2019 Long Term Care Provider State and Federal Legal Update

David C. Marshall, Esq.

Tanya Daniels Harris, Esq.

2019 PACAH Spring Conference

Introduction

- As always, federal and state agencies have implemented numerous policies and programs that require close attention from providers.
- Our goals today are to provide you with an update on changes in law and governmental enforcement/interpretations that have occurred over the last year.
- We'll also preview upcoming changes in law and how to position your organization to address these new requirements.

Industry Trends/Big Picture

- Record-low occupancies in nursing facilities reported, a trend continuing since 2012
  - Changing reimbursement systems, value based payments, staffing challenges, consumer preferences, ALF/PCH occupancy increases, all factor into this trend
  - As a result, increasing number of NFs have closed, and operators will continue to consider options to “repurpose” existing facilities (i.e. converting to personal care, low-income apartments, or memory care units) or downsize licensed bed capacity.
- Continuing expansion of managed care models of payment (e.g. Medicare Advantage, PACE, Medicaid Managed Care)
- Further developments of partnerships, collaborations and networks of providers to provide integrated care and control costs

Industry Trends/Big Picture

- In the for-profit world, increasing defaults under REIT leases and lending arrangements create licensure issues, as lenders and landlords seek remedies against operators unable to meet lease/debt payment obligations
- Increasing use of technology (e.g. Telehealth) to provide quality care in the most efficient and cost-effective manner possible
- Workforce challenges, including see increasing staffing challenges, workforce shortages, wage and benefit costs, and employment law enforcement

NURSING FACILITY SURVEY, CERTIFICATION, AND REGULATORY ISSUES

Final Revised Policies re: Immediate Imposition of Federal Remedies

- Substantive revisions to the prior guidance include:
  - When the current survey identifies Immediate Jeopardy (IJ) that does not result in serious injury, harm, impairment, or death, the CMS Regional Offices may determine the most appropriate remedy.
  - Past Noncompliance deficiencies are **not** included in the criteria for Immediate Imposition of Remedies
  - For Special Focus Facilities (SFFs), S/S level "F" citations under tags F812, F813, or F814 are excluded from Immediate Imposition of Remedies

QSO 18-18-NH
Posting Date – 06/15/2018

Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems

- June 2, 2017 Publication
  - Facilities are required to develop and adhere to policies and procedures that inhibit microbial grown in building water systems that reduce the risk of growth and spread *Legionella* and other opportunistic pathogens in water.
  - Facilities are expected to complete a risk assessment to identify where pathogens could grow, implement a water management program that considers industry standards and specifies testing protocols and acceptable ranges for control measures.
- July 6, 2018 Clarification
  - LTC surveyors will expect the facility to have a water management plan for review, but will not cite the facility based on the specific risk assessment or testing protocols in use.
  - CMS does not require water cultures for *Legionella* or other water borne pathogens, and testing protocols may be done at the provider's discretion.

QSO 17-30-Hospitals/CAHs/NHs
Posting Date – 07/06/2018

CMP Reinvestment Program

- CMS has announced a three-year initiative to support better care and outcomes under the Civil Money Penalty Reinvestment Program (CMPRP). CMS plans to develop staff competency assessment tools, instructional guides, training webinars, and technical assistance seminars to help staff reduce adverse events, improve dementia care, and strengthen staffing quality.
  - CMS released its first toolkit in the CMPRP series on 11/21/18 to provide competency assessments for CNAs and CMTs, LPNs/RNs, and administration.
  - The next toolkits will focus on nursing home employee satisfaction.

Payroll Based Journal (PBJ) Policy Manual Updates, Notifications to States and New Minimum Data Set (MDS) Census Reports

- CMS will provide CMS Regional Offices and State Survey Agencies with a list of facilities with potential staffing issues to support survey activities for evaluating sufficient staffing and improving resident health and safety.
- PBJ Policy Manual will be expanded to include guidance on the meal breaks policy to ensure consistency.
- PBJ Policy Manual will also now include guidance regarding reporting hours for “Universal Care Workers.”
- Further, there will be new MDS-based census reports in the Certification and Survey Provider Enhanced Reporting (CASPER) System.

QSO 19-02-NH
Posting Date – 11/30/2018

Notice of Final Rule Adjusting Civil Monetary Penalties (CMPs) for Inflation

- Prior to 2015, CMPs authorized under the Social Security Act were exempt from inflation adjustments.
- The Federal Civil Penalties Inflation Adjustment Act of 2015 required agencies to make an initial "catch up adjustment" and annual inflation adjustments thereafter on CMPs that may be imposed for noncompliance by SNFs/NFs, HHAs and clinical laboratories.
- The 2018 Annual Adjustment is effective as of October 11, 2018 and the adjusted amounts apply to CMPs assessed on or after October 11, 2018. The CMP Analytic Tool will be adjusted to reflect the new amounts.

QSO 19-04-NH/HHA/CLIA
Posting Date – 01/22/2019

Emergency Preparedness Requirements: Updates to Appendix Z of the SOM

- Adds “emerging infectious diseases” to the current definition of all-hazards approach to include planning for infectious disease preparedness and prevention
- Clarifies that facilities should use the most appropriate energy source or electrical system based on their review of their individual facility’s all-hazards risk assessments and as required by existing regulations or state requirements. Regardless of the alternate source of energy a facility chooses to utilize, it must be in accordance with local and state laws, manufacturer requirements, and Life Safety Code (LSC) requirements.
- If a facility risk assessment determines it is best to use a portable and mobile generator, rather than a permanent generator, then the LSC provisions would not be applicable except for NFPA 70 National Electrical Code. However, the revisions, as the provisions under emergency preparedness themselves, do not take away existing requirements under LSC, physical environment, or any other Conditions of Participation that a provider type is subject to.

QSO 19-06-All
Posting Date – 02/01/2019

EPA Final Rule on Hazardous Waste Pharmaceuticals

- Subjects hazardous waste at SNFs and inpatient hospice facilities to the Resource Conservation Recovery Act (RCRA) requirements
- Analysis to determine whether a given substance is a hazardous waste:
  - Is it a pharmaceutical?
  - Is it a solid waste?
  - Is it a hazardous waste product, either by being listed as one by the RCRA or by exhibited a characteristic of one?
- If facilities generate total hazardous waste in amounts exceeding the applicable thresholds, they must treat HWPs in accordance with the management standards

Doc. Cite – 84 FR 5816
Published – 02/22/2019
Effective – 08/21/2019

Enhanced Oversight and Enforcement of Non-Improving Late Adopters

- Since 2011, CMS has seen a reduction of 38.9% in long-term nursing home residents who were receiving an antipsychotic medication due to the National Partnership & Identification of Late Adopters. Despite this success, CMS identified approximately 1,500 facilities that had not improved their antipsychotic medication utilization rates for long-stay nursing home residents, referred to as Late Adopters. CMS notified these facilities of this identification.
- As of January 2019, there are 235 Late Adopter nursing homes that have been cited for noncompliance with federal regulations related to unnecessary or psychotropic medications two or more times since January 1, 2016 and who have not shown improvement in their long-stay antipsychotic medication rates.
- If these facilities are determined not to be in substantial compliance with requirements for Chemical Restraints, Dementia Care, or Psychotropic Medications during a survey, they will be subject to enforcement remedies for such noncompliance.
- CMS is also looking for opportunities to engage with corporate chains that have significant numbers of nursing homes identified as Late Adopters.

Revisions to Appendix Q, Guidance on Immediate Jeopardy

- Revision creates a Core Appendix Q that will be used by surveyors of all provider and supplier types in determining when to cite immediate jeopardy.
- Drafted subparts to Appendix Q focus on immediate jeopardy concerns occurring in nursing homes and clinical laboratories since those provider types have specific policies related to immediate jeopardy.
- To cite immediate jeopardy, surveyors determine that (1) noncompliance (2) caused or created a likelihood that serious injury, harm, impairment, or death to one or more recipients would occur or recur; and (3) immediate action is necessary to prevent the occurrence or recurrence of serious injury, harm, impairment, or death to one or more recipients.
- Removal of concept of "culpability" and replaced with concept of noncompliance.
- A template has been developed to assist surveyors in documenting the information necessary to establish each of the key components of immediate jeopardy.

QSO 19-09-ALL
Posting Date – 03/05/2019

April 2019 Improvements to Nursing Home Compare and the Five Star Rating System

- In April 2019, CMS will end the freeze on the health inspection domain of the Five Star Quality Rating System and will resume the traditional method of calculating health inspection scores by using three cycles of inspections. Inspections occurring on or after November 28, 2017 will be included in each facility's star rating.
- CMS is also making the following changes to ratings:
  - Introducing separate ratings for short- and long-stay measures to reflect the level of quality provided for these two subpopulations in nursing homes
  - Adding a system for regular updates to thresholds every six months
  - Weighting and scoring individual QMs differently
  - Adding the long-stay hospitalization measure and a measure of long-stay emergency department transfers to the rating system
  - Adopting two measures from the SNF Quality Reporting Program to replace duplicative existing measures
  - Adjusting the thresholds for staffing ratings
  - Reducing the threshold for the number of days without an RN onsite that triggers an automatic downgrade to one star from seven to four days

QSO 19-08-NH
Posting Date – 03/05/2019

Specialized Infection Prevention and Control Training for Nursing Home Staff

- CMS and CDC collaborated on the development of a free online training course in infection prevention and control for nursing home staff in the long-term care setting.
- The training provides approximately 19 hours of continuing education credits as well as a certificate of completion.
- The "Nursing Home Infection Preventionist Training Course" is located on CDC's TRAIN website. (https://www.train.org/cdctrain/training-plan/3814) It is free of charge and is on-demand.

QSO 19-10-NH
Posting Date – 03/11/2019

Phase 3 Requirements of Participation

- Final phase is to be implemented on November 28, 2019.
- Requirements to be implemented in Phase 3:
  - *Coordination of Abuse Policy and Procedure with QAPI Plan* (F607/§483.12(b)(4)) – requires facilities to ensure that its QAPI Plan includes regular evaluation and monitoring of compliance with Abuse, Neglect, and Exploitation policies and procedures.
  - *Trauma-Informed Care* (F699/§483.25(m)) and *Trauma-Informed Care Comprehension Care Planning* (F659/§483.21(b)(3)(iii)) – facilities will be required to ensure that residents who are "trauma survivors" receive "culturally-competent" and "trauma-informed" care in accordance with professional standards of practice.

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
  - *Behavioral Health Services as it relates to a history of trauma and/or PTSD* (F741/§483.40(a)(1)) – requires facilities to ensure that they can provide the necessary care and services and sufficient direct care staff with appropriate competencies and skill sets to care for residents with mental illnesses and psychological disorders.
  - *Administration – Governing Body is Responsible for the QAPI Program* (F837/§483.70(d)(3)) – requires the Governing Body to be responsible and accountable for the QAPI Program. This guidance instructs surveyors to request the names and contact information of the members of the governing body at the survey entrance.

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
- *QAPI* (F865/§483.75) – facilities must maintain documentation of the QAPI program to demonstrate ongoing compliance with the requirements and the Plan.
  - Ensuring the governing body is responsible and accountable for the program
  - Establishing and implementing procedures for feedback (from direct care staff, other staff, residents and representatives), data collection and monitoring, including monitoring of adverse events, including how such information will be used to identify high-risk, high volume or problem prone opportunities for improvement
  - Implementing performance improvement actions and after implementing the actions, measuring the success and tracking performance to ensure improvements are sustained

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
- *QAPI* (§483.75) cont.
  - Developing policies to demonstrate how they will use a systematic approach to determining underlying causes of problems, how corrective actions will be developed to prevent quality and safety problems, and how the facility will monitor the effectiveness of the performance improvement activities
  - Ensuring the Quality Assurance Committee regularly reviews and analyzes data, including data collected under the QAPI program and data resulting from drug regime reviews, and act on data to make improvements and reports to the governing body regarding the Committee's activities and implementation of the QAPI Plan.

QA Protection of Documents

- §483.75(h) Disclosure of Information – A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section. *[§483.75(h) was implemented November 28, 2016 (Phase 1)*]

- §483.75(i) Sanctions – Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. [*§483.75(i) was implemented November 28, 2016 (Phase 1)*]

QA Protection of Documents SOM Guidance –Appendix PP

- "Surveyors may only require facilities to disclose QAA committee records if they are used to determine the extent to which facilities are compliant with the provisions for QAA.
- Protection from disclosure is generally afforded documents generated by the QAA committee, such as minutes, internal papers, or conclusions. However, if those documents contain the evidence necessary to determine compliance with QAPI/QAA regulations, the facility must allow the surveyor to review and copy them. The key point is that the facility must provide satisfactory evidence that it has, through its QAA committee, identified its own high risk, high volume, and problem-prone quality deficiencies, and are making a "good faith attempt" to correct them.
- Information gleaned from disclosure of QAA committee documents will not be used to cite new issues (not already identified by the survey team) or to expand the scope or severity of concerns identified on the current survey."

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
  - *Infection Preventionist* (F882/§483.80(b)) – facilities are required to have an infection preventionist who has primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field; is qualified by education, training, experience, or certification; works at least part-time at the facility; and completed specialized training on infection control.

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
  - *Compliance and Ethics Program* (F895/§483.85) – requires the operating entity to have a compliance and ethics program in place that are capable of reducing fraud and abuse, designate personnel with the overall compliance responsibility, etc.
    - Written compliance and ethics standards and policies and procedures that are capable of reducing criminal, civil and administrative violations.
    - Assignment of specific individuals within the high-level personnel of the organization with the overall responsibility to oversee compliance and ethics standards for the organization.
    - Sufficient resources and authority for the individual(s) who have responsibility to oversee the compliance program that are necessary to effectively implement the program.

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
  - *Compliance and Ethics Program* (F895/§483.85) cont.
    - Due care not to delegate substantial discretionary authority to individuals who the organization knew, or should have known, have the propensity to engage in criminal, civil or administrative violations under the Social Security Act.
    - Establishment of procedures to ensure that the compliance standards and policies are effectively communicated to staff, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteer's role.
    - Taking reasonable steps to ensure compliance with the program, including ensuring that employees, those providing services under contractual arrangement and volunteers have the ability to report violations anonymously and without fear of retribution.
    - Consistent enforcement of the program through appropriate disciplinary mechanisms and taking all reasonable steps to respond appropriately to a violation and prevent further violations.
    - Operating organization for each facility must review the program annually and revise as needed to reflect changes in all applicable laws.

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
  - *Compliance and Ethics Program* (F895/§483.85) cont.
  - Operating organization with **five or more facilities**, must also meet the following additional requirements:
    - Mandatory annual training on the program;
    - Designated compliance officer for the organization for whom the compliance and ethics program must be a "major responsibility", and who must report directly to the governing body;
    - Designated compliance liaisons located at each of the organization's facilities

Phase 3 Requirements of Participation

- Requirements to be implemented in Phase 3 (cont.):
  - *Physical Environment – Call System* (F919/§483.90(g)(1)) – facilities must be equipped with a call system that allows residents to call for staff assistance directly from each resident's bed side.
  - *Training Requirements* (F940/§483.95) – facilities are required to train new staff, existing staff, contracted staff, and volunteers in the following areas:

    F941 communication

    F942 resident rights and facility responsibilities

    F944 QAPI

    F945 infection control

    F946 compliance and ethics

    F949 behavioral health training

Increase in DOH Oversight of Nursing Homes

- Pennsylvania DOH doubled its fines against nursing homes to approximately $2.5 million in 2018.
- Auditor General Eugene DePasquale to release a new review this year regarding an assessment of DOH's enforcement actions.
- Revisions to state nursing facility licensure regulations anticipated to be released for public comment in the summer of 2019.

DOH Survey/Enforcement Trends for 2018

- Total Surveys – 4,716
- Most Frequently Cited Tags
  - F684 (Provide Care/Services for Highest Well Being)
  - F689 (Infection Control)
  - F880 (Resident Records)
  - F812 (Fee of Accident Hazards/Supervision/Devices)
  - F656 (Food Procure, Store, Prepare, Serve)
- Sanctions Issued
  - Provisional I License – 3
  - Civil Penalty - 184

Source of Information:
PA Department of Health

Summary of DOH Civil Penalties Imposed

Year	Range of Civil Penalties	Total Amount of CP's for the Year
2016	$1,000 - $60,800	$412,200
2017	$1,500 - $100,000	$1,094,750
2018	$1,500 - $52,250	$2,569,171.27
2019 (As of February)	$4,250 - $30,500 (As of February)	$308,500 (As of February)

* Chart based on sanctions disclosed on DOH's website as of 4-17-19.

Appeal Options

- IDR
- State IIDR
- Federal IIDR
- DOH Appeal
- CMS Appeal
- DAB Appeal
- Federal Court

DOH Summary of IDR/IIDR Results for 2018

- **IDR**
  - 129 Tags disputed
  - 43% deleted (55)
  - 13% revised (17)
- **State IIDR**
  - 17 Tags disputed
  - 18% deleted (3)
  - 0% revised (0)
- **Federal IIDR**
  - 40 Tags disputed
  - 0% deleted (0)
  - 10% revised (4)

Source of Information:
PA Department of Health

NURSING FACILITY FEDERAL AND STATE REIMBURSEMENT ISSUES

SNF Patient-Driven Payment Model ("PDPM")

- May 2017 – CMS proposed to replace PPS with the Resident Classification System, Version I (RCS-I) case-mix model
- CMS goal is to design a more simplified system, with less paperwork requirements
  - 80 percent reduction in the number of payment group combinations compared to the RCS-I.
  - $2.0 billion in savings over 10 years due to less paperwork by providers
- PDPM will go into effect October 1, 2019.

SNF Patient-Driven Payment Model ("PDPM")

- 5 Case-Mix Adjusted Components:
  - PT: covers utilization of physical therapy (PT)
  - OT: covers utilization of occupational therapy (OT)
  - SLP: covers utilization of speech-language pathology (SLP) services
  - Nursing: covers utilization of nursing services and social services
  - NTA: covers utilization of non-therapy ancillary (NTA) services
- Non-case-mix component to cover utilization of SNF resources that do not vary according to resident characteristics also remains in place.

SNF Patient-Driven Payment Model ("PDPM")

- Payment Calculation:
  - Each resident classified into a resident group for each of the 5 case-mix adjusted components;
  - Base rate for each component multiplied by the CMI assigned to the particular resident group;
  - Separate adjustments would be applied to each resident's PT, OT, and NTA payments depending on the day of the stay.

SNF Patient-Driven Payment Model ("PDPM")

- Determinants of Payment:
  - PT and OT based on the primary reason for SNF care and functional status at admission
  - SLP based on the primary reason for SNF care, cognitive status at admission, SLP-related comorbidities, and the presence of a swallowing disorder or a mechanically altered diet
  - Nursing based on clinical information from the SNF stay, functional status, extensive services received, the presence of depression, and restorative nursing services received
  - NTA based on the presence of comorbidities and extensive services received

SNF Patient-Driven Payment Model ("PDPM")

- PDPM removes therapy minutes as the basis for therapy payment, and through the NTA component, intends to remove incentives for providing excessive therapy
- Variable Per Diem
  - PT and OT payments are reduced by established percentages, starting at Day 20 of the stay
  - NTA payments reduced from a factor of 3 to a factor of 1 after Day 3 of stay
  - CMS research notes that costs for PT/OT decline over course of stay, and NTA costs such as drugs are concentrated at beginning of stay
  - Significant change from constant SNF PPS Per Diem

Transition to PDPM

- There will be no transition period between RUG-IV and PDPM, because running both systems would be administratively infeasible for providers and CMS.
- To receive a PDPM HIPPS code that can be used for billing beginning 10/1/19, all providers will be required to complete an Interim Payment Assessment with an Assessment Reference Date no later than 10/7/2019 for all SNF Part A patients:
  - 10/1/19 will be considered Day 1 of the Variable Per Diem schedule under PDPM, even if the patient began his or her stay prior to 10/1/9.
  - Any “transitional IPAs” with an ARD after 10/7/19 will be considered late and a relevant penalty for late assessments will apply

PDPM Assessment Schedules

Medicare MDS Assessment Type	Assessment Reference Date	Applicable Standard Medicare Payment Days
Five-day Schedule PPS Assessment	Days 1-8	All covered Part A days until Part A discharge (unless an IPA is completed)
Interim Payment Assessment (IPA)	Optional Assessment	ARD of the assessment through Part A discharge (unless another IPA assessment is completed)
PPS Discharge Assessment	PPS Discharge: Equal to the End Date of the Most Recent Medicare Stay (A2400C) or End Date	N/A

PDPM Assessments

- With PDPM Implementation, CMS will continue to report RUG-III and RUG-IV HIPPS codes, based on state requirements, in item Zo200 through 9/30/2020.
- Case-mix states (PA) also may rely on PPS assessments to capture changes in patient case-mix, including scheduled and unscheduled assessments:
  - As of 10/1/19, all scheduled PPS assessments (except the 5-day) and all current unscheduled PPS assessments will be retired.
  - To fill this gap in assessments, CMS will introduce the OSA, which may be required by states for NFs to report changes in patient status, consistent with their case-mix rules.

PDPM IMPLICATIONS

- Will HMO/MCOs adjust rates, especially if the rates are RUG-based, rather than Level-of-Care based?
- Revisions to Therapy Ancillary Provider Agreements, as therapy component is now less important to determination of Medicare per diem.
- Coming changes to RAI Manual and CMS Provider Manuals to address change in reimbursement system.
- Software changes (e.g. Point Click Care) to address new assessment schedule.
- Operational Changes
  - Focused on initial assessment to capture all information
  - Even more intense documentation requirements/needs
  - Shorter lengths of stay?

Community HealthChoices

- January 1, 2019 – SE Pennsylvania
- January 1, 2020 – Central/Remainder of the Commonwealth
- Upcoming Dates for Provider Sessions for Phase Three (Central Region):
  - May 13-15: Lehigh/Capital Region Provider Summits
  - May 20-22: Northwest Region Provider Summits
  - June 4-6: Northeast Region Provider Summits

Community HealthChoices Contract Suggestions

- Rates: Ensure the rate methodology is defined consistently with DHS requirements:
  - No less than the average MA per diem for the facility for the last four quarters, plus supplemental payments
  - No downward adjustment for the first 36 months
  - Specify add-ons that must be included in the rate
- Credentialing: Enrollment should be consistent with DHS's "any willing provider" rule for the first 18 months of the contract.
- Providers should familiarize themselves with the Providers Manuals, ideally before signing the MCO agreement.

Fraud and Abuse/Compliance Issues

2018 Federal and State Recoveries

- DOJ/DHS recovered over $2.8 billion total from investigative cases in FY 2018.
- Medicaid Fraud Control Units (MFCUs) reported 1,503 convictions, 810 civil settlements and judgments, and approximately $859 million in criminal and civil recoveries in fiscal year FY 2018.
- Federal DHS participated in the largest health care fraud takedown in history in June 2018.
- More than 600 defendants in 58 federal districts were charged with participating in fraud schemes involving about $2 billion in losses to Medicare and Medicaid.
- OIG also issued exclusion notices to 587 doctors, nurses, and other providers based on conduct related to opioid diversion and abuse.

Compliance and Ethics

- **Compliance and Ethics Programs (§483.85)**
  - Written compliance and ethics standards policies
  - Assignment of specific “high-level” personnel to oversee
  - Sufficient resources and authority for person chosen
  - Due care not to delegate to a person that facility knows or should have known has propensity to engage in illegal acts
  - Communication of standards – Employee training
  - Reasonable steps to assure compliance, including routine monitoring
  - Appropriate response to violations
  - Consistent enforcement of standards and discipline of employees who fail to follow standards
  - Respond appropriately to all detected violations
  - Requirements for organization with 5 or more facilities

Escobar Case Implementation

- "Implied Certification Theory"
  - If a provider is not
    - (a) in compliance with either a "condition of payment" or a "condition of participation" at the time of the claim submission, and
    - (b) that compliance is *material to* the government's decision to pay, and
    - (c) the alleged noncompliance is not disclosed,
  - Then the provider may be subject to FCA liability.

Escobar Case Implementation

- The District Courts are split on whether Escobar sets forth **absolute** or **permissive** requirements.
- The two conditions set forth in Escobar are:
  - The claim makes specific representations about the goods or services provided; and
  - The defendant's failure to disclose noncompliance with material requirements makes those representations misleading half-truths.

Escobar Case Implementation

- However, courts have set aside verdicts in favor of federal programs, citing a lack of evidence that the government would have declined payment had it known of the alleged violations. In other words, there was no evidence of materiality.
- Thus, requiring proof that the regulatory violation is “material” to the government’s payment decision enables providers to argue that FCA liability is unwarranted because the errors at hand are not significant enough to deter payment.

U.S. ex rel. Ruckh v. CMC II, et al.

- Facts – A whistleblower alleged that over 50 nursing homes managed by CMC II, LLC failed to maintain "comprehensive care plans" as required by regulation, up-coded RUG levels on submitted claims, and failed to maintain adequate documentation of therapy services.
- Jury held that the federal programs paid nearly $115 million in false claims and set liability at approximately $350 million.
- On appeal, the verdict was set aside; there was no evidence that the government would have declined payment to the nursing homes had it known of the alleged violations in advance.
  - CMS continued to pay claims submitted by the facilities, even while aware of the allegations, and never threatened to cut off payment.
- Citing Escobar, the whistleblower needed to show the billing violations were "material" to the government decision to pay the claims submitted, and the provider would have known that the violations would be material.

Statistical Sampling and Extrapolation

- Providers may challenge the result of Statistical Sampling estimates for billing errors using the Medicare 5-step administrative appeals process.
- February 2018 OIG Announcement – if an extrapolation estimate is overturned during this process, the provider is liable for any overpayment upheld in the sample, but not for the full extrapolated total. This difference is often substantial.
- OIG will determine if Medicare Administrative and Qualified Independent Contractors are reviewing statistical evidence in an appropriate manner as part of the fee-for-service appeal process.

DOJ New Policy to Prevent "Piling On" – Announced 5/23/18

- Deputy Attorney General Rod Rosenstein announced a policy aimed at encouraging coordination among DOJ and other enforcement agencies to avoid "unfair duplicative penalties" for the same compliance violation.
- Also announced a new Working Group on Corporate Enforcement and Accountability to "promote consistency" and make "internal recommendations about white collar crime, corporate compliance, and related issues."

DOJ New Policy to Prevent "Piling On" – Announced 5/23/18

- Four policy features:
  - Federal government's criminal enforcement authority should not be used against a company for purposes unrelated to the investigation and prosecution of potential crime;
  - DOJ lawyers from different components should coordinate financial fines, forfeitures, and other penalties to avoid disproportionate punishment;
  - DOJ lawyers should similarly coordinate with other enforcement authorities seeking to resolve a case for the same misconduct; and
  - There are certain factors DOJ lawyers may evaluate in determining whether "multiple penalties serve the interest of justice," including:
    - Egregiousness of the wrongdoing;
    - Statutory mandates regarding penalties;
    - Risk of delay in finalizing a resolution; and
    - Timeliness of a company's disclosures and cooperation.

Revisions to Stark Law Coming

- CMS working on a major overhaul of the Stark Law and its implementing regulations; Proposed Rule expected in Fall 2019.
- Preview
  - Address removal of barriers to doctors participating in value-based arrangements;
  - Clarifying regulatory definition of “volume or value,” commercial reasonableness and “fair market value”;
  - Address issues of electronic health records and cybersecurity;
- Unclear how the changes will impact the LTC industry:
  - Medical Director arrangements
  - Controlled physician groups

Department of Justice Memorandums

- Granston Memo –During 2018, the DOJ moved to dismiss numerous FCA actions, citing the need to preserve scarce government resources and protect important police prerogatives, due to the issuance of Michael Granston's memo which directed DOJ attorneys to evaluate whether the government's interest would be served by seeking dismissal of *qui tam* actions in which the government declined intervention.
- Sessions Memo – On November 16, 2017, then-Attorney General Jeff Sessions issued a memo prohibiting the DOJ from issuing guidance documents that purported to create rights or obligations binding on persons or entities outside of the executive branch, stating that such documents may not be used as a substitute for rulemaking. This memo further stated that any guidance document issued by the DOJ should not use mandatory language (such as shall, must, required, or requirement), and may only set out voluntary standards.
- Brand Memo – On January 25, 2018, a memo was issued by then-Associate Attorney General Rachel Brand, prohibiting the DOJ from using noncompliance with *other* state agencies' guidance documents as basis for proving violations of law in civil cases.

HIPAA Issues

HIPAA Enforcement in 2018

- OCR settled ten cases and secured one judgment, together totaling $28.7 million, an all-time record in HIPAA enforcement activity.
- This total surpassed the previous record of $23.5 million from 2016 by 22%.
- OCR also achieved the single largest individual HIPAA settlement in history of $16 million with Anthem, Inc., representing a nearly three-fold increase over the previous record settlement of $5.5 million in 2016.

Opioid Use Disorder and HIPAA

- Following President Trump's declaration of a nationwide public health emergency regarding the opioid crisis, OCR has released new guidance explaining when HIPAA permits healthcare providers to share a patient's health information with loved ones.
- The guidance explains:
  - Providers can share information with an individual patient's loved ones in certain emergency or dangerous situations, such as when the patient is in a crisis and incapacitated or is facing a serious and imminent threat of harm.
  - Patients with decision-making capacity retain their right to decide when and whether their information will be shared, unless there is a serious and imminent threat of harm.
  - Patients' personal representatives, who have authority under state law to make health care decisions for patients, may request and obtain information on behalf of patients.

OCR Solicitation re: Applying Interoperability Rules to LTC

- Proposed rule to implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology developers under the ONC Health IT Certification Program and reasonable and necessary activities that do not constitute information blocking.
- The implementation of these provisions would advance interoperability and support the access, exchange, and use of electronic health information.
- OCR will be accepting public comments until May 3, 2019.

Doc. Cite – 84 FR 7424
Published – 03/04/19

HIPAA Compliance Risks of Transmitting Patient Care Information Using Text Messaging

- Security risks
  - Technological risks – traditional SMS not encrypted, the "cloud," varying security of personal mobile devices
  - Human risks – failure to maintain secure passwords and devices, misdirected messages
- PHI must be protected from any threats to unauthorized access/disclosure.
- Burden is on covered entities and business associates to implement or address "required" and "addressable" security safeguards in creating, storing, or transmitting PHI.

Nursing Facility Survey Risks of Transmitting PHI Through Text Messaging

- Medicare Requirements
  - F583 Privacy and Confidentiality
    - §483.10(h)(1) Personal privacy
    - §483.10(h)(3) Secure and confidential personal and medical records
  - F842 Resident Identifiable Information
    - §483.70(i) Medical records must be (i) complete; (ii) accurately documented; (iii) readily accessible; and (iv) systematically organized.
    - §483.70(i)(3) The facility must safeguard medical record information against loss, destruction, or unauthorized use.
- Surveyors are not responsible for accessing compliance with HIPAA rules; however, surveyors must assess compliance for maintaining the content and confidentiality of the medical record.
- Surveyor questions focus on how the information is communicated and if the confidentiality is maintained.

OCR Guidance on Cloud Computing and HIPAA

- Cloud Computing – the practice of using a network of remote servers hosted on the Internet to store, manage, and process data, rather than a local server or a personal computer.
- HIPAA permits the use of cloud computing services; Cloud Services Providers (CSPs) are subject to HIPAA requirements and the following regulations:
  - Covered entities and business associates must enter into a Business Associate Agreement (BAA) to use CSPs.
  - Parties may execute Service Level Agreements to address more specific business expectations, such as back-up and data recovery.
  - CSPs must return or destroy all protected health information upon termination of a BAA, but are not required to maintain electronic versions.

Case Law Update

Commonwealth v. Golden Gate Nat'l Senior Care, LLC, 194 A.3d 1010 (Pa. 2018)

- In June, 2015, the AG of PA sued a NF chain for violation of the PA Unfair Trade Practices and the Consumer Protection Law, asserting claims for false advertising and fraud due to understaffing. In March, 2017, PA Commonwealth Court found that the marketing statements were mere "puffery" rather than material representations.
- The AG appealed to the PA Supreme Court, and in September, 2018, the PA Supreme Court reinstated the claims against the NF, stating that the NF made materially misleading statements about the nature and quality of care provided to their residents. Specifically, representations in brochures guaranteeing clean linens, fresh bedside ice water, and snacks at any time were contradicted by poor care at the facility. The Court found that the UFTPCPL violations can be asserted for any fraudulent practice, whether or not the practice is related to advertising or an inducement to enter the facility.
- Moreover, the PA Supreme Court recognized that statements made in Plans of Care and in Medicare/Medicaid claim submissions can be actionable under the Unfair Trade Practices Act if the provider fails to deliver the care outlined in the plans or provide the services claimed.

U.S. ex rel. Streck v. Allergan, No. 17-1014, 2018 WL 3949031 (3rd Cir. 2018)

- Issue – whether Defendants, drug manufacturers, knowingly violated the False Claims Act by excluding certain credits they received from their customers in calculating a drug's Average Manufacturer Price (AMP).
- Defendants had agreements with wholesalers, under which the defendants would pay the wholesalers a reduced service fee. These types of service fee "credits" were designed to combat wholesalers from engaging in speculative buying of drugs. The Plaintiff, a CEO of a network of drug wholesalers, alleged that the manufacturers failed to include these credits when calculating the AMP.
- The district court dismissed the suit, holding that the Plaintiff failed to plead sufficient facts suggesting the Defendants had knowingly violated the FCA.

U.S. ex rel. Streck v. Allergan

- The 3rd Circuit affirmed the dismissal, creating the "3 Inquiry Conclusion" to determine if the defendants in an FCA case knowingly violated the law
  - (1) Is the relevant statute **ambiguous**;
  - (2) Is the defendant's interpretation of the ambiguity **objectively reasonable**; and
  - (3) Was the defendant warned away from the interpretation by administrative or judicial guidance.
- In this case, each of the three questions were decided in the Defendants' favor.
- In other words, if a defendant acts based on a **reasonable interpretation** of relevant law, he or she may not be liable under the FCA even if that interpretation is wrong.

Alina Health Servs. v. Price, No. 16-5255 (D.C. Cir. 2017)

- Hospitals filed suit challenging the formula used by the HHS for calculating certain Medicare reimbursement adjustments for FY 2012.
- D.C. Circuit held that HHS violated the Medicare Act when it changed its reimbursement adjustment formula without providing notice or the opportunity to comment.
- Central issue involves CMS' ability to make policy/reimbursement adjustments via changes to Manuals, rather than through regulation.
- Currently on appeal to the United States Supreme Court.

Good Shepherd Home for the Aged, Inc., DAB No. 2858 (Mar. 19, 2018)

- Good Shepard was cited during a survey for allowing a young resident in his 30's to leave its facility in a motorized wheelchair on a daily basis without supervision. The resident was able to make his own decisions and was actively looking for an apartment.
- Upon reviewing the resident's records, the surveyor noted that an occupational therapist who evaluated the resident's ability to use the motorized wheelchair noted that the resident was able to use the wheelchair on facility premises but nowhere else without supervision. The OT testified that she made this note because she is not able to assess residents for ability to use motorized wheelchairs off-premises. The facility staff testified that they believed it was the resident's right to leave when he wanted without supervision.

Good Shepherd Home for the Aged, Inc., DAB No. 2858 (Mar. 19, 2018)

- CMS argued that the facility violated the regulation by failing to keep track of the resident's whereabouts and expected return times when he left the facility. The ALJ disagreed, noting that the resident was not the facility's prisoner, the facility had taken adequate steps to enforce its sign-out policy with the resident without eliminating the resident's independence, and the facility otherwise took adequate steps to ensure it knew where the resident was. *See* DAB CR4785 (Feb. 7, 2017). CMS appealed the ALJ Decision to the DAB.

Good Shepherd Home for the Aged, Inc., DAB No. 2858 (Mar. 19, 2018)

- The DAB issued a decision reversing the ALJ Decision. The DAB held that the ALJ failed to adequately address whether the facility met its obligations when it allowed the resident to leave "in the motorized wheelchair without the supervision it had determined he required."
- In the response to the facility's argument that the resident had a right to refuse care and leave its facility when he wanted, the DAB stated: "Here, it is unclear that [the resident] actually refused supervision because although [the facility] allowed the resident to leave the facility despite the OT's limitation of his use of the motorized wheelchair to the facility's premises, there is no evidence that [the facility] developed a plan to supervise that offsite use, much less communicated the plan to him."
- DAB noted that while a resident has a right to leave, the SNF has a duty to identify factors that would impact residents health/safety when away.

Neighbors Rehabilitation Center, LLC v. HHS, 910 F.3d 919 (7th Cir. 2018)

- A nursing facility was cited by the Illinois Department of Public Health with an immediate jeopardy deficiency for failure to adequately address sexual interactions among three cognitively impaired residents. A younger male resident suffering from dementia and behavioral disturbances was found to be sexually touching an older male resident with dementia who functioned at a higher level, as well as a female resident with dementia who had very low cognitive functioning.
- The facility's policy was to intervene in "consensual sexual relationships between residents" only when outward signs of non-consent were displayed.
- CMS found that the policy was insufficient.

Neighbors Rehabilitation Center, LLC v. HHS, 910 F.3d 919 (7th Cir. 2018)

- CMS took the position that the facility was required to have ensured that the interactions were consensual by determining the capacity of the individuals involved to consent to the conduct.
- The ALJ affirmed the CMS decision because the facility presented insufficient evidence of consent and failed to adequately investigate such consent. The ALJ further found that the assignment of immediate jeopardy was not clearly erroneous because the non-intervention policy left residents at risk of victimization. The ALJ affirmed the CMP of $83,800. The DAB thereafter affirmed the ALJ decision, noting that the key inquiry was whether the facility "actually assessed whether the residents could consent, determined that they did consent, and monitored the residents to ensure their continued safety."
- 7th Circuit affirmed decision.

Statute and Regulatory Update

Reducing Unnecessary Senior Hospitalizations (RUSH) Act

- Lawmakers are putting the finishing touches on a reintroduction of the RUSH Act, which stalled in the House during the last legislative session.
- The bill sought to create an SNF provision of the “Preventative Acute Care and Hospitalization Reduction Program” overseen by CMS.
- The bill would enable nursing facilities to receive reimbursement for telemedicine and telehealth equipment described as “non-surgical items and services furnished at a hospital emergency department that may be safely furnished by a qualified group practice at a qualified SNF.”

Arbitration

- Forced Arbitration Injustice Repeal (FAIR) Act
  - Bill that has been introduced to Congress, would prohibit corporations from forcing workers, consumers, and small businesses to only resolve their disputes in private arbitration, by themselves, without access to courts.
  - Would also prevent companies from forcing workers to sign away their right to join together in a class or collective action.
- Act 55 of 2018
  - Revised Uniform Arbitration Act (RUAA)
    - Replaces the Arbitration Act of 1980, which promoted the resolution of disputes in a nonjudicial forum while still providing for the court's role in compelling or staying arbitration proceedings when requested.
    - Effective July 1, 2019, will require arbitrator to disclose known financial or personal interests with any party; will allow the arbitrator to fully oversee discovery; will allow the arbitrator to award punitive damages; and identifies provisions which may be waived by the parties.
  - Pennsylvania Collaborative Law Act (PCLA)
    - Addresses collaborative law which is a process to resolve disputes, outside of court litigation, in matters involving family relations, mostly in the context of divorce and custody, but also in the areas of business law and estates law.

Miscellaneous Updates

Telemedicine in Post-Acute Care

- Telemedicine/Telehealth – technology permitting secure two-way, real-time interactive communication between patient and a practitioner
- Common Uses – mental health and addiction services, primary care services, remote patient monitoring and CCM, non-complex wound care, specialty consultations, NOT emergency care
- Key Considerations for LTC
  - Qualified provider shortages nationwide, particularly in rural areas
  - LTC faces increasing challenge of vulnerable and varied population requiring individualized treatment plans and care for complex, co-occurring physical and mental disease states
  - Best practitioners and specialized providers often do not want to work in LTC environment and are either unavailable or too expensive to routinely bring on-site
- **Telemedicine represents efficiency and eliminates geography.**

Telemedicine in Post-Acute Care: Case Study

- Problem – Hospital readmissions at LTC cost Medicare more than $4 Billion annually.
- Study – Telehealth physician on call for "urgent/emergency" calls on weeknights (5pm – 11pm) and weekend days (10am – 7pm)
- Result
  - >15% reduction in hospitalizations
  - Average savings of $151,000 per year to Medicare
  - Reduction in cost for wasted/ineffective care
  - Increased feeling of resident privacy

Telemedicine in Post-Acute Setting Regulations/Compliance

- Licensure – the practitioner must be licensed in the state in which the *patient* is located.
- Medical Malpractice – insurance must be maintained by the provider and must cover telemedicine services.
- HIPAA – fully applies.
- Fraud and Abuse – Stark Law, Anti-Kickback Statute, CMPs, False Claims Act, OIG Advisory Opinions all still apply.
- Medicaid – Reimbursable with informed consent for use of any telemedicine services.
- Private Payors – PA telemedicine parity law failed in the House in October, 2018; private payors are not required to reimburse for telemedicine services.

Telemedicine in Post-Acute Care Medicare Reimbursement Required Elements

- Originating site
  - The location of an eligible Medicare beneficiary at the time the service is furnished. SNFs qualify.
  - Originating site **must** be in:
    - A county outside the MSA as determined by the Census Bureau, or
    - A rural Health Professional Shortage Area (HPSA) located in a rural census tract, as determined by HRSA.
- Distant site
  - The site where the physician or practitioner providing the professional service is located at the time the service is provided.
  - Practitioner must be licensed to provide the service under state law and the service must be within the petitioner's scope of practice.

Telemedicine in Post-Acute Care Medicare Reimbursement Required Elements

- Technology
  - Must be interactive audio and video telecommunications system that permits real-time communication between the distant site practitioner and beneficiary.
  - Telephones, fax machines, and e-mail systems are not allowed.
- Approved service
  - The use of a telecommunications system may substitute for an in-person encounter for certain limited services only.
    - Tobacco use
    - Alcohol misuse
    - Depression screening
    - Behavior counseling
  - Full list is available @ CMS.gov.

Downsizing/Repositioning/Bed Transfer Issues

- DHS's Bed Transfer process provides an option for facilities to downsize their operations and transfer beds to other Medical Assistance providers.
- Important parameters of the Bed Transfer process (codified at 55 Pa.Code 1187.161-.177, including the Bed Exception regulations):
  - The Bed Transfer process by regulation involves the transfer of beds to and from facilities that are currently enrolled MA providers. The regulations do not contemplate the transfer of beds to a new/unenrolled receiving facility, though DHS has made some exceptions in the past
  - The facilities must be located (a) in the same county; (b) within 25 miles of each other if located in an MSA; or (c) within 50 miles of each other if not located in an MSA.
  - The receiving facility must agree to maintain an MA occupancy percentage or Day One admission percentage equal to that of the surrendering facility, in the receiving facility's entire building

Downsizing/Repositioning/Bed Transfer Issues

- Important parameters of the Bed Transfer process (codified at 55 Pa.Code 1187.161-.177, including the Bed Exception regulations):
  - The transfer of beds will improve access to services for the receiving facility and its PSA, and either maintain or at least not harm access to services for the surrendering facility and its PSA
  - The transfer will not result in a reimbursement increase for either provider as a result of a change in Peer Group
  - The bed transfer will not result in an increase in costs to the MA Program
  - The surrendering facility must keep the beds on its active license until the receiving facility is ready to accept and license the beds; there is to be a simultaneous “licensure and de-licensure” at the facilities

Downsizing/Repositioning/Bed Transfer Issues

- This is a purely discretionary process with DHS. Even if the parties satisfy the requirements under the regulation, DHS can still deny the request if:
  - It believes that the transfer would negatively affect DHS's goal to "re-balance" the long term care system; or
  - It believes that there are other, HCBS options that are available at a lower cost than transferring nursing beds to meet an identified need
- DHS's Participation Review Unit oversees these requests
- Generally, it takes at least 4 months to get a decision on a bed transfer request; if denied, the requestor can go through the appeal process and either litigate the case or, more likely, attempt to negotiate a settlement/resolution with the Department.

Medical Marijuana

- While it is illegal to use and/or possess marijuana under federal law, Pennsylvania's Medical Marijuana Act ("Act"), which was signed into law on April 17, 2016 and became effective May 17, 2016, allows patients with a serious medical condition to access medical marijuana if the statutory requirements under the Act are satisfied.
- To date, neither the Department of Health (DOH) nor the Department of Human Services (DHS) has issued definitive guidance regarding the use of medical marijuana in the nursing home and personal care settings.

Medical Marijuana

- Issues for consideration:
  - Can a PCH or NF prohibit a resident from using marijuana prescribed under the Act? What resident rights are impacted?
  - Can a PCH or NF allow the use of medical marijuana, but require the resident or his/her caregiver to administer the drug, rather than a staff member?
    - Can the resident self-administer medications?
    - What happens when the resident can no longer do so?
  - Does the PCH/NF's insurance policy prohibit the distribution of "illegal drugs?"

Medical Marijuana

- Policy Considerations:
  - Who will be authorized to administer?
  - How will facility verify that resident has a legal prescription, and the caregiver is authorized to administer? (ID cards, registration, background checks)
  - How will facility confirm that resident has no more than the legal amount allowed (e.g. 30 day supply)
  - What storage requirements will facility implement?
  - Limitations on wheelchair/scooter use?
  - Will facility limit “form” of allowed marijuana (e.g. no “vaporization”)
  - All of this may be subject to guidance from DOH/DHS when issued

Preview For 2019 and 2020

- DOL has proposed an exemption to allow 16 and 17-year old employees in health care occupations to operate power-driven patient lifts (83 FR 48737).
- With the upcoming election year, health care will again be a focus of discussion
  - Proposals to both expand or constrict Medicare and Medicaid
  - “Work Requirements” for Medicaid
  - Cases and calls to repeal the ACA
  - Single Payor, Medicare-for-All and other options

Conclusions

- As always, so many different things are happening, so it can be difficult to keep up.
- The reality of the industry, though, is that change continues to come, and there are a number of significant issues that will require close scrutiny over the upcoming year.
- Be proactive and keep up-to-date, and we hope to be back next year to provide another update!

Contact Information

David C. Marshall, Esq.

dmarshall@ldylaw.com

Tanya Daniels Harris, Esq.

tharris@ldylaw.com

Latsha Davis & McKenna, P.C.

1700 Bent Creek Blvd., Suite 140

Mechanicsburg, PA 17050

Phone: (717) 620-2424