Mandatory Compliance is Here: Lessons Learned from CIAs



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Session Objectives



- Lessons learned from and SNF CIA, including challenges in working with the OIG, Federal Monitors and operationalizing changes
- Review of the RoP for SNFs and Mandatory Compliance Program under F895: Compliance and Ethics Program
- Tools and strategies for implementation and risk assessment specific for SNFs

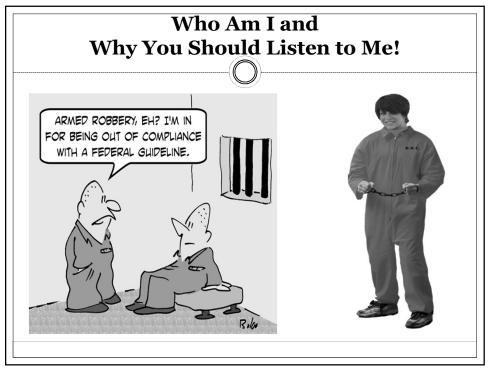
Topics

- Experience with Corporate Integrity Agreement
- Brief Overview of Fraud and Abuse Laws
- Recent FCA Cases in Post-Acute Care
- Anatomy of a False Claims Act (FCA) Case
- Corporate Integrity Agreement (CIA) Elements
- Case Studies: CIA Experience
- RoP F895 Compliance and Ethics Program
- Compliance Risks in LTC
- Questions and Answers

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Experience with CIA

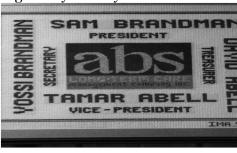
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My Tale of Woe

- ABS Management
 - o Third Generation
 - o Rural Facilities
 - o "Typical" Regulatory History



So What Happened?

- Qui Tam Relator / Whistleblower
- Worthless Care
- Settlement
 - o Monetary settlement
 - o CIA
 - **×** Quality of Care
 - × 5 years
 - **x** Federal Monitors

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Corporate Integrity Agreement

- · OIG enforced
- Typically 5 years
- Successor Liability- Stays with the facility even with new ownership
 - · Foundations Westgate Hills
 - · Andover Subacute
 - Extendicare

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Corporate Integrity Agreement

- CIA requirements:
 - · Hire compliance officer and appoint compliance committee
 - · Develop written standards and policies
 - Implement comprehensive employee training program
 - · Retain IRO and/ or Quality Monitor to conduct reviews
 - · Establish confidential disclosure program
 - · Restrict employment of ineligible persons
 - Report overpayments and other reportable requirements to Quality Monitors
 - · Provide implementation and annual reports to OIG
- Breach of CIA requirements can result in Stipulated Penalty

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Brief Overview of Fraud and Abuse Laws



Fraud and Abuse Laws

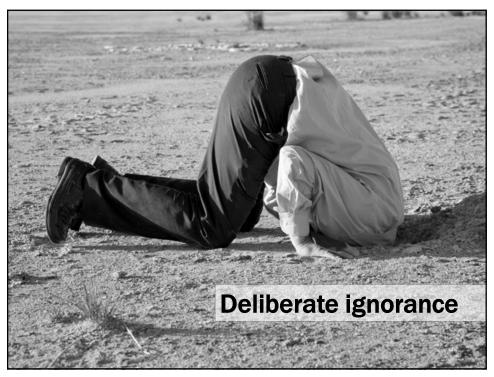
- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Stark Law
- Exclusion Statute
- Civil Monetary Penalties

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False Claims Act (FCA)



- Submission of false claims to government
- Can arise from violation of AKS
- Does not require "intent"
- Includes "Reverse False Claim" retaining an overpayment
- <u>Deliberate ignorance</u> or <u>reckless disregard</u> is enough



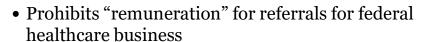
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False Claims Act (FCA)



- Financial risks under FCA (treble damages and \$11,000 per claim)
- New DOJ guidelines for "cooperation" credit when defendants cooperate during FCA investigation
 - o Voluntarily disclosing misconduct unknown to the DOJ
 - o Undertaking thorough root cause analysis of the misconduct
 - o Disciplining or replacing those responsible
 - o Accepting responsibility for misconduct
 - o Strengthening compliance efforts to prevent recurrence
 - o Credit could reduce damages multiplier and civil penalties

Anti-Kickback Statute (AKS)



- Asking for, or offering, remuneration is violation
- Can result in prison, fines, penalties and exclusion
- States may have their own AKS

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06/08/2018 - Signature Healthcare (125 SNFs)

- \$30 million settlement for allegations –
- Billing for rehab services that were not medically necessary, reasonable, and skilled
 - o Unrealistic financial goals
 - o Scheduling therapy at highest level without regard to patient need
- Submission of forged certifications of skilled nursing need to Tennessee Medicaid

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Recent FCA Cases



06/25/2018 - Caris Healthcare (Hospice)

- \$8.5 million settlement for allegations
 - o Company set aggressive admissions and census targets
 - o Patients were admitted and recertified but did not have a terminal prognosis
 - o Internal audits, the CMO and nurses caring for the patients, raised concerns regarding ineligibility
 - o Provider continued to submit claims and took no meaningful steps to determine if improper payments had been received



07/18/2018 - Consultants and 9 SNFs

- \$10 million settlement for allegations of
 - o Medically unnecessary rehab and inflated RUG levels
 - o Corporate policies and practices that encouraged therapy delivery without regard for patient's individual clinical needs
 - o False claims resulted from inflated RUG levels
- Consultants were Southern SNF, Dynamic Rehab
- 9 SNFs in GA and FL

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Recent FCA Cases



08/23/2018 - Reliant Rehab

- \$6.1 million for allegations that it offered improper inducements
 - o Kickbacks to SNFs and MDs to promote its therapy business
 - o ARNPs to work at client SNFs without charge or for a nominal, below market fee, to induce or reward SNFs for contracts
 - MDs above market compensation to supervise and collaborate with Reliant ARNPs



01/28/2019 - Clear Choice and Orlando SNF

- \$1.5 million settlement paid by
 - o SNF, NHA, management company, owners, orthopedic surgeon
- Allegations included
 - o Payments to the physician under "sham medical director" agreement
 - Payments designed to induce illegal referrals of patients to the SNF for rehab
 - o Settlement covered a similar agreement with a related HHA
 - o Agreements violated the Stark law
 - Use of "intricate kickbacks using directorships and other misrepresented positions"

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Recent FCA Cases



02/05/2019 - TN Health Management (THM)

- \$9.7 million settlement paid for FCA allegations -
 - $\circ~$ Submission of false claims to TennCare (Tennessee Medicaid) by its $27~\mathrm{SNFs}$
 - o TennCare requires that a placement evaluation be conducted and certified by an MD for admission to a SNF
 - $\circ\,$ THM submitted admission evaluations with photocopied or presigned MD certifications
 - Allegations encompassed 8 years (2010 2017)



06/11/2019 - Chicago PT Center and 4 SNFs

- \$9.7 million settlement paid for allegations
 - o Providing unnecessary services to increase Medicare payments
 - o Upcoding patients by furnishing skilled therapy to patients who did not need it or could not benefit from it
 - o Part of an effort to bill the highest possible amount to Medicare
 - o Owner of PT Center agreed to be excluded for 5 years from all federal programs

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Recent FCA Cases - HHA



<u>05/24/2019 – Doctor's Choice (Sarasota, FL)</u>

- Government intervened in qui tam case
- Allegations of:
 - Kickback payments to 3 physicians under sham medical director agreements
 - Some HHA employees were paid in a manner that accounted for the volume of referrals by their physician spouses (Stark law violation)

Recent FCA Cases - IRF



06/28/2019 - Encompass Health IRF

- \$48 million settlement to resolve allegations of a "nationwide scheme"
- Allegations included:
 - o Providing inaccurate info to Medicare to maintain IRF status and to earn high rate of reimbursement
 - o Admission that were not medically necessary
 - Some patients were too sick or disabled to participate in or benefit from intensive inpatient therapy

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Recent FCA Cases – "Worthless Care"



10/10/2014 - Extendicare Health Services

- \$38 million settlement in Worthless Care case 33 SNFs in 8 states
- Also involved its subsidiary rehab company
- All 146 SNFs in 11 states came under 5-year CIA
- Was the largest failure of care settlement with a SNF chain
- Allegations that Medicare and Medicaid were billed for "materially substandard nursing services that were so deficient that they were effectively worthless"
- Medicare was also billed for medically unreasonable and unnecessary rehabilitation therapy services

Recent FCA Cases – "Worthless Care"



05/21/2015 – 2 California SNFs

- \$3.8 million settlement
- Allegations that the SNFs:
 - o Overmedicated the elderly and vulnerable residents, causing infection, sepsis, malnutrition, dehydration, falls, fractures, pressure ulcers, and even premature death
- Entered into 5-year CIA

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Recent FCA Cases – "Worthless Care"



10/24/2016 – Texas Nursing Homes

- \$5.3 million settlement in Worthless Care case
- Allegations that SNFs billed Medicare and Medicaid for "materially substandard" nursing services
 - o Medication errors
 - o Failure to follow MD orders
 - o Inadequate pressure ulcer care, infection control, mental health treatment, capital expenditures and equipment
 - o Failed to investigate and report serious incidents

Recent FCA Cases – "Worthless Care"



05/31/2017 -SNF in New Jersey (Andover)

- \$888,000 settlement for materially substandard or worthless nursing services to some patients billed to Medicaid
- Services failed to meet federal standards of care and federal statutory and regulatory requirements
- \$395K to federal government
- \$492K to State of New York

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Recent FCA Cases – "Worthless Care"



02/02/2018 -SNF in Memphis (Spring Gate)

- \$500,000 settlement to US and Tennessee Medicaid
- For allegations of materially substandard services that were so deficient that they were essentially worthless
- Resulted from qui tam lawsuit
- SNF entered into 5-year CIA

Recent FCA Cases – "Worthless Care"



02/28/2019 - Vanguard Healthcare and 5 SNFs

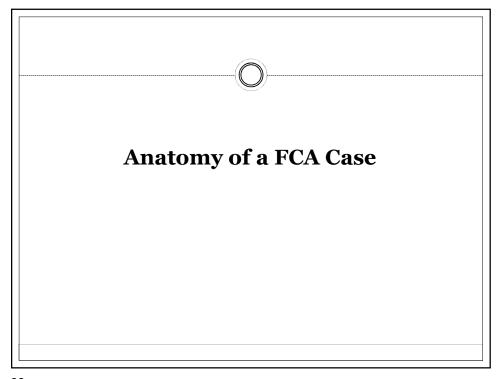
- \$18 million settlement to resolve allegations of billing Medicare and Medicaid for "grossly substandard" nursing home care
- CEO and Director of Operations also paid\$250,000 as part of the settlement
- Allegations included failure to:
 - o Administer medications or provide wound care as prescribed
 - o Provide standard infection control
 - o Meet basic nutrition and hygiene requirements
 - o Take steps to help prevent development of pressure ulcers
- Also alleged to submit preadmission forms with forged nurse or MD signatures

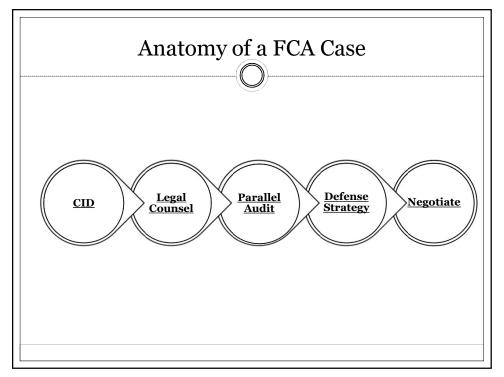
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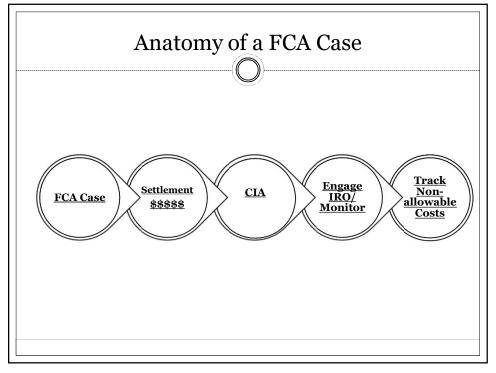
Polling Question # 1



• Have any of you had experience with a Worthless Care investigation or FCA case?







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Polling Question # 2

• Have any of you had experience under a Corporate Integrity Agreement?

What will this cost me?

- Costs associated with CID and/or FCA case
 - o Legal counsel
 - o Parallel audit
 - o Experts
 - o Document production and management
- Financial costs of FCA settlement
- Estimated Costs under a CIA

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5-Year CIA – Worthless Care Case



Estimated Costs 500-bed SNF - Year 1

o Training employees and tracking	\$ 97,500
o Exclusion checks	4,000
○ Hotline	2,000
o Legal	10,000
o Quality monitor	50,000
o Implementation (consultants, new staff)	150,000
Compliance officer	100,000

Cost Year 1 \$413,500

5-Year CIA – Worthless Care Case

Estimated Costs 500-bed SNF - Year 2

 Training employees and tracking 	\$ 97,500
o Exclusion checks	4,000
○ Hotline	2,000
○ Legal	10,000
o Quality monitor	30,000
o Implementation (consultants, new staff)	100,000
o Compliance officer	60,000

Cost Year 2 **\$303,500**

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5-Year CIA – Worthless Care Case



Estimated Costs 500-bed SNF – Year 3

 Training employees and tracking 	\$ 97,500
o Exclusion checks	4,000
○ Hotline	2,000
o Legal	10,000
o Quality monitor	20,000
o Implementation (consultants, new staff)	40,000
o Compliance officer	60,000

• Year 3 Costs **\$233,500**

5-Year CIA – Worthless Care Case

Estimated Costs 500-bed SNF - Year 4

 Training employees and tracking 	\$ 97,500
o Exclusion checks	4,000
○ Hotline	2,000
○ Legal	-0-
○ Quality monitor	20,000
o Implementation (consultants, new staff)	40,000
o Compliance officer	60,000

o Year 4 Costs **\$223,500**

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5-Year CIA – Worthless Care Case

Estimated Costs 500-bed SNF - Year 5

o Training employees and tracking	\$ 97,500
o Exclusion checks	4,000
○ Hotline	2,000
o Legal	-0-
○ Quality monitor	20,000
o Implementation (consultants, new staff)	30,000
o Compliance officer	60,000

o Year 5 Costs **\$213,500**

5-Year CIA – Worthless Care Case

Estimated Costs 500-bed SNF – Years 1 to 5

o Year 1	\$ 413,500
o Year 2	303,500
○ Year 3	233,500
o Year 4	223,500
○ Year 5	<u>213,500</u>

Year 1 - 5 Costs **\$ 1,387,500**

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Working with the OIG



- Negotiate well 5 year commitment
- Build a relationship goes a long way
- Implementation report
 - o Communicate
- Monthly calls
- Annual report
 - $\circ\,$ Be precise

Working with Federal Quality of Care Monitor

- Meeting prior to contract
- Transparency
- Take charge of monitor's visits
 - o Prepare Show and Tell
- Proactive Approach
 - o What keeps us up at night
- Use Them!
 - o Dashboard development
 - o Policy review

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Working with the OIG - Site Visit



- Propose an agenda to the OIG
- Prepare Key Staff Members
 - \circ OIG personnel are attorneys
 - o Review with key staff members- "key points"
 - o Review with Federal Monitor
 - o Review of code of conduct and compliance training

Working with the OIG - Site Visit



- o Most recent annual report
- o Compliance report presented at last board meeting
- o Current Dashboard
- o Completed QAPI project and ongoing- facility choice
- List of all current employees that include name, title and employment start date.
- o Disclosure Log

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Staff Interview



- Staff Interview
- Key employees plus 4 additional
 - o How did the CIA change the way the facility operates?
 - What system was implemented that you felt was a "game changer"?
 - o How do you communicate with the compliance officer?
 - How are initiatives deployed to the front line staff?
 - o Describe a typical day
 - o Greatest challenge of the CIA?

Verification of Training



- o Review of Training documents
- Evidence of compliance training of the 15 staff members pulled for exclusion
- o How does facility verify that all staff is trained
- o Where does the training "needs" come from
- o How do you prove competency with a training
- o What method is used for training
- How is the facility prepping content /staying current and relevant

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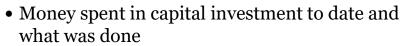
Exclusion Check Verification



Exclusion

- o 15 staff members
 - -ft and part time
 - varied departments
 - pre hire and monthly
- Process for completing the Exclusion checks

Owner /BOD Interview



- o EMR
- How is preventative maintenance evaluated
- Vision of life after CIA
- System for dealing with overpayment

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And the OIG says...

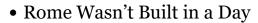


Common denominator for success:

- Empowering the Compliance Officer
- Know your Data
- Take it seriously
- Leadership backing the process



And Tamar Says....



- Don't Fake it Till You Make It
- Top Down Before bottom Up
- Know Thyself
- "But Why?"
- It's a Team Sport



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Requirements of Participation – F895 Mandatory Compliance and Ethics Program

Mandatory Compliance for SNFs is Here

Mandatory Compliance and Ethics Program

Phase 3 - November 28, 2020???



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Can Feel Very Overwhelming



Evolution of Compliance in LTC



- o Established in 1991
- OIG Compliance Guidance
 - o Began in 1998
 - Various provider types
 - o Voluntary

• Affordable Care Act

- o March 2010
- General provision calling for compliance /CMS to work with OIG
- o Oct 2016- outline of general requirements

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And finally... F895



- o Part of Phase 3 rollout
- o Mandatory effective November 28, 2020
 - **×** QAPI and Compliance
- Incorporated into the state survey process
- Federal Sentencing Guidelines and OIG have similar approaches
- o Comment period ended Sept 16, 2019

What does §42 U.S.C 483.85 require?

 "We propose to remove many of the requirements from this section not expressly required by statute. Proposed revisions include removing the requirements for a compliance officer and compliance liaisons and revising the requirement for reviewing the program from annually to biennially."

Federal Register / Vol. 84, No. 138 / Thursday, July 18, 2019 / Proposed Rules

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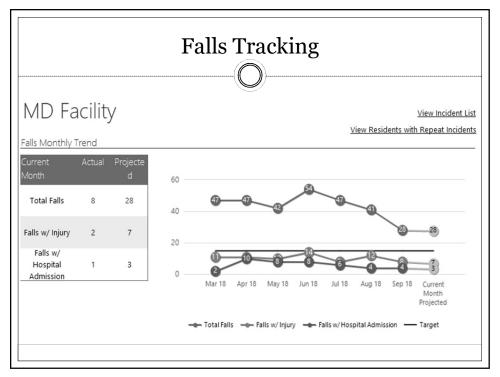
8 Elements of a Compliance Program

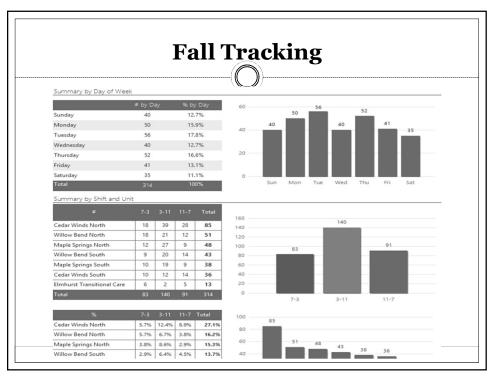
- 1. Compliance and Ethics Standards
- 2. Program Oversight
- 3. Sufficient Resources and Authority
- 4. Screening of Individuals
- 5. Effective Communication of Standards
- 6. Reasonable Steps to Achieve Compliance
- 7. Consistent Enforcement
- 8. Actions to Take

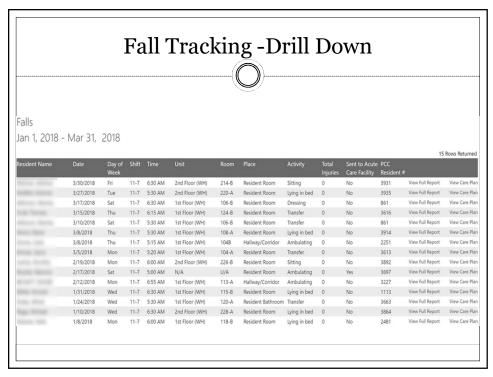
Element #7- Reasonable Steps to Achieve Compliance

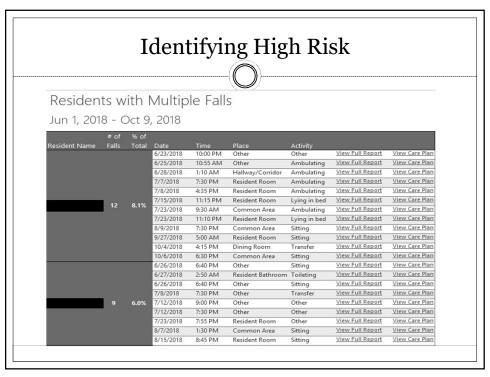
- Audit and Monitoring of Compliance System
 - o Clinical
 - o Financial
- System of checks and balance
- Data, Data, Data
 - **▼** Identify and review variations from established baselines
 - **×** Measurable outcomes
- "In God we trust- all others must use Data" Statistician's Credo (and verified by the OIG)

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Element #8- Actions to Take

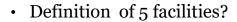


- We found it- how do we fix it
- Proactive versus Reactive
- Systems to correct and maintain NOT a bandaid





So What's 5 Facilities exactly??



 "Develop a compliance and ethics program that is appropriate for the complexity of the organization and facilities and that each facility assign a specific individual within the high-level personnel of the operating organizations with the overall responsibility to oversee compliance"

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How to Prepare?



- Systems to monitor your data
- Make sure exclusion checks are completed
- Develop a Code of Conduct
- Create a "Compliance Binder"
- Start using compliance "lingo"

Ready or Not – PDPM for SNFs is Here!

How should PDPM affect your Risk Assessment and Compliance Program Activities?

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Risk Assessment under PDPM for SNF



Why refocus compliance efforts for PDPM?

- PDPM = most significant change since PPS began
- · Risk of improper payment will change
- · Change itself increases risk of error
- RoP mandate Compliance Plan effectiveness
- CMS plans a "robust" monitoring program

Risk Assessment under PDPM for SNF



What areas does CMS plan to monitor?

- Shifts in utilization patterns in clinical categories
- · CMS noted that, "Some providers may stint on care"
- · Coding of functional status in Section GG
- · Changes in quality trends
- · "Case-mix creep"

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Risk Assessment under PDPM for SNF



CMS has outlined major focus on therapy

- · Changes in volume and intensity
- Changes in modes of delivery
- Increased use of concurrent and group
- Documentation to support group and concurrent
- Compliance with group and concurrent limits
- Effectiveness of therapy

Risk Assessment under PDPM for SNF



How will CMS monitor?

- · Therapy data on PPS Discharge assessment
- New QRP outcome and readmission measures
- Decline in QRP measures
- CMS will have many data sources available to track trends

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Risk Assessment under PDPM for SNF



Other Potential Concerns

- Increased coding of cognitive impairment and mechanically altered diet
- · Increased coding of depression
- Unsupported and/or inaccurate ICD-10 coding
- Improper application of "Interrupted Stay Policy"
- Nursing notes that do not support daily skilled assessments or evidence skilled care
- · Myriad of therapy-related risk areas

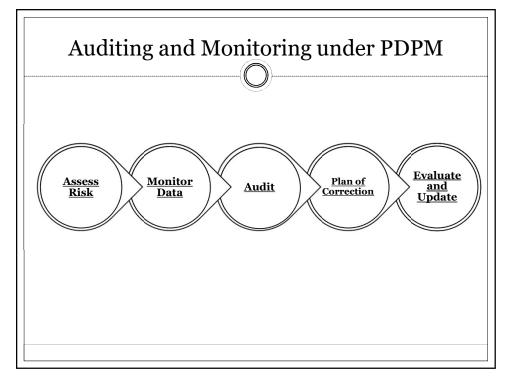
Risk Assessment under PDPM for SNF



Auditing and Monitoring under PDPM

- Current auditing and monitoring protocols must be updated
- Risk areas under PDPM are materially different than under RUG-IV
- See suggested checklist of potential risk areas (Attached)
- Create a dashboard to track most critical areas
- Involve the entire team and encourage open communication

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Resources

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- <u>Tbacompliance@gmail.com-</u> Tamar Abell
- <u>www.snfmetrics.com</u> Data Analytics

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Questions and Answers