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# Infusion Integration:

Site-of-Care Trends, Challenges, and Opportunities



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# Disclosure

**The following individuals report having no relevant conflicts of interest:**

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# Learning Objectives

1. Describe current specialty infusion trends and characteristics of different sites of care.
2. Discuss current practices in health systems to operationalize prescription routing and integrate specialty and infusion.
3. Identify challenges and barriers in specialty infusion.
4. List strategies to improve capture of revenue and improve margins for specialty infusions.

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# Specialty Infusion Site-of-Care Trends

- Payors are mandating use of lower-cost sites of care for outpatient infused drugs versus hospital outpatient infusion centers or physician-based centers.
  - Policy implementation generally occurs during the prior authorization stage for a new order or after a certain number of limited infusions.
- Payors are “carving out” certain infused medications and moving drug reimbursement to the pharmacy benefits.
  - This is driving “white bagging” from the payor's preferred specialty pharmacy to the infusion clinic.
  - This results in fragmented care, as well as administration burden on pharmacies that need to track, store, prepare, and deliver the products to the infusion clinic.
- 21 manufacturers are reducing 340B discounts for non-covered entity-owned contract pharmacies.
- Many infused biosimilars are entering the market and payor formularies vary.



# Examples of Site-of-Care Target Drugs

ACTEMRA® (tocilizumab)

BENLYSTA® (belimumab)

ENTYVIO® (vedolizumab)

Immunoglobulin

OCREVUS® (ocrelizumab)

ORENCIA® (abatacept)

REMICADE®, INFLECTRA®, RENFLEXIS®  
(infliximab)

SIMPONI ARIA® (golimumab)

SOLIRIS® (eculizumab)

STELARA® (ustekinumab)

## Site-of-Care Optimization Considerations



### Clinical Impact

- Coordination with labs
- Safety—ADR profile
- Infusion time
- Skilled nursing care



### Patient Experience

- Preference
- Social support
- Cognitive function
- Convenience



### Economic

- Payor's formulary rules
- Patient cost

# Site-of-Care Characteristics

Site of Care	Service	Billing Method and Place of Service	Payors	Regulatory	Pros	Cons
Hospital-Based Infusion Center (HOPD)	Drugs and supplies are prepared on site or in an infusion pharmacy and delivered to the infusion center for administration by a skilled IV nurse.	Billing through the hospital billing system with place of service 19—Outpatient Department On Campus or 22—Outpatient Department Off-Campus	All payors	Credentialed with Medicare as Hospital-Based Clinic or Department	340B eligibility	No claim reimbursement for status "N" drugs from Medicare (payment included as bundled payment for administration code); site-of-care restrictions from commercial payors are increasing.
Provider-Based Infusion Center	Drugs and supplies are prepared on site for infusion administration by a skilled IV nurse. Staffed by NP, PA, or MD.	Billing as an independent entity with place of service 11—Office	All payors	Credentialed with Medicare as Physician-Based Clinic or Office	No site-of-care commercial payor restrictions; higher drug reimbursement than HOPD for non-340B eligible drugs.	No 340B eligibility; lower administration reimbursement
Home Infusion	Drugs and supplies are prepared in a home infusion pharmacy and delivered to the patient's home for administration and/or self-care training by a skilled IV nurse.	Billing through the infusion pharmacy systems (CareTend or Brighttree) with place of service 12—Home	Commercial payors with a contract and Medicare Part D payors. Medicare Part D pays only for the drug.	DME/ Home Infusion Accredited	Reduces hospital LOS; patient convenience; provides options for site-of-care restrictions.	Limited Medicare reimbursement; rigorous compliance measure for 340B inventory compliance (must use split-billing software for mixed-use inventory or keep separate physical inventory).
Pharmacy Infusion Suite	Drugs and supplies are prepared in an adjacent or nearby infusion pharmacy and delivered to the infusion suite for administration by a skilled IV nurse.	Billing through the infusion pharmacy systems (CareTend or Brighttree) with place of service 11, 12, or 49 based on the payor contract	Commercial payors with a contract and Medicare Part D payors. Medicare Part D pays only for the drug.			Limited Medicare reimbursement; rigorous compliance measure for 340B inventory compliance (must use split-billing software for mixed-use inventory or keep separate physical inventory).

# Current U.S. market landscape

Home infusion pharmacy is a \$19 billion dollar industry that has seen 300% growth during the last 10 years, according to the National Home Infusion Association.<sup>1</sup> Currently, this market is dominated by three primary providers, who account for 50% of the market share, with the rest of the market being highly fragmented by more than 970 regional and national providers.<sup>2</sup>

## U.S. home infusion market<sup>1,3,9</sup>



**\$19B**

industry



**\$3.2M**

patients served annually



**300%**

growth during the last 10 years



**7.9%**

projected annual growth through 2030

# Key Home Infusion Growth Factors

- Decreasing hospital bed days
- Decreasing hospitalizations and rehospitalizations
- Managing payor site-of-care restrictions
- Increased comfort level with providing infusion in the home
- Greater number of infused drugs for chronic disease entering the market

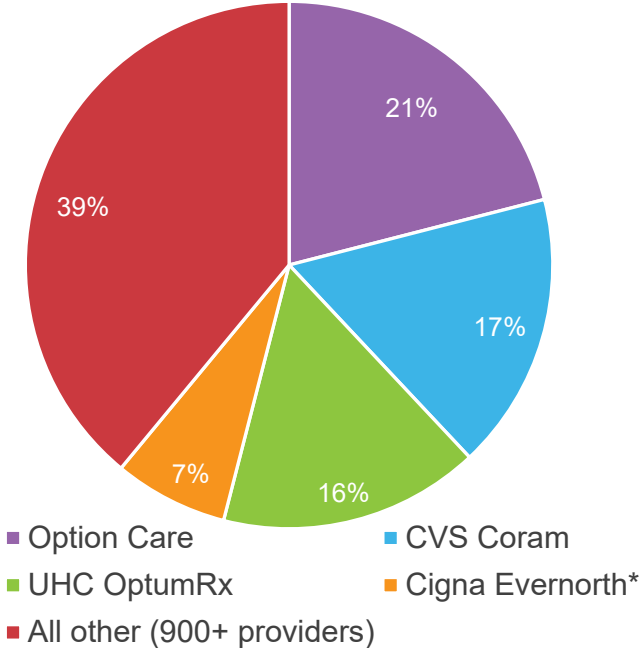
1. National Home Infusion Foundation 2020 Trend Report. Accessed February 2023.

3. About home and specialty infusion. National Home Infusion Association. Accessed February 2023.

9. Survey on the patient care impact and additional expense of white/brown bagging. Vizient 2021. Accessed May 2022.

# Ever-Changing Market

## Market share



Source: National Home Infusion Foundation 2020 trend report; Option Care investor presentation, 7/2020; \*Vizient estimate

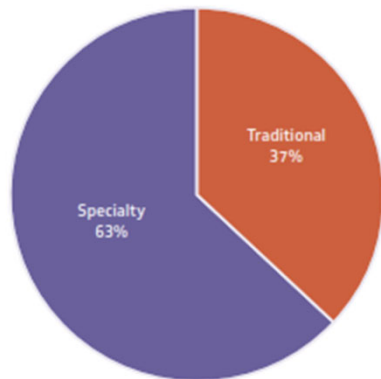
## Market dynamics

- The home infusion market is dominated by four companies (Option Care, Coram CVS, UHC OptumRx) that account for more than 50% of the market share.
- The rest of the market is highly fragmented, with 970+ regional and national providers accounting for ~40% of the market.
- In July 2022, Coram and Optum decided to get out of the traditional core therapy space, such as antibiotics and parenteral nutrition, and focus on the specialty therapy space.

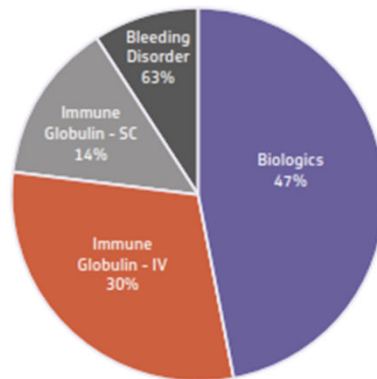


# Financial Implications of Therapy Mix

Specialty impact on provider revenues<sup>7</sup>



Revenue distribution by typical provider



Specialty revenue by product category

**9.5% of specialty infusion patients contribute 63% of all revenue for the typical provider**

- Home infusion utilization continues to increase in both specialty and traditional therapies.
- 90.5% of the 3.2M home infusion patients are receiving traditional home infusion therapy.
- From 2010 through 2019, revenue per patient for specialty therapies increased dramatically, whereas it decreased for traditional therapies.
- The decrease in reimbursement for traditional therapies is a cause for concern, as most of the profit margins are proportional to services rather than to the drugs.

Source: NHIF 2020 Trends report

# Payor Vertical Integration Continues

## Vertical Business Relationships among Insurers, PBMs, Specialty Pharmacies, and Providers, 2022

	Elevance Health	CVS Health	Centene	Cigna	Humana	UnitedHealth Group	Blue Cross Blue Shield
Insurer							
PBM (GPO)							
Specialty Pharmacy							
Provider Service							

1. In September 2022, CVS Health announced its acquisition of Signify Health. The transaction is expected to close in 2023.
2. Since January 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Prime for mail and specialty pharmacy services. In December 2021, Walgreens purchased Prime Therapeutics' 45% ownership in AllianceRx Walgreens Prime, so this business has no PBM ownership in 2022. Effective June 2022, the company has been known as AllianceRX Walgreens Pharmacy.
3. In 2022, Centene announced its intention to outsource its PBM operations to Express Scripts.
4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
6. Previously known as Cigna Medical Group.
7. In 2021, Cigna's Evernorth business acquired MDLive.
8. In 2021, Cigna invested \$2.7 billion for an estimated 14% ownership stake in VillageMD. Walgreens owns a majority of VillageMD.
9. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as Centerwell Senior Primary Care.
10. In 2022, Kindred at Home was rebranded as Centerwell Home Health. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. Humana also announced plans to close a majority of its SeniorBridge home care locations.

Source: [The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Exhibit 212. Chart updated in December 2022.





# What Can Health Systems Do to Embrace Site-of-Care Requirements?

- Proactively examine your common payors' current and annual policy changes.
- Examine who conducts benefit investigations and where prescriptions are routed when the PA team faces a site-of-care restriction.
- Examine leveraging your specialty pharmacy and retail to “clear bag” to the infusion center.
- Build your own home infusion and alternate site infusion center program.

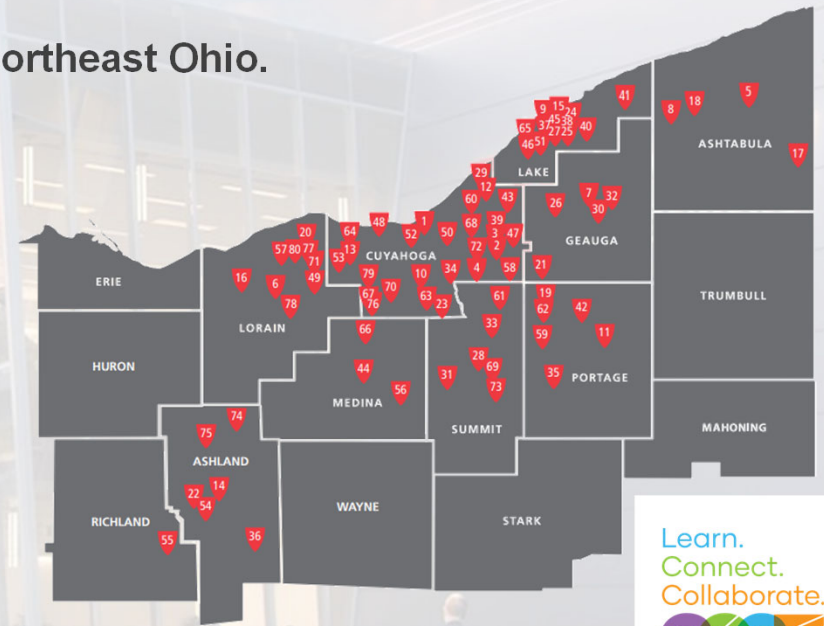
# Integrating Specialty and Infusion



## University Hospitals

University Hospitals is a large, integrated health system in Northeast Ohio.

- 21 hospitals
- 12 oncology infusion centers
- 2 ambulatory infusion centers
- 50+ outpatient health centers
- Specialty pharmacy services
- Ambulatory infusion pharmacy
- Home infusion pharmacy
- 100+ caregivers in specialty/infusion*



# Integrating Specialty and Infusion



Mercy Health System St. Louis

Mercy Health System is a large, integrated health system with locations in four states.



- Mercy Specialty Pharmacy St. Louis
- Mercy Specialty Pharmacy Oklahoma City
- Mercy Specialty & Home Infusion Pharmacy Springfield
- Mercy Specialty & Home Infusion Pharmacy Riverport



# Integrating Specialty and Infusion

## Traditional health system pharmacy practice

### Specialty pharmacy or infusion pharmacy?

- Separate workflows with differing services offered, operating in silos
- Differences in patient management and education



### Billing differences

- Medical benefit—infusion pharmacy
- Pharmacy benefit—specialty pharmacy

# Integrating Specialty and Infusion

## Traditional health system pharmacy practice

### Prescription Routing

#### What starts the process?

- Electronic prescribing
- Referral
- Fax
- Telephone
- Transition care coordinators

Lack of consistency between providers and how they send referral

# Integrating Specialty and Infusion

## Reimagining ideal health system pharmacy practice

Remove the differences and barriers to patient care!

### Electronic medical record and clinical decision support systems

- Route to or signal appropriate (health-system owned or contracted) pharmacy to send prescription order
- Pop-up best practice advisory (BPA) to assist prescriber

### Collaboration across teams

- Medications are moving from medical benefits to pharmacy benefits and vice versa
- Financial assistance for all medications, infusion and specialty pharmacy
- Avoid “sending it back to the office”
- Wow your providers!



What are  
the  
benefits?

# Integrating Specialty and Infusion

Reimagining ideal health system pharmacy practice



Better patient care



Patient satisfaction



Referrals retained within  
the health system



Relationship building with prescribers



Employee retention and career  
ladder growth

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# Integrating Specialty and Infusion



## Reimagining ideal health system pharmacy practice: Mercy Health System

### Prescription routing

- Mercy Specialty Pharmacy serving as prior authorization services
  - Market to providers to send \*specialty<sup>de0</sup> prescriptions for prior authorization support
  - Obtain authorization and coordinate with patient
  - Triage to external specialty pharmacy only when appropriate
  - Provide transparency to prescribers
- Mercy is currently piloting a Centralized Prior Auth Hub<sup>de1</sup>
- Experienced staff receiving \*all\* prescriptions
  - Obtaining prior authorization and sending clean prescription to intended pharmacy
  - Frees clinic staff to perform essential duties





# Integrating Specialty and Infusion



University Hospitals

UH Meds

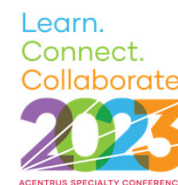
Reimagining ideal health system pharmacy practice: University Hospitals



## Prescription routing—Electronic medical records

Force ambulatory EMR to route a prescription for identified specialty medications to UH Specialty Pharmacy for onboarding and prior authorization, and to determine if in network.

Multistep order transmittal (MSOT): Epic EMR holds identified specialty medications in a “MSOT queue” while onboarding is completed. After onboarding is completed, the MSOT hold can be removed and the prescription will transmit to the appropriate pharmacy.



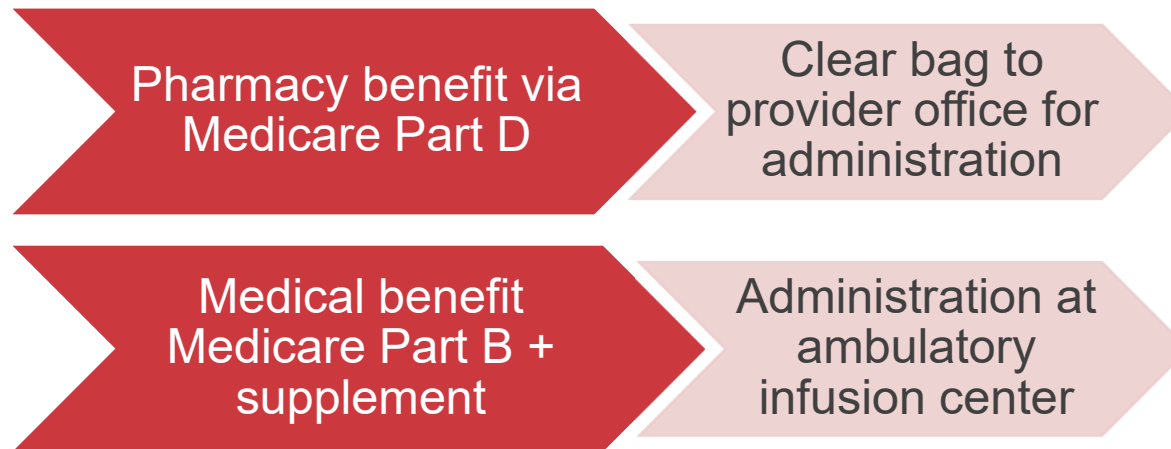
# Integrating Specialty and Infusion



## Case Study: University Hospitals

Decreased turnaround time and lowest out-of-pocket cost for patients for certain medications that cross service lines and are eligible under dual benefits

Example: denosumab, inclisiran





# Challenges and Barriers in Specialty Infusion

## Traditional barriers to care in specialty infusion

- Access to care
- Cost
  - Financial assistance, charity care
- Reimbursement challenges
  - Payor carve-outs and site of care
- Drug/supply shortages
- Clinical challenges
- Patient compliance
- Regulatory challenges
  - Accreditation
- Need for specialized staff

# Challenges and Barriers in Specialty Infusion

## Payor “carve-outs”: University Hospitals

Health plans establishing certain medications to be “carved out” of medical benefit and covered only by pharmacy benefit

### Clear Bag

Health system-owned and -operated pharmacy fills the prescription and delivers medication to health system infusion site

### White Bag

External pharmacy fills the prescription and delivers medication to health system infusion site

### Brown Bag

External pharmacy fills the prescription and delivers medication to the patient’s home; patient brings in medication

# Challenges and Barriers in Specialty Infusion

## Payor “carve-outs”: University Hospitals

### Dispensing challenges

- May require a separate prescription to be sent to the specialty pharmacy based on state pharmacy law
- The medication is dispensed and labeled for the specific patient
- Cannot be used for other patients
- Patient pays an upfront copay, which the patient may be unable to afford
- Logistical challenges
  - Pharmacy out-of-network issues
  - Drug needs to arrive at infusion center prior to appointment for preparation and mixing
  - Courier delays due to weather and transportation limitations
  - Limited window to dispense, transport to infusion site, and accept medication

# Challenges and Barriers in Specialty Infusion

Payor “carve-outs”: University Hospitals

## Overcoming challenges

- Prospective report run by infusion precertification team identifying patients with insurance and medication needing pharmacy precertification
- Standardized email communication templates to inform providers and the request for outpatient prescription
- Dispense medication with appropriate lead time to avoid transportation delays
- Fight for the overrides to clear bag instead of white bag
- Identified a need for a specialized technician in this role with experience in pharmacy and medical benefits

# Challenges and Barriers in Specialty Infusion

## Case Study: University Hospitals

Site-of-care denial under medical benefit for hospital infusion space. Plan mandates white bag dispense via pharmacy benefits from network specialty pharmacy to hospital infusion space.

de0

- Example: nivolumab
  - Hospital infusion precert team sends claim rejection to specialty pharmacy for next steps
  - Specialty pharmacy works with plan for prior authorization under clear bag override to hospital infusion space
    - Clear bag to provider office for administration

# Challenges and Barriers in Specialty Infusion



## Need for specialized staff: Mercy Health System

### Staffing challenges

- Difficult to hire and train talent
  - Pharmacists, technicians, nurses, intake/authorization, billing department
- Keeping up with changing regulatory and accreditation standards

### Overcoming challenges

- Serve as preceptor site to evaluate potential of future pharmacists
- Investing in the future: “It costs money to make money”
- Requires support of the health system





# Challenges and Barriers in Specialty Infusion

## Case Study: Mercy Health System



**Pre-pandemic, Mercy Specialty & Home Infusion had a single worker responsible for intake/auth**

- Unable to keep up with authorizations
- No time to reply to pharmacy audits
- Uneven financial health with large adjustments taken

**Now have two dedicated intake/auth co-workers**

- Affords time for proactive communication of auth status
- Average annual revenue increase of 285%
- Profit margin nearly doubled
- Prepared for growth



# Improve Capture of Revenue and Margins

Traditional strategies to improve revenue capture in specialty infusion

## Accurate and Timely Billing

- Collaboration with payors—site of care
- Revenue cycle management
- Medication purchasing

## Increasing Growth and Utilization

- Maximizing 340B opportunities
- Patient financial navigation
- Data analytics
- Patient volume
- Diversifying services
- Patient engagement

# Improve Capture of Revenue and Margins



## Case Study: Mercy Health System

### Patient financial navigation

- Specialty infusion benefits are complicated
- Patient pricing is not always straightforward
- Payor site-of-care restrictions
- Intake staff can connect patients to assistance or work with clinical staff to develop a more cost-effective plan of care
  - Patient relief through manufacturer, foundations, or internal assistance



# Improve Capture of Revenue and Margins



Case Study: Mercy Health System



**Home infusion**  
(sterile compounding)  
*Core and Specialty Infusion*



**Non-sterile compounding**



**Specialty pharmacy**



**“Buy and bill”**



# Improve Capture of Revenue and Margins

**Multiple site-of-care options for payors and patients in health system: University Hospitals**

## Hospital space

- Owned and operated as part of a hospital
- Facility fees
- Higher level of clinical oversight for high-risk infusions

## Doctor office space

- Think “outside the box”
  - Can still look like an “infusion suite”; doesn’t have to be 1970s-style office space E0
- No facility fees
- Oversight by medical provider, can be physician or nurse practitioner

# Improve Capture of Revenue and Margins

## Utilization of 340B: University Hospitals

### Child sites

- Convert “off-site” provider offices to spaces owned and operated by covered entity

### Contract pharmacy

- Contract with your specialty or infusion pharmacy as a contract pharmacy of the covered entity in order to have 340B dispenses for clear-bag opportunities

### 340B Telehealth

- For areas unable to be converted to child sites of the covered entity, consider 340B telehealth visits by pharmacists under collaborative practice agreements with your providers with provider co-signatures
- Define in health system policy that these are “provider” visits

# Improve Capture of Revenue and Margins

## Case Study: University Hospitals

### Ambulatory infusion centers

#### *Situation*

- Multiple commercial payor denials for site of care for hospital-owned infusion space due to cost and facility fees
- Payors require infusion in doctors' office space at initial infusion or after first infusion but many health system doctors' office spaces cannot handle authorization onboarding, drug inventory, infusion scheduling, or administration
- Health system loses many of these referrals and corresponding revenue to outside community infusion centers

# Improve Capture of Revenue and Margins

## Case Study: University Hospitals

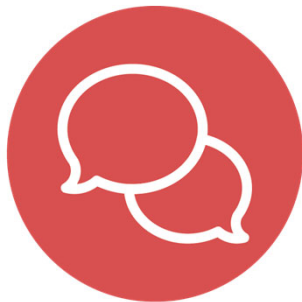
### Ambulatory infusion centers

#### *Coordinated response*

- New build and repurposed community ambulatory spaces designed to give patients the “infusion suite feel,” with bright, private spaces; large, comfortable chairs; and music
- Areas coded as “doctor’s office” space with oversight by physician medical director and day-to-day oversight by nurse practitioner
  - Lose facility fees but maintain the disproportionately large medication and administration fees
- Multimodal authorization and billing plan
  - Health system specialty pharmacy clear-bag dispense for 340B-eligible prescriptions, mandatory pharmacy benefit dispenses
  - Buy-and-bill administration and charging: Medicare Part B, non-340B eligible prescriptions



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# Questions



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