

Retail Pharmacy Ramps Up Compliance After Multimillion Dollar DOJ Settlement and  
Successfully Completes a Corporate Integrity Agreement (CIA)

1. Background – Consultant was engaged after a joint DOJ/U.S. Drug Enforcement Agency (DEA) investigation concerning the alleged improper dispensing of controlled and other prescription drugs resulted in a multimillion-dollar settlement and a three-year HHS/OIG Corporate Integrity Agreement.
  
2. Engagement – Consultant was engaged to assist Pharmacy with the implementation and ongoing management of the CIA, including ensuring compliance with all DEA and state pharmacy board rules. Throughout the three-year duration of the CIA, the Consultant assisted with Pharmacy's administration of all quarterly CIA-required audits performed by the designated Independent Review Organization, including providing services to coordinate, review in detail and deliver each quarterly audit's claim population, claim sample, supporting documentation set, and IRO audit report. In addition, Consultant developed Pharmacy's CIA-required training and education program, including a presentation module outlining relevant FDA, DEA and state pharmacy board laws and regulations. Finally, Consultant coordinated and assisted with drafting of all three Annual Reports, including detailed attached exhibits.
  
3. Results – After performing an initial onsite assessment, Consultant developed a written project plan. Early deliverables included development of a prescription review process and form, employee training process and form, and verification processes for the OIG Exclusion List and state Prescription Drug Monitoring Program (PDMP). Consultant assisted with drafting of Pharmacy's Implementation Report and developed a prescription review audit tool. He also performed a shadow audit of the first IRO review. These thorough, practical efforts laid in effective groundwork and sound processes, which in turn resulted in pharmacy's passing each and every quarterly IRO audit, throughout the entire duration of the CIA, with no errors, sanctions or financial penalties of any kind. The three Annual Reports were similarly unconditionally accepted by the OIG, thus concluding the entire engagement successfully.