Emerging Compliance Audit Issues

Presented by:

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Piedmont Healthcare

Agenda

• About our organizations
• Overview of emerging compliance audit issues
• Provider-Based Services and Provider-Based Physician Billing
• Disaster Recovery and Business Continuity
• Drug Diversion
### Piedmont Healthcare

Piedmont Healthcare Corporation is a private, not-for-profit health system in Georgia comprised of the following entities:

- Piedmont Atlanta Hospital *(North Atlanta)*
- Piedmont Fayette Hospital *(Fayetteville)*
- Piedmont Henry Hospital *(Stockbridge)*
- Piedmont Mountainside Hospital *(Jasper)*
- Piedmont Newnan Hospital *(Newnan)*
- Piedmont Newton Hospital *(Covington)*
- Piedmont Healthcare Foundation

### Piedmont also includes:

- **Piedmont Clinic**
  - Group of more than 1200 Piedmont physicians from across the system (all Piedmont employed physicians and 900+ independent) who are clinically integrated, sharing information to achieve higher clinical outcomes.

- **Piedmont Heart Institute**
  - Consists of more than 100 affiliated cardiovascular specialists in over 20 locations, spanning from south of Atlanta in Fayette and Coweta counties to communities across north Georgia. PHI offers a continuum of patient care and propels new programs in cardiovascular research, education and excellence.

- **Piedmont Physicians**
  - A multi-specialty physician group with more than 120 primary care physicians in over 35 offices, in addition to more than 136 specialists in over 34 locations across greater Atlanta. It encompasses 18 specialties including primary care, pediatrics, general, sport and orthopedic surgery, surgical and gynecologic oncology, neurology, podiatry and pulmonary services.
About Piedmont Healthcare

OUR MISSION:
Healthcare marked by compassion and sustainable excellence in a progressive environment, guided by physicians, delivered by exceptional professionals, and inspired by the communities we serve.

- Founded in 1905 by two physicians
- 1,218-bed health system
- Areas of clinical expertise include: cancer, heart, neuroscience, transplant and women's services
- Serves the metro Atlanta area as well as communities in Fayette, Coweta, Henry, Newton and Pickens counties
- More than 12,700 employees across its entities
- AlwaySafe program: system-wide safety behaviors and prevention tools to reduce the number of serious safety events
- Epic: industry-leading EMR and practice management system provides better care and enhances the patient experience

Community Medical Centers

Private, not-for-profit, locally-owned
40-year UCSF partnership on graduate medical education

Largest healthcare provider in California's central San Joaquin Valley

- 1,117 licensed beds in 3 hospitals, inpatient behavioral health center and subacute care center
- 172,383 ER visits, 57,733 admissions, 10,870 babies born last year

Valley’s largest private employer
- 8,100 employees
- 1,300 affiliated physicians
Serving 15,000-square-mile region

- Only Level 1 trauma and comprehensive burn center between Los Angeles and San Francisco
- Level 3 NICU and high-risk birthing center serves 5-county region

with unique health challenges

- Concentrated poverty – more than 35% of children live in poverty
- 100+ languages spoken, 43% adults don’t speak English well
- Higher than Calif. average rates of obesity, diabetes, lung disease and asthma
- 10% of Fresno County babies born premature – higher than some third world countries
- Lowest doctor-to-patient ratios in Calif.

Community Medical Centers

- Founded in 1897 in when doctors joined with successful boarding house
- Becker’s top 150 places to work in Healthcare list for 2015
- 3-year Health Ethics Trust certification for our compliance and ethics.
- GetWell Network’s national Leadership and Overall Achievement Awards in 2015
- Epic EMR integration throughout our system and connecting nearly 1,000 private physicians in our region
- 7 consecutive Outstanding Patient Experience Awards from Healthgrades to Fresno Heart & Surgical Hospital
- 2 consecutive Beacon Award for Critical Care Nursing
- Top Performer Distinctions on Key Quality Measures by the Joint Commission in 2013 for two of our hospitals
- Society of Thoracic Surgeons top 3-star ratings for coronary artery bypass graft surgery for two hospitals
Emerging Compliance Audit Areas

- Cybersecurity
- Social Media
- Pharmacy 340B
- Controlled Substance Waste Stream
- Medical Devices/Networked Biomedical Devices
- Provider-Based Services and Provider-Based Physician Billing
- Disaster Recovery and Business Continuity
- Drug Diversion/Impairment in the Work Place
Drug Diversion

• Debi Weatherford
• Executive Director, Internal Audit

What is Drug Diversion?

“The transfer of a prescription drug from a lawful to unlawful channel of distribution or use.”

• Most commonly diverted drugs – Opioids
• Most common purpose – personal use/addiction
• Annual estimated cost to public and private insurers: $72 billion
Cost

Boston based Massachusetts General agreed to pay a record $2.3 million settlement

- Two nurses allegedly stole over 14,000 pain pills from October 2011 through April 2015
- One nurse even appeared high while at work for an entire year – and no one reported her

Cost (cont’d)

Dignity Health in CA agreed to pay $1.55 million in July 2014

- More than 20,000 hydrocodone pills stolen in late 2010 and 2011
- System of controls was overhauled, including requirement of annual external audits
Cost (cont’d)

Swedish Medical Center in CO now offering HIV and Hepatitis testing to 2,900 patients

- Surgical tech stole syringes of fentanyl and replaced them with saline solution syringes
- He had a blood borne pathogen and may have used syringes before replacement
- He was court-martialed in 2011 from the Navy for stealing fentanyl while deployed in Afghanistan

Cost (cont’d)

- For the 5 years after his court-martial he was fired from 4 other hospitals in 3 states for theft of fentanyl
- No background check with the Navy was conducted by subsequent employers – his court-martialed records were readily available
- As a Surgical Tech, he was not certified or regulated like nurses/physicians, so no national records exist that would’ve shown his past diversions
- The potential cost of his diversions could be high as affected patients test positive for HIV or Hepatitis and require treatment or initiate litigation
The Risk of Drug Diversion CAN be Reduced:

- Thorough background checks for potential hires with access to control substances
- Training for staff that includes how to identify the signs and symptoms of substance abuse
- Strict drug waste management procedures and containment of wasted narcotic syringes
- Testing of wasted syringes for theft/replacement with saline

Controls (cont’d)

The Risk of Drug Diversion CAN be Reduced:

- Utilization of drug dispensing software to monitor staff access and dispense of controlled substances
- Tracking and reconciliation of ordering, dispensing and wasting of controlled substances
- Paying close attention to patients complaining of pain during and after procedures for possible diversion of narcotic analgesics during surgery
Summary

• Drug Diversion IS happening at an alarming rate
• Patient Safety IS being negatively impacted
• The Cost can be extremely high – especially where thousands of patients are at risk of exposure to pathogens
• Controls ARE available to significantly reduce risk
• Awareness is Key

Questions/Discussion
Provider-Based Services and Provider-Based Physician Billing
Presented by: Debra Muscio and Debi Weatherford

Agenda

• Background
• OIG Initiatives
• Provider-Based Considerations
• Monitoring Techniques to Protect Status
• Auditing for Compliance with Regulatory Requirements
• Key Controls
• Questions/Comments
Background – Provider-Based Regulations

- Current Provider-Based Status requirements are governed by the regulations at 42 C.F.R. § 413.65
  - Describes the criteria and procedures for determining whether a facility or organization is provider-based.
- Further explained in Program Memorandum Transmittal A-03-030
- Relationship between a main provider and another facility, department or related entity, whereby the other entity is considered a subordinate part of the main provider

Background - What is Provider-Based Status?

- Refers to services rendered in an integrated hospital outpatient clinic or location
  - On-campus - within 250 yards of the main hospital (measured in a straight line)
  - Off-campus within 35 miles of the main provider
- General Rule – requirements apply to a facility if its status as provider-based or freestanding affects Medicare payment amounts and/or beneficiary liability for services furnished in the facility
Background - Potential Advantages

- Net income benefits to the hospital for provider-based entities related to the ability to bill the hospital facility charge
- May result in higher combined reimbursement from Medicare and Medicaid
  - Commercial Payors – Problematic provisions
- Reimbursement for Medicare bad debts
- Access to hospital resources otherwise not available

Background - Potential Advantages

- Provider may qualify as a “child site” for purposes of the 340B Drug Discount Program
- An outpatient clinic that qualifies as provider-based may be included in the commercial payor contracts applicable to services furnished in the main provider
  - Rates may be higher than those paid in freestanding outpatient clinics
Background - Potential Disadvantages

- Negative impact on patients
  - Potentially higher charges and higher co-payments
  - Patients will receive two bills:
    - Facility Charge
    - Professional or Physician Fee Charge
  - Commercial Insurance and Other Payers
    - Higher Deductibles and Co-payments
- Greater billing complexities
- Potentially higher practice costs due to different wage scales/benefits
- Loss of physician control of hospital-based practice staff

Background – On Campus and Off Campus

- Licensure
  - The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except:
    - in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or.
    - in States, where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license.
  - 42 C.F.R. § 413.65(d)(1)
Background – On Campus and Off Campus

- **Clinical Services**
  - The clinical services of the facility or organization seeking provider-based status and the main provider are integrated
    - 42 C.F.R. § 413.65(d)(2)
    - Clinical privileges of the professional staff
    - Monitoring and oversight by the main provider
    - Reporting relationship of the Medical Director
    - Medical staff committees or other professional committees
    - Integrated medical records (unified retrieval system)
    - Integration of inpatient and outpatient services

- **Financial Integration**
  - Financial operations are fully integrated within the financial system of the main provider
    - 42 C.F.R. § 413.65(d)(3)
    - Shared income and expense
    - Cost reported in a cost center of the provider
    - Financial status incorporated and readily identified in the main provider’s trial balance
Background – On Campus and Off Campus

- Public Awareness
  - Held out to the public and other payors as part of the main provider
    - 42 C.F.R. § 413.65(d)(4)
    - All information (advertisements, signage, web-sites, patient registration forms, letterhead) should reflect that the site is part of the main provider
    - The name of the site should include the name of the main provider
    - CMS has said it is not sufficient for advertisements to show that the site is part of, or affiliated with, the provider’s network or health care system

Background – On Campus

- Anti-dumping rules
- Bill physician services with Correct Site of Service Indicator – off-campus outpatient hospital (19) or on-campus outpatient hospital (22) versus office (11)
- Comply with all terms of the hospital’s provider Agreement
- Hospital outpatient departments (other than RHCs) treat all Medicare patients for billing purposes, as hospital outpatients
- Subject to applicable payment window provisions (does not apply to CAHs)
- Meet all applicable hospital health and safety rules for Medicare-participating hospitals
Background – On Campus

- Joint Ventures
  - Partially owned by at least one provider
  - Located on the main campus of the main provider who is a partial owner
  - Be provider-based to the main provider on whose campus the facility or organization is located
  - Meet all other provider-based requirements

Background – Off Campus

- Operation under the ownership and control of the main provider
  - 100% owned by the main provider
  - Same governing body as the main provider
  - Operate under the same organizational documents as the main provider (bylaws, etc.)
  - Final responsibility lies with the main provider for:
    - Administrative decisions
    - Final approval of contracts, personnel actions/policies and medical staff appointments
Background – Off Campus

• Administration and Supervision
  • Maintain the same reporting relationships as other departments of the main provider
  • Facility or organization is under the direct supervision
  • Operated under the same monitoring and oversight, operated just as any other provider
  • Administrative functions are integrated with those of the provider (billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services)

Background – Off Campus

• Location
  • Within 35 mile radius of the campus of the main provider

• Exceptions
  • Owned and operated by a provider with DSH > 11.75%
  • Facility or organization demonstrates a high level of integration with the main provider (75% zip code test)
  • RHC located in a rural area attached to a hospital with less than 50 beds
**Background – Off Campus**

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- Management Contracts
  - A facility or organization that is not located on the campus of the potential main provider must meet all of the following criteria:
    - Main provider employs the staff
    - Administrative functions are integrated with those of the main provider
    - Main provider has significant control over operations
    - Management contract is held by the main provider itself

**Background – Off Campus**

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- New HCPCS Modifier
- Hospital Claims
  - Modifier “PO”
    - Short descriptor – “Serv/proc off-campus pbd”
    - Long descriptor – “Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments”
  - Reporting
    - Voluntary for 1 year (CY 2015)
    - Required beginning on January 1, 2016
  - Reported with every code for outpatient hospital services furnished in an off-campus provider-based department of a hospital
  - Not required to be reported for remote locations of a hospital defined at 42 C.F.R § 413.65 satellite facilities of a hospital defined at 42 C.F.R § 422.22(h), or for services furnished in an emergency department
Background – Off Campus

- Professional Claims – Updated POS Codes
  - POS code 19 (Off-campus outpatient hospital)
    - Services furnished in an off-campus PBD hospital setting
  - POS code 22 (On-Campus outpatient hospital)
    - Outpatient services furnished in on-campus, remote, or satellite locations of a hospital
  - Maintain POS code 23 (emergency room-hospital)

OIG Initiatives

- HHS OIG Work Plan FY 2014:
  - Impact of provider-based status on Medicare billing
  - Comparison of provider-based and free standing clinics (new)
- HHS OIG Work Plan FY 2015:
  - Medicare oversight of provider-based status
  - Comparison of provider-based and free-standing clinics

......extent to which such facilities meet CMS's criteria
....provider-based status can result in additional Medicare payments and increase beneficiaries' coinsurance liabilities
OIG Initiatives

• HHS OIG Work Plan FY 2016:
  • Medicare oversight of provider-based status (Revised)
    - Determine the number of provider-based facilities that hospital’s own and the extent to which CMS has methods to oversee provider-based billing
    - Determine extent to which provider-based facilities meet requirements described in 42 CFR Sec. 413.65

• Comparison of provider-based and free standing clinics

OIG Initiatives

October 15, 2014
Our Lady of Lourdes Memorial Hospital
$3.373 million settlement

“improperly submitted claims for hyperbaric oxygen therapy over a six year period as if such services were furnished in a provider based mobile unit, event though the unit did not comply with the requirements.....”
OIG Initiatives

TrailBlazer Health Enterprises, LLC (Texas)
$1,051,477 settlement

Medicare overpaid physicians due to incorrect place of
service coding.

Provider-Based Considerations

• Emphasis on provider-based self attestations for all locations
  • Attestation limits the recoupment time frame if future issues are encountered
  • Documentation submitted for facilities located on and off campus
  • Main provider lists each facility and states its exact location
  • Must be site specific – specific offices or suites
  • Provider-based physician billing sample CMS 1500 claim forms that denote the appropriate site of service (line 24B)

• Site of service rules the billing
  • Where the service was rendered governs billing
  • EKG performed in provider-based site but read remote must have provider-based site of service code
Provider-Based Considerations

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• Notice of co-insurance liability per 42 C.F.R. § 413.65(g)(7)
  • All off-campus locations billing as provider-based must have the Medicare Coinsurance form in place.
  • Patients are notified of the coinsurance liability for the service provided by the hospital and also for any physician service
  • An Advance Beneficiary Notification (ABN) does not meet the requirement of providing written notice of beneficiary liability
  • Hospital must provide written notice to the beneficiary, before the delivery of the services, of the amount of the beneficiary’s potential financial liability
  • CMS provided “Off Campus Medicare Outpatient Coinsurance Notice” shows a patient signature line while the actual regulation does not specify the requirement that the patient sign the acknowledgement

Provider-Based Considerations

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• Separate license/certificate required for each service or separate location
• Periodic review and update of documentation – how often, by whom, utilize shared folder
• Name of the site should include the name of the hospital (CMS rejected a provider-based entity’s application because it was named “John Hopkins at Greenspring” and not “Johns Hopkins Hospital at Greenspring” Rejected by Appeals Board but an expensive battle
Provider-Based Considerations

- Hospital role in physician proper billing – Requirement for billing of physician services with the appropriate site-of-service indicator

Federal Register/Vol. 65, No 68 (18519) Response to comment:
We agree that physicians (or those to whom they assign their billing privileges) are responsible for appropriate billing, but note that physicians who practice in hospitals, including off-site hospital departments, do so under privileges granted by the hospital. Thus, we believe the hospital has a role in ensuring proper billing.

Provider-Based Considerations

- Sharing of same space – What happens when a Medicare patient of the freestanding clinic must be seen during the block of time when it is a provider-based clinic and the treating physician insists that the provider waive its facility charge?

A site must not treat some Medicare patients as hospital outpatients and others as physician office patients.
Provider-Based Considerations

- Shared Space Concerns
  - Lack of proper signage and distinction of what space is provider-based vs. freestanding
  - Change in space from when the hospital attested to compliance with provider-based rules and received CMS approval
  - Business license should reflect hospital use of portion of the space for hospital-based

Provider-Based Challenges – What’s New

- Effective 1/1/2017 CMS will stop paying hospital outpatient PPS rates for off-campus provider-based departments that began after the date the Bipartisan Budget Act of 2015 was signed into law.

- Going forward payments will be under the Medicare Physician fee schedule or the ambulatory Surgical Center payment system

- Payment changes do not effect on-campus provider-based departments or emergency departments
Monitoring Techniques to Protect Status

- Annual review of documentation related to provider-based status
- Development of monitoring reports for employed physician provider-based billing
- Determine monitoring technique for non-employed provider-based physician billing

Auditing for Compliance - Regulatory Requirements

- Provider-Based Status
  - Request a listing of all locations billing as provider-based for the hospital
  - Obtain and review a copy of the attestation for each location
  - Review the confirmation letter from CMS
  - Policies and procedures exist, are followed, and comply with regulations
  - Analyze sample documentation
    - Licensure/Business License/Occupational Tax Application
    - Clinical staff integration
    - Financial integration
    - Public awareness/signage
    - Patient Notifications of Coinsurance
    - Provider-based entity operates under the hospital license and is 100% owned by the hospital
    - Common bylaws and same governing body
Auditing for Compliance - Regulatory Requirements

- Billing of Physician Services with the Appropriate Site-of-Service Indicator
- Communication Protocol
- Physician Audit Process:
  - Employed Physicians – structure reports to ensure appropriate site of service location is reflected on bill
  - Non-Employed Physicians
    - Request billing forms from sample of patients seen at provider-based facility
    - Meet with physician office manager to jointly review a sample of physician billing from list of patients seen at provider-based facility

Key Controls

- Policies/Procedures
- Shared Folder with Documentary Evidence Routinely Monitored and Reviewed
- Physician Training and Education (signed attestations that they understand provider-based billing rules and will include the correct place of service code on all patient billing claims)
- Monitoring for Compliance
- Right to audit clause in all provider-based physician contracts (employed and non-employed)
Questions/Discussion

Business Continuity/Disaster Recovery

- Presented by:
- Debra Muscio and Debi Weatherford
An Overview of BCP and DRP

- https://www.youtube.com/watch?v=cxE940f7ig0

BCP

Business Continuity Planning (BCP) is the processes and procedures that are carried out by an organization to ensure that essential business functions continue to operate during and after a disaster. The ultimate goal is to help expedite the recovery of an organization's critical functions. This includes disaster recovery, but also includes critical contingencies for personnel and business processes.
Key Elements of BCP

- Critical business functions have been identified and prioritized.
- Recovery time objectives have been determined for critical assets.
- Recovery point objectives have been established for critical applications.
- A comprehensive risk assessment has been conducted on critical facilities.
- Succession plans exist for key employees or consultants.
- A technology backup strategy exists and is tested regularly.
- Multiple sources are available for critical supplies and processes.
- People are identified, educated and trained on their duties during a disaster.
- Tools and training are in place to provide advanced warning of incidents.

DRP

Disaster Recovery Plan (DRP) is the process an organization uses to recover access to their software, data and/or hardware that are needed to resume the performance of normal business after the event of a disaster. The DRP takes care of the technology and supports the business. It lays out the process necessary to bring key IT resources - both data and systems back online.
Key Elements of DRP

- Remote storage and back up of data in a place that can be accessed from anywhere with an internet connection.
- Alternate communication lines for phones and email server.
- Backup people to spearhead implementation of the plan.
- An offsite location that will handle the company’s computers, telecommunications, and environmental infrastructure so that critical business functions and information systems are able to resume as quickly as possible.
- List jobs that will be performed at the offsite location and who will be performing them. Be sure to have a list of the equipment they’ll need to do their jobs.

Benefits of BCP and DRP

- Allows your organization to avoid certain risks or mitigate the impact of unavoidable disasters by:
  - Minimizing potential economic loss
  - Decreasing potential exposures
  - Reducing the probability of occurrence
  - Improving the ability to recover business operations
- Helps minimize disruption of mission critical functions – and recover operations quickly and successfully – in the event of a crisis by:
  - Reducing disruptions to operations
  - Ensuring organizational stability
- Assists in identifying critical and sensitive systems
- Provides for a pre-planned recovery by minimizing decision making time
- Eliminates confusion and reduces the chance of human error due to stress reactions
- Protects your organization’s assets and employees
- Minimizes potential legal liability
- Reduces reliance on certain key individuals and functions
- Provides training materials for new employees
- Reduces insurance premiums
- Satisfies regulatory requirements
Assess Readiness for Business Continuity and Disaster Preparedness*

- Can you identify your critical business activities that satisfy your customers' expectations and support your overall business operations?
- Can you identify the critical business information needed for these activities to succeed?
- Do you have information on the frequency, impact and causes of downtime?
- Does this information allow you to identify and rank your most vulnerable business activities?
- Are your legacy systems and IT resources adequately protected against hacker intrusion and viruses?
- Have you developed a checklist, by functional area, of what your organization will need to continue business effectively in the case of a disruption or emergency?
- Have you and your IT colleagues been successful in placing business continuity on the board agenda?
- Have you worked with your IT colleagues to develop an approved business continuity plan that accounts for all aspects of business continuity and recovery?
- Is your business continuity plan regularly tested?
- Do you have a change control process in place to keep your continuity plan current with process, organizational and technology changes?
- Are you confident that if a disaster were to strike this very minute, your organization could recover quickly and smoothly to prevent damage to your business?

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Audit Steps

Define the Scope of the Audit – What are the goals and objectives of the audit?

Planning – Identify and contact the primary source or auditee. Determine audit approach, such as review all plans or a sample of the plans. Develop audit checklists, questionnaires, audit programs and determine audit tests.

Fieldwork – Examine the individual BCP or DR program. Interview key stakeholders and participants in the program. Review planning and other IT related documents. Look for defined recovery times, verify if evidence meets the business goal. Review test plans and results.

Analysis – Analyze the results of tests performed and formulate recommendations.

Reporting – Prepare and present a formal report to management.
Additional Fieldwork Steps

• Perform a health check – Review the plans and interview key stakeholders
• Assess completeness and comprehensiveness over all aspects of the BCP or DR program
• Assess the completeness of the business impact analysis (BIA)
• Observe BCP or DR tests
• Participate as formal observers of mock drills
• Compare what was planned and achieved against management’s expectations. Compare to industry best practices

Examples of Key Findings

• No governance or steering committee has been established over BCP or DR
• Lack of a comprehensive enterprise wide Business Continuity Plan
• DR has not been fully tested
• No comprehensive listing of all application are tiered for criticality
• Business is not sure if recovery time objective and recovery point objective defined by Disaster Recovery Plan meets their needs
• Contact information and links noted within the Emergency Operations Plan and DR are not current
• Proximity of Data Center to the nearest facility has not been evaluated
• No formal agreement with a vendor is in place to purchase hardware if existing equipment is destroyed during a disaster
• Corporate policies that directly impact BCP and DR are not clearly defined and conflicted with facility policies (i.e. inclement weather policy)
Are all stakeholders at the table……