SHIELDS
HEALTH SOLUTIONS

WHITE PAPER

Pediatric Patients Benefit from An Integrated Specialty Pharmacy Care Model

HOW PEDIATRIC HOSPITALS CAN UTILIZE SPECIALTY PHARMACY TO ENHANCE PATIENT CARE

KEY CONCEPTS

- Pediatric patients are at high risk for fragmented care due to transitions between healthcare settings, transitions through developmental stages, and socioeconomic disparities.
- Increases in drug prices, labor expenses, and supply costs, along with declining federal reimbursement rates, are reducing the margins in pediatric hospitals.
- Shields' customized specialty pharmacy care model is uniquely positioned to help pediatric hospitals overcome barriers to improving patient care and reducing total cost of care.

INTRODUCTION

With the tremendous growth in the development of treatments for chronic pediatric diseases such as cystic fibrosis (CF), sickle cell, hemophilia, and many rare and orphan pediatric diseases, there has been an evolving recognition of the importance of an integrated health system specialty pharmacy (HSSP) in pediatric patient care. The recognition comes from the literature showing that HSSP improves clinical outcomes and medication adherence rates and lowers healthcare costs.[1] This model offers an advanced approach to pediatric patients and their families by integrating medical care with pharmaceutical care, supported by clinical services and financial solutions to improve the well-being and outcomes of pediatric patients with complex chronic and rare diseases.

As pediatric hospitals look to expand their specialty pharmacy offerings, Shields Health Solutions has demonstrated that an integrated HSSP model can be a valuable building block to defragment care, improve patient outcomes, and increase patient satisfaction with the healthcare system.

FRAGMENTED CARE IN PEDIATRIC PATIENTS IMPACTS OUTCOMES

Pediatric patients, especially those with complex, chronic conditions, are at high risk of fragmented care due to transitions between healthcare settings, developmental stages, and socioeconomic disparities. Fragmented care can lead to poor healthcare outcomes or even death for this highly compromised population.

Top Contributing Factors:

TRANSITION BETWEEN HEALTHCARE SETTINGS

- Multiple care settings and providers
- Transition from pediatric to adult care

SHIFT IN DEVELOPMENTAL STAGES

- Lack of established pediatric dosing
- Off-label prescribing
- Changes in height and weight
- Drug absorption, distribution, metabolism, & elimination

SOCIOECONOMIC DISPARITIES:

- Healthcare access
- Physical environment
- Health behaviors
- Family dynamic and financial status
- Social and peer pressures

LACK OF AUTONOMY IN HEALTHCARE DECISIONS:

- Rarely have choices when selecting providers
- Medical and pharmaceutical insurance coverage dependent upon guardians
- Dependent upon guardians to provide care

"Parents often find themselves operating as care coordinators between their child's healthcare professionals due to a lack of consolidated, cross-system communication.[2]"

"The newer the drug, the less likely the pediatric label information will be available because the pediatric post-marketing studies required by the FDA often take several years after drug approval to complete."

Transition Between Healthcare Settings:

Pediatric patients with chronic illnesses often receive care from multiple specialty physicians, clinics, and primary care providers, all while also receiving care at the hospital and home. This complex dynamic can often lead to gaps in care and communication among providers and parents. Parents often find themselves operating as care coordinators between their child's healthcare professionals due to a lack of consolidated, cross-system communication.[2] In addition to communication, care coordination, and caregiver burden, there could be treatment conflicts (drug interactions, drug duplications, and side effects), as well as fragmented decision making (conflicted opinions from multiple providers). Not only is this frustrating for the parents, but it also poses a risk to the patient's outcome if important medical information is overlooked.[2]

In addition to the transition between multiple providers and clinics, pediatric patients can also experience gaps in care as they transition from pediatric to adult care. There are several barriers: loss of healthcare coverage, lack of care coordination, lack of specialized providers, comorbidities, and fearfulness in leaving the familiar environment and providers.[3] Care management and healthcare decisions are left to the parents in a pediatric setting, but as pediatric patients transition to adult care, they become responsible for their own medical care and decisions, which can result in medication non-adherence and worse outcomes. For example, the transition period from pediatric to adult care for Sickle Cell Disease (SCD) patients has been shown to be a high-risk time for poor health outcomes due to loss of continuity of care, non-adherence to the medications, loss of insurance coverage for an established therapy, missing appointments with the new providers, and many other gaps in the system.[4]

The Shift in Developmental Stages:

Medication safety is more complex in a pediatric setting. Pediatric patients undergo continuous growth, with each developmental stage posing an additional risk that necessitates specific interventions from their care team. Changes such as height, weight, renal function, and other factors are more pronounced in pediatric populations, especially neonates and infants, and treatments that are not adjusted accordingly can pose serious clinical risks.

Many medications for complex and chronic conditions do not have established pediatric dosing and safety information and are thus prescribed "off label." In addition, the newer the drug, the less likely the pediatric label information will be available because the pediatric post-marketing studies required by the FDA often take several years after drug approval to complete.

There is also broad variability in weight and body surface area in the pediatric population. This variability significantly influences how the medication is absorbed, distributed, metabolized, and eliminated compared to adults.[5] Medication dosing errors in pediatric patients are related to the use of, and the need to adjust, adult-formulated medications.[6] Failing to calculate weight-based dosing medication as well as to adjust the dose of a growing child may cause overdosing or underdosing.

Adverse drug effects (ADEs) are common in pediatric patients and can result in disability or even death. Literature shows that the prevalence of adverse drug effects in pediatric patients may be as high as 16.8% and can lead to as much as 10.3 % of pediatric hospitalizations.[7] The combination of off-label prescribing, and the high frequency of medication errors in the home—caused by unclear instructions, low health literacy or other factors—makes the pediatric population uniquely vulnerable to the consequences of safety issues. Home medication administration errors are common, especially when liquid or subcutaneous preparations are involved. Medication errors in the home involving children under six years old constitute nearly a third of those reported to poison control centers in the U.S[8]

62-85%

Off-label prescribing in pediatrics, U.S.[9]

Socioeconomic Disparities:

Socioeconomic disparities also create barriers to accessing healthcare among pediatric patients. A comprehensive review of the literature connecting worse CF outcomes with inequities caused by social determinants reveals multiple factors that could exacerbate fragmentation, including intermittent insurance coverage, educational attainment, lack of transportation, and chronic social stressors.[10] In another study focusing on irritable bowel syndrome (IBD), younger age ranks alongside other factors such as substance abuse and public payer or uninsured status as a risk factor for fragmented care.[11] Family and social dynamics also play into the risk of fragmented care in a pediatric environment. For example, medication errors can occur, or medication adherence can be compromised, when a child moves between residences because of custody arrangements.

The interplay among these factors is dynamic, and families of children with medical complexity, a small fraction of all pediatric patients, may experience serious financial consequences regardless of their socioeconomic status, because of direct medical expenses, indirect expenses such as travel, and loss of income when one parent leaves paid employment to take care of the child.[12] Minimizing the fragmentation of care is a widely recognized goal in healthcare, but for pediatric patients with complex, chronic diseases, it is critical.

The Average Medicaid Reimbursement Only Covers

80% OF THE COST OF CARE

42%

Of Medicare Enrollees are Children

6 Million

Children Covered by Medicaid & CHIP

PEDIATRIC HOSPITALS FACE FINANCIAL BARRIERS

Children's hospitals often face unique financial and operational challenges. Unlike other hospitals that focus mainly on treating adults, pediatric hospitals rely heavily on state Medicaid programs as their primary payer, thus making Medicaid reimbursement policies one of their most pronounced financial challenges.

As the largest third-party payer and the largest public health insurance provider in the United States, Medicaid provides coverage to or fills coverage gaps for many children with chronic illnesses.[13] Pediatric hospitals have a high Medicaid payer mix and are more vulnerable to and greatly impacted by state and/or federal budget cuts compared to adult hospitals. It is important for pediatric hospitals to pay specific attention to each state's reimbursement policies, as any cuts to Medicaid equal less reimbursement to the hospital. According to the Children's Hospital Association, the average Medicaid reimbursement to children's hospitals, even including supplemental payments, covers only 80% of the cost of care.[13]

In addition to Medicaid, pediatric hospitals also rely heavily on the Children's Health Insurance Program (CHIP), a state-administered program that provides health insurance coverage for children whose family income is low but nevertheless falls above the Medicaid threshold.[14] Between Medicaid and CHIP, more than 81 million people are covered, and according to data gathered by the Children's Hospital Association, 42% of Medicaid enrollees are children, and nearly 6 million children with special health care needs rely on coverage by Medicaid and CHIP.[14]

THE SHIELDS INTEGRATED CARE MODEL PROVIDES NEW OPPORTUNITIES FOR PEDIATRIC HOSPITALS

In the current environment, hospital leadership is faced with the extraordinary challenge of reducing the total cost of care while optimizing patient care outcomes and generating revenue. A customized, health-system owned pediatric specialty pharmacy program can be put in place to help meet this challenge. While some upfront investment can be expected, specialty pharmacy programs offer pediatric hospitals a way to improve patient care across multiple disease states, ease the administrative burden on clinics and families, and increase revenue by reaching more patients with an integrated care model that improves outcomes. Shields' care model, experience, and expertise in partnering with pediatric hospitals across the country positions the company to uniquely address the barriers to improving outcomes for patients and optimizing revenue while reducing total cost of care.

ENGAGE & INTERVENE | Pediatric Training & Expertise

A high-touch integrated pharmacy care model provides greater support for families. Parents whose child has received a difficult diagnosis are often grieving and overwhelmed, and clinical pharmacists are in a unique position to help.

Shields partners with pediatric hospitals to customize a care model based on the health system's preference. The model consists of liaisons and pharmacists who are uniquely trained and positioned to integrate with and adapt to the care team within the health system. They perform various administrative tasks to help ease the burden on patients, their families, and their caregivers.

Shields liaisons, for example, conduct benefits investigations to determine eligibility for patients to obtain their prescribed specialty medications. They have the capacity to also manage the prior authorization process to ensure patients get their medications in a timely manner and to help secure financial assistance to ensure patients can afford their specialty medications, one of the most significant barriers to care. Shields provides additional patient outreach services to enhance the awareness of specialized pharmacy services for the health system, which positively impacts medication adherence, provider, and patient satisfaction.

Shields clinical pharmacists, some of whom hold Pediatric Pharmacy Specialty Certifications (BCPPS), are also integrated within the health system's specialty pharmacy, making them uniquely positioned to support pediatric patients and their families through high-level patient engagement to provide ongoing comprehensive drug therapy education personalized to each patient's care goals. Shields pharmacists conduct comprehensive risk assessment for patients before medication is initiated. These assessments help identify potential risks such as non-adherence, financial toxicity, and other factors that may impact the patient's treatment. Shields pharmacists follow patients routinely after the treatment initiation and play a crucial role in proactive monitoring of the ongoing safety and efficacy of the treatment. They also coordinate patient, provider, and insurance activity through timely interventions, as needed. Such careful supervision helps close the gap between multiple healthcare providers, settings, and other data points to ensure continuity of care.

As outlined, communication between health care providers and pharmacists, with detailed medical history tracking, is essential when treating pediatric patients, who often move between many providers and healthcare settings and often experience shifts in developmental stages and socioeconomic disparities. In a typical health system, all providers have access to the patient's electronic medical record (EMR), giving them access to the patient's full medical and medication history. While this is key in keeping communications streamlined, it often lacks the inclusion of the patient's pharmacist, who can also benefit from having full visibility into patient charts. This is where the Shields integrated care model can help close communication and care gaps.

INTERVENE & COORDINATE | EMR Integration

Shields' integrated pharmacists frequently help improve a patient's care plan. They closely monitor patients' drug therapies, related barriers, and potential adverse effects. If they identify any drug therapy-related issues such as dosing, medication administration, adherence barriers, or communication concerns, the pharmacist will intervene, collaborating with the provider to make any necessary adjustments. In 2023, Shields pharmacists completed 48,964 clinical interventions across its health system network of partners, helping improve care pathways for millions of patients.

Integration with the EMR is the critical factor in enabling communication and collaboration between pharmacists and providers and making these clinical interventions possible. The purpose-built Shields specialty pharmacy data management platform, TelemetryRx®, communicates with the EMR and allows the physician and pharmacist to track each patient as they move through therapy. This makes it possible for physicians and pharmacists to collaborate on drug interactions and make quicker decisions about treatment.

Through a combination of engagements, interventions, communications, and coordinated care, the Shields care model help ensure patients receive their medication without delay and maintain the appropriate therapy(ies), resulting in improved patient outcomes and reduced healthcare costs. The table below shows how the Shields model compares to national benchmarks in satisfaction, adherence, time to therapy, and average copay (across patients of all ages).

MEASURED OUTCOME	BENCHMARK	Shields' adult & pediatric patients across Shields Health Network
Net Promoter Score (NPS)	Health System Specialty Pharmacy average[18]: 81.6	83.4%
Proportion of Days Covered (PDC)	Pharmacy Quality Alliance[19]: >/=80%	93%
Time to Therapy	~10 days[20]	48 hours
Average Copay	National Average of $100[21]	~$10

Health systems and their patients using the Shields model also experience clinical outcomes that consistently surpass national benchmarks. The table below shows just a few examples of clinical outcomes for patient under 18 years of age, compared to national benchmarks and recent publications.

MEASURED OUTCOME	BENCHMARK	Shields Patients < 18 years old
INFLAMMATORY BOWEL DISEASE (CROHN'S ULCERATIVE COLITIS)		
Need for steroid therapy	Percent of Patients Treated with Steroids: <30[15,16]	18%
CYSTIC FIBROSIS		
FEV1 percent of predicted (ppFEV1)	>/=97.5[17]	98.4%
Pulmonary Exacerbations, %	<10 year old: 15-20%[17] 11-17 year old: <20%[17]	7%
Patients treated with IV antibiotics	Percent of patients treated with IV antibiotics[17] Birth to 11: <10% 12-17 years: <15%	2%
Absenteeism	Missed school, work, planned activities	5%

ENHANCE & RENEW | Clinical Outcomes & Transitions of Care

Effective medication therapy management in an integrated specialty pharmacy model helps to improve the quality of life and prevent hospitalizations, hospital readmissions, and emergency department visits. Averting these events has clinical and financial benefits, but also the practical benefits of reducing disruption to the family's routine and reducing days of work missed by parents or other family caregivers.

Effective therapy management can also reduce the total cost of care by eliminating prescriptions if a patient no longer responds to a drug, has adverse reactions that cause them not to take the drug, or if for some other reason—such as body composition changes due to growth and development—the drug is no longer appropriate for the patient.

Revenue Growth & Financial Health

In partnership with Shields, hospitals and health systems can incrementally expand their pediatric specialty pharmacy offering by adding programs for specific disease states and gradually building out their capabilities. Shields often recommends that hospitals begin by expanding capabilities around drugs to which the hospital already has access, such as growth hormones. The convenience of the medications being readily available is valuable to the providers and the patients, since it supports appropriate medication access, speed to therapy, adherence, and both provider and patient satisfaction. Treating pediatric patients with medications the hospital already has access to creates a "quick win" that improves provider relationships and leads to parents choosing to utilize the pediatric specialty pharmacy for their medication-related needs. Then, to build capabilities further, Shields can help partners gain access to high-margin medications and build expertise around the corresponding disease states.

To date, there are limited published studies that specifically analyze the impact of an integrated pharmacy model on the pediatric patient population. However, a study conducted between Optum Advisory Services and Shields demonstrated that patients filling with an HSSP were associated with a 13% lower total cost of care compared to patients filling at an outside pharmacy. As pediatric hospitals continue to seek ways to provide improved care to this unique and vulnerable patient population, Shields believes that hospital-owned specialty pharmacy can facilitate this transition.

The Loredo Family's Story - Patients of Phoenix Children's (PC)

Melissa Loredo, a single mother of two teenagers, both with cystic fibrosis, depends on multiple medications for her children's treatment, one being TRIKAFTA™. This drug specifically has shown remarkable results for both children and is the closest thing they have to a cure right now. Until recently, Melissa had to work with four different pharmacies to access their medications, even though her kids are doubly insured. Prescription formularies change yearly, forcing Melissa to renegotiate with each pharmacy on the medicines they will provide for her children.

In the middle of 2022, Melissa heard from all four pharmacies that the rules for TRIKAFTA had changed and co-pays for TRIKAFTA were now $7,500 per child. "I fought for three weeks with four pharmacies and two insurance companies to receive a medicine that is vital to sustaining my kids' lives," Melissa said. "I was at the end of my rope."

Out of the blue, Melissa received a call from Meredith Reams, CPhT, specialty pharmacy patient liaison at PCH's Pharmacy Services. Meredith had heard about Melissa's challenges and wanted to help. Melissa did not expect Meredith to be successful, but she was in for a surprise. Meredith stepped in and offered critical help at a time when Melissa's family really needed it. Melissa shared, "Meredith was able to do within three days what four other pharmacies were still trying to figure out after three weeks! In three days, I had TRIKAFTA in my hands for both kids with a $0 copay. Words cannot express my gratitude and appreciation for this service!"

Since that time, Melissa has moved two more of her children's specialty medications to the Pharmacy Program, where Meredith will contact her when refills are due and will help Melissa make the best decisions each new year, when formularies for those drugs change. Melissa said, "Having to deal with fewer pharmacies is such a gift. When you have the weight of the world on your shoulders, even taking an ounce or two off feels wonderful. That's what Meredith does for me. What a godsend."

"It has been a pleasure working with the Loredo family. As a liaison, my job is to make healthcare easier, and I am thankful that I was able to assist them because I know that healthcare can be frustrating," Meredith explained. The Specialty Pharmacy [at PC] offers services that simplify every aspect of our cystic fibrosis patients' medication needs. The pharmacy helps families find financial support, navigate insurance requirements, coordinate with doctors, and manage refills.

READ THE ENTIRE STORY

CONCLUSION

Many pediatric diseases are lifelong; some are rare and incurable conditions requiring costly specialty medications. Pediatric patients face distinct challenges that can impact obtaining and adhering to medication, a critical component of their care plan and health outcome. A patient-centered pediatric specialty pharmacy care model, such as the Shields integrated care model, provides a host of benefits to patients, their families, providers, and other stakeholders in a complex healthcare system, where complexity is amplified by the unique challenges of children's hospitals. Partnering with Shields allows hospitals and health systems to provide much-needed continuity of care, improved education and support for patients and caregivers, enhanced medication management, improved treatment outcomes, and uninterrupted communication and collaboration among healthcare professionals, ultimately leading to enhanced patient safety and better outcomes for more pediatric patients.

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ABOUT SHIELDS HEALTH SOLUTIONS

Shields is the premier specialty pharmacy accelerator in the country. The Shields Performance Platform, an integrated set of solutions, services and technology, is intentionally designed to elevate payer and drug access for specialty pharmacies, elevate health outcomes for complex patients, and elevate growth throughout the entire health system. As the foremost experts in the health system specialty pharmacy industry, Shields has a proven track record of success including access to over 80 percent of all limited distribution drugs (LDDs) and most (health insurance) payers in the nation; and a clinical model proven to lower total cost of care by 13%. In partnership with more than 80 health systems across the country through national-scale collaboration, Shields has a vested interest in delivering measurable clinical and financial results for health systems.

To learn more visit Shieldsrx.com

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