BPW
HEALTHCARE CONSULTING

COMPLIANCE AND REGULATORY GUIDELINES

FEDERAL REGULATIONS

Medicare Fraud & Abuse: Prevent, Detect, Report (cms.gov)

CMS defines fraud as making false statements or misrepresenting facts to obtain an underserved benefit or payment from the federal healthcare program

Examples of fraud/abuse:

- Billing for services or supplies that were not furnished
- Altering claim forms and/or receipts to receive a higher payment
- Billing for services at a higher level
- Misrepresenting the DX to justify payment
- Misusing codes on a claims
- Charging excessively for services that are not medically necessary
- Failure to maintain adequate medical/financial records
- Improper billing practices
- Billing Medicare patients a higher fee schedule than non-Medicare patients

FEDERAL FALSE CLAIMS ACT (FCA)

- A person is liable under the FCA who:
  A. Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval
  B. Knowingly makes, uses, or causes to be made, or used a false record or statement material to a false or fraudulent claim
  C. Conspires to commit a violation of a sub paragraph, A, B, D, E, F or G
  D. Has possession , custody, control of property or money used or to be used by the government and knowingly delivers or causes to be delivered , less than all the money or property
  E. Is authorized to make or deliver a document certifying receipt of property used or to be used by the government, makes or delivers the receipt without knowing the information on the receipt is true
  F. Knowingly buys or receives a pledge of an obligation or debt, public property, from an officer or employee of the government or a member of the Armed Forces, who lawfully may not sell or pledge property; or
  G. Knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government or knowingly conceals and improperly avoids or decreases an obligation to pay or transmit money or property to the government

THE REVERSE FALSE CLAIM SECTION

- The FCA is violated when there is knowledge that you are submitting a false claim.
- A violation can also occur when there is no intent
- The FCA allows reduced penalties if the person self-discloses and:
  - The person responsible discloses to investigators all details in 30 days of obtained information
  - Cooperates with the investigation
  - The person did not have knowledge of the existence of investigation and no criminal activity, civil action or administration action occurred during investigation

C-FRAUDS_FCA_Primer.pdf (justice.gov)

Section A.1.G. of the FCA-statue seeks to protect those who come forward with information of wrong-doing

Provides liability where a person acts improperly to avid paying money owed to the government

- Falsifying a medical chart notation
- Submitting claims for services not performed, not requested or unnecessary
- Submitting claims for expired drugs
- Upcoding/unbundling
- Submitting claims for physician services performed by a NPP without incident to guidelines.

PHYSICIAN SELF-REFERRAL AND ANTI-KICKBACK LAW

Physician Self-Referral law aka Stark Law

- Bans physicians from referring patients for certain services to entities where the physician has a direct or indirect financial interest.
- The Stark Law bans referrals to entities for designated health services
  - Labs
  - P/T/OT services
  - Radiology services/Radiation therapy services
  - DME/HHA
  - RX
  - Hospitals

Anti-Kickback Law

- Applies to anyone, not just physicians
- Requires proof of intention and states a person must willfully and knowingly violate the law
- Harsh penalties including fines and imprisonment

EXCEPTIONS IN STARK LAW

General exceptions

In office ancillary

Related to ownership in publicly traded securities and mutual funds

Personal services arrangements, rental of office space and equipment

CHRG-114shrg26440.pdf (govinfo.gov)

EXCLUSION STATUE

A physician may be banned from participating in any federal or state healthcare program

Excluded providers may not bill the federal government for any services, whether participating or non-participating.

Ban applies to:

Excluded person:

Anyone employed or contracted with the excluded person

Any hospital or other provider for which the excluded person provides services.

Any other provider or supplier

CIVIL MONETARY PENALTIES LAW- CMP

The Social Security Act authorizes the Secretary of HHS to seek civil monetary penalties and assessments for many types of conduct.

- Range from $10,000 to $50,000 per violation
- Amount is based on the Federal Civil Penalties Inflation Adjustment Act and can include an assessment up to 3 times the amount
- OIG sends a demand letter to initiate the process
- Providers and healthcare facilities are responsible for those submitting their claims

OIG may seek CMP for improper filings of claims to any federal or state agency that the Secretary determines:

- Service was not provided and the person knows or should know it was not provided
- A person knows the claim is fraudulent or should know
- A person knows the provider is not licensed or should know.
- A person provided service during the exclusion period
- Pattern of services for items not medically necessary

OIG WORK PLAN/CIA

WORK PLAN | OFFICE OF INSPECTOR GENERAL | U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS.GOV)

Office of Inspector General detects and prevents fraud, waste and abuse to improve the efficiency of HHS programs.

OIG provides oversight of MCR, MCD, CDC, NIH and FDA

- Practice makes perfect, so strengthen your familiarity with the presentation

OIG publishes the Work Plan on the OIG website monthly

- Auditors should know the work plan for the current year
- OIG chooses the work plan based on relative risks in the programs it oversees, areas needing most attention
- Each project will list the focus area and primary objective of review
- Identify "New" as those not included in the previous work plan

Corporate Integrity Agreements-CIA

- Function of the OIG; negotiating and developing a CIA as a condition of not seeking exclusion from participation when an entity seeks to settle civil healthcare fraud
- Require a claim review, sampling of claims
- If the sample, yields a 5% error rate, a full sample must be reviewed

CIA Requirements

1. Hire a compliance officer
2. Develop written standards and policies
3. Implement employee training
4. Independent Review Organization-annual review
5. Establish a confidential disclosure program
6. Restrict employment of ineligible persons
7. Report overpayments, reportable events, legal proceedings
8. Provide implementation and annual reports to the OIG

CIA-CONTINUED

- Compliance Program Guidance for Third-Party Medical Billing Companies (hhs.gov)

In lieu of a CIA, OIG will consider

- Whether the provider self-disclosed the alleged misconduct
- The monetary damage
- Whether the case involves successor liability
- Whether the provider is still participating in the federal program
- Whether the alleged conduct is capable of repetition
- The age of the conduct
- Whether the provider has an effective compliance plan
- Other circumstances as appropriate

COMPLIANCE PLAN

- Represents comprehensive documentation that a provider, practice or facility or healthcare entity is taking the necessary steps to adhere to federal and state laws
- ACA of 2010 makes compliance programs mandatory for providers and other healthcare providers who offers services and procedures to Medicaid and Medicare patients

Culture of Compliance

- Make compliance plans a priority
- Know your fraud and abuse risks areas
- Manage your financial relationships
- Just because your competitor is doing something doesn't mean you can or should
- When in doubt, ask for help

- 7 Elements that should be present in every compliance plan
  - Implementing written policies, procedures and standards of conduct
  - Designating a compliance officer/or compliance committee
  - Effective training and education
  - Develop effective lines of communication
  - Enforcing standards, disciplinary guidelines
  - Conducting internal monitoring and auditing
  - Responding properly to detected offenses and corrective action
  - **Non-compliant conduct must be documented**
    - Date of incident
    - Name of the reporting person and responsible person
    - Follow up action

COMPLIANCE PROGRAMS FOR INDIVIDUAL/SMALL GROUP PHYSICIAN PRACTICES

- Potential benefits for a compliance plan
  - Increasing accuracy of documentation
  - Increasing the speed and optimization of proper payment of claims
  - Minimizing billing mistakes
  - Reducing the chances of an audit
  - Avoiding conflicts with self referral and anti-kickback statutes

Coding and Billing	Reasonable and Necessary Services	Documentation	Improper Inducement	Other Risks
Billing for items/services not provided	Physicians can bill for tests and labs deemed appropriate	Verification that clean claims are submitted	Financial arrangements with outside entities	Space rental
Double Billing, Unbundling, Modifier Usage Upcoding, Improper Member ID information	CMS will only pay for those test s and services it believes is medically necessary	Medical record should support submitted claim such as identity of provider performing services, site of service	Joint ventures	Unlawful advertising
Use of 3rd party billing service	Is there an ABN?	Accurate billing	Consulting contracts	Soliciting, accepting or offering gifts

CMS TRANSMITTALS AND AUDIT RESOURCES

R11641G1	Update Medicare Deductible, Coinsurance and Premium Rates for Calendar Year	MM12903 - Medicare Deductible, Coinsurance & Premium Rates: Calendar Year 2023 Update (cms.gov)
R11644CP	Home Health Claims-New Grouper Return Code Edits and Informational Unsolicited Response	MM12924 - Home Health Claims: New Grouper Edits (cms.gov)
42 CFR 416	Ambulatory Surgical Centers	eCFR :: 42 CFR Part 416 -- Ambulatory Surgical Services
42 CFR 485 Subpart F	Critical Access Hospitals	eCFR :: 42 CFR Part 485 Subpart F -- Conditions of Participation: Critical Access Hospitals (CAHs)
42 CFR 482	Hospitals	eCFR :: 42 CFR Part 482 -- Conditions of Participation for Hospitals
42 CFR 482.24	COP-Medical Records	eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.
NCCI Edits	National Correct Coding Initiative	NCCI for Medicare | CMS
MUE	Medically Unlikely Edits	Medicare NCCI Medically Unlikely Edits | CMS

RAC AUDIT PROCESS

- RAC auditors identify overpayments and underpayments made to healthcare providers and suppliers submitting claims to Medicare for services provided to Medicare beneficiaries.
- Review claims on a post-payment basis and use the CMS regulations that providers are required to follow.
- Auditors may request claims going back 3 years and have a maximum # of medical records they can request each 45 days.
- **Two Types of Reviews**
- Automated: no medical record needed, based on systematic claim determination
- Complex: Recovery Auditor reviews the medical record to make a determination
- A letter is sent to the provider to provide decision rationale. MAC will adjust the claim and send a demand letter for the overpayment.

Provider Agrees	Provider Disagrees
Ask for a recoupement from a future payment	Submit a discussion period request within 30 days from the date the demand letter was received.
Extended payment plan	Submit a rebuttal with 15 days to the MAC, can also submit a reconsideration request with 120 days from the demand letter, Last option is a first level appeal

RAC AUDIT-PROVIDER OPTIONS

Provider Options - RAC Overpayment Determination

	Discussion Period	Rebuttal	Redetermination
Which option should I use?	The discussion period offers the opportunity for the provider to provide additional information to the RAC to indicate why recoupment should not be initiated. It also offers the opportunity for the RAC to explain the rationale for the overpayment decision. After reviewing the additional documentation submitted the RAC could decide to reverse their decision. A letter will go to the provider detailing the outcome of the discussion period.	The rebuttal process allows the provider the opportunity to provide a statement and accompanying evidence indicating why the overpayment action will cause a financial hardship and should not take place. A rebuttal is not intended to review supporting medical documentation nor disagreement with the overpayment decision. A rebuttal should not duplicate the redetermination process. (See 42 CFR 405.374-375)	A redetermination is the first level of appeal. A provider may request a redetermination when they are dissatisfied with the overpayment decision. A redetermination must be submitted within 30 days to prevent offset on day 41.
Who do I contact?	Recovery Audit Contractor (RAC)	Claim Processing Contractor	Claim Processing Contractor
Timeframe	Day 1 - 30	Day 1-15	Day 1-120 Must be submitted within 120 days of receipt of demand letter. To prevent offset on day 41 the Redetermination must be filed within 30 days.
Timeframe Begins	Automated Review: Upon receipt of the Initial Findings Letter (IFL) Complex Review: Upon receipt of Review Results Letter	Date of Demand Letter	Upon receipt of Demand Letter
Timeframe Ends	Day 30 (offset begins on day 41)	Day 15	Day 120

Look where improper payments have been found.

Know if you are submitting claims with improper payments. Conduct internal compliance assessment.

Appeal when necessary. Know the appeal process.