CCHP Health Plan

Fraud, Waste, and Abuse (FWA) Laws
And
CCHP Compliance Program

Cultivating a Culture of Compliance

1. Compliance Program Basic
2. Operating an Effective Compliance Program
3. Navigating Fraud and Abuse Laws
4. Reporting Potential Fraud and Non-Compliant Issues

Compliance Program Basic

Operating an Effective Compliance Program

The CCHP Compliance Plan describes the details and the requirements of its Compliance Program (CP). CCHP must have an effective CP:

An effective compliance program fosters a culture of compliance within an organization within an organization and, at a minimum:

- Prevents, detects, and corrects non-compliance
- Is fully implemented and is tailored to an organization's unique operations and circumstances
- Has adequate resources
- Promotes the organization's Standards of Conduct
- Establishes clear lines of communication for reporting non- compliance

An effective compliance program is essential to prevent, detect, and correct Medicare non-compliance as well as fraud, waste, and abuse (FWA). It must, at a minimum, include the seven core compliance program requirements

Elements of a Compliance Program:

- Written Policies and Procedures
- Compliance Officer and Governing Body Oversight
- Effective Training and Education
- Effective Lines of Communication
- Well-publicized disciplinary standards
- Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks
- Procedures and System for Prompt Response to Compliance Issues

Compliance Program's Written Policies and Procedures

- These articulate the CCHP's commitment to comply with all applicable Federal and State standards and describe compliance expectations according to the CCHP's Standards or Code of Conduct.
- Policies and procedures are up-to-date and must be reviewed periodically and are aligned with State and Federal regulations.
- Policies and procedures must be enforced.

Compliance Program's Compliance Officer and Governing Body

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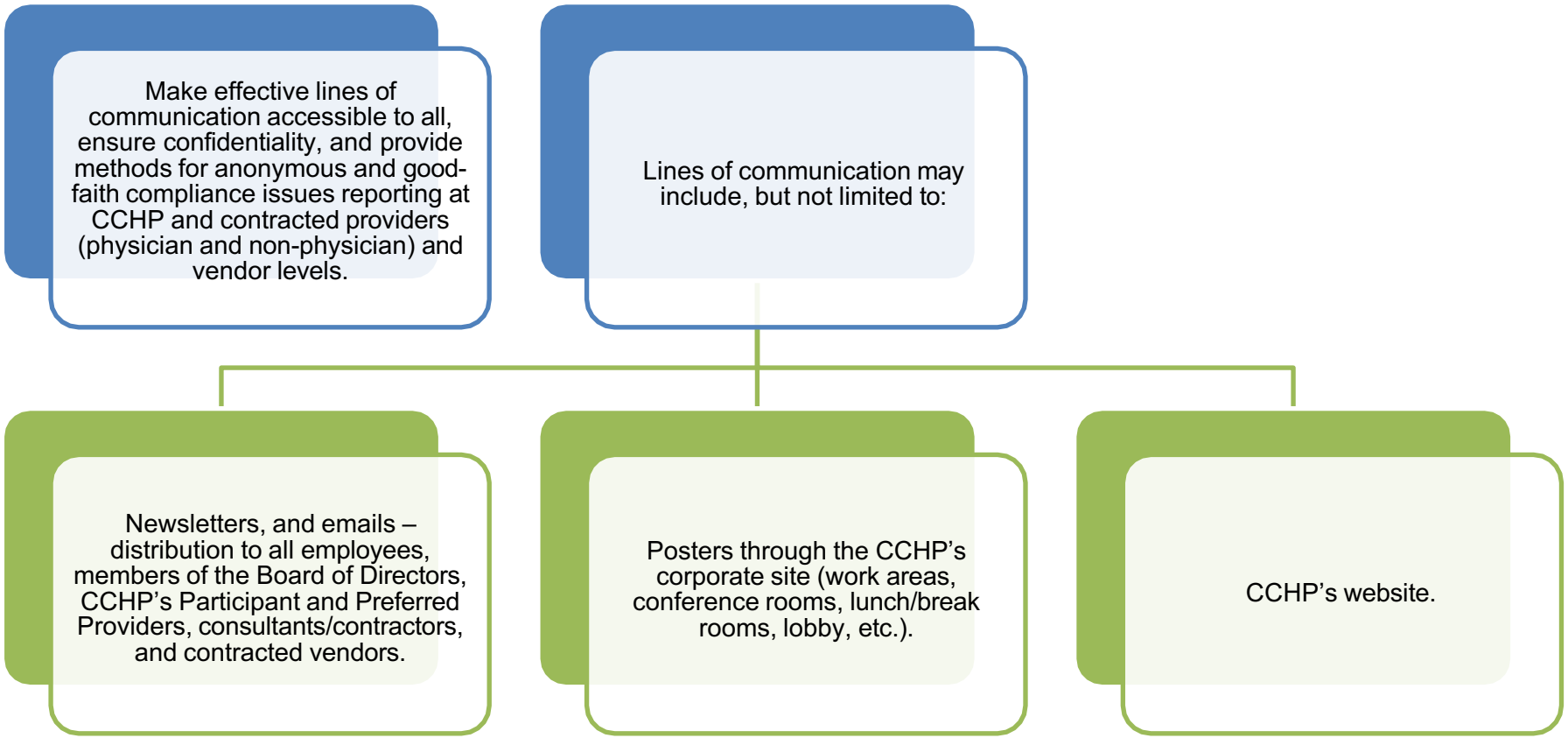
CCHP must designate a compliance officer accountable and responsible to the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

The CCHP's senior management and governing body must be engaged and exercise reasonable oversight of the CCHP's compliance program.

Compliance Program's Effective Training and Education

- This covers the elements of the compliance program as well as preventing, detecting, and reporting fraud, waste, and abuse. Training also should tailor to the different CCHP employees, Board of Directors, and contractors; and their responsibilities and job functions.
- Training may include:
  - The CCHP's Code of Conduct
  - Fraud and Abuse Laws
  - HIPAA Privacy and Security
  - Specialized training on core CCHP functions

Compliance Program's Effective Lines of Communication



Compliance Program's Well-Publicized Disciplinary Standards

CCHP must enforce standards through well-publicized disciplinary guidelines. It **must be clear** to the CCHP's employees, Board of Directors, Network Providers, and contracted vendors/entities - through various mechanisms – **the consequences of non-compliance**. Mechanisms may include, but not limited to:

- CCHP's Code of Conduct
- CCHP's Policies and Procedures
- Contracts or Agreements
- Newsletters, CCHP Website, & Intranet

Compliance Program's Effective System of Routine Monitoring, Auditing, and Identification of Risk Areas

Conduct routine monitoring and auditing of CCHP's and delegated operations to evaluate compliance with requirements, identify potential program integrity risks as well as the determine the overall effectiveness of the compliance program. Oversight activities may include, but not limited to:

- Site visits to Network Providers, contracted vendors and other entities
- Desk Audits of Charts and medical records
- Documentation Requests
- Questions and Surveys

Compliance Program's Procedures and System for Prompt Response To Compliance Issues

CCHP must use effective measures to respond promptly to non-compliance and undertake appropriate corrective action. CCHP must:

- Investigate, process, document, and track reports of potential or suspected non-compliance, including fraud, waste, and abuse.
- Substantiated findings of violations and non-compliance must be corrected to ensure future non-recurrence.

- **Fraud** is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program. **Fraud is intentionally submitting false information to the Government or a Government contractor to get money or a benefit.**

- **Waste** includes practices that, directly or indirectly, result in unnecessary costs to the Medicare/Medicaid Programs, such as overusing services. Waste is generally not considered to be caused by criminally negligent actions but rather by the misuse of resources.

- **Abuse** includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare/Medicaid Programs. Abuse involves paying for items or services when there is no legal entitlement to the payment, and the provider has not knowingly or intentionally misrepresented facts to obtain payment.

Navigating the Fraud and Abuse Laws

- Stark Law or Physician Self-Referral Law
- Healthcare Fraud Statute
- Anti-Kickback Statute
- False Claims Act
- Civil Monetary Penalties Law
- Exclusion Authorities

Navigating the Fraud and Abuse Laws

Improper Referrals can lead to:

- **Overutilization**
- **Increased Costs**
- **Corruption of medical decision-making**
- **Patient steering**
- **Unfair competition**

Navigating the Fraud and Abuse Laws

Physician Self-Referral Law:

- Limit physician referrals when there is a financial relationship with the entity.
- The law is complicated and consists of the original statute (Stark I in 1989) and the amended provisions (Stark II in 1996)

Stark Statute (Physician Self-Referral Law)*

•The Stark Statute prohibits a physician from making referrals for certain designated health services to an entity when the physician (or a member of his or her family) has:

a) An ownership/investment interest or

b) A compensation arrangement

c) Exceptions may apply*

- If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services ("DHS"), the physician cannot refer the patient to that entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship is an exception.

- **Damages and Penalties****
- Medicare claims tainted by an arrangement that does not comply with the Stark Statute are not payable. A penalty of around $24,250 can be imposed for each service provided. There may also be around a $161,000 fine for entering into an unlawful arrangement or scheme

•* *42 USC Section 1395nn; ** Physician Self-Referral webpage and the Act, Section 1877*

Types of Designated Health Services (DHS)

- Clinical laboratory
- Physical Therapy
- Occupational Therapy
- Radiology and imaging Services (MRI, CAT, scan, ultrasound)
- Durable Medical Equipment (DME) and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

What is a Financial Relation-ship?

- **Nearly any type of investment or compensation agreement between the referring physician and the DHS entity will qualify as a financial arrangement under the Stark Law**.
- **Examples:**
  a) Stock ownership
  b) Partnership interest
  c) Rental contract
  d) Personal service contract
  e) Salary
- **Compensation agreements can be direct or indirect.**
  a) Exceptions for certain indirect compensation arrangements
  b) Compliance is mandatory
  c) Types of Exceptions:
    - In-office ancillary services (an exception that applies to both ownership and compensation)
    - Personal physician services by member of group practice (an exception that applies to both ownership /investment interests and compensation)
    - Pre-paid health plans
    - Rural providers (investment interests) (an exception that applies only ownership /investment interests)
    - Hospital ownership
    - Rental office space equipment (a compensation only exception)
    - Bona fide employment
    - Personal services arrangement (a compensation only exception)
    - Physician recruitment
    - Electronic Health Records (is a compensation exception only)
    - Electronic Prescribing (a compensation only exception)
    - The Exception for Technology as part of the community-wide system (a compensation exception only)
- **There are a number of Stark Law exceptions. Each of the Stark law exceptions has specific and technical requirements that must be met.**

Example of Stark Statute (Physician Self-Referral Act):

A California hospital was ordered to pay more than $3.2 million to settle Stark Law violations for maintaining 97 financial relationships with physicians and physician groups outside the fair market value standards or that were improperly documented as exceptions.

Navigating the Fraud and Abuse Laws

Three Questions:

1.Is there a *referral* from a *physician* for a *designated health service* (DHS)?

2. Does the physician (or an immediate family member) have a *financial relationship* with the entity providing the DHS?

3. Does the financial relationship fit in an *exception*?

Navigating the Fraud and Abuse Laws

Penalties for Physician Self-Referral/Stark Law Violations:

1. Payment Denial
2. Monetary Penalty
3. Exclusion

Health Care Fraud Statute*

The Health Care Fraud Statute states, “Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program…shall be fined under this title or imprisoned not more than 10 years, or both.”

Conviction under the statute does not require proof the violator had knowledge of the law or specific intent to violate the law.

Persons who knowingly make a false claim may be subject to:

- Criminal fines up to $250,000
- Imprisonment for up to 20 years

•If violations resulted in death, the individual may be imprisoned for any term of years or for life.

* *18 USC Sections 1346-1347*

Navigating the Fraud and Abuse Laws

Anti- Kickback Statute (AKS)

Prohibits asking for or receiving anything of value to induce or reward referrals of Federal health care program business.

•It is unlawful to knowingly and willfully offer or pay any remuneration (including kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such a person--

a) To refer an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

b) To purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

The Anti-Kickback Statute (AKS) prohibits knowingly and willfully soliciting, receiving, offering, or paying remuneration (including any kickback, bribe, or rebate) for referrals for services that are paid, in whole or in part, under a Federal health care program (including the Medicare program); **prohibits anyone from purposely offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federaal health care program.**

Damages and Penalties**

- Violations are punishable by:
  - A fine up to $25,000
  - Imprisonment up to five (5) years

Anti-Kickback Statute*

- **42 USC Section 1320a-7b(b)(2)*
- **Social Security Act (the Act), Section 1128B(b).*

Navigating the Fraud and Abuse Laws

Criminal Penalties for Kickbacks:

1. Fines up to $25,000
2. Prison Time – felony, imprisonment up to 5 years.
3. Mandatory Program Exclusion from participating in Federal health care programs.
4. Brought on by the Department of Justice (DOJ)

Navigating the Fraud and Abuse Laws

Administrative Penalties for Kickbacks:

1. **Monetary penalty of $50,000 per violation and assessment of up to three times the remuneration involved**
2. **Discretionary exclusion from participating in Federal health care programs.**
3. **Brought on by the Office of Inspector General (OIG)**

Navigating the Fraud and Abuse Laws

Civil Penalties for Kickbacks:

1. **A violation of the AKS constitutes a false or fraudulent claim under the civil False Claims Act (FCA)**
2. **Penalties are the same as the FCA (refer to the FCA slides).**

Navigating the Fraud and Abuse Laws

Exceptions and Safe Harbors:

- **Many harmless business arrangements may be subject to the statute**
- **Approximately 24 exceptions (“Safe Harbors”) have been created by the OIG**
- **Must meet all conditions to qualify for Safe Harbor protection**

Navigating the Fraud and Abuse Laws

Linkage to False Claims Act (FCA):

- **Many courts have held under an express or implied certification theory that a violation of AKS is actionable under the FCA.**
  - **a) Allows for significant penalties**
  - **b) Allows for whistleblowers to bring actions**
- **The following language in the Statute presents as follows:**

“ in addition to the penalties provided for in this section…a claim that includes items or services resulting from a violation of this section (i.e., Anti-Kickback Statute) constitutes a false or fraudulent claim for purposes of the [False Claims Act].” § 1128B9g

AKS Elements:

ELEMENTS:

- Remuneration

a) Anything of value

b) “In-cash or in-kind

c) Paid directly o indirectly

d) Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations.

- Offered, paid, solicited, or received
- Knowingly and willfully
- To induce or in exchange for Federal program referrals
    a) any Federal health care program
    b) A connection between payments and referral
    c) Covers any act that is intended to influence and cause referrals to a Federal health care program
    d) One purpose test and culpability can be established without showing of specific intent to violate statutory prohibitions

Example of AKS:

From 2012 through 2015, a physician operating a pain management practice in Rhode Island:

- Conspired to solicit and receive kickbacks for prescribing a highly addictive version of the opioid Fentanyl
- Reported patients had breakthrough cancer pain to secure insurance payments
- Received $188,000 in speaker fee kickbacks from the drug manufacturer
- Admitted the kickback scheme costs Medicare and other payers more than $750,000

The Physician must pay more than $750,000 restitution and will be sentenced appropriately.

Navigating the Fraud and Abuse Laws

The False Claims Act (FCA):

Prohibits the submission of false or fraudulent claims to the Government.

Civil False Claims Act (FCA)*

The civil provisions of the FCA make a person liable to pay damages to the Government if he or she knowingly:

- Conspire to violate FCA
- Carries out other acts to obtain property from the Government by misrepresentation
- Conceals or improperly avoids or decreases an obligation to pay the Government
- Makes or uses a false record or statement supporting a false claim
- Presents a false claim for payment or approval

Any person who knowingly submits false claims to the Government is liable for three times the Government's damages caused by the violator plus a penalty.

- ** 31 United States Code (USC) Sections 3729-3733*

FCA Bases for Liability

1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment.
2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid.
3. Conspiring to commit a violation of the FCA
4. Knowingly making, using, or causing 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 concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government.
   - ❑ Obligation defined as an established duty, whether or not fixed, arising…from retention of any overpayment.

Elements of an FCA Offense:

The Defendant must:

1. Submit a claim (or cause a claim to be submitted);
2. To the Government;
3. That is false or fraudulent;
4. Knowing of its falsity;
5. Seeking payment from the Federal Treasury.

Knowing & Knowingly

- No proof or specific intent to defraud is required
- The Government need only show person:
  - Had “actual knowledge of the information”; or
  - Acted in “deliberate ignorance” of the truth or falsity of the information; or
  - Acted in “reckless disregard” of the truth or falsity of the information.

Qui Tam Actions & Government Intervention

- A private person ("Relator") may bring a False Claims Act action under the *qui tam* provisions of the FCA—The Whistleblower
- Government may intervene in a suit brought by the Relator
- If the Government intervenes and obtains recovery, the Relator receives between 15% and 25% of the proceeds
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including investigation, initiation, testimony for, or assistance in the action (Anti-Retaliation Provision and Cause of Action)

Navigating the Fraud and Abuse Laws

Civil Money Penalties (CMP) Law

Civil Money Penalties (CMP) Law*

The Office of Inspector General (OIG) may impose civil penalties for several reasons, including:

- Arranging for services or items from an excluded individual or entity
- Providing services or items while excluded
- Failing to grant OIG timely access to records
- Knowing of and failing to report and return an overpayment
- Making false claims
- Paying to influence referrals

Damages and Penalties

- The penalties can be around $15,000 to $70,000 depending on the specific violation. Violators are also subject to three times the amount:
  - Claimed for each service or item
  - Of remuneration offered, paid, solicited, or received

**42 USC 1320a-7a and the Act, Section 1128A(a)*

Example of CMP Law:

•A California pharmacy and its owner agreed to pay over $1.3 million to settle allegations they submitted unsubstantiated claims to Medicare Part D for brand name prescription drugs the pharmacy could have not dispensed based on inventory records.

Exclusion Statute*:

•No Federal health care program payment may be made for any item or service furnished, ordered, or prescribed by an individual or entity excluded by the OIG. The OIG has authority to exclude individuals and entities from federally funded health care program and maintains the List of Excluded Individuals and Entities (LEIE).

•The U.S. General Services Administration (GSA) / System Award Management (SAM) administers the GSA/SAM or Excluded Parties List System (EPLS) which contains debarment actions taken by various Federal Agencies, including OIG. The EPLS may be accessed on the SAM website.

When looking for excluded individuals or entities, check both the LEIE and the EPLS/SAM since the lists <u>are not</u> the same.

* *42 USC Section 1320a-7 & 42 Code of Federal Regulation s Section 1001.1901.*

Example of Exclusion Statute:

•A pharmaceutical company pleaded guilty to two felony counts of criminal fraud related to failure to file required reports with the U.S. Food and Drug Administration concerning oversized morphine sulfate tablets. The pharmaceutical firm executive was excluded based on the company's guilty plea. At the time the unconvicted executive was excluded, there was evidence he was involved in misconduct leading to the company's conviction.

Reporting Potential Fraud or Non-Compliant Issues

CCHP must have a mechanism for reporting potential fraud or non-compliant issues by the CCHP employees, contracted providers, and other contractors. CCHP must accept anonymous reports and cannot retaliate against good-faith reporting.

- Report FWA. When in doubt, call the CCHP's Compliance Officer, Compliance Department or the CCHP Compliance Hotline.

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