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An Overview of BOC Retail Pharmacy Accreditation

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The Board of Certification/Accreditation (BOC) Retail Pharmacy Accreditation Standards, inclusive of the U.S. Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), Drug Enforcement Agency (DEA) and Insurance Provider Manuals, are developed to assure the public of the availability of comprehensive pharmaceutical services, consistent with federal, state and local laws and regulations.

Pharmacy and Medicare Part D Accreditation is provided under the deemed authority granted to BOC as an accrediting organization by the Centers for Medicare & Medicaid Services (CMS) and third-party insurance carriers. BOC requires that all accredited pharmacies submit any documentation necessary to reflect continued compliance with the standards at the time of annual renewal. Accredited pharmacies are required to reapply every three years. Pharmacy and Medicare Part D Accreditation is available in conjunction with DMEPOS accreditation or as a stand-alone accreditation.

The Pharmacy must follow HHS, CMS, DEA, FDA and the respective state Board of Pharmacy standards as well as the following BOC Pharmacy Accreditation Standards.

Pharmacy services encompass the provision of community retail and long-term care (LTC) pharmacies.

Business Administration

Chapter 1 - Corporate Structure and Governance

Section 1.1 - Compliance

The Pharmacy complies with all federal, state and local laws and is a legally constituted entity in the state in which it is located. When applicable, the organization must have a corporate charter and governing body that sets policy for the entity.

Section 1.2 - Leadership

The organization must have one or more individuals who perform leadership functions with the authority, responsibility and accountability to direct the organization and its key activities. The organization must identify those individuals who serve as its leadership and management. The leadership must ensure that the organization complies with these standards, as well as all other applicable laws and regulations, and that its programs and services meet patient needs. The Pharmacy must submit an organizational chart indicating the lines of authority and accountability.

Section 1.3 - Governance

Governance defines responsibilities in writing, provides for organizational management and planning, approves the written scope of services for the organization, selects the Pharmacist-In-Charge, provides for the resources necessary to maintain safe quality care and works with other leaders to annually evaluate the organization's performance in relation to its mission, vision and goals.

Section 1.4 - Changes

The Pharmacy agrees to notify BOC of any changes in ownership, corporate officers/structure or Pharmacist-In-Charge within 30 days of hiring or termination.

Section 1.5 - Designations

The Pharmacy must have a designated Pharmacist-In-Charge and a **Compliance Officer** to assure compliance with applicable laws and regulations. These individuals must be identifiable by employees and patients to enable contact if issues or concerns arise.

Compliance Officer: An employee or contracted individual whose responsibilities include ensuring that the company follows outside regulatory requirements and internal policies.

Section 1.6 - Patient Care

The Pharmacy's policies and procedures must be designed to promote the provision of high-quality patient care in compliance with all applicable federal and state laws, regulations, professional certification guidelines (e.g. FDA, DEA, HHS, HIPAA, ADA and OSHA) and pharmacist scope of practice.

Section 1.7 - Physical Location

Section 1.7.1: The Pharmacy must maintain a **physical facility** on an appropriate site. The location must be at least 200 square feet and must contain space for storing business records, including the pharmacy's delivery, maintenance, financial and patient communication records.

A post office box or commercial mailbox is not considered a physical facility.

Section 1.7.2: When a Pharmacy has multiple locations, each location must meet the respective state Board of Pharmacy regulations and be licensed and accredited as a separate pharmacy. In the case of a multi-site pharmacy, records may be stored and maintained at a centralized location.

Section 1.7.3: The Pharmacy must permit HHS, DEA, FDA or their agents and state Board of Pharmacy inspections to conduct on-site inspections to ensure the Pharmacy's compliance. The pharmacy location must be accessible to patients during

reasonable business hours and maintain a visible sign and posted hours of operation. If the pharmacy is a “Closed” Long Term Care or an infusion pharmacy, patients do not have access to the pharmacy as products are delivered to the patient or a facility. When required by the respective state, pharmacy and pharmacist licenses must be maintained and displayed in the pharmacy.

Section 1.7.4: The Pharmacy must maintain a primary business telephone listed under the name of the business in a local directory or a toll-free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.

Section 1.7.5: The Pharmacy must inform BOC when a new location is opened.

Section 1.8 - Scope of Service

Section 1.8.1: The Pharmacy receiving payment must be the entity furnishing and billing for the items and services.

Section 1.8.2: Pharmacies must have individuals on staff to support the specialties, products and services provided. The professional staff must be employed by the Pharmacy as W-2 or 1099 employees (e.g. Pharmacists, Pharmacy Technicians, Registered Nurses, Physician Assistants, Certified Nurse Practitioners). Current licenses and/or certifications must be displayed in the Pharmacy. Evidence must be available to verify licenses and certification are valid.

Section 1.8.3: All 1099 employees must have a HIPAA Business Associate Agreement on file.

Section 1.9 - Standard Business Practices

Section 1.9.1: The Pharmacy must have a comprehensive liability insurance policy in the amount set by the state pharmacy board. If a Pharmacy compounds patented or proprietary compounds, the insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the pharmacy’s accreditation. BOC must be listed as a certificate holder.

Section 1.10 – Ethics

Section 1.10.1: The Pharmacy and its staff must subscribe to the respective state Board of Pharmacy ethical statements respective to pharmacy or professional categories, credentials or licensure. The Pharmacy must recognize its responsibility to patients.

Section 1.11 - Health Literacy and Culturally Appropriate Communication Requirements

Section 1.11.1: The Pharmacy shall ensure procedures are developed to assist with a form of communication the patient can understand.

Section 1.12 - Limited English Proficiency

Section 1.12.1: The Pharmacy must have the means to communicate with patients who have limited English proficiency.

Chapter 2 - Financial Management

Section 2.1 - Implementation

The Pharmacy must implement financial management practices that ensure accurate accounting and billing to CMS, third-party payors and patients. Financial records must be accurate, complete and current. Records (i.e. QuickBooks, Peachtree, pharmacy computer system) must reflect cash or accrual based accounting practices. The accounting system must maintain a mechanism to track actual revenues and expenses. The Pharmacy must maintain accounts that link products and services to the patient and revenues and expenses on an ongoing basis related to patient services.

Section 2.2 - Records

The Pharmacy agrees to produce records as requested by the BOC site surveyor for the purpose of completing the site survey and proof of compliance with BOC Standards.

Section 2.3 - Annual Operating Budget

Section 2.3.1: The Pharmacy must have an annual operating budget, as appropriate to the business' size and scope of services, to meet the needs of patients and maintain business operations. If the Pharmacy utilizes accounting software such as QuickBooks, Peachtree, etc. which can produce accurate records on demand, a formal budget is not required.

Section 2.3.2: Management must periodically review the business's actual financial performance in relation to the operating budget, making adjustments as necessary utilizing year-end projections on services and appropriate infrastructure to determine budget variance. A Certified Public Accountant's Quarterly Financial Statement is one method for meeting this requirement.

Section 2.4 - Income Statements and Balance Sheets

Section 2.4.1: The Pharmacy must periodically produce financial statements that include a balance sheet denoting the Pharmacy's assets and liabilities and an income statement reflecting the revenue earned over a specific time period. Guidelines for corporate balance sheets are provided by the **International Accounting Standards Committee (IASC)**.

IASC Website: http://www.iasplus.com/standard/standard.htm

Section 2.5 - Service Contracts

Section 2.5.1: The Pharmacy must maintain **service contracts**, as needed. The Pharmacy should ensure that contracts specify job requirements, including policies and related qualifications for contracted personnel to include necessary licensures and certifications. The contracts must be signed by both parties with date of execution noted. Contracts include, but are not limited to:

- Drug Wholesaler Agreement
- 1099 licensed professionals (HIPAA Business Associate Agreement also required)
- Pharmacy Software Agreement
- Pharmacy Point of Sale (POS) agreement

Service Contracts: Agreements between the Pharmacy and outside entities to perform certain functions at an agreed price over a fixed period of time.

Chapter 3 - Human Resource Management

Section 3.1 - Documentation

The Pharmacy must document the individual skills, qualifications, health assurances and number and types of personnel needed. The mission, scope, complexity of services, pharmaceuticals, compounds, equipment and products provided and, as required by applicable state and federal laws, define the number of personnel needed to operate the Pharmacy. This applies to all employees and contractors. The Pharmacy must maintain a **personnel file** on each employee. Contractors (1099 licensed professionals) who work with and around Protected Health Information (PHI) must have a signed Business Associate Agreement and annual FWA and HIPAA training documentation.

Section 3.1.1: All Pharmacy Technicians must be competent to process and fill prescriptions for the Pharmacist's review. The Pharmacy must monitor performance in providing patient services. The Pharmacy must document personnel issues and how they are addressed within individual employee records. Procedures for contractors follow the same requirements.

An employee personnel file *must* include:

- Name, address, phone number(s) and date of hire
- W-4, I-9 and other required tax forms
- Verification of employment eligibility, credentials and continuing education
- Emergency contact information
- Documentation of annual work performance
- Documentation of health assurance
- Criminal background check, as required by law
- Signed HIPAA associate

Section 3.2 - Licenses, Registrations and Certifications

Section 3.2.1: The Pharmacy must display all federal, state or local licenses, registrations or certifications of the Pharmacy and all personnel who maintain a license or certification. This includes:

- Pharmacy licenses (all state licenses)
- DEA license
- Pharmacist licenses (all state licenses)
- Pharmacist Intern licenses
- Pharmacy Technician certifications and/or licenses
- Registered Nurses

Section 3.2.2: Proof of license verification is required.

Section 3.3 - Continuing Education (CE)

Section 3.3.1: The Pharmacy must develop, implement and maintain written or electronic staff education for all pharmacy employees, specific to the respective responsibilities and the individual tasks and services provided to patients. This education includes online courses.

Section 3.3.2: Pharmacist Continuing Education (ACPE) credits are maintained at the National Association for the Board of Pharmacies (NABP). Pharmacist must ensure sufficient CE credits are obtained to meet their state licensure requirement.

Section 3.3.3: Pharmacy Technician Continuing Education credits are maintained by the Pharmacy Technician Certification Board (PTCB). Certified Pharmacy Technicians must ensure sufficient CE credits are obtained to meet PTCB certification.

Section 3.3.4: Pharmacy staff annual education includes HIPAA Compliance; Fraud, Waste & Abuse; **OSHA** Bloodborne Pathogen; **OSHA** Hazard Communications; **OSHA** Fire Extinguisher and DEA Pseudoephedrine. Training should also include safe pharmacy practices, Continuous Quality Improvement program and pharmacy operational requirements for patient care.

The supplier must conduct a workplace hazard assessment to ensure compliance with OSHA.

Section 3.4 - Employee Manual

Section 3.4.1: The Pharmacy must prepare and provide an Employee Manual/Handbook. Each employee must receive or have available the current copy of the manual. An Employee Manual should not be the Pharmacy's policy and procedure manual. The manual must include at a minimum:

- Americans with Disabilities Act
- Code of conduct and ethics

- Confidential information requirements
- Emergency contacts
- Employee benefits
- Equal employment opportunity
- Health insurance
- Holidays
- Job descriptions for each position
- Pharmacy hours of business and closures
- Sexual harassment policy and reporting requirements

Section 3.5 - Background Checks

Section 3.5.1: Criminal background checks are required for all employees at the time of employment. An individual who has a criminal record is not automatically disqualified from employment. However, leadership must look at the individual offense as related to the employee's job tasks to determine the risk (i.e. a criminal record for drug distribution would not be a good fit in a pharmacy).

Section 3.5.2: If the employee indicates they have no criminal record on their employment application, but the background check reveals a criminal history, this is grounds for termination.

Chapter 4 – Fraud, Waste and Abuse Prevention

Section 4.1 – Compliance Program

Section 4.1.1: The Fraud, Waste and Abuse (FWA) compliance program must, at a minimum, include the following core requirements:

- Written policies, procedures and standards of conduct
- Compliance officer, compliance committee and high level oversight
- Effective training and education
- Effective lines of communication
- Well-publicized disciplinary standards
- Effective system for routine monitoring and identification of compliance risks
- Procedures and system for prompt response to compliance issues

Section 4.1.2: The Pharmacy must maintain Fraud, Waste and Abuse policies and procedures to meet Medicare Part D standards. Required policies and procedures are:

- General compliance
- Fraud, waste and abuse
- Medicare prescription drug coverage and your rights
- Anti-kickback
- False claims submissions

- Whistleblower protection
- OIG/GSA/SAM exclusion verification
- HHS Exclusion review process
- Conflict of interest

Section 4.1.3: These policies and procedures must implement business practices to prevent and control fraud, waste and abuse by using procedures that articulate standards of conduct to ensure the organization's compliance with Pharmacy and Medicare Part D standards, applicable laws and regulations.

Section 4.1.4: Overutilization of services or other practices that, directly or indirectly, result in unnecessary cost to the Medicare Program. Waste is generally not considered to be caused by criminally negligent actions, but rather the misuse of resources.

Section 4.1.5: Medicare Prescription Drug Coverage and Your Rights. The policy and procedure must explain the process when a drug is not on the Part D formulary and the method to give the patient a CMS 10147 appeal document. The Pharmacy must post the CMS 10147 form in the public area of the facility.

Section 4.1.6: Anti-Kickback. The policy and procedure must explain what a kickback is, how to report a suspected violation and the restrictions of the Stark Law.

Section 4.1.7: False Claims Submissions. The policy and procedure must explain and define what a false claim is and the reporting procedures.

Section 4.1.8: Whistleblower Protection. The policy and procedure must provide a clear process for receiving and managing issues and concerns of internal staff when a suspected violation is reported. The procedure must include measures to protect the individual who is making the report.

Section 4.2 – OIG/GSA/SAM Exclusion Verification Checks

Section 4.2.1: The Pharmacy must conduct monthly Exclusion Verification Checks with all three federal exclusion lists. No person or company associated with the Pharmacy that is on any exclusion list may work in, for or with the Pharmacy in any capacity. Proof of monthly exclusion reports must be maintained and available for review for 10 years.

Section 4.2.2: Federal exclusion lists are maintained by the following federal entities:

- OIG – Health and Human Services, Office of the Inspector General (provides oversight to the U.S. healthcare system)
- GSA – General Services Administration (purchases all equipment and supplies for the U.S. government)

- SAM – System of Awards Management (U.S. Contracting Officers list)

Section 4.3 – Conflict of Interest

Section 4.3.1: The policy and procedure must define a Conflict of Interest and the expectations of management, staff and 1099 employees. Every owner, member of a board of directors, professional staff and general workforce must sign a Conflict of Interest Certification which declares the individual has no financial or employment conflict with their current position.

Section 4.4 – Fraud, Waste and Abuse Training

Section 4.4.1: The Compliance Officer must train and educate employees, contractors and agents on compliance policies, procedures, internal monitoring and reporting of deficiencies. All employees who have direct or indirect access to medication dispensing and billing must complete annual Fraud, Waste and Abuse Training that meets or exceeds the Medicare Part D FWA Training requirements.

Section 4.4.2: A training log must be signed by each trainee and a FWA Training Certificate must be placed in the individual's personnel folder. These records must be available for surveyors and Medicare Part D inspectors and auditors.

Section 4.4.3: Management must document and keep records regarding compliance efforts (e.g. training, situations and actions taken).

Chapter 5 – Pharmacy Operations

Section 5.1 – Usual and Customary

Section 5.1.1: The Pharmacy shall have a procedure to develop and establish a medication's or product's Usual and Customary (U&C) price. The U&C is commonly referred to as the cash price for the product.

Section 5.1.2: The U&C pricing is submitted to insurance companies for reimbursements. The procedure must restrict cash patients from receiving a lower fee.

Section 5.2 – Patient Intake

Section 5.2.1: The Pharmacy must have a procedure established to receive new patients and gather all of the demographic, medical and insurance information.

Section 5.2.2: The Pharmacy must have procedures in place for partial filling of prescriptions and follow-up processes to ensure

the patient receives the balance of their prescription before the patient has exhausted the quantity in their possession.

Section 5.2.3: The Pharmacy must have procedures in place for receiving prescriptions from the prescribing physician.

Section 5.2.4: The Pharmacy shall have a process to enter prescriptions into the pharmacy dispensing software. The software will generally dictate the pharmacy workflow, from entering patient and prescription data, processing the prescription for payment and filling the prescription.

Section 5.2.5: The Pharmacy will ensure a properly licensed Pharmacist visually reviews each prescription by National Drug Code (NDC), the medication or product and the prescription before passing to the patient.

Section 5.3 – Electronic Prescribing

Section 5.3.1: The Pharmacy is to establish a procedure to receive and validate authenticity of electronic prescribing prescriptions, also known as eScripts. eScripts must follow the latest National Council for Prescription Drug Plans (NCPDP) format.

Section 5.4 – Medicare Prescription Drug Coverage and Your Rights

Section 5.4.1: The Pharmacy will ensure procedures are established so staff understands the Medicare Prescription Drug Coverage and Your Rights, CMS Form 10147. This form must be posted in the public area of the Pharmacy.

Section 5.4.2: The Pharmacy staff must understand the procedures when a “569” rejection error codes (provide beneficiary with CMS Notice of Appeal Rights). Procedure must include the following:

- Notify physician for an alternate medication which is in the Medicare Part D formulary.
- If no alternative is available, provide the patient with a CMS 10147 form.
- Charge the patient the usual and customary (U&C) fee.

Section 5.5 – Safe Medication Practice

Section 5.5.1: Procedures are to be established and implemented to ensure the ten 10 principal areas of safe medication practices as defined by the Institute for Safe Medication Practice (http://ismp.org). These areas are:

- Patient information
- Drug information
- Communication of drug orders and other drug information
- Drug labeling, packaging and nomenclature
- Drug standardization, storage and distribution

- Medication device acquisition, use and monitoring
- Environmental factors, workflow and staffing patterns
- Staff competency and education
- Patient education
- Quality process and **risk management**

Risk Management: reduce a certain type of event. Example: wrong medication, wrong patient, interaction, etc.

Section 5.6 – Sound-Alike/Look-Alike Drugs

Section 5.6.1: The Pharmacy must have procedures for segregating and identifying drugs that fall into the category of Sound-Alike and/or Look-Alike.

Section 5.7 – Mis-Fill Procedures

Section 5.7.1: The Pharmacy must have procedures in place to prevent a mis-fill of prescription drugs.

Section 5.7.2: The Pharmacy must have emergency procedures to contact the patient if a mis-fill of a medication is found after the patient has picked up their medication.

Section 5.7.3: Mis-fill prescriptions must be documented on a Quality Related Event (QRE) as defined in the Continuous Quality Improvement (CQI) section of this standard.

Section 5.8 – Auto-Fill/Auto-Ship Program

Section 5.8.1: Procedures must be implemented to prevent an Auto-Fill/Auto-Ship process without patient approval from occurring within the Pharmacy operations. There must be patient communication prior to all medication dispensing.

Section 5.9 – Patient Counseling Practices

Section 5.9.1: A patient counseling area must be established for patient/pharmacist counseling, which must be in a separate or discreet area of the Pharmacy.

Section 5.9.2: Procedures must be implemented so all patients are offered counseling with a licensed Pharmacist when medications are dispensed.

Section 5.10 – Return to Stock

Section 5.10.1: The Pharmacy will establish procedures to review the “Will-Call” bin weekly to identify any prescriptions that are filled but not picked up by the patient. The procedure must include the prescription claim being reversed from the Pharmacy computer system and medication being marked and placed in the pharmacy stock.

Section 5.10.2: If the medication is listed on a perpetual inventory log, the inventory must be adjusted on the log, if applicable.

Section 5.11 – Perpetual Inventory

Section 5.11.1: The Pharmacy's state Board of Pharmacy regulations may mandate a perpetual inventory of narcotics and controlled drugs. When required by state law or by individual pharmacy preference, a perpetual inventory for narcotics and Schedule II drugs will account for all specified drugs per individual inventory sheet, receipt of drugs received from drug wholesalers and other pharmacies and dispensing to patients.

Section 5.11.2: When perpetual inventories are used, the actual inventory within the Pharmacy must match the inventory log.

Section 5.11.3: Physical inventory count must be validated at least quarterly or as required by state law.

Section 5.11.4: Procedure must include reporting theft or loss of controlled medication to the Drug Enforcement Agency (DEA) and to the state if required.

Section 5.12 – Generic/Brand Price Disclosures

Section 5.12.1: The Pharmacy will establish procedures to notify patients who are requesting brand drugs that a generic is available and the price difference between brand and generic pricing, including co-pays.

Section 5.12.2: When required by state law, generic pricing signage will be posted within the public area of the Pharmacy.

Section 5.13 – Pharmacy-to-Pharmacy Drug Transfers

Section 5.13.1: Pharmacies will routinely assist neighboring pharmacies when a drug shortage occurs when filling a prescription for a patient. Drug wholesalers will normally replenish the Pharmacy's stock within 24 hours. When the Pharmacy receives from or sends a drug to another pharmacy, these transfers must be accounted for.

Section 5.13.2: The Pharmacy will establish procedures for accounting of all pharmacy-to-pharmacy medications and controlled drugs. The procedure will indicate whether the transfer is to be replaced when the item is received from the wholesaler or will be purchased. Replenishment is the normal process. In some states, transfer of medications to another pharmacy for payment is prohibited.

Section 5.14 – Drug Supply Chain Security (Track and Trace)

Section 5.14.1: The Pharmacy will establish procedures to comply with the Food and Drug Administration's (FDA) Drug Supply Chain Security.

Section 5.14.2: The Pharmacy must demonstrate the capability to track and trace the chain of custody of any drug by National Drug Code (NDC) and Lot Number from the original manufacturer through the transportation system to the Pharmacy. The Pharmacy has a 24-hour requirement to produce the documentation.

Section 5.15 – Drug Utilization Reviews

Section 5.15.1: The Pharmacy will establish procedures to provide comprehensive Drug Utilizations Reviews (DUR) of the patient's prescriptions to improve patient outcomes through alternate drug therapies. The procedure must include DUR procedures in three categories:

- Prospective
- Concurrent
- Retrospective

Section 5.16 – Non-Resident Pharmacy Delivery Procedures

Section 5.16:1: Each state has its own respective requirements for a pharmacy to ship medications and compounds to patients within the respective state. The Pharmacy must have reviewed the patient's state Board of Pharmacy's regulations to ensure compliance with pharmacy licensing and the Pharmacist who is preparing the medication for shipment to the respective state.

Section 5.17 – Retired and Expired Items

Section 5.17:1: Procedures must be established to review drug inventory to ensure medications on the Pharmacy shelves cannot be dispensed to a patient when the medication expires. It is recommended that any medication due to expire within six months should be removed from the shelf, quarantined and returned to the drug wholesaler or drug returns company.

Section 5.18 – Proper Hand Hygiene

Section 5.18.1: The Pharmacy will establish procedures for proper hand hygiene. The procedure must include, but is not limited to:

- Acceptable fingernail conditions, which are:
  - Nails must be no longer than ¼ inch in length (white part of nail)
  - Nails must be clean and free of debris
  - Nail polish cannot be chipped
  - Nail extensions are not recommended
- Proper hand-washing including the use of water and soap, rubbing hands and spending an appropriate length of time washing (including fingernails), rinsing and drying

- Hand-washing at the beginning of the shift, after breaks and after restroom breaks
- Use of gloves during the following but not limited to:
  - Administering immunizations
  - Cleaning up bloodborne pathogen spills
  - Non-sterile compounding
  - Simple compounding
  - Sterile compounding
- Varying types of supplies and anti-bacterial soaps, including:
  - Liquid anti-bacterial soap
  - Running hot water
  - Air-drier or single-use disposable towels
- Signage in restroom indicating all employees must wash hands prior to returning to work

Section 5.18.2: The Hazardous Communication Plan must include the following:

i. Name of the person responsible for ensuring labeling of containers
ii. The location of hazardous materials and hazardous waste
iii. A description of the OSHA Globally Harmonized System (GHS) labeling system
iv. The procedure for reviewing and updating label information
v. The procedure for reviewing and training OSHA GHS requirements
vi. Safety rules and procedures, including the cleanup and disposal of hazardous materials
vii. The procedure for reporting non-compliance
viii. The appropriate steps to limit exposure to employees
ix. The location of protective equipment
x. A plan for emergency evacuation
xi. A list of emergency phone numbers

Section 5.19 – Safe Glove Procedure

Section 5.19.1: The Pharmacy will establish a procedure for glove usage and proper glove removal to prevent contamination to the employee, coworkers, the patient or the workplace.

Section 5.19.2: Procedures must include bio-hazard procedures.

Chapter 6 - Pharmacist and Physician Collaboration

Section 6.1 - Overview

Pharmacist and physician collaboration is in important part of the patient's overall health care treatment plan. Interaction with the patient, physician and the Pharmacist ensures information is passed between every party. This is also a key component of a viable medication adherence program.

Section 6.2 – Confirming Prescriptions

The Pharmacy must establish procedures for confirming prescriptions with the physician when:

- a prescription is not legible,
- a prescription or eScript is not written correctly,
- a drug reaction with another medication the patient is prescribed occurs and
- when notification of patient non-adherence with medications is required.

Section 6.3 – Coordination of Treatment

The Pharmacy establishes procedures for coordination of treatment and care of patients at their residence. The physician may request compliance packaging, additional instructions for the patient and confirmation of refills.

Chapter 7 – Product Information, Delivery, and Documentation

Section 7.1 – Patient Intake Processes

Section 7.1.1: **Order Intake**. The Pharmacy should develop procedures for order entry for new patients into the Pharmacy computer software

Section 7.1.2: Patient Instructions.: The Pharmacy must provide drug information when dispensing medications to the patient. Patients are offered counseling on the dispense medications to cover side effects, when and how to take medication and any possible drug interaction.

Section 7.1.3: Patient Record. The Pharmacy must develop access controls to the Pharmacy computer system so unauthorized individuals cannot access patient records.

Order Intake Form may include:

- Type of equipment and service prescribed
- Pertinent diagnoses, including mental status
- Frequency of visits
- Prognoses
- Potential for rehabilitation
- Functional limitations
- Permitted activities
- Safety measures to protect against injury
- Instructions

Section 7.2 - After Hours Emergency Care

The supplier must provide patients with a telephone number to be used in the case of an emergency after facility business hours. This number should be able to contact the supplier at all times by beeper, home phone or cell phone. The emergency number is to be provided to the patient in written form upon delivery of an item and should be clearly noted on the facility's exterior entrance. All emergencies are to be addressed immediately and documented by the supplier in an emergency log and in the patient's record. Documentation should indicate the reason for the emergency, the action taken and the follow up with the patient.

Section 7.3 - Delivery Instructions

When a Pharmacy provides delivery services, delivery drivers must have procedures for delivering medications and other products to the patient, whether at their residence, assisted living facility, group home or anywhere else the patient may reside. Instructions must include:

- Collecting co-pays
- Communications with the patient or their representative
- Directions to the patient residence
- Policy when a patient or their representative is not home
- Securing delivery vehicle when leaving the delivery vehicle

Section 7.4 - Mail Order

Section 7.4.1: The Pharmacy must have procedures when medications and other products are mailed to the patient. Shipping method must include a delivery signature with an electronic receipt from the shipping company (FedEx, USPS, UPS). The patient must confirm and document the need for the medication and product prior to shipping.

Section 7.4.2: The Pharmacy will not ship Medicaid medications and products out of state.

Chapter 8 - Quality Assurance

Section 8.1 – Patient Safety

Section 8.1.1: Medication safety is paramount in the Pharmacy. Procedures must be established to ensure pharmaceuticals are properly labeled, marked and stored within the Pharmacy.

Section 8.1.2: Procedures to ensure Sound-A-Like/Look-A-Like medications are not inadvertently given to the patient must be established and followed.

Section 8.1.3: Procedures must be established to ensure proper dispensing, medication labeling, warning labeling and safety instructions are provided to the patient. Labeling is generated by the Pharmacy software system, but a check and balance system must be created to reduce the possibility of errors.

Section 8.1.4: Procedures must be established to receive notification of a medication recall by the drug wholesaler, DEA, FDA or any other agency. These processes must identify how to remove medication from the Pharmacy storage and how to contact patients who have received the recalled medication.

Section 8.1.5: Procedures must be established for patient consultation. Consultation must be in a separate or discreet area of the Pharmacy. Consultation must include:

- Allergies
- Medication administration
- Medication interactions
- Medication review

Section 8.2 – Continuous Quality Improvement

Section 8.2.1: The Pharmacy must implement procedures for a Continuous Quality Improvement (CQI) Program. The CQI program must define and implement a process for identifying, analyzing, reporting, managing and preventing adverse events, both preventable and non-preventable. The organization should utilize a standardized form to record and document Quality Relate Events (QRE). A copy of the Pharmacy's CQI program description and policies and procedures should be maintained and readily available to all Pharmacy personnel. The policies and procedures should address, at a minimum, a planned process to:

1. Train all Pharmacy personnel in relevant phases of the CQI program;
2. Identify and document all events that reach the patient, whether they caused harm or not;
3. A plan to minimize the impact of incidents that reach the patient;
4. Consider the collection of near misses and unsafe conditions to minimize the impact of potential patient harm;
5. Analyze QRE data collected to assess the causes and any contributing factors relating to the events;
6. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce future events; and
7. Periodically, but at least annually, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy

policies, procedures or systems or processes because of CQI program findings.

Section 8.2.2: Each Pharmacy shall conduct a Quality Self Audit at least quarterly to analyze the effectiveness of the CQI program. The analysis is to determine whether there has been compliance with preventative procedure.

Section 8.2.3: BOC strongly recommends the Pharmacy CQI program works with and reports to a Patient Safety Organization (PSO).

Section 8.2.4: If the Pharmacy is reporting to a PSO, all collected data and quality improvement work, documents, reported data and Peer Review related to quality improvement are considered "privileged and confidential" and shall not be released to individuals not part of the Pharmacy's patient safety evaluation system. The PSO utilizes the reported data for the purposes of encouraging a culture of safety and to provide feedback and assistance to the Pharmacy to minimize patient risk.

Section 8.2.5: Proof of a viable CQI reporting program is the presentation of a PSO Quality Certificate as proof of compliance with this standard. If the Pharmacy is NOT reporting to a PSO, all records and support materials are available for the surveyor to review to ensure compliance.

Section 8.2.6: The Pharmacy must develop procedures to document and measure all QREs. An investigation of all incidents must be initiated within 24 hours of the Pharmacy's awareness of the incident or a reaction resulting in the patient's seeking medical attention, or death. For other occurrences, the Pharmacy should investigate within 72 hours after being made aware of the incident.

Section 8.2.7: Workflow management practices must be established to reduce medication errors. These practices must also include the identification, reporting and corrective action on all suspected medication errors. This process includes but is not limited to:

- Documenting errors
- Reporting errors to Pharmacist-In-Charge
- Reviewing reported errors to identify source of error
- Retraining of individuals/staff so errors will not occur again

Section 8.2.8: Pharmacists must review all medications prior to dispensing. The Pharmacist must check the National Drug Code (NDC), medication origin container and medication against the prescription label and warning labels to ensure proper medication and dosage is dispensed.

Section 8.2.9: The PSO, if applicable, develops reporting and measuring requirements. This information is “Confidential” and “Privileged.”

Chapter 9 - Medication Adherence

Section 9.1 – Rating and Outcomes

Section 9.1.1: The Centers for Medicaid and Medicare Services established a Star Rating program to rate individual Medicare Part D Plans. The rating system is based on patient outcomes through the interaction of the patient and their pharmacist and physician collaborating on the patient’s overall health care. The Part D plans receive a Star Rating from zero to five with half-degree marks.

Section 9.1.2: Medication adherence is designed to ensure patients take their medications at the proper time of day, every day. Patients who are compliant with their medications are healthier and require less advanced medical care.

Section 9.1.3: The Pharmacy who maintains a working relationship with the patient and their physician will produce higher patient outcomes. The outcomes are reported monthly by the insurance companies to Electronic Quality Improvement Platform for Plans & Pharmacies (EQuIPP™). EQuIPP™ scores rate the Pharmacy against all pharmacies on a High Level (5 Star Rating) and the PSAO and State averages.

Section 9.2 – Medication Adherence Setup

Section 9.2.1: The Pharmacy must establish procedures to develop a medication adherence program. This program will manage patients, their medications and time of month dispensing.

Section 9.2.2: The medication adherence procedures must define the length of fills (28, 30, 90 days, etc.) and the type of dispensing packaging. The date the Pharmacy fills the patient’s medications is called the Synchronization Date or Sync Date.

Section 9.2.3: The Pharmacy must demonstrate they have access to Mirixa and OutcomesMTM to manage patient medication therapy management (MTM).

Section 9.3 – Marketing

Section 9.3.1: The Pharmacy must establish procedures for marketing to their patients for enrollment in the Pharmacy’s adherence program.

Section 9.3.2: The Pharmacy is permitted to market to the general public or a specific section. However, the Pharmacy may not purchase mailing lists for direct mail for a specific diagnosis.

Section 9.4 – Enrollment

Section 9.4.1: The Pharmacy must develop procedures and documentation to enroll patients into the medication adherence program. The enrollment application must explain to the patient that the Pharmacy will:

- call every month prior to filling their prescriptions,
- determine if there are any changes to their health and
- notify them when their medications are available for pickup or delivery.

Section 9.4.2: The procedure must define the process to notify the patient's physician when the patient is non-adherent with their medications.

Section 9.5 – Fulfilment

Section 9.5.1: Procedures must be established for the dispensing of medications within a Medication Adherence Program. The processes may be manual or through the Pharmacy's computer software.

Section 9.5.2: The established processes will identify the following:

- Patient's synchronized fill date
- Number of days prior to the sync date to call the patient
- New and requested prescriptions that are received prior to the sync date
- Workflow process:
  - Computer data input
  - Filling the prescription
  - Labeling the medication container
  - Establishing the method to provide medications to the patient

Section 9.6 – Medication Therapy Management (MTM)

Section 9.6.1: The Pharmacy must have procedures to ensure MTMs that are assigned by Mirixa or OutcomesMTM are received and MTMs are scheduled with the patient.

Section 9.6.2: When conducting a MTM with the patient, a licensed Pharmacist will conduct or oversee the MTM with a:

- Pharmacy Technician (a trained Pharmacy Technician may perform certain functions)
- Registered Nurse
- Certified Nurse Practitioner

Section 9.6.3: Complete the MTM within 30 days of assignment, which includes updating all information with Mirixa or OutcomesMTM software.

Chapter 10 - Immunizations and Vaccines

Section 10.1 – Policies and Procedures.

Pharmacies providing immunizations must have a policy and procedure manual which encompasses the Centers for Disease Control (CDC) and the Immunization Action Coalition (IAC) recommendations and OSHA Bloodborne requirements.

Section 10.1.1: Credentialing for the immunizer must be presented upon request. Credentials are regulated by each state. Credentials include: pharmacist licenses, pharmacist injectable licenses, Registered Nurses (RN) and Certified Nurse Practitioners (CNPT) licenses.

Section 10.1.2: The Pharmacy must establish a Vaccine Coordinator who is responsible for the overall control of vaccine storage.

Section 10.1.3: Immunizations must be conducted in a safe and clean environment. This area must be private. Use of fitting rooms or privacy curtains is permitted. The immunization process must include:

- Established storage requirements and inventory control
- Immunizations provided by a licensed Pharmacist Immunizer and/or Licensed Nurse or other healthcare professional operating under their licensure scope of practice
- Maintenance of current Standing Orders which are signed by a licensed physician
- Placement of Emergency Protocols and Medical Management of Vaccine Reactions signed by a licensed physician for adverse reactions
- Maintenance of an intake process which includes, at a minimum:
  - Screening questionnaires for adults, teens and children
  - Mass immunization rosters
  - Vaccine immunization records
  - Vaccine handouts
- Mandatory temperature control. Use of temperature monitoring thermometers is recommended by the CDC and is required for accreditation.
- Maintenance of a vaccine disposal policy Implementation of recommendations issued by the CDC and the IAC

Chapter 11 - HIPAA Compliance

Section 11.1 – Policy and Procedures

HIPAA Website: http://www.hhs.gov/hipaa/privacy.html

The Pharmacy must have a current **HIPAA** Compliance Policy and Procedure Manual. The policy and procedure manual must satisfy the requirements for both the HIPAA Privacy Rule and the Security Rule.

HIPAA Security and Privacy Rules: http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html

Section 11.1.1: Notice of **Privacy Practices** must be available upon request, posted in the public area of the Pharmacy and on the Pharmacy's website, if applicable.

Section 11.1.2: Develop a Risk Analysis using the National Institute of Standards and Technology (NIST). The Risk Analysis identifies potential threats to the Pharmacy in four main areas:

- Environmental
- Human
- Natural
- Technological

Section 11.1.3: Develop a Risk Management Plan using the NIST. The Risk Management Plan implements the recommended controls and alternate solutions for threats and vulnerabilities identified within the Pharmacy.

Section 11.1.4: Develop a Contingency Plan or Disaster Recovery Plan using the NIST. The Disaster Recovery Plan enables the Pharmacy to react to any type of disaster. This plan provides all contact information for key employees, vendors, software providers and wholesalers. The plan also identifies what a disaster is, when to implement the plan and establishes an alternate facility in the event the Pharmacy is damaged or destroyed.

Section 11.1.5: Develop procedures, review, analyze and evaluate all potential breaches. Determine if the breach is reportable to the Secretary of Health and Human Services.

Section 11.1.6: Procedures must be established to respond to patient complaints. Patient must be acknowledged in writing within five (5) calendar days of receipt of the complaint. An investigation of the complaint must be conducted and the results of the investigation must be given to the patient within fourteen (14) calendar days. If a personnel action is required, the patient will only be informed that action has been taken.

Chapter 12 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Section 12.1: Refer to BOC's DMEPOS Accreditation Standards.

A pharmacy that provides equipment or services *must* provide the following to patients and caregivers:

- Instructions
- Information regarding expected delivery time
- Verification of receipt
- Documentation of make and model
- Option to rent or purchase when applicable
- Contact information for regular business hours and after hours

Chapter 13 - Non-Sterile Compounding

Section 13.1: Refer to BOC's Pharmacy Compounding Accreditation Standards.