

# Introduction to Specialty Pharmacy

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## Objectives

- ▶ Obtain an understanding of specialty pharmacy
- ▶ Equip community pharmacists and technicians with the tools to provide care for specialty patient populations
- ▶ Summarize billing and patient assistance programs including grants and manufacturer assistance programs to help decrease costs
- ▶ Explore URAC accreditation
- ▶ Discuss specialty patient care
- ▶ Review specialty pharmacy operations
- ▶ Gain understanding of specialty packaging and shipping
- ▶ Discuss quality management

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## Specialty Pharmacy

- ▶ In 2018, 58% of new FDA-approved therapeutic agents were specialty medications
- ▶ Specialty prescription volume is 1-2% of total prescription volume, yet accounts for nearly half of prescription dollars in the US

(Anguiano 2021)

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## Definition of Specialty Pharmaceuticals

- ▶ Lack of Universal Definition
- ▶ Medicare Part D definition for specialty: any drug for which the negotiated monthly price is \$600 or more
- ▶ "Biologic, biological, biopharmaceutical, biotech"
- ▶ Can include high cost injectables, infused product, oral agent of infused medication
- ▶ May require close supervision, monitoring, and handling requirements
- ▶ Often require special billing

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## Examples of Specialty Pharmacy Service Lines

- |                    |                          |
|--------------------|--------------------------|
| ▶ Allergy          | ▶ Hepatology             |
| ▶ Transplant       | ▶ Infectious Disease/HIV |
| ▶ Cardiology       | ▶ Neurology              |
| ▶ Cystic Fibrosis  | ▶ Oncology               |
| ▶ Fertility        | ▶ Osteoporosis           |
| ▶ Gastroenterology | ▶ Rheumatology           |
| ▶ Cystic Fibrosis  |                          |

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## Benefits of Specialty Pharmacy Program

- ▶ To Optimize Care and Reduce Barriers
- ▶ To Streamline Dispensing
- ▶ To Ensure Appropriate Use
- ▶ To Facilitate Medication Access
- ▶ To Improve Medication Adherence

(Anguiano 2021)

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## Limited Distribution Drugs (LDD)

- ▶ Therapies only made available to a small number of pharmacies
- ▶ Why do so many drug manufacturers limit distribution of lifesaving medications?

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## Specialty Pharmacies

- ▶ Provide high-touch comprehensive support for patients with complex or chronic conditions to improve medication adherence and compliance, including:
  - ▶ Medication Adherence Programs
  - ▶ MTM
  - ▶ Drug Utilization Reviews

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## Overview of Workflow in Specialty Pharmacy

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    graph LR
      A[Clinician Prescribes New Specialty Prescription] --> B[Assessment of Drug Availability and Insurance Coverage]
      B --> C[Pharmacy Contacts Patient and Addresses Barriers]
      C --> D[Ongoing Monitoring and Communication with Patient and Provider]
    
```

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## URAC: Overview

- ▶ Currently the performances for Health Plans is calibrated using standard measures set by Quality Regulating bodies i.e. CMS, NCOA etc.
- ▶ These measures assess various parameters related to preventive care, clinical processes, intermediate outcomes, care experiences, outcomes etc.
- ▶ National Committee for Quality Assurance (NCQA) and Utilization Review Accreditation Commission (URAC) are 2 major organizations which accredit health plans on various healthcare measures

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## Patient Billing & Financial Assistance

- ▶ Prior Authorizations
  - ▶ Electronic (Cover My Meds)
  - ▶ Verbal
  - ▶ Manual Written
- ▶ PA Approvals
  - ▶ Dispense
  - ▶ Triage to appropriate pharmacy
  - ▶ Financial assistance if necessary
- ▶ PA Denials
  - ▶ Alternate therapy
  - ▶ Appeal
- ▶ Grants and Foundations
  - ▶ Funded by donations
  - ▶ First come, first serve
  - ▶ Income requirements
  - ▶ Must renew annually
- ▶ Manufacturer Patient Assistance Programs
  - ▶ Income requirements
  - ▶ Must fill with manufacturer's in-house pharmacy

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## Patient Case # 1: Transplant

Patient from Taos, NM is being discharged with recent deceased donor renal transplant. The hospital protocol issues standard course of immunosuppressive therapy, including tacrolimus IR, mycophenolic DR, and prednisone.

After several weeks of therapy, the patient's tacrolimus levels are still stable, and the patient is experiencing slight tremor.

Patient has also developed new onset diabetes mellitus due to the immunosuppressive therapy.

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### Patient Case #1: Transplant

Pharmacist contacts patient and transplant team to ensure all medications are appropriate and drug interactions are addressed. Patient is thoroughly counseled on the appropriate administration and potential side effects of the medications.

Pharmacist contacts provider about side effects. Pharmacy works with provider and patient to transition to extended-release version of tacrolimus.

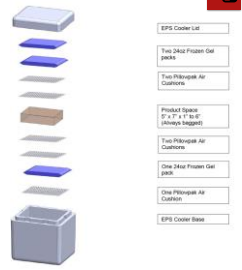
Patient counseled on new diabetes medications and glucose monitoring, as well as lifestyle modifications, to help patient learn to manage new disease state.

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### Patient Case #1: Transplant

Medications shipped directly to patient in rural location.

Pharmacy is equipped with supplies to send both temperature sensitive medications and refrigerated medications via priority delivery, to ensure patient has access to medications without delay.



The diagram shows a stack of shipping supplies: a white EPS Cooler Lid, two 26oz Frozen Gel packs, two Priority Air Cushions, a Priority Sign (2" x 2" x 1/4" Always Tagged), two Priority Air Cushions, one Heat Frozen Gel pack, one Priority Air Cushion, and an EPS Cooler Base. To the right is a checklist with the following items: EPS Cooler Lid, Two 26oz Frozen Gel packs, Two Priority Air Cushions, Priority Sign (2" x 2" x 1/4" Always Tagged), Two Priority Air Cushions, One Heat Frozen Gel pack, One Priority Air Cushion, and EPS Cooler Base.

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### Patient Case #2: Migraine

Patient from local neurologist sent down for oral CGRP-antagonist to be used as abortive therapy. Patient has a history of ongoing oral prophylactic migraine therapy. Patient suffers severe migraine with aura and is wanting to take home today.

When processing the prescription, the intake technician discovers the medication requires a prior authorization and the cash price is prohibitive.

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### Patient Case #2: Migraine

Prior authorization initiated by pharmacy.

If eligible, patient may apply for patient assistance coupon to cover the cost of the medication while PA is pending.

Pharmacist counsels on the new medication at dispensing:

- ▶ Checks for drug interactions
- ▶ Administration and dosing
- ▶ Discusses prophylactic vs abortive therapies

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### Patient Case #3: Hepatitis C

Pharmacy in a prescription for Epclusa, a medication used to cure Hepatitis C.

Prescription processed by pharmacy, but insurance initially denies the claim.

During initial call to obtain patient history, it was discovered that the patient had end stage renal disease.

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### Patient Case #3: Hepatitis C

Pharmacy keeps patient informed of the reason for the delay in therapy.

Pharmacy has designated personnel work with prescriber to assist in processing of Prior Authorization and/or grant assistance programs to help ensure patient is able to obtain therapy.

Pharmacist recognized that because of the history of ESRD, Epclusa was contraindicated.

Pharmacist consulted with the prescriber and suggested that the therapy be changed to Mavyret, indicated in patients with end stage renal disease.

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## Demonstrating Program Value

### Clinical Benefits

- ▶ Study of outcomes of 414 HCV patients at specialty pharmacy vs non-integrated pharmacies [Zepfel 2017]
  - ▶ Improved median days to dispense (26 vs 30)
  - ▶ Improved sustained virologic response (SVR) rate (93% vs 89%)
  - ▶ Improved adherence (100% vs 97%)
- ▶ Study of 185/219 HCV patients filled with the on-site intensive specialty pharmacy vs off-site pharmacy [Iran 2018]
  - ▶ Improved SVR (95% vs 87%)
- ▶ Study of DDI in 200 HCV patients [Sabourin 2021]
  - ▶ Reduced mean number of DDIs from baseline to one month follow-up (1.38 vs 0.16)
- ▶ Study of 164 oncology patients [McCabe 2020]
  - ▶ Reduced time to treatment
  - ▶ Improved percent days covered (PDC) (0.95 vs 0.7)

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## Demonstrating Program Value

### Financial Benefits

- ▶ Study of team-based integration intervention for prior authorization in HCV patients [Dunn 2017]
  - ▶ Improved time to process (23.4 days vs 15.6 days)
- ▶ Patient Satisfaction
- ▶ Quality of Life

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## Provider Satisfaction

- ▶ Multi-site, cross-sectional, online survey of specialty clinic healthcare providers at 10 academic health systems with integrated specialty pharmacies
- ▶ Overall mean satisfaction significantly higher for integrated models
  - ▶ 4.72 (0.58) vs 2.97 (1.20); 95% confidence interval (1.64-1.87); P<0.001



(Anguiano 2021)

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## Citations

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# Questions?

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