



Healthcare Institute - Part 3: Compliance and Contract Negotiations

SPEAKERS

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Compliance

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Acronyms

- CFR: Code of Federal Regulations
- CMS: Centers for Medicare & Medicaid Services
- FDR: First tier, Downstream and Related entity
- FWA: Fraud, Waste and Abuse
- HHS: Department of Health & Human Services
- HIPAA: Health Insurance Portability & Accountability Act
- MA: Medicare Advantage
- OIG: Office of Inspector General
- PHI: Protected Health Information

Diving into Compliance

Start with the Basics

Compliance Program Requirements for Plan Sponsors (Health plans offering Medicare Advantage and/or Part D)

- Medicare + Choice: In 1999, the Office of Inspector General offered specific compliance measures that “may be implemented”; It is now mandatory

Applicability of HIPAA Privacy and Security Rules

Session will answer the questions:

- What are the Compliance Program elements?
- How do I fit into HIPAA?
- How are these requirements pertinent to me?
- Where do I start?

MA Compliance Program Elements



Code of Federal Regulations (2017). Retrieved from [42 C.F.R. §§ 422.503\(b\)](#); also [423.504\(b\)](#).



HIPAA Privacy, Security and Breach Notification

2000

- Privacy Rule finalized, sets national standards for when PHI may be used and disclosed

2003

- Security Rule finalized, specifies safeguards that covered entities and their business associates must implement to protect the confidentiality, integrity, and availability of electronic PHI (ePHI)

2009

- Breach Notification Rule finalized, requires covered entities to notify affected individuals, HHS, and in some cases, the media of a breach of unsecured PHI

HIPAA Privacy and Security Rules

Apply to Covered Entities and Business Associates

A Health Care Provider	A Health Plan	A Health Care Clearinghouse
<p>This includes providers such as:</p> <ul style="list-style-type: none">• Doctors• Clinics• Psychologists• Dentists• Chiropractors• Nursing Homes• Pharmacies <p>...but only if they transmit any information in an electronic form in connection with a transaction for which HHS has adopted a standard.</p>	<p>This includes:</p> <ul style="list-style-type: none">• Health insurance companies• HMOs• Company health plans• Government programs that pay for health care, such as Medicare, Medicaid, and the military and veterans health care programs	<p>This includes entities that process nonstandard health information they receive from another entity into a standard (such as standard electronic format or data content), or vice versa</p>

Business Associate

A person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a Covered Entity. A member of the covered entity's workforce is not a Business Associate. A covered health care provider, health plan, or health care clearinghouse can be a Business Associate of another Covered Entity. The Privacy Rule lists some of the functions or activities, as well as the particular services, that make a person or entity a Business Associate, if the activity or service involves the use or disclosure of protected health information. The types of functions or activities that may make a person or entity a Business Associate include payment or health care operations activities, as well as other functions or activities regulated by the Administrative Simplification Rules.

Health Information Privacy (2018). Retrieved from:
<https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>

Who is who?

Important to understand terms used to understand roles, responsibilities and obligations. An **effective compliance program creates a framework** to minimize or eliminate instances of non-compliance, FWA and data breaches.

Health Plan	Meals on Wheels
MA Plan Sponsor	First Tier, Downstream or Related Entity (FDR)
Covered Entity	Business Associate

Why These Requirements Matter



Partnering with a health plan requires a Meals on Wheels to understand their compliance program and implement an effective program of its own



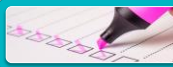
The Compliance Program elements were established for MA organizations and Part D plans



HIPAA Privacy and Security Rules established for Covered Entities and Business Associates



CMS also established requirements for FDR oversight



On an annual (or other) basis, expect to provide attestations to MA organizations



Contracting (to be discussed further) but let's not get ahead of ourselves!

What Obligations to Expect

- ❖ Pre-delegation audit, visit or desk review
- ❖ General Compliance and FWA Training*
- ❖ Compliance Program and Standards of Conduct Distribution
- ❖ Exclusion List Screening
- ❖ System for Reporting Potential FWA and/or Non-Compliance
- ❖ Delegated Activity Detail including Reporting Requirements
- ❖ Oversight of your FDRs

*Final Rule Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

Start From the Very Beginning

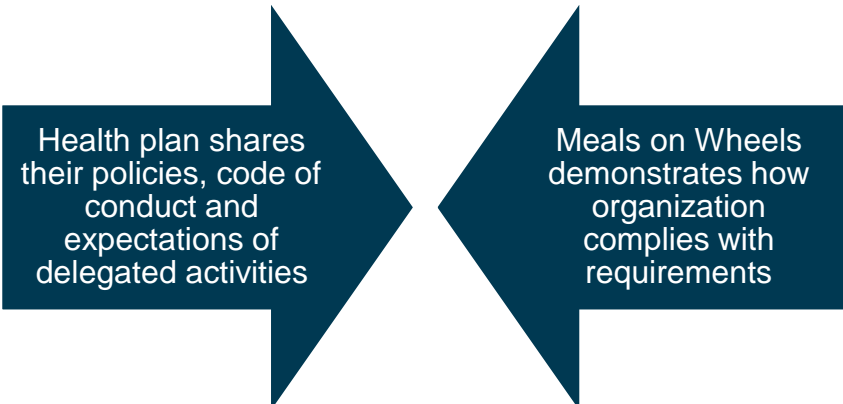
(A very good place to start)

Determine **what elements and safeguards are in place already** that support your program

- Compliance Program elements
- Privacy and security safeguards
- Record confidentiality, accuracy and retention
- Compliance with all applicable Medicare laws, regulations, and CMS instructions
 - Critical that someone at the FDR stay up-to-date on laws, regulations, and sub-regulatory guidance
 - Reliance on the MA organization is not enough

Working with your Plan Partner

Partner is the Key Word!



Health plan shares their policies, code of conduct and expectations of delegated activities

Meals on Wheels demonstrates how organization complies with requirements

MA Compliance requirements written for health plans
Expect expectations to be outlined in contract, delegation agreement, Code of Conduct

Common Misses in the Industry

Reportable to Health Plan

- Failure to check the correct exclusion lists for applicable employees
 - Who is applicable?
- PHI accessed for reasons other than **treatment, payment and healthcare operations** activities
 - Examples for discussion
- Leaving PHI or ePHI unsecured
- Billing for services not rendered
- Failure to report non-compliance – health plan provides multiple methods

References

- ❖ Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans (1999). Retrieved from <https://oig.hhs.gov/fraud/docs/complianceguidance/111599.pdf>
- ❖ Code of Federal Regulations (2017). Retrieved from [42 C.F.R. §§ 422.503\(b\); 423.504\(b\)](#)
- ❖ Health Information Privacy (2018). Retrieved from: <https://www.hhs.gov/hipaa/for-professionals/index.html>
- ❖ Final Rule Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (2018).