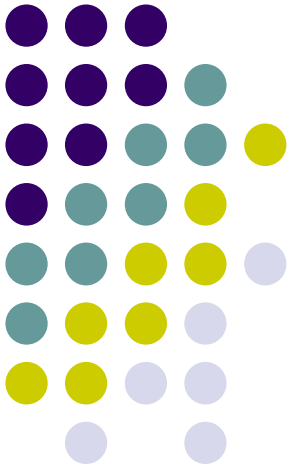
Compliance

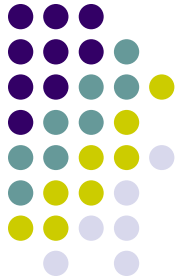
Lori Blaire, OTR/CHC

Vice President, Compliance Officer

Tender Touch Rehab



Ethics



- A branch of philosophy that involves systemizing, defending and recommending concepts of right and wrong

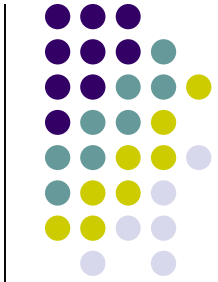
- Synonyms – Morals, values, principles, ideals and standards

Ethics

- Sociologist Baumhart asked business people "What does ethics mean to you"?
- Responses:

1. "It is what my feelings tell me is right or wrong" (can't just go on feelings)
2. "It's doing what the law allows" (not all laws are ethical or make sense)
3. "Consists of standards of behaviors that society accepts" (society may not be a good barometer)

Ethics

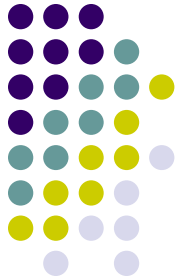


- Baumhart defined ethics as a well founded standard of right and wrong which prescribes what people ought to do, rights, obligations and benefits to society, fairness or virtues
- Ethics should be reasonable, moral beliefs and conduct should live up to your standards (measure up to your own values)

Gracyk's 4 Fundamental Principles of Healthcare Ethics

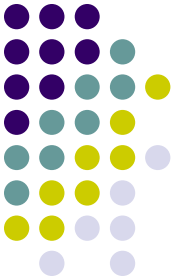
- Respect for autonomy and decisions made by others
- Obligation to bring about good in all our actions
- Obligation to not harm others
- Obligation to provide others with whatever they are owed or deserve

5 Top Ethical Issues in Healthcare



- Balancing care quality with efficiency (Compliance)
- Improving access to care
- Building and sustaining a healthcare workforce for the future
- Addressing end of life issues
- Allocating limited medication and donor organs

5 Top Ethical Issues in Healthcare (cont'd)



- **So if we are all ethical and follow the rules, why is it that the government is after all of us for waste, fraud and abuse?????**

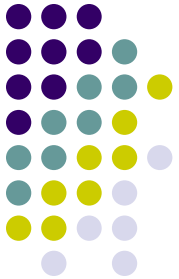
Enforcement Environment

- **Kindred Rehab Care -** Settled FCA for $125 million for allegations that Rehab Care routinely scheduled patients for higher levels of therapy than needed, as well as allegedly scheduled patients for therapy after D/C was recommended (whistleblowers got $24 million) January 2016 (Catholic Health $4.7 million, 2 SNF's for decreased time after ARD). (In September, got hit with a $2 million penalty for not changing billing practices as was required by CIA).

Enforcement Environment (cont'd)

- **Extendicare -** (Progressive Step Rehab) settles FCA for $38 million for substandard nursing care, 33 homes in 8 states. Allegations stated that the facility failed to provide adequate care, failed to provide adequate catheter care as well as failed to follow appropriate protocols to prevent pressure ulcers. (October 2014) Largest failure to care settlement to date. (Also in PA they settled a Medicaid FCA for $2.2 million).

Enforcement Environment (cont'd)

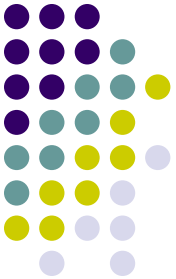


- **Wingate Healthcare –** 16 SNF's settled FCA for $3.9 million alleging Medicare billing fraud for unreasonable and unnecessary therapy services and did not prevent pressure ulcers and falls (January 2016).
- **Hebrew Homes Network –** (5 year CIA), no admission, alleged kick-backs hiring numerous physicians as medical directors with roles and responsibilities not done. $17 million settlement (whistleblower was the CFO who received $4.25 million) (June 2015).

Enforcement Environment (cont'd)

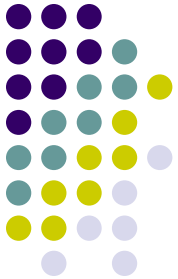
- **Pediatric Services of America –** $6.88 million to FCA for failure to investigate credit balances to determine if there was an overpayment (August 2015).
- **The DOJ –** Announced that the National Health Care Fraud Division had the largest fraud take-down in history with charges against 301 defendants for approximately $900 million for fraud schemes, anti-kickbacks, money laundering, home health OT, PT, DME and prescription meds (June 2016).

Enforcement Environment (cont'd)



- **North American Healthcare –** 35 SNFs in CA. The company agreed to pay $28.5 million to settle claims for medically unnecessary rehab services and a 5 year CIA. The CEO pays $1 million and the VP of reimbursement pays $500,000 (September 2016).

Enforcement Environment (cont'd)



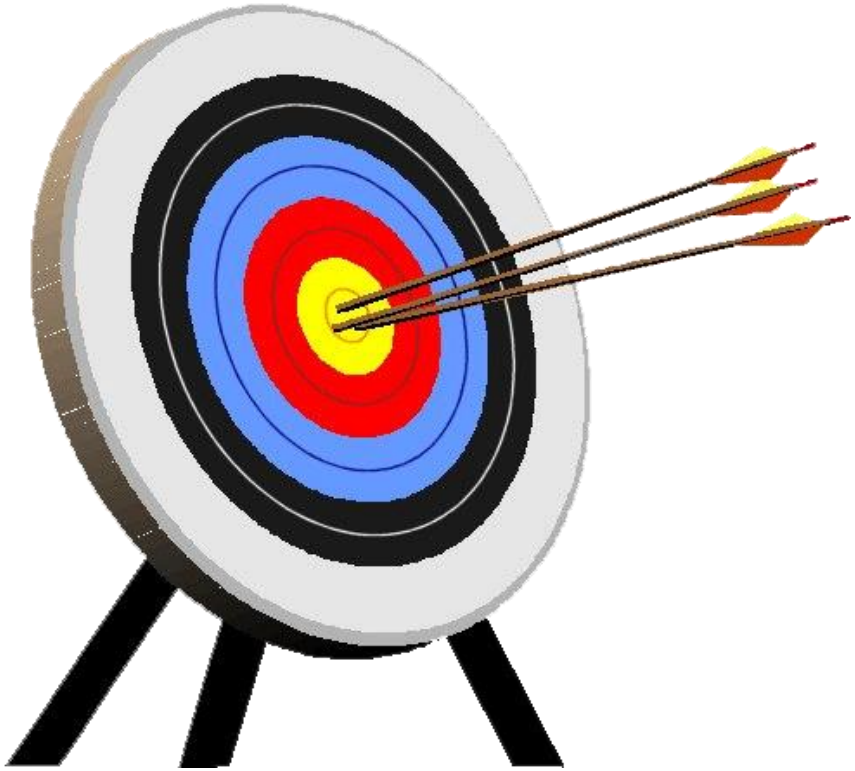
- **Country Villa Service Group in CA** – settled for $3.8 million to resolve allegations of substandard or worthless services, and alleged the employees overmedicated elderly and vulnerable residents causing falls, fractures, pressure ulcers, etc... HHS chose a quality monitor to be done quarterly and they are under a 5 year CIA (May 2015).
- **Common Wealth of PA –** was ordered to pay $48.8 million to settle civil FCA that PA provided benefits to ineligible aliens in violation of federal law (January 2015).

Enforcement Environment (cont'd)

- **Life Care Centers of America –** First FCA case involving SNF and Therapy that we heard about offered a settlement proposal in June, waiting for DOJ to accept and was granted a 90 day extension (LCC paid $4.2 billion from Medicare and Medicaid between 2010 and 2016).
- **Genesis -** $52.7 million settlement for improper billing of hospice services (company they acquired through a merger in 2015).
- Biggest settlement to date is with Pharma Co. $2.3 billion in 2009 for illegal promotion of the drug Bextra, promoted for uses not approved by FDA.

Who's Being Targeted

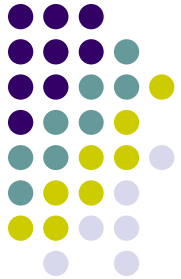
- Medical Transportation
- Clinical Labs
- DME
- **Therapy**
- Hospice
- Home Health
- **Nursing Homes**
- Hospitals



Who is Focusing on Healthcare Fraud?

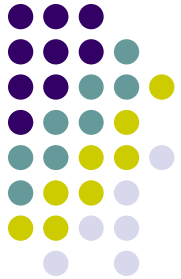
- OIG
- DOJ
- CMS, Medicare, Medicaid
- HHS
- MFCU
- ZPIC, RAC
- Medicare Strike Force (HEAT)
- State AG
- Commercial Insurances
- Competitors
- Attorneys and Whistleblowers

Government Focus on Compliance, Compliance Initiatives



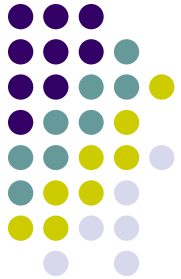
- DOJ hired a compliance expert (new focus on executive board and management, arrangement reviews, quality of care, medical necessity)
- CIAs now include companies must have a compliance program
- April 2016 the OIG Program Exclusion Criteria was updated to include that:
  - Providers are expected to implement a robust compliance program

Lesson Learned from Current Compliance Environment



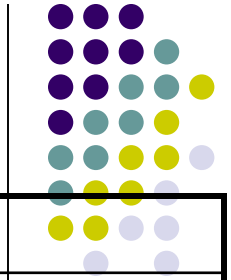
- DOJ recovered more than $3.5 billion in 2015
- $1.9 billion from the healthcare industry ($330 million from hospitals)
- $2.8 billion from whistleblowers (suits exceeded 600)
- Government has invested in data analytics to prevent fraudulent claims and identify trends (state of the art predictive analysis technology since 2011, health partnership between government and private health and anti-fraud division to share info to prevent fraud (Healthcare Fraud Partnership Prevention System)
- New investigative and enforcement strategies (HEAT, OIG Healthcare Fraud Prevention Team)

Lessons Learned from Current Compliance Environment (cont'd)



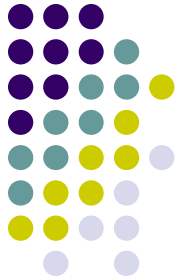
- OIG formed a new litigation team in 2015 to focus on exclusively pursuing CMP and exclusions.
- September 2015 - Yates Memo - Titled Individual Accountability in Corporate Wrong-doing.
- Do not give cooperation credit to company unless company provides facts on individuals involved in misconduct.
- Focus on the individual from inception of both civil and criminal investigation.
- No release of culpable individual absent to any extraordinary circumstances.
- No settlement with a company without a clear plan to resolve individual cases before the statue of limitation expires.

Enforcement Authorities



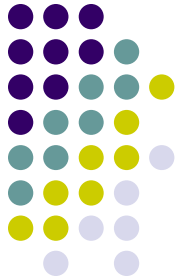
Civil	Criminal	Administrative
FCA Funds from criminal investigations Big settlements with large corporations Physician targets Individual targets	Medicare Strike Force Reviewing civil cases Increased rile of the state AGs office	CMS Center for Program Integrity OIG CMP Authority OIG Exclusion Authority Focus on providers that employ excluded individuals Amplified focus on individuals
379 civil actions between October 1, 2015 and March 1, 2016	384 criminal penalties between October 1, 2015 and March 1, 2016	1,662 individuals excluded between October 1, 2015 and March 1, 2016
$43.8 million CMP	$1.86 billion in investigative receivables due HHS	$48.1 million in receivables from self-disclosures

What do we do?



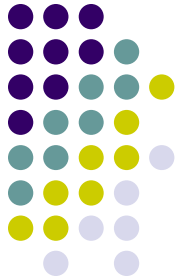
- Understand and navigate the Fraud and Abuse Laws
- Implement the 7 basic compliance elements of the compliance program
- Cultivate and operationalize culture of compliance
- Proactive compliance activities
- Embed compliance in all departmental activities
- Know how to conduct a thorough investigation and action plan

Quick Review of the Fraud and Abuse Laws



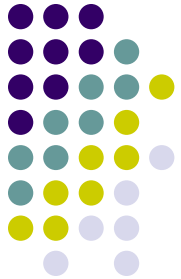
- Purpose of the laws are to reduce over utilization, decrease medical costs and decrease medical steering and unfair competition (violation, CMP, payment denials, exclusion, fines, jail time)
- **Physician Self-Referral Laws (Stark)** Limits the physician referrals when there is a financial relationship with the entity

Quick Review of the Fraud and Abuse Laws (cont'd)



- **Anti-Kickback -** Prohibits asking for or receiving anything of value to induce or reward referrals of federal healthcare programs business (safe harbors, investments, space rental, equipment rental)
- **Swapping -** Providers and suppliers give discounts on Part A services in exchange for Part B and D referrals

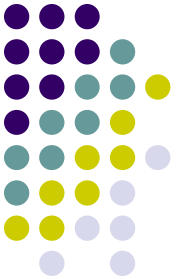
What is an OIG Exclusion?



- The OIG can exclude an individual or an entity from being paid directly or indirectly by a Federal Health Care Program for any item or service they provide for a period of time, or indefinitely for wrong doing. Any entity receiving reimbursement from a federal/state program may not employ excluded individuals.

- www.oig.hhs.gov/fraud/exclusion

What is an OIG Exclusion? (cont'd)

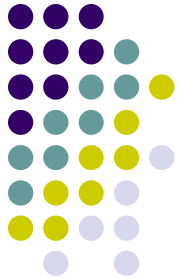


- There are 35 exclusion lists. They advise checking the exclusion list monthly (vendors).
- By law, we must self-disclose if we hire an excluded individual.
- People are excluded for felonies, misdemeanors, and for failure to pay back student loans.

OIG Revised Exclusion Criteria

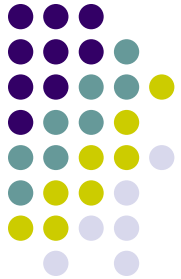
1. New criteria for exclusions to replace the 1997 guidelines
2. Notable as it raises the bar, making it more difficult for providers to avoid exclusions
3. Compliance programs expected/failure to do so increases risk of exclusion
4. Risk spectrum

OIG Revised Exclusion Criteria (cont'd)



5. Factors increasing likelihood of exclusion
    1. Conduct causing harm (physical, mental, financial) to beneficiary
    2. Potential loss to federal health program
    3. Conduct/pattern of wrongdoing
    4. Improper actions not stopped until government investigation
    5. If management planned unlawful activity

OIG Revised Exclusion Criteria (cont'd)

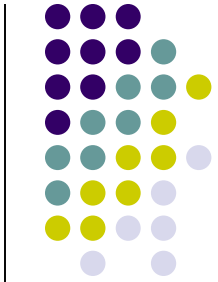


6. Prior history of judgments/convictions (civil, criminal or administrative)
7. Provider previously under CIA
8. Obstruction of investigations
9. Failure to comply with subpoena/ reasonable time frame
10. Inability to pay to resolve case
11. Absence of a compliance program

Fraud and Abuse Laws

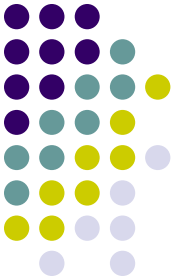
- **False Claims Act –** The act prohibits the submission of false or fraudulent claims to the Government. Initially enacted in 1863, amended in 1986, is the DOJs principle enforcement tool for recovery of civil damages resulting from false or fraudulent claims for payment by the Government. Can have civil penalties ($5,500 - $11,000 per claim, treble damages).

Reverse False Claims



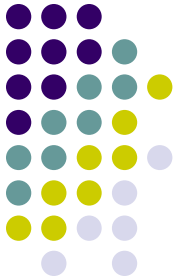
- **Updated in 2009** – Places liability on any person who knowingly makes, uses or causes to be made, a false record or statement material to an obligation to pay or transmit any money to the Government, or knowingly conceals and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

Fraud Focus Areas (FCA)



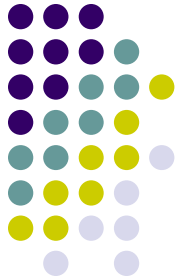
- Medically unnecessary services
- Services billed, not provided
- Up-coding
- Unbundling services
- Worthless services
- Payment as a result of a kick-back

Medicare Overpayment Rule 60 Day Rule



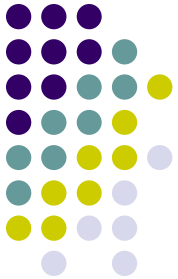
- **May 2010 -** Affordable Care Act (Section 6402 (2) required a person receiving an overpayment must both "report and return" the overpayment "an overpayment not timely reported and returned constitutes an obligation for purposes under the FCA").
- **May 2014 -** Overpayments Rule final for Parts C and D.

Medicare Overpayment Rule 60 Day Rule (cont'd)



- **February 2016 -** CMS issued a Final Rule for return of Medicare Parts A and B (although the Final Rule is for all, the February 2016 applies only to Med A and B).
- No rule for Medicaid overpayments at this time; however, HHS says "providers that identify overpayments for Medicare or Medicaid should return the overpayment to the appropriate payer".

Overview of the Rule

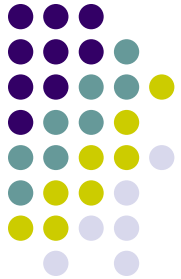


- Coded at 42 CFR 401.301-401.305
- Estimated to be an annual cost burden to suppliers and providers of $120-200 million
- Requires suppliers and providers to report overpayment by 60 days of identification
- Or at the date of the corresponding cost report
- FCA liability, CMP, exclusion

Identification

- As stated in the Final Rule - When a person has or should have through the exercise of **reasonable diligence** determined that a person has received an overpayment and **quantified** the amount of the overpayment (42 CFR 401.305 (a) (2))
- Overpayment is not identified until it **is quantified;** however, you can not delay in quantifying the amount.

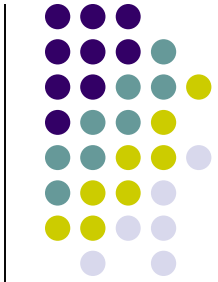
Reasonable Diligence



2 Parts

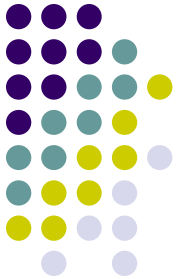
1. **Proactive Activities –** qualified individual who monitors overpayments on a regular basis
2. **Investigations –** in a timely manner and in good faith to **credible information (info that supports a reasonable belief that an overpayment was received)**

What is Credible Information?



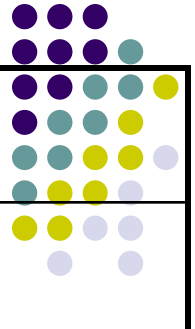
- Hotline info
- Incorrect coding is discovered resulting in higher bill, or significant unexplained increase in bill is noted.
- You discover that a patient expired before service date.
- Service was provided by unlicensed provider.
- Internal audit discovers overpayment.
- Government agency (RAC, ZPIC, etc.)

Overpayment Rule

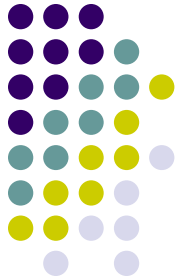


- **Overpayment** – Any funds that a person received or retained which a person after applicable reconciliation is not entitled.
- May be received or retained due to an error, fraud activities, or inadvertently. None will excuse or alleviate the responsibility to return payment (Medicaid, NYC Hospital, $500 grand, settled for $2.95 million for a computer glitch).
- Examples of overpayments.

Simple	Moderate	Complicated
Pt not on service	Excluded service	Falsified doc
Duplicate payment	Insufficient doc	Anti–kickback or Stark Law arrangement
Billing after d/c	Lack of medical necessity	Up-coding
Excess payment after allowable amount	RAC pre or post audit	Keeping payment for a patient not on service
Paid by Med, not primary payer	Unlicensed employee	Misrepresented dollar amount for allowable service
Non-reimbursable item		Emp excluded
Error		



Knowledge Defined

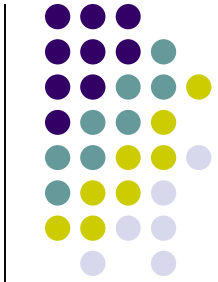


- A person has identified an overpayment
- Person has knowledge of the overpayment
- Acts in reckless disregard or deliberate ignorance
- Must act on knowledge
- The 60-day rule explicitly states that the overpayment retained after 60 days of identification constitutes a FCA

Clarification

- Government agency audit, letter, full investigation.
- Provider has credible information – they must start investigation.
- Provider has **6 months** from the day of receiving credible information to complete investigation. Keep detailed records of the investigation.
- Once confirmed and **quantified**, the provider has **60 days** to report, refund (8 months in total) RAT STATS statistical sample and methodology. Self-disclosure forms, etc. (rare cases extension).
- Look-back is 6 years (maintain records).
- MAC usually has a look-back of 2 years, although they cannot initiate re-opening a claim if they can request from OIG, CMS or DOJ.

Report and Return

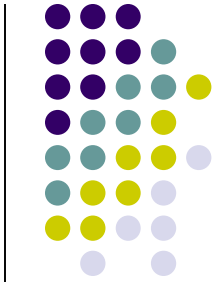


- **Self-Disclosure Protocol and Forms –** False or improper claims, falsification of documents, intentional miscoding, services not medically necessary, payments not covered, anti-kickback and Stark Laws)
- Outside counsel
- Submit cover letter, documentation and statistics
- Pay money or installment plans
- Does the facility also have a CIA

HHS

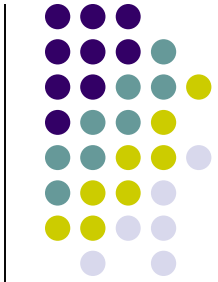
- In the Final Rule it says “If a person has received an overpayment, the person shall both report and return the overpayment to the Secretary of HHS, an intermediary, a carrier or a contractor to whom the overpayment was returned must put in writing the reason for the overpayment”.
- The secretary may waive some federal laws to carry out provision of testing models (shared savings, CJR, ACO).

Cultivate and Operationalize Culture of Compliance
Why Compliance Now?



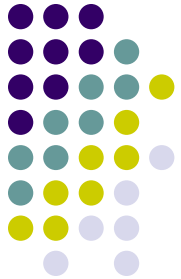
- Quality reporting is here
- Reputational risk
- FCA potential
- Whistleblowers
- Audits
- Data Analytics

Compliance Team



- CEO, CFO, ADM
- Compliance
- Legal
- Audit
- UR
- Nursing
- Admission
- HR
- Therapy

Creating a Culture of Compliance

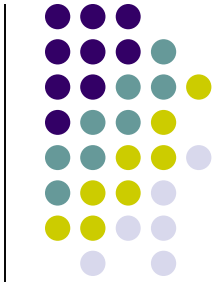


- Demonstrate commitment from the top down
- Training
- Monitoring/auditing
- Technology/infrastructure
- Incentive ethical behavior
- Align strategies, values and conduct
- Openly communicate expectations
- Empower employees
- Be accountable for the failures - make others accountable

7 Practical Tips for Creating a Culture of Compliance

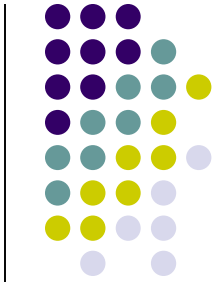
1. Make compliance plans a priority now
2. Know your fraud and abuse risk areas
3. Manage financial arrangements
4. Don’t mimic competitors if not compliant
5. Demonstrate compliance activity effectiveness
6. Role model for compliance
7. Consult compliance professionals when needed

Compliance Program Elements/ Compliance 101



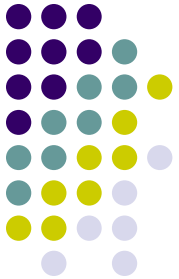
- SNF mandatory program since 2013
- Program must contain:
    1. Written policies and procedures (updated)
    2. Compliance professionals (responsibilities)
    3. Effective communication
    4. Effective training
    5. Enforcement standards, discipline
    6. Prompt investigations/AP
    7. Internal monitoring/auditing, risk assessments

SNF Focus Areas for Compliance Plan



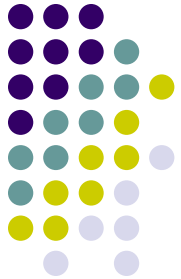
- Eligibility review
- Documentation in order
- MDS review
- Therapy reviews
- Financials
- Claims
- Kick-back exposure
- Hospice

Compliance SNF Plan and Prevention



- Marketing
- Billing practices
- Clinical care
- Medical necessity/appropriateness of services
- Up-coding
- Recycling patients
- DME schemes
- High turnover rates
- Theft (identity)

Potential Compliance Issues



- Violation of Law
- Quality Care events
- Overpayments
- Policy Updates
- Risk Assessments
- Auditing
- Billing and Coding
- Medical Necessity

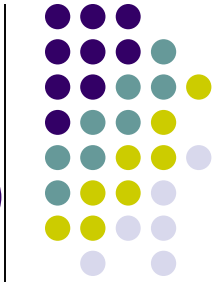
PEPPER

- RUGS Utilizations, Ultra-high
- ADL Scores
- UB04
- Readmission
- Part B Utilizations
- LOS
- LOS/Diagnosis
- ARDs
- Revenue per episode
- Medical Necessity
- MDS Accuracy

Embedding Compliance, Operationalizing Compliance

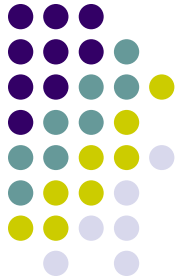
- **P&Ps –** Are you reviewing P&P with staff, ensuring training on updates, are you providing "real life" examples?
- **Measuring effectiveness –** Are you setting realistic benchmarks and measurable goals, are you setting up your systems to measure your performance, are you auditing, are you investigating issues, informing board of risks?
- **Training –** Are you reviewing and updating training, is training a job requirement, maintain documentation on training?
- **Lines of communication –** Do you have a Hotline, are you referring all issues to the Hotline, do you have open lines of communication, are you enforcing the non-retaliatory policy, use surveys and interview staff?

Embedding Compliance/ Operationalizing Compliance (cont'd)



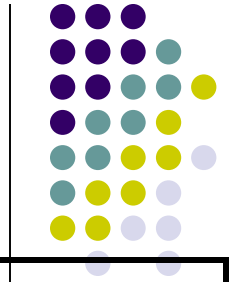
- **Auditing -** Are you initiating proactive reviews on billing, coding, contracts, quality of care or just waiting for the quarterly, did you do a risk assessment to identify risks and then mitigate risks, audit plans? Have you implemented an action plan and how is it going? Where is the documentation, monthly control audits, are you following up on the outcomes that you found and monitoring corrective actions?
- **Enforcement -** Do you use your team to help ensure that there is an objective view of compliance, do you prompt investigations, corrective action plans, enforce compliance through disciplinary action?
- Do you track complaints and action plans?

Areas to be Addressed in Trainings



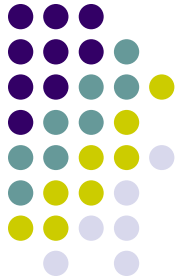
- General Compliance (Organizational Chart, Compliance Program, Compliance Guidelines, Handbook)
- Job Specific Ethics and Compliance
- Code of Ethics and Behavior
- Clinical Quality
- Billing and Coding
- Postings
- Hotline
- Fraud and Abuse Laws
- Internal Controls and Auditing

Investigations



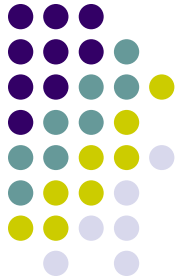
Internal Investigations	Government Investigations
Initiated by company usually due to a complaint	Initiated by Government subpoena, search warrant, whistleblower, agents of OIG and FBI
Goal is to assess wrong doing	
Review documentation and billing	Collect, review and produce documents
Interview staff	Interview relevant employees
Result can be a self-disclosure, revision of policies, disciplinary action, training, voluntary refund	Outside Counsel
	Presentation to Government
	Penalties, disclosures, revised policies, CIA, CMP and criminal prosecution

Effective Investigations Complainant Interview



1. Establish a comfort level with complainant
2. Ensure proper interview conduct
3. Interview employee, gather facts for who, what, when, where and why
4. Inform employee of non-retaliatory and follow-up procedures
5. Determine motivation
6. Document, summarize interview and number sequentially

Accused Employee Interview

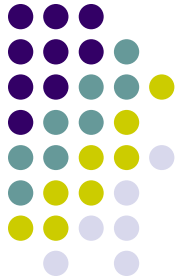


- Organize investigation (know policies, procedures, guidelines, bring relevant documents)
- Prep (outline of facts, detailed explanation of issue, anticipate questions)
- Determine who should do interview (obj)
- Meet with employee, discuss focus of the investigation, ask for facts, ask easy/hard questions

Recommendations

- Contact deciding authority
- Was any policy or procedure violated, did this happen in the past and disciplined in the past?
- Did the employee request counsel?
- Devise corrective action plan while still being conscious of confidentiality, attorney/client privilege?
- Act on findings expeditiously?
- Social Media influence?

Compliance

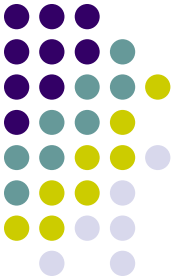


- If an organization is found guilty of a violation of State or Federal Laws, the Government may offer a reduction in penalties if an effective compliance plan is in place (Medi Tract 2016)

Demonstrating Effectiveness

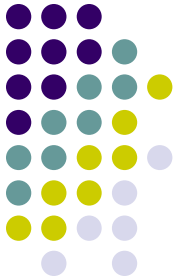
ADM	Board	Manuals	Hotline	Audit Monitor	Misc
Organizational Chart Budget Board Meetings Compl. Doc. Compl. Roles Code of Conduct Annual Reports	Charter Compliance Committee Charter Operations Compliance Charter	Self disclosures Non-retaliatory Policy Training Conflict of Interest Risk Assessments	Reports Tracking Incidents Doc.	Audit Finding Reports Corrective Actions Doc.	Newsletter Articles Updates

PAC Relationship Compliance



- Information and Billing Systems
- EHR Integration
- Marketing
- Governance and Decision Making Authority
- Adequate Care Coordination

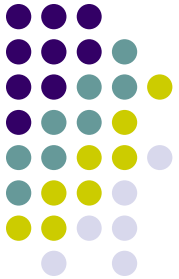
Social Media



Statistics

- 73% of the US population had a social network profile
- In 2014, cell phones outnumbered people
- By 2017, it is projected that 50% of employers will have their employees using their own mobile device at work

HIPAA Rule



- Designed to protect PHI
- Has administrative, technical and physical safeguards
- Flexible, covered entity determines specific measures
- No specific rules or guidelines for social media (Yet)

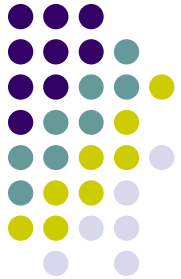
HIPAA

- Cyber crime – Important to know the real cost to victims
- Release from Office of the National Coordinator from Healthcare Technology “Healthcare cyber security will only continue to evolve”. We need a better understanding of the possible threats.
- $100 million medical records compromised in breeches in 2015. First time patient records exposed to hacking.
- Real threat is Ransomware (February 2016, Hollywood Presbyterian Medical Center).
- Review data security, policies for technology, employee training.
- Balance between innovation and security.

Cyber Crime

- If there is a hacking incident, can a healthcare provider still provide care?
- IV Hacker (white hat hacker, Billy Rios), demonstrated that IV pumps were vulnerable to hacking FDA in 2016. Took action against IV company and wrote first draft of mandates for medical device companies for cyber security management of medical devices.
- To date, an average of 7 out of 10 risk assessments for cyber security reviewed by OCR during compliance investigations are deficient or fail entirely.
- National Institute of Standards and Technology (NIST) has a methodology called IRM, which offers organizations a cyber security framework, process and a model to help protect patient safety and information (consultant).

HIPAA Law Mandates

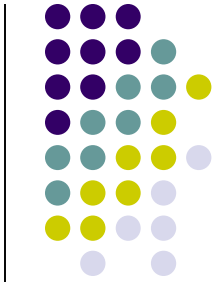


- Comprehensive analysis of risks
- Reasonable measures to protect PHI
- Breech reporting, remediation and penalties
- Employers are limited from taking any employment action based on protected status discovered via social media (Anti-discrimination laws)

Prohibits

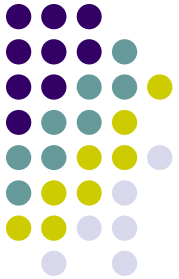
- From insisting employees provide access to non-public information or hack into a persons social media account (Privacy Laws)
- From interfering with an employee's right to engage in activities, discussing terms of employment via social media (Section 7 National Labor Relations Act, Glass Door)
- Freedom of Speech Cases

A Word on Texting



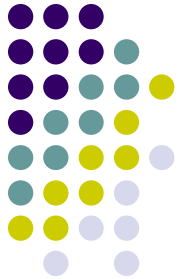
- Physician requests password protected?
- Communication between staff.
- Family request updates.
- Policy addressing use of cell phones for business purposes, texts containing PHI. BYOD policies, business vs. personal phones, encryption.
- A mention for faxing vs. mailing (disclaimer). OCR against provider who sent patient info to employer, not provider.

Negative Posts



- Remove
- Discipline
- Ignore it
- Social media policy regarding disparaging comments

Post Photos



- Post photos of patients
- Employee training
- 8/8/2016 – CMS announced that they will be checking to see if nursing homes have polices prohibiting staff from taking demeaning photos of residents

Best Practices

- Develop a social media policy
- Update your HIPAA policy to include social media
- Post signs in facility to prevent photography
- Educate workforce
- Manage privacy levels on social media site (Facebook, LinkedIn, Instagram, YouTube and Twitter)

Conclusion

- HHS, OIG, CMS, HEAT, DOJ and the OCR will continue to aggressively pursue perpetrators of waste, fraud and abuse, as well as HIPAA violations. All facilities need to strengthen their internal compliance programs and foster a culture of compliance throughout every department.
- Employees should be encouraged to report potential issues and areas of exposure.
- There needs to be prompt action, investigations and corrective actions.
- Be proactive rather than reactive.

Questions?

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