

	COMPLIANCE ELEMENTS	DESCRIPTION	RESPONSIBLE COMMITTEE	FREQUENCY	POLICIES & RECOMMENDED CONTENT
HU	MAN RESOURCES				
1	Personnel File Documentation	Review personnel files to ensure required documents are accurate and up to date	Human Resources	Upon hire and annually	Personnel Policy
2	Onboarding and Ongoing Training	Review required training to ensure completion and documentation	Human Resources; Manager	Upon hire and annually	<ul> <li>Employee Orientation Policy</li> <li>Orientation checklist.</li> <li>Employee Education Policy</li> <li>Program frequency and methods.</li> </ul>
3	Initial and Ongoing Competencies	Review competencies to ensure applicability, documentation, and completion	Manager	Upon hire and annually	<ul> <li>Employee Performance Policy</li> <li>Performance assessment.</li> <li>Re-training procedures (if necessary).</li> <li>Corrective action(s).</li> </ul>
PA1	TIENT MANAGEMENT	•		•	
4	Clinical Protocols	Review and revise clinical protocols/care plans to ensure adherence to current evidence-based medicine	Quality/Accreditation Manager	Annually	Patient Management Program Policy  Define initial and reassessment periods for patients enrolled in the patient management program (PMP).  List disease states included in the organization's PMP.  Criteria for enrollment in the PMP.  PMP oversight.



5	Patient Care	Audit patient records for	Quality/ Accreditation	Quarterly	Patient Management Program Policy
		compliance with accreditation, legal and best practice criteria	Manager		<ul> <li>Define elements of the plan of care that will be addressed during initial assessment and reassessment of patients enrolled in the PMP.</li> </ul>
					<ul> <li>List required documentation criteria for patient assessments.</li> </ul>
					<ul> <li>Define the timeframe for completion of clinical documentation in the patient record.</li> <li>Establish metrics/goals for documentation accuracy.</li> </ul>
6	Patient Educational and	Review and revise	Clinical Committee	Annually	Patient Education Policy
	m N	patient educational and marketing materials; Maintain a systematic method of tracking			<ul> <li>List type(s) of non-verbal patient education materials utilized and how confirmation of receipt/understanding of materials is obtained.</li> <li>Describe the approval process and target literacy level for patient education materials to be utilized.</li> <li>Describe the procedure for providing interpreter services and/or any other necessary accommodations.</li> <li>Marketing Communications Policy</li> </ul>
					<ul> <li>Define the approval and review process for provider/client/patient-facing marketing materials.</li> </ul>
					Patient Management Program Policy
					Patient Rights and Responsibilities, including:
					<ul> <li>Methods for including patient/caregiver in the shared decision making, plan of care, etc.</li> </ul>



7	Patient Management Program Evaluation	Review and Revision of Clinical, Financial, QOL, and other outcomes	Clinical Committee	Annually	Establish achievable program goals: Clinical, Financial, Health-Related Quality of Life (HR-QOL), clinical intervention outcomes.     Describe the process for developing and revising program goals, evaluating the impact/success of program.
					<ul> <li>Describe organizational oversight and leadership involvement in the program evaluation.</li> </ul>
OPE	ERATIONS				
8	Shipment Testing	Audit results of shipment	Quality Committee	Biannually (seasonally)	Pharmacy Distribution Policy
		testing to ensure appropriate temperatures are maintained			<ul> <li>Describe cold chain and room temperature testing procedures. Include packaging method, how these are validated, and criteria for modification after validation test failure.</li> <li>Describe the process for confirming team members are packing shipments correctly based on temperature profiles and delivery locations.</li> <li>Describe procedures for packaging selection based on temperature profiles and shipping locations.</li> </ul>
9	Dispensing and	Review and analysis of	Quality Committee	Quarterly	Pharmacy Distribution Policy
	Distribution Accuracy	dispensing and distribution accuracy for trends			<ul> <li>Procedures for handling:         <ul> <li>Delayed shipments (patient notifications).</li> <li>Holding shipments.</li> </ul> </li> <li>Lost/stolen shipments.</li> <li>Quality Assurance Policy         <ul> <li>Describe how error and near-miss data is used to inform decision making and Quality Improvement (QI) initiatives.</li> </ul> </li> </ul>



10	Proactive Risk Assessments  IENT EXPERIENCE	Audit of new medications dispensed and completion of proactive risk assessment	Clinical Committee	As needed and quarterly	Medication/Product Risk Assessment Policy     Describe the Medication Risk Assessment procedure.     Describe how hazardous medications are identified, resources available to staff, etc.     Methods for categorizing drugs (e.g., Specialty, Non-Specialty, other).
11	Phone Metrics	Review of phone metrics such as abandonment, speed of answer, and call volume; Analyze for trends and implement action plans when needed	Quality Committee	Monthly and quarterly	Define performance metrics for call center staff (time to answer, abandonment rate, service level, etc.).      Define how data is used to inform decision making and QI initiatives.
12	Patient and Provider Complaints	Review patient and provider complaint logs; Analyze for trends and implement action plans when needed	Quality Committee	Quarterly	How data is used to inform decision making and QI initiatives.     Internal procedure for complaint escalation, investigation, and resolution timeframe.     Explain how the organization will communicate to consumers: (patients, clients, providers) how they can file a complaint, the expected resolution timeline, etc.
13	Patient and Provider Satisfaction	Distribution and analysis of patient and provider satisfaction	Quality Committee	Annually	Define procedures for collecting patient/provider/client satisfaction data.     Define how data is used to inform decision making and QI initiatives (action plans).



REG	REGULATORY & QUALITY					
14	Business Continuity Plan	Develop business continuity plan and testing exercises to include all critical systems	Quality Committee	Annually	Policy  Describe procedures in place for immediate emergency response and recovery of operations.  List the chain of command and succession plan. emergency contacts (boards of pharmacy, DEA, accrediting organizations, etc.).  Define the frequency of testing for emergency plans and other relevant exercises (e.g., fire drill).	
15	Licensure, Rule, and Regulation Monitoring	Monitor and track state and federal laws and regulations	Compliance Officer; Quality/Accreditation Manager	Quarterly	Rules & Regulations Policy     List the agencies tracked and how changes to laws and regulations are communicated to staff.     Define responsibility (which staff track which organizations for updates to laws & regulations).     Describe the primary source verification process.     Attest that the pharmacy complies with all federal, state, and local laws governing its business.     Include any relevant Board of Pharmacy requirements (e.g., the WV Pharmacy Law Book must be available to all staff, on-site).	
16	Annual Quality Program Evaluation	Assess compliance with annual reports and evaluations of the program	Quality Committee	Annually	Quality Assurance Policy     List individual staff/roles involved in the Quality Program Evaluation process.     Describe the required annual report(s) and approval authority.     Define how program effectiveness is measured and thresholds for action	