CHIAP BOK: Regulatory Environment

DEBRA A. MUSCIO, MBA, CHC, CCE, CFE, CHP, CHIAP
SVP/CHIEF AUDIT, ERM, PRIVACY, SECURITY,
COMPLIANCE OFFICER
COMMUNITY MEDICAL CENTERS

Learning Objectives for Today's Webinar

Overview of the CHIAP Body of Knowledge (BOK): Regulatory Environment

Walkthrough high level:

- Regulatory Bodies
- Regulations

Regulatory Environment
Regulatory Bodies

Department of Health and Human Services (HHS)

- Centers for Medicare & Medicaid Services (CMS)
  - Affordable Care Act (ACA)
    - Physician Payment Sunshine Act
  - CMS Conditions of Participation
  - CMS Conditions of Payment
  - Emergency Medical Treatment and Labor Act (EMTALA)
- Office of Civil Rights (OCR)
  - Health Insurance Portability & Accountability Act (HIPAA)
    - Individually Identifiable Health Information (IIHI)
- Social Security

Regulatory Environment
Regulatory Bodies – cont.

Department of Justice (DOJ)

- False Claims Act
- Federal Anti-Kickback Statute and the Stark Law
- Office of Inspector General (OIG)

Drug Enforcement Agency (DEA)

Food and Drug Administration (FDA)

Federal Trade Commission (FTC)

Internal Revenue Service (IRS)

The Joint Commission

State Regulators

Centers for Medicare and Medicaid

The Centers for Medicare & Medicaid Services (**CMS**) is part of the U.S. Department of Health and Human Services. **CMS** oversees many federal **healthcare** programs, including those that involve health information technology such as the meaningful use incentive program for electronic health records (EHR).

In addition to Medicare (the federal health insurance program for the elderly) and Medicaid (the federal needs-based program that helps with medical costs), CMS administers the Children's Health Insurance Program (CHIP), the Health Insurance Portability and Accountability Act (HIPAA) and key portions of the 2015 Medicare Access and CHIP Reauthorization Act (MACRA)law.

https://www.cms.gov/

https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html

The Medicare Access and CHIP Reauthorization Act (MACRA)

The **Medicare Access and CHIP Reauthorization Act** of 2015 (**MACRA**) is a bipartisan **legislation** signed into **law** on April 16, 2015. **MACRA** created the Quality Payment Program that: Repeals the Sustainable Growth Rate (PDF) formula. Changes the way that **Medicare** rewards clinicians for value over volume.

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs

MACRA created the Quality Payment Program that:

- Repeals the Sustainable Growth Rate (PDF) formula
- Changes the way that Medicare rewards clinicians for value over volume
- Streamlines multiple quality programs under the new Merit Based Incentive Payments System (MIPS)
- Gives bonus payments for participation in eligible alternative payment models (APMs)
- MACRA also required us to remove Social Security Numbers (SSNs) from all Medicare cards by April 2019.

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Meaningful Use

The American Reinvestment & Recovery Act (ARRA) was enacted on February 17, 2009. ARRA included many measures to modernize our nation's infrastructure, one of which was the "Health Information Technology for Economic and Clinical Health (HITECH) Act". The HITECH Act included the concept of electronic health records – meaningful use [EHR-MU], an effort led by Centers for Medicare & Medicaid Services and the Office of the National Coordinator for Health IT (ONC). HITECH proposed the meaningful use of interoperable electronic health records throughout the United States health care delivery system as a critical national goal.

Meaningful Use was defined by the use of certified EHR technology in a meaningful manner (for example electronic prescribing); ensuring that the certified EHR technology connects in a manner that provides for the electronic exchange of health information to improve the quality of care. By using certified EHR technology, the provider must submit to the Secretary of Health & Human Services (HHS) information on the quality of care and other measures. The concept of meaningful use rested on the five pillars of health outcomes policy priorities, namely:

1. Improving quality, safety, efficiency, and reducing health disparities
2. Engage patients and families in their health
3. Improve care coordination
4. Improve population and public health
5. Ensure adequate privacy and security protection for personal health information

CMS renamed the EHR Incentive Programs - Promoting Interoperability Programs in April 2018.

This change has moved the programs beyond the existing requirements of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information.

Eligible entities: Eligible Professionals (EPs) and Eligible Hospitals (EHs)/Critical Access Hospitals (CAHs), treating Medicare and Medicaid patients.

Public Health Objective included in the programs: Public Health Registry and Clinical Data Registry Reporting. The specific measures included under the above objective are-

1. Immunization Registry Reporting.
2. Syndromic Surveillance Reporting.
3. Electronic Case Reporting.
4. Public Health Registries Reporting*
5. Clinical Data Registries Reporting
6. Electronic Reportable Laboratory Test Reporting (for Hospitals only).

https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index?redirect=/ehrincentiveprograms/

Affordable Care Act

The comprehensive health care reform law enacted in March 2010 (sometimes known as ACA, PPACA, or "Obamacare").

The law has 3 primary goals:

- Make affordable health insurance available to more people. The law provides consumers with subsidies ("premium tax credits") that lower costs for households with incomes between 100% and 400% of the federal poverty level.
- Expand the Medicaid program to cover all adults with income below 138% of the federal poverty level. (Not all states have expanded their Medicaid programs.)
- Support innovative medical care delivery methods designed to lower the costs of health care generally.

https://www.healthcare.gov/glossary/affordable-care-act/

ACA Compliance for Employers: Avoiding an IRS Audit

Identify Employees that are Full-Time and Benefit Eligible

By now, most Applicable Large Employers (ALEs) understand that employees who work 30 or more hours per week or average more than 130 hours per month are considered full-time and eligible for coverage. In order to identify these employees, it is important that you are actively managing employee eligibility for the entire calendar year.

Offer Quality Coverage to Full-Time Employees

Once an ALE has identified all of its full-time, eligible employees, it is important to extend offers of coverage at the correct time. Also, in order for employers to be in compliance with the ACA's employer coverage mandate, employers must offer quality coverage. This means that employers must ensure that they are offering all full-time, eligible employees health coverage that meets minimum essential coverage, minimum value, and affordability guidelines.

Generate and Audit 1095-C Forms for Accuracy

ALEs must provide 1095-C forms to all full-time eligible employees at the end of each year. This form requires information such as whether each employee was offered health insurance, at what cost, and of what quality. One of the main triggers of an IRS audit is filing inaccurate data. Therefore, it is equally important for employers to review the 1095-C forms for accuracy before they are distributed. There are many different 1095-C code combinations for various coverage scenarios. You may want to use this blog as a resource to assist in reviewing your 1095-C forms.

ACA Compliance for Employers: Avoiding an IRS Audit

Meet the IRS 1095-C Mailing Deadline

Employers must be sure to furnish accurate 1095-C forms to their employees by the IRS deadline. Failure to comply with the IRS deadline cannot only make you vulnerable to auditing, but it can also subject you to potential IRS penalties for non-filing. The IRS mailing deadline for sending out 1095-Cs to employees is March 2 (extended from January 31).

Audit Form 1094-C

The key to avoiding an IRS audit is being pro-active about auditing and reviewing your information before it is sent to the IRS. Here are a few key items to review when auditing your 1094-C form:

Ensure company name and EIN are correct.

- Also be sure that your affiliated ALE members are listed in Part III (if applicable).

Ensure that the authoritative transmittal box is checked (Line 19) for each EIN for which you are reporting.

Ensure that the "Minimum Essential Coverage Offer Indicator" (Part III, Column a) is accurately checked for all 12 months or appropriate months.

- Generally, if you offer an MEC plan, this should be marked "Yes" for All 12 Months – Individual months are then left blank.

Ensure that the month full-time employee counts are correct (Part III, Column b), *unless you have selected the 98% Offer Method.

What is the DOL Auditing in Regards to the ACA?

A DOL audit requests documents showing compliance with the ACA based on numerous factors. A primary focus is on whether a plan is claiming grandfathered status. A grandfathered plan must have been effective before March 23, 2010 and any changes made to the plan must be in accordance to strict regulations. Plans that claim grandfathered status must provide the following:

- **Proof that the plan is grandfathered**
  - Plan documents from before March 23rd and anything needed to verify grandfathered status
- **Copy of disclosure statements**
  - Grandfathered plan provides were required to send a notice to their participants describing the benefits provided under the plan.

What is the DOL Auditing in Regards to the ACA? continue

For plans not claiming grandfathered status, the group must provide:

- Documentation showing the preventative services covered under the plan
- The plans internal claims and appeals procedures
- Contracts or agreements with independent review organizations (IROs) or any third-party administrators that provide external reviews.
- Notices relating to adverse benefit determinations and final external review determination
- Copies of documents describing coverage for emergency services
- A copy of notice informing participants of the right to chose a primary care provider.

All plans regardless of their grandfathered status are being asked to provide the following to the DOL:

- Notice describing the enrollment process for dependents up to the age 26.
- A list of participants that had their coverage rescinded and the reason for rescission.
- Documents relating to lifetime or annual limits that were imposed since September 23, 2010.

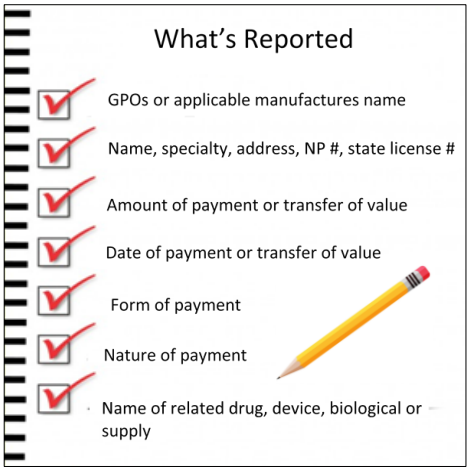
Physician Payment Sunshine Act

The Physician Payments Sunshine Act (PPSA)--also known as section 6002 of the Affordable Care Act (ACA) of 2010--requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals.

https://www.cms.gov/OpenPayments

Open Payments is a federal program that collects and makes information public about financial relationships between the health care industry, physicians, and teaching hospitals. ... These **payments** and other transfers of value can be for many purposes, like research, consulting, travel, and gifts.

https://www.healthaffairs.org/do/10.1377/hpb20141002.272302/full/



Open Payments - Audits & Penalties

Applicable manufacturers and applicable group purchasing organizations (GPOs) may be audited at any time for compliance to ensure the submission of timely, accurate, and complete reports of payments or other transfers of values made to physicians and teaching hospitals and physician ownership or investment interests.

Applicable GPOs may be audited to ensure the submission of timely, accurate, and complete reports on ownership or investment interests held by physicians and their immediate family members at any time.

CMS requires that your organization keep all records related to payments or other transfers of value for at least five years from the date that the payment or other transfers of value are posted.

Civil monetary penalties (CMPs) of up to $1,000,000 may be imposed on your organization if it fails to report information in a timely, accurate, or complete manner. Any CMPs collected will be used to implement Open Payments.

It should also be noted that physician-owned distributors are considered applicable GPOs and are not exempt from reporting.

https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Audits-and-Penalties

CMS Conditions of Participation

False Claims Act concept

CMS develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs / CfCs.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index

Conditions of Payment

False Claims Act concept

Conditions of Payment. As the name suggests, a **condition of payment** is a rule, regulation, or requirement that must be met in order for a healthcare provider to lawfully request and receive reimbursement from a federal healthcare coverage provider (e.g., **Medicare**, Medicaid, or TRICARE). The government imposes conditions of payment to ensure providers are offering patients quality service congruent with set standards within the medical community.

https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/Medicare-Fee-for-Service-Payment-Regulations/index

https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol3/xml/CFR-2017-title42-vol3-part424.xml

Emergency Medical Treatment and Labor Act (EMTALA)

The Emergency Medical Treatment and Labor Act (EMTALA) is a federal law that requires anyone coming to an emergency department to be stabilized and treated, regardless of their insurance status or ability to pay, but since its enactment in 1986 has remained an unfunded mandate.

The purpose of EMTALA is to prevent "'patient dumping,' the practice of refusing to provide emergency medical treatment to patients unable to pay, or transferring them before emergency conditions [are] stabilized."

https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/index

https://www.acep.org/life-as-a-physician/ethics--legal/emtala/emtala-fact-sheet/

Office of Civil Rights (OCR)

The Office for Civil Rights (OCR) is the enforcement agency for Health and Human Services (HHS). Through the federal civil rights law, OCR insures that people have equal access and opportunity to participate in certain healthcare and human services programs without unlawful discrimination. In addition, under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, OCR protects patients' health information privacy.

https://www.hhs.gov/ocr/index.html

Health Insurance Portability & Accountability Act (HIPAA)

Protects the patient's right to privacy of health information.

What is Protected Health Information (PHI)?

- PHI is patient's information that must be protected from unauthorized access, use and disclosure
- PHI is patient information created, as well as, information received from other healthcare providers

State and Federal Laws mandate the protection of patient health information

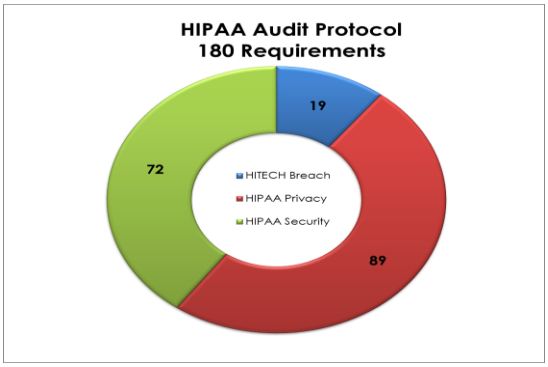
The HITECH Privacy Rule allows you to share information without patient's authorization for treatment, payment, or operations (TPO). Share the minimum amount necessary for TPO purposes.

Individually Identifiable Health Information (IIHI)

Under Federal HIPAA and State regulations all identifiers listed below are considered protected and if accessed, used and disclosed inappropriately could be considered a breach:

- Name
- Date of Birth
- Address, city, county, zip code
- Medical Record #
- SSN #
- Account #
- Name of relative or employer
- Health Plan #
- Telephone #
- Device Identifiers and Serial #
- Photographic images and other comparable images
- Any other unique identifying #, code, or characteristic
- Email address, Web URL

Auditing Privacy and Security



Some violations result in significant fines. These are the top 10:
1.Database breaches
2.Third-party disclosure of PHI
3.Improper disposal of PHI
4.Mishandling medical records
5.Employees disclosing information
6.Not performing an organization-wide risk analysis
7.Employees illegally accessing patient files
8.Lost or stolen devices
9.Lack of training
10.Not encrypting PHI on portable devices

To learn more about OCR's Phase 2 Audit program, visit website at http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html

Social Security

Sections of the Social Security Act piggyback on patient rights regulations by making it illegal for hospitals to pay physicians to limit services to Medicare or Medicaid patients. In contrast, organizations can be penalized for offering gifts to a patient to get their business.

https://www.ssa.gov/OP_Home/ssact/ssact-toc.htm

Department of Justice

It is a federal crime to devise a scheme to defraud another of property, when either mail or wire communications are used in furtherance of the scheme.

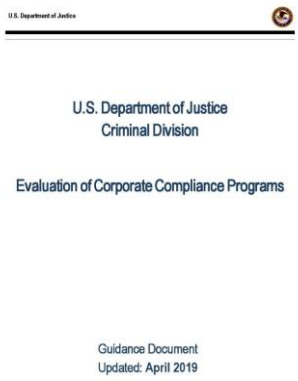
Mail or wire fraud includes schemes to:

- defraud another of honest services
- when the scheme involves bribery or a kick back
- and may also constitute a violation of one or more other federal crimes

Offenders face the prospect of imprisonment, fines, an order to pay victim restitution, and the confiscation of any property realized from the offense.

https://www.justice.gov/jm/jm-9-43000-mail-fraud-and-wire-fraud

DOJ - Guidance for Compliance



U.S. Department of Justice

U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

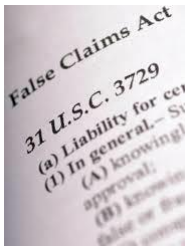
Guidance Document
Updated: April 2019

https://www.justice.gov/criminal-fraud/page/file/937501/download

False Claims Act

False Claims Act - Prohibits submission of a fraudulent bill to a government agency.

This includes **claims** submitted to **Medicare** or **Medicaid**. Violating the **False Claims Act** is a very serious matter. ... They **can** be required to pay three times the amount of damages sustained by the United States government, and they may also be excluded from participation in **Medicare and Medicaid**.



Be on the lookout

2019 Mid-Year False Claims Act Update
https://www.gibsondunn.com/2019-mid-year-false-claims-act-update/

Audits and the False Claims Act's

Medicare-participating providers are in violation of the False Claims Act if they submit Medicare bills, and are paid, for care that is deemed any of the following:
•Inappropriate
•Unnecessary
•Misrepresented (e.g., through upcoding or false documentation)
•Not provided

Federal Anti-Kickback Statute and the Stark Law

Anti-Kickback Statute – Prohibits giving or receiving any remuneration (something of value) in exchange for referring a patient or purchasing an item or service that will be paid for by a government program (Medicare).

Stark Act - Prohibits physicians from referring patients to facilities or providers if physician or immediate family has a financial relationship with the facility or provider.

Office of Inspector General (OIG)

Anti-Kickback Provisions (AKS)
https://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf

Physician Self-Referral ("Stark") Law
https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm

False Claims Act (FCA) & Whistleblower Provision
https://oig.hhs.gov/faqs/whistleblower-faq.asp

Exclusion Statute
https://oig.hhs.gov/exclusions/background.asp

Civil Monetary Penalties
https://oig.hhs.gov/fraud/enforcement/cmp/background.asp

Drug Enforcement Agency (DEA)

The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

https://www.fda.gov/home

Food and Drug Administration (FDA)

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

https://www.fda.gov/drugs/guidance-compliance-regulatory-information

31

PROTECTING AMERICA'S CONSUMERS

Federal Trade Commission (FTC)

RED FLAGS RULE

The **Red Flags Rule**, a law the **Federal Trade Commission (FTC)** begin enforcement on August 1, 2009, requires certain businesses and organizations — including many doctors' offices, hospitals, and other **health care** providers — to develop a written program to spot the warning signs — or "**red flags**" — of identity theft.

https://www.ftc.gov/tips-advice/business-center/privacy-and-security/red-flags-rule

https://www.ftc.gov/tips-advice/business-center/guidance/fighting-identity-theft-red-flags-rule-how-guide-business

32

Federal Trade Commission (FTC)
Red Flags Rule

The Red Flags Rule tells you how to develop, implement, and administer an identity theft prevention program. A program must include four basic elements that create a framework to deal with the threat of identity theft.

1. A program must include reasonable policies and procedures to identify the red flags of identity theft that may occur in your day-to-day operations. Red Flags are suspicious patterns or practices, or specific activities that indicate the possibility of identity theft. For example, if a customer has to provide some form of identification to open an account with your company, an ID that doesn't look genuine is a "red flag" for your business.
2. A program must be designed to detect the red flags you've identified. If you have identified fake IDs as a red flag, for example, you must have procedures to detect possible fake, forged, or altered identification.
3. A program must spell out appropriate actions you'll take when you detect red flags.
4. A program must detail how you'll keep it current to reflect new threats.

IRS REGULATIONS - 501 (r)

501(r): **IRS Regulations** and the Hospital Revenue Cycle. First enacted as part of the Affordable Care Act in 2010, **501(r)** imposes four requirements on nonprofit hospitals and health systems in order to maintain their tax-exempt, nonprofit status. **Three of these requirements** relate directly to a hospital's revenue cycle operations. Failure to comply could result in substantial penalties or the loss of nonprofit status, so it's important to understand what's required under this law.

1. **Conduct a Community Health Needs Assessment (CHNA).**
2. **Establish a written Financial Assistance Policy (FAP).**
3. **Set charge limits for FAP-eligible patients.**
4. **Make reasonable effort to determine FAP eligibility.**

IRS Finalizes **Regulations** Under Section 501 (r) These requirements include the obligation to perform a community health needs assessment every three years, the obligation to establish written policies on financial assistance and emergency care, and the imposition of certain limitations on billing and collection actions.

https://www.irs.gov/charities-non-profits/section-501r-reporting

The Joint Commission

The mission of the Joint Commission on Accreditation of Healthcare Organizations is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

Accreditation means that our staff has made an extra effort to review and improve the key areas that can affect the quality and safety of your care. Accreditation by The Joint Commission is considered the gold standard in. health care.

https://www.jointcommission.org

State Regulators

California Department of Public Health (CDPH) is responsible for public health in California. It is a subdivision of the California Health and Human Services Agency, which is the state agency tasked with administration and oversight of "state and federal programs for health care, social services, public assistance and rehabilitation" in California.

CDPH ensures compliance with state licensing laws as well as with federal regulations in their role as the state survey agency for the Centers for Medicare and Medicaid Services. They certify facilities to receive Medicare and Medi-Cal reimbursements.

https://www.cdph.ca.gov/

State Regulators

CALIFORNIA LABOR & EMPLOYMENT LAW

Differences Between California Employment Law & Federal Employment Law

Generally, California labor law is more pro-worker. And typically, the damages and penalties a worker can recover are higher under California labor law than under federal labor law.

https://www.edd.ca.gov/

https://www.dfeh.ca.gov/

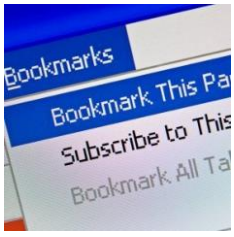
https://www.eeoc.gov/

https://www.labor.ca.gov/

https://www.dir.ca.gov/dlse/

Wrap-up

- We cannot know every regulatory body and all the regulatory information!
- We can bookmark the sites, register to receive updates and read frequently to stay current.



Questions & Answers

Please submit your questions to AHIA as follows:

- AHIA ListServ / AHIA Connected Community
- EMAIL: info@ahia.org or certification@ahia.org

- PHONE: 888-ASK-AHIA

Speaker contact info

Debra A. Muscio, MBA, CFE, CCE, CHC, CHP, CHIAP

SVP, Chief Audit, ERM, Privacy, Security, Ethics and Compliance Officer

Community Medical Centers

dmuscio@communitymedical.org