TIPS AND TOOLS FOR COMPLIANCE PROFESSIONALS

A Complement to OIG's Guide on Measuring
Compliance Program Effectiveness

Part One

NATRICHA LEVY MCFARLANE, MPHIL

SANJAYA KUMAR, MD, M.Sc., MPH

PolicyMedical | 28 Fulton Way, Unit 2, Richmond Hill, Ontario, L4B 1J5, Canada

Table of Contents

Compliance Programs and Health Care

Compliance in healthcare simply refers to adhering to all the laws and ethical guidelines that govern the delivery of healthcare. A compliance program is basically a system of internal controls that assist individuals working in an organization, and by extension the organization itself, to adhere to all relevant federal and state laws, program requirements of these laws, and professional standards. It is designed to prevent and detect criminal conduct.

Compliance programs have been a part of the US healthcare industry for over 20 years and the Affordable Care Act, 2010, made it mandatory that Medicare and Medicaid providers institute compliance programs. Agencies such as the Office of Inspector General (OIG), have championed the effort for healthcare organizations to develop compliance programs and have provided numerous educational resources – compliance program guidance documents, webcasts, presentation materials, video and audio podcasts – all in a effort to encourage and support healthcare organizations as they develop and institute their compliance programs. The first compliance program guidance document was developed by OIG in 1997 and was targeted to clinical laboratories. Since then, the OIG has developed guidance documents for other segments of the industry such as hospitals, home health agencies, nursing facilities, third-party billers, and durable medical equipment suppliers.

The initial guidance for what a corporate compliance program should constitute came from the US Sentencing Commission Federal Sentencing Guidelines which resulted from the Federal Sentencing Reform Act, 1984. The OIG espoused the concept of voluntary corporate compliance in healthcare in 1997, stating the seven (7) elements of a compliance program as:

1. Implementing written policies, procedures, and standards of conduct

2. Designating a compliance officer and compliance committee

3. Conducting effective training and education

4. Developing effective lines of communication

5. Enforcing standards through well publicized disciplinary guidelines

6. Conducting internal monitoring and auditing

7. Responding promptly to detected offenses and developing corrective action.

Compliance Programs and Health Care

Having a compliance program is a great way for healthcare organizations to show their commitment to preventing and detecting fraud, abuse and waste, and obeying all requisite laws and regulations while advancing their mission to provide quality patient care. However, the existence of the program by itself is not adequate to achieve these goals. To ensure that a compliance program is achieving its mandate, it has to be enforced and measured.

Measuring the Effectiveness of a Compliance Program

A measurement may be defined as a means of determining the extent to which something matches to a standard. It involves putting a figure/value to a particular condition, for example, 65% of staff attest to reading the compliance program manual. To obtain a measurement, in addition to what is being measured (metric), there must be some means of measuring it.

Measuring a compliance program for effectiveness would determine how well such a program matches up to what is expected. OIG declarations are generally accepted as the standards against which healthcare compliance programs are measured. There are many metrics to consider when conducting such measurements – knowledge of the program, adherence to the components of the program, penalty for non-adherence, existence of policies to address relevant regulations, competence of compliance personnel, etc. Surveys, focus group discussions, key informant interviews, reviews, audits, and checklists are all ways to measure different aspects of a compliance program

Overview of the OIG's Resource Guide

The Office of Inspector General (OIG) of the US Department of Health & Human Services (HHS), is dedicated to fighting fraud, waste, and abuse in Medicare, Medicaid and other HHS programs. Towards this end, the OIG has over the years developed numerous educational resources to assist those in the health care industry in understanding the laws governing health care fraud and abuse, and the consequences of violating these laws. These educational resources are also aimed at providing health care organizations with guidance in developing and maintaining their own compliance programs.

While having a compliance program is essential to avoid violations of the regulatory laws and prevent abuse, the program by itself is not enough to ensure compliance. To be effective, the program must be evaluated so that gaps can be identified and corrective measures implemented, while redundant or out-dated processes can be eliminated.

To assist health care organizations with evaluating their compliance programs, on March 27, 2017, the OIG issued a resource guide for measuring the effectiveness of compliance programs. This guide was developed by OIG staff in collaboration with compliance professionals and provides detailed metrics for assessing the seven (7) elements of a compliance program. The categories in the Detailed Content Outline section of the Health Care Compliance Association's (HCCA) Certified in Healthcare Compliance (CHC) Candidate Handbook were used to guide the process to ensure that all the elements were covered:

1. Standards, Policies, and Procedures

2. Compliance Program Administration

3. Screening and Evaluation of Employees, Physicians, Vendors and other Agents

4. Communication, Education, and Training on Compliance Issues

5. Monitoring, Auditing, and Internal Reporting Systems

6. Discipline for Non-Compliance

7. Investigations and Remedial Measures

The metrics were developed by determining, under each element of compliance, what to measure and how to measure it. The suggestions are numerous and are applicable to different health care organizations and as such, each organization will need to select what metric best applies to their setting.

At PolicyMedical, we aim to provide value to our clients not only through our world-class software solutions, but also through producing meaningful content to ease the process of achieving and maintaining compliance standards. Accordingly, we are putting together a series of e-guides as an accompaniment to the OIG's resource guide, to offer some tips and tools to assist in implementing the suggestions recommended by the OIG. This first installment of the e-guide will focus on general tips and tools to consider as you begin to use the OIG's resource guide, while the other instalments will offer up tips and tools for assessing the metrics in each of the elements of a compliance program.

Tips and Tools for Implementing the OIG's Resource Guide

If you have decided to use the OIG's resource guide to measure the effectiveness of your compliance program, the most important thing to be mindful of is that **the suggested metrics are wide ranging, apply to different organizations and you should not try to implement all of them**. With this mindset, we suggest you do the following:

◆ Establish a team (or an individual based on your resources) – implementation team - who will be responsible for ensuring that the implementation is achieved. Individuals to be considered for this team are:
  o Compliance Managers/Officers/Analysts/Specialists/Auditors
  o Risk Assessment Managers/Officers
  o Patient Safety and Quality Managers/Officers
  o Privacy and Security Managers/Officers

◆ Inform your organization through email, internal memo, bulletin board etc., of the OIG's resource guide, it's purpose, and the decision to use it to assess the effectiveness of your compliance program.

> You can use the announcement feature in PolicyManager for this purpose!

◆ Circulate the guide and encourage key staff to read and become familiar with its contents.

> The iAttest feature in PolicyManager is ideal for this!

The Implementation team should:

◆ Review the OIG's Guide in detail.
◆ Highlight metrics that are applicable to your organization.
◆ Select metrics that are achievable for the organization based on your needs and resources.
  o Ensure that at least one metric from each element of a compliance program is selected.

◆ Determine the timeline for starting and completing each selected metric.

◆ Determine the frequency with which these metrics will be assessed.

◆ Develop a detailed workplan with objectives, tasks, timelines, and responsible persons for each metric.

   o A project management software can be used to track activities and set reminders through email notifications to responsible personnel to prompt them to complete tasks.

◆ Share the workplan within the organization so that everyone is aware and on board.

◆ Create a budget detailing the needs for implementing the selected metrics and any associated costs.

◆ Submit budget to management for approval. Management should ensure that any funding required for the implementation is provided.

◆ Conduct the assessment based on the workplan.

◆ Have regularly scheduled meetings of the implementation team to keep abreast of the progress of the implementation.

◆ Prepare and share a report of the outcome of the assessment with the entire organization (depending on the metrics selected and the timeframe required for assessment, it may be necessary to prepare interim reports as well as a final report).

◆ Review the outcome report to determine what is going well and identify any gaps in the compliance program.

   o An interactive workshop can be held to accomplish this.

◆ Commend staff on successes and inspire them to make requisite changes to improve on any area that fell below acceptable standards.

Other points of Note

In addition to the tips and tools provided above, we believe it is important to note the following:

- ◆ **If the organization has the necessary financial resources, it can hire a company that specializes in this area to conduct the assessment.** This should ensure that an independent, objective point of view is obtained and will also prevent over-burdening staff who are already pressured by their daily tasks.

- ◆ Ensure that staff is sensitized to the fact that the assessment is for the benefit of the organization and the patients it serves and should not be seen as an indictment on any individual(s).

The tips and tools recommended in this e-guide are not exhaustive and you are free to use those that are applicable to your circumstances and add others that are more suitable for you. We are very happy to provide you with this e-guide and hope that it proves beneficial as you prepare to assess your compliance program with the aid of the OIG's resource guide.

Look out for the next installment of our Tips and Tools for Compliance Professionals: A Complement to the OIG's Guide on Measuring Compliance Programs Effectiveness.

Bibliography

Compliance 101*.* Office of Inspector General, US Department of Health & Human Services. Last accessed on May 1, 2017 from https://oig.hhs.gov/compliance/101/.

Merritt M, ***ABCs of Healthcare Corporate Compliance****.* Physicians Practice, February 15, 2015. Last accessed May 1, 2017 from http://www.physicianspractice.com/blog/abcs-healthcare-corporate-compliance-programs.

Schipske G, ***Why Compliance and Ethics Programs in Healthcare are Mandatory for Quality Care****.* The Compliance & Ethics Blog, October 11, 2016. Last accessed May 1, 2017 from http://complianceandethics.org/compliance-ethics-programs-healthcare-mandatory-quality-care/.

Smith ML, ***Healthcare Compliance: An Overview of the Basics for Organizations and Providers***. The Health Law Firm. Last accessed May 1, 2017 from http://www.thehealthlawfirm.com/resources/health-law-articles-and-documents/Healthcare-Compliance.html.

Publication of OIG Compliance Program Guidelines for Clinical Laboratories*.* Federal Register, Vol. 63, No. 163, Monday , August 24, 1998/Notices. Last accessed May 1, 2017 from https://oig.hhs.gov/authorities/docs/cpglab.pdf.

2015 Chapter Eight – Sentencing of Organizations. United States Sentencing Commission. Last accessed on May 1, 2017 from http://www.ussc.gov/guidelines/2015-guidelines-manual/2015-chapter-8.