

Practice Guidance for Pharmacy-Based Medication Administration Services



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Dear Pharmacist,

Our profession is rapidly changing and constantly evolving. As a result, there are increasing opportunities for pharmacists to more fully engage as integral members of the health care team by offering advanced patient care services, building upon services that patients have come to rely on from their pharmacist. Pharmacists offer knowledgeable, accessible, and personal care to patients, improving quality of care and patient experiences. An example of a growing service is pharmacy-based medication administration services (MAS). Pharmacy-based MAS can improve public health by providing patient care, facilitating access to needed services, decreasing stigma, and enhancing collaboration with the health care team.

Patients who could benefit from MAS may encounter challenges, such as scheduling conflicts with prescribers, difficulty with medication adherence, and a lack of knowledge of the medication or administration of the medication. In the provision of MAS, pharmacists meet with patients regularly to provide education on medications, help patients manage prescribed medications, support interventions that improve the quality of care, engage as part of the health care team, and ensure that patients are receiving the expected benefits from treatment. Pharmacy-based MAS can also assist patients who struggle with self-injection by providing initial education and support on medication self-administration, ensuring appropriate follow-up to monitor proper technique, reporting any adverse events, and addressing barriers to adherence.

This document is intended to support pharmacists who wish to initiate or expand MAS and it provides tools and resources to guide these efforts. APhA is proud to represent pharmacists who are continuously searching for new and innovative ways to serve patients and grow as health care providers.

Sincerely,

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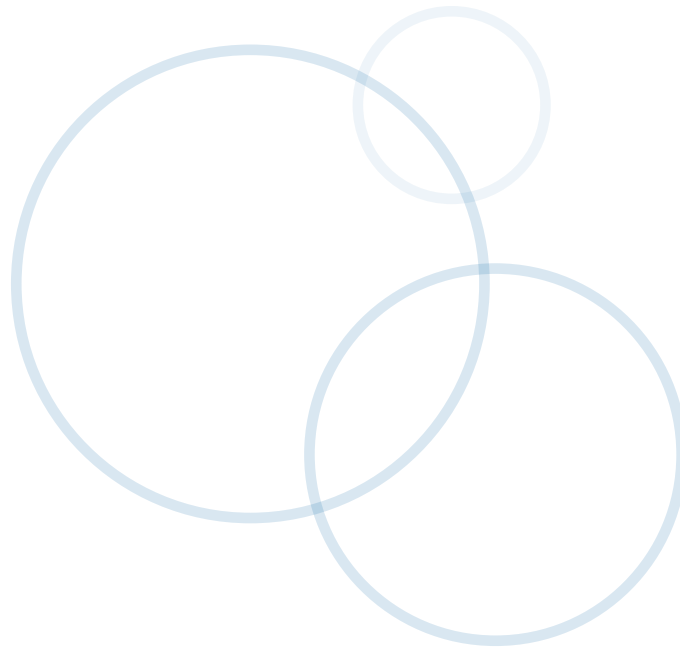


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Purpose

For more than ten years, the American Pharmacists Association (APhA) has worked through advocacy, policy, and practice initiatives to expand pharmacists' scope of practice to include administration of medications beyond vaccines. APhA initiated policy on this topic in 1998 and refined it in 2005. Through this policy, APhA:

- Supports pharmacist administration of prescription and nonprescription medications as a component of pharmacy practice.
- Supports the development of programs and practice guidelines for pharmacist administration of medications.
- Urges the adoption of state laws and regulations that authorize pharmacist administration of prescription and nonprescription medications.
- Supports compensation for pharmacist administration of medications.

Pharmacy-based medication administration services (MAS) encompass pharmacist administration of medications, support of patient self-administration, and provision of all related care coordination and care management services. Pharmacy-based MAS should be considered broadly, although most activity is currently focused on injectable medications. Pharmacists and members of the pharmacy team, such as pharmacy technicians and student pharmacists, have important roles and responsibilities in the care of patients who have medications administered. This document addresses these roles and outlines general principles and practice guidance for the provision of MAS to patients.

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Background

It is generally accepted within the U.S. health care system that pharmacists provide benefits that improve care across a range of disease states and enhance access, convenience, adherence, and quality of care for patients using medication therapies that require administration by a health care professional. Pharmacy-based MAS provides benefits to both patients and the health care system, including increased access to care, improved adherence to pharmacotherapy, and increased quality of care. Pharmacies are often a convenient location for patients to receive medication administration. Pharmacy-based MAS also provides benefits to the pharmacy practice. MAS enhances patient care service offerings, improves patient satisfaction, increases collaboration between pharmacists and prescribers, and, most importantly, improves relationships with patients and their caregivers, enhancing patient loyalty.¹

In December 2016, the APhA Stakeholder Conference on Improving Patient Access to Injectable Medications explored how the profession could advance a broad, profession-wide practice model for medication administration across a comprehensive spectrum of therapeutic classes.¹ There is a significant public health need to expand access

for patients and make MAS a widely available, predictable, measurable, sustainable, and scalable service provided by pharmacists.

The opportunities to provide MAS are broad. For example, patients with behavioral health conditions report that a lack of stigma within community-based pharmacy practice contributes to both an improved patient experience and adherence to treatment. Pharmacists involved in pandemic preparedness efforts could evaluate patients' needs and administer antiviral medications used to treat influenza and anthrax in accordance with guidelines established by the Centers for Disease Control and Prevention and other public health authorities, similar to other health care team members. In other cases, pharmacists can support patients who might receive expensive, complex medications through specialty pharmacies for conditions such as infertility, oncology, and multiple sclerosis.¹ Pharmacist engagement in medication-assisted treatment for substance use disorders may also incorporate MAS. Furthermore, specific patients may have other barriers, such as transportation restrictions, injection phobias, or other physical or psychological challenges, and they could benefit from pharmacy-based MAS.

It is generally accepted within the U.S. health care system that pharmacists provide benefits that improve care across a range of disease states and enhance access, convenience, adherence, and quality of care for patients using medication therapies that require administration by a health care professional.

In these examples, patients who are provided education and training by pharmacists or receive pharmacist administration of the medication show improved adherence, enhanced quality of care, and achievement of desired patient care outcomes. There are tremendous opportunities for pharmacists to provide services to help patients with their self-injectable medications through MAS. Oftentimes, patients prescribed injectable medications receive minimal initial education and limited follow-up, and consequently they may fail to self-inject properly.¹

Pharmacy-based MAS provides opportunities to improve collaborative efforts between pharmacists and prescribers. Pharmacists can be an educational resource to other health care providers regarding medication administration techniques and information on specific injectable medications that are administered in the outpatient setting. Pharmacists also serve as a referral source for physicians, monitoring complex medications closely and ensuring that patients are referred back to prescribers when issues, such as nonadherence and adverse effects, threaten the success of the treatment plan.¹

The development of this Practice Guidance, the Principles for Pharmacy-Based Medication Administration Services, and the Implementation Tool Kit were informed by the results of the 2016 APhA Stakeholder Conference on Improving Patient Access to Injectable Medications¹ and the 2016 National Alliance of State Pharmacy Associations (NASPA) and College of Psychiatric and Neurologic Pharmacists (CPNP) Stakeholder Conference on Identifying and Developing State Policy Best Practices for Pharmacist Administration of Medications² and guided by a group of expert advisors from a range of pharmacy practice settings, academia, and national pharmacy association leadership. These documents were released for public comment to obtain input and support from across the pharmacy profession as well as other professions and representatives from public health organizations with an interest in medication administration.

Pharmacists can be an educational resource to other health care providers regarding medication administration techniques and information on specific injectable medications that are administered in the outpatient setting.

Principles for Pharmacy-Based Medication Administration Services

Pharmacists and members of the pharmacy team have important roles and responsibilities in the provision of pharmacy-based medication administration services (MAS). MAS encompasses pharmacist administration of medications, supporting patient self-administration, and all related care coordination and care management services.

Principle 1—The Pharmacist’s Role

Improve patient health by implementing, advancing, and promoting pharmacy-based medication administration. Pharmacists should:

- (a) Offer MAS to any patient who may benefit from increased access to care, pharmacist education and support, and timely options for care.
- (b) Establish the pharmacy as an accessible site of care for medication administration and related services, whenever feasible.
- (c) Meet or exceed established practice standards, guidelines, and expectations for health care professionals providing similar MAS.
- (d) Provide MAS in coordination and partnership with other stakeholders.
- (e) Align MAS delivery with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process.
- (f) Deliver MAS in an environment that promotes patient comfort and safety while respecting patient privacy and confidentiality.

Principle 2—Empowerment of Patients, Families, and Other Caregivers

Engage patients, families, and other caregivers to determine medication administration preferences and respect care delivery decisions. Pharmacists should:

- (a) Collect relevant information from patients, families, other caregivers, and the health care team to assess patient well-being and individual needs before administering any medication.
- (b) Discuss with patients, families, and other caregivers the risks and benefits of medications to be administered and the associated services, before medication administration.
- (c) Collaborate with patients, families, other caregivers, and the health care team to set shared expectations regarding MAS, the details of the patient care plan, and plan implementation.
- (d) Work with patients, families, and other caregivers to enhance the quality of care by serving as a trusted resource for medication-related issues or questions.

Principle 3—Pharmacist Education and Training

Achieve and maintain competence to administer medications. Pharmacists should:

- (a) Be properly trained and knowledgeable in disease pathophysiology, medication characteristics, disease and patient management, administration technique, emergency responses, patient and societal concerns, and related topics before administering a medication.
- (b) Actively engage in a process of continuous professional development to maintain competency and proficiency in the provision of MAS.

Principle 4—Documentation and Communication

Document MAS utilizing a standardized, consistent, thorough procedure, and communicate information to the patient's other health care providers as appropriate. Pharmacists should:

- (a) Establish a system of documentation and record retention related to MAS that follows established guidelines, standards, privacy regulations, and best practices.
- (b) Obtain informed consent, consistent with state law, before the administration of any medication.
- (c) Maintain medication administration records and offer an electronic or printed personal record to patients, families, other caregivers, and members of the patient's health care team, as authorized by the patient.
- (d) Inform patients, families, and other caregivers that applicable documentation of medication administration will be shared with the patient's identified medical provider and other appropriate administrative entities (e.g., Risk Evaluation and Mitigation Strategy reporting, payers, manufacturer programs in which the patient has elected to participate).
- (e) Document and report adverse events following medication administration to any appropriate members of the patient's health care team and adverse event monitoring programs.
- (f) Implement and utilize follow-up mechanisms to determine and respond to patient satisfaction concerns, issues and questions related to the MAS, deviations from the care plan, and any problems with the administered medication.

Principle 5—Collaboration and Coordination

Work with patients, families, other caregivers, members of the health care team, public health departments, and community support services to assess patient well-being, achieve positive patient outcomes, and ensure access to and coordination of care. Pharmacists should:

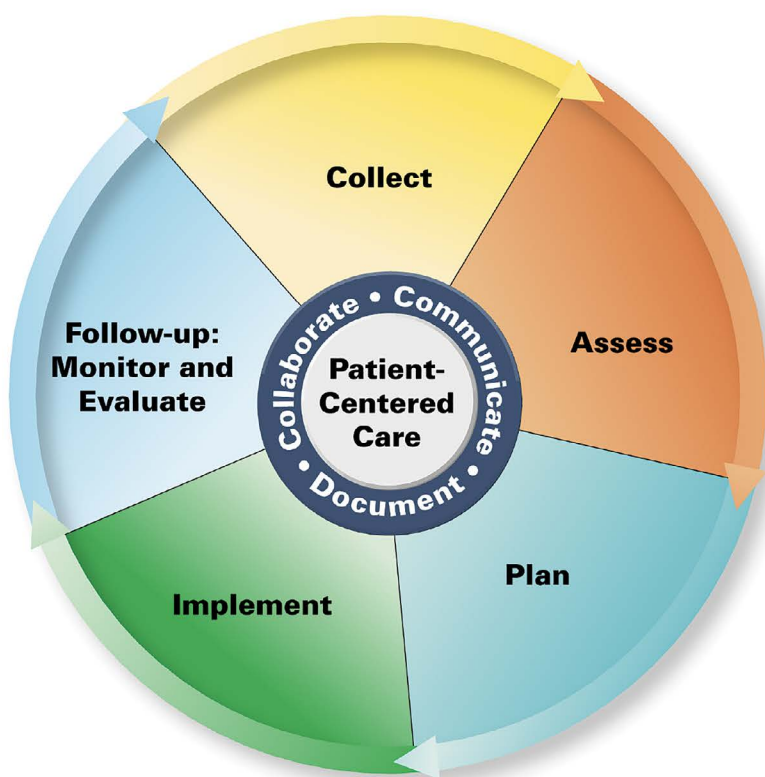
- (a) Collaborate with patients, families, other caregivers, and members of the health care team in the provision of pharmacy-based MAS.
- (b) Collaborate with other health care providers to assure seamless care transitions for MAS.
- (c) Facilitate overall care coordination, including benefits coverage, service scheduling, assessment of patient clinical status, provision of medication administration and patient education, and assessment of socioeconomic status and other unmet needs (e.g., immunizations, smoking cessation, comprehensive medication review).
- (d) Appropriately refer patients to other providers for treatment, follow-up, or other services.
- (e) Work with communities, public health authorities, and advocacy groups to provide outreach, information, and education that support population health initiatives.

Providing Medication Administration Services Using the JCPP Pharmacists' Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes. An essential first step is the establishment of a patient-pharmacist relationship that supports engagement and effective communication with patients, families, and other caregivers throughout the process. At the core of the

process, pharmacists continually collaborate, document, and communicate with physicians, other pharmacists, and other health care professionals in the provision of safe, effective, and coordinated care. This process is enhanced through the use of interoperable information technology systems that facilitate efficient and effective communication among all individuals involved in patient care (Figure 1).

Figure 1. Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process



Pharmacists' Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes.

Using principles of evidence-based practice, pharmacists:

Collect

The pharmacist assures the collection of the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient.

Assess

The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care.

Plan

The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

Implement

The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

Follow-up: Monitor and Evaluate

The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

Source: Reference 3.

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Collect

The pharmacist assures the collection of necessary subjective and objective information about the patient in order to understand the relevant medical and medication history and clinical status of the patient. Information may be gathered and verified from multiple sources, including existing patient records, the patient, and other health care professionals. This process includes collecting:

- A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements.
- Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings.
- Patient lifestyle habits, preferences, beliefs, health and functional goals, and socioeconomic factors that affect access to medications and other aspects of care.

Necessary Information

A pharmacist should collect information that supports decision making about the provision of MAS, and this information may vary based on the product to be administered and the needs of the patient. Information collected includes patient medical and medication history, lifestyle and social history, patient preferences, relevant psychosocial history, immunization and other injection history, and results of physical assessments, laboratory tests, and biometric tests. The information may be gathered and verified from multiple sources, including but not limited to pharmacy dispensing records, electronic health records, primary care providers, patients, families,

other caregivers, public health departments, and reports from manufacturer administration programs. Collected information must be complete and accurate to allow the pharmacist to assess and educate the patient on precautions, contraindications, potential adverse events, patient management, and the importance of medication adherence. Contact information for patients and caregivers should be as complete as possible to facilitate follow-up, reach emergency contacts, or manage scheduling changes. This information may include the mailing address, email addresses, and work, home, and mobile phone numbers.

Medical History

Pharmacists should collect information to determine if a patient may safely receive an administered medication and to conduct a comprehensive patient care assessment. Necessary information on a patient's medical history includes:

- Age.
- Sex/gender.
- Race.
- Allergies.
- Immunization status.
- Smoking and/or use of tobacco products.
- Current health status.
- Current diagnoses, treatment plans, and goals.
- Pregnancy status (for women).
- Family medical history (e.g., heart disease, stroke, depression).
- Psychosocial history.

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For patients presenting for MAS, additional inquiry may be necessary to collect specific information that will allow medications to be administered safely. An understanding of any potential bleeding disorders, issues with coagulation, or the use of anticoagulation medications is important for patients who may receive administration of an injectable medication. For patients receiving specific medications for administration, it may be necessary to collect additional historical information to determine contraindications or additional considerations related to medication administration. For example, history of neuroleptic malignant syndrome or a life-threatening dystonic reaction should be documented in the patient's record and treatment should be discussed with the prescriber prior to administering long-acting antipsychotic medications.

Medication History

A pharmacist should reconcile all medications currently being taken by the patient, including prescription medications, over-the-counter medications, vitamins, dietary or other supplements, and illicit drugs or use of prescription medications that have not been prescribed for the patient. The types of information that should be collected include:

- Medication name.
- Medication dose.
- Route of administration.
- Medication indication.
- Frequency of administration.
- Time of administration.
- Experience with medication, including history related to previous medication administration.

- History of adverse events, including injection site reactions.
- Medication adherence and persistence.
- Awareness and knowledge of medication use.
- Attitudes, beliefs, and medication-taking behaviors.
- Patient preference for site of medication administration (if injectable medication).

Physical Assessment, Laboratory Results, and Biometric Tests

When available, results of physical assessment, laboratory tests, and biometric tests can be helpful to inform decisions about the delivery of MAS. Information that may be collected includes:

- Body mass index.
- Blood pressure.
- Heart rate.
- Laboratory test results (e.g., electrolytes, lipid profile, liver panel, renal panel, hemoglobin A1C, metabolic panels, pregnancy test).

Lifestyle and Social History

- Alcohol use.
- Smoking and/or use of tobacco products.
- Diet and nutrition.
- Occupation.
- Opioid drug use.
- Illicit drug use.
- Physical activity and exercise.
- Sleeping patterns and disorders.
- Stress.

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- Travel.
- Primary language.
- Contact information for emergency contacts.

APhA has developed a checklist to assist pharmacists in collecting information to support delivery of MAS; the checklist for the Pharmacists' Patient Care Process for Medication Administration Services can be

accessed at <http://www.pharmacist.com/sites/default/files/files/MASPPCPChecklist.pdf>. Pharmacists can also use a sample patient intake form (<http://www.pharmacist.com/sites/default/files/files/MASpatientintakeform.pdf>) to support them in collecting necessary information before the delivery of MAS. There are numerous examples of medical history questionnaires on the Internet that can be customized for individual practices.

Assess

The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care. This process includes assessing:

- Each medication for appropriateness, effectiveness, safety, and patient adherence.
- Health and functional status, risk factors, health data, cultural factors, health literacy, and access to medications or other aspects of care.
- Immunization status and the need for preventive care and other health care services as appropriate.

Assess Collected Information

Before providing MAS, pharmacists should assess how the prescribed treatment should be administered, communicated, and documented. As part of the Pharmacists' Patient Care Process, pharmacists collect a myriad of information to support the delivery of MAS. During the assessment process, pharmacists must determine if the patient has any contraindications to receiving an administered medication or if the patient has experienced side effects or adverse events from the medication. For some medications, it may be important to assess if there are signs of toxicity or immunogenicity from the previous administration.

Consideration must be given to ensure the appropriateness of the medication for the individual patient and the condition being treated. In some cases, assessment also refers to determining if the patient has a medical

condition that is not being adequately treated or prevented. It is important to determine if the prescribed medication is the most effective medication to achieve determined goals and ensure that the prescribed dose is appropriate to achieve the goals of treatment. For patients regularly receiving MAS for injectable medications, pharmacists should assess the injection site, ensure that injections are being delivered to alternating sites, and evaluate for potential signs of injection site reactions.

Determine Ability to Consent

One of the first steps the pharmacist should take in assessing a patient to receive MAS is to determine the patient's ability to consent to receive the service. Patients seeking treatment for substance use disorders and behavioral health conditions are two of the largest populations that access pharmacy-based MAS. For these patient populations that may be considered at-risk, it is particularly important that they understand both the risks and benefits of the proposed service. Patients also must be competent to sign the informed consent or have a family member or other caregiver who can provide legal consent to receiving services.

Support Medication Adherence

As with all prescribed medications, it is important to ensure that factors that negatively impact a patient's ability to maintain medication therapy are minimized. Pharmacists should assess if the patient is able and willing to receive the medication as prescribed and work with patients, families, and other caregivers to identify and resolve

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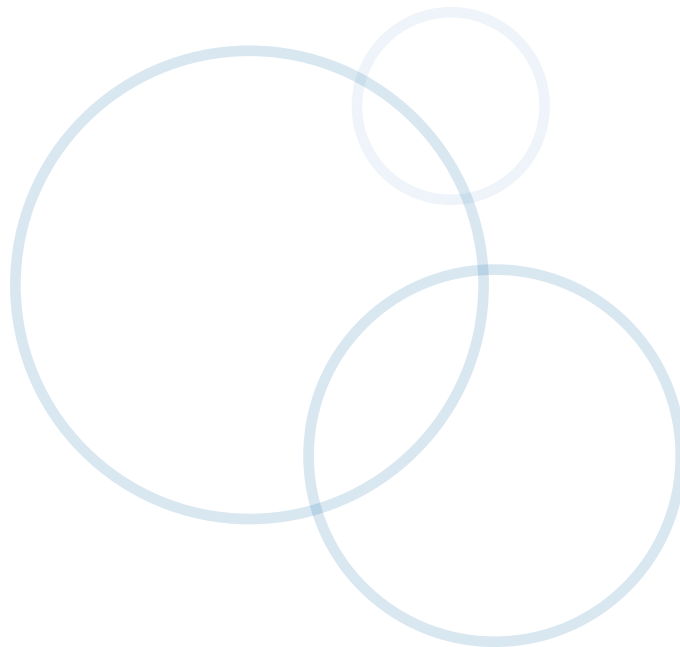
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issues that may prevent access to receiving the medication. Factors such as eliminating stigma associated with receiving services and establishing a strong patient-pharmacist relationship can also contribute to improved patient adherence to medications.

Determine Health Status

Pharmacists should assess other patient medical conditions as they relate to MAS. If the patient has unmet needs, such as a need for a comprehensive medication review, immunizations, or support with tobacco cessation, the pharmacist should work with the patient, family, other caregivers, and the patient's health care team to arrange and deliver these services.

Factors related to lifestyle and social history should also be assessed. For example, patients who receive administered medications for opioid treatment should be assessed for recent or current drug use. Patients who are taking injectable medications to improve bone health may need to be assessed to ensure adequate calcium supplementation and appropriate weight-bearing exercise. In some cases, it is important for the pharmacist to assess the patient's current mental status, particularly if the patient is receiving administration of long-acting antipsychotic medications. If the patient is showing signs of relapse or deterioration, the pharmacist needs to immediately communicate and collaborate with the prescriber, family member, other caregiver, or case manager to ensure appropriate care is provided.



Plan

The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregivers, that is evidence-based and cost-effective. This process includes establishing a care plan that:

- Addresses medication-related problems and optimizes medication therapy.
- Sets goals of therapy for achieving clinical outcomes in the context of the patient's overall health care goals and access to care.
- Engages the patient through education, empowerment, and self-management.
- Supports care continuity, including follow-up and transitions of care as appropriate.

Develop Plan

Pharmacists should develop a patient-centered care plan that includes evidence-based recommendations for treatment and follow-up. The plan should be developed in collaboration with the patient, the family, other caregivers, and other members of the health care team as appropriate and it should include treatment goals. The care plan should be documented in the pharmacy record or the electronic health record and be readily available. Both the care plan and associated recommendations should be based on the pharmacist assessment and address all aspects of care required to provide MAS. Development of care recommendations occurs during the plan development phase and is reinforced throughout plan implementation.

Set Goals

A patient-centered plan includes discussions with patients, families, and other caregivers to determine individual needs before prioritizing and formulating recommendations and includes the prescriber's goals for the patient, if possible. The plan should set goals to optimize medication therapy and improve patient health outcomes and may include information such as patient preferences for MAS (including the site of administration, if injectable), appointment scheduling, relevant educational needs, and ensuring a thorough understanding of diagnosis and associated treatment. Incremental goals to help support successful plan implementation should also be included.

Consider Patient-Specific Needs

The pharmacist should assume responsibility for ensuring that the patient has the appropriate information and understanding to contribute to discussions concerning the care plan. Information such as health literacy and cultural beliefs should be considered when formulating the care plan. Respect for patient decisions and desires regarding delivery of care is paramount. Pharmacists should develop strategies to educate and empower patients to be their own health care advocates and to meet established goals concerning patient education, medication use (including adherence), and lifestyle modification. Patients should be coached and encouraged to maintain a positive and proactive attitude toward achieving the goals in their care plan.

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Consider State Laws and Regulations

During the process of implementing the care plan, pharmacists must consider the state laws pertaining to their authority to administer medications. Laws vary among states regarding scope of practice, necessary training, and other procedural requirements. As such, pharmacists should initiate, modify, administer, or discontinue medication in accordance with state laws, collaborative practice agreements, clinical protocols, and prescriber approval of pharmacist recommendations as applicable.

Ensure Coverage Eligibility

Ensuring that patients have health coverage for their MAS, particularly during transitions of care, should be part of the plan. For some patient populations, particularly in behavioral health, it may be imperative for the pharmacist to understand the patient's legal status and if there are specific conditions of release from a hospital or institution. In some cases, pharmacists engaged in MAS can provide information and support to the patient in documenting and communicating information about the care plan to providers, institutions, and even the court system.

Coordinate Care

As it relates to MAS, pharmacists and their team have a responsibility for care coordination, which may include benefits investigation, scheduling, administration, and patient education. Some functions, such as benefits investigation and scheduling, may be performed by support staff. The plan should include preferences expressed by the prescriber regarding administration and other elements of MAS. Pharmacists should outline plans to contact the prescriber if there are specific issues or concerns or if referrals to health care providers or other urgent care facilities may be warranted. The plan should also include a schedule for needed follow-up appointments and a shared understanding of communications to patients, families, other caregivers, and members of the patient's health care team if MAS appointments are missed. In some cases, pharmacists could advise on the value of a medical alert identification bracelet that could facilitate appropriate care in case of emergency.

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Implement

The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver. During the process of implementing the care plan, the pharmacist:

- Addresses medication- and health-related problems and engages in preventive care strategies, including vaccine administration.
- Initiates, modifies, discontinues, or administers medication therapy as authorized.
- Provides education and self-management training to the patient or caregiver.
- Contributes to coordination of care, including the referral or transition of the patient to another health care professional.
- Schedules follow-up care as needed to achieve goals of therapy.

Administer Medications

As part of the implementation process, pharmacists administer the prescribed medication, taking information obtained during the assessment process into consideration. Pharmacists must be trained and competent to provide MAS and manage any potential adverse events that may occur upon administration. Any previous doses of medication that were administered by other providers or within health care facilities should be verified by pharmacists. Before administration, pharmacists should ensure that the patient has appropriate refills authorized by the prescriber. Correct administration of medication is essential to ensure the safety and

efficacy of the medication, which includes but is not limited to the appropriate dose, route, site, needle size, and injection or administration technique (e.g., intranasal, oral observation). In addition to clear, written protocols on medication administration, pharmacists providing MAS should be trained and certified in basic and/or advanced cardiac life support as well as first aid. Pharmacists should have appropriate emergency supplies (e.g., epinephrine, diphenhydramine, blood pressure cuff, stethoscope) and be prepared to initiate rescue treatment as authorized or delegated.

Provide Education and Support

Implementation of the patient care plan involves education and support to achieve treatment and lifestyle goals as outlined. Patients, families, and other caregivers should work with the pharmacist to maintain and keep easily accessible copies of the patient's updated medication list and care plan. Specific patient education should be provided on the medication, including any potential side effects or adverse reactions and how they can be managed. Patients should also be educated about how to monitor, document, and report any issues or concerns with medication therapy and when it may be appropriate to seek medical follow-up. The care team should work to implement strategies to engage patients, improve medication adherence, and achieve agreed-upon behavioral modifications, such as decreasing stress, engaging in cognitive behavioral therapy, increasing physical activity, and improving nutrition.

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MONITOR AND EVALUATE

Ensure Care Coordination

Achievement of the care plan requires coordination and collaboration among many stakeholders to ensure plan implementation, refer patients to other health care providers as necessary, and schedule follow-up visits. Documentation of MAS should be conducted in a standardized, reproducible format that can be linked to billing codes and quality measures.

Particular care must be taken to document and communicate missed appointments. Pharmacists should utilize a standardized process to document procedures employed to implement the care plan and communicate with patients, families, other caregivers, and members of the health care team as appropriate.



COLLECT

ASSESS

PLAN

IMPLEMENT

**FOLLOW-UP:
MONITOR AND EVALUATE**

Follow-up: Monitor and Evaluate

The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed. This process includes the continuous monitoring and evaluation of:

- Medication appropriateness, effectiveness, safety, and patient adherence through available health data, biometric test results, and patient feedback.
- Clinical endpoints that contribute to the patient's overall health.
- Outcomes of care, including progress toward or the achievement of goals of therapy.

Monitor Adherence, Safety, and Efficacy

The final step in the Pharmacists' Patient Care Process is to ensure appropriate follow-up through monitoring and evaluation of factors such as the efficacy of medication therapy, medication adherence, experience with adverse events, and progress toward established goals of therapy. Pharmacists should have management and monitoring processes in place to identify and resolve medication-related and health issues. Serious adverse events should be reported to the Food and Drug Administration's MedWatch program or other appropriate program.

Assess Progress and Modify Plan

During follow-up visits, the pharmacist should repeat the care process as required to assess progress and make any necessary adjustments to the care plan. Care plan adjustments and progress toward outlined treatment goals should be documented and communicated to the prescriber and other appropriate members of the health care team. At each visit, the pharmacist should review and update the medication list to ensure accuracy and provide the revised list to patients, families, other caregivers, and members of the health care team as appropriate. With many medications for administration, pharmacists must dedicate attention at each visit to ensure that patients can continue to have access to prescribed medications. At each follow-up visit, pharmacists should ensure that the patient has the appropriate professional and social support to maintain treatment, and follow-up appointments should be scheduled.

Considerations for Pharmacy-Based Medication Administration Services

Legal Authority

As the practice of pharmacy-based MAS evolves, laws and regulations related to medication administration continue to advance. It is important that pharmacists understand applicable state legal authority before providing MAS. A report developed by the NASPA and CPNP presents an overview of state policy recommendations for pharmacist administration of medications. The report provides an overview of existing policy on the authority for pharmacist administration of medications, required training, and other requirements, such as policies and procedures, orders to administer, and board notification. Specific recommendations resulting from these expert discussions include:²

- Pharmacists should be authorized to administer any medication, pursuant to a valid prescription and proper training.
- Medication administration training should be obtained from an Accreditation Council for Pharmacy Education-accredited program (which may include educational experiences obtained through pharmacy school curricula) appropriate for the medications being administered and the patient populations that the pharmacist serves; administration techniques must be covered but not necessarily in the same program.

- State laws and regulations should not identify a specific number of continuing education hours, but there should be an expectation that the pharmacist maintains continued competency regarding the populations served, medications administered, and current guidelines.
- Pharmacy practice must develop and maintain written policies and procedures covering all aspects of the administration of medications that ensure patient safety, coordination of care, and appropriate documentation.
- Pharmacists should not be required to notify the board of pharmacy that they have been trained and should not be required to obtain a certification beyond licensure in order to administer medications.

Information on state-specific laws and regulations that pertain to pharmacy-based medication administration can be found at <https://nasp.us/resource/med-admin-resources/>.

Pharmacists may also contact their state boards of pharmacy with specific questions about authority to provide MAS. Contacts for state board of pharmacy representatives can be accessed at <https://nabp.pharmacy/boards-of-pharmacy/>.

As the practice of pharmacy-based MAS evolves,
laws and regulations related to medication administration
continue to advance.

Education and Training

Pharmacists who wish to engage in MAS should ensure that all staff members have both the clinical confidence and competence to provide the services. Until standardized education and training programs are developed to support pharmacist provision of MAS, individual practitioners must assume responsibility for demonstrating competency regarding the medications they administer, understanding the unique needs of the patient populations they serve, and ensuring they are compliant with all applicable practice guidelines and best practices.

Pharmacists providing MAS should have sufficient depth of knowledge in therapeutic categories for which MAS can be provided and they should be clinically prepared to provide disease state education and support to patients. Pharmacists should develop and adhere to specific treatment algorithms and standard operating procedures to support their MAS and they should be familiar and prepared to address all administration-related adverse drug reactions. A list of examples of medications appropriate for pharmacy-based MAS can be found at <http://www.pharmacist.com/sites/default/files/files/MASmedicationsforadministration.pdf>. As with immunization services, pharmacists providing MAS should be trained in emergency procedures, certified in basic and/or advanced cardiac life support, and comply with required Occupational Safety and Health Administration (OSHA) training.

Storage and Handling

Pharmacists must understand the unique storage and handling issues for medications provided through MAS. For example, before a refrigerated medication is administered, pharmacists must ensure that the product (e.g., insulin, long-acting injectable antipsychotic) has been stored and kept within required temperature ranges during transit and

while in storage prior to the administration. Before administration, pharmacists must also review requirements for medication preparation, be knowledgeable and diligent about documenting expiration dates for reconstituted products, and be trained in aseptic techniques related to preparation and administration. Pharmacists engaged in MAS should appreciate the potential exposure to hazardous medications in the preparation and administration of some medications.

MAS policies and procedures should incorporate requirements from OSHA, the National Institute for Occupational Safety and Health, the U.S. Pharmacopeia (USP Chapter <800>), and state laws and regulations as appropriate. In addition, special considerations for storage of high-risk medications, disposal of medications (e.g., residual versus unused portions of medications not administered), injection supplies, needles, and take-back conditions should be addressed. Lastly, procedures for occupational safety regarding needlestick precautions and post-exposure prophylaxis must be outlined.

Administration Techniques

For administration of injectable medications, pharmacists must be comprehensively trained and demonstrate skill proficiency in all administration techniques for MAS, including intramuscular (IM) and subcutaneous (SC) injections. Pharmacists should be trained on the various sites of IM and SC administration, which may include the deltoid, thigh, ventrogluteal, and dorsogluteal areas for IM administration, and the abdomen, inner thigh, posterior lateral upper arm, and upper/outer buttock for SC administration. Pharmacists should be trained to perform the Z-track method for administering IM injections, provide direct observation of oral medication administration, and administer medications intranasally. Pharmacists must also understand how to inject and/or administer medications that are approved for patient self-injection upon patient request.

Training to administer medications should include both didactic study and administration practice under the guidance of an experienced health care professional. Pharmacists should understand different types of injectable devices and be trained in how to select the appropriate needle size, if not already packaged with the product to be administered. Information such as proper dose preparation, maximum injection volume, and push rate should also be researched before providing medications by injection. Review of package instructions for medications to be administered can provide important information for pharmacists providing MAS.

Sensitivity Training

A key element of training should focus on sensitivity, providing specific guidance to all pharmacy staff members to help them understand how to meet the needs of specific patient populations, particularly with mental and behavioral health diagnoses. All patients should be treated equally and with respect. For example, providing education and support for a patient or the family member of a patient receiving naltrexone or an opioid reversal agent requires sensitive inquiry concerning the patient's recent health history and opioid use to assess potential withdrawal risk. Pharmacists should understand the importance of working with patients to set realistic treatment goals and reinforce the importance of implementing the established care plan.

Policies and Procedures Training

Training in administrative aspects of MAS should be provided. Important components of service delivery include review of the pharmacy's policies and procedures related to MAS, study of administration protocols, overview of required documentation, understanding of appropriate communication and reporting of MAS, and knowledge of processes for billing and reimbursement.

Practice Development and Patient Advocacy

Engage Providers

One of the keys to success in building services for patients requiring medication administration is to engage with local providers to inform them of the program, discuss the collaborative nature of the service, establish credibility for the clinical offering, and encourage them to refer patients to the service. Often, providers may not have the resources within their practice to provide MAS, and a pharmacy-based option may provide solutions for both patients and their providers.

For pharmacies new to MAS, begin discussion with a couple of providers who are known to the practice. Demonstrating initial success, with a few patients, can provide information and support to grow the service offering. Identifying patients within the pharmacy records who may benefit from this service is also a good way to initiate the program. For example, patients who are taking oral antipsychotic medications may be candidates for long-acting injectable therapy and having access in a setting that is professional—and where they are comfortable—may be of interest to these patients. Some pharmacies may even offer support in navigating patient assistance programs, which could facilitate patients' ability to maintain adherence with their prescribed medications.

When prescribers refer patients to the pharmacist's practice for MAS, it is important to deliver flawless execution of the service and establish a strong working relationship, reinforcing the value of the pharmacist in patient management. A highly influential factor for establishing successful pharmacy-based MAS involves increasing relationships with local providers. Demonstrating that both pharmacists and physicians are focused on patients' best interests and establishing trust

provides a valuable baseline for communication and collaboration about MAS. Pharmacists are the medication experts, and through monitoring complex medications closely, they can refer patients back to prescribers when issues such as nonadherence or adverse events threaten the success of the treatment plan.¹ Pharmacists and collaborating physicians should create processes to refer patients to one another as an aspect of strengthening professional relationships. An example of a physician referral form can be found at <http://www.pharmacist.com/sites/default/files/files/MASpatientreferralform.pdf>. In some communities, local manufacturer representatives or public health departments may be good sources to identify prescribers with a need for MAS.

Increase Patient Access

Pharmacists appreciate the value of having strong relationships with patients, families, and other caregivers who rely on them for medications and counseling. Community-based pharmacy practice offers an access point for patients, with approximately nine in ten Americans living within five miles of a community pharmacy.⁴ Pharmacy-based MAS provides a significant convenience factor for both patients and prescribers. Patients do not need to obtain the medication from the pharmacy and then transport it to the prescriber for administration. Prescribers are relieved of managing inventory, navigating reimbursement issues, storing medication, or keeping track of subsequent administration dates. Emphasizing how pharmacy-based MAS can help improve medication adherence, improve care coordination, and increase options for convenient access to care will garner support for MAS. For patients who may not have access to reliable transportation or who may need care after traditional work hours, pharmacy-based MAS may be an extremely valuable service.

Pharmacies should look to their current patient population and inform patients about the availability of MAS. Using a clear and simple information sheet may be helpful to patients—and their providers—to understand the benefits of pharmacy-based MAS. An example of this information sheet can be found at <http://www.pharmacist.com/sites/default/files/files/MASservicesheet.pdf>.

Work With Other Stakeholders

Pharmacists can work with other stakeholders, such as public health departments, health clinics, provider specialists, and inpatient facilities to highlight the public health benefits of MAS and reinforce the value of the service in improving patient care. Communication, coordination, and collaboration with these organizations can help increase access to care for patients in the pharmacist's local community. Pharmacists may also benefit from contacting local pharmaceutical representatives about administered medications. These company contacts may have educational information, tools, and other resources that can support the pharmacist's MAS. Notably, some companies have structured programs that support the delivery of MAS to patients who take specific medications and may offer patient assistance programs that can help defray medication costs for patients.

Program Structure

Possibly the most critical step in establishing a new program or service is to appoint a pharmacist champion within the practice. This champion should take responsibility for planning and implementing the service; ensuring that the practice is meeting established standards, guidelines, and best practices; and making certain that pharmacy personnel are trained and prepared to deliver MAS.

Implementing Policies and Procedures, Quality Assurance, and Risk Management Strategies

Pharmacies delivering MAS must have written policies and procedures covering all aspects of the administration of medications to ensure patient safety, manage the coordination of care, and provide appropriate documentation. Specific elements of policies and procedures for MAS should include:

- Pharmacists' scope of practice.
- Required education, training, and knowledge.
- Roles and responsibilities of staff members.
- Pharmacists' patient care process.
- Patient informed consent process.
- Product handling and management.
- Patient privacy and confidentiality.
- Chaperone policies.
- Processes for service documentation and record retention.
- Policies for reporting adverse drug reactions.
- Billing instructions.
- Prescriber notification.
- Referrals to other providers.
- Care coordination.
- Quality assurance procedures.

An overview of example content for a policies and procedures document for MAS can be found at <http://www.pharmacist.com/sites/default/files/files/MASpoliciesprocedures.pdf>.

Pharmacies engaged in MAS must ensure the provision of high-quality services. Ensuring compliance with state and federal regulations (e.g., OSHA bloodborne pathogen training, hepatitis B vaccination) is the responsibility of the pharmacy. Proper management of unique medication storage and handling issues associated with MAS should also be a focus within quality assurance procedures and internal quality assurance audits. Pharmacists should routinely seek feedback from patients, caregivers, and prescribers to identify areas for improvement and implement processes and procedures to enhance service offerings. Provision of a high-quality experience may help support patient adherence. As with any patient care service, pharmacists should ensure appropriate coverage through their professional liability insurance provider and comply with any necessary risk-management strategies suggested by the carrier.

Developing Collaborative Practice Agreements and Protocols

Pharmacists must understand the distinct state laws, regulations, and requirements for establishing MAS. Practices should also appreciate that as MAS becomes more widespread, these requirements are rapidly changing. Some states, where medication administration is not part of pharmacists' authorized scope of practice, require collaborative practice agreements between a pharmacist and physician or other authorized individual to administer medications. Specific recommendations and the supporting evidence for the broad use of collaborative practice agreements have been published in a white paper from the APhA Foundation, and this information may be useful to pharmacists establishing MAS.⁵ Pharmacists may also find practical guidance for developing a collaborative practice agreement in the Centers for Disease Control and Prevention's publication titled *Advancing Team-Based Care Through Collaborative Practice Agreements*:

*A Resource and Implementation Guide for Adding Pharmacists to the Care Team*⁶ and through the NASPA website at <https://naspa.us/resource/cpa/>.

Development of specific policies and procedures for each product delivered through MAS is recommended. Protocols typically outline the process for service delivery, any specific rules or requirements for patients regarding the injectable medication, the process for screening patients, requirements for providing patient education, procedures for adverse event management and reporting, and applicable documentation and record keeping. Developed protocols should be reviewed and updated, at a minimum, annually or as new information becomes known. An example of a protocol for medication administration can be accessed at <http://www.pharmacist.com/sites/default/files/files/MASprotocol.pdf>.

Obtaining Patient Consent and Documentation

Before initiation of MAS, pharmacists should obtain informed consent from patients or their legal representatives. Patient consent ensures that the patient understands the benefits and risks of the proposed service and has had an opportunity for his or her questions to be addressed by the pharmacist. The patient consent form may also be combined with the MAS documentation form, which serves as a record to document requisite information collected in the process of delivering MAS, such as patient demographics, medication allergies, medication administered, dose, lot number, expiration date, product manufacturer, route of administration, and site of injection. Documenting the time of administration is particularly important in the event of an allergic reaction. Pharmacists should refer to state board regulations on the length of time required to maintain patient consent documentation for MAS. An example of a patient informed consent form can be found at <http://www.pharmacist.com/sites/default/files/files/MASinformedconsent.pdf>.

Ensuring Patient Privacy and Confidentiality

As with any patient care service, patients have a right to expect that their privacy and confidentiality are respected and preserved. Privacy and confidentiality are core tenets of pharmacy practice. As outlined in the Code of Ethics for Pharmacists, a pharmacist focuses on serving the patient in a private and confidential manner.⁷ Privacy may be particularly important for some MAS activities, such as gluteal injections, where ensuring the patient feels safe and comfortable is paramount. Patients should also have access to a chaperone and should be comfortable with the person performing this role.

Federal privacy rules do not require pharmacists to obtain a signed consent form before sharing information for treatment purposes. Health care providers can freely share information for treatment purposes without a signed patient authorization.⁸ Pharmacists should communicate pertinent information to members of the patient's health care team, including monitoring and reporting that the patient has attended scheduled administration appointments and completed the prescribed treatment regimen. Pharmacists must always comply with laws associated with privacy and confidentiality. With some patients receiving MAS, there may be unique requests for release of medical information from probation officers, court systems, and other authorities. Other patients receiving MAS may have reporting obligations to health departments, caseworkers, and the judicial system. Pharmacists should ensure that they have obtained proper patient authorization to provide required or requested information.

Engaging Pharmacy Technicians, Student Pharmacists, and Pharmacy Residents

All members of the pharmacy team have important roles to play in ensuring the success of MAS. These pharmacy staff members can provide support to the pharmacist and manage many of the operational or administrative aspects of the service. In a recent APhA survey, 56% of MAS practices indicated that pharmacy technicians were involved in associated administrative activities. These technicians provide support, such as appointment scheduling, patient intake, care coordination, billing and reimbursement activities, management of patient assistance programs, and providing patient reminders.

Student pharmacists and pharmacy residents can work to develop educational materials or information that can serve to promote the service to patients, physicians, health clinics, or public health departments. As with all pharmacy-based activities, pharmacists are responsible for ensuring appropriate training and oversight of their pharmacy staff that may be engaged in clinical programs.

Understanding Workflow Considerations

As with any pharmacy service, pharmacists must design and implement the program in a way that is effective within the workflow of the practice. For some practices, MAS may be provided to walk-in patients. In other practices, developing an appointment-based service may serve to be more efficient and practical. The APhA Foundation has developed an implementation guide for pharmacy practices that supports an appointment-based model in pharmacy practice.⁹ This model can be adapted for use in the provision of MAS. Ensuring patient access to care should be the focus for how the service is developed and implemented.

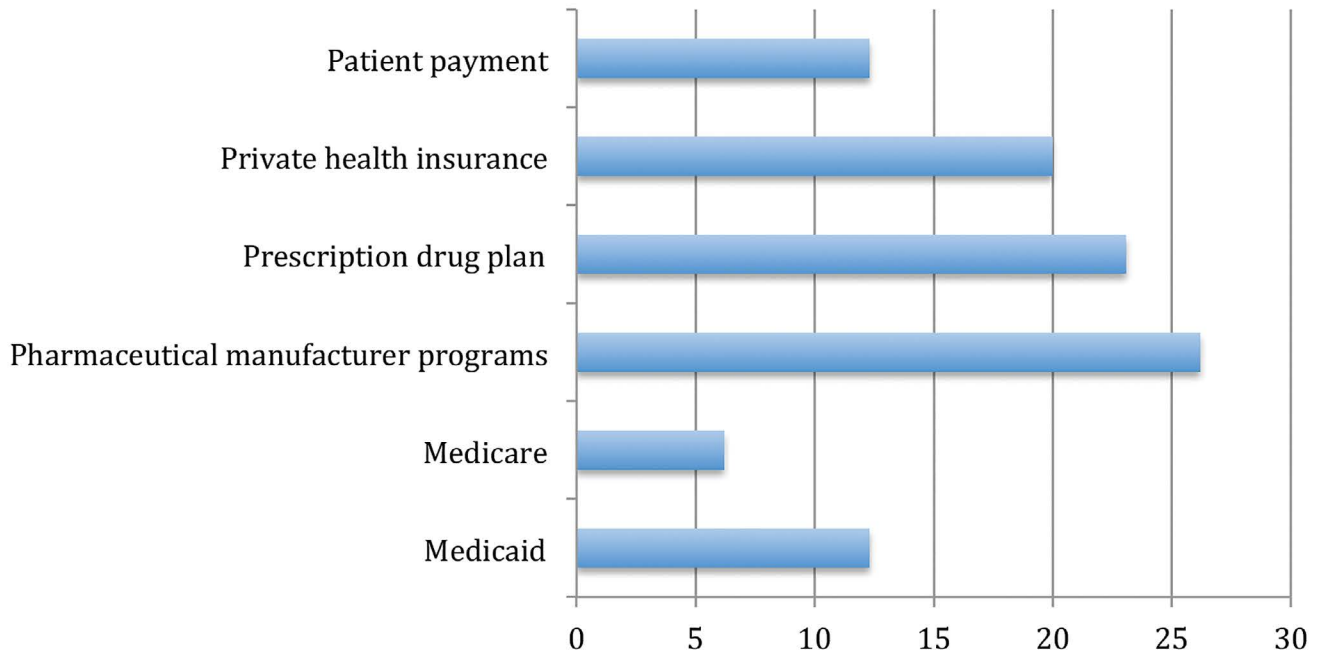
Set-up and delivery of MAS may vary depending on the patient population and the medication product to be administered. Pharmacy technicians can be tasked to manage the paperwork and processes to facilitate workflow. Allowing sufficient time within pharmacy workflow to prepare medications, provide the administration, ensure appropriate delivery of patient education, monitor the patient for any adverse reactions, and facilitate documentation, communication, and follow-through is critical to program success. In a recent APhA survey of pharmacists providing MAS, the time for administration service varies considerably. Most medication administrations were reported to take 16 to 20 minutes (41% of respondents), with 25% of respondents indicating an average of 11 to 15 minutes, and 16% of respondents indicating 26 to 30 minutes. Pharmacists may be able to coordinate MAS with other services such as medication synchronization.

Finally, appropriate expectations should be set for the patient and caregiver. This service may be different from other services that patients have experienced in a community-based pharmacy. Taking time to explain the service, its benefits, and how patients should expect the service to be delivered helps put patients at ease and fosters a strong clinical relationship between the pharmacist and the patient.

Billing and Reimbursement

For any patient care service to be successfully implemented, it must be financially viable. Payment for pharmacists' patient care services, including MAS, can come from different types of payers. According to National Health Expenditure Data, the three largest payer sectors in health care are Medicare, Medicaid, and private health plans, including self-insured employers. In some cases, patients pay for health care services out of pocket, accounting for 11% of national health care expenditures.¹⁰ Results of a recent APhA survey show that of the 31 practices providing MAS, 74% of them are being reimbursed for these services. The sources of payment for MAS are shown in Figure 2.

Figure 2. Sources of Reimbursement for Medication Administration Services



Source: American Pharmacists Association. Unpublished survey data; 2017.

For most current MAS, payment occurs through patient self-pay or fee-for-service arrangements with specific pharmaceutical manufacturer programs. To participate in manufacturer-sponsored programs, pharmacists must enroll in each individual program, complete necessary contracting and training requirements, and fulfill necessary program reporting. While many of the current payment opportunities are limited to manufacturer-supported programs, it is anticipated that additional opportunities for payment will increase as the number of pharmacists and practices providing MAS increases.

Billing for MAS can be complex for pharmacists within the current payment framework. Some medications eligible for administration are paid solely through the medical benefit, and

this may create barriers for some pharmacy providers and decrease access to patients in need. Although financially viable business models for pharmacy-based MAS continue to be a challenge, opportunities do exist. There are limited examples of payer contracts with successful partnerships occurring with regional or local payers. Payment from health plans is continually evolving. Some organizations may have billing departments or work with external billing vendors; these entities should be leveraged to assist in navigating billing processes for MAS.

Currently, processes for pharmacists to be included in payer networks are ambiguous, time-intensive, and often challenging to navigate. However, these processes are necessary for pharmacists to be eligible for service compensation. Health plan contracts

are unique and must be negotiated individually. These varied processes, forms, guidelines for participation, and rules for processing payments may make it challenging for pharmacy practices to scale MAS. Different payers require varying billing processes, and pharmacists' patient care services are often covered in the medical benefit rather than the drug benefit.¹ In regard to MAS, pharmacists should be proactive in contacting payers to:

- Determine if and how pharmacists' claims will be recognized.
- Clarify billing procedures.
- Obtain claims processing information.
- Obtain billing codes that will be recognized for pharmacists' services.
- Clarify any other requirements (e.g., prior authorization, specific submission instructions).
- Contract for pharmacists' services.

Ensuring reimbursement for MAS is a crucial part of the service delivery. Pharmacists cannot sustain delivery of patient care services unless there is payment associated with those services; therefore, the business model and the patient care service model are inextricably linked. Advances in state and federal provider status legislation will continue to drive positive movement in service compensation for pharmacists.

Administrative Roles and Activities

The practice has oversight responsibilities for essential administrative roles and activities associated with the delivery of MAS. These include benefits investigation and management, service scheduling, patient follow-up, and prescriber notification.

Benefits Investigation and Management

Working to minimize delays and inconveniences are particularly important for patients receiving MAS. The pharmacy should confirm that it is authorized to provide MAS, particularly when assigned in the coordination of care. The pharmacy must verify patient eligibility with the payer, and eligibility should be confirmed in advance of each appointment for MAS. Pharmacy staff should complete the process to ensure a "clean claim" one to two days before the patient arrives for a scheduled appointment so that there is sufficient time to resolve any unforeseen issues. For MAS, it is also important that pharmacists procure the product to be administered before the patient appointment.

Patient Follow-up and Prescriber Notification

For patients receiving MAS, appropriate follow-up to ensure continuity of care is critical. Whenever possible, pharmacists should make sure the next visit for MAS is scheduled while the patient is still in the pharmacy. Pharmacists may wish to use reminder calls or appointment cards to help support patients with follow-through of their scheduled appointments. A sample of a patient appointment card can be found at <http://www.pharmacist.com/sites/default/files/files/MASappointmentcard.pdf>. Reminders can be an important tool, and pharmacists can utilize multiple means of contact, depending on the preference of the patient or caregiver. For some patient

populations, phone numbers may change frequently or may not be consistently active. Pharmacy staff may wish to gather multiple contact numbers for the patient to facilitate needed follow-up.

Furthermore, pharmacists should develop processes to inform physicians that prescribed medications have been successfully administered. Appropriate notification should also be provided to the physician if a patient is overdue for medication administration or has missed an administration appointment. Pharmacists should work collaboratively with patients and physicians to ensure continuity of care. An example follow-up letter to a prescriber can be accessed at <http://www.pharmacist.com/sites/default/files/files/MASprescriberfollowup.pdf>.

Role of Pharmacy Management

Pharmacy management has an important role to play in the delivery of MAS. Management can ensure that pharmacists have adequate time and appropriate space to provide MAS. Management should ensure that sufficient investments are made to provide adequate facilities to provide MAS. Spaces within the pharmacy should be private, professional, and convey an atmosphere similar to a medical or office space. Pharmacists providing MAS need a clean environment for parenteral product preparation that is in compliance with USP Chapter <797>. Management should also provide adequate time and staffing for MAS so that the pharmacist does not feel pressured with other workload issues and can provide required attention to the patient that is conducive to developing patient-pharmacist rapport and confidence.

Conclusion

Pharmacists have an important role to play in advancing the provision of MAS. There is a significant need to expand access to patients and make MAS an available, predictable, measurable, sustainable and scalable service provided by pharmacists. APhA is pleased to provide information and resources to help inform pharmacists and support their expanded role in this patient care service.

Practice Resources

For pharmacists who are interested in learning more about pharmacist-administered MAS and programs that help support delivery of these services, the following articles and resources may be helpful:

- Joint Commission of Pharmacy Practitioners. The Pharmacists' Patient Care Process. Available at: <https://jcphp.net/patient-care-process/>.
- Skelton JB, Rothholz MC, Vatanka P. Report of the APhA Stakeholder Conference on Improving Patient Access to Injectable Medications. *J Am Pharm Assoc.* 2017;57(5):e1-e12.
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Pharmaceutical manufacturers have programs and resources for pharmacists that provide MAS. For example:

- Otsuka's ASSURE Program is designed to anticipate and address the support needs of patients. Pharmacists can learn more about the program and how to become a Local Care Center (LCC) at www.ASSURE.com.

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- 6 Centers for Disease Control and Prevention. *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team.* 2017. Available at: <https://www.cdc.gov/dhds/pubs/docs/CPA-Team-Based-Care.pdf>. Accessed November 14, 2017.
- 7 American Pharmacists Association. Code of Ethics for Pharmacists. Adopted October 27, 1994. Available at: http://www.pharmacist.com/node/25832?is_sso_called=1. Accessed November 13, 2017.
- 8 U.S. Department of Health and Human Services. Health Information Privacy: Fast Facts for Covered Entities. Available at: <http://www.hhs.gov/hipaa/for-professionals/covered-entities/fast-facts/index.html>. Accessed November 13, 2017.
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