ASCO® Standards NCODA

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
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| **Topic** | **Standard** |
| **Domain 1. Patient-Centered Quality Standards** | |
| **1.1.** Health equity and social determinants of health | **1.1.1.** Patients should be evaluated for social risks, health literacy, diagnosis and/or disease perceptions, and medication beliefs before prescribing oral anti-cancer medications. Refer to community and practice resources, such as NCODA's process, as appropriate. |
| | **1.1.2.** Patient care should be tailored to address cultural, linguistic, and socioeconomic factors. |
| **1.2.** Patient communication and documentation | **1.2.1.** Patient onboarding activities should include an explanation of the specialty pharmacy process, including the affiliation and close working relationship with the prescribing physician and healthcare team. |
| | **1.2.2.** Activities focused on securing drug access by coordination and submission of prior authorization, evaluating patients' ability to afford co-pays, and seeking financial assistance or support programs to ensure therapy initiation should be a seamless transition by accessing and providing documentation in the patient record. Point of contact, if someone other than the patient, including confirmation of authorization under HIPAA, should also be included. |
| | **1.2.3.** A direct phone line must be available during normal business hours for immediate assistance. Messages left on this line should aim to be returned within the same business day, but no later than 24 hours. Patients should have access to 24/7 support. If an answering service or other technology is utilized, the pharmacist or staff members should be available for call-back within a reasonable timeframe. A phone tree must be in place appointing alternate points of contact for escalation if needed. Patients should be provided with clear instructions on how and when to contact the pharmacy, including, but not limited to, questions about medication use, side effects, potential adverse events, reporting missing or damaged medications, and requesting refills or updates on prescription orders. All information should be provided to the patient verbally and in writing with their prescription medication. |
| | **1.2.4.** Pharmacies may utilize technologies that facilitate remote communication, which may include telehealth, apps, and electronic portals. |
| | **1.2.5.** Every patient encounter should be documented in the patient record. In most cases, this would be an electronic medical record, and the Expert Panel for these standards endorses the use of electronic documentation. All questions posed by the patient or guardian and/or caregiver, related to process or clinical matters regarding therapy, should be documented in the patient's record. In cases where the patient cannot be reached, attempts should be documented, and follow-up should be coordinated with the extended medical team during the next scheduled clinic visit, as appropriate. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| | **1.2.6.** All tools used to communicate with patients must be compliant with the Health Insurance Portability and Accountability Act and sanctioned by the MIP's affiliated institution or practice. |
| **1.3.** Benefits investigation and access coordination | **1.3.1.** Staff members within the MIP with specialized expertise should be assigned to each respective step of the patient journey to ensure coordinate and comprehensive access to care. |
| | **1.3.2.** All aspects of benefit investigations will be coordinated by the MIP, including primary and secondary insurance coverage, determination of formulary coverage including preferred drug or step edit requirements, prior authorization requirements and completed submission including biomarker testing, patient out-of-pocket cost inclusive of deductibles and co-pay amounts, evaluation for financial assistance eligibility, and comprehensive support for program enrollment including but not limited to charitable foundation, patient assistance programs, low-income subsidy programs, manufacturer co-pay cards or assistance programs, or the Medicare Prescription Payment Plan as applicable. A non-pharmacist MIP team member (e.g., pharmacy technician) may assist in managing the patient medication acquisition process, discussions with the patient, and completing applications on the patient's behalf.[1] |
| | **1.3.3.** Prescription benefits should be documented in the patient's record. |
| | **1.3.4.** The MIP will implement strategies and standard operating procedures to address prescription abandonment due to financial toxicity or situations where a filled prescription is not picked up. |
| **1.4.** Education and medication dispense | **1.4.1.** Before initiation of therapy with an oral anti-cancer medication, a formal patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician's assistant. The discussion should include drug name (generic and brand), dose and schedule, potential adverse effects and how to properly manage them, potential drug-drug interactions, fertility (if applicable), treatment goal, duration of therapy, storage and handling, and financial and affordability considerations.[2-4] |
| | **1.4.2.** An informed consent form (or assent if applicable) outlining the intent of therapy should be reviewed with the patient (and their caregiver, if applicable) by a patient educator. The patient consent may be provided verbally or by signing a consent form. The patient should provide consent only after all questions have been addressed. For written consent, the patient will receive a copy for their records, and the original document will be included in the patient's record. Verbal consent should be documented as determined by institutional policy. |
| | **1.4.3.** Members of the MIP team should identify whether a patient has a caregiver, and if so, emphasize the importance of educating the caregiver in addition to the patient. |
| | **1.4.4.** Patient education should include diagnosis and the medication being dispensed. The patient's ability to understand the treatment plan and self-administer medication should be assessed. Additionally, a thorough review of current medications, allergies, and baseline lab results should be conducted to ensure safety and efficacy. |
| | **1.4.5.** At the time of any new therapy initiation, written patient education should be provided. This information should be provided in plain language with translation options wherever possible. The clinician should use techniques such as a teach-back to confirm that the patient understands the information contained in the written materials. |
| | **1.4.6.** Patient education must comply with federal, state, and Risk Evaluation and Mitigation Strategy requirements when applicable. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
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| | **1.4.7.** Educational materials should be provided in multiple formats and may include medication kits with supportive care resources, self-care management strategies, as well as assistance in procuring devices or tools for self-monitoring when applicable.[5] |
| | **1.4.8.** The MIP will confirm medication dispense, confirm logistics for delivery or pick-up, maintain clear communication on any delays, and/or address any issues that may arise in this process. |
| | **1.4.9.** The MIP should document the exact date the patient begins therapy, in both the medical and pharmacy records, serving as the baseline for monitoring therapy effectiveness, adherence, and potential adverse events and aligned to the MIP care plan for patient follow-up on first dose experience, immediate concerns, and adherence review and reinforcement. |
| **1.5.** Adherence | **1.5.1.** A baseline adherence assessment should be conducted prior to dispensing the medication to evaluate potential barriers and risk of nonadherence. A specific nonadherence risk assessment tool, such as the one jointly developed by NCODA and Oncology Nursing Society, may be utilized for this purpose. This assessment should be completed prior to providing formal education and initiating therapy. Identified barriers to adherence should be addressed, and appropriate interventions implemented, to mitigate barriers and provide patient support before treatment begins. |
| | **1.5.2.** A multidisciplinary collaborative approach to monitoring adherence is recommended.[6-10] |
| | **1.5.3.** The MIP may provide calendars or other scheduling communications. If a patient calendar is provided, the calendar should include refill dates and medication schedules, clearly outlining specific dates to take medication, as well as laboratory and other monitoring parameters (e.g., electrocardiogram and/or echocardiogram) and clinician visits. A visual calendar may be helpful to illustrate combined oral and intravenous regimens. Include documentation of calendar information in the patient record. |
| | **1.5.4.** Use of an electronic portal, app, or written tool to obtain patient-reported outcome measures is encouraged.[11-15] |
| | **1.5.5.** Communication with patients and educational follow-up is essential to determine comprehension and retention of initial instructions, adherence, and toxicities.[16-18] Communications should be tailored to specific medications and patient comorbidities; re-education may be required. Subsequent follow-up calls to the patient should have a drug-specific cadence based on the anticipated time to onset of potential adverse events and be tailored to individual patient characteristics and risk factors, such as education, comprehension, performance status, tolerance to previous therapies, etc. |
| | **1.5.6.** The physician must be directly notified by the MIP team of any issues related to patient compliance, including delayed therapy initiation, tolerability, missed doses, in-home inventory, or missed lab appointments. |
| | **1.5.7.** Oral anti-cancer medication should be dispensed in the original container as directed by the label. If medication is not dispensed in the original container or blister pack, pill caddies may be appropriate and helpful for patient adherence. |
| | **1.5.8.** The MIP should continually evaluate electronic and manual tools that may be helpful in advancing patient adherence. Smart pill bottles and mobile apps may be utilized to increase adherence.[6,19-24] |

 

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| | **1.5.9.** The MIP should assess patient adherence and monitor toxicity at each clinical encounter. Metrics such as medication possession ratio or proportion of days covered can help evaluate adherence but have limitations when applied to oral anti-cancer medications. Therapy interruptions, such as those for toxicity management or disease response evaluation, require direct patient engagement and clinical context to provide a complete picture of adherence. Any variances, such as drug holidays or dose holds, should be documented within the patient record. |
| | **1.5.10.** Adherence assessment and documentation should include (1) confirmation the patient received the prescription, (2) the start date for the medication, and (3) verification that the patient fully understands how to take the medication, including the number of pills to take, specific days the medication should be taken, the dosing frequency per day, particularly for intermittent dosing, whether the medication should be taken with or without food, and instructions on safe handling. |
| | **1.5.11.** Ongoing drug utilization reviews should be conducted to verify the patient's active medication list, including all prescription and over-the-counter and herbal medications. These reviews should identify potential interactions or other concerns that may impact safety or efficacy. |
| | **1.5.12.** It is recommended to routinely inquire about any life changes, such as updates to insurance or financial status, that may affect the patient's ability to afford their medications. |
| | **1.5.13.** For prescriptions that will be dispensed outside the MIP, roles of the external specialty or mail-order pharmacy and the MIP should be determined and communicated to the patient. MIP teams are encouraged to apply the same rigorous clinical evaluation, counseling and documentation as they would for an internally dispensed prescription. |
| **1.6.** Safety | **1.6.1.** The MIP should implement a dual-check system for patient identity verification at the point of dispensing, using at least two patient identifiers (e.g., name, date of birth, and address) at both prescription entry and dispensing. |
| | **1.6.2.** The most recent physician note should be reviewed to validate the treatment plan, ensuring an appropriate diagnosis for newly prescribed oral anti-cancer medications or confirmation of therapy continuation. The stated dose must align with the prescribed dose and directions. |
| | **1.6.3.** Prescriptions for an oral anti-cancer medication, either processed internally at the MIP or transferred to an external pharmacy for fulfillment, should undergo the same rigorous review by the MIP personnel, including checks for duplicate therapies, potential drug interactions, toxicity risks, and an assessment of social determinants of health that may impact the patient's ability to access or adhere to the prescribed treatment. |
| | **1.6.4.** Drug utilization review should be conducted at each patient encounter to confirm recent medication changes, including over-the-counter medications, alternative medicines, and/or herbal therapies. |
| | **1.6.5.** Patient follow-up visits for toxicity evaluation and management should be scheduled throughout the course of therapy, with confirmation documented in the patient chart. This includes an initial tolerability and assessment visit shortly after the start of a new oral anti-cancer medication. Additional visits may be necessary for oral anti-cancer medications with potential side effects presenting later in therapy to ensure ongoing monitoring and management. |
| | **1.6.6.** Safety management and monitoring programs may be beneficial in improving patient co-morbidities and managing side effects.[25-28] |
| | **1.6.7.** Labeling of prescriptions should follow legal labeling requirements. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| **1.7.** Refilling of prescriptions | **1.7.1.** Scheduled outreach via phone, text, or email should be conducted to confirm that the patient is taking the oral anti-cancer medication as directed, assess for side effects or toxicities, address medication-related concerns, and determine the number of pills on hand. Findings related to adherence and persistence should be documented within the EMR. |
| | **1.7.2.** The date of the patient's most recent clinic visit, the date of the next scheduled visit, and any scheduled labs, imaging, or relevant appointments should be verified. Additionally, the most recent progress note should be reviewed to confirm the prescribing physician's intent to continue therapy. |
| | **1.7.3.** Any patient concerns or indications in the patient's record suggesting therapy modifications or discontinuation or upcoming clinic visits should be discussed with the physician to determine whether the refill should be processed. |
| | **1.7.4.** Refill requests will be submitted electronically to the prescribing physician for approval, or an existing authorized refill on file may be utilized. |
| | **1.7.5.** Secured financial assistance should be applied during medication refill processing. Patients should be informed of their co-pay amount, and any changes in co-pay compared to previous fills should be communicated to the patient and investigated for additional financial assistance if necessary. |
| | **1.7.6.** The date and method by which the patient secures the medication refill should be confirmed. The next pharmacy outreach should be scheduled and confirmed. The patient should be reminded of the refill process, the availability of the pharmacy, and how to reach the pharmacy with any questions or concerns. |
| | **1.7.7.** All interventions related to the patient's refill (e.g., coordination with injectable chemotherapy or newly prescribed medications) should be documented in the patient record. The intervention may need to be clarified with the patient, and the staff should be prepared to address any questions the patient may have. |
| **1.8.** Medication disposal | **1.8.1.** Resources should be developed to establish a consistent and compliant framework for directing patients to authorized drug take-back locations and mail-back programs for proper medication disposal. |
| | **1.8.2.** MIP staff should be trained in effective patient communication regarding proper medication disposal, emphasizing protocols and general principles, such as avoiding flushing or disposing of oral anti-cancer medications in regular household trash. |
| **1.9.** Patient satisfaction | **1.9.1.** A consistent, patient-centered process should be established to collect, analyze, and act on patient satisfaction feedback. Key areas should include staff communication, navigation of the fulfillment process, education provided, timeliness, and overall satisfaction. Insights from this feedback should be systematically incorporated into pharmacy operations to drive continuous improvements in service quality and patient outcomes. |
| | **1.9.2.** Feedback should be solicited from patients through surveys to identify and address continuous improvement opportunities at MIP practices. |
| | **1.9.3.** Participation should be voluntary, offering patients multiple feedback options including in-person or phone surveys (direct or automated), paper forms, digital surveys, or patient portals. |
| | **1.9.4.** Patient satisfaction data results should be analyzed and trended as part of continuous quality improvement efforts to inform, evaluate, and enhance pharmacy practices. |

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|---|---|
| **Topic** | **Standard** |
| **1.10.** Patient navigation | **1.10.1.** To ensure optimal treatment outcomes, MIPs should establish a structured patient navigation program aligned with Principal Illness Navigation principles. Certified professionals (e.g., pharmacists, nurses, social workers) should conduct patient-centered assessments addressing medical, emotional, cultural, and linguistic needs, providing individualized guidance through treatment plans, medication regimens, and transitions in care while offering emotional support and connecting patients with relevant community, financial, and social resources. All interactions and care interventions should be documented and maintained within the EMR to ensure transparency and continuity of care. |
| | **1.10.2.** Patient-reported outcomes should be integrated into the MIP workflows to capture real-time feedback, evaluate treatment effectiveness and refine navigation strategies as needed. |
| **1.11.** Quality Management | **1.11.1.** MIPs are encouraged to seek specialty pharmacy accreditation through recognized organizations. Accreditation standards support effective quality management (continuous quality improvement, quality assurance, and performance improvement) within clinical oversight, operational excellence, and patient-centered care requirements. |
| | **1.11.2.** A quality management plan should be developed to monitor, evaluate, and improve all aspects of pharmacy services. |
| | **1.11.3.** The MIP should establish a quality management committee to report and analyze performance metrics and trends at regularly scheduled meetings. |
| | **1.11.4.** All staff members should complete regular training and competency assessment on pharmacy operations, patient communication, and clinical updates. |
| | **1.11.5.** Performance metrics and audits of quality management activities should be transparently shared with leadership, the MIP, and medically integrated teams to promote continuous quality improvements and measurable success in patient outcomes. |
| | **1.11.6.** Key performance indicators should be tracked, including medication dispensing accuracy and operational efficiency. Root cause analysis can be helpful in identifying underlying factors of errors or suboptimal outcomes. |
| | **1.11.7.** Data analysis and staff feedback should continually refine process improvement initiatives, including refinement of operational workflows. |
| **Domain 2. Operational Quality Standards** | |
| **2.1.** Dispensing | **2.1.1.** Workflow and process flow diagrams are recommended for interdisciplinary teams operating within both embedded and decentralized MIP settings. These diagrams should outline interdepartmental workflows, communication protocols, and documentation process to promote consistent collaboration and minimize redundancies. All relevant updates, including patient encounters, workflow progress or delays should be documented within the EMR, ensuring that all team members have access to up-to-date information for care coordination. |
| | **2.1.2.** A decision tree or flow map should be established to standardize the prescription dispensing process. This framework should encompass all steps, from prescription generation by the physician to medication delivery, receipt confirmation, and the patient's initiation of therapy. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| | **2.1.3.** Routine staff training and scheduled meetings are recommended to enhance MIP team awareness of policy updates and flow changes. These sessions should also address updates to workflow as necessary. Regular audits of documented processes are encouraged to ensure accuracy and adherence to established procedures. |
| | **2.1.4.** Consider establishing pre-built, standardized instructions, including details for special instructions, to promote consistency and accuracy in labeling. Ensure all auxiliary labels are consistent with prescribing instructions and clearly communicate critical information. |
| | **2.1.5.** A final review process should be established to ensure that labeled instructions align with the patient's treatment plan and that any potential inconsistencies in dosing schedules or drug interactions are flagged, investigated, and resolved prior to dispense. |
| | **2.1.6.** Implement a dispensing audit process to detect and prevent mislabeled prescriptions, incorrect fills (e.g., wrong drug, strength, or quantity), and incorrect patient-to-medication matching. Real-time quality control checks should be conducted during the dispense workflow, and incidents of near misses should be recorded in a quality improvement log to track trends, identify systemic issues, and determine the need for corrective action plans. |
| | **2.1.7.** Standardized packing and shipping protocols should be established. These protocols should include processes for tracking shipments, addressing delays or lost shipments requiring re-shipment, and verifying that appropriate conditions (e.g., temperature, humidity) are maintained throughout the shipping process. Periodic reviews of these procedures are recommended to ensure compliance with quality standards. |
| | **2.1.8.** In the event of a lost or damaged medication, or any other issue in the patient receiving their prescription, the circumstances of the issue should be documented, the patient made aware, and the incident documented within the EMR. Determine if re-shipment will be covered by the plan provider, submit a new claim if required, and escalate to the appeals process as needed, or evaluate options for patient assistance programs or internal financial support to allow re-dispensing and avoid any delays in therapy. |
| | **2.1.9.** A structured approach to effectively manage drug shortages should be developed. This includes maintaining strong communication channels with wholesalers, exploring alternative suppliers, and regularly monitoring inventory levels to identify potential issues as early as possible. When shortages occur, the MIP should assess available allocation from wholesalers, evaluate alternative sourcing options, and determine the expected duration of the shortage. Plans for managing the shortage, including identifying suitable alternative therapies, incorporating national guidelines such as those from ASCO when available, or developing internal guidance if no publicly available recommendations exist, should be shared promptly with the healthcare team. Proactive communication with patients is essential during drug shortages. The MIP should inform patients about any potential delays or changes to their medication regiment, providing timely updates on the status of the shortage and any adjustments, including alternative therapy options, to minimize disruption to treatment. Ensuring alignment with evidence-based practices and maintaining continuity of care are critical. |
| **2.2.** Care coordination | **2.2.1.** Assigning a dedicated care coordinator can help oversee patient treatment plans, ensure timely execution of therapy milestones, and maintain accurate documentation within the EMR. Real-time communication to the care team reduces deviations from the treatment plan and enhances coordination of care across disciplines. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| | **2.2.2.** Clear protocols should be established to facilitate seamless coordination for a variety of therapies, including multiple oral anti-cancer medications, oral anti-cancer medication and retail medications, oral anti-cancer medication and injectable medications, and oral anti-cancer medication with other treatment modalities, such as radiation or surgery. These protocols should include detailed instructions tailored to the patient's regimen, a process for medication fill synchronization, comprehensive therapy calendars to manage overlapping treatment schedules, procedures to identify and address potential interactions between therapies, and communication plans to align all members of the care team, including external clinicians. |
| | **2.2.3.** A collaborative practice agreement between pharmacists and physicians may be considered to shorten the turnaround time for processing prescriptions. Clinical activities of the pharmacist under the collaborative practice agreement may include dose rounding, dose adjustments, prescription refill renewals, and ordering laboratory tests.[29] |
| | **2.2.4.** Proactive measures should be taken to address any potential logistical challenges, e.g., insurance authorizations, delivery delays, backorders or impending inclement weather, to avoid treatment interruptions. |
| | **2.2.5.** Ensure patients receive consistent education about their treatment plan and how different therapies interact. |
| | **2.2.6.** Develop mechanisms to capture, track, trend, report, and respond to patient-reported outcomes or concerns related to therapies. |
| | **2.2.7.** A multidisciplinary team, including clinical, operations and administrative staff with relevant expertise, should evaluate newly approved drugs reviewing prescribing information, clinical data, approved indications, and determination of ordering access. Staff training should be developed and conducted to ensure proficiency in dispensing and managing the new medication, and workflows and documentation protocols should be established and integrated into EMR and pharmacy system. A mechanism for addressing barriers to access, reimbursement challenges, and distribution limitations should be developed. Information about new medications, including overview and education and confirmation that the medication has been reviewed and loaded into all systems and is available for physician prescribing and dispensing from the MIP, should be disseminated to all pharmacy and practice staff. |
| **2.3.** Cost avoidance and waste | **2.3.1.** Implementing strategies to mitigate financial toxicity and reduce waste is highly encouraged. Approaches such as split-fill programs and drug repositories for dispensing unused medications can result in significant cost savings.[30-32] Additional strategies include comprehensive clinical evaluation and coordination, such as: assessing imaging for signs of disease progression that may necessitate therapy discontinuation or adjustment prior to next dispense; monitoring laboratory values for abnormalities that could require dose reduction, hold, or discontinuation; identifying intolerable side effects that would prompt a change in dose or discontinuation; and drug utilization review. |
| | **2.3.2.** Waste mitigation strategies should be integrated into patient management practices and tracked for their impact. Monitoring and documenting pharmacy-led interventions and estimated healthcare cost savings can demonstrate the value of these efforts. Tools such as NCODA's Cost Avoidance and Waste Tracker or other similar tools, are recommended to quantify those savings and highlight their significance to stakeholders. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| **2.4.** Health Disparities | **2.4.1.** Operational processes that incorporate social determinants of health assessments into MIP workflows to streamline access and reduce barriers to treatment may be aligned to principles of the Community Health Integration. The MIP should consider developing partnerships with local and national organizations to provide patient access to resources, such as transportation, housing, nutrition, and financial aid, to enhance patient-centered care and promote patient self-advocacy and quality of life. |

| **Domain 3. Foundational Standards** | |
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| **3.1.** Mission statement | **3.1.1.** A mission statement should include three elements:<br>1. Our Cause: Define the who, what, and where the MIP serves.<br>2. Our Actions: Highlight the services and actions provided to support patients.<br>3. Our Impact: Describe the positive impact for the integrated care team and the patients throughout the patient journey and in outcomes delivered. |
| **3.2.** Organizational chart | **3.2.1.** The MIP should establish and maintain an up-to-date organizational chart detailing roles and responsibilities. |
| **3.3.** Business plan | **3.3.1.** Scope of Business: Specify closed-door status, ensuring exclusivity of services for patients within a specific practice. |
| | **3.3.2.** Licensing Requirements: Specify operations type as a licensed pharmacy or a physician dispensing program, adhering to state regulations. |
| | **3.3.3.** Proforma Analysis: Evaluate prescription coverage and identify payer or pharmacy benefits manager limitations, including a review of regional payer relationships. |
| | **3.3.4.** Limited Distribution: Identify any LDD networks that may impact patient access. Engage with pharma and biotech companies during the development of phase to understand and provide input on distribution models selected for emerging therapies. Keep an up-to-date list of all LDD and respective networks to ensure transparency and streamline operations including direct shipments. Develop and implement SOPs to assist patients in navigating options when the MIP is unable to access or dispense a medication. This should include proactive and clear explanation to patients for any LDD restrictions, coordinating with outside specialty pharmacies to minimize delays in treatment and continuing patient engagement, where possible, with education and care management. |
| | **3.3.5.** Medication Scope: Determine the type of prescriptions to be dispensed, including: oral anti-cancer medication, generic medications utilized in combination with an oral anti-cancer medication, supportive medications for symptom management (e.g., antiemetics), and controlled substances for pain control. |
| | **3.3.6.** Staffing Model: Provide a detailed staffing plan, with the preference for oncology trained pharmacist and certified pharmacy technicians, navigators, and oncology certified nurses. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| | **3.3.7.** Facility Requirements |
| | **3.3.7.1.** Ensure compliance with State Board of Pharmacy requirements, as applicable, including state specific design or infrastructure standards such as the presence of a sink near the dispensing area for handwashing and sanitation. |
| | **3.3.7.2.** For any planned renovations or relocations to meet operational and compliance needs, ensure timely notification to any relevant credentialing or accrediting bodies as required by regulatory guidelines. |
| | **3.3.7.3.** Conduct a post-renovation or relocation assessment to verify compliance with applicable regulations prior to resuming dispensing operations. |
| **3.4.** Implementation timeline | **3.4.1.** Ensure all state Board of Pharmacy requirements, payer contracts, and physical space designs are finalized well before dispensing begins. Checkpoints to validate operational readiness must be completed in advance of the first prescription being processed. |
| | **3.4.2.** Develop a comprehensive, clear, actionable timeline for launching MIP services, including milestones for facility readiness, licensing approval, payer onboarding and staff training. |
| | **3.4.3.** Establish an internal communication plan to ensure all members of the medically integrated team and administrative teams are fully informed about the scope of services to be provided by the MIP. Communication, timelines, and training plans should be developed for operationalizing any workflow changes associated with the MIP integration. |
| | **3.4.4.** Outreach strategy to inform patient of MIP services should highlight the benefits of the MIP, such as improved coordination of care, timely access to medications, and a dedicated support team. Clear instructions should be provided to patients regarding the option to transition care, how prescriptions will be managed, and next steps should they desire to receive or transfer care to the MIP. A plan for coordination and standardization of patient messaging and interactions should be developed and executed. |
| **3.5.** Business elements | **3.5.1.** The Central business office and MIP leadership should collaboratively oversee establishment and management of business operations to ensure compliance, efficiency, and sustainability. Dedicated staff, distinct from buy-and-bill, are recommended to ensure clear role delineation and continuity. |
| | **3.5.2.** Pharmacy Service Administrative Organization selection and activation to support pharmacy operational, administrative and regulatory requirements.<br>• Payor contracts including negotiated reimbursement rates, terms and conditions, network participation and credentialing support services such as monthly Office of Inspector General exclusion<br>• Central pay services from respective pharmacy benefits managers and payers, reconciliation, aged accounts receivable<br>• Patient billing and statements<br>• Fulfilment of state, federal, and pharmacy benefit manager regulation and reporting requirements, such as monthly OIG exclusion and annual fraud waste and abuse training |
| | **3.5.3.** Pharmacy processing system selection with workflow design developed to support the specialty prescription fulfillment process. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
|---|---|
| **Topic** | **Standard** |
| | **3.5.3.1.** Ensure system integration capabilities with the EMR and/or practice management systems supporting patient demographic feed at a minimum. |
| | **3.5.3.2.** Workflow design set up within the system to support documentation and work queues throughout the prescription fulfillment process and refill management including patient communication and documentation. Comprehensive staff training should be provided with staff sign-off acknowledging receipt, understanding and proficiency in completing assigned responsibilities. Training materials should be developed, including step-by-step procedures and screenshots should be developed for all new hire training. An audit plan, including frequency of conducting, should be established, with recommendation that audits be conducted no less than annually, for determination of any root-cause analysis and following on-boarding of new staff members. |
| | **3.5.4.** Identify and contract with a switch company to facilitate the electronic transmission of claims. |
| | **3.5.5.** Establish affiliation with a primary wholesaler and group purchasing organization. Develop infrastructure and workflow for online catalog access, ordering, and price file updates. Collaborate with wholesaler on drug delivery and timing as a component of inventory management. |
| | **3.5.6.** Obtain liability insurance coverage as required by payer contracts, considering facility coverage and individual professional coverage. |
| | **3.5.7.** Contract with a credit card processing company to facilitate secure and efficient payment processing. |
| | **3.5.8.** Develop and maintain workflow for claims submission, editing, adjudication, and reconciliation including SOP for obtaining patient insurance, application of secondary insurance or available assistance, evaluation of received adjudication amount and audit preparation and readiness for payer and regulatory requirements. |
| **3.6.** Dispensing space requirements | **3.6.1.** Establish a patient counseling area that ensures privacy and confidentiality for patient interactions. |
| | **3.6.2.** The need for the following infrastructure items should be considered: secure storage areas and shelving for medications, adequate workstations for pharmacy staff tailored to specific functions and sufficient space to promote productivity and safety, counting trays and bins for efficient workflow, a sink for handwashing (as required by state regulation), a refrigerator for temperature sensitive medications, and software and hardware to support dispensing operations. |
| **3.7.** Communication plan | **3.7.1.** Develop a central communication mechanism to ensure timely and consistent communication with:<br>• Physicians, staff, and patients<br>• Practice leadership<br>• Practice business office and/or contracting department |
| | **3.7.2.** Ensure that marketing materials (e.g., brochures, flyers, or website) are reviewed and approved by the MIP team and leadership before dissemination to maintain accuracy and compliance. |
| **3.8.** Policies and procedures | **3.8.1.** Establish and maintain policies and procedures (P&P) to ensure clarity, consistency, and operational excellence. Policies should define overarching principles and goals of the MIP, while SOPs provide a detailed step-by-step process to implement and operationalize policies. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
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| | **3.8.2.** Integrate continuous quality improvement, quality assurance, root cause analysis and corrective action/preventative action processes into both P&P and SOPs. These processes should cover the following areas:<br>• Daily dispensing operations and workflow management, defining workflows and establishing monitoring protocols to ensure accuracy and adherence to SOPs. Quality assurance measures should include routine checks and documentation audits to identify and address discrepancies proactively.<br>• Comprehensive staff training with a quality assurance process to evaluate training effectiveness and staff proficiency. Use root cause analysis to investigate knowledge gaps or recurring errors and refine training programs accordingly, for both onboarding new staff and annual competency of existing staff.<br>• Detail processes for internal and external audits, including a checklist of documentation and regulatory requirements.<br>• Include procedures for secure shipping, tracking, and confirmation of medication deliveries independent of patient confirmation to document timely and accurate patient receipt.<br>• Ensure uniform processes across all satellite locations, with defined documentation and tracking for medication receipt, storage and patient pick-up.<br>• Establish clear guidelines for returning medications to stock in compliance with regulatory requirements and standards.<br>• Define and document staff responsibilities and duties, ensuring accountability of individual roles and seamless workflows across functions. An ongoing education and training program should be implemented to ensure staff remain proficient and up to date on clinical guidelines, regulatory requirements, operational procedures, and technologies. Job descriptions should be provided and regularly reviewed and updated to reflect evolving organizational needs and advancements in patient care. Performance evaluations should be provided no less than annually and professional growth opportunities promoted across all functional areas.<br>• Detailed procedures for recalled, discontinued, expired, damaged, adulterated, misbranded, and/or medications determined to be counterfeit in compliance with federal and state regulations.<br>• Disaster plans and emergency preparedness to address potential disruptions, including loss of power, severe weather, and other emergency situations should include a robust data backup and systems recovery plan to protect patient information and maintain continuity of operations through remote access to critical systems. Recovery systems, data backup, and remote access should be tested regularly. Protocols should be established for maintaining telephone support, communication plans, coordinating with external pharmacies to facilitate seamless prescription transfer if operations are temporarily interrupted. Periodic emergency preparedness drills should be performed, and an emergency plan should be developed and distributed to staff.<br>• Compliance with HIPAA requirements regarding personal health information. |
| **3.9.** EMR and pharmacy | **3.9.1.** Integrate the practice's EMR, pharmacy dispensing system, and practice management or other applicable systems to enable seamless bi-directional, real-time data exchange where possible. Integrate capabilities with external systems, such as transport vendors and specialty pharmacies to facilitate care coordination and prescription tracking. |

| Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update | |
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| **Topic** | **Standard** |
| dispensing system infrastructure | **3.9.2.** Equip workstations with dual or ultra-wide screens to optimize workflow efficiency, allowing simultaneous access to EMR and pharmacy dispensing programs. Utilize cloud-based or hybrid system architectures to enhance accessibility, scalability, and disaster recovery readiness. |
| | **3.9.3.** Ensure access to multifunctional devices such as secure network-connected printer, copier, fax, and/or scanner machines for documentation, communication and prescription processing. |
| | **3.9.4.** Provide barcode scanners for inventory management and electronic verification of prescriptions. |
| | **3.9.5.** Implement secure mobile devices or tables for patient counseling, inventory review or EMR updates, particularly in telehealth scenarios. |
| | **3.9.6.** Ensure compliance with the latest HIPAA requirements and cybersecurity best practices, including multi-factor authentication, encryption, and regular penetration testing. User access level controls should be established based on roles and responsibilities to reduce the risk of unauthorized data exposure. |
| **3.10.** Processes and guidance for handling of medication | **3.10.1.** Establish and maintain robust safety protocols consistent with USP <800> Standards, ASCO Standards for Safe Handling, and other relevant occupational health guidelines and provide regular competency training to ensure staff understanding of proper handling, storage, and disposal procedures. Implement personal protective equipment requirements tailored to each task, including gloves, gowns, and mask or respirators, to minimize exposure risk. Establish protocols for handling spills, exposure incidents or emergencies, including easy access to spill kits and immediate reporting procedures. |
| | **3.10.2.** Develop protocols for receiving medication orders aligned with USP standards, the NIOSH guidelines, and OSHA regulations to mitigate occupational hazards. Ensure dedicated space and process for unpacking and inspecting hazardous drugs and secure medications chain of custody from receipt to patient delivery. |
| | **3.10.3.** Provide patients with education on safe handling and disposal of sharps, including the use of FDA-cleared sharps containers, ensuring emphasize on risks of improper disposal. Maintain a resource guide of authorized sharps disposal sites or mail back programs. |

**Abbreviations.** EMR, electronic medical record; FDA, U.S. Food and Drug Administration; HIPAA, Health Insurance Portability and Accountability Act; LDD, Limited Distribution Drug; MIP, medically integrated dispensing pharmacy; NIOSH, National Institute for Occupational Safety and Health; OSHA, Occupational Safety and Health Administration; P&P, policies and procedures; SOP, standard operating procedures; USP, US Pharmacopeia

**References.**


1. Lau G, Alwan L, Chi M, et al: Expanding pharmacy practice through the use of pharmacy technicians as process navigators to facilitate patient access of oral anticancer agents. Journal of the American Pharmacists Association 59:586-592, 2019
2. Zerbit J, Chevret S, Bernard S, et al: Improved time to treatment failure and survival in ibrutinib-treated malignancies with a pharmaceutical care program: an observational cohort study. Annals of Hematology 99:1615-1625, 2020
3. Feral A, Boone M, Lucas V, et al: Influence of the implementation of a multidisciplinary consultation program on adherence to the first ever course of oral antineoplastic treatment in patients with cancer. Journal of Oncology Pharmacy Practice 28:1543-1551, 2022
4. Lin M, Hackenyos D, Savidge N, et al: Enhancing patients' understanding of and adherence to oral anticancer medication: Results of a longitudinal pilot intervention. Journal of Oncology Pharmacy Practice 27:1409-1421, 2021

5. Sikorskii A, Given CW, Given BA, et al: Patient Engagement With an Automated Telephone Symptom Management Intervention: Predictors and Outcomes. Annals of Behavioral Medicine 54:484-494, 2020
6. Mir O, Ferrua M, Fourcade A, et al: Digital remote monitoring plus usual care versus usual care in patients treated with oral anticancer agents: the randomized phase 3 CAPRI trial. Nature Medicine 28:1224-1231, 2022
7. Sargent W, Whalley A: Implementation and outcomes of a pharmacist-led oral chemotherapy clinic at VA Maine Healthcare System. Journal of Oncology Pharmacy Practice 28:1704-1708, 2022
8. Megeed A, Magas H, Accursi M, et al: The impact of a pharmacist-led oral anticancer clinic on medication adherence and laboratory monitoring. Journal of Oncology Pharmacy Practice 29:1921-1927, 2023
9. Curry MA, Chineke I, Redelico T, et al: Adherence to Oral Anticancer Medications After Implementation of an Ambulatory Adherence Program at a Large Urban Academic Hospital. JCO Oncology Practice 16:e350-e356, 2020
10. Krikorian S, Pories S, Tataronis G, et al: Adherence to oral chemotherapy: challenges and opportunities. Journal of Oncology Pharmacy Practice 25:1590-1598, 2019
11. Nachar VR, Farris K, Beekman K, et al: Clinician report of oral oncolytic symptoms and adherence obtained via a patient-reported outcome measure (PROM). JCO Clinical Cancer Informatics 3:1-6, 2019
12. Collomb B, Dubromel A, Caffin AG, et al: Assessment of patient reported outcomes (PROs) in outpatients taking oral anticancer drugs included in the real-life oncoral program. Cancers 14:660, 2022
13. Doolin JW, Berry JL, Forbath NS, et al: Implementing Electronic Patient-Reported Outcomes for Patients With New Oral Chemotherapy Prescriptions at an Academic Site and a Community Site. JCO Clinical Cancer Informatics:631-640, 2021
14. Harbeck N, Kates R, Schinkothe T, et al: Favorable impact of therapy management by an interactive eHealth system on severe adverse events in patients with hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer treated by palbociclib and endocrine therapy. Cancer Treat Rev 121:102631, 2023
15. Saadeh C, Hill M, Snowaert S: Patient-reported outcomes for oral oncolytic therapy: A pilot study utilizing an electronic patient portal in a community cancer center. Journal of Oncology Pharmacy Practice:10781552231162013, 2023
16. Cakmak HSG, Kapucu S: The effect of educational follow-up with the motivational interview technique on self-efficacy and drug adherence in cancer patients using oral chemotherapy treatment: a randomized controlled trial. Seminars in Oncology Nursing 37:151140, 2021
17. Bandiera C, Cardoso E, Locatelli I, et al: A pharmacist-led interprofessional medication adherence program improved adherence to oral anticancer therapies: The OpTAT randomized controlled trial. Plos one 19:e0304573, 2024
18. Başoğlu S, Ü. P: The Effect of Education and Monitoring via Tele-Nursing to Elderly Cancer Patients Using Oral Anticancer Agents on Self-efficacy and Medication Adherence: A Randomized Controlled Trial. Seminars in Oncology Nursing:151692, 202448
19. Collado-Borrell R, Escudero-Vilaplana V, Ribed A, et al: Effect of a Mobile App for the Pharmacotherapeutic Follow-Up of Patients With Cancer on Their Health Outcomes: Quasi-Experimental Study. JMIR mHealth and uHealth 8:e20480, 2020
20. Mauro J, Mathews KB, Sredzinski ES: Effect of a smart pill bottle and pharmacist intervention on medication adherence in patients with multiple myeloma new to lenalidomide therapy. Journal of Managed Care & Specialty Pharmacy 25:1244-1254, 2019
21. Park HR, Kang HS, Kim SH, et al: Effect of a Smart Pill Bottle Reminder Intervention on Medication Adherence, Self-efficacy, and Depression in Breast Cancer Survivors. Cancer nursing 45:E874-E882, 2022
22. Greer JA, Jacobs JM, Pensak N, et al: Randomized Trial of a Smartphone Mobile App to Improve Symptoms and Adherence to Oral Therapy for Cancer. J Natl Compr Canc Netw 18:133-141, 2020
23. Karaaslan-Eser A, Ayaz-Alkaya: The effect of a mobile application on treatment adherence and symptom management in patients using oral anticancer agents: A randomized controlled trial. European Journal of Oncology Nursing 52:101969, 2021
24. Krok-Schoen JL, Naughton MJ, Young GS, et al: Increasing Adherence to Adjuvant Hormone Therapy Among Patients With Breast Cancer: A Smart Phone App-Based Pilot Study. Cancer Control 26:107327481988328, 2019
25. Wang G, Truong H, Dang R: Impact of a pharmacist-led hypertension management program for oral chemotherapy in a specialty pharmacy setting. Journal of Oncology Pharmacy Practice 29:52-59, 2023

26. Bouleftour W, Muron T, Guillot A, et al: Effectiveness of a nurse-led telephone follow-up in the therapeutic management of patients receiving oral antineoplastic agents: A randomized, multicenter controlled trial (ETICCO study). Supportive Care in Cancer 29:4257-4267, 202124
27. Chow S, Tan B: Effectiveness of mHealth apps on adherence and symptoms to oral anticancer medications: a systematic review and meta-analysis. Supportive Care in Cancer 32:426, 2024
28. De Raya J, Modlin J: Evaluation of Pharmacist-Driven Approach to Monitoring for Neutropenia Related to CDK4/6 Inhibitors in Women With Advanced Breast Cancer. Journal of Hematology Oncology Pharmacy 14, 2024
29. Wright AL, Matta SF, Kerr JR: Expansion of pharmacist practice in oral oncolytic therapy with a collaborative practice agreement. Journal of Oncology Pharmacy Practice 26:1886-1893, 2020
30. Smale EM, Van Den Bemt BJF, Heerdink ER, et al: Cost Savings and Waste Reduction Through Redispensing Unused Oral Anticancer Drugs. JAMA Oncology 10:87, 2024
31. Smale EM, van Vlijmen B, Colen HB, et al: Feasibility of an Individualized Dispensing Program for Patients Prescribed Oral Anticancer Drugs to Prevent Waste. JCO Oncology Practice 19:e618-e629, 2023
32. Staskon FC, Kirkham HS, Pfeifer A, et al: Estimated cost and savings in a patient management program for oral oncology medications: Impact of a split-fill component. Journal of Oncology Practice 15:e856-e862, 2019

This summary table is derived from recommendations in *Medically Integrated Dispensing Pharmacy (MIP): ASCO-NCODA Standards Update*. This is a tool based on ASCO Standards and is not intended to substitute for the independent professional judgment of the treating physician. Standards do not account for individual variation among patients. This tool does not purport to suggest any particular course of medical treatment. Use of the standards and this tool are voluntary.