

Corporate Compliance Plans Under HIPAA & Beyond

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eHealth & the
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Who am I?

- LT US Navy JAGC VietNam War
- Goulston & Storrs, Boston, 33 years
- Osborne, 18 lbs., 2 5-1/4" floppies
- Past President: Health Lawyers '91-'92
- Moderator, HIT listserv
- Telemedicine: Emerging Legal Issues
- Adjunct Prof., Suffolk U. Law School
- BNA eHealth Law & Policy Report
- ABA Health Law Section eHealth Group

Alan S. Goldberg's Privacy Policy

- **Nothing I say in this room is private**
- **Everything you say in this room is public**
- **You & I have zero privacy in this room:
get over it.**
- **How's that for a simple privacy policy?**

Alan S. Goldberg's COPPA Disclaimer

- **This presentation is not for children.**
- **If you are under age 13, please go away.**
- **I do not give out cookies, Java, or milk.**
- **How's that for a simple COPPA policy?**

Why Have Compliance Plan

- **Reduces Non-compliance Costs**
 - Sanctions
 - Survey compliance issues
- **Reduces Potential Penalties**
 - US DOJ sentencing guidelines
 - Criminal and civil fines & penalties
 - Program exclusion
- **Reduces Likelihood of Enforcement Action**
- **Government strongly recommends**

The Director Likes HIPAA

Risk Assessment

Employees

Vendors

Patients

**Corporate Compliance
Officer**

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graph TD; CO[Corporate Compliance Officer] --> E[Employees]; CO --> V[Vendors]; CO --> P[Patients];
```

Compliance in a Nutshell

- What you cannot do: violate the law by, among other things, not using the data sets and standard transactions; or violating the prohibitions against disseminating protected health information or have bad security
- What you must do: institute a QA-type process to monitor, track, correct and prevent non-compliance

When Things Go Badly

Why is Compliance So Important

- **Investigations & prosecutions are widespread**
- **Reimbursement pressures demand efficient, compliant operations**
- **GAO reports**
- **OIG has promulgated draft guidance**

What Are The Laws?

- **False Claims Act (Civil/Criminal/State)**
- **Anti-Kickback Statute**
- **Federal Health Care Offense**
- **Health Care Fraud**
- **Theft or Embezzlement**
- **False Statements**
- **Obstruction of Investigations**
- **Wire Fraud/Mail Fraud**
- **General (consumer protection)**
- **HIPAA**

"I am an icon...."

False Claims Act (Criminal)

“Whoever...knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program....”

Max. Penalty: \$25,000/5 years in jail

False Claims Act (Criminal)

- Criminalizes Billing For Services:
 - never delivered
 - never documented
 - different than delivered
 - doubly billed to two payors
 - not medically necessary
 - not accurately coded
 - delivered in violation of Conditions of Participation
 - *in violation of HIPAA rules???*

False Claims Act (Criminal)

Whoever ... having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit/payment, or (B) the initial/continued right to any such benefit/payment of any other individual in whose behalf he has applied for or is receiving such benefit/payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit/payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized

False Claims Act (Civil)

- Civil War era statute
- Prohibits “knowingly” submitting a claim to the federal government for payment of a false or fraudulent claim, or using a false record to support a claim for payment.
- Penalties: up to \$10,000 plus double or treble damages

False Claims Act (Civil)

- **“Knowing” or “Knowingly” is not solely specific intent, instead it means any of the following:**
 - **having actual knowledge of the information**
 - **acting in deliberate ignorance of the truth or falsity of the information; or**
 - **acting in reckless disregard of the truth or falsity of the information.**

False Claims Act (Civil)

- Qui Tam
- “honest mistakes” and “mere negligence”
- quality of care cases
- violation of HIPAA = poor care?

False Claims Act (Civil)

- **OIG/DOJ Guidelines**
- **Eight Factors to Determine Whether a Violation Was “Knowing”**
- **Permitted Provider Responses**

False Claims Act (Civil)

Eight Factors the DOJ/OIG Must Consider

- 1. Notice of Rule or Policy**
- 2. Clarity of Rule or Policy**
- 3. Pervasiveness/ Magnitude of False Claims**
- 4. Adherence to a Compliance Plan**
- 5. Identification of/Response to Noncompliance**
- 6. Guidance Sought from HCFA**
- 7. Previous Audits for Same Issues**
- 8. Any Other State of Mind Information**

False Claims Act (Civil)

Five Responses DOJ/OIG Must Consider

- good faith reliance upon applicable statutory and regulatory provisions and interpretations
- misled by inconsistent and often contradictory guidance from the carrier
- provider's well-documented compliance and self-reporting procedures did not reveal the billing mistake
- error was immaterial
- "innocent" mistake/no intent to defraud

Anti-Kickback Statute

illegal to knowingly and willfully **solicit, receive, offer or pay** remuneration in cash or in kind to induce or in return for **referring, recommending or arranging** for the furnishing of any **item or service** payable by Medicare or Medicaid.

\$25,000/5 years in jail

civil penalties and program exclusion

HIPAA Corporate Compliance

Compliance

Is A

Way of

Life

Ministry of Spirit of HIPAA

Do we believe in privacy?

YES!

Are we all patients?

YES!

Will we take the HIPAA pledge?

YES!

HALLELULA, PRAISE HIPAA, AMEN!

Take the HIPAA Pledge

“I pledge to preserve, protect, and defend the security, privacy & confidentiality of protected individually identifiable health information (IIHI) to the best of my ability & and in furtherance of the best interests of 280,000,000 patients.”

HALLELULA, PRAISE HIPAA, AMEN!

What is a HIPAA?

HIPAAAs typically sleep during the day & maintain activity at night. HIPAAAs are extremely graceful in the water, despite their clumsy appearance. They can sink to the bottom of rivers & literally walk or run along the bottom. HIPAAAs may occur singly or in groups of up to 30.

Nice HIPAA

Penalty For Failure to Comply With Requirements & Standards

- Not > \$100 for each violation, total for violations of identical requirement or prohibition during a calendar year not > \$25,000
- Except *if did not know*, and a person exercising *reasonable diligence* would not have known, that such person violated such provision
- Penalty may be waived if failure due to *reasonable cause* & *not to willful neglect*

BAD HIPAA

Wrongful Disclosure Individually Identifiable Health Information

- **Knowingly & in violation of Part C**
 - **Uses or causes to be used unique health identifier**
 - **Obtains IIHI relating to an individual**
 - **Discloses IIHI to another person**

HIPAA Wrongful Disclosure

- Fine of not > \$50,000, imprisoned not > one year, or both
- If under false pretenses, fine not > \$100,000, imprisoned not > five years, or both
- If with intent to sell, transfer or use PHI for commercial advantage, personal gain, or malicious harm, fine not > \$250,000, imprisoned not > ten years, or both

HIPAA Compliance Program

- **Civil & criminal penalties**
- **Federal and state confidentiality, privacy, security**
- **Patients & families as claimants**
- **Technological compliance:**
 - **hardware**
 - **software**
 - **peopleware**

An Effective Compliance Plan

- 1. Establish written standards & procedures**
- 2. Designate responsible individuals**
- 3. Regular & effective training**
- 4. Effective means of communication**
- 5. Audit & monitor compliance**
- 6. Compliant hiring & discipline**
- 7. Establish investigation protocols**

Organizational Structure

- **Designation of a Privacy/Compliance Officer**
 - **who**
 - **reporting obligations**
 - **oversight & monitoring**
 - **develop training programs**
 - **coordinate personnel & contractors**
 - **oversee audits**
 - **conduct investigations**

Organizational Structure

- Form HIPAA Compliance Committee
 - Composition
 - Function
 - *“high integrity, good judgment, assertiveness and an approachable demeanor”*
 - develop standards of conduct
 - resources for compliance officer

Your Compliance Team: Where Everyone Knows Your Name

● Cheers!

Written Standards: Code of Conduct

- **Brief statement of general principles**
- **Expectations of employees**
- **Summary of basic laws**
- **Basic instructions for reporting & response**
- **Management involvement**
- **Readable (translated if necessary)**
- **Posted & distributed**
- **Attestations of receipt & understanding**

Written Standards: Risk Areas

- **Baseline audit recommended**
- **Written data**
- **Electronic data**
- **Access to information**
- **Document, document, document**
- **Minimally necessary information**

Employee Screening

- Pre-employment screening (CORI)
- *“a...facility also should seriously consider whether to employ individuals who have been convicted of crimes of neglect, violence, theft or dishonesty, or financial misconduct”*
- avoid excluded individuals & contractors
- OIG Exclusions List:
<http://exclusions.oig.hhs.gov/epl>

Excluded Individuals

- **September 1999 Special Advisory Bulletin**
- **Examples of Excluded Providers**
 - nurses, nurse aides & others
 - pharmacists
 - ambulance drivers
 - contractors, suppliers and manufacturers
 - billing agents and claims processors
- **\$10,000 CMP for each excluded item or service**

Written Standards: Record Retention

- System for creating, storing and securing records
- resident & billing records
- compliance program records
- safe & secure place
- hard copy back-up
- limit access

Written Standards: Employee Performance

- **Compliance knowledge & activity
a factor in all reviews**
- **Condition of employment**
- **Discipline managers who do not
train**
- **Mock surveys**
- **Incentives**

Effective Training & Education

- **Overview of compliance for everyone**
- **Specific training for each job area**
- **Interactive, understandable**
- **Documented by compliance officer**
- **Scope & time**
- **Condition of employment**
- **Internet education**

Effective Lines of Communication

- **Access to privacy/compliance officer**
 - confidentiality & non-retaliation policies
 - positioned as a resource for questions
 - log & publish questions and answers
- **Means of communication**
 - hotline, email, suggestion box
 - information available to all
 - anonymity option
- **Tracking & Reporting**

"How' m I doing?"

Auditing and Monitoring

- Documented monitoring & response
- initial “snapshot”
- Identify risk areas
- Target audits based on “snapshot”
- Use results
 - decide on most urgent priorities
 - focus policies & education
 - plan corrective activity
 - use baseline for future evaluation

Discipline & Enforcement

- Enforce compliance through “well published disciplinary guidelines”
- Range of sanctions
- Stipulate procedures
- All levels subject to discipline
- Consistent response
- Document response

Response to Non-Compliance

- **Create Investigative Handbook**
- **Document**
 - concerns
 - response process
 - findings
 - resolution
- **Governmental reporting**

**“My HIPAA Plan is better
than your HIPAA Plan”**

Response to Non-Compliance

- **Reporting obligations**
 - credible evidence of misconduct
 - reasonable inquiry
 - reason to believe non-compliance
- **Voluntary disclosure protocols**
- **Consult legal counsel first**
- **Contingency plans**

Never Be Behind a HIPAA

Alan S. Goldberg's Year 3000 Readiness Disclosure

- To the best of my knowledge, this presentation will not cause the interruption or cessation of, or other negative impact on, business or other operations, attributable directly or indirectly to the processing (including but not limited to calculating, comparing, sequencing, displaying, or storing), transmitting, or receiving of date data from, into, and between the 20th and 21st centuries, and during the calendar year 1998 and thereafter (including but not limited to the calendar years 1999 and 2000), and leap year calculations, or give rise to the inability of one or more computer software or hardware programs, machines or devices accurately to receive, store, process or transmit data on account of calendar information applicable to such programs, machines or devices, including without limitation calendar information relating to dates from and after Dec. 7, 2000.

Be A HIPAA Hero



Words of Wisdom

- **"So far, the Internet seems to be largely amplifying the worst features of television's preoccupation with sex and violence, semi-literate chatter, shortened attention spans, and near-total subservience to commercial marketing...." The Librarian of Congress, James Billington**

Words of Wisdom

- **"Never make forecasts, especially about the future." Sam Goldwyn.**
- **"In the times of rapid change, learners inherit the Earth, while the learned find themselves beautifully equipped to deal with a world that no longer exists." Eric Hoffer.**
- **"You already have zero privacy: get over it." Scott McNealy.**

HIPAA Corporate Compliance: A New Way of Life

- Why is this man smiling?



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