Business of Pediatrics

Pediatric Health Network

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HealthCare Compliance Network

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Putting Your Practice in a Defensible Position: Practical Compliance Strategies for Today's Environment

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Agenda: A Defensible Compliance Position – 7 Elements

What:
- Having a culture of compliance
- Doing the right thing
- Documenting everything compliance
- Assessments-Billing/charts, SRA, HVA, Threats, Property
- Policy and Procedures
- Ingrained in all we do- first thing we do is read directions

Why:
- It is the law and the right thing to do
- Lawsuits-Civil, Employee, Visitors-you should have known
- Monetary Damages, Fines and penalties,
- Reputational damage
- Creates clear lines of communication
- Safe Harbors-best foot forward

Who:
- State, Federal, Boards
- Patients, Employees, Partners
- CMS and Private payors
- SEO reviews

Healthcare Compliance

Healthcare is one of the most highly regulated industries in the country – more acronyms than any!

Current areas of particular concern, but are not limited to:

- Fraud, waste & abuse
- Diversion-drugs
- Workplace violence
- Privacy & Security
- Exclusions
- Technology – Telehealth, AI
- DOJ-ADA and quality of care

Audit Trends 2025

Telehealth and virtual care
- Patient consent, proper doc
- Federal and State

Data privacy and cybersecurity
- Privacy and Security-3rd party vendor oversight
- SRA

Billing and coding
- Consultations, High Level E/M & Modifiers , accurate coding, proper documentation
- AI-clear guidelines, internal audits

Safety and Emergency Operations
- Violence, Sharps/Needles, Chemical,
- HVA, Disasters (Nature, Human and Tech)

Acronyms to Know

CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
DOJ	Department of Justice
NFPA	National Fire Prevention Association
FCA	False Claims Act FDRs First-tier, Downstream, and Related Entities
FWA	Fraud, Waste, and Abuse
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
LEIE	List of Excluded Individuals and Entities
DEA	Drug Enforcement Agency
DOH	Department of Health
CLIA	Clinical Laboratory Improvement Amendments
ADA	Americans with Disabilities Act
OIG	Office of Inspector General
OSHA	Occupational Safety and Health Administration
OCR	Office of Civil Rights

Who Else is Looking: Private Insurance, OIG, OCR

UnitedHealth Group Ethics and Integrity Program

UnitedHealthcare Compliance program incorporates the required elements of a compliance program as outlined by the U.S. Sentencing Guidelines:

- Oversight of the Ethics and Integrity program.
- Development and implementation of ethical standards and business conduct policies.
- Creating awareness of the standards and policies by educating employees.
- Assessing compliance by monitoring and auditing.
- Responding to allegations of violations.
- Enforcing policies and disciplining confirmed misconduct or serious neglect of duty.
- Reporting mechanisms for workers to alert management.

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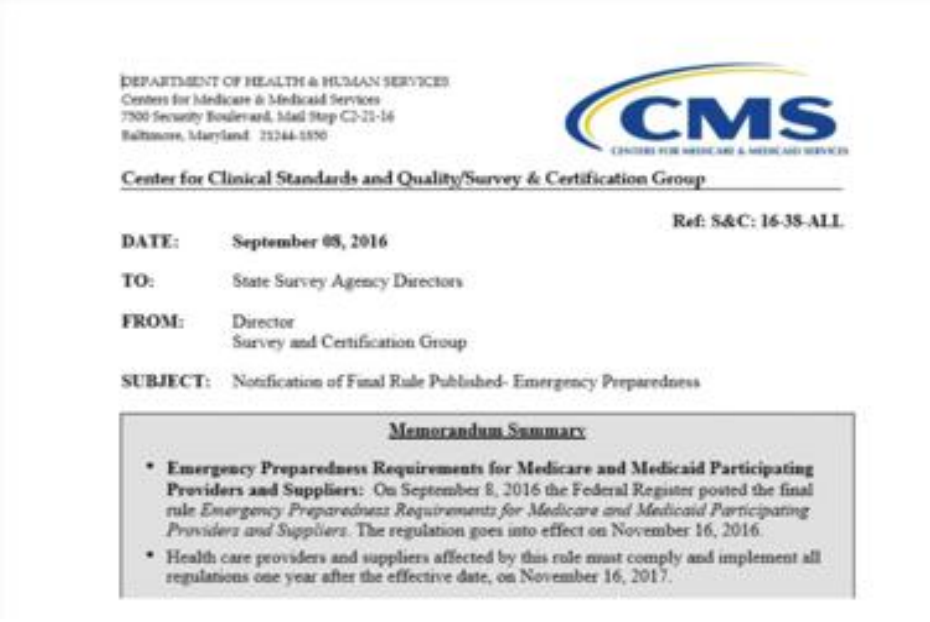
Regulation: 4 Core Elements

- Annual Risk Assessment & Emergency Planning (All-hazards Approach)
- Policies & Procedures
- Communication Plan
- Training & Testing



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-38-ALL

DATE: **September 08, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Notification of Final Rule Published- Emergency Preparedness

Memorandum Summary

- **Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers:** On September 8, 2016 the Federal Register posted the final rule *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers*. The regulation goes into effect on November 16, 2016.
- Health care providers and suppliers affected by this rule must comply and implement all regulations one year after the effective date, on November 16, 2017.

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HIPAA Mandates

Written Program
Policies & Procedures

Training Program
(Staff Education)

Security Risk
Assessment (SRA)

Possible Damages

Federal Sentencing Guidelines – Fines and Penalties - 3x

- **OSHA** current maximum fine for a Repeat or Willful violation grew from $70,000 to as much as $125,000 for each violation. Similarly, a serious violation increased from $7,000 to $12,500 for each violation.

- **CMS and Commercial payers** recover anywhere from $6 - $13 for every $1 they invest in enforcement, per published reports-Billions of dollars stolen.

- **OCR HHS/HIPAA**
  - Civil suits
  - Ransome costs skyrocket - wall of shame
  - Reputational Damage/Human Capital/Lost time
  - $10,000 fines increased to $20,000, $15,000-$30,000 and $50,000-$100,000

HR 7898 – Safe Harbor

HIPAA Safe harbor Bill Becomes Law; Requires HHS to Incentivize Security

On January 5, the President signed the HR 7898 HIPAA Safe Harbor Bill into law, which amends the HITECH Act to require HHS to incentivize best practice security.

The legislation directs HHS to take into account a covered entity's or business associate's use of industry-standard security practices within the course of 12 months.

Safe Harbors - CMS

Safe harbors for the Centers for Medicare & Medicaid Services (CMS) are provisions that protect certain payment and business practices from being considered illegal kickbacks.

Anti-Kickback Statute (AKS) are the regulations that define arrangements that are not offenses, ensuring that legitimate healthcare business practices remain lawful.

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7 Elements

7 Elements

1. Conducting internal assessments, monitoring and auditing

- Compliance Inspections
- Building walk through-weekly, monthly
- SRA-yearly or when changes occur
- HVA-yearly or when changes occur
- Exclusion-monthly
- Chart audits- Yearly

A Threat Assessment/Inspection

- The goal of a threat assessment is to determine the facility's vulnerabilities (mother nature, manmade, technology, etc.)

- Walkaround or full company inspection, document review, employee interviews, training

    - Step 1 – Identify threats. What ae the threats and vulnerabilities?
    - Step 2 – Assess threats/vulnerabilities
    - Step 3 – Develop controls to those threats/vulnerabilities
    - Step 4 – Evaluate your response and shore up the gaps.

- Government-Provided Assessment/Surveys
    - HVA
    - SRA
    - Safety

Be Aware of Common Hazards – Situational Awareness

- Physical
  - Overexertion
  - Violence
  - Falling
  - Noise
- Biological & Infectious
  - COVID/SARS-CoV-2/RSV
  - Bloodborne pathogens
    - Needlestick injuries
  - Tuberculosis
  - Hepatitis
- Psychosocial
  - Shift work
  - Long hours
  - Overtime
  - Competing demands
  - Bullying
- Chemical Hazards
  - Latex
  - Glutaraldehyde
  - Ethylene Oxide
  - Antineoplastics
  - Volatile organic compounds (VOCs)

Hazard Vulnerability Analysis/Assessment (HVA)

- A systematic approach used primarily by hospitals and healthcare facilities to identify and prioritize potential hazards (e.g., natural disasters, cyber attacks, power outages) to help plan for emergency preparedness and response.
- Ideally, the HVA should be adjusted each year based on real events and exercises conducted.
    - Example: an organization that activates their EOP most winters due to severe winter weather, should improve their EM plans as lessons are learned which should improve their response/recovery.
- JCAHO

Maryland's HVA

- Findings
  - 100-year flood was projected to cause billions of dollars in damage to buildings with residential buildings accounting for most losses.
  - Specific infrastructure, such as 33 bridges, were found to be highly vulnerable.

The Office of Inspector General (OIG)

The OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" outlines the importance of internal monitoring and auditing.

- **Frequency:** The OIG recommends conducting periodic audits at least **annually**.
  - If high error rates are found, audits should be performed more frequently.

- **Sample Size:** A basic guide is to review five or more medical records per federal payer (e.g., Medicare, Medicaid) or five to ten random medical records per physician.

The Office of Inspector General (OIG)

1. Develop Written Standards: Establish clear, written compliance policies and procedures that address all aspects of operations, from patient care to billing.

2. Conduct a Baseline Audit: Perform an initial "snapshot" audit of claims to identify existing vulnerabilities ad establish a benchmark for future comparison.

3. Perform Periodic Audits: Conduct regular (at least annual) audits to monitor progress and ensure ongoing compliance.

4. Involve Appropriate Staff: Internal audits should ideally involve both billing/coding personnel and medically trained staff (or physicians).

5. Document and Remediate: Document all audit methodologies and findings. If problems are identified, the practice must develop and implement corrective action plans and, if necessary, return overpayments to the appropriate payer.

6. Provide Education: Use audit results to inform ongoing training and education for all staff and physicians regarding documentation and coding requirements.

Security Risk Assessment (SRA)

- CODE FEDERAL REGULATION (45 C.F.R. § 164.308(a)(1))
- Assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by your organization
- Assessment should be done annually and when you have IT changes
- Pros/cons of doing SRA internally vs. externally

Exclusion Authority

- The OIG has the authority to exclude persons or entities (e.g., hospitals) from participating in federally-funded healthcare programs like Medicare and Medicaid.
    - When a person or party is excluded, the federal government will not pay for any item or service provided, ordered, or prescribed by that person or entity.
    - Practices are required to check the federal and state Exclusions Lists for excluded individuals and the organizations they are contracted with.
    - Practices or organizations receiving federal or state income cannot employ or pay an excluded individual or entity.

Exclusions

- **Regulations:** Practices cannot employ or contract with individuals or entities debarred or excluded from participation in any federal health care program under ss. 1128 and 1128A of the Social Security Act, nor with an individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation at 48 CFR 2.101, of a person described in 42 CFR 438.610 (a)(1); or subcontractors.

- On at least a monthly basis, check current staff, subcontractors and providers against the federal LEIE and the federal SAM, state lists, or their equivalent, to identify excluded parties.

Maryland Medicaid

- **Maryland Medicaid Sanctioned Providers**
  - Maryland Medicaid suspends or excludes some providers from working with the program.
  - The list is updated monthly, if needed.
  - Maryland Medicaid Sanctioned Provider List (as of 11/7/2025)
  - For sanction type LB on the Sanctioned Providers list, verify the provider's license status through the Maryland State Board.

7 Elements

2. Designating a compliance officer and compliance committee

- Compliance Advisory Committee
  - Management and Staff
- Should not be the CEO, CFO
  - Senior level management
- Has reporting responsibilities directly to board

7 Elements

3. Implementing written policies and procedures

- Standards of Conduct Guide
- Ethics policy – do the right thing
- Safety/OSHA
- HIPAA – Federal & State

HIPAA Policies & Procedures

- Policies and procedures should be written and available and include:
  - review dates, revisions, owners and approved status.
  - definitions for terms that may not be easily recognizable (i.e., PHI – Protected Health Information ,phishing).
- Assign Privacy Officer and assign Security Officer
- Have BAAs in place with organizations that have access to PHI
- Document employee access to PHI
- Keep a hardware inventory lists of equipment used with PHI
- Document HIPAA training for all employees

- The Health Sector Cybersecurity Coordination Center (HC3) has published a threat brief that highlights the importance of developing an effective cybersecurity incident response plan.

Basic Features of a WPV Program

- Facility assessment
- External/Internal threat assessment
- Panic alarms
- Response processes
- Include your staff
- Open communication

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4. Conducting effective training and education

- Compliance training
  - Continuous – yearly and if changes occur
  - New hires – upon hire
  - Specific to your P&P and site
  - Robust – not off the shelf

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7 Elements

5. Developing effective lines of communication

- Hotline
  - Posters/suggestion box
  - Should have a way to make it confidential
    - Third party
    - Follow through with investigation

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Process for Reporting Compliance Issues

Reporting Compliance Concerns

- Everyone should feel comfortable asking questions and reporting concerns about any situation or practice they believe could place themselves or another employee at risk.
- All employees are required to report suspicious or improper behavior.
  - Report to your Compliance Officer and/or your compliance hotline.
- Any report of suspicious or improper behavior is kept confidential.
- Any report can be made anonymously through the hotline number.
- Have a Non-Intimidation and Non-Retaliation policy in place for compliance reporting.

7 Elements

6. Enforcing standards through well-publicized disciplinary guidelines

- Consequences levied consistently, regardless of employee's stature
- Enforcement consistent with appropriate discipline action
- Escalation to termination

OCR Reminder on the Importance of a Sanctions Policy

"The HHS' Office for Civil Rights has reminded HIPAA-regulated entities of the importance of sanctions policies. Sanctions policies help covered entities develop a culture of compliance, improve cybersecurity vigilance, and prevent common employee HIPAA violations."

HIPAA Journal

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7 Elements

7. Responding promptly to detected problems

- Undertake corrective action
- Team approach
- Follow through
- Keep good notes

Audit Time

- How was the practice notified?
  - Addressed to admin, provider, company?
  - First class, signature required, hand delivered?
- Who addressed the letter to the practice?
  - Law firm, state or federal agency?
- How many documents are being requested?
  - Charts, logs, P&P, training, self-assessments?

Do's and Don'ts

- DO comply with the correspondence and audit
  - Pay close attention to dates
- DO copy all records
  - Charts requested, training logs, incident reports, security breach
- DON'T give up control
  - Your time, your workstation, your office
- DON'T send what is not asked for
  - All P&P, All staff training (not just individual), SRA
  - Keep a copy of what was produced!

OSHA Request for Information

- Did the facility perform a risk assessment regarding exposures of its employees?
  - If so, attach or describe.
- Was the risk assessment shared with employees?
  - If so, provide training records.
- Was the risk assessment implemented?
  - Describe how.
- Provide a copy of Safety Data Sheets (SDSs) for any cleaning/sanitizing chemicals utilized.

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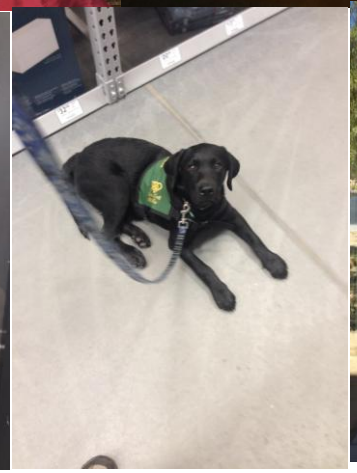
New & Existing Issues



Other Compliance Issues

- Waste stream
- Workplace violence/active shooter
- CSA 405 (d): Health Industry Cybersecurity Practices cybersecurity framework
- Business Associates/Business Associate Agreement (BA/BAA)
- Americans with Disabilities Act (ADA)
- Fraud, Waste & Abuse (FWA)

Pharma Waste

- All that is necessary for proper disposal is a Pharmaceutical Disposal Bin
  - Pharmaceuticals cannot be packaged in a standard medical waste or sharps disposal box
  - Needs to be put into a pharma-safety bin
- Pharmaceutical waste will be manifested separately from regular regulated medical waste

Legislation & Standards

- Federal
  - H.R.1195 – Workplace Violence Prevention for Health Care and Social Service Workers Act
  - https://www.congress.gov/bill/117th-congress/house-bill/1195

- State Laws
  - 10 states with laws requiring implementation of WPV programs (CA, CT, IL, MD, MN, NJ, OR, WA, NV & NY (public employees only))
  - 40 states with assault protection laws
  - All laws are variable

- Joint Commission
  - New WPV standard effective January 2022
  - https://www.jointcommission.org/standards/prepublication-standards/new-and-revised-workplace-violence-prevention-requirements/

CSA of 2015 Section 405(d)

- Identifies **ten (10) practices** – tailored to small, medium, and large organizations

  - Email protection systems
  - Endpoint protection systems
  - Access management
  - Data protection and loss prevention
  - Asset Management
  - Network Management
  - Vulnerability Management
  - Incident Response
  - Medical Device Security
  - Cybersecurity Policies

BA & BAA

- First to be audited after breach
- In place and updated – how many?
- BAA vs. Confidentiality
- Does BA have a compliance program?
- Disaster recovery
- Get documentation

Section 1557 of the Affordable Care Act (ACA)

- Section 1557 of the ACA is a nondiscrimination law that prohibits discrimination based on disability, race, color, national origin (including limited English proficiency), sex (including sexual orientation and gender identity), and age in covered health programs and activities.

- Requires covered entities to (with certain exceptions) make their programs, activities, and facilities physically accessible to individuals with disabilities, in compliance with applicable accessibility standards outlined in the Americans with Disabilities Act (ADA) and Section 504, if the facility was started on or after July 18, 2016.

- Exam rooms , exam table , scale-Title III

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Laws of Fraud, Waste & Abuse

- False Claims Act (FCA)
  - Prohibits submitting false claims for payment, using false records
- Anti-Kickback Statute (AKS)
  - Criminal law that prohibits the exchange of anything of value to induce or reward referrals of business paid for by federal healthcare programs like Medicare or Medicaid
- Physician Self-Referral Law (Stark Law)
  - These laws specify the criminal and/or civil remedies that the government can impose upon individuals or entities that commit fraud and abuse in the Medicare Program, including Medicare Parts C and D, Medicare Advantage, Managed Medicare, and the Medicaid Program.
  - Violations of these laws may result in nonpayment of claims, Civil Monetary Penalties (CMPs), exclusions from participation in federal health care programs, and civil and/or criminal liability.

Conclusion

- Evaluate the effectiveness of your overall compliance program
- There is a "recipe" to a successful compliance plan
- "I didn't know" is not an excuse
- Foster compliance with your employees
- Train, Refresh, Remind, Update

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7 Elements

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Thank you!

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