

Physician Practice Enforcement Actions:
Could You be Next Year's News?

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Compliance Institute



PHYSICIAN PRACTICE ENFORCEMENT ACTIONS

Speakers



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**HEALTHCARE REGULATORY COMPLIANCE; PROGRAM OVERSIGHT;
AMBULATORY COMPLIANCE OVERSIGHT**

- Certification: CHC
- More than 20 years of Academic Medical Center experience, focusing on the Physician and Hospital Based Clinical settings.
- Glenna also supports the compliance activities of the University of Kentucky College's of Dentistry, Health Sciences, Medicine, Nursing, Pharmacy and Public Health, helping them achieving their mission of excellence in academics, research and clinical care.

**HEALTHCARE COMPLIANCE; RESEARCH BILLING
COMPLIANCE; CLINICAL AND MEDICAL
NECESSITY AUDITING**

- RN
- Certification: CHC
- Compliance program expertise in academic medical center, hospital, physician practice, pharmacy, long-term care, and research settings, including interim staffing, program development and assessment, risk assessment, training, and clinical trial billing.
- Twenty years of combined clinical and compliance experience in hospital, physician practice, pediatric, skilled nursing facility, Federally Qualified Health Center, and free clinic settings.

PHYSICIAN PRACTICE ENFORCEMENT ACTIONS

1. **Sixteen-Month Summary of Published Enforcement Actions Against Providers and Physician Practices**
2. **Simplified Approach to Risk Assessment for Physician Practices, Large or Small**
3. **Practical Compliance Plan Based on Risk Assessment**



ENFORCEMENT SUMMARY

Sixteen-Month Summary of Published Enforcement Actions Against Providers and Physician Practices



Highlighted Enforcement Actions

Billing for services not provided

A NY cardiologist sentenced for 20 months in prison for billing the VA for 350 procedures that were not performed.

<https://www.justice.gov/usao-nj/pr/cardiologist-gets-20-months-prison-billing-veterans-affairs-hundreds-bogus-medical>

Controlled Substances

A NY family practice physician was charged with unlawful distribution of opioids with no legitimate medical purpose to FIVE patients, one of whom died as a result two days after his last visit with the physician. The mandatory minimum sentence is 20 years in prison.

<https://www.justice.gov/usao-edny/pr/medical-doctor-convicted-brooklyn-federal-court-causing-overdose-death-patient>



Highlighted Enforcement Actions

Receipt of healthcare kickbacks

A FL pain management physician agreed to pay \$2.8 million to resolve allegations that he accepted illegal kickbacks in the forms of cash payments in exchange for pain cream prescriptions, and sham speaker fees in exchange for sublingual fentanyl spray prescriptions. He also faces a maximum of ten years imprisonment.

<https://www.justice.gov/usao-mdfl/pr/fort-myers-pain-management-physician-pleads-guilty-healthcare-offenses-and-agrees-28>

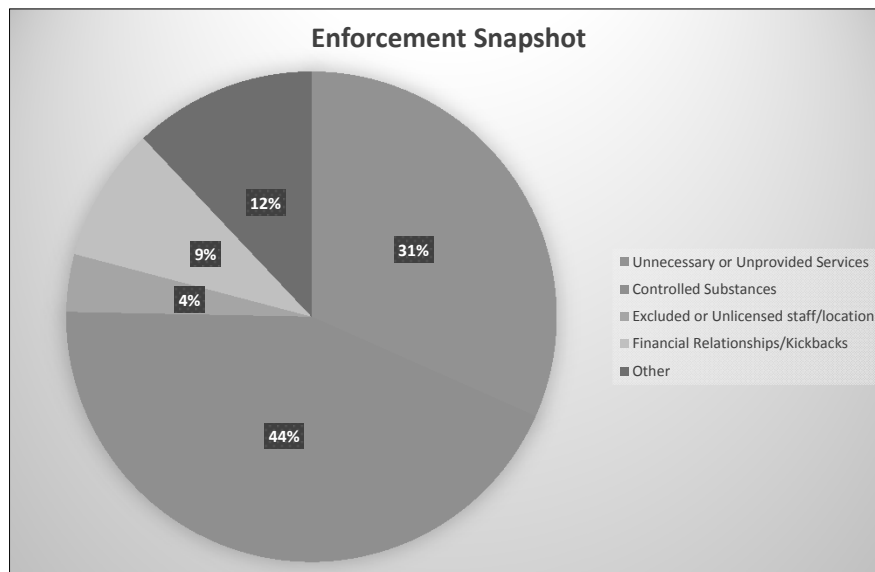
Billing for misbranded (foreign) drugs

A NY oncologist and his office manager wife have agreed to pay over \$500,000 for submitting claims to Medicare for discount foreign oncology drugs that were administered to Medicare cancer patients.

<https://www.justice.gov/usao-ndny/pr/queensbury-oncologist-and-spouse-pay-500000-submitting-false-claims-medicare>



October 2017 through January 2019 Enforcement Snapshot



Controlled Substance Enforcement Actions

- Distributed outside usual course of professional practice
- Not for legitimate medical purposes
- Prescribed without exam, evaluation, or diagnostic testing
- Accepting cash payments for controlled substances
- Physicians writing controlled substances for themselves or their family members or friends that were not examined/not patents.

Enforcement Actions Related to Medically Unnecessary Services or Services Not Provided

- Billing for services not provided
- Providing unnecessary services
- Automatic scheduling of annual diagnostic testing without exam to confirm medical necessity
- Double billing
- Unbundling
- Billing for too many units of an item
- Billing insurance for free samples provided to the patient
- Falsifying records/documentation



Enforcement Actions Related to Excluded or Unlicensed Staff

- Hiring excluded individuals
- Billing for services provided by unlicensed staff as if they were licensed, i.e., physical therapy services
- Billing for services that the physician is not qualified to perform or qualified to interpret
- NPs or PAs billing under billing number of physician
- Refills authorized by someone without prescriptive authority
- Licensure and credentialing of physicians/identity theft



Enforcement Actions Related to Kickbacks and Inappropriate Financial Relationships

- Providing a free medical director to induce referrals
- Accepting kickbacks to refer specimens to a specific lab or to prescribe unnecessary medication
- Kickbacks disguised as sham educational speaker payments
- Leases
- Giving patients inducements/ “recruiting” patients that do not need care
- Bribing police to provide unredacted accident reports to help recruit patients
- Tying contracted physicians bonuses or contract terms to volumes or referrals



Other Enforcement Actions

- False EHR certifications
- Allowing inappropriate access to PHI
- Billing for service without required face-to-face time minutes
- Administrators or staff stealing reimbursement money
- Not refunding overpayments by 60-day requirement
- Purchasing, distributing, and billing federal healthcare programs for misbranded/foreign drugs



Simplified Approach to Risk Assessment for Physician Practices, Large or Small



An Effective Compliance Program Must be Based on an Accurate Risk Profile

- What are you doing (the activity or work that is the foundation for the risk)?
- What are the rules and regulations that govern what you are doing?
- How do you mitigate the risk?



Creating Your Risk Profile: Examples of External Risks

- **OIG Compliance Program Guidance**
- **CMS Conditions of Participation**
- **OIG Work Plan**
- **Industry and regulatory changes**
- **Enforcement actions**

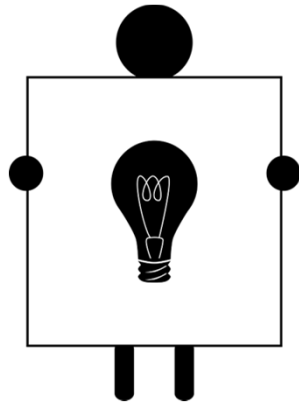


Creating Your Risk Profile: Examples of Internal Risks

- **Staff Interviews**
- **Current and past external audit results**
- **Internal auditing and monitoring results**
- **Collaboration with business leadership**
- **Tone at the top**
- **Culture**
- **Organizational structure**
- **General or Specialized Practice**
- **Independent coding or outsourcing**
- **Collections and cash handling**
- **Electronic or paper records**



Identify and Understand the Rules, Standards, and Regulations Related to the Specific Risk



HIPAA

Excluded Individuals

OSHA

Conditions of Participation

False Claims Act

Office of Inspector General

Anti Kickback Statue (AKS)

Deficit Reduction Act (DRA)

Identify and Understand the Rules, Standards, and Regulations Related to the Specific Risk

- **False Claims Act (FCA)**
 - Imposes liability on persons and companies who defraud governmental programs
 - No proof of specific intent to defraud is required to violate the civil FCA
- **Deficit Reduction Act (DRA)**
 - Medicaid Program Integrity
- **Conditions of Participation**
 - EMTALA, TJC, Medicare/Medicaid
- **STARK Law**
 - Self-Referral for designated services

Identify and Understand the Rules, Standards, and Regulations Related to the Specific Risk

- **Anti-Kickback Statue (AKS)**
 - Criminal Statue that prohibits exchange (or offer to exchange) anything of value, i.e., gift cards, to induce referrals
 - Conflict of Interest—Physician Owned Distributorships
- **Occupational Safety and Health Administration (OSHA)**
 - Employee safety
 - Whistleblower Protection Statues
- **Exclusion Statue**
 - Excludes providers and suppliers from participation in all Federal health care programs
- **HIPAA**



Starting a Risk Assessment From Which to Base the Compliance Plan

- **Start a list—Simple list of the things you do that have a risk implication? (documentation, procedures, controlled substances, APP's etc...)**
- **Give the Risk a ranking for Impact and Probability—Low, Moderate, High**
 - What would be the impact if “it” happens? Financial, Legal, Reputational
 - What is the probability “it” is or could happen?
 - If “it” would have a high impact and there is a high probability that “it” is occurring you have a ranking of H H and would go to the top of your list of priorities.
 - Controls in place could help lower the ranking to an acceptable risk



Examples of Risk and Ranking

Controlled Substances

- What would be the impact if controlled substance management was totally wrong?
 - Financial—Legal—Reputational
 - Would it be a small or large impact?
- What is the probability controlled substance issues are occurring?
 - High because:
 - You have a pain management clinic?
 - You regularly treat family and friends without proper exam, evaluation, or diagnostic testing?
 - Self prescribe?
 - Low because:
 - Your practice does not prescribe CS?
 - You have policies and procedures that prohibit treating family and friends as patients?
 - E-prescribe through EMR that ties to patients of record?



Examples of Risk and Ranking

Documentation

- What would be the impact if documentation was totally wrong, insufficient or missing?
 - Financial—Legal—Reputational?
 - Would it be a small or large impact?
- What is the probability the incorrect/insufficient or missing documentation is occurring?
 - High because:
 - Provider is coding own documentation without any checks or balances?
 - Pressure for production?
 - Providers do not know the rules surrounding unbundling, timed units, etc.?
 - Low because:
 - Controls in place to prevent billing for services without sufficient documentation?
 - Certified coders/abstractors review documentation and submits claims?
 - Policy, Procedures, and Training to support ethical and compliant billing practices?



Examples of Risk and Ranking

Billing for excluded or unlicensed staff

- What would be the impact if an excluded or unlicensed provider billed for services?
 - Financial—Legal—Reputational?
 - Would it be a small or large impact?
- What is the probability that an excluded or unlicensed staff is billing for services?
 - High because:
 - Verification of licensure is not required?
 - Monthly checks against the exclusion databases are not conducted?
 - No centralized location for back-up documentation?
 - Low because:
 - Controls in place to validate licensure and credentials?
 - Monthly exclusion checking done with retention of results?
 - Centralized location and responsible party?



Examples of Risk and Ranking

Language Services

- What would be the impact if you failed to provide interpreter services?
 - Financial—Legal—Reputation?
 - Would it be a small impact or a large one?
- What is the probability you will need interpreters but won't be able to meet this requirement?
 - Low—because of location of practice and ????
 - High—because of location of practice in a predominately high English as a Second Language area?

Notice of Privacy Practices

- Would there be an impact if you failed to provide and post NPP?
 - Financial—Legal—Reputation?
 - Would it be a small impact or a large one?
- What is the probability you won't or can't be able to meet this requirement?
 - Low—because it is standard practice for new patient packets?
 - High—staffing turnover and lack of standardized processes?



RISK ASSESSMENT

Define Risk and Assign Ranking

Activity	Impact	Probability	Ranking
Controlled Substances	H	L	HL
Documentation	H	H	HH
Language Services	M	M	MM
Advanced Practice Providers	M	H	MH
Notice of Privacy Practices	M	L	ML
Referrals	L	L	LL
Sedation	M	L	ML
Petty Cash	L	H	LH
Credit Balances	H	H	HH
Computer Assisted Coding	H	M	HM
Access Outside Scope	M	H	MH
Place of Services Codes	H	H	HH



RISK ASSESSMENT

Sort and Color Code

2.Simple Risk Assessment	Impact	Prob	Ranking
Documentation	H	H	HH
Credit Balances	H	H	HH
Place of Service Codes	H	H	HH
Computer Assisted Coding	H	H	HH
Controlled Substances	H	L	HL
Advance Practice Providers	M	H	MH
Access Outside Scope	M	H	MH
Language Services	M	M	MM
Notice of Privacy Practices	M	L	ML
Sedation	M	L	ML
Petty Cash	L	H	LH
Referrals	L	L	LL

HH	HH
HM	HM
HL	HL
MH	MH
MM	MM
ML	ML
LH	LH
LM	LM
LL	LL

Simple Risk Assessment	HH	HH	HH	HM	HL	MH	MH	MM	ML	ML	LH	LL
	Documentation	Credit Balances	Place of Service	Computer Assisted Coding	Controlled Substances	Advanced Practice Providers	Access Outside Scope	Language Services	Notice of Privacy Practices	Sedation	Petty Cash	Referrals



RISK ASSESSMENT

Starting Point of Practical Compliance Plan Based on Risk Assessment

1. Simple Risk Assessment	HH	HH	HH	HM	H	MH	MH	MM	ML	ML	LH	LL
	Documentation	Credit Balances	Place of Service	Computer Assisted Coding	Controlled Substances	Advanced Practice Providers	Access Outside Scope	Language Services	Notice of Privacy Practices	Sedation	Petty Cash	Referrals



COMPLIANCE PLAN

Practical Compliance Plan Based on Risk Assessment



Compliance Plan Development Steps

- Analyze each risk
- What is currently being done to address the risk?
- What needs to be done to mitigate the risk?
- Develop and enact plan



Compliance Plan Development Steps

Analyze each risk

- What are the regulations concerning the risk?
- What is the current state of the risk at your organization?
- Where is it occurring?
- What players are involved?
- Do you need legal representation?



Compliance Plan Development Steps

What is currently being done to address the risk?

- Are leadership and staff aware that the issue is a risk?
- What controls currently exist surrounding the risk?
 - Policies and Procedures
 - Education
 - Auditing and Monitoring



Compliance Plan Development Steps

What needs to be done to mitigate the risk?

- Engagement: Board or Senior Leadership, Physicians, Staff
 - Gain buy-in through interaction and education about the risk itself and the entity's plan to address the risk
- Partnership and Collaboration
 - With whom will Compliance need to partner to ensure risk is addressed?
 - Compliance Committee or Team
 - Physician leadership
 - Operations leadership



Compliance Plan Development Steps

What needs to be done to mitigate the risk?

- Address the risk with the Seven Elements
 - Policies and procedures
 - Education
 - Auditing and monitoring
 - Consistent discipline and enforcement related to risk

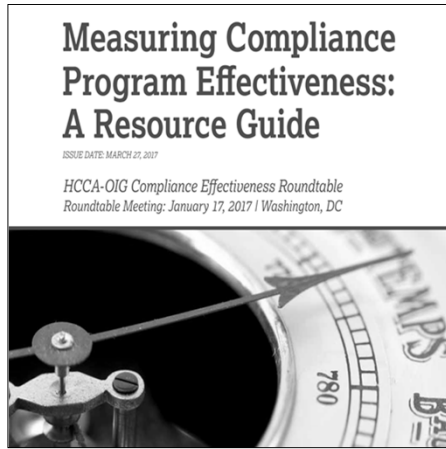


Compliance Plan Development Steps

- **Develop and enact plan**
 - Should include risk name, risk ranking, responsible party, mitigation actions, and expected completion date, status/update, and ongoing auditing efforts
- **Report on risk mitigation plan and ongoing progress**
 - Compliance lead report to leadership on progress and actions
 - Ensure ongoing documentation of response to the risk
- **Stay on it!**
 - Regularly assess progress and status
 - Once risk appears to be mitigated, establish an auditing plan to confirm ongoing success



Compliance Plan Effectiveness



- 52 pages of suggestions
- Some used frequently, some not at all
- Frequency and use will be based on size and risk areas
- Not intended to be a check list or to do all
- If you do none—obviously not enough



Group Discussion Risk: Controlled Substances

Risk	Risk Ranking	Responsible Party	Mitigation Actions	Expected Completion Date	Status Updates	Progress: Auditing Plan
Controlled Substances						
Medical Necessity, Documentation, and Billing						
Anti-Kickback						
Stark Law						
Exclusions						
Licensing and Credentialing						



Group Discussion Risk: Controlled Substances

- Risk Ranking- Impact and Probability
- Analyze the risk
 - Regulations, current state, what departments, what players, notify legal?
- What is currently being done to address the risk?
 - Leadership and staff awareness, current controls?
- What needs to be done to mitigate the risk?
 - Engagement, collaboration, seven elements?
- Develop and enact plan
 - Plan format, plan reporting, documentation, ongoing assessment



Follow-up

QUESTIONS?

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THANK YOU!

