Pharmacies operating in the United States are subject to a host of compliance obligations under federal law. These compliance obligations touch on all aspects of pharmaceutical practice, from drug ordering and inventory management to billing public and private payors. Despite the extraordinary scope of pharmacies’ compliance obligations, federal authorities do not excuse oversights. If an audit, investigation, or whistleblower complaint reveals evidence of shortcomings in any respect, pharmacy owners and pharmacists-in-charge can expect to face significant ramifications.

With this in mind, for pharmacies in the U.S., compliance needs to be a priority. Pharmacies cannot rely on the excuse of being overburdened with high demand, and they cannot expect to escape scrutiny if their compliance efforts are anything less than comprehensive. However, by taking a proactive approach to compliance, pharmacies can meet their compliance obligations, and pharmacy owners and pharmacists-in-charge can protect themselves (and their staff) against federal liability.

“In today’s world, pharmacies face constant scrutiny from the Drug Enforcement Administration (DEA) and other federal authorities. If prescription or billing data place a pharmacy outside of the norm, an audit or investigation is very likely to follow.” – Dr. Nick Oberheiden, Founding Attorney of Oberheiden, P.C.

What does it take for a pharmacy to be compliant? Here is a non-exclusive list of 20 examples of key components of an effective pharmacy compliance program:

1. Prescription Drug Ordering

When ordering prescription medications, pharmacies must do so through the use of DEA Form 222, and they must ensure that they are ordering legitimate drugs from legitimate sources. Pharmacies must maintain documentation of all orders placed for prescription medications, and they must also document and track all shipments received.
2. DSCSA Compliance

The Drug Supply Chain Security Act (DSCSA) is a federal law that is intended to protect against the distribution of counterfeit prescription medications. In the area of **DSCSA compliance**, pharmacies’ obligations include: avoiding transactions with entities that are not registered with the U.S. Food and Drug Administration (FDA) or licensed under state law; utilizing drug tracing documentation in order to detect counterfeit medications; and, investigating suspicious medications and notifying the FDA of suspected counterfeit medications.

3. Prescription Drug Inventory Management

Effective inventory management is crucial for avoiding unwanted scrutiny from the DEA and other federal authorities. In order to avoid discrepancies and losses, pharmacies should implement comprehensive inventory tracking protocols, and they should maintain comprehensive documentation of all incoming and outgoing drugs.

4. Electronic Prescription Compliance

Accepting electronic prescriptions entails additional compliance obligations above and beyond those that apply to filling paper prescriptions. Among other obligations, pharmacies must utilize appropriate software applications for managing electronic prescriptions, and they must thoroughly document all transactions involving digitally-received scripts.

5. Prescription Fraud Monitoring

Pharmacies must implement effective policies and protocols to identify and prevent prescription drug fraud. This includes adopting adequate means to assess the validity of prescriptions received from providers, as well as means to evaluate prescriptions and refill requests presented by patients.

6. Prescription Drug Security

In addition to prescription fraud monitoring protocols, pharmacies also have an obligation to adopt physical and logical security measures in order to prevent theft of prescription drugs. This applies to medications in inventory as well as those in transit.

7. Transfer and Disposal Compliance

Prior to transferring or disposing of prescription medications, pharmacies must ensure that they have adequate documentation, and they must consistently adhere to their internal policies and procedures regarding transfer and disposal. For pharmacies that utilize third-party service providers, it is necessary to ensure that their third-party providers have adequate controls in place as well.

8. Dispensing and Diversion Control

Pharmacists and pharmacy technicians must adhere to stringent protocols with respect to filling prescriptions and dispensing medications in order to ensure that the correct drugs are dispensed in the correct quantities. Pharmacies must also adopt appropriate measures to mitigate the risk of **prescription drug diversion**.
9. Coding Compliance

When billing Medicare, Medicaid, Tricare, private insurance companies, and other payors, pharmacies must ensure that they are coding all reimbursement requests correctly. Coding errors, even if unintentional, can lead to substantial liability in the event of a pharmacy fraud audit or investigation. Some common examples of errors that can lead to scrutiny include using incorrect billing codes, “upcoding” prescriptions in order to bill at higher rates, billing for the incorrect quantity or drug, and billing for medications not actually dispensed to patients.

10. Establishing Medical Necessity

Another aspect of billing compliance for pharmacies involves taking reasonable measures to confirm the medical necessity of all prescriptions they fill. If a payor deems a prescription non-medically-necessary, then it can deny reimbursement and potentially pursue remedies or penalties for fraud. While pharmacists are not expected to second-guess healthcare providers’ decisions in every circumstance, they are expected to know how and when to identify questionable prescriptions.

11. Pharmacy Benefit Manager (PBM) Compliance

For pharmacies that work with pharmacy benefit managers (PBMs), maintaining compliance with the terms of their PBM contracts is important not only for avoiding “retractions” and civil liability, but potentially for avoiding federal scrutiny as well. If accused of insurance fraud under federal law, pharmacy owners and pharmacists-in-charge can face substantial fines and long-term imprisonment.

12. Third-Party Service Provider Monitoring and Enforcement

When engaging third parties to provide transfer, disposal, billing, and other services, pharmacies must conduct thorough due diligence and negotiate adequate protections into their service agreements. Pharmacies cannot assign their federal compliance obligations; so, if a third-party service provider violates the law, the pharmacy can still be held directly accountable.

13. Cannabidiol (CBD) Compliance

Pharmacies’ cannabidiol (CBD) prescription practices are facing enhanced scrutiny at the federal level as a result of the growing number of states that have legalized marijuana for medicinal use. For pharmacies that fill CBD prescriptions based on legalization under state law, it is necessary to adopt policies and procedures that are specific to CBD compliance.

14. Specialty and Compound Pharmacy Compliance

Specialty pharmacies and compound pharmacies face additional compliance burdens as well. Compound pharmacies in particular have been a particular focus of the DEA in recent years, and specialty pharmacies must be prepared to demonstrate comprehensive compliance to both the DEA and their PBMs.

15. Written Policies and Procedures

In order to effectively implement their compliance protocols and be prepared demonstrate compliance to the DEA, PBMs, and other federal authorities when necessary, pharmacies need to adopt
comprehensive written policies and procedures. These policies and procedures should address all aspects of compliance (including, but not limited to, those discussed above), and they should be custom-tailored to the pharmacy’s specific legal obligations and operational risks.

16. Internal Auditing, Assessment, and Response

Pharmacies’ compliance efforts must also include affirmative steps to assess the effectiveness of their compliance programs and determine when additional or remedial measures are necessary. This includes conducting routine internal audits, conducting periodic assessments of new compliance risks, and having documented protocols that can be executed in the event of an actual or suspected compliance violation.

17. Pharmacist and Technician Training

Once all requisite policies and procedures have been drafted, pharmacy personnel should be trained with regard to their respective roles in establishing and maintaining compliance. Training needs will differ for personnel in different roles, and all personnel should be required to affirmatively certify as to completion of the required training programs.

18. Appointment of a Compliance Officer

Appointing a compliance officer is a crucial step toward effectively maintaining compliance and demonstrating to federal authorities that your pharmacy is taking its compliance obligations seriously. Compliance officers should be intimately familiar with all aspects of the pharmacy’s operations; and, just as importantly, they should have time available to devote to thoroughly assessing the pharmacy’s compliance risks and needs on an ongoing basis.

19. Pharmacy Recordkeeping

As indicated above, recordkeeping is a core component of many aspects of pharmacy compliance. From a federal law enforcement and PBM compliance perspective, if a pharmacy cannot provide documentation to substantiate compliance, then it can face serious liability risks even if it has complied with the law and its contractual duties. With this in mind, pharmacies’ compliance policies and procedures should include provisions specific to generating and storing documentation, and pharmacies must emphasize the importance of documentation in all aspects of their operations.

20. Audit and Investigation Preparedness

Finally, when addressing compliance, pharmacies must also address the need to demonstrate compliance during an audit or investigation. The DEA and PBMs conduct routine audits of registered and participating pharmacies, and apparent compliance deficiencies can trigger invasive federal investigations with the potential for civil or criminal penalties.

Under the Controlled Substances Act (CSA) and its enabling regulations, pharmacies have an obligation to produce compliance documentation upon request from the DEA, and the inability to respond effectively to civil investigative demands (CIDs), subpoenas, and other requests can expose pharmacies, pharmacy owners, and pharmacists-in-charge to potential liability as well. As a result, in many respects, documentation of compliance is just as important as compliance itself, and pharmacies should work with experienced legal counsel to ensure that they are taking the necessary
steps to protect their owners, their personnel, and themselves.

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