**Provider Compliance Program Guidance**

1. **Introduction**

Effective compliance programs are essential to any provider navigating the complex world of government benefit programs. The Department of Health Care Finance (DHCF) believes the utilization of compliance programs by providers serves as a positive step towards ensuring adherence to applicable statutes, regulations, and program requirements. In addition, an effective compliance program assists providers in preventing the submission of erroneous claims or engaging in unlawful conduct involving health care programs.

There is no “one-size fits all” approach to compliance. Effective compliance programs must be tailored to suit your organization’s needs. This guide covers the following topics:

* **Implementing a Compliance Program**
* **Seven Core Elements of an Effective Compliance Program**
* **Compliance Program Do’s and Don’ts**
* **Additional Compliance Program Resources**

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1. **Implementing a Compliance Program**
2. **Overview**

The Patient Protection and Affordable Care Act (ACA) mandates compliance programs for Medicare, Medicaid and Children’s Health Insurance Program (CHIP) providers.[[1]](#footnote-2) While the law sets specific mandates for individual and small group practices, the intent is for all health care professionals to implement a compliance program in their offices/practices.

A good compliance program can provide a number of benefits, such as:

* Increasing the potential of proper submission and payment of claims;
* Reducing billing mistakes;
* Improving the results of reviews conducted on claims;
* Avoiding the potential for fraud, waste and abuse;
* Promoting patient safety and ensuring delivery of high quality patient care; and
* Saving staff time by avoiding duplicate training from other insurance plans.

Although a compliance program is not a guarantee that fraud, waste, abuse or inefficiency will not occur, implementation of a good compliance program will provide protection from the risks of improper conduct. Section 6401 of the ACA lists seven core elements for an effective compliance program[[2]](#footnote-3):

1. **Seven Core Elements of an Effective Compliance Program**
   1. **Written Policies, Procedures and Standards of Conduct**

Establishing written policies and procedures is necessary to promote consistency and uniformity. The written policies, procedures and standards should be composed with guidance from the Compliance Officer (CO) and the Compliance Committee.

The guidelines need to be made readily available to all employees, and should be reviewed with employees within 90 days of hire and at a minimum of annually thereafter. All employees should be required to certify that they have read, understand and agree to comply with the standards. The Compliance Committee needs to establish how frequently these policies, procedures and standards will be monitored and reviewed; also, how changes will be made to these guidelines.

The written standards for conduct or the “code of conduct” should clearly state and outline the office’s or practice’s commitment to compliance, values and quality treatment of customers/patients and employees. Standards of conduct should detail your organization’s commitment to ethical behavior, as well as your vision and values. The standards of conduct should also indicate that compliance is the responsibility of all employees and describe how to report incidents of non-compliant or unethical behaviors. Written policies and procedures should be detailed and specific as well as easy to read and comprehend.

The written policies and procedures should describe the operational duties and responsibilities for the following:

* Compliance Officer;
* Compliance Committee Members; and
* Management and all office/practice staff.

The policies and procedures should also include at least the following items:

* How and when employees will be trained;
* Operation of compliance program:
  + Compliance reporting structure,
  + Training requirements,
  + Reporting mechanisms,
  + How investigations will be conducted,
  + How issues are resolved, and
  + Monitoring and auditing.
* Duties and responsibilities for operational areas
* How the compliance department interacts with the internal audit department
* How the compliance department interacts with the legal department
* How the compliance department interacts with the Human Resources (HR) department; and
* How to measure effectiveness of the code of conduct and the compliance policies and procedures.
  1. **Compliance Program Oversight**

A Compliance Officer and a Compliance Committee are two different entities. Many programs have both.

* A **Compliance Officer is** a single employee who is solely responsible for the day‐to-day workings of the compliance program and structure.
* The **Compliance Committee** isa multi-disciplinary committee whose members have various backgrounds and expertise.

A Compliance Officer or Compliance Committee should be established to oversee the compliance program structure and administration within the organization. The officer or committee must be an employee that demonstrates involvement in and detailed familiarity with the organization's operational and compliance activities. These employees will report directly to the CEO or other senior management (depending on leadership structure).

The Compliance Officer or Committee should be responsible for “reasonable oversight” of the program, such as:

* Approving standards of conduct;
* Understanding and administering the compliance program structure;
* Being informed about the outcomes of audits and monitoring;
* Reporting on compliance enforcement activity; and
* Reviewing and performing effectiveness assessments of the compliance program

The Compliance Officer and Compliance Committee are responsible for certain duties related to the administration of the compliance program. Those responsibilities include:

* Developing and/or reviewing policies and procedures that implement the compliance program;
* Attending operations staff meetings;
* Monitoring compliance performance by operational areas;
* Enforcing disciplinary standards and ensuring consistency of discipline;
* Implementing a system for assessment of risk;
* Developing an auditing work plan;
* Reviewing auditing and monitoring reports;
* Coordinating with Human Resources; and
* Monitoring effectiveness of corrective actions.

The Compliance Officer and Compliance Committee also have the authority to conduct certain functions related to the compliance program. Those authorities include:

* Interviewing employees;
* Reviewing collected data;
* Seeking advice from legal counsel;
* Reporting potential fraud, waste and abuse within the organization;
* Conducting operations audits;
* Recommending policy, procedure, process improvements; and
* Enforcing compliance program requirements at all levels of the organization.
  1. **Training and Education**

All employees must be trained to ensure that staff is aware of the expectations and standards. Training needs to effectively communicate the requirements of the compliance program and the company's code of conduct. Annual trainings should be established to update employees on program changes and new developments.

Below are sample topics to include in the training:

* + General compliance training that effectively communicates the requirements of the compliance program, including the company’s code of conduct;
  + Initial compliance training for new employees occurring at or near the date of hire; and
  + Annual refresher compliance training that highlights compliance program changes or other new developments.

There are other important things to keep in mind for the design of compliance program training and education, such as:

* + The refresher training should re-emphasize the organization's code of conduct.
  + Training should, when appropriate, use actual compliance scenarios and/or investigations of non-compliance as examples of risks that employees and managers may encounter. This could include using case-based or scenario-based training examples as well as reporting on any noticed or reported trends.
  + The training should be as interactive as possible to increase the takeaway value to employees.

There are also many methods to use for staff training and education, such as:

* + Interactive educational modules that keep users engaged, e.g., games
  + Mixed mediums, e.g., using both live and electronic/digital training
  + Incentives such as CME credit, lunch or dinner.
  1. **Opening the Lines of Communication**

Creating an effective compliance program includes establishing open lines of communication regarding compliance issues, education, and concerns. An "open door" policy ensures that all employees have access to the Compliance Officer and/or Committee and all levels of management. All employees must be aware that the compliance staff duties include answering routine questions regarding compliance or ethics issues. Open lines of communication must ensure that staff are aware of the following:

* + Requirements for all employees to be proactive and report issues in a timely manner.
  + A formal process for managers to communicate compliance issues and results to staff.
  + A process to allow anonymous reporting without fear of retaliation.

Good communication is important for all organizations. How to achieve it will depend on the size and structure of the organization. For example, large organizations may have anonymous hotlines, while smaller organizations may promote open door policies. What is most important is to identify what works best for your organization.

* 1. **Auditing and Monitoring**

Auditing and monitoring is necessary to ensure compliance with CMS requirements and identify compliance risks. This should include a combination of internal monitoring and audits and external audits, as needed. Monitoring includes regular operational reviews of day to day functions to confirm ongoing compliance. Auditing includes formal reviews of compliance against a set of base measure standards. The written policies and procedures should be used consistently to handle every compliance offense.

While some organizations use the terms "monitoring" and "auditing' interchangeably, the two activities have different meanings and expectations:

* + **Monitoring** includes regular reviews performed as a part of normal operations to confirm ongoing compliance. It:
* occurs on a regular basis (e.g., daily, weekly, monthly);
* is performed by staff;
* ensures procedures are working as intended; and
* serves as a means of following up on recommendations and corrective action plans to ensure they are being implemented.
  + **Auditing** includes formal reviews of compliance with a particular set of standards as base measures. It:
    - ensures compliance with statutory and CMS requirements in critical operations areas;
    - includes regular, periodic evaluations of the compliance program to determine the program's overall effectiveness;
    - is performed at least annually; and,
    - includes written reports containing findings, recommendations, and proposed corrective actions.

Audits may be performed internally or by an external organization by auditors who:

* + Are independent of, and not employed in the department being audited;
  + Are competent to identify potential issues within the critical review areas; and
  + Have access to existing audit resources, relevant personnel and operational areas.

To assist providers who conduct internal, or self-audits, additional information, guidance, and reporting documents are provided on the DHCF Division of Program Integrity webpages under the link for “Provider Self-Audit”.

When offenses are detected through the compliance program, consistent written policies and procedures are needed. Written policies and procedures for auditing and monitoring should, at a minimum, cover the following areas:

* + A plan of how internal investigations should be conducted;
  + A time limit for closing an investigation;
  + Options for corrective action;
  + When to have an investigation performed by an outside, independent contractor; and
  + How and when to refer an act of non-compliance to CMS or law enforcement authorities.

Another important component of auditing and monitoring is assessing the level of risk. Risk assessment is a formal baseline assessment of major compliance and fraud, waste, and abuse areas to assess compliance risks. It should include areas of concern identified by CMS, beneficiaries and providers, as well as identify risk levels (e.g., high, medium, or low). High-risk areas should be audited regularly, and the results included in monitoring and auditing work plans to help guide decisions regarding resources. Additional details on assessing the level of risk is contained in documents is provided on the DHCF Division of Program Integrity webpages under the link for “Provider Self-Audit”.

Overall, monitoring and auditing work plans should:

* + Outline monitoring/auditing specifics;
  + Be based on results of risk assessment;
  + Include a process for responding to results; and
  + Include corrective actions.
  1. **Consistent Discipline**

Disciplinary policies must be written that state the appropriate sanctions applied to those who fail to comply with the applicable requirements and written standards of conduct. These policies must be clearly written describing expectations and consequences for noncompliant behavior. All staff should be educated on the policy and review annually. Disciplinary policies should be widely publicized and readily available to staff. The plan set forth in the policies should enforce consistent discipline when an investigation confirms a compliance offense. These offenses include:

* + - * Non-compliance;
        + Failure to detect non-compliance when routine observation or due diligence should have provided adequate clues; and
      * Failure to report actual or suspected non-compliance.
  1. **Corrective Actions**

When vulnerabilities or non-conformances are identified and/or reported as the result of a risk assessment, audit, or monitoring, corrective action must be conducted in response to potential violations. Examples of corrective action include repayment of overpayments and disciplinary action against responsible employees.

1. **Compliance Program Do’s and Don’ts**
   * 1. **Know where to locate easy and free resources.**

Various compliance organizations, such as the Health Care Compliance Association, have valuable resources. HHS-OIG and CMS also provide resources on how to design a good compliance plan. The Health Care Fraud Prevention and Enforcement Team (HEAT) has numerous fact sheets, podcasts and reference materials.

* + 1. **Keep the plan simple.**

The best compliance plans are simple and easy to read. If the plan is long or contains difficult language (e.g., hard to understand legal terms), the providers and employees might not read it. It is best to keep the compliance plan concise and straightforward.

* + 1. **Set a date to review the plan every year.**

It is also important to review the compliance plan every year. This is the time for making revisions to items in the plan that did not work in the previous year or increase efforts on items that did.

* + 1. **Engage physicians** (e.g., through educational meetings).

While engaging providers and staff to "buy into" the compliance program can be challenging, scheduling educational meetings to discuss the components of the plan can be very helpful.

* + 1. **Make plan seen positively and frequently.**

Use every opportunity to highlight the importance of compliance, for example, add compliance topics to newsletters, the intranet, at board meetings.

* + 1. **Identify a spokesperson for the plan.**

The compliance point of contact should be a role model for the plan. The plan needs to be real and the Compliance Officer needs to be accessible.

* + 1. **Keep it friendly and fair.**

All compliance plans should spell out the consequences of not following the rules; however, it is not necessary to be unduly punitive. Everyone benefits when the rules are clear and easy to understand.

1. **Additional Compliance Program Resources**
   1. [**HHS-OIG Voluntary Compliance Program Guidance Documents**](https://oig.hhs.gov/compliance/compliance-guidance/index.asp)

HHS-OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to statutes, regulations, and program requirements. The documents provide principles to follow when developing a compliance program that best suits your organization's needs. The documents also identify fraud and abuse risks to watch out for when creating a program. The guidance documents are available at: <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>

* 1. [**CMS Medicare Learning Network, Provider Compliance Resources**](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html)

The Centers for Medicare and Medicaid Services (CMS) also has a webpage that provides compliance-related resources through its Medicare Learning Network (MLN). The resources are available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html>.

* 1. **Provider Compliance Training**

Below are links to free training for health care providers, compliance professionals, and attorneys. OIG's Provider Compliance Training was an outreach initiative developed as part of HHS's and the U.S. Department of Justice's Health Care Fraud Prevention and Enforcement Action Team.

* **[Videos and Audio Podcasts](https://oig.hhs.gov/newsroom/video/2011/heat_modules.asp)**
* [**Webcast**](https://oig.hhs.gov/newsroom/video/2011/heat_modules.asp#modules)
* [**Presentation Materials**](https://oig.hhs.gov/compliance/provider-compliance-training/index.asp#materials)
  1. **Education Materials for Physicians**

HHS-OIG has also compiled a series of educational materials assist in teaching physicians about the Federal laws designed to protect Medicare and Medicaid and program beneficiaries from fraud, waste, and abuse. The materials summarize the five most important Federal fraud and abuse laws that apply to physicians and provide tips on how physicians should comply with these laws in their relationships with payers, vendors, and fellow physicians and other providers.

* + [A Roadmap for New Physicians, Safeguarding your Medical Identity](https://oig.hhs.gov/compliance/101/cme.asp" \l "safeguarding)
  + [A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse](https://oig.hhs.gov/compliance/physician-education/index.asp)

1. **References**
2. U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. Medicare Learning Network. “Affordable Care Act Provider Compliance Programs: Getting Started Webinar.” June 17, 2014; June 24, 2014. Retrieved November 15, 2017, from <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/MLN-Compliance-Webinar.pdf>.
3. U.S. Department of Health and Human Services. Office of Inspector General. “Compliance Education Materials, Compliance 101.” Retrieved November 15, 2017, from <https://oig.hhs.gov/compliance/101/index.asp>.
4. U.S. Department of Health and Human Services. Office of Inspector General. “Compliance Guidance.” Retrieved November 15, 2017, from <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>.
5. U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. Medicare Learning Network. “Provider Compliance.” Retrieved November 15, 2017, from <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html>.

1. Section 6401 of the Affordable Care Act provides that a “provider of medical or other items or services or supplier within a particular industry sector or category” shall establish a compliance program as a condition of enrollment in Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP). [↑](#footnote-ref-2)
2. The Affordable Care Act further required that the HHS Secretary, in consultation with HHS-OIG, establish “core elements” for provider and supplier compliance programs within a particular industry or sector. [↑](#footnote-ref-3)