

Specialty Pharmacy : What is so “Special” about it?

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340B Midwest Regional Conference & Expo
August 25 & 26, 2025





DISCLOSURE STATEMENT

- Brenda Reitz or Becky Nugent have no relevant financial relationship(s) with ineligible companies to disclose.

and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.





LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:

- Identify the steps required to become specialty pharmacy accredited
- Describe how to utilize your pharmacy staff to expand services and revenue

Family Health Services of Darke County



Located in Rural Southwest Ohio

6 Site locations

Established in 1973 to serve the migrant population

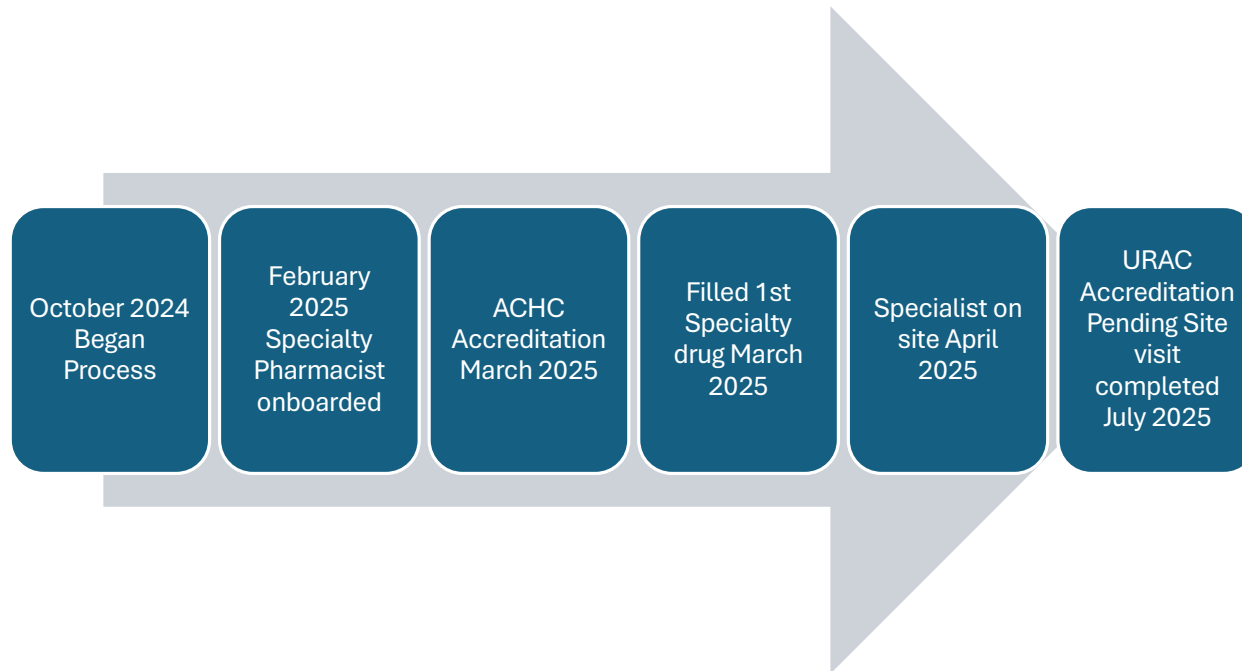
Services – Primary Care, Behavioral Health, Psychiatry, School Based Care, Dental, Eyecare, Medication Assistance Treatment, Patient Assistance, Entity owned and Contract Pharmacy, Clinical Pharmacy, Specialty Pharmacy, Needle Xchange Clinic, Walk-in Care Clinic, WIC, Home Care

Patients seen in 2024-27,486 UDS

265 Employees



Family Health's Journey



FHS Scope of Service

Current Specialist	Planned Specialist
Chronic Disease Management	Gastroenterology
Rheumatology	
Dermatology	
Neurology	

Two Specialty Pharmacist (Clinical Pharmacist)
One Patient Engagement Specialist



Why we considered Specialty Pharmacy Opportunity for CHCs

2% of
prescriptions

=

~50% of pharmacy
spend

The challenge:

- Without specialty pharmacies, CHCs are missing out on 50% of pharmacy spend
- Many CHCs outsource specialty pharmacy to contract pharmacies and they lose touch with patients and 340B margin due to manufacturer blocks

Owning the model enables:

- CHCs to improve care coordination for patients taking specialty medications, improving adherence and long-term outcomes
- Retain revenue in-house at the CHC, avoiding costly contract pharmacy fees and manufacturer blocks



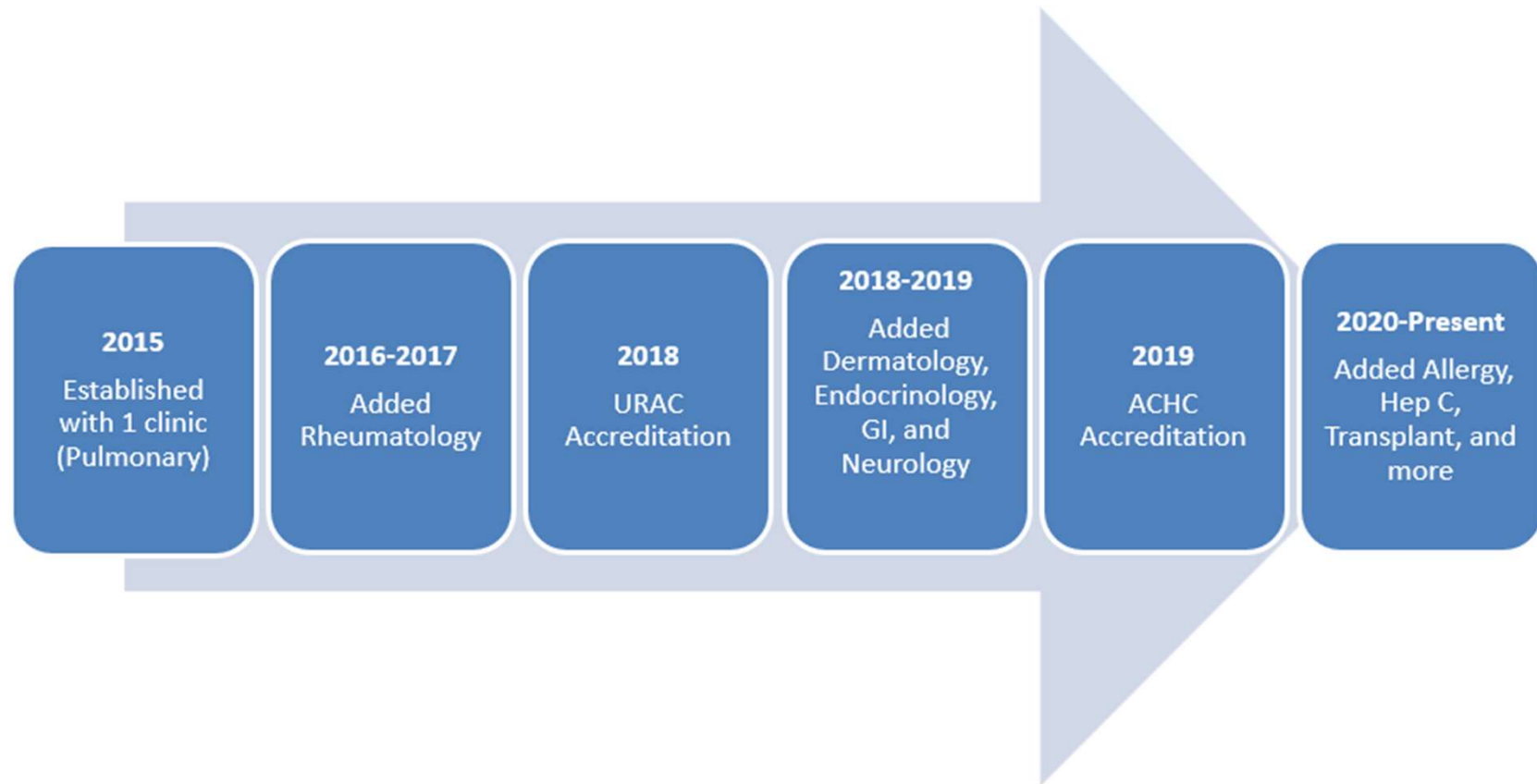
Nationwide Children's Hospital (NCH)

- America's **third largest** children's hospital*
- Named by *U.S News & World Report* as tied for the number one pediatric hospital in Ohio and the Midwest
- Patients came from all **50 U.S. states** and **49 countries** in 2024
- **340B** covered entity
- Total employees: **16,557**



** Most recent data from CHA-member pediatric hospitals based upon number of staffed beds*

NCH Specialty Pharmacy's Journey



NCH Specialty Pharmacy Overview



60,860 Rxs
Dispensed*



Dual-
Accredited



> 1,500 PMP
Patients**



34 Team
Members

*Dispensed in 2024 (SP = 16,366 and Non-SP = 44,494)

** As of March 2025



Scope of Services

1. Managed by an NCH provider in the following specialty clinics or specific disease states:

Specialty Clinic	Disease State
<ul style="list-style-type: none">• Allergy• Dermatology• Endocrinology• Gastroenterology• Neurology• Pediatric & Adolescent Gynecology• Pulmonary• Rheumatology	<ul style="list-style-type: none">• Hepatitis C• Solid Organ Transplant

2. Prescribed a specialty or outpatient plus medication under the specific specialty clinic/disease state as listed on the NCH Specialty Pharmacy Medication List.
3. Insurance allows the medication to be filled at NCH Specialty Pharmacy.
4. Lives within Ohio or West Virginia.



Why We Decided to Pursue Specialty Pharmacy



Need for prior authorization



Directing prescriptions to specialty pharmacy



High copayments



Uncaptured revenue opportunity

Why We Decided to Pursue Specialty Pharmacy



Prior authorization coordination



Streamlined communication with clinic staff



Copay assistance enrollment



Revenue kept with NCH

Accreditation



Importance of Accreditation



Ensures High
Standards of Care and
Quality for Patients



Often Required by
Third-Party Payers for
Acceptance into
Specialty Contracts



Select an Accreditation Organization



...and MANY more...



URAC and ACHC Overview

URAC

- 3-year accreditation cycle
- Standards are specific to specialty pharmacy
- Accreditation process takes at least 6 months
- Significant revision of standards over time
- "Gold Star" accreditation

ACHC

- 3-year accreditation cycle
- Standards are general
- Accreditation process takes 4-6 months
- Minor revision of standards over time



Are you ready for URAC's Specialty Pharmacy Accreditation?



Your Patient Management program includes patient education and protocols that are disease state and/or drug specific.

ENSURE clinical protocols are based on specific clinical guidelines and are not generalized for all patients.



Initial clinical assessments and periodic reassessments are performed and documented.

AUDIT a random sample of patient files to confirm documentation of clinical assessments that evaluate appropriateness of therapy.



Clinical interventions are performed when appropriate and documented.

SURVEY a random sample of patient files to confirm documentation of clinical interventions.



The value and effectiveness of your Patient Management program is evaluated at least annually.

CONFIRM the program evaluation reviews clinical, financial, and quality of life metric data and makes recommendations and updates to the program based on the evaluation.



Processes to maintain medication temperature and integrity during shipping have been implemented and tested.

VERIFY you have a medication distribution initial testing plan that includes all temperature ranges in all seasons, and you have a plan to audit these processes at least annually.



Performance metrics for dispensing accuracy, distribution accuracy, and adherence are tracked.

REVIEW Quality Management Committee meeting minutes to ensure documentation of monitoring these performance metrics and implementation of quality improvement when needed.



Telephone performance metrics are monitored.

CHECK your monthly and quarterly telephone metric reports to make sure you are meeting URAC's Average Abandonment Rate (5% or less) and Average Speed of Answer (80% of calls within 30 seconds) thresholds.



Clinical inquiries are handled 24/7.

AFFIRM you have processes in place to answer clinical questions 24 hours a day 7 days a week.



Verification of licensure or certification for clinical staff is documented.

REVIEW personnel records to ensure all staff whose job description requires a licensure or certification have evidence of primary source verification of the required credential.



Your organization's Business Continuity Plan is in place and tested at least every two years.

ENSURE you have a documented plan to address all systems and processes to minimize patient impact in an emergency.

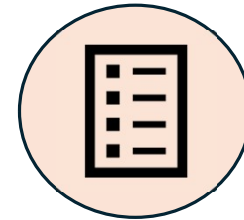
For more information, please contact businessdevelopment@urac.org or 202-216-9413

340B
Midwest Regional
Conference & Expo



Submit Application

Timeframe: Organization-Specific



- Contracting/Application Agreement
- For each standard, determine what information will be used to demonstrate compliance
 - Examples:
 - Audits
 - Policies
 - Procedure documents
 - Training materials
 - Shipment testing results
- Upload supporting documentation on web-based platform

Desktop Review

Timeframe: 30-45 days



- Lead Reviewer determines if uploaded documentation demonstrates full compliance with standards and provides scoring (met, partially met, or not met)
- Reviewer provides guidance on how to strengthen your policies or procedures to comply with the standards
- You will have up to two opportunities to upload additional information or modifications to policies/procedures

Validation Review

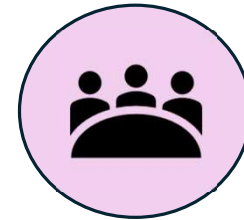
Timeframe: 1-3 days



- Onsite, virtual, or a combination of the two
- Announced
- Reviewer will validate that your organization is following the standards and policies in practice
- Validation includes:
 - Personnel file review
 - Patient chart review
 - Interviews with leadership and staff
 - Review of documentation
- Transparency around findings

Committee Review

Timeframe: Up to 1 month



- Review team presents a blinded report to the accreditation committee.
- Accreditation determination is reached:
 - Full accreditation
 - Conditional accreditation (deficiencies require correction)
 - Provisional accreditation (for start-ups with less than the required amount of case files)
 - Corrective action needed (non-accredited status. Deficiencies require correction)
 - Denial

Accreditation Maintenance

- Ongoing Compliance:
 - Quality Committee – Quarterly Improvement Metrics
 - Personnel File Maintenance
 - Policy and Procedure Compliance
- Annual Measures Reporting
 - Data Validation
- Periodic Monitoring Validation Reviews
- Reaccreditation process mirrors initial accreditation
 - 3-year look-back to ensure your organization was following the standards



Assess Your Knowledge

Which answer lists the accreditation steps in the correct order?

- a) Submit Application, Committee Review, Validation Review, Desktop Review
- b) Committee Review, Desktop Review, Validation Review, Submit Application
- c) Submit Application, Validation Review, Desktop Review, Committee Review
- d) Submit Application, Desktop Review, Validation Review, Committee Review



Utilizing Pharmacy Staff to Expand Services and Revenue



Specialty Pharmacy Matters for Patients

Without In-House Specialty Pharmacy

Diagnosis

Specialist or PCP identifies a complex condition

Script Written

Patient sent to outside specialty pharmacy

PA Delays

PA requests bounce between provider and external pharmacies with days/weeks lost

Copay Shock

No proactive copay assistance; Patient may abandon therapy

Fragmented Care

Provider lacks visibility into adherence or refill timing

Limited Outcomes

Missed doses, disease flare-ups, more ED visits/hospitalizations

With In-House Specialty Pharmacy

Powered by AndHealth

Diagnosis

Provider writes script directly to CHC Specialty Pharmacy

Benefits Check + PA

Pharmacy team starts PA immediately

Financial Assistance

Patient connected to copay support immediately

Rapid Dispense

Med delivered directly to patient by in-house pharmacy

Ongoing Monitoring

Pharmacist documents side effects and plans for refills

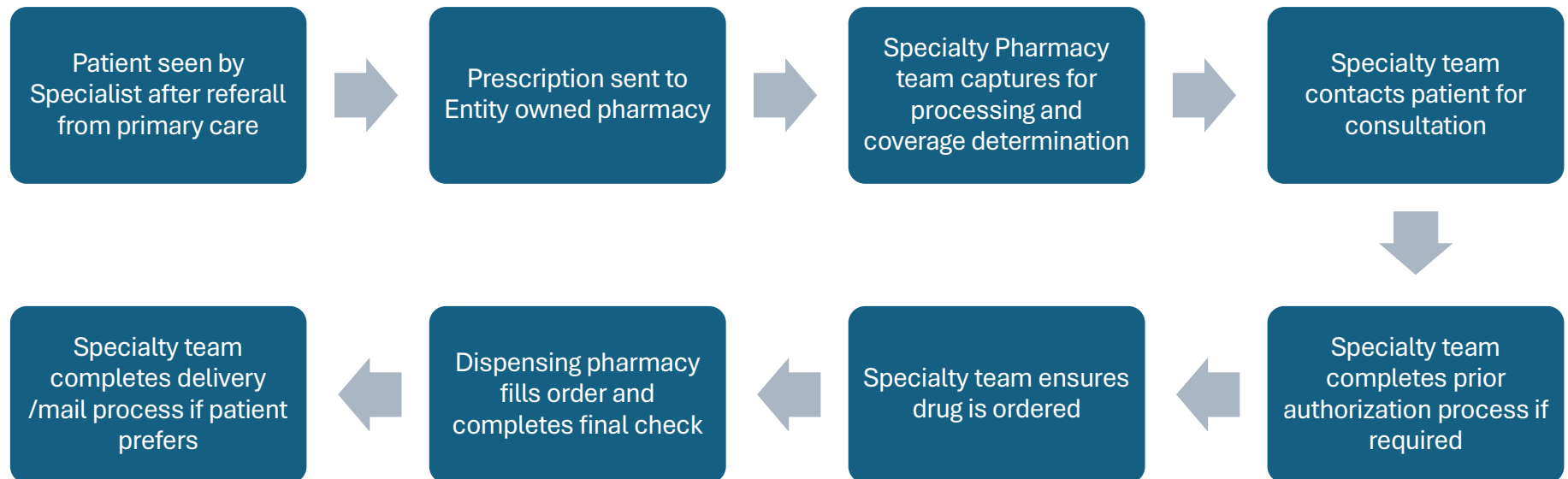
Improved Outcomes + Experience

Higher adherence, fewer flare ups

Even what patients are forced to fill at an outside pharmacy, the in-house specialty pharmacy team can provide direct support to enable patients to experience the benefits of an in-house pharmacy.

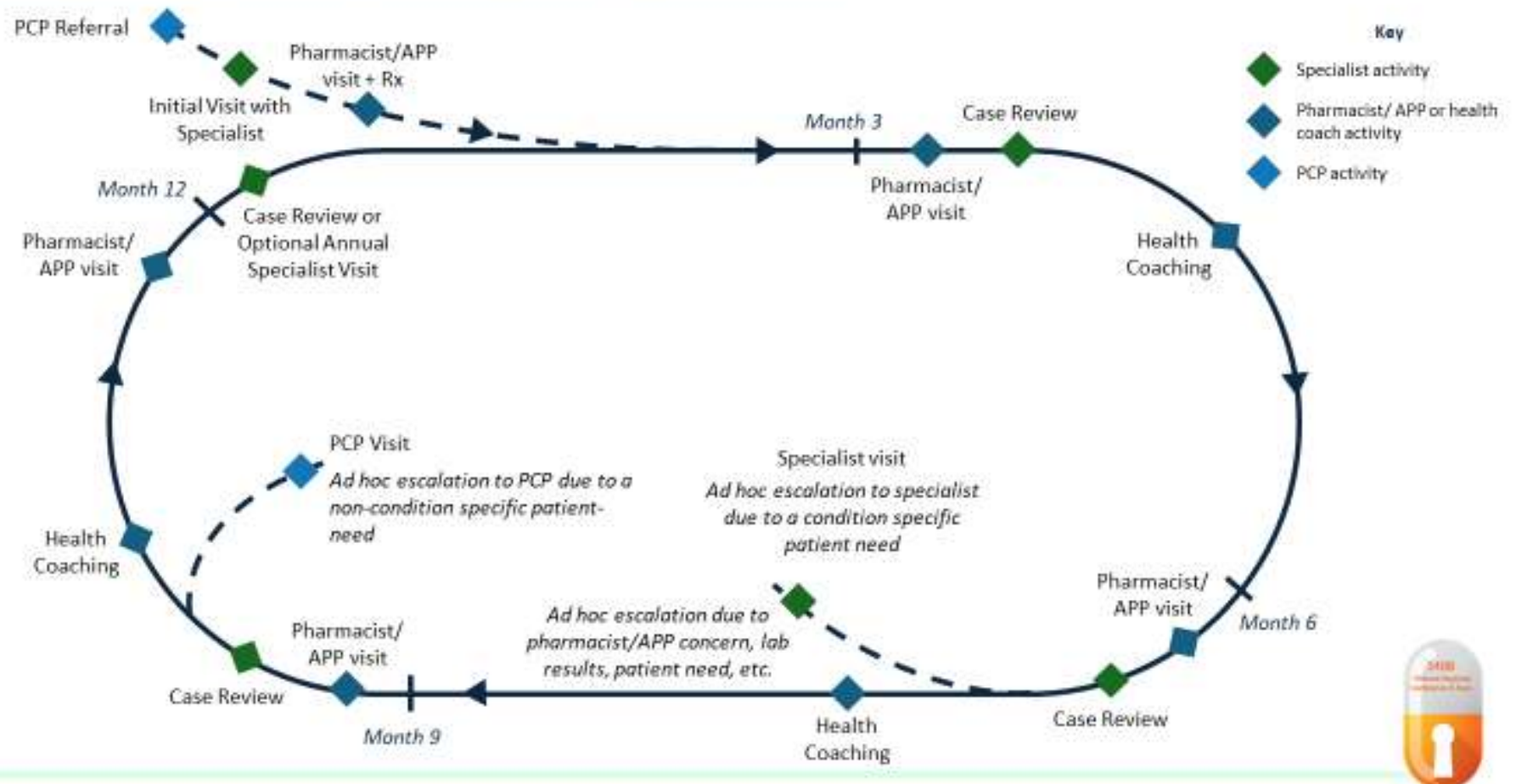


FHS workflow utilizing pharmacy staff

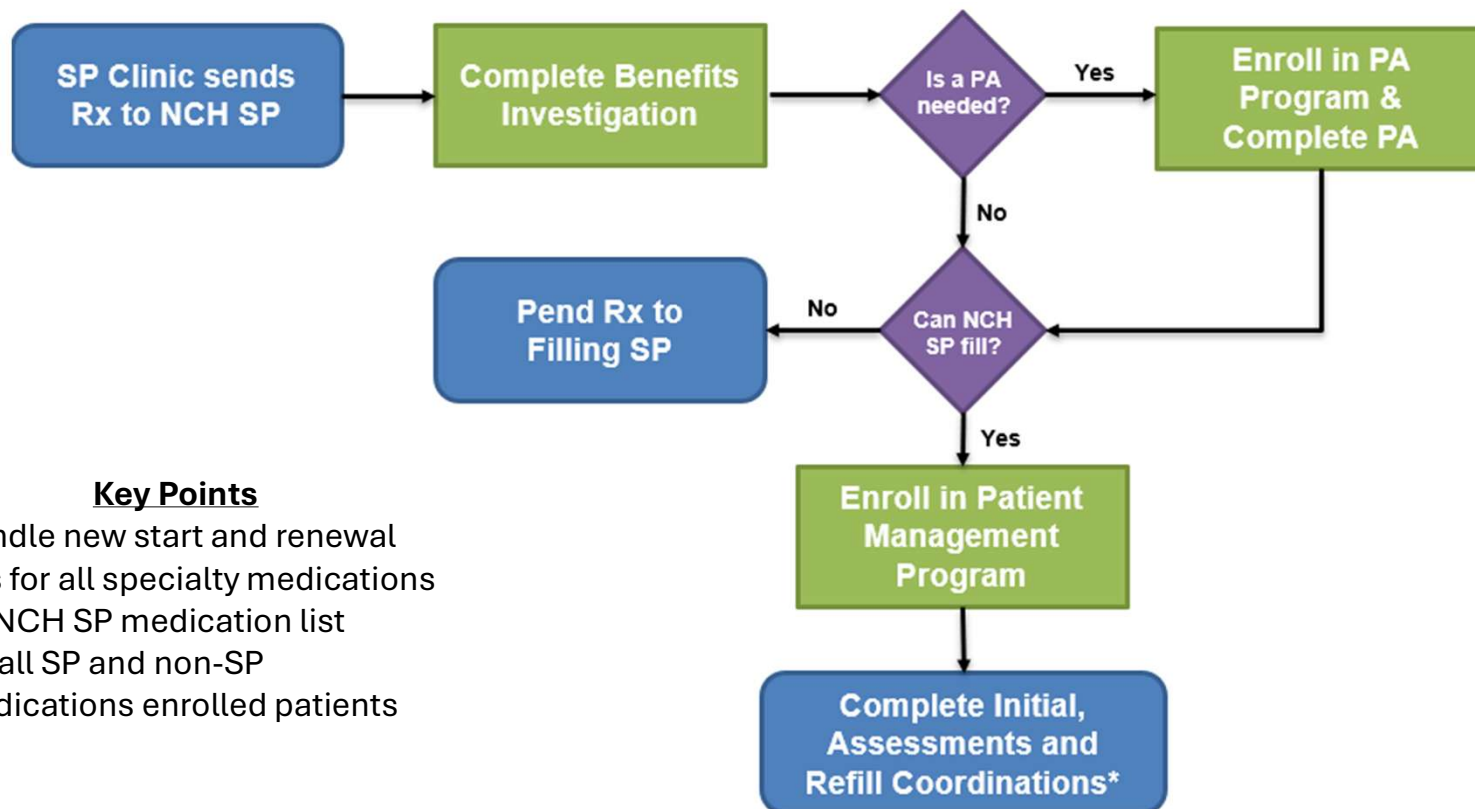


Clinical Pharmacists Practicing within CPAs

Clinical Pharmacists practicing within CPAs can directly support patients and provide a linkage to the in-house pharmacy as a part of a whole-person specialty care model



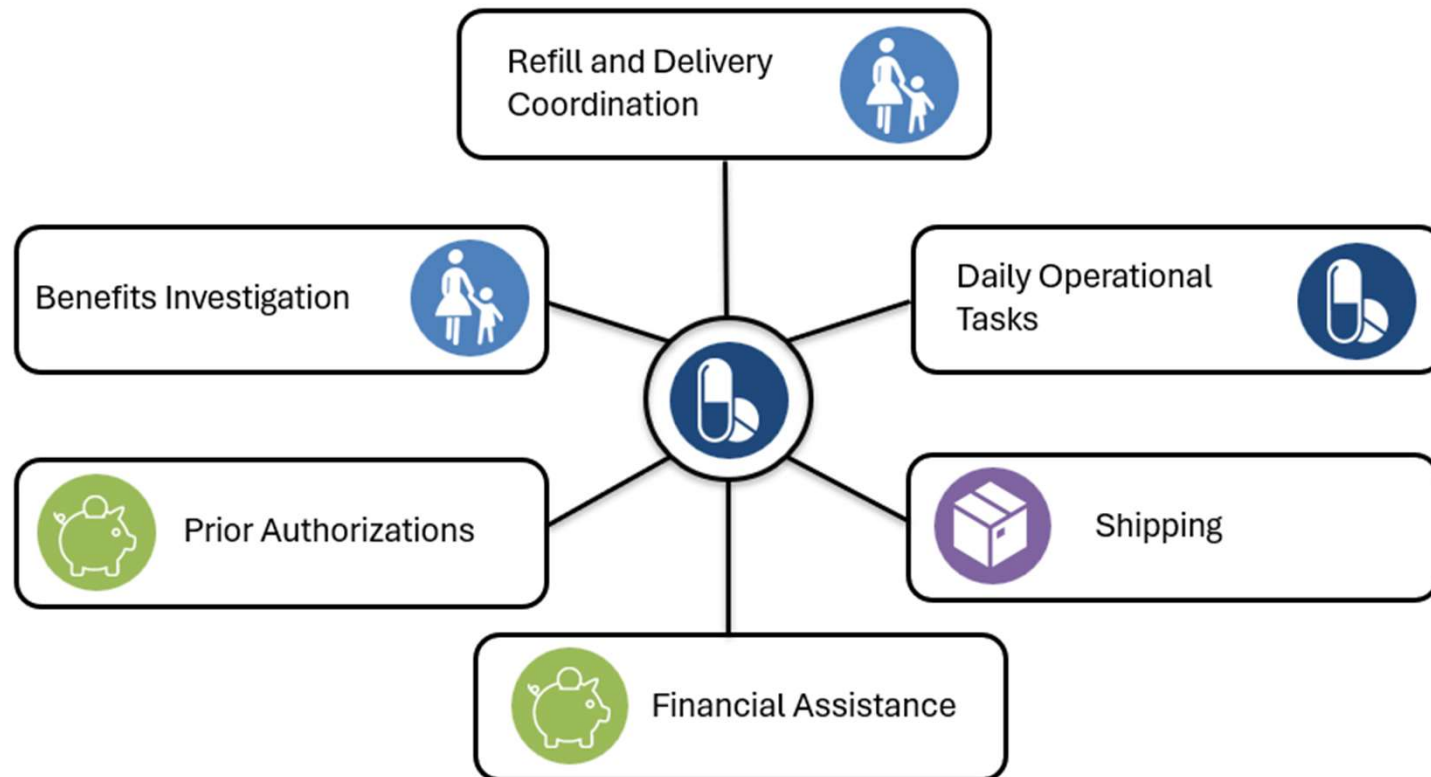
NCH Workflow



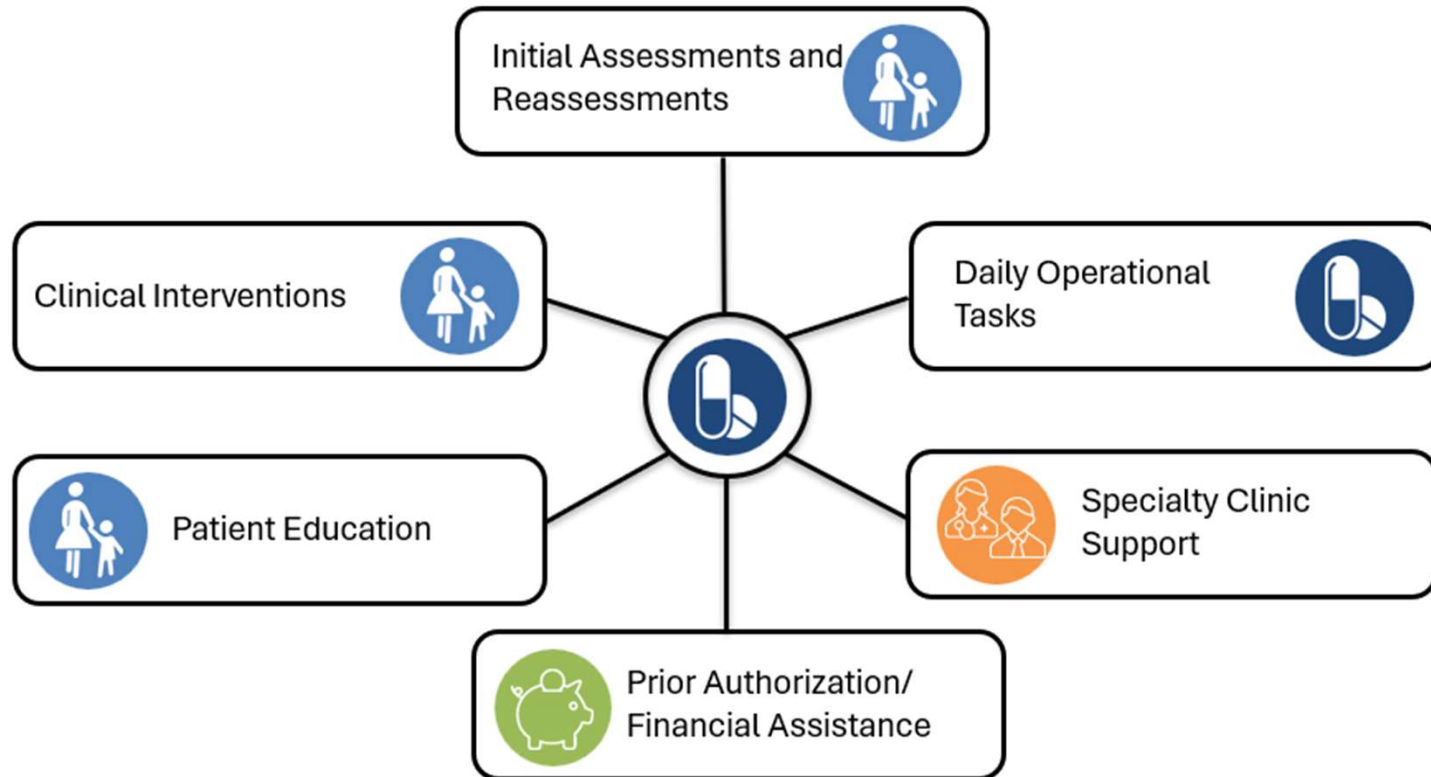
Key Points

- Handle new start and renewal PAs for all specialty medications on NCH SP medication list
- Fill all SP and non-SP medications enrolled patients

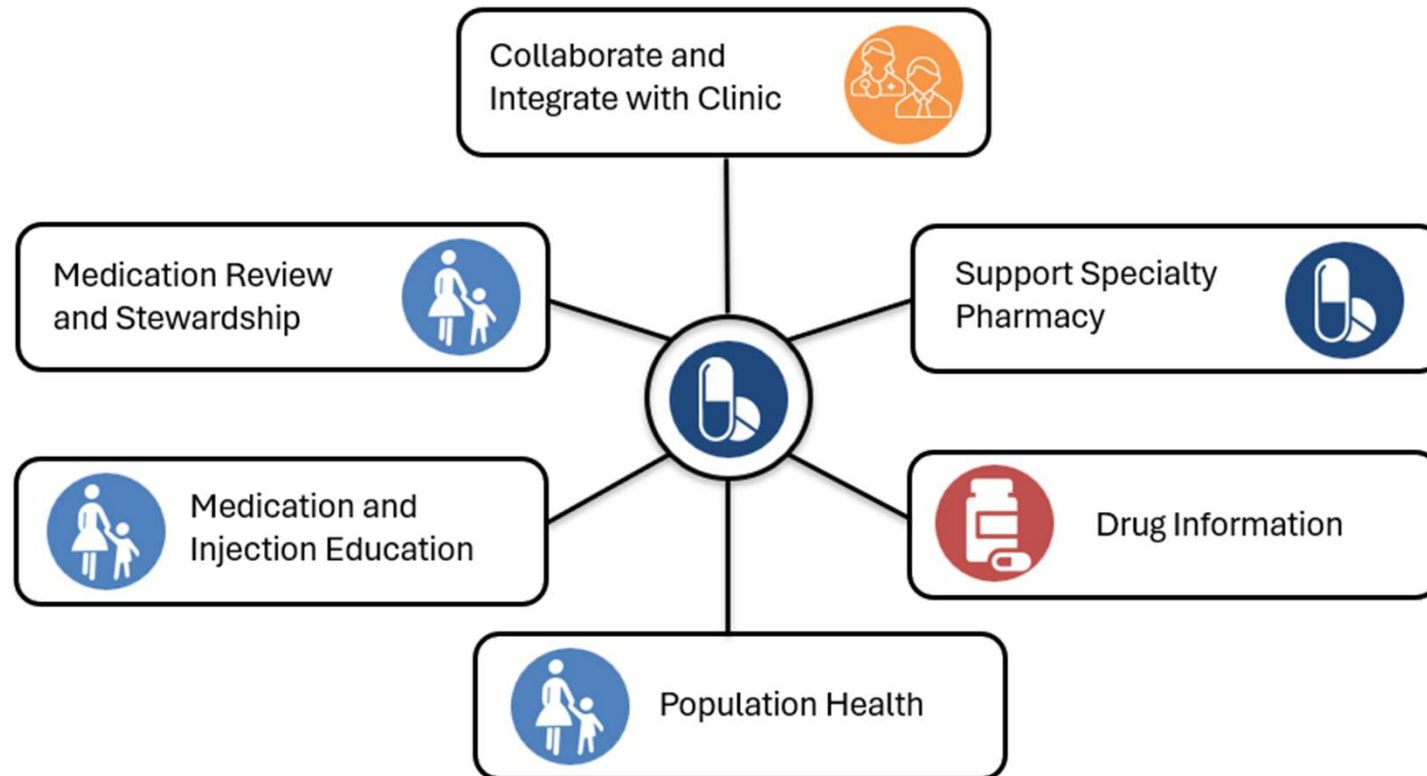
NCH SP Staff – Pharmacy Technician



NCH SP Staff – Staff Pharmacist



NCH SP Staff – Clinic-Embedded Pharmacist



Growth experienced at FHS with Specialty services

- **1st month on-site**
 - **Credentialed Specialist**
 - CDM
 - **Following 17 patients**
 - **Filled 17 prescriptions**
(9 In-House vs 7 Contract)

- **5th month on-site**
 - **Credentialed Specialist**
 - CDM
 - Rheumatology
 - Dermatology
 - Neurology
 - **Following 81 patients**
 - **Filled 76 prescriptions** (55 In-House vs 15 Contract)

FHS Future Growth Plan

Specialist yet to onboard : Gastroenterology

Other services the specialty team will assist/integrate

- **Adherence calls**
- **Prior authorizations**
- **MTM**

Increase capture rate

- **Transition from specialty only provider to primary care with FHS thus filling all patients' medications 340B**
- **Move contract pharmacy scripts in-house as contracting opportunities grow to increase 340B revenue and avoid manufacturer restrictions**



Assess Knowledge Question

The following pharmacy staff may assist in expansion of services and revenue

- a. Pharmacy Technician
- b. Clinical Pharmacist
- c. Dispensing pharmacy
- d. All the above

Barriers vs Reward



Barriers to Overcome when Launching Specialty Pharmacy

Operations + Infrastructure

- Physical space + equipment
- Licensing + accreditation
- Clinical / Provider buy in
- Technology integration
- Inventory management
- Workflow : Rx thru delivery

Clinical + Patient Care

- Specialty clinical expertise for pharmacists
- Prior authorization complexity
- Financial navigation
- Adherence monitoring

Business + Strategy

- Payer + PBM contracting
- 340B Compliance
- Referral capture
- Capital investment
- Change management
- Negotiations with Partners



The Option to Partner

- ☐ **Limited or no local access to Specialty Providers**
 - Provides patient access to credentialed Specialty Providers via in person or telehealth
 - Provides a care team approach for best patient outcomes
 - Increase capture rate to entity owned pharmacy vs contract pharmacies
- ☐ **Limited capital to afford upfront cost of Accreditation**
- ☐ **Limited resources to devote to the entire process of accreditation and maintenance of Specialty care or develop additional services lines**

**Be sure to involve your legal team when making contracting decisions to ensure clarity of integration and financial relationship.
The devil is in the details and single words can matter.**



The Specialty Pharmacy Opportunity for CHCs

1 patient can yield
>\$8,000 in 340B
Gross Margin
annually

- 340B capture is maximized when scripts are filled in-house
- Referral capture processes are critical to fill and capture highest value prescriptions
- Specialty pharmacy revenue creates additional mission funding for expanded services for patients
- **Continued growth** is dependent on identifying outside prescribers for CHC patients and pulling patients in-house while identifying additional specialties that can be provided in-house



"Samantha"

70s, Rheumatoid Arthritis

Family Health Services | CDM Patient

CHALLENGES:

Samantha lost access to her biologic and had to rely on a sample pack after her refill was denied. She spent months trying to regain access but had no success. Without the right coverage, the medication was too expensive to afford, no matter how carefully she managed her finances. The stress of losing her biologic made it harder for her to stay active and spend time with her grandchildren, as her limited mobility and pain held her back. She also struggled with sleep due to her chronic pain and lack of treatment.

PROGRESS:

- Samantha's new care team met with her to address her concerns about Medicare copay assistance and put a plan in place.
- Her provider and pharmacy team partnered with her Family Health community center to get her back on Kevzara at no cost through a pharmacy financial assistance program, which has helped relieve her symptoms.
- She's now following a supplement and nutrition plan tailored to her biologic, health history, and symptoms, and she feels more motivated with less pain.
- She's using an Oura Ring to track her sleep patterns and works with her health coach to adjust her care plan for better sleep.

"Hello, I just want to say a huge thanks to all of you for working with me to get my Kevzara at no cost! I was frantic thinking of not being able to continue it, as it is the only biologic that has worked for me after trying many in last few years. Your team of health care professionals has been amazing! Virtual appointments are always on time and excellent communication from all of you who I have talked with. I am extremely grateful for your assistance, professionalism, compassion and your very prompt response to all communication."



Conclusion

- Accreditation ensures patients receive high quality care and is often required by third party payers.
- Staff can expand services and revenue by supporting medication access, streamlining communication, and providing clinical support to improve outcomes.
- Maximizing 340B and specialty pharmacy revenue through referral capture and in-house dispensing drives mission funding for expanded patient services.



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NEED MORE INFORMATION?

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