

# ITEMS NEEDED FOR SURVEY

## CUSTOMIZED FOR INFUSION PHARMACY (IRX), INFUSION PHARMACY WITHOUT STERILE COMPOUNDING (IRX-NO797), INFUSION NURSING (IRN), SPECIALTY PHARMACY (SRX), SPECIALTY PHARMACY ONLY (SRXONLY), & AMBULATORY INFUSION CENTER (AIC)



PHARMACY

Below are items the Surveyor will review during your Accreditation Commission for Health Care (ACHC) survey. Please have these items available before your Surveyor's arrival to expedite the process. If you have any questions, please contact your Account Advisor.

- Policy and procedure manual and crosswalk, if applicable
- Current list of active clients/ patients by type and service dates, or a copy of Explanation of Benefits (EOB)/third- party payment documents from the past six months to allow the Surveyor to choose client/patient files
- Script fill/appointment schedules (provide the Surveyor the schedule on the day of survey)
- Discharge/transfer client/patient census for past six months or since the start of operation if less than one year
- Personnel list with titles, disciplines and start dates (including direct care contract personnel)
- Admission packet and educational materials given to clients/patients (DRX2-2A, 2-2A.01,2-2C,2-4C,2-5A,2-6A,5-5B-E,7-4C, 7-16A)
- Personnel meeting minutes if they contain documentation of required annual in-services (DRX4-8A)
- Governing body meeting minutes for the past 12 months, if applicable

ACHC Standard	Required Items	Located
Multiple	<p>Access to policy and procedure manual with the following policies and procedures flagged:</p> <ul style="list-style-type: none"> <li>■ DRX2-4A: Grievance/complaint process</li> <li>■ DRX2-5A: Health Insurance Portability and Accountability Act (HIPAA) policies and procedures</li> <li>■ DRX2-9A: Compliance Program</li> <li>■ DRX4-7A: Minimum education, training, and competencies for personnel</li> <li>■ DRX5-11B: Shipping procedures</li> <li>■ DRX6-1A: Performance Improvement (PI) Program/policies</li> <li>■ DRX6-3F/7-11A: Handling incidents</li> <li>■ DRX7-7A: Medication and product recall</li> </ul>	

ACHC Standard	Required Items	Located
	<ul style="list-style-type: none"> <li>■ DRX7-12A: Use of equipment and supplies in the provision of care</li> <li>■ DRX7-14A: Calibration and cleaning of equipment used for dispensing, labeling, and shipping of medications</li> </ul>	
DRX1-1A, B	Copy of current applicable licenses or permits	
DRX1-2A	List of governing body members, documentation of orientation, and, if applicable, signed confidentiality statement(s)	
DRX1-5A	Organizational chart	
DRX1-7A	All required federal and state posters are placed in prominent locations	
DRX1-10A/B	Prior negative regulatory inspection reports (board of pharmacy, Food and Drug Administration [FDA], Drug Enforcement Agency [DEA], and fire department)	
DRX2-1A, B	Marketing materials	
DRX2-4A/B	Grievance/complaint log* or plan to enact this standard once accredited	
DRX2-5C	Business Associate Agreements (BAAs)	
DRX2-6C	Resuscitation cart inventories (AIC)	
DRX2-6D	Emergency medication and related supplies inventories (AIC)	
DRX2-7A	Reports of ethical issues provided to organizational leaders, if applicable	
DRX2-9A	PI activity to monitor the compliance program	
DRX2-10D, DRX4-9C, D	On-call calendar/logs	
DRX2-10F	Tracking logs for communication/call abandonment and response time frames in which communications are answered (SRX, SRXONLY)	
DRX3-1A,	Annual operating budget**	
DRX3-4A	Listing of client/patient care charges	
DRX3-5A	Financial hardship applications/documents, if applicable	
DRX4-1C	Personnel records contain evidence of the items listed in the standard	
DRX4-2I	Employee handbook or personnel policies	
DRX4-2K	For cause or post-accident drug testing results for personnel with access to pharmaceuticals (SRX, SRXONLY)	
DRX4-6A	Orientation checklist or other method(s) to document orientation	
DRX4-7A, DRX4-14B, C	Competency evaluation** and/or training materials, if applicable (AIC, IRN, IRX, SRX, SRXONLY) Didactic training/testing, media fills, fingertip testing**, training on cleaning/disinfecting procedures and hand hygiene/garbing (IRX)	
DRX4-8A	Evidence of ongoing education** and written education plan	
DRX4-11C	Contracts and copies of professional liability insurance certificates for personnel/ organizations providing direct care or shared responsibility for care/service	
DRX4-14F	Personnel training records on equipment use (setup, pickup, and maintenance), if applicable	

ACHC Standard	Required Items	Located
DRX4-15B	Reference library (SRX, SRXONLY)	
DRX5-1A (Review client/ patient records in advance of survey for required contents)	Client/patient records containing information according to the requirements specified in this standard and as specified in other standards pertaining to client/patient record information (DRX2-2, 2-4, 2-5, 2-6, 3-4, 3-5, 3-6, 5-1, 5-2, 5-4, 5-5, 5-6, 5-7, 5-15, 5-17, 7-4, 7-7, 7-8, 7-9, 7-10, 7-12, 7-16, 7-17, 7-18, 7-21)	
DRX5-6A, DRX7-7A, DRX7-8E, F, DRX7-12A	Recall logs	
DRX5-12A	Referral log or similar tool	
DRX5-17C	Training and competency testing for administration guidelines and monitoring requirements (AIC only)	
DRX6-1A	Performance Improvement (PI) Program	
DRX6-1B	Job description for the individual responsible for the PI program	
DRX6-1D, G	PI annual report** (if PI Program has been in place >1 year)	
DRX6-1E, F	Quarterly PI meeting minutes (SRX, SRXONLY) and reports (AIC, IRN, IRX, SRX, SRXONLY)	
DRX6-2A	PI activity descriptions** and plans of correction**	
DRX6-3A-G	Completed PI activities** (or for initial surveys, data collection tools to be used once data is able to be collected)	
DRX6-3F, DRX7-11A	Incident reports/logs**	
DRX6-3I	Monitoring of contracted care/service providers**	
DRX6-3J	PI reports for monitoring of contracted care/service providers (SRX, SRXONLY)	
DRX7-1A	Annual TB risk assessment,** TB exposure control plan, Occupational Safety and Health Administration [OSHA] Bloodborne Pathogens plan, and infection control educational material for clients/patients	
DRX7-1D	Infection control tracking logs** and PI reports** for tracking trends	
DRX7-4A	Emergency disaster plan and results of annual emergency disaster drill evaluation**	
DRX7-5B	Report of annual fire drill** and emergency power tests**	
DRX7-6B	Access to Safety Data Sheets [SDS]	
DRX7-8E, DRX7-8M	Dispensing/compounding records (IRX)	
DRX7-8F	Temperature and humidity logs for pharmaceutical storage areas (IRX)	
DRX7-8G	Calibration and maintenance logs of equipment used for preparing, dispensing, labeling, and shipping (IRX)  Verification that temperature sensing devices are verified and if necessary, calibrated in conformance to NIST standards (IRX)	

ACHC Standard	Required Items	Located
DRX7-8J.01	Documentation of labeling errors and discrepancies (IRX, IRX-NO797, SRX, SRXONLY)	
DRX7-8K	Certificates of Analysis [CofAs] (IRX)	
DRX7-8L	Master Formulation Records [MFR] (IRX)	
DRX7-8P	Controlled air environment cleaning logs, certifications, air pressure differential monitoring, viable airborne particle sampling, and surface sampling (IRX)**	
DRX7-8Q	Sterility and endotoxin testing documentation (high-risk IRX)	
DRX7-9A	Temperature logs for pharmaceutical storage areas (AIC, IRN, IRX-NO797, SRX, SRXONLY)  Documentation of cleaning and disinfecting including the cleaning/disinfection agent used  Verification that temperature sensing devices are verified and calibrated in conformance to NIST standards	
DRX7-9B	Shipping/delivery container temperature testing and cleaning records Shipping system third party validation studies, if applicable	
DRX7-9D	Training and competency assessment in aseptic processes for aseptically mixed single dose products (AIC only)  List of products that may be aseptically mixed (AIC)	
DRX7-11A	OSHA forms 300, 300A, and/or 301, if applicable	
DRX7-12A	Cleaning, testing, maintenance, and calibration logs of equipment used in the provision of care (IRN, IRX, IRX-NO797, SRX, SRXONLY)	
DRX7-14A	Cleaning, testing, maintenance, and calibration logs of equipment used for dispensing, labeling, and shipping of medications (SRX, SRXONLY)	
DRX7-19A, C	Clinical Laboratory Improvement Amendment [CLIA] certification of the lab where specimens are referred for testing; calibration and maintenance of equipment used for waived tests; and documentation of quality controls, if applicable (AIC, IRN, IRX, IRX-NO797)**	
DRX7-19B	Training of personnel to perform waived tests, if applicable (AIC, IRN, IRX, IRX-NO797)	
DRX7-20A	Calibration and maintenance records for equipment used while monitoring patients receiving infusion therapy (AIC)	
DRX7-20C	Annual evaluation of evacuation plan* (AIC only)	

\*\* Provide for the past three years if a renewal.