its employees, agents, etc
Privacy and Confidentiality

- Resident information must be kept confidential
- That concept is not new because of HIPAA
- Always required to keep information confidential
- HIPAA forced additional policies
- PHI: protected health information

PHI

- Protected Health Information:
  - Individually identifiable health information
  - Such as name, social security number, diagnoses, telephone number, the fact that the person is a resident
  - Anything that can identify the resident and/or health conditions
  - Very broad inclusion

Inappropriate Access to Information

- PHI should be secured
  - Records should be covered on the med cart
  - Items not left lying around at the nurses station or in the resident’s rooms
  - Not used as scrap paper and write other information on the same paper as PHI
  - Computer access restricted
Loss of Information
• Information can be lost
  — Paper
  — Electronic such as stolen lap top
• Notify your administrator immediately
• Facilities must have policies and procedures regarding “breach” notification and investigation

Business Associates
• Facilities must have a business associate agreement with all vendors that handle PHI
  — Examples:
    • Medical supply company
    • Oxygen company
    • Lab company
    • Many others
  — Most recent amendments require new BA agreements and require BAs to be held to same standards

Who Enforces HIPAA?
• State Attorney Generals enforce state laws
• Office for Civil Rights at US Department of Health and Human Services enforces on the national level
• www.hhs.gov/ocr
• Detailed information about health privacy
New Fines for Breach

• HITECH Act imposes fines as of February, 2010 for breach
  – Fines tied to the level of intent
    • Didn’t know and exercised reasonable due diligence: fine from $100/violation to $25,000
    • Reasonable cause $1,000/violation to $50,000/violation
    • Willfull neglect minimum $50,000 up to $1,500,000

Recent Example

• Connecticut Attorney General sued a health insurer for failing to secure private patient medical records
• 446,000 persons affected
• First case by a state attorney general with recent updates to HIPAA
• Portable computer disk drive lost

Social Media

• Facilities need to have a policy about social media
• Violation of HIPAA rights
  – Pictures
  – Discussions about work and resident information
    • Even tangential
  – Board of Nursing ramifications
    • Summer 2012 article with scenarios
  – PHI
    • Definition
    • Example:
Quality Alert: Handling Breaches

- Required notification in certain instances
- Investigation
- Notification of individual and others
- Reach out for assistance

Compliance Issues

Nursing Home Compliance Programs

- 2000 and 2008 OIG recommendations for compliance programs
- Some areas to focus:
  - Sufficient staffing
  - Care plans
  - Psychotropic medications
  - Financial reporting
  - Accurate and timely MDS
Nursing Home Compliance Programs
- Resident safety: mistreatment, abuse, neglect
- Billing integrity
- Medicare/Medicaid payments
- Anti-kickback regulations
• Effective Compliance Officer
• Effective compliance investigations

Nursing Home Compliance Programs
• Will be required in 2013
• No new guidance yet
  – Start now
  – Materials available
  – Seek out experienced guidance

Quality Alert: Compliance Issue
• Some compliance issues requiring disclosure to the government
• Never ignore
• Reach out for assistance
Miscellaneous Tidbits

Drug Diversion in LTC
• Misappropriation of resident property
  – Report misappropriation to regulatory authorities
• Diversion for personal use
  – Risk to residents with additional injuries
    • Post accident urine sample
    • Other important aspects of policies
    • Suspension pending investigation
      – Employment action
      – Regulatory requirements
• Diversion for sale
  – Criminal issues
• Examples

Alzheimer’s On the Increase
• USA Today article
• Increase 5005 by 2050 reaching $1.1 trillion
  – 70% of costs for Alzheimer’s care are billed to Medicare and Medicaid
  – Spend 3 times the amount for health care
  – $43,847 for health care compared to $13,879
  – Number to rise from 5 million to 13.8 million in 2050
    • (federally funded report published in Neurology)
DAB Cases

Departmental Appeals Board

- Formal survey appeals
- Informal setting with Administrative Law Judge
- Not a typical court setting
- CMS and State Agency with presumption of validity of citations
- Requires experienced counsel

DAB Case: Qualicare Nursing Home

- C-11-630, November 16, 2012
- Upheld citation and $2,500 per instance penalty
- G level on complaint
- Failed to protect resident from sexual abuse
- Brother of roommate acting “strangely”
- Should have intervened
  - Monitoring
  - One on one
Washington Christian Village
• DAB: CR2403; July 27, 2011
• Challenging citations for unnecessary drugs with a CMP
• Antipsychotics ordered for at least 2 residents without appropriate diagnoses (dementia and behavior symptoms)
• ALJ upheld citations

Cedar Lake Nursing Home
• DAB Decision No CR1967
• Decided October 23, 2009
• Texas facility cited for IJ with $5,000 per instance CMP
• Elopement
• Previous elopement attempts
• Care plan with “constant observation”

Cedar Lake Nursing Home
• Resident found by visitor walking on shoulder of road by the highway
• Door alarms did not sound because new alarms were being installed and the alarms were turned off
• Failed to take reasonable steps to prevent elopement
Bon Secours
- September 6, 2011 case in Michigan
- Allegation with the wrongful death claim of intentional tort
  - False imprisonment
  - Intentional infliction of emotional distress
- Related to lack of consent for restraint and failure to properly train staff about restraints

Resource: Caring for the Ages
- Available on the web: www.caringfortheages.com
- Focus on restraints turns from physical to chemical
- Choking carries significant risk
- Falls and accidents
- C. Diff and infection control risks
- Oversight and monitoring

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