



california**pharmacists**association

Guidelines for Pharmacists Ordering and Managing Tests to Ensure Safe and Appropriate Medication Therapy

(Version 5)

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Subcommittee Members:

Steven Chen, PharmD (Chair)
Robert Chun, PharmD (Sutter Health)
Rebecca Cupp, PharmD (Ralphs Pharmacies)
Robert Deamer, PharmD (Kaiser Permanente)
Hyunah Eom, PharmD (Sutter Health)
Paul Gregerson, MD, MBA (JWCH Institute)
Ashley Gutierrez, PharmD (PGY1 Resident, USC)
Michael Hochman, MD (AltaMed Health Services)
Paul Huynh, PharmD (Walgreens Pharmacies)
Rory O'Callaghan, PharmD (USC)
Michelle Schlueter, PharmD (UCSD)
Ken Thai, PharmD (Independent Pharmacy)
Robert Young, MD (Assistant VP of Patient Financial Services, AltaMed Health Services)



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I. Purpose and Objectives

The purpose of this guideline is to identify the professional standards pharmacists should follow when ordering and interpreting tests for the purpose of monitoring the efficacy and safety of drug therapy. Specific objectives are as follows:

1. Establish best practices for pharmacists ordering and managing tests in the course of monitoring and managing the efficacy and safety of medication therapy in collaboration with the patient's primary care provider, diagnosing prescriber, medical home, etc. The priority of these best practices is to ensure that test ordering by pharmacists is performed only when necessary and that results are managed appropriately and promptly. These best practices are based on research, government reports, and decades of combined experience from California and other states.
2. Provide resources to educate other healthcare professionals, testing organizations, health plans, and other third party payers about the role of pharmacists in ordering and managing tests in coordination with primary care providers and other members of the healthcare team.
3. Describe payment models for test ordering by pharmacists.

II. Background / Rationale

With the signing of Senate Bill 493 by Governor Brown in 2013, California licensed pharmacists are now recognized as healthcare providers and are granted certain authorities in all practice settings that had previously been limited to inpatient settings or integrated systems. One of these authorities is ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. Specifically, the section of SB 493 that describes this authority is as follows:¹

4052.(a)(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber

The basis for this authorization includes decades of published experience and evidence demonstrating that granting pharmacists the clinical privilege to order medication-related tests is associated with improvements in healthcare quality measures, medication safety, and overall healthcare costs. The literature containing this information is best summarized by the U.S. Public Health Service.² In addition, the importance of these clinical privileges on patient and health system outcomes is emphasized by many government and interdisciplinary national healthcare

1: Official California Legislation Information, available at: http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_bill_20131001_chaptered.pdf

2: Giberson S, Yoder S, Lee MP. Improving patient and health system outcomes through advanced pharmacy practice. A report to the U.S. Surgeon General. Washington, DC: Office of the Chief Pharmacist, U.S. Public Health Service; 2011.

organizations such as HRSA, CDC, and the Patient Center Primary Care Collaborative.^{3,4,5} In fact, the services outlined in SB 493, including ordering tests, are already performed by pharmacists in California health system settings working collaboratively in accordance with physician-endorsed policies and procedures and evidence-based practice guidelines as well as in other states. For over five decades, pharmacists have been engaged as primary care providers in team-based federal health care models such as the Indian Health Service, Department of Veterans Affairs and Department of Defense. Kaiser Permanente has similarly integrated pharmacists into their medical practices for over 30 years. The California Right Care Initiative, from the California Department of Managed Healthcare, recognizes pharmacists with clinical privileges as a key to improving health outcomes and is supporting efforts to help health plans and medical groups identify methods for initiating or expanding clinical pharmacy programs.⁶ Ultimately, a pharmacist's responsibility as a member of the healthcare team is to consider all relevant information when determining the appropriateness, safety, and effectiveness of medication therapy, and oftentimes test results are essential to make such a determination. Examples include individualizing dosing for drugs with narrow therapeutic windows or requiring dosage adjustment in renal or hepatic impairment, ruling out an adverse drug reaction, monitoring a chemistry panel for patients receiving medications that can alter electrolytes or renal function markers, or screening patients for untreated medical conditions that may prompt further follow-up with the assigned primary care provider.

III. Guidelines for Test Ordering, Interpretation, and Management by Pharmacists

Key principles for test ordering, interpretation, and management by pharmacists are:

- Testing should be for ensuring safe and effective medication therapy in coordination with the patient's primary care provider or diagnosing prescriber.
- Tests must only be ordered when necessary.
- Test results must be managed appropriately and promptly;
- Patients should receive feedback on their tests in a timely manner.
- Quality assurance should be integrated into the test ordering, interpretation, and management process.

A. Responsibility⁷

Pharmacists are individually responsible for personal competence in ordering tests and interpreting results. Variables that may impact test results must be considered by pharmacists when interpreting results including timing of testing, medications, renal or hepatic function, fluid status, lab error, etc. The Advanced Pharmacist Practitioner designation as described in SB493 is designed to establish a minimum level of competence.

3: HRSA Patient Safety and Clinical Pharmacy Services Collaborative (PSPC), Available at: <http://www.hrsa.gov/publichealth/clinical/patientsafety/>

4: The Centers for Disease Control. A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases (2012). National Center for Chronic Disease Prevention and Health Promotion. Available at:

http://www.cdc.gov/dhdsp/programs/nhdsp_program/docs/pharmacist_guide.pdf

5: The Patient-Centered Primary Care Collaborative. Integrating Comprehensive Medication Management to Optimize Patient Outcomes, Second Edition. June 2012. Available at: <http://www.pcpcc.net/files/medmanagement.pdf>

6: The California Right Care Initiative. Available at: http://www.dmhc.ca.gov/healthplans/gen/gen_rci.aspx

7 : Guidelines for Pharmacists Ordering Laboratory Tests and Using Laboratory Data. Alberta College of Pharmacists. Available at: https://pharmacists.ab.ca/Content_Files/Files/GuidelinesForOrderingLabTests.pdf

Pharmacists are expected to maintain competency demonstrated with ongoing education, training, and experience. Specific institutions or third party payers may apply their own credentialing and privileging requirements, to enhance requirements for specific needs, within their organizations.

B. Using test results

In situations where tests could impact medication therapy decisions or medication therapy might alter testing results, pharmacists should review relevant tests that are required to make this determination. If required tests are not available, e.g., tests that are mandated in current treatment guidelines, FDA recommendations, or medication prescribing information, then the pharmacist should consider ordering or facilitating the ordering of these tests in collaboration with the relevant medical entity (see section III.C.) Examples where a review of test results is indicated include but are not limited to:

1. Individualizing drug dosing
 - a. Serum drug levels for medications with narrow therapeutic indexes (e.g., lithium, antipsychotics, anticonvulsants)
 - b. INR for warfarin patients
 - c. Renal and hepatic function tests for medications requiring dose adjustment in renal or hepatic impairment.
 - d. Culture and sensitivity results for antibiotic therapy
2. Selection of appropriate drug therapy (Note per section III.D. that the pharmacist is not necessarily the individual who will interpret the test results, depending on expertise and training.)
 - a. Patient with unspecified heart failure (e.g., no echo report, PCP and other members of healthcare team unaware of ejection fraction and other information relevant to treatment).
 - b. Adult patient diagnosed with new onset asthma with vague symptoms and no history of spirometry testing.
 - c. Patient with diagnosis of Type 2 diabetes and no response to oral diabetes medications or very widely fluctuating glucose levels with minor changes in insulin doses, no history of insulin antibody and C-peptide testing.
 - d. Chest X-ray to screen for long-term adverse drug effects (e.g., amiodarone)
3. Attainment of patient specific treatment goals outlined in established guidelines and government standards
 - a. A1c for diabetes treatments
 - b. Thyroid function tests for thyroid replacement therapy
 - c. Uric acid for gout therapy
4. Medication safety and monitoring, as mandated by guidelines and government standards
 - a. INR for change in medications/diet/ health that may affect warfarin therapy
 - b. Chemistry panel for patients with recent changes in doses of diuretics, ACE-inhibitors, ARBs, etc., particularly those at risk for renally-related adverse effects (e.g., heart failure, renal impairment).
 - c. Liver function tests for Tb treatment, methotrexate therapy, etc.
 - d. Urine drug test screening
 - e. EKG for QT interval screening
 - f. Pregnancy testing for risk evaluation and mitigation programs (urine beta-HCG)
 - g. Lab monitoring for alcohol use disorders (AST, ALT, MCV, GGT)
5. Recognition of untreated health conditions: screen patients at risk of developing various health conditions



- a. Bone density test for individuals at risk for osteoporosis
- b. Patient with Type 2 diabetes for several years and no history of UACR testing
- c. Metabolic panel and weight gain monitoring with antipsychotics
- d. Patient assessment with PHQ-9 for depression

C. Ordering tests

1. If specific tests are important for determining the appropriateness, efficacy, or safety of medication therapy and test results have not been previously ordered or are out of date then pharmacists should order the tests or follow the procedure within their collaborative practice to ensure that the appropriate test is ordered.
2. Pharmacists must pursue all reasonable approaches to ensuring that tests are not duplicative prior to ordering, e.g., review of the electronic health record, contact with test technician if such a line of communication is available. An exception is when a result is questionable and warrants a repeat test (e.g., abnormal potassium level and suspected hemolysis of blood sample based on previous test results).
3. Pharmacists should only order those tests that they are personally competent to order; otherwise, an appropriate authority should be consulted.
4. Tests must be necessary (e.g., per treatment guidelines, government mandates, prescribing information; clinical evaluation requirement) and limited to patients under the care of the pharmacist / pharmacy service.

D. Interpretation of test results

1. Pharmacists should only order tests that they are experienced in interpreting. An exception is when a test is necessary and, in a pre-arranged collaboration, the test is ordered but planned for interpretation by a qualified healthcare professional.
2. Pharmacist must use professional judgment and consider all variables when interpreting test results. For example, tests can be influenced by multiple variables including lab error, gender, other drugs, pregnancy, diet, organ function, genetics, or incorrect timing of tests.

E. Following-up on test results

1. Pharmacists who order tests must have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day or establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc.
2. Patients should be informed of what to expect by having the pharmacist order tests, e.g., who will follow-up and how soon. The timeliness of follow up will depend on multiple variables such as the urgency of the test or the availability of the patient; in some cases (e.g., homeless or transient patients), the next appointment may be acceptable for follow up.

It may be reasonable to involve capable patients in following up on their own test results after an appropriate time interval. This does not relieve the pharmacist of their duty to follow up, but add a level of safety to the test follow-up process while engaging patients in their own care.

3. If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.
4. Pharmacists must take appropriate action if the result of a lab test ordered is a critical value, defined as, "A laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken".⁸ No national standard exists for critical value thresholds; these values are best defined by healthcare organizations utilizing the literature, local and national peer institutions or networks, and input from medical service groups or healthcare leadership committees.
5. At minimum, a pharmacist who receives a critical value should contact the physician responsible for the care of the patient at the time of notification (e.g., PCP, MOD). Examples of other actions taken by the pharmacist include, but are not limited to:
 - Repeat the test if the value does not seem plausible based on other subjective and objective findings or consult with the testing organization about the abnormal finding.
 - Discuss the results with the patient in an attempt to correlate results with clinical presentation
 - Consult with other members of the healthcare team, in particular informing the assigned primary care provider regardless of the action(s) taken
 - If the test relates to an existing diagnosis, modify drug therapy or (depending on collaborative practice agreement) recommend modifying drug therapy to the primary care provider in accordance with test results.
 - If the test suggests a new medical problem, refer the patient to the appropriate member of the healthcare team.

F. Standards for documentation

1. As required by SB 493, all actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) must be documented within 24 hours in a system readily accessible to all involved healthcare team members involved. The documentation system of choice, the electronic health record, should be made available to pharmacists who are part of the care team regardless of location / care venue (e.g., integrated into medical home, community pharmacies, remote telehealth clinical pharmacy services). In addition to supporting real-time communication, EHR access will reduce the likelihood of unnecessary or duplicative testing.
2. Documentation of pharmacist decisions involving test results should include:
 - Interpretation of the result

8: Lundberg GD. When to panic over abnormal values. MLO Med Lab Obs. 1972;4:47-54.



- Rationale for the decision based on the result and any other patient-related information
- What was communicated to the patient and other healthcare team members involved in the patient's care

G. Quality Assurance of Testing Management

1. A quality assurance program is essential for ensuring the reliability of the testing process used by any healthcare professional. It is recommended that pharmacists work with collaborating healthcare organizations to determine the most effective and efficient method of integrating a quality assurance process. One approach may be to include pharmacists in the organization's existing peer review process.
2. Tools are available to examine how tests are being managed, from ordering to patient notification of results and any decisions made as a result of the tests. A recent quality assurance resource for testing from AHRQ requires the following elements for adoption:⁹
 - A commitment to improvement
 - Senior leadership support for quality and safety improvement
 - Teamwork and an acceptance that everyone is responsible for the success of the process
 - Commitment to honest and open communication.
 - Regular peer review and sharing of performance results among staff.
 - A focus on systems / processes instead of blame on individuals.

9: Improving Your Office Testing Process: A Toolkit for Rapid-Cycle Patient Safety and Quality Improvement. Available at: <http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/office-testing-toolkit/>

IV. Information and Resources for Other Stakeholders / Partners Regarding Pharmacists Ordering, Interpreting, and Managing Tests

Every stakeholder and partner involved with patient care needs to understand the pharmacist's role in ordering, interpreting, and managing tests under SB 493. Information shared should include background about provider status under SB 493 and reference to language in the bill regarding test ordering and interpretation by pharmacists. Other clarifying information may include the rationale for pharmacists ordering tests, procedures used to ensure that test results are managed appropriately and in a timely manner, methods of communication / documentation, and quality assurance of the testing process. A sample 1-page (double-sided) Q&A information sheet is attached in Appendix A that may be appropriate for healthcare professionals, third party payers, and testing organizations.

V. Reimbursement for Tests Ordered and Managed by Pharmacists

Section 4052.(a)(12) of SB493 states that pharmacists are able to, "*Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies.*" Furthermore, the section clarifies that the ordering of tests by pharmacists must be, "*...done in coordination with the patient's primary care provider or diagnosing prescriber...*" As a result, reimbursement for tests ordered and managed by pharmacists is achieved through agreements between the pharmacist / pharmacy, primary care provider or diagnosing prescribers, and third party payers. Third party payers need to understand the role of pharmacists in ordering and managing tests to ensure that tests ordered by pharmacists in collaboration with the appropriate care provider are accepted and processed. The nature of reimbursement will vary, ranging from negotiated fees for specific tests to shared payments under value-based reimbursement contracts.

In other states where pharmacists have provider status, test ordering by pharmacists in and of itself is not directly reimbursed. For example, test ordering by pharmacists in North Carolina is facilitated through collaborative practice agreements, signed by supervising physicians, that list "approved tests". Some but not all institutions have pharmacists undergo credentialing and privileging. The benefits to institutions from allowing pharmacists to order and manage tests include finances to the institution through billing for tests (fee for service) and improvement in healthcare quality and safety through improved monitoring and attainment of treatment goals, as well as increased physician access as patients requiring greater time and resources for monitoring are managed by the pharmacist (value-based).

Appendix A: Information about pharmacists ordering and managing tests

In October of 2013 Governor Brown signed Senate Bill 493, making California the 4th state in the nation to recognize pharmacists as healthcare providers. A primary driver behind the Governor's decision to sign the bill is the proven impact pharmacists have on improving healthcare quality and safety while reducing healthcare costs. To accomplish this, pharmacists must consider all information relevant to the safety and efficacy of medication therapy, including tests results. As a result, one of the authorities granted to pharmacists in SB493 is ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, in coordination with the patient's primary care provider or diagnosing prescriber.¹⁰

Q: What qualifies pharmacists to order tests?

A: All pharmacy schools today confer the Doctor of Pharmacy degree to graduates, requiring didactic and experiential training in comprehensive management of medication therapy including testing relevant to medication efficacy and safety. In addition, residency training for pharmacists provides in-depth experience with direct management of patient drug therapy, and board certification for pharmacists provides ongoing assessment to achieve a high level of clinical knowledge that includes appropriate use of tests. Every healthcare institution or third party payer should apply credentialing standards for pharmacists that are similar to other healthcare providers.

Q: Won't pharmacists ordering tests lead to duplication and wasted resources?

A: Pharmacists review all sources of test results before ordering any test, and tests ordered by pharmacists should be for the purpose of, "...monitoring and managing the efficacy and toxicity of drug therapy."⁸

Q: Who interprets tests ordered by pharmacists?

A: Pharmacists only order tests that they are experienced in interpreting UNLESS a pre-arranged collaboration is established for a qualified individual to interpret the test result. Pharmacist are trained to use professional judgment and consider all relevant variables when interpreting test results including lab error, gender, other drugs, pregnancy, diet, organ function, genetics, or incorrectly timing of tests.

Q: Who is responsible for following-up and managing tests ordered by pharmacists?

A: Pharmacists who order tests will have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day or establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc. Patients will be informed of what to expect by having the pharmacist order the test, e.g., who will follow-up and how soon. If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.

10: Official California Legislation Information, available at: http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_bill_20131001_chaptered.pdf



Q: How will pharmacists manage highly abnormal test results (“critical values”)?

A: Pharmacists must take appropriate action if the results of a lab test that ordered is highly abnormal and exceeds critical value limits established by the collaborating healthcare organization. Examples of such actions, established in agreement with the appropriate primary care provider or prescriber, include:

- Repeat the test if the value does not seem plausible based on other subjective and objective findings or consult with the testing organization about the abnormal finding.
- Discuss the results with the patient in an attempt to correlate results with clinical presentation
- Consult with other members of the healthcare team, in particular informing the assigned primary care provider regardless of the action(s) taken
- If the test relates to an existing diagnosis, modify drug therapy or (depending on collaborative practice agreement) recommend modifying drug therapy to the primary care provider in accordance with test results.
- If the test suggests a new medical problem, refer the patient to the appropriate member of the healthcare team.

Q: How will pharmacists communicate their decisions and actions to other members of the healthcare team?

A: All actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) will be documented within 24 hours in a system readily accessible to all involved healthcare team members involved. The documentation system of choice, the electronic health record, should be made available to pharmacists who are part of the care team regardless of location / care venue (e.g., integrated into medical home, community pharmacies, remote telehealth clinical pharmacy services). In addition to supporting real-time communication, EHR access will reduce the likelihood of unnecessary or duplicative testing. Documentation of pharmacist decisions involving test results should include:

- Interpretation of the result
- Rationale for the decision based on the result and any other patient-related information
- What was communicated to the patient and other healthcare team members involved in the patient’s care

Q: How will pharmacists ensure that the process used to order and managed tests remains safe, appropriate, and effective?

A: Pharmacists are responsible for ensuring that a quality assurance assurance is in place for verifying that the testing process is safe, appropriate, and effective. In many instances, collaborating healthcare organizations can integrate pharmacists into their internal peer review process for test ordering and other quality measures. Tools such as the AHRQ Toolkit for Rapid-Cycle Patient Safety and Quality Improvement for Testing (<http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/office-testing-toolkit/>) can be utilized for this purpose.