Session #T39:

It's a Bit Breezy!

Legal Updates: Survey, Enforcement, HIPAA & Compliance

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Objectives:

- Identify current regulatory requirements and challenges for long-term care facilities, including new transmittals and other issuances.
- Discuss how to proactively address facility challenges faced by the long term care industry.
- Discuss potential impact of the Office of Inspector General's work plan on post acute care providers.
- Discuss the Office of Inspector General's requirements for the nursing home's compliance plans.
- Discuss multiple governmental agencies focus on fraud prevention and targeted enforcement in the post-acute area.
- Identify the changes in HIPAA and the importance of understanding the Office of Civil Rights enforcement of HIPAA.

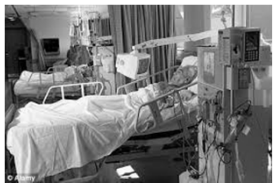
Janet Feldkamp

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. She is also co-author of *The Long Term Care Handbook: Regulatory, Operational and Financial Guideposts* published by the American Health Lawyers Association.

Long Term Care Services

- Changes over time



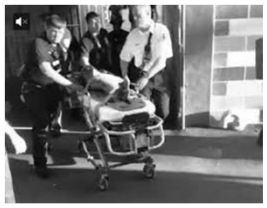
Assisted Living Updates

- Continuing to be increased in RCFs in Ohio
- Allows for choice for seniors
- Variety of types of facilities with a variety of services
- Acuity is increasing

Assisted Living Updates

- Proposed expedited initial licensing for RCFs
  - Expected to be finalized in Summer 2015
  - Additional filing fee for survey within a week
- Top citations: fire drills; food contamination; kitchen sanitation; incident logs

Adverse Events & Outcomes



OIG Report February 2014

- Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries
  - OEI06-11-00370
- Estimated 22% of Medicare SNF residents experienced adverse events during their SNF stays
- Similar study completed for Hospitals in the past
  - Look out for take backs in the future

Adverse Events Identified Among Medicare SNF Residents by Category

Types of Adverse Events	Percentage
Events Related to Medication	**37%**
• Medication-induced delirium or other change in mental status	12%
• Excessive bleeding due to medication	5%
• Fall or other trauma with injury secondary to effects of medication	4%
• Constipation, obstipation, and ileus related to medication	4%
• Other medication events	14%
Events Related to Resident Care	**37%**
• Fall or other trauma with injury related to resident care	6%
• Exacerbations of preexisting conditions resulting from an omission of care	6%
	5%
• Acute kidney injury or insufficiency secondary to fluid maintenance	4%
• Fluid and other electrolyte disorders (e.g., inadequate management of fluid)	4%
• Venous thromboembolism, deep vein thrombosis (DVT), or pulmonary embolism (PE) related to resident monitoring	14%
• Other resident care events	

Adverse Events Identified Among Medicare SNF Residents by Category

Types of Adverse Events	Percentage
Events Related to Infections	**26%**
• Aspiration pneumonia and other respiratory infections	10%
• Surgical site infection (SSI) associated with wound care	5%
• Urinary tract infection associated with catheter (CAUTI)	3%
• *Clostridium difficile* infection	3%
• Other infection events	5%
Total	**100%**

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Adverse and Temporary Harm Events by Preventability Rationales

Adverse and Temporary Harm Preventability Rationales	Percentage
Preventable Events	
Appropriate treatment was provided in a substandard way	56%
The resident's progress was not adequately monitored	37%
Necessary treatment was not provided	25%
Error was related to medical judgment, skill, or resident management	14%
Resident care plan was inadequate	11%
Care plan was incomplete or not sufficient in describing resident's condition	7%
The resident's health status was not adequately assessed	4%
Not Preventable Events	
Resident was highly susceptible to event because of health status	59%
Event occurred despite proper assessment and procedures followed	32%
Resident's diagnosis was unusual or complex, making care difficult	27%
Care provider could not have anticipated event given information available	20%

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

OIG Adverse Events Study

- Over ½ with harm went to the hospital for treatment
  - Estimated $136 million spent adverse events care from SNFs in August 2011
  - 2% of the $10.2 billion that Medicare spent on inpatient stays in August 2011
- Another recent study: hospitalization outcome issues when the physicians from LTC and the hospital do not interact

Regulatory Environment

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE & MEDICAID INNOVATION

The best approach when things aren't going your way.

Look straight ahead, blend in and be quiet!!

Appendix PP

- Updated December 2014
- 27 tags
  - Knowledge is power
  - Lack of knowledge will equal citations
- Teach your staff

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

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

More likely to result in actual harm or above

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

Citation Trends

Relatively Stable

- Citations per survey **5.7**
- Facilities in substantial compliance **10.3%**
- Substandard care surveys **3.0%**
- Immediate jeopardy surveys
  - 2012 to 2014: **2.1%**

Other Statistics

- Trends in Resident ADL Dependence
  - 2005: **3.92**
  - **2015: 4.21**
- AON Liability Findings: 2014
  - Long term care loss rates increased by 5.5% annually
  - Loss rates per occupied bed $990 in Ohio (up $50)(increases with claim severity)

Other Statistics

- Nursing Home Compare Quality Measures
  - Most of the October 2014 measures were at or better than the national average for Ohio
    - Pain (adjusted)(long stay) 7.7% (7.2% national)
    - Antipsychotic medication (long stay) 21.0% (19.1% national)
      - Antipsychotic medication Alaska 7.8%
      - Antipsychotic medication Texas 25.5%

Remedies

Region V: FY 2014

- Total amount of per day CMPs:
  - IL $3,919,274(133) to MN $441,605 (27)
- Total amount of per instance CMPs:
  - OH $275,584 (98) to MN $36,184 (8)
- Denial of payment for new admissions
  - MI 31 to MN 7

Remedies

- Region V FY 2014
  - Total Per diem CMPs 1736
    - $47,877,889
  - Total Per instance CMPs 954
    - $2,826,262
- About the same as previous year

Remedies: Ohio 2014

- Standard Surveys
  - 10 IJs; 59 Actual harm; 2,588 level 2; 194 level 1
  - 2,851 total deficiencies
- Complaint Surveys
  - 35 IJs; 55 Actual harm; 1103 level 2; 46 level 1
  - 1239 total deficiencies

Remedies: Ohio 2014

- Per Day CMPs: $1,700,166 (77) with average days 38
- Per Instance CMPs: $275,584 (98)
- Denial of Payment for New Admissions: 16: 14 mandatory and 2 discretionary
- Special focus facilities: 5 in Ohio

Federal IDR

- Offered for all states
- May offer better opportunities
- Know state IDR and Federal IDR requirements
- May be more impartial

Importance of IDR/IIDR in 2015

- Fines/sanctions
- Impact on 5 Star Rating
  - Indirect impact on
    - Managed Care
    - Admissions

Recent Caring for the Ages Articles

Reducing Smoking Risks while Honoring Residents Choices

April 2014

- 2011 Death in Illinois
  - Video footage
  - Inadequate and slow response from staff
  - Assessments for safety
  - Control of smoking materials

Caring Article: Smoking

Smoking Risk (continued)

- Virginia resident ember ignited garden area
- $1.45 million jury verdict

Caring Article: Accidents

Address Risks Before They Cause Accidents

December 2013

- DAB case (CR2829)
- Meadowwood Nursing Center
- Bed rail death

Caring Article: Accidents

Courtyard Healthcare Center

- CR2712
- Wandering resident found outside
- Keypad on door lock defective

Caring Article: Cameras

Cameras, Citations and Abuse Investigations

September 2013

- Ohio facility with covert cameras placed by Attorney General
- Footage utilized for citations
- Facility decertified in 6 month noncompliance

Upcoming Article

- Elopement has been a significant issue throughout the country
- Article discussing the importance of assessment, monitoring and ongoing supervision
- How much supervision is adequate supervision?

MDS Focused Survey (S&C 15-06-NH)

- CMS conducted pilot program in 2014
- Will be expanded in "Early 2015"
- 2 surveyors for each survey with estimated time of 2 days
- Validate MDS 3.0 and staffing levels

Dementia Care Focused Survey (S&C 15-31-NH)

- 2014 5 state pilot project: CA, MN, NY, IL and LA
- 20 centers surveyed and 16 were cited: **80% cited**
- **F309 and F329 cited 11 of 20 centers**
- 4 G or harm cites of 68 total deficiencies cited

Dementia Care Focused Survey

- Expanding dementia care focused survey
- Currently asking for states to volunteer
- Will occur in the summer and can be used in traditional and QIS Survey Dates
- Criteria for surveys yet to be determined
- Goal of 30% reduction in antipsychotic use by the end of 2016.

Five Star

S&C 15-26-NH issued February 13, 2015

Changes to the methodology for 5 Stars

Facilities have experienced changes to their ratings

Lots of information available about the changes

My Care Ohio

- Ongoing challenges
- Concerns about payment
- Concerns about directions related to notification of physicians
- Things continuing to smooth out over the period of time

HIPAA: Privacy & Security

What is HIPAA?

- Health Insurance Portability and Accountability Act of 199
  - Amended by Health Information Technology for Economic and Clinical Health (HITECH) Act
  - Promotes use of information technology
  - Provides for more enforcement of HIPAA
- Provides federal protection of individually identifiable health information

What is protected? Who must comply?

Protected Health Information:

- Individually identifiable health information: very broad
- Such as name, social security number, diagnoses, telephone number, the fact that the person is a resident
- Health care entities and business associates now required to meet all requirements

HIPAA

- Office of Civil Rights charged with enforcement
  - HIPAA updates effective and now with enforcement
  - Receives reports of breach and may request additional information and/or apply sanctions
  - Now charged with proactive auditing
    - Privacy
    - Security
    - Breach notification

HIPAA Audits

- Can be for any type of provider required to be HIPAA complaint
- National program has yet to be initiated
- Expected in 2015?

Civil Penalties

Circumstances of Violations	Minimum Penalty per Violation	Maximum Penalty per Violation	Annual Maximum Penalty for Violating Same Requirement
Entity did not know (even with reasonable diligence)	$100	$50,000	$1.5 million
Reasonable cause, not willful neglect	$1000	$50,000	$1.5 million
Willful neglect, but corrected within 30 days	$10,000	$50,000	$1.5 million
Willful neglect, not corrected	$50,000	None	$1.5 million

Criminal Penalties

- Criminal to knowingly obtain or disclose "individually identifiable health information" in violation of HIPAA's privacy provisions.
  - Violator may be fined up to $50,000, imprisoned for up to one year, or both.
  - If violation is committed under false pretenses, the person may be fined up to $100,000, imprisoned for up to 5 years, or both.

Enforcement Activity

- **$1.2M Settlement regarding Copying Machine (Aug. 2013)**
  - Returned copier to leasing agent, did not delete PHI
- **Hospice of Northern Iowa (Dec. 2012)**
  - Breach involving less than 500 patients
  - $50,000 fine

Response with a loss of PHI

- Breach analysis
- Required reporting
  - Timing of reporting
  - Notification of the resident
- Education of staff
- Monitoring the practices
- OCR will often ask for additional information
- May need assistance with HIPAA program and/or breach issues

Most Common HIPAA Compliance Issues

1. Impermissible uses and disclosures
2. Lack of safeguards
3. Lack of patient access
4. Failure to adhere to "Minimum Necessary"
5. Lack of administrative safeguards to Ephi

Random OCR audits in 2015

OCR Enforcement Results: 2013

- http://www.hhs.gov/ocr/privacy/hipaa/enforcement/data/historicalnumbers.html#eleventh

Compliance Issues

What is a Compliance Program?

- Genesis: 2000 Guidance and 2008 Updated Guidance
- March 2013 requirement
- Elements
  - Standards of Conduct
  - Choosing a CCO and Compliance Committee
  - Education
  - Internal Monitoring
  - Screening
  - Enforcement and Discipline
  - Responding promptly to detected problems and implementing corrective measures

Nursing Home 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

- Required in 2013
- No new guidance even as of 2015
  - Facilities must be engaged in the process
  - Materials available
  - Seek out experienced guidance

Corporate Compliance

- Office of Inspector General ("OIG")
  - Fraud police: goal to reduce waste, prevent fraud in governmental health care programs
- Website: 10 most wanted health care fugitives
- Corporate compliance programs are beneficial and required

OIG Enforcement

- Focus on fraud and abuse preven
- Multiple criminal penalties
- Multiple civil penalties
- Prevention of fraud and abuse through robust and active corporate compliance program

STOP Medicare Fraud
U.S. Department of Health & Human Services and U.S. Department of Justice

HHS & DOJ Report

- Overall accomplishments
  - $4.33 billion in judgments and settlements
  - Return on investment $8.10 for every $1.00 expended
- HEAT (Health Care Fraud Prevention and Enforcement Team)
  - Collaboration of top level law enforcement
  - Focuses in several areas of the country
  - Medicare Fraud Strike Force

HHS & DOJ Report

- Nursing Homes
  - $2.7 million settlement to resolve False Claims Act allegations of billing for unreasonable and unnecessary rehabilitation services
- Hospice
  - Certification of ineligible individuals and inflated billing including pressure staff to find more patient eligible for Medicare hospice benefits and delayed discharges

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

HHS & DOJ Report

- Found Medicare paid approximately $5.1 billion for stays in which SNFs did not meet quality-of-care requirements.
  - 37% of care plans didn't meet requirements or services delivered didn't meet care plan
  - 2009 ¼ of Medicare claims from SNFs in error.
    - 47% claims from MDS were incorrect with RUGs

Admission Agreement

- Who needs to sign and when
- Under what circumstances can you ask for guarantees?
- Important not for profit provisions
- Representative payee status
- Arbitration clauses

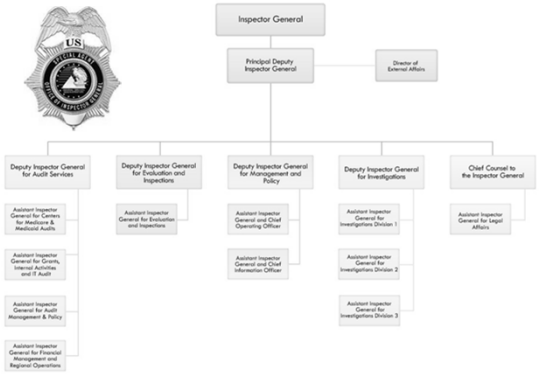
Governmental Enforcement

Governmental Agencies

- Office of Inspector General (OIG)
- State Medicaid Fraud Enforcement Unit (MFCU)
- Centers for Medicare and Medicaid Services (CMS)
- Office of Civil Rights
- Medicare Strike Force Teams
- Governmental contractors
  - Medicare Area Contractors (MACs)
    - Interactive map
      - http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html

Governmental Agencies

- Health Care Fraud Prevention and Enforcement Action Team (HEAT)
  - HEAT teams: multidisciplinary and multijurisdictional
  - Targeted in a number of cities
    - Baton Rouge, Louisiana
    - Brooklyn, New York
    - Chicago, Illinois
    - Dallas, Texas
    - Detroit, Michigan
    - Houston, Texas
    - Los Angeles, California
    - Miami–Dade, Florida
    - Tampa Bay, Florida



Exclusion from Program

- Federal law allows the government to exclude individuals, who have been convicted of certain offenses or engaged in certain conduct, from participating in any federal health care program.

Overpayments and False Claims Liability

- Overpayments must be reported and returned within 60 days of identity or the date a corresponding cost report is due, whichever is later.
- Repayments may be made to the carrier, the contractor or the intermediary.
  - Any overpayment retained after the 60-day deadline is considered an obligation for purposes of the False Claims Act.
    - H.R. 3590, Sec. 6402

Suspension of Payments

- DHHS may suspend payments to a provider of services or supplier pending an investigation of a credible allegation of fraud against the provider of services or supplier.
- DHHS must consult with the OIG to determine whether there is a credible allegation of fraud against a provider of services or supplier.
  - H.R. 3590, Sec. 6402

Suspension of Payments

- 42 C.F.R. §§ 405.370 and 405.371
- Medicare payments to providers and suppliers, may be –
  - In cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments

OIG Work Plan for FY 2015

- FY2015 with +90 pages
- All areas of health care addressed including:
  - Hospice
  - Home health
  - DME providers
  - Part B payments for prescription drugs
  - Part D payments for prescription drugs

OIG Website

- Criminal and Civil Enforcement
  - Updates everyday to website
  - 10 most wanted health care criminals
  - Multiple convictions and settlements

Medicaid Fraud Control Units

- MFCU in each state
- Look to issues related Mediaid fraud and abuse
- Each state has its own manner of handling investigations and convictions
- Review of MFCU Statistical Data for Fiscal Year 2014

Medicare Area Contractors

- 2014 with continuing changes to the MACs
- http://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Consolidated-AB-Map-Vision.pdf

GAO Report

- GAO-14-474; July 2014
- Increased Oversight and Guidance Could Improve Effectiveness and Efficiency of Postpayment Claims Reviews
- Providers with incredible delays in postpayment claims reviews

GAO Postpayment Study

- CMS uses several types of contractors to reduce improper Medicare payments
- Medicare Administrative Contractors (MAC)process and pay claims and also recoup overpayments
- Zone program Integrity Contractors (ZPIC) investigate potential fraud
- Recovery Auditors (RA) conduct post payment reviews

GAO Postpayment Study

- CMS does not have sufficient information to determine whether the contractors are conducting inappropriate duplicative claims reviews
- Lack consistent guidance and ensure that contractors comply with requirements to improve efficiency and effectiveness of communication with providers

2015 & OSHA

- Obligation to furnish workplace free from recognized hazards.
  - Workplace violence
  - Ergonomics
  - Infectious diseases (ebola & others)
- New recordkeeping requirements
  - All employers required to report employee death or hospitalization of 3 or more

How Can Things Go Awry?

- Home Health Care Owner sentenced to prison for falsifying CMS audit
  - $1.9 million in care records falsified
  - 8 month prison sentence, 500 hours of community service, plus payback
  - Backdated plans of care
  - Physician also pled guilty

How Can Things Go Awry?

- Physician sentenced to 151 months in prison in connection with $77 million Medicare scheme
  - 13 others being prosecuted in the same massive scheme
  - Billing at clinic for services and procedures never delivered
  - Paid kickbacks to corrupt Medicare beneficiaries
  - Government used a court ordered audio/video recording device hidden in a clinic room

How Can Things Go Awry?

- 2 SNFs in Ohio terminated from Medicare/Medicaid participation
  - Both were on the Special Focus Facility list
  - SFF targets facilities with a history of noncompliance
- Cameras placed by Ohio Attorney General in facility
  - Knowledge/consent of families
  - No knowledge of facility or staff
  - Article in September 2013 Caring for the Ages
    - http://www.caringfortheages.com

How Can Things Go Awry?

- Failure to cross-check shareholders, owners, managers, and employees against Medicare List of Excluded Individuals and Entities and General Service Administrative System for Award Management
  - http://oig.hhs.gov/fraud/exclusions.html
  - http://www.arnet.gov/epls/

How Can Things Go Awry?

- Baton Rouge woman sentenced to 8 years in prison
- Restitution of $43,528,584
- Conspiracy to commit health care fraud and conspiracy to pay and receive kickbacks
- 3 community mental health centers with 17 others convicted
- Activities over 7 years

How Can Things Go Awry?

- HIPAA breach: St. Anthony's (St. Louis) laptop and flashdrive stolen from physician's care
  - Not encrypted
  - 2,500 nursing home residents information
  - Public notice, report to OCR, individual notices and more . .
- Breach analysis and remediation vital
- Anthem breach most recently in the news
  - Liabilities can be almost limitless

Questions

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