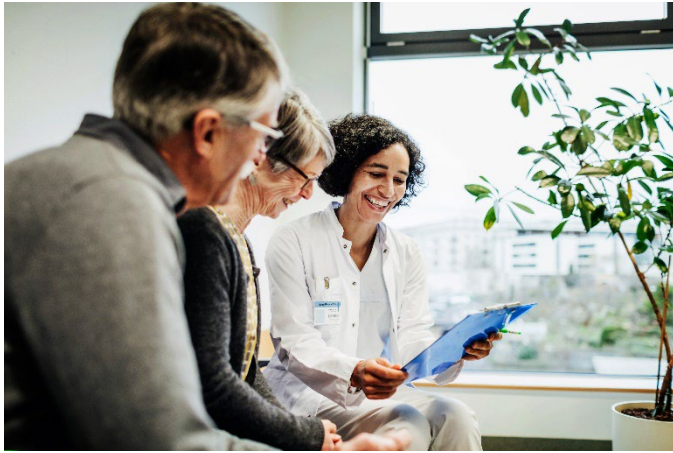

Ambulatory Patient Safety Toolkit 2024

A resource for clinicians and staff provided by
HealthPartners Ambulatory Safety Program



HealthPartners is committed to eliminating harm due to error in the delivery of medical care. The HealthPartners Ambulatory Safety Toolkit provides practical tools and suggestions that you may wish to incorporate into clinical operations or adapt to create your own initiatives. We include links to national and local safety resources and protocols, organized by topic. A complete listing of HealthPartners administrative policies can be found on the Provider Portal at <http://www.healthpartners.com/provider-public/administrative-policies/>.

To date, little research has focused on patient safety in the ambulatory setting. Yet most care is delivered in these settings. Although the ambulatory setting might seem less intense (and less “critical”) than an inpatient setting, lapses in safety can and do occur, with adverse consequences.

A “culture of patient safety” is an essential element of the safe health care organization. “Culture” can be understood as habits, attitudes, and beliefs that live in the minds of individuals who work in the organization and guide the work that they do. Concepts closely related to “culture” are “environment” and “mindset.”

The knowledge, skill and judgment of the clinician are essential, of course. In the modern group practice, clinic, and outpatient center, the clinician operates through organizational systems and processes, which together produce the desired clinical outcome.

Research has shown that serious errors occur more often from a failure of process and systems, rather than the action of a single individual. Well-designed systems and processes allow the organization to deliver care with reliability, consistency, and resiliency (the ability to detect and quickly recover from an error before harm occurs).

Our goal with this toolkit is to promote these sorts of systems and processes. Together, we can improve the safety of care delivered in the ambulatory setting. We welcome comments and feedback. We are committed to continually improving this toolkit. Please feel free to contact us by email at quality@healthpartners.com.

Sara Spilseth, MD, MBA
Associate Medical Director for Quality
HealthPartners Health Plan

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Clinic Assessment of Safety Culture

◆ Identify the Safety Risk

Evaluation of a culture of safety refers to measurement components such as management behaviors, safety systems, and employee perceptions of safety. A variety of survey tools is available to identify potential gaps and improvement initiatives concerning patient safety. While many surveys address the safety climate, we endorse the Agency for Healthcare Research and Quality (AHRQ) Surveys on Patient Safety Culture



Suggestions for Improvement

- Clinics should track errors that occur within the standard practice of medicine.
- All staff members should use a standard error report. All staff must be comfortable with reporting errors.
- Review Tools for Incident Reporting. Establish a “Safety Learning Report” format.
- Consider providing a thank you note or “kudos” when someone submits an error report or “good catch.”
- Complete culture surveys to assist in identifying progress in this area. A safety officer, committee, or leader could review the reports and monitor trends to prioritize improvement projects. If a clinic is large enough, the detail could be entered into a database to track and assist in analysis.

Sample Forms & Article

[AHRQ Patient Safety Culture \(SOPS\) Hospital Survey](#)

[HealthPartners Sample of Medication/Incident Report](#) *links to sample in appendix*

Other Resources –Links

[Agency for Healthcare Research and Quality](#)

[AHRQ Patient Safety Tools and Resources](#)

References

AHRQ [Healthcare-Associated Infections Program](#)

AHRQ [Surveys on Patient Safety Culture](#)

Infection Control/Hand Hygiene

◆ Identify the Safety Risk

Since 2019, the coronavirus (COVID-19) global pandemic has impacted people, businesses, and institutions across national and international health care systems. These systems created different protocols and procedures to navigate and mitigate the spread of COVID-19.

Infection prevention and control are essential in achieving the triple aim of health, such as patient experience, affordability for our patients, and providing a safe work environment for our employees. Infection control promotes safe practices related to the prevention and spread of disease and provides best practice information and consultation regarding infectious disease management.

Hand washing is the single most important means of preventing the spread of infections, germs, and viruses.



Suggestions for Improvement

- Set standards and guidelines for hand hygiene and infection control in clinics
- During a pandemic, additional infection control measures should be put into action to minimize the spread of the virus
- Develop a pandemic response plan or team to ensure the health and safety of the organization's employees and patients in clinics

Sample Forms & Article

[Infection Prevention and Control Hand Hygiene](#)
[World Health Organization HealthPartners Covid-19 Resources](#)

Other Resources –Links

[Infection Prevention and You Centers for Disease Control and Prevention](#)
[Minnesota Department of Health](#)

References

CDC [Coronavirus \(Covid-19\)](#)

Safety Learning Reports

◆ Identify the Safety Risk

Sometimes system errors such as "near misses" occur in the clinic unnoticed. If these errors continue, they can lead to patterns of concern. However, once mistakes are reported, it is unknown where the errors originated from. The standard practice of medicine leans towards Safety Learning Reports to track the trend of errors, "good catches" when they occur.

Incident reports lead to negative connotations that change the tone of the statement. Identifying these errors as safety learning or quality improvement (QI) reports may minimize incident reports, promote open dialogue, and review an event from a systems perspective. Even near-misses could be tracked and collected.

Safety learning, or QI reports, can help identify things that may be wrong with the system that leads to errors or provide details on what was right with the design that helped prevent a mistake.



Suggestions for Improvement

- Establish and utilize a survey tool to assess safety risk within the clinic's safety culture
- Use the safety culture results to determine the team's comfort level in reporting incidents and in reviewing learning reports, near misses, and good catches
- If survey results indicate improvement, develop an education toolkit and schedule teambuilding around reporting incidents, near misses, good catches, and safety learning
- If you do not have a current safety learning report format (or report for incidents), obtain samples, and form a committee to review and select one, or use one and implement updates specific to the clinic
- Establish a protocol for safety learning reports. Make sure that the protocol addresses learning definitions such as near misses and good catches
- Have a safety champion review and compile data on the safety learning events identified through reports each quarter. Enter details into a database and monitor for trends
- Use this analysis to identify and prioritize areas for improvement
- Develop action plans around the outcomes seen
- Continue ongoing monitoring of safety culture and quality improvement

Other Resources – Links

[Patient Safety Network](#)

[MN Alliance for Patient Safety](#)

[AHRQ Quality Reports](#)

[Institute for Healthcare Improvement \(IHI\)](#)

References

AHRQ [Reports and Resources](#)

Health Literacy

◆ Identify the Safety Risk

Effective communication is the heart of health care relationships. At least 50 percent of the US population cannot understand and use the information provided by their clinicians.

Health Literacy is an individual's ability to read and comprehend prescription bottle labels, appointment slips, and other essential health-related materials required to function as a patient successfully.

Research shows health literacy is a stronger predictor of health status than age, income, employment status, education level, or racial and ethnic group. Health literacy barriers lead to misunderstood health care instructions, prescriptions, and appointment slips (no-shows), poor health outcomes, and medical errors.

HealthPartners recommends taking a universal precautions approach. This means to approach all patients the same. All patient education materials, forms, and letters are at a seventh grade reading level. All explanations use non-medical language. Health Literacy affects a person's ability to engage in self-care chronic disease management. See the "Patient Engagement Section" of this toolkit for additional ideas.



Suggestions for Improvement

- Use non-medical terminology, focus on one to three key messages, show, or draw a simple picture when giving instructions or educating the patient about their medical condition.
- Ask patients to recall and restate instructions about their medication, what they are to do when they get home, etc.
- Provide detail on cultural appropriateness. Several resources have educational materials available in multiple languages.
- Create a calendar to continue to covert materials by topic in your clinic over time. Create a shame-free environment and use patient-friendly and culturally appropriate materials.

Sample Forms & Article

[HealthPartners Literacy Guidelines](#)

[AHRQ Patient Assessment Tools](#)

[Round table on Health Literacy](#)

[Teach-back Method](#)

References

CDC [Health Literacy](#)

AHRQ [Health Literacy](#)

NPIN [Health Communication Language and Literacy](#)

Patient Engagement (motivational interviewing)

◆ Identify the Safety Risk

A critical component of ongoing medical care is having the patient engaged and empowered in their care. Patient's interest levels in their care can change over time: motivational interviewing combines person-centered care and patient engagement. Steps can be put in place to promote your patient/patient family health engagement by removing literacy barriers. Informed patients are more engaged and actively involved in their therapy. Patient partnering will include providing patients with tools to help them become more knowledgeable. What efforts has your clinic made to involve patients in their safety?



Suggestions for Improvement

- When providing patients with written materials, be sure that they are at the seventh grade reading level and are in plain language. When explaining medical conditions or educating patients, use the "[Teach-Back Method](#)." See the [Health Literacy](#) section of this toolkit for additional ideas.
- Use a tool to assess the underlying knowledge, skills, and confidence of a patient's health and healthcare needs, such as the Patient Activation Measure (PAM).
- Provide all patients with an understanding of the roles and responsibilities of their care delivery team
- Engaged patients may want additional help when faced with multiple options for the care of specific conditions/diseases. Shared decision-making tools address this need.
- Provide each patient with copies of their medication lists. "Apps" will show a picture of the medication for people with low health literacy.
- Engage patient family members or, if appropriate, assist the patient in engaging home health resources for medication distribution.
- Make it a routine part of your care process to create an after-visit summary regarding the patient's self-care and medication safety.
- Include Motivational Interviewing in the script or when doing a patient assessment

Other Resources – Links

[The PAM® Survey](#)

[Motivational Interviewing](#)

References

AHRQ [Patient Engagement and Education](#)

AHRQ [Motivational Interviewing Strategies to Engage Patients](#)

IHI [What is Motivational Interviewing?](#)

Medication Safety: Sampling

◆ Identify the Safety Risk

The use of samples leads to prescribing and use which may not be the most effective or efficient for patients: sample drugs represent potential risks as pharmacists are eliminated from the dispensing process. There is an increased risk of documentation errors, use of non-formulary drugs, outdated medications, and drug interactions.

It is recommended that clinics eliminate sampling of all prescription pharmaceutical products supplied by manufacturers. Clinics choosing to stock and dispense sample medications must follow safe medication practices consistent with The Joint Commission standards. HealthPartners identifies sampling of prescription pharmaceuticals as inconsistent with the six aims of quality, primarily due to concerns for patient safety.



Suggestions for Improvement

- Eliminate sampling
- Review or implement a sample drug protocol in your clinic. Form a work group to assess the protocol (providers, nurses, medical assistants).
- Implement protocol. If sampling is not yet eliminated, set a future date and goal for elimination.
- Determine which samples should be maintained, where they should be maintained and the level of security necessary. All samples should be locked in a secure place.
- Eliminate drug samples from exam rooms and doctors' offices and store them in a secure location in clear view of a nursing station.
- Create a written documentation and monitoring system for samples and include duplicate written instructions to keep in the log and to give to the patient. Include expiration date and drug details.
- Track the total starting number of samples per drug, the number distributed with the date distributed and the number of sample drugs remaining with a date.
- Create labels for the samples and attach them prior to giving to the patient.
- Provide educational handouts on each drug within the sample space and make sure adequate copies are available and easily obtainable for each sample. Place a copy of the education piece given to the patient in the log and in the medical record.
- Make pharmaceutical representatives aware of your protocol and their roles in ensuring safe sample distribution. Consider a sign in/out log for pharmaceutical representatives to use during every visit. Enter a name, medication(s) delivered, lot numbers, quantity, and expiration date. Clinic staff who removes samples should sign them out on the same log.
- Assessments for hidden caches of samples within physician offices or exam rooms should be done regularly, every quarter to every six months.

Sample Forms & Article

[HealthPartners Drug Sample Policy](#)
links to sample in appendix

[AHRQ Medication Management strategy](#)

Other Resources –Links

[American Pharmacists Association- Patient Safety Resources](#)

References

[AHRQ Medication Management Strategy](#)

[FDA Drug Sample Distribution Requirements](#)

Medication Safety: Do Not Use Abbreviations

◆ Identify the Safety Risk

HealthPartners and Regions Hospital are part of a metro area-wide effort to eliminate unsafe prescribing practices and reduce medication errors. Our efforts are part of the Safest in America (SIA) and The Joint Commission initiatives to eliminate dangerous abbreviations, acronyms, and symbols. We provide this information to encourage the elimination of unsafe prescribing practices in all clinical settings.



Suggestions for Improvement

- Establish a protocol and try to eliminate all handwritten prescriptions.
- Perform an audit of prescriptions written and e-prescribed in the clinic on twenty records to monitor for compliance with your clinic's protocol. If 100 percent compliance is not seen, share results with providers and set goals for improvement.
- Continue to monitor for compliance. Consider additional initiatives with providers if 100 percent compliance is not seen.
- Obtain examples of poor prescription writing from pharmacies and have them block out the names to protect patient confidentiality. You can show these to providers as examples.
- Assess prescription writing or e-prescribing practice by assigning a nurse to review all the prescriptions written or e-prescribed in a day as patients exit the clinics.
- Collaborate with a pharmacy and provide them with standards and a chart to track a clinic's prescriptions. Ask them to assess every prescription for one week or one month and give feedback. Review at least twenty prescriptions. Generate provider specific data and give feedback with suggestions for improvement. We suggest monitoring every 3 to 6 months once standards are in place.
- If a medical practice has an electronic medical record, an electronic prescription writing platform may already be in place. Create a monitoring system (through EMR data reports) to check for accuracy.
- Member interviews and pharmacy reports are additional resources to use in monitoring and validation checks.

Other Resources – Links

[Joint Commission Do Not Use List](#)

References

[Joint Commission](#)

Medication Safety: Medication Reconciliation

◆ Identify the Safety Risk

Medication reconciliation is the process of comparing a patient's medication orders to all the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medications are ordered or existing orders are rewritten.

HEDIS instituted a measure regarding Medication Reconciliation Post-Discharge (MRP). The specification from CMS requires that medication reconciliation occur within 30 days post-discharge from an inpatient facility. Even though this measure has a restricted population, the standard of care should apply to any member with complex medical care needs on multiple medications



Suggestions for Improvement

- Establish a spot in the medical record where the current medication list is stored. This should be accessed upon opening a medical record or on the encounter page in an electronic medical record (EMR).
- Implement a process for obtaining and documenting a complete list of each patient's medications upon admission/discharge to clinic and hospital using member's preferred pharmacy. Establish a communication method (fax or EMR) where an inpatient facility provides the patient's current list of medications upon discharge from an inpatient facility.
- Develop a tool for the member to use and carry with them to bring for each visit to keep medications up to date
- Consider a pre-visit or a post visit phone call to review medications with the patient.

Implement a process for obtaining and documenting a complete list of each patient's medications upon admission/discharge to clinic and hospital using member's preferred pharmacy. Establish a communication method (fax or EMR) where an inpatient facility provides the patient's current list of medications upon discharge from an inpatient facility. Include a statement in scripting about how the patient's provider gives recognition of legitimate authority. For example, "Dr. X wants to know your medications and would like you to know them too."

- Develop scripting messages around medication reconciliation to promote consistency, assure an important level of service, help staff to manage difficult situations, and set clear expectations. Scripts also promote a verbal commitment and compel people to follow through. Commitment influences behavior and may increase compliance.
- Once you have developed the medication reconciliation script with input from front line staff, evaluate it in a small group. Make changes as needed.

Sample Forms & Article

[My Medicine List Tool](#)
[HealthPartners Medication Improvement](#)
[HealthPartners Medication Reconciliation](#)

Other Resources –Links

[AHRQ & Patient Safety Network \(PSNET\)](#)
[Medication Reconciliation Pitfalls](#)
[NIH Seniors and Medication](#)
[Medication Reconciliation Roadmap](#)
[Joint Commission National Patient Safety Goals](#)

References

[IHI Medication Reconciliation](#)
[AHRQ Medication Reconciliation](#)

Medication Safety: Protocols for Use of Hazardous Drugs and Controlled Substances

◆ Identify the Safety Risk

Warfarin, Amiodarone, Insulin, and controlled substances such as opioids are the most common potentially hazardous drugs prescribed in the outpatient setting. Research demonstrates that standardized prescribing of these medications may improve safety and potentially prevent misuse or abuse.

Warfarin, Amiodarone, Insulin, and controlled substances such as opioids are the most common potentially hazardous drugs prescribed in the outpatient setting.

Protocols for a Coumadin prescription, along with standing orders for INR determination are available through multiple sources, including the product manufacturer. Clinics should have standing orders that allow nurses or pharmacists to renew or alter doses based on lab test results or changes in the patient's circumstances. Standing orders that require regular assessment of INR should also be in place.

Sliding scales for Insulin have improved care by allowing those at the actual point of contact with the patient to modify medication orders based on point of care testing. Protocols, guidelines, and standing orders should be developed to allow nurses, Medication Therapy Management (MTM) pharmacists or Certified Diabetes Educators (CDE) to provide the greatest level of patient care in the safest manner.

Use of chronic Opioid therapy for chronic nonmalignant pain (CNMP) has increased substantially; therefore, effective management is considered a major problem in both primary care and out-patient medicine. It presents a major challenge for both the patient and health care provider. Opioids are associated with potentially serious harms, including adverse effects and outcomes related to the abuse potential and diversion.

Does your clinic have protocols in place and standing orders for Coumadin, Amiodarone, Insulin, and controlled substances (CS)? Are CS locked in a safe place with a sign out procedure? How complete are the protocols for hazardous drugs?

Have you compared them to guidelines? How well are the protocols and standing orders followed in your clinic? Does your clinic have a protocol for disposing of controlled substances or hazardous medications?



Suggestions for Improvement

- Establish protocols for the use of hazardous drugs in your clinic. Make sure that the protocol addresses standardized daily dosing algorithms, monitoring, and management plans. Include details on lock up and sign out procedures for certain medications.
- Form an improvement/quality group of providers to review the current methods of providing safe care to patients who are on controlled substances. Evaluate the results and implement change if improvement is needed.
- Update protocols and standing orders as needed to be in compliance with guidelines.
- Perform a sample audit of records (such as twenty records) to compare with each of the medication guidelines and orders in your protocol(s). Review compliance outcomes with your clinic's quality team.
- Continue to monitor for compliance against the clinic protocols for hazardous drugs.
- If you use an electronic medical record, and as computers become more common in exam rooms, incorporate the guidelines, standing orders and other safety tools into the workflow of patient care.

Other Resources –Links

[Anticoagulant Therapy Management](#)

[Guidelines: Diabetes](#)

[Standards of Care in Diabetes](#)

[CDC Guidelines for Prescribing Opioids for Chronic Pain](#)

[Pain Assessment, Non-Opioid treatment approach and Opioid Management](#)

[American Pharmacists Association: Patient Outreach Tools](#)

References

[AHRQ](#)

[Controlled Substances Act](#)

[MN Pharmacy Board: Prescription Monitoring Program](#)

[National Practice Guideline for Opioids](#)

Medication Safety: Antibiotic Prescribing

◆ Identify the Safety Risk

To reduce risk, monitor the overuse (multiple dispensing) of antibiotics and/or inappropriate use of antibiotics. Some potent antibiotics, while highly effective against certain types of infections, have a considerable risk for toxicity. This risk is even greater with patients who have impaired renal function.

When using antibiotics that have a considerable risk of toxicity, such as Aminoglycosides and Vancomycin, use protocols or other standardized dosing guidelines to assist prescribers in selecting appropriate doses based on clinical condition and renal function.

Ongoing provider monitoring completed by Minnesota Community Measurement includes the following measures:

- Appropriate Treatment for Children with Upper Respiratory Infections
- Appropriate Testing for Children with Pharyngitis
- Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis

Performance information will provide meaningful and useful information to clinicians for therapeutic decision making and management.



Suggestions for Improvement

- Develop a protocol to follow with antibiotic prescriptions.
- Review the Minnesota Community Measurement provider monitoring for the measures listed above.
- Use existing guidelines and protocols with appropriate criteria to meet before ordering an antibiotic. If possible, implement these guidelines into your EMR or patient workflow to use when prescribing antibiotics.
- Consider creating a tool with criteria to check for quarterly chart audits on children and adults who have received antibiotics. Review results and try to identify if greater action is needed for appropriate use of antibiotics.

Other Resources – Links

[IDSA Practice Guidelines:](#)

[CDC Antibiotic Prescribing Use](#)

References

[MN Community Measurement](#)

[AHRQ Safety Program for Improving Antibiotic Use](#)

[IHI Antimicrobial Prescribing](#)

Medication Safety: Prescription Refills

◆ Identify the Safety Risk

All providers will have a process for prescription refills to ensure patients receive approvals in a timely and safe manner. Providers should develop a standing order policy and procedure regarding frequent medication refills.

Research studies have proven the effectiveness of automated or electronic prescription writing programs to reduce errors in handwritten prescriptions. E- Prescribing allows for clear, concise, and legible instructions. HealthPartners encourages the adoption of E-prescribing in all clinical settings.

Electronic prescribing can offer enhanced safety features for patients. Prescriptions are legible, and pharmacists can eliminate worries over misunderstood phone messages for a prescription or refill of a medication consisting of a sound alike name.

Online prescription refills are another technology that can reduce errors and improve prescription processing efficiency. With online refills, patients can submit their refill requests electronically.



Suggestions for Improvement

- Create or implement a protocol on prescription refills for your clinic. This could be incorporated into an electronic medical record or an on-line refill system.
- Create an assessment sheet for auditing purposes. The assessment could include how the refill was provided, by what provider, who picked up the order, what pharmacy refilled the prescription, did the member need to be seen prior to the refill, and, if so, was the member seen?
- Integrate the clinic protocol parameters into the assessment. Complete a random audit of twenty members with refills. Use the assessment sheet to track audit results.
- Form a work group to assess the audit data (providers, nurses, medical assistants). Compare data to the policy parameters. If parameters were not met, evaluate if changes are needed in the policy.
- Review and analyze the other data results. Is there an area where improvement is needed in the refill process? If so, have the work group develop an improvement initiative.
- Once the initiative is implemented, evaluate quarterly until improvement is seen, or until other changes are made.
- Continue to monitor for compliance with your clinic's prescription refill protocol on an ongoing basis.
- Consider implementing a refill reminder system to increase compliance.

Other Resources – Links

[AHRQ Article](#) *Best Practices in Medication Safety: Areas for Improvement in the Primary Care Physician's Office*

References

[AHRQ standing order](#)

Medication Safety: Generic Prescribing

◆ Identify the Safety Risk

Generics are a safe, effective alternative to many brand name drugs. Generic drugs, have been on the market for a long time, making them a more dependable, cost effective, and safe choice compared to newly introduced or brand-named drugs. Pharmacies are required to dispense equally effective generic drugs when available unless the physician or patient refuse.

Prescription drugs can be a costly medical expense. Each state which allows pharmacists to substitute less expensive generic drugs for many brand-name products. Generic drugs are less expensive because generic manufacturers do not have the investment costs that the developer of a new drug has.



Suggestions for Improvement

- Create a generic drug protocol in your clinic.
- Choose one common brand name drug to focus on in your clinic.
- Identify patients and target to move them toward generic conversion from the brand name drug to the equivalent generic.
- Perform an audit to identify patients who are on the drugs and run a cost summary of the past year. The summary should include cost of the drug and cost to the patient.
- Create a generic education sheet and describe the medication conversion on which you are focusing.
- Identify twenty patients and flag their medical record to focus on conversion to a generic equivalent on their next office visit.
- Make a follow-up phone call to the patient three to five days after the prescription was written for conversion.
- Submit a questionnaire to check on satisfaction and send to patients two months after conversion. Review the satisfaction outcomes and determine if you can broaden the conversion program.
- Re-run the cost analysis data in three to six months and again in one year and compare that to the brand cost data.

Other Resources – Links

[FDA Generics \(Orange Book\)](#)

[HealthPartners formulary](#)

[HealthPartners generics RX](#)

References

[HealthPartners Provider Portal](#)

Reporting Results: Follow up from Tests and Procedures

◆ Identify the Safety Risk

All providers will have a process and written protocol to identify abnormal diagnostic results, reporting abnormal results to clinicians and actions taken.



Suggestions for Improvement

- Examine your practice and review your current “results reporting” process. Is there a protocol in place? If not, form a work group to establish a clinic wide result reporting policy. Questions to answer may include: What critical values require phone calls?
- What tests require a written letter from the provider?
- What is the turnaround time required for a test to be completed and reported initially?
- What is the turnaround time goal for reporting the results to the patient?
- Is there a difference between a turnaround time and type of notice given for normal verses abnormal results?
- Is there a provider back up plan to notify patients of results if the provider who ordered them is not available to get back to the patient?
- Is there a rule about leaving information on results on answer machines or with other people?
- What documentation needs to occur in the notification process and who is responsible for this?
- Try to address all these issues and define parameters for the notification process in your clinic policy.
- Develop a form letter for reporting normal results to the member to simplify reporting normal results to the patient.
- If your clinic uses patient e-mail notification, consider adding detail in the protocol to address reporting results through this process.
- Perform a random audit of normal and abnormal result notifications under your current process. Use this as baseline data.
- Implement the new process and policy. After one month, perform a random survey of charts. Document results and evaluate if any changes need to be made. Resurvey compliance on a regular basis.
- If failure to notify patients in a timely manner is rare, an annual evaluation should be sufficient. If you are seeing problems, try to perform a gap analysis, adjust the process, and update the policy. If problems are noted, a quarterly audit for compliance may be required.

Other Resources – Links

[Communicating Critical Test Results: Safe Practice Recommendations](#)

References

[HealthPartners Clinical Indicators](#)
[HealthPartners Provider Portal](#)

Have a question?

Contact quality@healthpartners.com

Appendix

HealthPartners Drug Sampling Policy – page 1 of 4



Subject Pharmaceutical Sampling	Attachments <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Key words Drug samples, pharmaceutical sampling, drug dispensing, pharmacy	Number GHI EC HPMG Ops 03
Category Environment of Care, Work Service (EC)	Effective Date 3/2022
Manual HealthPartners Medical Group and Clinic Operations Manual	
Issued By HPMG Pharmacy Committee; HPMG Care Group	Next Review Date 11/22
Applicable HPMG, HealthPartners Clinics, Regions Hospital, Hudson Hospital, Westfield Hospital, Lakeview Hospital and their affiliated clinics.	Origination Date 11/90
	Retired Date
Review Responsibility HPMG Pharmacy Committee; HPMG Care Group, Hospital P & T and clinic operations	Contact Dir. of Pharmacy

I. PURPOSE

To define a process for the control, accountability, security and safety of pharmaceutical samples throughout the HealthPartners organization.

II. POLICY

Individual clinics or care units wishing to continue or initiate storage and distribution of prescription pharmaceutical samples must apply to the HPMG Pharmacy Committee for pharmaceutical sampling privileges. Applications will include a detailed written plan for compliance with the procedures outlined below. Applications will be reviewed upon initial request and approved or denied by the Pharmacy Committee. The Chief of Professional Services or Department Head will be responsible for the implementation and compliance of the Pharmaceutical Sampling Policy for his/her clinic and/or department.

The management of pharmaceutical samples will adhere to this policy and be compliant to laws, regulations and standards (eg. Joint Commission, Board of Pharmacy and FDA) regarding the storage, prescribing, dispensing and documentation of prescription pharmaceuticals and will be consistent with other organization policies and procedures for medication use.

This policy does not pertain to NON-prescription pharmaceutical items.

III. PROCEDURE(S)

- A. For approval of the approval of sampling of prescription pharmaceuticals complete the application requesting the use of pharmaceutical samples, including the elements listed below.
 - 1. The designated requesting physician and chief or department head.
 - 2. Clinic location.

3. Purpose for providing pharmaceutical samples. Include how the proposed pharmaceutical sampling practice will satisfy the following principles for drug dispensing/distribution:
 - i. Safety—the use of pharmaceutical services/agents within our systems will not pose a threat to our patients/members.
 - ii. Effective—patients/members will receive the most appropriate pharmaceutical interventions, avoiding underuse and overuse.
 - iii. Equitable—pharmaceutical services/agents will be consistent and fair to all patients/members. Individual personal characteristics will only guide pursuit of optimal outcomes.
 - iv. Patient Centered—pharmaceutical services/agents will be respectful of individual patient/member needs, preferences and values.
 - v. Timely—the delivery of pharmaceutical services/agents will eliminate unnecessary waits and harmful delays to both patients/members and providers.
 - vi. Efficiency—pharmaceutical services/agents will be guided by wise stewardship of resources, avoiding waste and inefficiencies.
 4. A designated coordinator who is responsible for oversight of the sample inventory and compliance with this policy.
 5. A list of prescription pharmaceuticals that will be maintained in the sample inventory.
 6. A specific location where:
 - i. Samples can be securely stored with access limited to authorized staff,
 - ii. Storage conditions such as temperature, light and moisture according to manufacturer recommendations..
 - iii. Samples are organized so as to reduce the risk of a dispensing error. This includes the requirement of samples to be within the expiration date.
 - iv. Cytotoxic agents are stored separately from other medications, if applicable.
 7. Identity of individuals or staff roles authorized to access, prescribe and dispense sample prescription pharmaceuticals.
 8. Log of all prescription pharmaceuticals signed into the sample inventory with lot numbers and expiration dates.
 9. Clear process to identify outdated, damaged, discontinued and recalled medications and remove from the sample inventory. (removal from inventory must be documented on the inventory log)
 10. Clear pharmaceutical waste disposal plan that prevents unusable medications from being dispensed and properly disposes of sample medications as hazardous waste (black bins).
 11. A clear dispensing process that outlines who is authorized to prescribe and dispense samples, the labeling of samples, any information that will be provided to patients, and appropriate documentation in the patient's medical record (in the Active Medication List).
 - i. A medication for sampling, can be appropriately entered into the "Active Medication List" of Epic, without generating a prescription, by the following process:
 1. Go to the "Order Entry" tab of Epic
 2. Enter the prescription information as normal
 3. In the "Class" section of "Order Entry", click "No Print/No Fill" button.
 12. Log the pharmaceutical sample that was dispensed to the patient in the inventory log, including patient information, medication name and lot number.
 13. A process to monitor patients for the effects of the dispensed sample medication, and how to respond to adverse drug events/reactions and medication errors.
 14. A monthly audit process to monitor compliance with this policy and ensure quality control of samples. Each month will require that sample inventories are verified and ensure that samples are not expired.
 15. Communication plan to notify all staff of sample policy, procedures and expectations.
- B. Send completed request/application to the Chair of the HPMG Pharmacy Committee.

- C. Any additions/deletions/changes to the Sample List must be provided to the Pharmacy Committee at least yearly. Normally this can be communicated at the time of the "Annual Sampling Audit". Additions for sample drugs utilized must be approved in advance by the Pharmacy Committee.
- D. Attestations and audits must be resubmitted annually.
- E. Clinics who sample agree to participate and respond to the annual sampling audit as distributed by the Pharmacy Committee.
- F. Documentation must exist that samples were provided to patients. Documentation of the patient should be listed in the inventory log or dispensing log as well as in the medical record.
 - 1. Samples will be logged out of the sampling inventory if inventory is removed or destroyed.
 - 2. All dispensed pharmaceutical samples will be documented in the sampling log.
 - 3. All pharmaceutical samples dispensed to the patient must be documented in the patient medication record (Epic).
 - 4. All sampling logs will be kept on site for a minimum of 2 years.

IV. DEFINITIONS n/a

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS See Medication Sampling Log

VII. OTHER RESOURCES

Internal HealthPartners Safety Toolkit at Healthpartners.com/quality

Other Joint Commission Standard, TX.3.17

VIII. APPROVAL(S)

Nancy McClure
Chief Operating Officer, Care Group

Mark Sannes, MD
Sr. VP and Co-Executive Medical Director, Care Group

IX. ENDORSEMENT n/a

