10 – Introduction

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

These compliance program guidelines reflect the Centers for Medicare and Medicaid Services (CMS) interpretation of the Compliance Program requirements and related provisions for Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP) (Chapter 42 of the Code of Federal Regulations, Parts 422 and 423, hereinafter collectively referred to as "Parts C & D"). This chapter is designed to assist sponsors to establish and maintain an effective compliance program.

These compliance program guidelines apply fully to the prescription drug benefit programs of sections 1833 and 1876 Cost Plans. In addition, these compliance program guidelines apply to the prescription drug benefit programs of Program of All-Inclusive Care for the Elderly (PACE) plans only with respect to those portions of this chapter that pertain to Elements 6 and 7, which are embodied in 42 C.F.R. 423 §§504(b)(4)(vi)(F) and (G) respectively. These compliance program guidelines do not apply to the PACE plans or to sections 1833 and 1876 Cost Plans that do not have a prescription drug benefit program. However, given the Office of Inspector General (OIG) guidance promoting compliance programs for all sponsors, the CMS strongly encourages sponsors to voluntarily develop and implement effective compliance programs.

This guidance is subject to change as policy, technology and Medicare business practices continue to evolve.

Each sponsor must implement an effective compliance program that meets the regulatory requirements set forth at 42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi). Sponsors should apply the principles outlined in these guidelines to all relevant decisions, situations, communications and developments. Any new rule-making or interpretive guidance (e.g., annual call letter or Health Plan Management System (HPMS) guidance memoranda) may update the guidance provided in this document. Sponsors may also wish to consult the resources listed in the Appendices, which provide additional information on some topics addressed in this chapter.

In this chapter, the word "must" is used to reflect requirements created by statute or regulation. The word "should" is used to indicate expectations created by this guidance. Recommendations are noted as "best practices."

Chapter 9 previously addressed the prevention of fraud, waste and abuse (FWA) by only Part D sponsors. In contrast, this chapter provides interpretive rules and guidance to help all sponsors to establish and maintain an effective compliance

program to prevent, detect, and correct FWA and Medicare program noncompliance

These guidelines, published in both Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 9 and in Pub. 100-16, Medicare Managed Care Manual, chapter 21, are identical and allow organizations offering both Medicare Advantage (MA) and Prescription Drug Plans (PDP) to reference one document for guidance.