ACCREDITATION 30-MONTH COMPLIANCE CHECKLIST

PHARMACY

Use this checklist to audit your Pharmacy and operations 30 months after your survey visit. At this point, you are three to four months from your regular three-year visit. Have you submitted your application, deposit, and other requested information to your Accreditation Advisor? Visit your ACHC customer portal for more information.

Section 1: Organization and Administration
☐ All applicable licenses/pharmacy licenses/permits for each state serviced are displayed and current (Including states into which products are shipped).
☐ Board of Director/Governing Body minutes are properly documented.
☐ Organizational chart is up to date.
☐ Federal and state labor law posters are posted.
☐ Negative outcomes from sanctions, regulatory inspections, and/or audits have been reported, if applicable.
☐ Changes in ownership or managing employees have been reported, if applicable
☐ Surety bond and insurance documents are current and available for review.
☐ Policy and procedure manuals have been reviewed.

Section 2: Program Services and Operations
☐ Marketing materials are current and accurately reflect care/service provided, if applicable.
☐ A description of company services is provided to all new clients/patients.
☐ Client/Patient Rights and Responsibilities include all requirements.
☐ Client/Patient Rights and Responsibilities are distributed to all clients/patients.
☐ DMEPOS supplier standards are provided to all new Medicare clients/patients.
☐ Complaint information provided to clients/patients includes a telephone number, contact person, and the organization's process for receiving, investigating, and resolving grievances/complaints about its care/service, and ACHC's contact information.
☐ All grievances/complaints have been documented, invested, resolved and outcomes reported to leadership through the Performance Improvement (PI) committee.
☐ Business Associate Agreements (BAAs) exist as required by HIPAA.

Section 2: Program Services and Operations
☐ AIC emergency medication and supplies have been inventoried every 30 days to ensure correct inventory and non-expired products.
☐ Summary of ethical issues submitted to the governing body, if applicable.
☐ Mechanisms are in place to assist with language and communication barriers.
☐ The compliance program is complete and active. Compliance issues have been reported, documented, and corrective action taken as appropriate.
☐ The compliance program's effectiveness is monitored through the PI program.
☐ Services and a supervisor are available 24 hours a day, seven days a week as necessary (appropriate to the services provided) to meet client/patient needs.
☐ Hours of operation compliant with CMS are posted. (AIC, IRX, IRX-NO-797, SRX)

Section 3: Fiscal Management
☐ The budget includes projected revenue and expenses for all programs and care/service provided.
☐ The budget was reviewed and updated at least annually.
☐ Clients/patients are informed of their financial responsibility and insurance verification information at or prior to the receipt of care/service.
☐ Charges for care/service are available upon request.
☐ Financial Hardship forms were completed when clients/patients are unable to pay for the products/care/services provided.
☐ Prescriptions and medical necessity documentation are obtained as required by payors.

Section 4: Human Resource Management
☐ Complete personnel records are available for inspection. See DRX4-1C for required contents.
☐ All direct care personnel have been tested/screened for TB upon hire and as needed based on the annual TB risk assessment.
☐ All direct care personnel have access to the Hepatitis B vaccine.
☐ Job descriptions are consistent with the organizational chart.
☐ All direct care personnel have had a criminal background check, Office of Inspector General (OIG) exclusion list check, and national sex offender registry check.
☐ All personnel with access to client/patient records have had a criminal background check and an OIG exclusion list check completed.

Section 4: Human Resource Management
☐ Annual personnel evaluations have been completed, shared, reviewed, and signed by the supervisor and personnel.
☐ Source verification of all licensed/certified personnel was conducted and documented at hire and upon renewal.
☐ Ambulatory Infusion Center (AIC) personnel have been educated annually on the use of monitoring equipment.
☐ Orientation materials cover all required topics. All personnel have received an orientation.
☐ Competency assessments were completed upon hire and annually for personnel who set up, train, clean, test, repair and/or educate the use of equipment, medication, and/or supplies.
☐ For infusion pharmacies annual or semi-annual media fill testing, gloved fingertip sampling, didactic training and testing consistent with the risk level of compounding were completed. (IRX)
☐ Ongoing education containing all topics required by standards has been completed.
☐ Current copies of professional liability insurance certificates for all contract personnel/shared service organizations are available.
☐ Contracts/Agreements with outside organizations/personnel are reviewed upon renewal and are available.

Section 5: Provision of Care and Record Management
☐ An accurate record is maintained for each client/patient.
☐ All client/patient records are safeguarded against lost or unauthorized use.
☐ Audits of client/patient records are being completed to ensure compliance with all regulatory and payor requirements.
☐ All clients/patients referred for care/service have had an evaluation/assessment of need completed.
☐ There is a written plan of care/service or medication action plan for each client/patient accepted. Reviews have been completed as required by standard.
☐ There is a medication profile for each client/patient accepted. Reviews have been completed as required by standard.
☐ Receipt of all education is documented in the client/patient record.
☐ Products or services provided to current clients/patients were requested by the physician or client/patient.
☐ Prescriber credentials have been verified.
☐ Clients/patients are notified of when equipment/supplies will be delivered. (MORX, SRX, SRXONLY)

Section 5: Provision of Care and Record Management
☐ Prescribers/referral sources have been notified within 5 days if the equipment/service could not be provided. (N/A to MORX)
☐ Transfer/discharge activities and documentation meet standard requirements.
☐ Drugs/routes not approved for administration are identified. (AIC, IRN)
☐ Proof of delivery is documented in each client/patient record.

Section 6: Quality Outcomes/Performance Improvement
☐ There is an effective, ongoing, organization-wide PI Program.
☐ There is an individual responsible for coordinating PI activities.
☐ Quarterly PI meetings (MORX, SRX, SRXONLY) and quarterly PI reports have been completed.
☐ Annual summaries of PI activities have been completed.
☐ Specialty Pharmacy providers also include additional requirements of standard in their annual PI summary.
☐ PI activities must monitor at a minimum:
☐ Adverse events
☐ Client/patient grievances/complaints
☐ Client/patient records
☐ Satisfaction surveys of clients/patients, and input from personnel and referral sources
☐ Billing and coding errors for DMEPOS products
☐ At least one important aspect related to care/service provided
☐ Ongoing monitoring of processes that involve risks including infections and communicable diseases (if applicable)
☐ Review of care/services provided under a contract/agreement.
☐ Payor contracts/agreements and data collection requirements (SRX/SRXONLY)
☐ Ongoing monitoring of prescription activities (MORX)
☐ Client/patient educational materials have been reviewed annually (MORX)
☐ All personnel are involved in the PI program.
☐ Each PI activity/study has the following defined:
☐ A description of indicator(s) to be monitored/activities to be conducted

Section 6: Quality Outcomes/Performance Improvement
☐ Frequency of activities
☐ Designation of who is responsible for conducting the activities
☐ Methods of data collection
☐ Acceptable limits for findings
☐ Who will receive the reports
☐ Written plan of correction when thresholds are not met
☐ Plans to re-evaluate if findings fail to meet acceptable limits
☐ Any other activities required under state or federal laws or regulations
☐ Client/patient incidents, accidents, variances, and unusual occurrences are documented and investigated.

Section 7: Risk Management: Infection and Safety Control
☐ There is an effective infection control program that protects clients/patients and personnel by preventing and controlling infections and communicable diseases.
☐ Annual TB risk assessments have been completed.
☐ Infection control tracking of personnel and clients/patients (N/A to MORX) has been analyzed for trends.
☐ Infection control education has been provided to personnel and clients/patients.
☐ Personnel follow infection control procedures.
☐ Personnel have received safety training and training on home safety.
☐ Annual evaluations of the adequacy of the emergency preparedness plan have been completed.
☐ Clients/patients/caregivers receive emergency preparedness education. (N/A to MORX)
☐ Smoke detectors, fire alarms, and extinguishers are placed in secure areas and have been inspected, maintained, and tested on a regular basis as recommended by the manufacturer.
☐ Exits are clearly marked.
☐ A first-aid kit is available and of appropriate size (check for any expired products).
☐ Eyewash is available (check for expiration date).
☐ Fire drills and tests of backup power systems have been conducted at least annually.
☐ Hazardous waste, chemicals, and materials are handled/stored/labeled appropriately. Current Safety Data Sheets (SDS) are accessible to personnel.

Section 7: Risk Management: Infection and Safety Control
☐ Documentation is kept to verify that storage area(s), refrigerator, and freezer temperatures maintain the appropriate storage condition as described in USP <659>.
☐ Verification that temperature sensing devices are verified and if necessary, calibrated in conformance to NIST standards. (IRX)
☐ The cleaning and disinfecting process, including the disinfection agent used for pharmaceutical storage areas is documented. (N/A to IRX-NO797)
☐ Equipment used for preparing, dispensing, labeling, and shipping preparations have been tested, calibrated, and cleaned as required. (N/A to AIC, IRN)
☐ The shipping system utilized has been either validated by a third-party or by internal studies for the environmental extremes experienced by transported pharmaceuticals. (N/A to IRX-NO797)
☐ Enteral products are stored in the required environment (e.g., refrigerated or room temperature, as required). (N/A to AIC, IRN)
☐ Personnel incidents, accidents, variances, and unusual occurrences are documented and investigated
☐ Warehouse products are properly segregated and stored.
☐ Expired products are separated, removed, and disposed of.
☐ Products with lot and/or serial numbers are tracked and manufacturer recalls have been properly addressed.
☐ Cleaning, testing, and calibration of equipment, including client/patient monitoring equipment have been completed per manufacturer's guidelines.
☐ Routine/preventative maintenance and repairs have been completed per manufacturer's guidelines.
☐ Infusion pharmacy clean rooms have had certifications every 6 months.
☐ Personnel who access the buffer room are authorized, trained, and competent staff or visitors who comply with garbing and gloving policies.
☐ Appropriate equipment cleaning agents are used (if applicable).
☐ Resuscitative carts/boxes have been inventoried every 30 days to ensure correct inventory and non-expired products. (AIC)
☐ Emergency medication and supplies have been inventoried every 30 days. (AIC)
☐ Client/patient care area cleaning/disinfection logs. (AIC)
☐ Call logs/tracking systems are operational and results are reviewed.
☐ Pharmacies performing sterile and non-sterile compounding have reviewed their infusion practices to ensure they are in compliance with USP General Chapter <797>, USP<71>, if applicable, and USP <85>, if applicable.

Section 7: Risk Management: Infection and Safety Control
☐ AICs preparing aseptically mixed single dose product for single patient use have prepared doses and educated and evaluated personnel as required by policy.
☐ Risk Evaluation Mitigation Strategy (REMS) protocols have been followed. (MORX, SRX, SRXONLY)
☐ Clinical Laboratory Improvement Amendment (CLIA) procedures and state regulations for waived tests have been followed (if applicable). (AIC, IRN, IRX)
☐ The evacuation plan has been evaluated annually. (AIC)