Considerations for Providing Ambulatory Pharmacy Services for Pediatric Patients

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Pediatric clinical pharmacists are an integral part of the health care team. By practicing in an ambulatory care clinic, they can reduce the risk of medication errors, improve health outcomes, and enhance patient care. Unfortunately, because of limited data, misconceptions surrounding the role of pharmacists, and reimbursement challenges, there may be difficulty in establishing or expanding pediatric clinical pharmacy services to an ambulatory care setting. The purpose of this paper is to provide an overview of considerations for establishing or expanding pharmacy services in a pediatric ambulatory care clinic. The primer will discuss general and pediatric-specific pharmacy practice information, as well as potential barriers, and recommendations for identifying a practice site, creating a business plan, and integrating these services into a clinic setting.

ABBREVIATIONS ACCP, American College of Clinical Pharmacy; CPA, collaborative practice agreements; MTM, medication therapy management; PCMH, patient-centered medical home

KEYWORDS ambulatory care; pediatric; pharmaceutical services; pharmacy

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Introduction

Ambulatory care pharmacy practice is defined as the provision of integrated, accessible healthcare services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community. This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management. The ambulatory care pharmacists may work in both an institutional and community-based clinic involved in direct care of a diverse patient population.¹

Studies have demonstrated a positive impact of pharmacy services in the ambulatory care setting.^{2–4} However, literature discussing the role and impact of a pediatric pharmacist in an ambulatory care setting is sparse. Pediatric pharmacists practicing in an ambulatory care clinic can aid in reducing the risk of medication errors, improving outcomes, and enhancing patient care.^{5–9} Unfortunately, because of limited data and reimbursement challenges, there may be difficulty in establishing or expanding pediatric clinical pharmacy services to an ambulatory care setting. In addition, many clinicians are still unfamiliar with the differences between a clinical pharmacist and a dispensing pharmacist and may not understand the role of pediatric-trained pharmacists.

The purpose of this primer is to provide an overview

of considerations for establishing or expanding pharmacy services in a pediatric ambulatory care clinic. General and pediatric-specific pharmacy practice information, barriers to establishing pharmacy services in a pediatric ambulatory care clinic, recommendations for identifying a practice site, creation of a business plan, and integration of services into a clinic will be discussed.

Pediatric Ambulatory Care Clinic: Considerations

Identify a Pediatric Ambulatory Care Site. A variety of sites exist as options for establishing pharmacy services in a pediatric ambulatory practice. Settings may include private pediatric or family medicine practices, institution-based ambulatory clinics, federally qualified health centers, and state-funded facilities, to name a few.^{10–12} Opportunities and barriers commonly associated with each practice setting are highlighted in Table 1. An additional factor to consider, regardless of location, is whether the practice has an interprofessional or team approach to patient care with existing clinical pharmacy services. If so, the site's health care providers (e.g., physicians, physician assistants, and nurse practitioners) may already be familiar with the knowledge and practice abilities of a pharmacist. If this practice model is not present, the pharmacist needs to identify and align the clinic's desires with patient needs. Where there is little familiarity with the clinical role of a pharmacist, more time may be necessary to integrate into clinic workflow and to justify the pharmacist's role.

Table 1. Potential Benefits and Barriers of Various Pediatric Ambulatory Care Practice Sites

Clinic Setting	Opportunities	Barriers
Physician or provider office-based practice	Office has internal control of computer access and privileging, which makes it easier to establish a practice May be faster to get an agreement with the organization	Usually not a teaching center, and thus may not be familiar with pediatric clinical pharmacy services Computer system not linked to health care system, making transitions of care from an inpatient setting to the clinic challenging
Institutional ambulatory clinic	May have more resources and personnel to accommodate making changes to practice Access to multiple specialists or additional services as part of the health system	May or may not be a teaching environment May take longer to get an agreement because multiple people may be required for approval Workspace may be difficult to find May be less flexible to establish or change policies/procedures related to the “role of a pharmacist”
Federally qualified health center or state-funded facility	Access to 340B medication discount program Professional satisfaction due to serving an underserved population Opportunities to observe and participate in culturally competent care	Limited funds may make it difficult to establish site if funds for services need to be provided by facility Recurring grant cycles can be labor intensive Variable state and private funding sources

However, one advantage of being the initial pharmacist in a practice setting is the opportunity to create services and responsibilities.

The practice site may also be classified as a teaching facility. Practicing in a teaching facility often provides more opportunities for learner integration because of the familiarity of patients and caregivers with interacting with trainees and multiple health care professionals. In addition, there may be more potential to enhance patient care through education and discussions with health care providers at all levels, including attending physicians, physician assistants, nurse practitioners, fellows, residents, and student learners. For a non-teaching facility, the addition of clinical pharmacy services may alter workflow pace because the practitioner may be accustomed to moving from one patient to the next without stopping to discuss the treatment plan with the health care team. It may be more challenging to provide recommendations and interventions for each individual patient, and as such, an alternative workflow may be necessary. This may include a pharmacist-specific patient and family education visit, which may reduce the time the practitioner needs to spend with each patient, thus allowing a potential increase in provider patient volume.

While determining the type of practice site, one should also consider whether the setting will be a general or a specialized practice. General pediatric clinics, typically staffed by primary care providers for children or adolescents, are where a large majority of well-child visits occur. Because of the quantity of healthy children seen in the primary care setting, there is often an associated misconception that children are not on medications, and therefore a role for a pharmacist in

this setting does not exist. However, numerous opportunities exist to complete medication reconciliation (including non-prescription and herbal supplements), provide preventative care services (e.g., immunization education, education regarding safe use of over-the-counter products in children), address medication-specific questions (e.g., drug-drug interactions that may occur when an acute prescription is added to chronic therapy, medication use during pregnancy and breastfeeding), and assist in education to patients and staff (e.g., barriers to medication access, provision of adherence aids to patients, development of in-services).

As in adults, a variety of specialty clinics exist in pediatrics, such as allergy and immunology, pulmonology, endocrinology, cardiology, nephrology, neurology, behavioral health, and infectious disease. General pediatric clinics may have specific hours or days devoted to specialties, which lends itself nicely to the integration of the clinical pharmacist. Additionally, comprehensive, coordinated care is needed for children and adolescents with medically complex health care needs. Such services for this population may exist as an extension of a primary care clinic or an independent specialty clinic, typically in a patient-centered medical home (PCMH), which is instrumental in coordinating care between various providers.

Once a practice site is identified, it is important to establish a strong, trusting, and mutually beneficial relationship with the various decision-makers (e.g., administrators, providers) involved with the clinic. If pharmacy services are currently in existence, the pharmacy director may be able to identify and initially contact the appropriate person. If another pharmacist is providing clinical services, this person would be

Table 2. Tips for Implementing Pediatric Ambulatory Care Pharmacy Services

1. The initial contact may be by phone or email, but it is critical to request a face-to-face appointment to discuss service opportunities.
2. A written proposal is preferred, but consider a brief presentation to the medical director (or equivalent) and medical staff.
3. Use simple and empowering language to describe and justify the pharmacy services outlined in the business plan.
4. Ensure resources are obtained and in place prior to initiating pharmacy services. To obtain access to resources, it might be necessary to become a member of the department (e.g., pediatrics, family medicine, pharmacy).
5. Develop policies and procedures to delineate the role of the pharmacist to ensure that the pharmacist does not become responsible for clerical duties, such as faxing and tracking letters of medical necessity.
6. Maintain personal professional liability insurance even if the employer or practice site maintains liability insurance.
7. Consider obtaining additional certification, such as Certified Asthma Educator (AE-C), Certified Diabetes Educator (CDE), or International Board Certified Lactation Consultant (IBCLC).
8. Beginning the first day pharmacy services are provided, integrate monitoring of performance measures into the daily routine.
9. During the initial weeks at the site, educate all staff, nurses, providers, and other personnel about the role and responsibilities of the clinical pharmacist as delineated in the business plan.

a resource to help determine areas for expansion of patient care and to whom to direct the proposed business plan. Additional individuals to consider as an initial point of contact include the clinic manager, clinic medical director, or administrative assistant to either of these persons. If the clinic setting is affiliated with a medical school, it may be necessary to contact the Department of Pediatrics or Family Medicine department head (Table 2).

Business Plan or Proposal. After determining a potential practice site, a business plan or proposal is created to present to the medical director (or equivalent). The purpose is to outline services to be provided by the pharmacist, the qualifications of the pharmacist(s) providing the services, the necessary resources, and the financial or legal considerations, if any. The business plan or proposal serves as a platform to initiate conversation between the pharmacist, health care providers, and facility prior to establishing services or developing an agreement. There are many approaches to the development of a business plan, and components for consideration in the construction of a business plan or proposal are listed in Table 3. Additional resources are available from the American College of Clinical Pharmacy (ACCP) and the American Pharmacists Association to guide the pharmacist in the development of a business plan or proposal.^{12,13}

Market Assessment. A market assessment should be completed that includes not only the patient population being served, but also the goals and objectives of the practice site. Although not always possible, it is ideal to perform a direct evaluation of current gaps in patient care and a review of site-specific initiatives prior to completing the market assessment. This will help determine which outcomes can be most improved by pharmacy services and can help justify and support

the business plan. If a practice has PCMH recognition through the National Committee for Quality Assurance, there will be internal quality improvement standards that need to be achieved to maintain PCMH status. A practice that is part of a hospital system may also have additional performance parameters that are required by the accrediting agency or by an insurer that is providing value-based incentive payments. Surveying the clinic's health care providers may add additional insight into the providers' perceptions of gaps in care at their practice site.

If site-specific information is difficult to obtain, local and national benchmarks, used in conjunction with the clinic's needs, as identified by the providers and administration, can be used to guide program development or expansion. Benchmark data can be obtained from the Healthcare Effectiveness Data and Information Set, insurer claims data, or the department of public health to help guide the development of outcome-based initiatives. The national Healthy People 2020 initiatives can also be used to provide guidance on targeted outcomes.¹⁴ Examples of pediatric-related Healthy People 2020 objectives that can be impacted by a pharmacist's interventions are provided in Table 4.

Additionally, in 2010, more than 263 million outpatient retail prescriptions were dispensed for pediatric patients with ages from 0 to 17 years.¹⁵ The most commonly prescribed medications were for treatment of infection, allergy, cough and cold, depression, pain, attention deficit/hyperactivity disorder, asthma, atopic dermatitis, contraception, seizure disorders, gastroesophageal reflux, and acne.¹⁵ This information can be used to provide guidance on the most common disease states and medications for a pharmacist's interventions.

Regardless of the method used to do an initial assessment, the pharmacist must recognize that the needs

Table 3. Components of a Business Plan^{12,13}

Component	Description
Mission statement	Succinct and concise statement of the services to be provided, whom the services are intended for, and expected outcome
Executive summary	Brief overview of the intended components of the services
Market assessment/needs assessment	Brief assessment of the needs of the population or community for the potential services provided by the pharmacist
Provision of pharmacy services	Detailed description of the services to be provided, including the specific patient population and potential pharmacy learners that may be incorporated into the practice
Operational considerations	Description of the reporting structure, required access to patient medical records, necessary materials and supplies, space for clinical services and pharmacists, computer access, requirement of specific equipment, if necessary
Regulatory and legal requirements	Description of credentialing and privileging, collaborative practice agreement, liability insurance, risk management requirements
Marketing and promotion	Plan for advertisement to providers and patients
Reimbursement	Plan for payment for pharmacist time, billing considerations, employer expectations
Timeline	Timeline for implementation, milestones, expansion of services
Evaluation of services	Performance evaluation of pharmacist by medical director, measurement of outcomes

of the clinic and providers will likely vary once the pharmacist's services are integrated. Thus, after initial integration, a reassessment of clinic needs should be completed to further guide the specific services pharmacists can champion. Using a SWOT (i.e., Strengths, Weaknesses, Opportunities, and Threats) analysis may help to provide objective evidence of what services need to be changed and how to change them and to identify new services.

Provision of Pharmacy Services. To date, there is not a defined practice model for pharmacists in pediatric ambulatory care, yet many opportunities exist. In the business plan or proposal, it is important to detail the individual who will be providing services, the services to be provided, the entity (e.g., patient, caregiver, health care team) to whom services will be provided, the time required for the services, the expected outcomes, and a proposed workflow (Table 2). Ultimately, the goal would be to implement the Pharmacists' Patient Care Process as defined by the Joint Commission of Pharmacy Practitioners.¹⁶ In such a process, the pharmacist is integrated into the delivery of care for the patient in an interprofessional setting.¹⁶ Services to consider implementing include medication reconciliation, medication therapy management (MTM), preventative services, and patient-specific medication education and behavioral counseling.¹⁷

Also included in the provision of pharmacy services section of the business proposal should be a timeline and plan for precepting pharmacy learners, especially if required through an academic agreement. Learners may be prospective students, current students, or

postgraduate pharmacy residents or fellows. Incorporation of the learner should not occur until pharmacy services are established and the availability of space is assessed. Additionally, the role of the pharmacy learner and his or her requirements for participation in patient care must be determined well in advance. Site-specific policies to consider include required training (e.g., HIPAA training), volunteer/employee requirements (e.g., immunization status, background check), and access to the electronic health record. Lastly, site-specific goals and objectives, expectation requirements, and methods to evaluate the learner should be developed in order to guide learning opportunities and allow for a positive experience for all parties involved.

Resources Allocation and Pharmacist Requirements/Responsibilities. To maximize services provided to the practice, a list of resources needed by the pharmacist(s) must be included in the business plan or proposal.¹⁸ At a minimum, access to patient medical records is essential. Resource requests may also include office space with a phone and voicemail, computer or other technologic devices, access to electronic resources (e.g., email, interlibrary loan, clinic and institutional policies and procedures), and private space to provide clinical services, such as an examination room. If patient encounters are pharmacist specific, it is best practice to provide a pharmacist schedule. The pharmacist should work with the clerical staff or information technology group to develop an appointment template to allow office staff to schedule visits directly with the pharmacist. Other resources that may be considered include placebo-training devices for inhalational medications

Table 4. Examples of Healthy People 2020 Objectives¹⁴

Objective Identifier*	Objective	Baseline	Target
<u>Early and middle childhood</u>			
BDBS-6	(Developmental) Increase the proportion of children with sickle cell disease who receive penicillin prophylaxis from ages 4 mo to 5 y	N/A	N/A
IID-5	Reduce outpatient visits for ear infections where antibiotics were prescribed to young children	77.8% in 2006–07	70.0%
IID-7	Achieve and maintain effective vaccination coverage levels for universally recommended vaccines among young children	Varies by vaccine	Varies by vaccine
RD-7.4	Increase the proportion of persons with current asthma who do not use more than 1 canister of short-acting inhaled β agonist per month according to National Asthma Education and Prevention Program guidelines	87.9% in 2008	90.2%
<u>Adolescents</u>			
TU-2.1	Reduce use of tobacco products by adolescents in the past 30 days	26.0% in 2009	21.0%

*Abbreviated topic identifier for the specific Healthy People objective.

and self-administered injectable medications, as well as oral syringes to aid with liquid medication delivery education (Table 2).

Regardless of the type of practice site, pharmacist responsibilities and requirements should be expressly specified, rather than being referred to broadly as “providing clinical services.” If the pharmacist is an affiliate of or a consultant to the practice site and not an employee, ensure that basic staff privileges and requirements, such as employee identification, site-specific training, documentation of pharmacist-specific encounters, and access to services (e.g., use of clerical staff, triage nurse, social worker), are extended to the pharmacist. Clarification of reporting structure and workload requirements, such as attendance at staff and/or provider meetings, representation on committees, and involvement in quality improvement initiatives, should be outlined. Allocation of time divided between direct patient care services and administrative work (e.g., facilitation of prescription renewals and completion of prior authorizations) should also be defined (Table 2). It is also critical to ensure that a backup process is in place during occasions when the pharmacist is not present at the clinic (e.g., coverage during illness or personal leave vacation), which may include providing an on-call schedule for the pharmacist.

Regulatory and Legal Requirements. Requirements, such as credentialing and privileging, collaborative practice agreements (CPAs), liability, and risk management, must be addressed and clarified prior to initiating pharmacy services at the practice site. The responsibility of risk management should be determined by the attorney of the organization; however, all involved individuals must agree upon a procedure in the event

of a liability issue. It is equally important to determine who will maintain liability insurance (Table 2).

Credentialing and Privileging. From an employment standpoint, credentialing refers to the process an organization uses to obtain, verify, and assess an individual’s qualifications to provide patient care services. Privileging is the process by which an organization reviews an individual’s credentials and performance and determines whether they are acceptable, thereby granting permission to that individual to perform patient care services within that organization. Both processes are important to ensure a pharmacist is capable and competent in providing clinical pharmacy services.¹⁹ Unfortunately, for the pharmacy profession these processes are often not established. However, if a credentialing and privileging process needs to be established, the institution likely has a process in place for other health care professionals that can be used as a model for pharmacists. In addition, the Council on Credentialing in Pharmacy provides guidance on these processes.²⁰

Because it may not be well known to others outside the pharmacy profession what pharmacy education and training entails, it may be necessary to outline in detail the education, training, certifications, and qualifications of pharmacists, particularly if initiating a credentialing and privileging process. For example, the Doctor of Pharmacy degree has been a requirement for approximately 15 years, yet other health care providers or administrators may be unaware of the minimum education requirement to become a licensed pharmacist. Additionally, the extent of postgraduate residency or fellowship is not uniform among the profession, and it differs from that of other health care professions. A

general overview of pharmacy residency and fellowship definitions can be found on the ACCP Web site.²¹ The qualifications of a pediatric-trained pharmacist may be less well understood; thus, it is important to provide a concise summary describing these qualifications. Descriptions of pediatric pharmacists can be found in the joint statement paper by the ACCP Pediatric Practice Research Network and the Pediatric Pharmacy Advocacy Group.²²

Acronyms for other specialized certifications may not be well known to administrators outside of the pharmacy profession; therefore, all certifications and qualifications, such as Board Certified Pharmacotherapy Specialist (BCPS), Board Certified Ambulatory Care Pharmacist (BCACP), Board Certified Pediatric Pharmacy Specialist (BCPPS), Certified Asthma Educator (AE-C), or Certified Diabetes Educator (CDE), should be clearly defined (Table 2). A list of certification programs for pharmacists can be found on the ACCP Web site.²¹

Once established, the credentialing and privileging process is cyclical and will require ongoing documentation of qualifications and performance measures to maintain privileges. The pharmacist is responsible for ensuring that patient care services provided are within the approved scope of practice.¹⁹

Collaborative Practice Agreements. Collaborative practice agreements are essential to defining the formal relationships between the pharmacist(s) and providers (e.g., physicians).^{23,24} Under a CPA, a licensed provider makes a diagnosis and supervises patient care; however, the provider refers patients to the pharmacist to perform specific components of patient care. For example, the provider may refer a patient to the pharmacist for adjustment of medication doses, assessment of self-injection technique, or disease state and/or medication education.²⁵ The CPA will define the patient care services that the pharmacist can autonomously provide under specified circumstances, such as initiation, adjustment, or discontinuation of medications; ordering of laboratory tests to monitor drug therapy; or performance of targeted physical examinations in order to assess medication efficacy or toxicity.^{17,24} An expert panel has provided strategies for advancing pharmacists' patient care services through CPAs and team-based care, and these strategies can be helpful when developing a CPA within the pediatric practice setting.²⁵ Limited data exist for CPAs for pharmacists in ambulatory pediatric settings; thus, extrapolation from literature in the adult setting (e.g., diabetes, transplantation, anticoagulation) may need to be used to develop an initial CPA.²⁵

Examples of CPAs in the pediatric setting that may include a pharmacist:

- practicing in a pediatric endocrinology clinic that autonomously adjusts insulin therapy and orders laboratory tests;
- practicing in a general pediatrics or pulmonary/

allergy subspecialty clinic that manages pharmacotherapy for patients with asthma;

- performing follow-up evaluations and adjusting medications in children receiving a diagnosis of depression or other behavioral health disorders managed in the primary care setting;
- monitoring drug concentrations after transplantation and adjusting immunosuppressive therapy accordingly;
- adjusting the doses of chronic medications for significant changes in patient weight (i.e., of more than 10%); and
- revising antiretroviral therapy based on resistance testing results.

Although CPAs are recognized in most states, the scope of practice allowed varies by state. Some states restrict this care model to specific diseases and populations.^{26,27} In 2012, a group of experts analyzed CPAs and the pharmacists' role in delivering patient care services.²⁸ Some states had no laws or regulations for pharmacist CPAs, whereas other states authorized pharmacists to provide drug therapy management for health conditions as specified by a written protocol.²⁵ As such, it is necessary to be cognizant of the rules and regulations that control pharmacists' care activities for pediatric patients, typically imposed by state boards of pharmacy.

Reimbursement. Developing a sustainable business model for ambulatory care pharmacy services is essential to the success of the practice.²⁹ One of the major pillars of the business model is compensation. Areas of compensation to consider include but are not limited to: cost savings, pay-for-performance, shared savings, and revenue generation or billing. In the era of health care reform, there is an increased focus on pay-for-performance and receiving compensation for improving outcomes. It is important to consider all 3 components and to work with the practice to determine the goals for compensation.

Because billing for clinical services is most likely the primary revenue opportunity, the focus will be placed on billing or revenue generation to provide financial support for the pharmacist. Specific billing options depend on a multitude of factors. In most states, pharmacists are not recognized as health care providers and may be unable to directly bill for clinical services. Even in states in which pharmacists are recognized as a provider, variables such as practice site location and payer mix may directly impact billing opportunities. The gold standard for medical billing is Medicare, which covers beneficiaries older than 65 years, rarely covers children.³⁰ Commercial payers and state Medicaid plans use a variety of models (i.e., per state law regulations or per contract). The variation in billing processes makes having access to a specialized expert in billing and compliance imperative.

In the pediatric population, most prescribers will bill

Table 5. Description of Incident-to Billing Codes With Pediatric-Specific Examples for Reimbursement^{†*56}

CPT Code	Code Description	Example
99211	Evaluation or management of an established patient that may not require the presence of a physician or other qualified health care professional. Usually the presenting problems are minimal. Typically, 5 min are spent performing or supervising these services.	A mother of a 6-year-old child requiring a refill of a medication for gastroesophageal reflux disease
99212	Evaluation and management of an established patient that requires at least 2 of the 3: 1) problem-focused history; 2) problem-focused examination; and/or 3) straightforward medical decision-making. Self-limited or minor nature of presenting problem with straightforward medical decision-making. Typically, 10 min are spent face-to-face with the patient and/or family.	4-year-old child being evaluated for a rash 10 days after receiving the measles, mumps, rubella, and varicella vaccine
99213	Evaluation and management of an established patient that requires at least 2 of the 3: 1) expanded problem-focused history; 2) expanded problem-focused examination; and/or 3) low or moderate severity of the presenting problem with medical decision-making of low complexity. Typically, 15 min are spent face-to-face with the patient and/or family	10-year-old child with stable asthma seen for follow-up
99214	Evaluation and management of an established patient that requires at least 2 of the 3: 1) detailed history; 2) detailed examination; and/or 3) moderate to high severity of the presenting problem with medical decision-making of moderate complexity. Typically, 25 min are spent face-to-face with the patient and/or family.	15-year-old adolescent with type 1 diabetes mellitus with a recent change in insulin requirement
99215	Evaluation and management of an established patient that requires at least 2 of the 3: 1) comprehensive history; 2) comprehensive examination; and/or 3) moderate to high severity of the presenting problem with medical decision-making of high complexity. Typically, 40 min are spent face-to-face with the patient and/or family	A 10-year-old patient with nephrotic syndrome presenting with new-onset edema

* Modified from CMS.gov (<https://www.cms.gov/medicare-coverage-database/staticpages/cpt-hcpcs-code-range.aspx?DocType=LCD&DocID=32007&Group=1&RangeStart=99211&RangeEnd=99215>). Accessed December 19, 2017.

private insurance payers or state Medicaid plans, both of which are non-Medicare billing types. Non-Medicare incident-to billing is an indirect billing mechanism whereby a pharmacist provides patient care services through indirect supervision by a physician or other approved provider.³⁰ Incident-to billing includes Current Procedural Terminology codes such as 99211 to 99215, depending on the services provided (Table 5).²⁹ For a pharmacist visit independent of a provider, 99211 billing codes are typically used. Medicaid and commercial payer rules may allow a pharmacist to bill higher codes as long as services and documentation support the code.³⁰ In order to bill higher codes, some states require the provider to be present in the office and also see the patient during the visit. Incident-to billing can be used at an independent non-institutional physician group or clinic or at an institutional outpatient clinic, but it cannot be used in a hospital or extended-care facility.³⁰ In the pediatric setting, incident-to billing seems the most logical. This billing scheme optimizes patients' evaluations into 1 visit so that the pharmacist would see the patient with the provider. It is often difficult to schedule children with a pharmacist for an independent visit because parents want to minimize the amount of time their child misses school and the caregivers miss work for health care visits. Other billing options do exist and

include education or self-management training (e.g., codes for diabetes self-management training), laboratory testing, and spirometry measurement. Ultimately, billing is very state and institution specific and requires discussion with the medical director as to how funds are distributed to the pharmacist or pharmacist's employer.

With new health care models emerging because of the Patient Protection and Affordable Care Act, the addition of a pharmacist to a PCMH or accountable care organization may assist in meeting quality measures and improving outcomes. Incentivized reimbursements may support the salary of a pharmacist in these interdisciplinary health care teams.³¹

Evaluation of Patient Care Services. There are 2 methods to evaluate services. The first is an individual performance evaluation by a manager or supervising physician. This would be consistent with any employee review but should also include any evaluation components required to maintain practice privileges, such as direct observation and/or chart audits. Discussion during this evaluation could also consist of identifying opportunities and determining methods to further justify expansion of pharmacy services. The second method to evaluate services includes measurement of outcomes.

Measurement of Outcomes and Research. To advance the practice of pediatric pharmacy in the ambula-

tory care setting, it is essential to measure and report outcomes demonstrating the benefits of such services (Table 2). Outcomes should ultimately demonstrate an improvement in patient health, such as a decrease in asthma exacerbations, a decrease in frequency of seizures, or a decrease in adverse drug reactions. Preventing pediatric medication errors and adverse drug reactions and improving medication adherence should be key outcomes to monitor. Areas that can be a focus for improvement include pediatric-specific technology enhancements for electronic prescribing and increased communication with and education for parents and children regarding medication administration.^{32,33}

In addition, there are numerous opportunities for quality improvement studies and research projects. These can stem from the initial market assessment of commonly prescribed medications or may be driven by clinic-specific needs. One example includes evaluation of the psychostimulant prescribing practices and management of attention deficit/hyperactivity disorder in comparison with the evidence-based guidelines. In care models participating in payment improvement initiatives, performing cost analyses may be beneficial, especially when trying to demonstrate return on investment for pharmacy services. Examples here may include a commercial insurance that audits the clinic for immunization completion rates or numbers of patients receiving a diagnosis of persistent asthma who have received an asthma action plan and an annual influenza vaccination. The pharmacist can be the key contact person for evaluating this baseline data and for developing and implementing a plan to achieve these outcomes. Regardless of the service provided, the pharmacist should set up the evaluation as a well-designed research project, so that it can be described, analyzed, and reported in the literature to support expansion of such services to other pediatric ambulatory care settings.

Patient Care Pharmacy Services

There are many direct and indirect patient care services pharmacists can provide in the pediatric ambulatory care setting (Table 2). Examples of services to consider when implementing or expanding a practice site are described below. These include medication reconciliation, MTM, preventative services, education and behavioral counseling, pediatric self-management and adherence assessment, transition of care implementation, facilitation of patient access to medications, and development of medication administration protocols and staff education sessions.

Medication Reconciliation. The Joint Commission defines medication reconciliation as “the process of comparing a patient’s medication orders to all of the medications that the patient has been taking.”³⁴ The process of medication reconciliation is vital to ensure patient safety and improve health outcomes. The Joint

Commission requires a process for medication reconciliation at any point in which a patient enters a health care setting (e.g., hospital, ambulatory clinic, emergency department) or has a change in the level of care within an institution (e.g., intensive care unit to a step-down unit). Equally important to obtaining a complete medication history from the patient or caregiver is to update the patient’s medical records and alert the health care providers of any inconsistencies.³⁴ Regardless of practice site, all medications across health care settings should be documented at each patient encounter to monitor for any medication-related problems.

Because of the unique nature of the medication use process in pediatric patients, pharmacist involvement in medication reconciliation may be especially beneficial. For example, patients and caregivers often express the dose of liquid medications in milliliters or other volumetric units, rather than the equivalent weight-based unit. Pharmacists are knowledgeable of the various concentrations available and can provide an accurate weight-based dose conversion to avoid potential error and to verify accuracy of dosing. Secondary to age or school policies, many pediatric patients do not self-administer medications or have control over the timing of medication administration. Because there can often be multiple caregivers responsible for medication administration, the pharmacist should ascertain how individual caregivers are administering medications and at what time, documenting any deviations from the prescribed instructions. Thus, pediatric pharmacists can facilitate and provide accurate medication reconciliation that often is overlooked or not entirely completed.

Medication Therapy Management. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (known as the Medicare Modernization Act, or MMA) introduced the Medicare Advantage voluntary drug benefit for Medicare beneficiaries.³⁵ The law requires that each prescription drug plan offer an MTM program for qualifying beneficiaries. The current federal requirements to qualify for MTM services are that beneficiaries have at least 3 of the listed chronic diseases (e.g., diabetes, hypertension, asthma, dyslipidemia); take at least 6 chronic medications; and be likely to incur a specified amount of drug costs annually (2015 threshold of \$3,138).³⁶ At this time, the formalized service of MTM has not been widely offered to pediatric patients. A pediatric ambulatory care setting is an opportune arena in which to offer MTM services, because the pharmacist will have direct access to medical records, prescribers, and patients.

Medication therapy management services provided by the pediatric ambulatory care pharmacist must incorporate age-related pharmacokinetic, pharmacodynamic, and physical maturational changes into medication therapy assessment. This would include evaluating the appropriateness of dosage forms (e.g., solid versus liquid, immediate versus extended release);

monitoring for adverse effects that are more prominent in the pediatric population; and assessing for appropriateness of age and weight-based dosing, including the need for titration of doses of chronic medications as the patient ages and gains weight.

In the adult population, MTM has been shown to improve adherence and improve patient outcomes, particularly for those with chronic diseases.³⁷ Because MTM services have not been clearly delineated in pediatric patients, pediatric pharmacists performing such services should have defined processes, documentation, and outcomes. A proposed model has recently been published but has not yet been validated.³⁸

Preventive Services. The American Academy of Pediatrics and Bright Futures provide recommendations for preventive pediatric health care for the well child.³⁹ Pharmacists can assist in preventive care for pediatric patients, particularly during well-child appointments. Some opportunities include immunization screenings and sexually transmitted infection and pregnancy prevention. Pharmacists may review the medical history, immunization records, and risk factors to determine the necessity of vaccinations. Preemptive laboratory screening (e.g., lipids, lead) is recommended for specific age groups, and the pharmacist can assist in ensuring adherence with requirements, interpreting results, and providing recommendations for treatment. Additionally, pharmacists can address the prevention of sexually transmitted infections and pregnancy in adolescent patients, not only by educating patients about safe sex practices and contraceptive options, but also by incorporating emergency contraception and pre-exposure prophylaxis for human immunodeficiency virus education into the practice.

Education and Counseling. Most pediatricians spend between 9 and 16 minutes with each patient, and this time must be divided among all of the components of an office visit, leaving little time, if any, for education regarding the patient's disease state, recommended lifestyle modifications, and medications.⁴⁰ Appropriate education is vital to the success of treatment regimens, and pharmacists are adequately trained to provide education regarding a patient's disease(s), as well as any recommended therapies.⁴¹ For this reason, many guidelines (e.g., Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma⁴², and the Clinical Practice Guidelines For Chronic Kidney Disease: Evaluation, Classification and Stratification⁴³) specifically mention pharmacists as part of the health care team. Evidence has demonstrated positive outcomes when patients are provided with medication education, including adherence counseling.^{44,45} However, there is limited evidence in pediatrics, and this should be an area considered for future research.

Disease State Education. Education should be provided to both the patient and caregiver(s) regarding specific disease states and related pharmacotherapy.

However, because a child's level of understanding varies across the pediatric age spectrum, the amount and complexity of information provided must be tailored to each patient. Therefore, education should be repeated periodically as the child ages and his or her level of understanding increases. When explaining the patient's disease state, the pharmacist should incorporate the patient's medication regimen and how the medication works for the specific disease. When any lifestyle modifications are recommended, the pharmacist can provide education, with encouragement given for full family participation (e.g., exercise for obesity).

Counseling on All New Prescriptions. Caregivers and patients should be counseled about when anticipated effects should occur, common and serious adverse effects, and when to contact a health care professional. Because there are often multiple individuals administering medications to pediatric patients, it is important to ascertain who will be administering medications and to provide education to all individuals, if possible, either face-to-face, by phone, or through concise written communication. In addition to counseling on administration and storage, the pediatric pharmacist can elucidate ways to improve patient intake of medication, particularly with regard to improvement in taste, which is often a significant barrier to medication administration in young children. The pediatric pharmacist can demonstrate the proper use of an oral syringe for any liquid medications, with opportunities for the patient and/or caregiver(s) to demonstrate understanding.⁴⁶ Documentation of counseling and any interventions should be completed in the patient's medical record, noting patient and/or caregiver understanding.

Device Training and Review of Technique. Medical devices, such as nebulizers, metered dose inhalers, and blood glucose meters, are often confusing to patients and caregiver(s) and require thorough patient education for appropriate use. The pediatric ambulatory care pharmacist can provide initial education regarding device use and should assess and review the technique frequently. Education should be provided to both the child and the parent/caregiver. As a child ages, the responsibility of medication use will evolve from caregiver administration to child self-administration with adult supervision to independent medication administration.

Pediatric Self-Management and Adherence Assessment. Ineffective self-management and non-adherence will negatively impact health outcomes and increase health care costs; thus, both should be assessed routinely.^{47,48} Self-management is the "interaction of health behaviors and related processes that patients and families engage in to care for a chronic condition."⁴⁷ Adherence is defined as the "extent to which a person's behavior coincides with medical or health advice."⁴⁷ As in adults, social and economic factors, the health care team/system, characteristics of the disease, disease therapies, and patient-related

factors influence self-management and adherence.⁴⁸ However, compared with adults, family dynamics and encouragement, or lack thereof, from caregivers and siblings have a stronger influence on pediatric self-management and behaviors. For example, increased family conflict will negatively impact self-management in pediatric patients.⁴⁷

As pediatric patients transition from childhood to adolescence, the goal is for them to take on a more active role in their health care. Although caregivers often provide less guidance as a child ages, self-management usually worsens as a child transitions to adolescence.⁴⁷ During this time, pharmacists should educate the family on the importance of continued parental involvement and ensure family members play a role in empowering and guiding their child to take responsibility for his or her own health care.^{47,49} Additionally, when educating adolescents about self-management, the patient's readiness should be based on intellectual ability, maturity level, and emotional status, rather than age alone, because these factors can influence the patient's ability to self-manage. For example, adolescents with emotional disturbances, such as depression, are more likely to be non-adherent. Lastly, since peers can have a strong positive or negative influence on self-management, pharmacists should evaluate the peer support system of all adolescents and discuss ways to improve support.⁴⁷

Non-adherence rates for children and adolescents with chronic conditions range from 50% to 75%.⁴⁷ More common in pediatric patients, unpalatable medications and inappropriate drug delivery devices or unavailability of appropriate devices may lead to non-adherence. These barriers may result in administration difficulty for all routes of administration but are especially problematic for medications administered by mouth or via an enteral tube. Pharmacists can implement methods that have been found to improve medication adherence, regardless of age, such as education, case management, reminders, telephone-based counseling, and decision aids.⁵⁰ Medication adherence aids to consider in the pediatric population include pillboxes, medication calendars, and text reminders. If pillboxes are recommended, further education should be provided and include methods to decrease the risk of a child opening the pillbox and inadvertently ingesting the medication.

Transitions of Care. Similar to adults, transition from an acute care setting to the outpatient setting can lead to poor health outcomes and have the potential to cause patient harm.⁵¹ During this time, pharmacists, as part of an interprofessional ambulatory care team, have the potential to decrease preventable readmissions, decrease emergency department visits, prevent errors, and enhance outcomes.^{51,52} Although all patients are at risk for adverse outcomes, children with special health care needs and those who take more than 5 medications have a higher risk.⁵¹ As an ambulatory care

pharmacist, an effective method to reduce the risk of readmissions is to provide a telephone follow-up call 2 to 4 days after discharge to discuss with the caregiver and/or patient any questions or concerns; verify receipt of medication upon discharge; offer assistance with any insurance-related challenges that may have occurred; and schedule a clinic visit.⁵¹ In addition, the ambulatory care pharmacist can coordinate with community pharmacists to ensure timely access to medications, detect adherence problems, and resolve medication discrepancies.⁵²

Unique to the pediatric population is the additional transition of care from pediatric to adult health care. Even though the American Academy of Pediatrics, in collaboration with the American Academy of Family Physicians and American College of Physicians, has a recommended process to support and facilitate the transition of adolescents with special health care needs into adulthood,⁴⁹ this process could benefit all adolescents transitioning to adult care. The 4 key components include: "assess for transition readiness, plan a dynamic and longitudinal process for accomplishing realistic goals, implement the plan through education of all involved parties and empowerment of the youth in areas of self-care, and document progress to enable ongoing reassessment and movement of medical information to the receiving (adult care) provider." The transition process should be initiated at age 14 years⁴⁹; however, the age to start this process may vary among practice sites. Pharmacists are well suited to aid in the transition process, especially in children with complex needs who are managed by multiple specialists and prescribed numerous medications. Depending on medical conditions, children with special health care needs may be taking 8 to 10 prescription medications and may reach up to 20 medications.^{53–55} During the transition process, a transfer plan with documentation should be created and discussed regularly.⁴⁹ The pharmacist could be responsible for the medication-specific components of the plan, such as medication use in an emergency (e.g., asthma action plan) and evaluation of the patient's level of self-management and understanding of his or her health conditions and associated treatments. Self-management incorporates not only the understanding of health conditions, but also how to access health care providers, obtain medication refills, and self-administer medications.

Facilitating Access to Medications. Patients and caregivers often come across barriers (e.g., insurance denials, drug supply shortages, pharmacy dispensing limitations) when trying to obtain prescribed medications. In most practices, a nurse or other support staff member, who may not have a thorough understanding of pharmacotherapy, is responsible for communicating with patients, insurance companies, and pharmacies about medication-related issues. For more complex issues, it is beneficial to have a pharmacist intervene

Table 6. Sample Pharmacist-Driven Protocol: Travel Medicine and Immunization*

Parameter	Description
Objective	To allow clinical pharmacists [insert clinic name /practice location] to safely and effectively manage the immunization and medication needs of a traveling patient. The goal is to educate patients who are traveling about how to prevent food-, water-, and vector-borne diseases, and to assess the need for appropriate vaccinations and travel-related medications, as indicated in this protocol.
Protocol type	Initiated by non-physician, based on predefined clinical criteria in protocol.
Procedure	<p>The clinical pharmacist will assess and write prescriptions for immunizations and medications, as indicated, based on the patient's travel itinerary.</p> <ol style="list-style-type: none"> Upon determination of the patient's travel itinerary, the pharmacist will develop a medication and immunization plan using the CDC's Travelers' Health Web site [insert proper link to allow clinician to access directly from protocol] to determine which immunizations and medications the patient is a candidate for based on the patient's age, weight, food and drug allergies, immunization history, and past medical history. The patient's medication insurance coverage (i.e., formulary medications) will also be taken into consideration. The information, including benefits and risks of each recommended vaccine and medication, will be presented to the patient or guardian, if an infant or child. The patient and/or guardian will then determine which agent he or she would like to receive. The clinical pharmacist will also assess the patient's need for updating his or her routine vaccinations per the CDC guidelines (in particular MMR and hepatitis A). If the patient is to receive immunizations in the clinic, the clinical pharmacist will document a travel clinic note, detailing the recommendations, and forward this to the primary care provider or provider covering clinic that day. A clinic visit will then be scheduled where the RN/LPN will administer the necessary vaccinations, per physician order. As an agent of the patient's prescriber, the clinical pharmacist will enter prescriptions for necessary travel medications (e.g., malaria prophylaxis, treatment of traveler's diarrhea); send it to the patient's pharmacy of choice; and counsel on proper use, administration, and possible adverse effects. Follow-up visits will only be necessary if the patient is to return for completion of the vaccine series.

CDC, Centers for Disease Control and Prevention; MMR, measles, mumps, rubella

*Adapted with permission from The University of Illinois Hospital and Clinics.

to ensure medications are obtained in a timely manner.

Many of these barriers are caused by pharmacies and insurance companies changing policies, procedures, or medication formularies to cut costs. For example, some community pharmacies may no longer dispense certain specialty medications (e.g., transplant immunosuppressants, such as tacrolimus and mycophenolate), and thus centralize dispensing. This adds an extra step in which the family needs to obtain prescriptions either through the mail or by traveling to a specialty pharmacy that may not be as conveniently located. Additionally, medications that have historically been covered by an insurance company may now require a prior authorization. In this situation, a pharmacist is well suited to recommend an acceptable cost-effective alternative to a medication that is covered by the patient's insurance. If there is not an appropriate alternative available, the pharmacist may author the letter of medical necessity, including evidence-based pharmacologic, pharmacokinetic, pharmacodynamic, and pediatric-specific rationale for use of the requested medication. As medication experts, ambulatory care pediatric pharmacists can help overcome these obstacles.

Furthermore, medications for pediatric patients

frequently require compounding or are prescribed for an off-label indication. Depending on the community pharmacy, there may be a delay in dispensing the medication if compounding services are not available or further information is required to verify the appropriateness of the off-label use of the medication. The pediatric ambulatory care pharmacist can serve as a liaison with the pharmacy by providing recipes for extemporaneous preparations, literature for off-label use of medications, and resources and guidance for additional pediatric-related medication needs.

Clinical Policies, Procedures, and Precepting Services. Medication Administration Protocols and In-services to Staff. Most pediatric ambulatory care clinics provide administration of medications in the office, such as albuterol and oral steroids for asthma or antibiotics (e.g., intramuscular penicillin, ceftriaxone) for pharyngitis or sexually transmitted infections. Specialized practices may administer a variety of infusions. A pharmacist would be the ideal health care professional to develop medication administration protocols. These should include information about the specific medication, premedication, and emergency medication and necessary monitoring to occur before, during, and

after the medication administration or infusion. In-office protocols that can be developed may include treatment of mild pain and fever, travel vaccination consultations, and infusion administration. An example of an in-office protocol can be found in Table 6. All developed clinical care protocols should promote safe and effective medication use within the practice setting, providing health care staff with guidance for administration, dosing, and monitoring for possible adverse effects, along with guidelines for documenting interventions and encounters.

In addition, the pediatric ambulatory care pharmacist can provide in-services or periodic newsletters to the providers and support staff with updates on current medication-related topics. Topics that might be of interest to other health care professionals include Black Box warnings/completion of REMS (risk evaluation and mitigation strategies) requirements, new drugs on the market, medication use during pregnancy and lactation, drug shortages and appropriate alternative(s), and updates to clinical guidelines. A review of frequently used and appropriate medication references is also very helpful for providers and nurses to become familiar with pediatric medication dosing and formulations.

Summary

Establishing clinical pharmacy services in the pediatric ambulatory setting is both a rewarding and a challenging experience. When considering a practice site, it is important to identify opportunities for enhancing pediatric care and align individual interests with the clinic's strategic plan. The pediatric pharmacist should highlight his or her education and training so that providers better understand that pediatric pharmacists are highly qualified to promote safe, effective, and comprehensive medication management. Once a location is identified, the business plan is developed and presented to the appropriate stakeholders. The business plan should include the role and services to be provided by the pharmacist, expected outcomes, required resources, reimbursement opportunities, and reporting structure. When integrating pharmacy services, the pharmacist should be flexible with workflow and day-to-day activities. During the first few weeks, the pharmacist should take time to understand the workflow and determine the practice preferences of the providers. Periodic assessment of pharmacy services should be conducted to improve patient care, clinical outcomes, and satisfaction by the other members of the health care team. The role of pharmacy learners should be included in the business plan.

Pediatric clinical pharmacists are an integral part of the health care team and can provide a wide scope of pharmaceutical care services, from educating the patient with persistent asthma on proper inhalation technique and adherence to providing medication management for the child with complex medical conditions.

In order to justify the pediatric pharmacist's role and to further expand pediatric ambulatory care pharmacy services, patient encounters and services rendered should be documented, and outcomes should be published.

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