

Specialty Pharmacy: Delivering Specialty Care

Jill McClellan, PharmD
Lead Production Clinical Pharmacist
Ardon Health



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Ardon Health.

1

Conflict of Interest

- Nothing to disclose.



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Ardon Health.

2

Pre-assessment Questions

Which group of disease states is often managed by clinical pharmacists practicing in specialty pharmacy?

- a) Rheumatoid arthritis, diabetes mellitus, hepatitis C and hemophilia
- b) Hepatitis C, hemophilia, osteoarthritis and multiple sclerosis
- c) Rheumatoid arthritis, multiple sclerosis, hepatitis C and hemophilia
- d) Hemophilia, hepatitis A, rheumatoid arthritis and multiple sclerosis



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anjan Health.

3

Pre-assessment Questions

PW is 73-yo female, treated for asthma, HTN, GERD, RA and osteoporosis. Her medication list includes montelukast, chlorthalidone, esomeprazole, hydroxychloroquine, abatacept and abaloparatide. Which medications might she get from a Specialty Pharmacy?

- a) Hydroxychloroquine and abatacept
- b) Montelukast, hydroxychloroquine and abatacept
- c) Abaloparatide and abatacept
- d) Montelukast, hydroxychloroquine and abaloparatide



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anjan Health.

4

Pre-assessment Questions

What factors will this patient's Specialty Pharmacy take into consideration when filling medications for PW that are different than what her neighborhood community pharmacy considers when dispensing her other medications?

- a) Documenting patient allergies
- b) USP <659> after medication leaves the pharmacy
- c) HIPAA privacy
- d) Patient counseling requirements



5

Pre-assessment Questions

Which organizations provide accreditation for specialty pharmacies?

- a) ACHC
- b) URAC
- c) AFLAC
- d) All of the above
- e) A and B



6

Learning Objectives

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

- Name disease states that may require medication distribution by specialty pharmacy.
- Identify medications that may require distribution by a specialty pharmacy.
- Describe differences between specialty pharmacy practice and other medication distribution practice models.
- Recognize pharmacist credentialing and pharmacy accreditation agencies in specialty pharmacy.



This information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Ardon Health.

7

Topics We'll Cover

- Definitions around Specialty Pharmacy
- Disease States and Specialty Medications
- Patient Care Model
- Technician Utilization
- Specialty Pharmacy Business Models and Practice Considerations
- Accreditation and Certification in Specialty Pharmacy

This information is confidential and proprietary and may not be reproduced in whole or in part unless permitted in writing by an authorized representative of Ardon Health.

8

Definition of Specialty Pharmacy

- Not clearly defined
- Often varies by state, health plan or professional association
- SP definition is often a mix of some of the following features
 - Treating complicated disease states
 - Providing clinical patient management
 - Complex medication regimens
 - High cost medications
 - Medications require special handling
 - Accredited by one or more independent agency
 - 24-hour, 7 days per week patient access to pharmacist



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anson Health.

9

AM [2]2

Definition of Specialty Pharmacy

- Specialty Pharmacies dispense medications (injectable, intravenous or oral) to a client's/patient's home, physician's office, or clinic specializing in certain disease states. Specialty medications target a specific population with a chronic and sometimes life-threatening disease. Specialty Pharmacy services include disease-specific clinical monitoring, as well as patient compliance and adherence programs.
- ACHC website, <https://www.achc.org/pharmacy.html>



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anson Health.

10

What are Specialty Medications?

AMCP
Academy of
Managed Care
Pharmacy

"Medications generally prescribed for people with complex or ongoing medical conditions such as multiple sclerosis, hemophilia, hepatitis, and rheumatoid arthritis. These medications also typically have one or more of the following characteristics: injected or infused, but some may be taken by mouth; unique storage or shipment requirements; additional education and support required from a health care professional; usually not stocked at retail pharmacies."

NASP
National
Association of
Specialty
Pharmacies

"Specialty drugs are more complex than most prescription medications and are used to treat patients with serious and often life threatening conditions including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders. These medications may be taken orally but often must be injected or infused and may have special administration, storage and delivery requirements."



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anasir Health.

11

Disease States in Specialty Pharmacy

- Oncology
- Multiple Sclerosis
- Hemophilia
- Hepatitis C
- HIV/AIDS
- Asthma
- Transplant

**Chronic
Inflammatory
Diseases:**

- Crohn's Disease
- Ulcerative Colitis
- Rheumatoid Arthritis
- Juvenile Arthritis
- Psoriatic Arthritis
- Psoriasis
- Ankylosing Spondylitis



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anasir Health.

12

Examples of Specialty Medications

adalimumab

- Injectable, requires cold-chain, complex dosing regimen, self-administered

ocrelizumab

- IV infusion, requires cold-chain, administered at infusion center

temozolomide

- Oral, oncology, weight-based dosing, complex regimen, self-administered

fingolimod

- Oral, first-dose monitoring, strict adherence required in first 4 weeks



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anika Health.

13

Limited Distribution Drugs

Manufacturer restricted access to specialty medications

- Product characteristics
- Patient education
- Market reach
- Administration and dispensing characteristics

Manufacturer influences patient services

- Patient education programs
- Risk evaluation and mitigation strategies (REMS)
- Safety monitoring
- Medication adherence

Data collection by Specialty Pharmacy



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anika Health.

14

Examples of Limited Distribution Drugs

cladribine tablets

- Multiple Sclerosis

erdafitinib

- Bladder cancer

emicizumab-kxwh

- Hemophilia

esketamine

- Treatment resistant depression



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Amgen Health.

15

Patient Care Model

Clinical Pharmacist role in patient care

- Most patient care activity occurs over the phone
- Ensures appropriate dose for patient and indication
- Provides initial medication counseling to patient
- Pharmacy-based and manufacturer-guided clinical assessments
- Monthly follow up counseling for adherence, side effect management
- 24 hour / 7 day a week availability to patients



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Amgen Health.

16

Technician Utilization

Certified Pharmacy Technician roles in Specialty Pharmacy

Call Center Specialists

- Inbound and outbound patient and provider calls

Insurance Specialists

- Manage claims processing, prior authorizations

Manufacturer Program Specialists

- Manufacturer patient assistance programs

Operations

- Prescription order entry, medication dispensing



This information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Amgen Health.

17

Specialty Pharmacy Models

Call Center

- Pharmacy professionals in Call Center setting, separate from dispensing
- Call Centers in multiple locations, teams divided by disease state or geography

AM [2]6

Fulfillment Center

- Dispensing and distribution by local or interstate courier, separate location

Joint Location

- Call Center personnel and dispensing/distribution all in same location

Specialty Pharmacist in Clinic

- Specialty Pharmacist in health system clinic, involved in medication selection, initiation and monitoring.



This information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Amgen Health.

18

Multi-state Practice Considerations

Regulatory Considerations

- State and federal pharmacy practice laws
- Non-resident pharmacy licensure in states where medications are shipped
- Pharmacists licensed in multiple states

Cold-chain Management

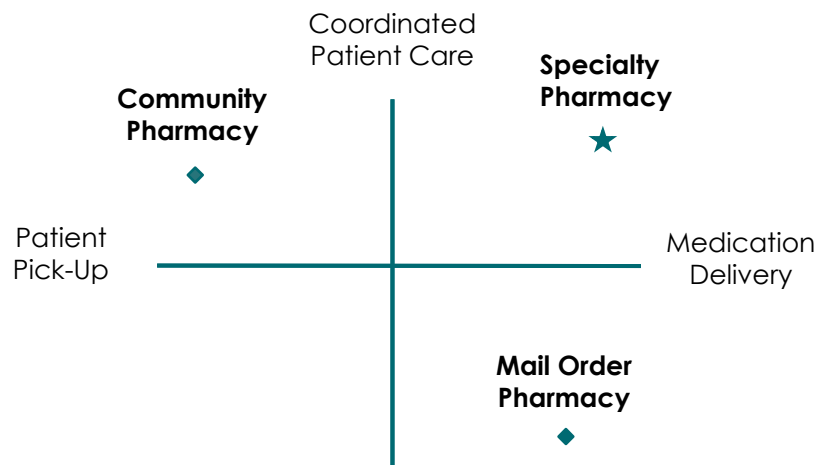
- USP<659> Packaging and Storage Requirements
- Medications must be kept at recommended temperatures during shipment



This information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anika Health.

19

Practice Differences & Similarities



20

AM [2]1

Specialty Pharmacy Accreditation

- Accreditation Commission for Health Care (ACHC)
- Utilization Review Accreditation Commission (URAC)
- Center for Pharmacy Practice Accreditation (CPPA)




All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anson Health.

21

Specialty Pharmacy Accreditation

URAC

- The URAC accreditation process demonstrates a commitment to quality services and serves as a framework to improve business processes through benchmarking organizations against nationally recognized standards.
- URAC-accredited Specialty Pharmacies
 - Provide therapy-specific patient management services
 - Promote safety and accuracy in dispensing practices
 - Qualify all medication distribution processes for appropriate temperature ranges
 - Provide 24/7 patient and prescriber support
 - Comply with foundational standards on risk management, consumer empowerment and performance management
 - Report annual performance measures to URAC



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anson Health.

22

Certified Specialty Pharmacist (CSP)

Certification developed to recognize pharmacists with intermediate knowledge and skill to provide competent specialty pharmacy services

Eligibility Requirements

- Education
- Licensure
- Continuing Education
- Experience
- Attestation
- Examination

NCCA-Accredited Certification Program



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Aniston Health.

23

Additional Resources

National Association of Specialty Pharmacy (NASP)

- www.naspnet.org

American Society of Health-System Pharmacists (ASHP)

- www.ashp.org/Pharmacy-Practice/Resource-Centers/Specialty-Pharmacy

Specialty Pharmacy Times

- In print
- www.specialtypharmacytimes.com

Specialty Pharma Education Center (SPEC)

- www.specialtycme.org



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Aniston Health.

24

Additional Resources

Specialty Pharmacy Certification Board (SPCB)

- <http://www.spcboard.org/>

URAC Specialty Pharmacy Accreditation

- <https://www.urac.org/programs/specialty-pharmacy-accreditation>

ACHC Pharmacy Accreditation

- <https://www.achc.org/pharmacy.html>



25

Assessment Question #1

Which group of disease states is often managed by clinical pharmacists practicing in specialty pharmacy?

- Rheumatoid arthritis, diabetes mellitus, hepatitis C and hemophilia
- Hepatitis C, hemophilia, osteoarthritis and multiple sclerosis
- Rheumatoid arthritis, multiple sclerosis, hepatitis C and hemophilia
- Hemophilia, hepatitis A, rheumatoid arthritis and multiple sclerosis



26

Assessment Question #1

Which group of disease states is often managed by clinical pharmacists practicing in specialty pharmacy?

- a) Rheumatoid arthritis, diabetes mellitus, hepatitis C and hemophilia
- b) Hepatitis C, hemophilia, osteoarthritis and multiple sclerosis
- c) Rheumatoid arthritis, multiple sclerosis, hepatitis C and hemophilia
- d) Hemophilia, hepatitis A, rheumatoid arthritis and multiple sclerosis



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anjan Health.

27

Assessment Question #2

PW is 73-yo female, treated for asthma, HTN, GERD, RA and osteoporosis. Her medication list includes montelukast, chlorthalidone, esomeprazole, hydroxychloroquine, abatacept and abaloparatide. Which medications might she get from a Specialty Pharmacy?

- a) Hydroxychloroquine and abatacept
- b) Montelukast, hydroxychloroquine and abatacept
- c) Abaloparatide and abatacept
- d) Montelukast, hydroxychloroquine and abaloparatide



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anjan Health.

28

Assessment Question #2

PW is 73-yo female, treated for asthma, HTN, GERD, RA and osteoporosis. Her medication list includes montelukast, chlorthalidone, esomeprazole, hydroxychloroquine, abatacept and abaloparatide. Which medications might she get from a Specialty Pharmacy?

- a) Hydroxychloroquine and abatacept
- b) Montelukast, hydroxychloroquine and abatacept
- c) Abaloparatide and abatacept
- d) Montelukast, hydroxychloroquine and abaloparatide



29

Assessment Question #3

What factors will this patient's Specialty Pharmacy take into consideration when filling medications for PW that are different than what her neighborhood community pharmacy considers when dispensing her other medications?

- a) Documenting patient allergies
- b) USP <659> after medication leaves the pharmacy
- c) HIPAA privacy
- d) Patient counseling requirements



30

Assessment Question #3

What factors will this patient's Specialty Pharmacy take into consideration when filling medications for PW that are different than what her neighborhood community pharmacy considers when dispensing her other medications?

- a) Documenting patient allergies
- b) USP <659> after medication leaves the pharmacy
- c) HIPAA privacy
- d) Patient counseling requirements



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anika Health.

31

Assessment Question #4

Which organizations provide accreditation for specialty pharmacies?

- a) ACHC
- b) URAC
- c) AFLAC
- d) All of the above
- e) A and B



All information is confidential and proprietary and may not be reproduced in whole or in part unless authorized in writing by an authorized representative of Anika Health.

32

Assessment Question #4

Which organizations provide accreditation for specialty pharmacies?

- a)ACHC
- b)URAC
- c)AFLAC
- d)All of the above
- e)A and B



33

Thank you!

34



34

Definition of Specialty Pharmacy

A specialty pharmacy is a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. In addition to being state-licensed and regulated, specialty pharmacies should be accredited by independent third parties such as URAC®, the Accreditation Commission for Health Care (ACHC), the Center for Pharmacy Practice Accreditation (CPPA) or the Joint Commission, in order to ensure consistent quality of care.

Specialty pharmacies connect patients who are severely ill with the medications that are prescribed for their conditions, provide the patient care services that are required for these medications, and support patients who are facing reimbursement challenges for these highly needed but also frequently costly medications.

Specialty medications have a complex profile that require intensive patient management. Some specialty medications also require special handling. Though some are taken orally, many of these medications need to be injected or infused, some in a doctor's office or hospital. Specialty pharmacies provide services that include training in how to use these medications, comprehensive treatment assessment, patient monitoring, and frequent communication with caregivers and the patient's physician or other healthcare providers.

The expert services that specialty pharmacies provide drive adherence and persistency, proper management of medication dosing and side effects, and ensure appropriate medication use. The specialty pharmacy's patient-centric model is designed to provide a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions, achieve superior clinical and economic outcomes, and expedite patient access to care.

National Association of Specialty Pharmacy (NASP), 2016



35

Definition of Specialty Medication

Specialty drugs are more complex than most prescription medications and are used to treat patients with serious and often life threatening conditions including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders. These medications may be taken orally but often must be injected or infused and may have special administration, storage and delivery requirements. Many of these injectable medications are self-administered in the patient's home. Infused specialty medications are administered in various treatment settings such as a patient's home with the support of a home health care professional, sometimes in a doctor's office or even in a hospital.

The complexity of these medications may be due to the drug itself, the way it is administered, the management of its side effect profile, the disease or condition it is used to treat, special access conditions required by the manufacturer, payer authorization or benefit requirements, patient financial hardship or any combination of these. As a result, patients being treated with specialty medications require comprehensive patient care, clinical management, and product support services.

Specialty prescription medications cannot be routinely dispensed at a typical retail community pharmacy because the therapy typically requires special handling as well as significant patient education regarding appropriate utilization. Typical retail pharmacies are not designed to provide the patient care or other services that specialty medications require.

National Association of Specialty Pharmacy (NASP), 2016



36