

*Guidelines for Constructing a Compliance
Program for Medicaid Managed Care
Organizations and PrePaid Health Plans*



*A Product of the
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In June 1997, CMS's Southern Consortium assumed leadership of the Medicaid Alliance for Program Safeguards (Alliance). This Alliance was established with the primary goal of preventing fraud and abuse by assisting States in their efforts, identifying proactive strategies, and sharing information with other program integrity players. Through leadership, the Alliance strives to encourage participation and communication among State and Federal entities working to fight fraud and abuse.

The Medicaid Alliance for Program Safeguards created these guidelines to be used by managed care entities including managed care organizations (MCOs) and prepaid health plans (PHPs) which contract to do business with state Medicaid agencies. These guiding principles may also be used by health insurance organizations (HIOs) and primary care case managers (PCCM) programs.

Although CMS has issued some specific guidelines and general operating parameters to states regarding Medicaid managed care, CMS continues to allow states the latitude to establish state specific managed care contracting requirements and monitoring standards. The Balanced Budget Act (BBA) of 1997, attempts to provide state agencies with sufficient flexibility to continue to be innovative in the development of their state Medicaid managed care programs. However, with this flexibility, states must become more aware of program vulnerabilities and the various opportunities for fraud and abuse.

The Medicaid Alliance for Program Safeguards believes that a compliance program will help to establish and promote a managed care entity's awareness of applicable program regulations and help to define a standard of organizational values regarding regulatory compliance. These elements are key to combating fraud and abuse while establishing accountability and responsibility. The Medicaid Alliance for Program Safeguards and the Office of the Inspector General strongly support the implementation of compliance programs. This document has been created for use on a voluntary basis; however, states may recommend or mandate MCOs and PHPs to implement a compliance program using this tool.

Most compliance guidance for healthcare as well as non-healthcare entities follows the principles set forth in the Federal Sentencing Guidelines Manual. Similarly, this document adheres to the same compliance principles.

Operationally, there are many similarities between Medicare and Medicaid managed care entities. Therefore, this document may reflect similar areas addressed in the *Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans* which was published by the Office of the Inspector General in November 1999.

Additionally, this document references the *Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care* published by the Medicaid Alliance for Program Safeguards which provides guidance to State Medicaid Agencies, Medicaid Fraud Control Units, and

managed care organizations in preventing, identifying, investigating, reporting, and prosecuting fraud and abuse in a Medicaid managed care environment.

What is a Medicaid Managed Care Compliance Program?

A Medicaid Managed Care Compliance Program is a set of procedures and processes instituted by a managed care entity to regulate its internal processes and train staff to conform to and abide by applicable state and federal regulations which govern the managed care entity.

A well-structured compliance program has a written document, termed a **compliance plan** that details the means by which an organization will conform to specific regulations to achieve and maintain compliance. The compliance plan defines standards, describes the methods for monitoring standards, and identifies corrective action processes.

Perspective on Compliance Programs

CMS strongly believes that in order to contract with a state, the MCO or PHP should have administrative and management arrangements and procedures that include a mandatory compliance plan that is designed to guard against fraud and abuse. The Medicaid Alliance for Program Safeguards realizes that organizations vary in size and structure which affect the make-up of the organization's compliance program. However, there are some common elements that should be present regardless of the type or the size of a compliance program.

SECTION I. BENEFITS AND ELEMENTS OF A COMPLIANCE PLAN

Benefits of A Compliance Program

To be effective in preventing and detecting fraudulent and abusive activities, a compliance program must be practical in its design, implementation, and enforcement.

An effective compliance program with buy-in from the top-down aids in setting the tone for an organization by providing parameters and benchmarks in specific areas as well as identifying vulnerabilities. Additionally, continuous quality monitoring demonstrates an organization's commitment to compliance and ensures the integrity of the program.

If a program fails to prevent or detect an offense, it does not mean that the program was not effective. However, according to the *Federal Sentencing Guidelines Manual of 1984*, "the hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct by

its employees and other agents.” A properly structured compliance program may serve as a key element in this process.

A Compliance Program:

Administratively

- Communicates the organization’s commitment to compliance.
- Communicates specific organizational objectives to staff and supports organizational standards of integrity in reporting inappropriate conduct, fraudulent activities, and abusive patterns.
- Establishes a consistent process for distributing and communicating new regulations, regulatory changes, and modifications within the organization.
- Creates accountability for receiving regulatory information, operationalizing regulatory requirements, and monitoring performance against standards.

Programmatically

- Identifies specific regulatory statutes that govern the entity’s Medicaid managed care program operations.
- Establishes program standards in accordance with the specific regulations.
- Establishes a consistent process for analyzing and interpreting the organizational impact of regulations.

Monitoring

- Provides a process to assess organizational performance against regulatory requirements and established internal performance standards.
- Provides guidance and standards for monitoring plan activities such as claims processing, customer service, and enrollment functions.

Disciplinary and Corrective Actions

- Provides a process for disciplinary actions for wrongdoing and unlawful behavior.
- Provides a structure for the formation and implementation of corrective measures.

Elements Of A Compliance Program –

The following elements have been identified as being essential to an effective compliance program.

Standards and Procedures

The organization must have written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

High Level Oversight and Delegation of Authority

The MCO must designate a compliance officer and a compliance committee that are accountable to senior management.

Employee Training

The Medicaid Managed Care Organization must provide for effective training and education for the compliance officer and the organization's employees.

Communication

Effective lines of communication must be established between the compliance officer and the organization's employees.

Monitoring and Auditing

The organization must have taken reasonable steps to achieve compliance with its standards by utilizing reasonably designed monitoring and auditing systems.

Enforcement and Disciplinary Mechanisms

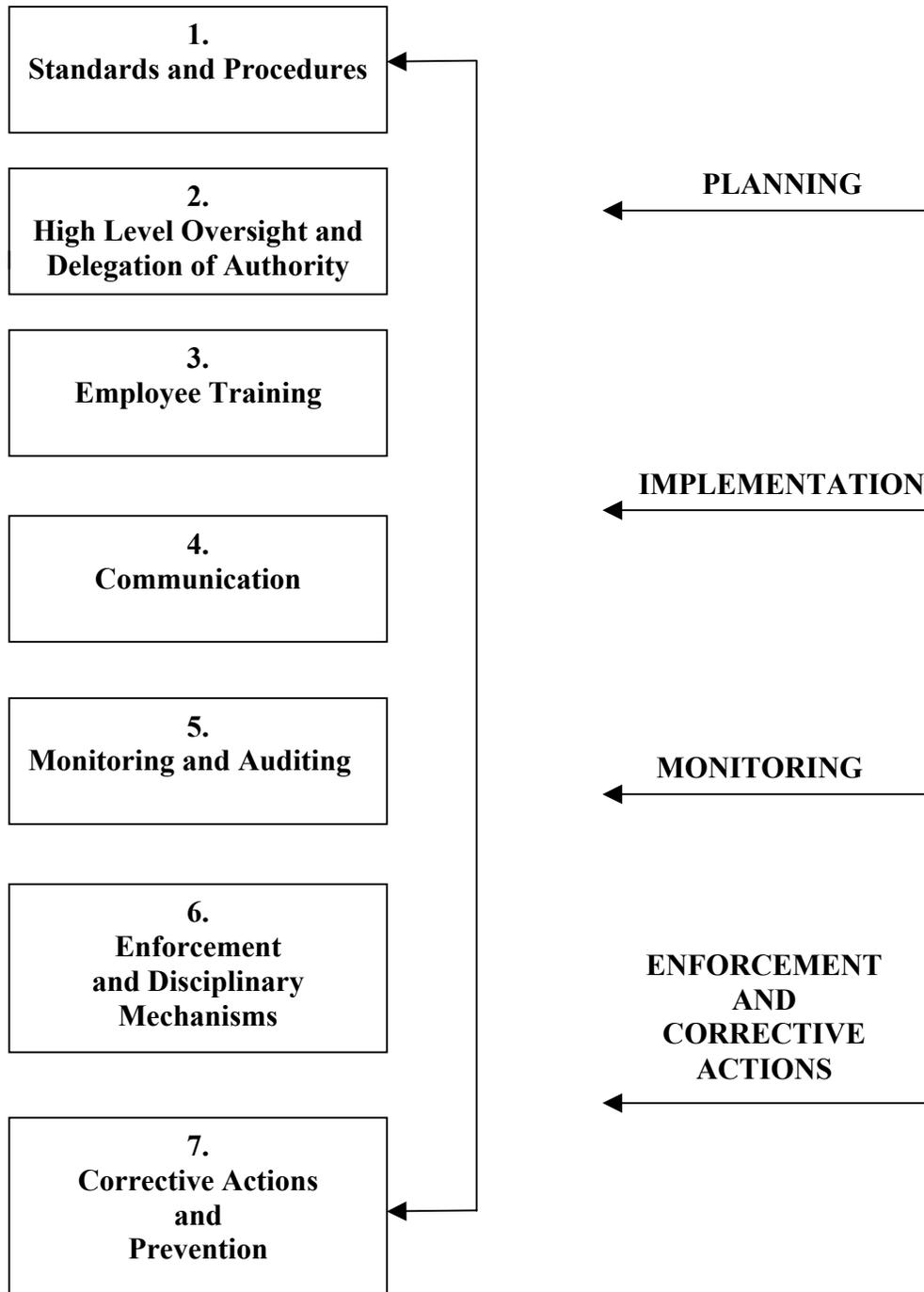
Standards must be enforced through well-publicized disciplinary guidelines.

Corrective Actions and Prevention

After an offense has been detected, the organization must take reasonable steps to respond appropriately to the offense and to develop corrective action initiatives relating to the MCO's contract, including specific reporting requirements.

TABLE I.

ELEMENTS OF A COMPLIANCE PROGRAM



SECTION II. STAGES OF PROGRAM DEVELOPMENT

Stage I. - Planning

In the initial phase of developing a compliance program, the concept should be presented to the Board of Directors or Trustees to adopt as an integral part of the operations of the organization. Remember that the success of a compliance program begins with buy-in, support, and commitment from the top of the organization. With this commitment comes the designation of a top-level staff member to oversee compliance efforts, the allocation of resources as necessary, and the creation of a compliance committee. This person often termed the *Compliance Officer* is responsible for program oversight and ensuring the overall development, implementation and success of the program. To be effective as a Compliance Officer, the individual must not only have the responsibility and accountability but also the authority to get the job done.

Written Policies and Procedures - Critical to the compliance program is the development of written policies and procedures, standards, and documentation of practices that govern the Medicaid managed care organization's efforts to identify risk and areas of vulnerabilities. Usually, this is the most time consuming part of developing a compliance program.

Identification of Applicable Regulations and Program Standards

One of the first steps in becoming a compliant organization is knowing and understanding the regulations with which the organization must comply and identifying systems and process weaknesses. The managed care organization must identify governing regulations including applicable Medicaid managed care regulations, program policies and standards, and areas of operational vulnerabilities.

Some excellent resources to locate Medicaid Managed Care regulations include -

- The state's Medicaid managed care Request for Proposal (RFP);
- The organization's Medicaid managed care contract;
- State Laws governing Medicaid managed care operations; and,
- Applicable Federal Laws.

Establishing Internal Compliance Standards

Defining standards is vital to the success of a compliance program. Operational standards are the measurements by which the organization's processes will be assessed for compliance. Guidance for setting operational standards may be found in the documents listed above, in addition to:

- The organization's Response to the Request for Proposal;
- Industry standards; and
- Organizational experience.

Often an organization will state operational standards in its Response to the RFP. These standards should be included as part of the organization's compliance plan. Remember that RFP standards represent performance expectations and contractual commitments made to the Medicaid agency. Other sources that provide information for setting standards include organizational results from past audits or reviews performed internally or by external entities including independent organizations and state and federal agencies.

Another key component is involving the right people when creating, adopting and writing program standards and policies and procedures. Individuals responsible for the respective program and functional area must be an integral part of the process. Additionally, top-level management officials and possibly general counsel should sign off on the proposed standards. Remember that setting standards often involve costs and the allocation or reallocation of resources.

Initial Audit – An audit is an independent, objective assessment of an area with specific objectives usually seeking to validate and give credence to reported information or compliance with governing regulations.

An internal audit is essential to establishing a compliance program. It will provide a picture of the current operational status of the organization. The audit may be conducted by internal staff, if properly trained, or an independent audit entity. Audits are most successful when the individuals involved understand the purpose of the audit and how they will be affected by the results of the audit. Another component of a successful audit is alleviating the fear of repercussion for divulging information.

Although there are various types of audits, most audits address either financial or performance objectives. The compliance audit seeks to assess compliance with laws and regulations applicable to the program.

Other purposes of a compliance audit include:

- to assess internal controls for measuring, reporting, and monitoring a program;
- to assess the effectiveness of the program or functional area;
- to identify factors inhibiting satisfactory performance; and,
- to identify program improvement initiatives.

Audit results can provide a baseline to aid with setting compliance standards, the identification of vulnerable areas, and associating risk. The results of the audit will help the organization rank specific operational areas of risk - low, medium, or high and monitor accordingly. Although the audit may reveal a current high level of compliance in a certain area, the area may still be considered a high-risk area because of the area's vulnerability such as the function of marketing and enrollment.

In addition to the quantitative analysis that is performed during the initial audit, below are other questions to consider:

1. Is the system or process producing the desired or intended output?

2. What oversight and audit mechanisms (checks and balances) are included in the design of the system or process?
3. Is the system or process flexible to allow for program and regulatory changes as needed?
4. Can the system or process be audited?
5. What basic reports can be produced from the system or process? Does the system have ad-hoc report production capabilities?
6. System safeguards - Does the system or process offer the kind of controls that protect it from being compromised or corrupted? How is the integrity of the system or process protected?
Example: Is there an audit trail to identify system users? Is there an audit trail that allows for the tracking of data modifications? How is system access restricted (i.e., passwords, etc...)?
7. What are the system storage capabilities? As enrollment and data grows can the system accommodate the growth?
8. What are the interface capabilities of the system?

Stage 2. - Implementation

Implementing a compliance program consists of the establishment and dissemination of policies and procedures - standards, staff education, and training. Education begins with educating the Board of Trustees or Board Members regarding the importance and benefits of a compliance program. Education continues with communicating the organization's compliance vision and the substance of the compliance program to staff; preparing staff for the initial and subsequent audits. Education is ongoing throughout the life of the compliance program.

Stage 3. - Monitoring

Monitoring is the process of evaluating the organization's practices against set criteria such as program regulations and internal standards. Two essential components of the monitoring process are internal audits and reports. Monitoring is vital to establishing and maintaining compliance. Monitoring also aids in the assessment and the identification of areas of risk and vulnerability.

Stage 4. - Enforcement

The MCO or PHP should have a structure in place to identify, investigate and refer suspected fraud and abuse cases. There should be mechanisms in place for staff to report suspect activities within the organization such as a hotline or anonymous comment cards.

The system implemented to identify, investigate, and refer cases must also set forth the criteria by which the assessments will be made and associate the offense with specific punishment. The system's methodology must also take into consideration the rights of the suspected individuals and their entitlement to due process. It is recommended that these procedures be developed in cooperation with state and federal regulators and law enforcement officials with particular attention given to the case referral process.

The initial obligation to conduct an investigation rests with the organization. If sufficient evidence exists, then it becomes necessary to determine who conducts the full investigation and how the information is communicated to the appropriate agency. The MCO or PHP must have a system in place to promptly report violations.

The findings of a completed investigation may determine the following:

1. prosecution - criminal or civil;
2. administrative resolution such as: termination, suspension, warning, recovery, or etc...; or,
3. lack of sufficient evidence to proceed.

Stage 5. - Corrective Actions

Corrective actions are written planned objectives or measures to rectify a cited deficiency or non-compliant situation. Usually, these objectives are expressed in a corrective action plan. The corrective action plan should capture the standard or regulation, state the deficiency, and expound on the measures and timeframe for remedy.

It is highly recommended that a workplan be developed in writing for the corrective action. The workplan should detail specific steps or tasks that must be completed to remedy each deficiency and associate proposed completion dates, and responsible individuals with each identified task. An individual must be designated to oversee the corrective action plan and to ensure that the objectives of the corrective action plan are met, in a timely manner.

Regardless of whether the deficiency was found by an internal or external audit, a corrective action plan should be constructed with buy-in from the appropriate top officials. This is very important because many remedies to a deficiency require the allocation of financial and staffing resources.

SECTION III. - CREATING A MEDICAID MANAGED CARE COMPLIANCE PLAN

The design and structure of an organization's compliance program will differ based on the size and general make-up of the organization. Larger managed care entities with corporate compliance structures may have several layers of compliance personnel within their compliance organization and numerous staff members dedicated to compliance functions. Smaller organizations may have fewer staff members dedicated to compliance functions or limited staff performing multiple functions that include compliance activities as well as other duties not related to compliance.

This section is structured to aid the managed care entity in creating a compliance plan by providing recommended content and examples.

Important things to remember about a compliance plan:

1. It is the blueprint for the organization's compliance program;
2. It is the written document that conveys the intent of the organization's compliance program;
3. It describes the steps that the organization will take or has taken to build its compliance program;
4. It communicates ongoing operational initiatives to prevent, detect, and correct wrongdoings;
5. It expresses the organization's initiatives to exercise due diligence in its pursuit to prevent and detect fraud and abuse;
6. It may differ from organization to organization; and,
7. Without commitment, action, implementation, and follow-up, a compliance plan is merely a collection of papers inside a binder, which occupies a place on a shelf and collects dust.

RECOMMENDED COMPLIANCE PLAN ELEMENTS

The following are recommended elements to be included in an organization's Medicaid managed care compliance plan:

Compliance Oversight

- I. Resolution to Create a Compliance Organization and/or Other Documents that Express the Organizations Commitment to Compliance (i.e., Board Resolution, Board Minutes, etc..)**

Usually, a compliance plan begins with a statement of the intent of the program, program goals, and a statement regarding organizational commitment. The expression of this

action maybe promulgated by the execution of a Board Resolution, noted in Board Minutes, or made known through the adoption of a policy statement. The Board Resolution or other information that created the compliance program is also found in the beginning of the compliance plan. There are various Board Resolution formats from simple to very detailed.

II. Policies And Procedures that Govern Compliance Related Activities

- **Reporting Structure of the Compliance Organization**
- **Job Descriptions of Key Compliance Personnel**
- **Criteria for selecting Compliance Officer**

The compliance reporting structure and compliance personnel are key to the success of a compliance program. The compliance organization must be able to act independent of the operational and program areas and without the fear or threat of repercussion for citing and reporting deficiencies. It is strongly recommended that the compliance organization not report to a program or operational area, but directly to the executive board or another high ranking official without direct responsibility for operations.

The organization should have criteria for selecting a compliance officer and a job description that clearly outlines the responsibilities and the authority of this position. The designated compliance officer should be one of reputable character. Most often the compliance officer is not directly responsible for a business or functional area (e.g. claims, marketing, and provider relations) and does not control an operational budget, therefore, organizational support and commitment is essential to the success of this position. A commitment to compliance means having the commitment of the officials with the authority and power to allocate and commit resources, including staff and money, to ensure that deficiencies are cured.

III. Policies and Procedures that Govern the Compliance Committee

- **Procedures and Criteria for Selecting Committee Members**

The organization should have a compliance committee made-up of the compliance officer, a budgetary official, and other senior executive officials with the authority to commit resources. The compliance committee is usually charged with tasks such as prioritizing risk areas; committing resources to remedy deficiencies; and reviewing risk assessments. In some organizations the compliance officer has a dual reporting structure reporting to the chief executive officer and the compliance committee. The compliance plan should include the policies and procedures that govern this committee and the criteria used to select committee members.

IV. Policies and Procedures Governing the Handling of Regulatory Information

It is highly recommended that the Medicaid managed care organization structure a process for receiving, interpreting, distributing, and implementing regulatory guidance. These policies and procedures should be a part of the compliance plan. The organization must be able to perform these functions in a timely and effective manner.

Governing Regulations and Program Vulnerabilities

V. Identification of Pertinent Medicaid Managed Care Regulations, Program/Policy Standards, and Program Vulnerabilities

The organization must **identify** appropriate regulations and established program standards that should be monitored for compliance. Additionally, the organization must identify operational areas most vulnerable to fraud and abuse. Unlike other businesses, the regulations that are applicable to most federal programs including the Medicaid program are readily accessible. The MCO or PHP contract is an excellent starting place. *The Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care* provides guidance for the identification of vulnerable areas.

In the *Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care*, the Medicaid Alliance for Program Safeguards identifies several program areas where fraud and abuse are likely to occur such as: the procurement of the managed care contract, marketing, enrollment and disenrollment, underutilization, claims submission and billing procedures, embezzlement, and theft. Careful consideration should be given to these areas when identifying governing regulations, developing standards, and assessing for program frailties.

Next, the managed care organization must **interpret** each regulation and its application to the managed care entity's internal operational processes. This exercise may involve paraphrasing, and rewriting the regulation using terminology that is easily understood by staff. The organization should examine operational processes and **determine** which functions are governed by the particular regulation.

It is recommended that the organization construct a document which assimilates the three elements discussed above:

- (1.) a synopsis of the identified regulation or the regulatory citation;
- (2.) the organization's interpretation of the regulation; and
- (3.) the identification of organizational functions governed by the regulation;

and, these three elements which are discussed in the following sections:

- (4.) the organizational standard for complying with the regulation;
- (5.) the location of supporting policies and procedures; and
- (6.) the method(s) for monitoring the standard.

It is highly recommended that this be an integral part of the Medicaid managed care compliance plan, although some organizations include it as a compendium to the compliance plan. Appendix “A” provides a sample format.

Governing Standards

VI. Establishment of Organizational Standards, and Measurements to Comply with Medicaid Managed Care Regulations

Another critical step in the compliance process is the establishment or identification of organizational standards or measurements. The standard is the unit that may be used by the organization and external auditing entities to measure the organization’s progress, successes and/or failures. In many areas, regulations only state the regulatory requirement. When standards are not defined by regulations, it is up to the managed care entity to decide how to meet the requirement. Operational standards may be based on prior experience, audit reports, industry standards, or managerial expectations or goals. An MCO should try to be realistic when setting standards. An MCO may be cited for not complying with self-imposed internal standards stated in its RFP. Management must be careful to distinguish between standards and goals.

Example I. -

Contractual Requirement Regarding Customer Service

*Phone numbers shall be specified by the plan for the complainant to call to present a complaint or to contact the grievance coordinator. Each phone number shall be toll-free within the complainant’s geographic area and provide reasonable access to the plan without due delays. **There must be an adequate number of phone lines to handle incoming complaints and grievances.***

This regulation does not state a specific number of telephone lines, except to state that the number of telephone lines must be adequate. Unless defined by the state Medicaid agency, it is up to the MCO to establish standards to measure “adequacy”.

In response to the above regulation, based on prior experience, an MCO may set a standard that *95% of all telephone calls will be answered within one minute with an average wait time of less than three minutes and an abandonment rate of 2%.*

Example II. -

Contractual Requirement Regarding Claims Processing

Payments to health care providers for hospitals, medical or other health care services, shall be made no more than 35 days from the date of eligibility for payment is determined....

This regulation identifies a specific timeframe not to exceed 35 days for payment or adjudication of eligible claims. Therefore, the standard may state a timeframe less than 35 days, but the standard should not exceed 35 days.

In response to the above regulation, the MCO may establish a claim processing standard of 35 days or less for claims adjudication. The standard may state that *100% of claims will be adjudicated for payment or denial in {35 or less} days from the date of receipt.*

Note: The regulation should be thoroughly reviewed to determine if the regulation distinguishes between a clean and a non-clean claim and the respective processing time for each as well as any other factors that may alter the processing timeframe. Additionally, to properly effectuate this regulation further research or a regulatory interpretation may be required to determine the following: a definition of “eligibility for payment”; whether the regulation applies to denied claims; and a definition of the phrase “payments...shall be made” (when is payment considered made?).

Example III. -

Contractual Requirement Regarding Marketing Material

All marketing material must be approved by the agency, in writing, prior to use, in accordance with Section 1932 of the Social Security Act

This regulation identifies that all marketing material must be approved by the agency prior to use.

Therefore, the MCO standard may reflect that *100% of all marketing material will be submitted to the {state agency} for written approval prior to use.*

Note: The organization should develop: relevant policies, which define marketing material according to appropriate statutory guidance; internal procedures to assure that all marketing material is submitted to the state agency for approval prior to use; and, a system of checks and balances for tracking submitted marketing material and verifying written approval from the agency.

General Rule - To provide effective oversight for *most* functions, the following components should be present:

- (1.) There must be an identifiable standard;
- (2.) The standard should be measurable and quantifiable, whenever possible; and,
- (3.) *Appropriate* output data about the activity should be captured to evaluate the standard. This is usually in the form of data specific reports used to analyze and trend the activity over a period of time.

Supporting Policies - It is also recommended that supporting program policies and procedures for the particular regulation be referenced in the compliance plan.

Why should the compliance plan only reference the location of pertinent program policies and procedures? The compliance plan is more than a mere compilation of program policies and procedures. If you start to include the content of all-applicable program policies and procedures, the document will become voluminous and lose its identity as a compliance plan. Additionally, compliance plan will need to be updated every time a program policy or procedure changes, in addition to updating the original policy and procedural documents. Therefore, organizations are encouraged to reference the location of lengthy program policies and procedures, rather than including the entire document in the compliance plan.

Monitoring

VII. Methods and Tools Used to Assess Activities for Regulatory Compliance

- **Reports**
- **Audits (Internal And External)**

For each applicable regulation and/or standard, the organization should seek to establish quantitative methods of evaluation to assess associated processes. Quantitative assessment methods are more desirable than qualitative methods because of the association of numerical values with the levels of output (i.e., the results of the activity) which attributes more creditability and validity to the evaluation process.

During the monitoring process the organization assesses its operational practices **by applying** the regulation or the established standard. There are many means by which monitoring is performed. This document distinguishes two methods of monitoring, routine and periodic. Routine monitoring consists of regular daily, weekly, monthly and/or ad hoc reports and periodic monitoring consists of scheduled and random audits.

Reports - Reports provide a snapshot in time of operational processes or a summarization of an activity over a period of time. Report generation is fundamental to the compliance program whether as a by-product of a process or the end product of an audit.

Appropriately designed reports provide a good source of consolidated information about the function. The specifications for the report should yield appropriate quantifiable data (when possible) about the operational area, so that the areas performance may be effectively evaluated against regulations or organizational standards. To aid in evaluating a function, the activity should be trended over a period of time. This will enable the reviewer to observe patterns and variations of certain practices. It is recommended that the title, frequency, and location of the report(s) used to monitor a particular regulation or standard be included in the compliance plan.

Periodically, the user of the report should evaluate the usefulness of the report and revise the report, as necessary. A report is only as good as the data that makes up the report. If corrupt or bad data goes into a report, the report will yield corrupt or bad results.

Example I. -

***Using the example - Contractual Regulation Regarding Customer Service
“ Telephone Line Adequacy”***

Standard - *95% of all telephone calls will be answered within one minute with an average wait time of less than three minutes and an abandonment rate of 2%.*

To effectively monitor and evaluate this standard, the MCO will need to produce, trend, and review periodic (hourly, daily, weekly, and monthly) telephone activity reports to monitor average speed to answer time; average wait time; average abandonment rates; and, customer service complaint reports regarding telephone wait time. Based on the results of these reports, the organization will be better able to meet the stated standard by adjusting staff such as adding additional staff during peak hours, scheduling staff to work different hours, or adding additional telephone lines, as necessary.

Example II. -

Using the example – Contractual Requirement Regarding Claims Processing

Standard - *100% of claims will be adjudicated for payment or denial in {35 or less} days from the date of receipt.*

To effectively monitor and evaluate this standard, the MCO will need to establish a system that track claims from the time of receipt until payment or final disposition (as defined by statutory guidance).

Periodic Aging and Suspense/Pend Reports must be produced and worked diligently. If the standard is 35 days or less, then one report produced every 35-Days of aging is not sufficient. It is recommended that a Suspense/Pend Report be produced and worked frequently. An Aging Report should be produced at intervals that allow management to gauge and reallocate resources as needed to meet the 35-Day Claims Processing Standard.

Audits –The compliance plan should state the frequency of the organization’s auditing activity. Internal staff or an external entity may conduct the compliance audit. However, auditors must be properly trained and possess the necessary skills to perform an audit. The development of appropriate audit tools and the consistency of the use of the audit tools are critical to the outcome of an audit. Proper audit standards should be observed in planning and conducting the audit and reporting the results to maintain the integrity and reliability of the audit results.

As an additional audit function, it is recommended that the organization periodically challenge its internal processes and systems from the staff and contractor perspective to help identify weaknesses and limitations. The results of this activity will be beneficial when setting and adjusting internal controls.

Reporting

VIII. Report Generation

- Policies and Procedures for Reporting Identified Deficiencies

It is recommended that the compliance plan include the policies and procedures for report production and distribution. It is advised that a written report be generated within a specific timeframe after each periodic or random audit as well as any other compliance activity which reveals a significant issue of non-compliance. Policies and procedures should also identify certain individuals for report distribution including specific high-ranking accountable officials within the organization by title, the relevant function heads, the compliance committee members, and others as determined.

Corrective Actions

IX. Policies and Procedures that Govern the Corrective Action Process and Follow-through to Completion of Corrective Actions

The compliance plan should include the policies and procedures for constructing and implementing corrective actions. The policy and procedure may state that if the corrective action involves the allocation of certain resources such as the hiring of staff or monetary allocations over a certain threshold amount, then the signature of the executive responsible for that particular area is required. Remember that corrective measures that do not have the buy-in of the “right” officials are less likely to be implemented or implemented effectively.

The compliance plan should also address the procedures for following through on the implementation of corrective measure(s) and include a process for evaluating the effectiveness of the corrective action.

Employee Training

X. Policies and Procedures that Govern Employee Training

The most important element in effectuating a compliance program and critical to achieving compliance is employee education. Employees must be trained regarding the importance of compliance and their obligation as employees.

Staffing education should:

- Convey overall organizational standards for integrity and “doing the right thing”;
- Convey the organization’s commitment to compliance;
- Explain the purpose and importance of complying with applicable federal and state regulations;

- Alleviate employee fear of certain retribution for providing information regarding operational practices, but emphasize compliance expectations;
- Include a mechanism for obtaining anonymous information from employees regarding suspect activities and feedback for process improvement;
- Educate employees regarding the organizational policies on wrongdoing and other acts subject to criminal scrutiny. Additionally, these policies should be distributed in writing to each employee;
- Train staff regarding appropriate program regulations and organizational standards, as well as, provide a process for staffing updates regarding new or modified regulations in a timely manner;
- Emphasize the importance of on-going monitoring such as internal audits and report generation; and,
- Educate management regarding how to effectively formulate and implement corrective action plans.

All compliance training initiatives should be documented in writing. It is important to keep the following items as part of the permanent compliance training record: an attendance roster with attendee signatures, the date of the training, and a description of the presented subject matter. This information, especially the attendance rosters, may become a critical piece of evidence if the organization is asked to demonstrate its compliance training efforts. Compliance training sessions should be mandatory for all impacted employees. Additionally, employee training should be an on-going, continuous process for new and existing employees, especially as new regulations are created and/or existing regulations are changed.

Enforcement Activities

XI. Policies and Procedures for Enforcement Activities and Employee Feedback Mechanisms

It is imperative that the compliance plan outline the organization's policies and procedures for investigating and documenting alleged violations and a process for reporting potential civil and criminal violations.

The compliance plan should set parameters for employee behavior by establishing acceptable and expected Codes of Conduct. The compliance plan should also establish disciplinary and punitive measures for non-compliant behavior and the failure to detect noncompliance. Note: there are many facets of employee conduct and the compliance plan should not be used to address all aspects such as a sexual harassment and substance abuse policies. However, the Codes of Conduct addressed in the compliance plan should be "overarching", to ensure that all work is done in an ethical and legal manner and to ensure that all employees are aware of their obligation to help detect and prevent fraud and abuse. The compliance plan may reference the employee handbook or other human resource publications that provide additional employee conduct information.

It is recommended that the compliance plan contain the governing policies and procedures for employee feedback mechanisms to ensure that all alleged violations are fully investigated and reported, as necessary. The managed care organization must decide on the type of feedback mechanisms to be used to solicit employee feedback and an internal process for reporting suspected violations. The organization may consider such feedback mechanisms as locked comment boxes, anonymous surveys, and an employee hotline, to name a few.

Sanctions and Penalties

XII. Listing of Pertinent Laws and Associated Penalties.

The compliance plans should also include the organization's policies and procedures for obtaining, reviewing, and effectuating the sanction report published by the Department of Health and Human Services - Office of Inspector General and the General Services Administration's list of parties excluded from participating in federal programs.

The Medicaid Alliance for Program Safeguards has established a Medicaid Fraud Statute website by state which provides a comprehensive listing of official state statutory citations that are used to prosecute civil and criminal fraud, those used to maintain program integrity, and those used to combat program abuse. The website is located at <http://fightfraud.hcfa.gov/mfs>

Confidentiality and Records Retention

XIII. Policies and Procedures on Confidentiality and Record Retention

The MCO has an obligation to retain enrollee records and safeguard the privacy and accuracy of such records. The Medicaid managed care organization should review relevant state and federal laws and establish organizational policies to govern confidentiality, accuracy of enrollee records, record retention efforts, and the disclosure of mental health records, medical records, and other health and enrollee information.

In closing, remember that compliance plans will differ. However, as stated in the *Federal Sentencing Guidelines* - An "effective program to prevent and detect violations of law" means a program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct. Failure to prevent or detect the instant offense, by itself does not mean that the program was not effective. The hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct by its employees and other agents.

AREA OF COMPLIANCE

{Marketing and Enrollment Fraud and Abuse}

REGULATORY CITATION - { State of }
{ **Section 1932(d)(2) of the Social Security Act Restrictions on Marketing** }

REGULATION

{ A managed care entity may not distribute marketing materials without prior State approval and they cannot contain false or misleading information. }

PURPOSE AND INTERPRETATIVE GUIDANCE

{ If needed, the MCO or PHP should paraphrase the regulation to ensure that staff understand the essence of the regulation and its application to their work. }

MONITORING STANDARDS

{ Example:
An organization may establish a standard that 100% of all marketing material will be reviewed through the organization’s internal process and submitted to the state for review and approval.
Quarterly, the organization will sample X% of its marketing material to assure compliance. }

REPORTS

List of applicable reports used to monitor the standard.

APPLICABLE POLICIES AND PROCEDURES

The MCO may include relevant policies and procedures or state the location of relevant policies and procedures to address the regulation. If the policies and procedures are extensive, it maybe more desirable to state the location.

Example:

1. Marketing - Binder #1, (page XXX).
2. Sales – Sales Representative Training Manual, (page XX)

Contributing Resources

- (1.) Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans: Office of Inspector General, November 1999.
- (2.) Federal Sentencing Guidelines of 1984.
- (3.) Government Auditing Standards, July 1999.
- (4.) Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care: The National Medicaid Fraud and Abuse Initiative, August 2000.
- (5.) Section §1932 of the Social Security Act
- (6.) The Federal Register: 42 CFR Part 400, et al. Medicaid Program; Medicaid Managed Care; Proposed Rule.