HOD Conversions

Maximizing Reimbursement and Compliance

BJ Roberts
CFO, Mercy Hospital Springfield

Your life is our life's work.

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Learning Objectives

At the end of this session, participants should be able to:

1. Identify the Key Benefits: Understand the primary financial and operational advantages of converting a clinic to a Hospital Outpatient Department.
2. 340B Program Eligibility: Learn how HOD conversions facilitate eligibility for the 340B Drug Pricing Program and the implications for cost savings.
3. Medicare Cost Reporting: Gain insights into the process of associating outpatient costs and charges with hospital Medicare cost reports for optimal reimbursement.

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Poll Question #1

What do you consider your proficiency level with 340B?

A. New / Beginner
B. Intermediate Still learning
C. Advanced / Veteran in 340B operations

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Poll Question #2

Do you currently have your specialty clinics aligned under the hospital & eligible for 340B?

A. Yes, the majority are already 340B eligible
B. No, the majority are not 340B eligible
C. Mixed, some qualify & some do not

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Poll Question #3

Are you considering any changes to your free-standing clinics to align under the hospital?

A. Yes
B. No

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Mercy…by the numbers

- Hospital Pharmacies (24-hour/onsite): **13**
- Non 24-hour Hospitals w/ off-site coverage after hours (Smaller Hospital/Critical Access): **32**
- Hospital-based Oncology/OP Infusion/ASC Pharmacies: **15**
- Ambulatory Pharmacies: **61**
- Retail/Specialty Prescriptions (annually): **2.6 million**
- Hospital Medication Orders (annually): **23.8 million**
- Drug Spend: **$1.4 billion**
- Pharmacy Co-workers: **1,200+**
- 340B Program Participation
  - Disproportionate Share Hospital (DSH) Facilities: **10**
  - Rural Referral Center (RRC) Facilities: **2**
  - Critical Access Hospital (CAH) Facilities: **17**
  - *Contract Pharmacy Relationship Pairs:* **31**

Hospital · Clinic · Urgent/Convenient Care · Virtual Care · Outpatient Surgery Center · Outreach Ministry

Headquarter in St. Louis with a multi-state footprint, Mercy is one of the largest Catholic health systems in the US.

Outreach ministries in Arkansas, Louisiana, Mississippi, and Texas.

Mercy's IT division, Mercy Technology Services and Mercy Virtual commercially serve providers & patients from coast to coast.

Serving millions each year.

1827
Founded

45
Hospitals

948
Physician practices & outpatient facilities

4,700
Integrated providers

45,000
Co-workers

$8B
Revenue

Mercy Data and Images. CY2023/Annual Stats (with August 2024 updates). Not for reuse without permission of Mercy.

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340B Program Expansion

Program goals include:

- ❖ Increase access to affordable medications to our most vulnerable patients
- ❖ Generate savings to fund programs that create great community benefit
- ❖ Enhance Quality Assurance & Compliance program

What is the 340B Drug Discount Program?

- 340B is a federal program that allows specific categories of not-for-profit health providers to buy outpatient prescription drugs at discounted prices.
- It requires drug manufacturers to provide outpatient drugs to eligible covered entities at a reduced cost.

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Medicare Disproportionate Share (DSH) Calculation

Medicare Disproportionate Share (DSH)	Jul-24	Aug-24	Sep-24
Medicaid/Medicaid Managed, Non-Medicare Part A Eligible Days Proven			
-Medicaid/Medicaid Managed Primary	2,738	5,313	8,358
-Medicaid/Medicaid Managed Secondary	387	1,047	1,717
-Medicaid/Medicaid Managed Tertiary	0	40	43
Medicaid/Medicaid Managed Confidence Factor Days [1]	3,125	6,400	10,118
Pending Medicaid, Non-Medicare Part A Eligible Days			
-Medicaid Pending Primary	510	976	1,087
-Medicaid Pending Secondary	249	533	510
Medicaid/Medicaid Managed Pending Rate Days [2]	633	1,252	1,335
Total Medicaid, Non Medicare-Part A Eligible Days	3,758	7,652	11,453
Total Patient Days	15,602	30,937	45,366
-Medicaid Utilization Percentage	24.09%	24.73%	25.25%
-SSI Percentage [3]	5.88%	5.88%	5.88%
Total DSH Percentage (Medicaid Utilization Percentage + SSI Percentage)	**29.97%**	**30.61%**	**31.13%**
Less: Applicable DSH Threshold	20.20%	20.20%	20.20%
Difference	9.77%	10.41%	10.93%
DSH Adjustment Factor	82.50%	82.50%	82.50%
Adjusted DSH Percentage	8.06%	8.59%	9.01%
DSH Add-On	5.88%	5.88%	5.88%
Estimated Allowable DSH Payment Percentage (340b)	**13.94%**	**14.47%**	**14.89%**

- 1. Medicaid/Medicaid Managed Confidence Factor Days applies the EY rate of 1 for Primary Medicaid and 1 for Secondary/Tertiary Medicaid

- 2. Medicaid/Medicaid Managed Pending Rate Days applies the Medicaid Eligibility Program approval rate of 0.9 for primary applications and 0.7 for secondary applications

- 3. SSI Percentage is a CMS value based on prior year Medicare Part A/SSI Days divided by Total Medicare Part A Days

The minimum allowable DSH percentage to qualify for 340B is 11.75%.

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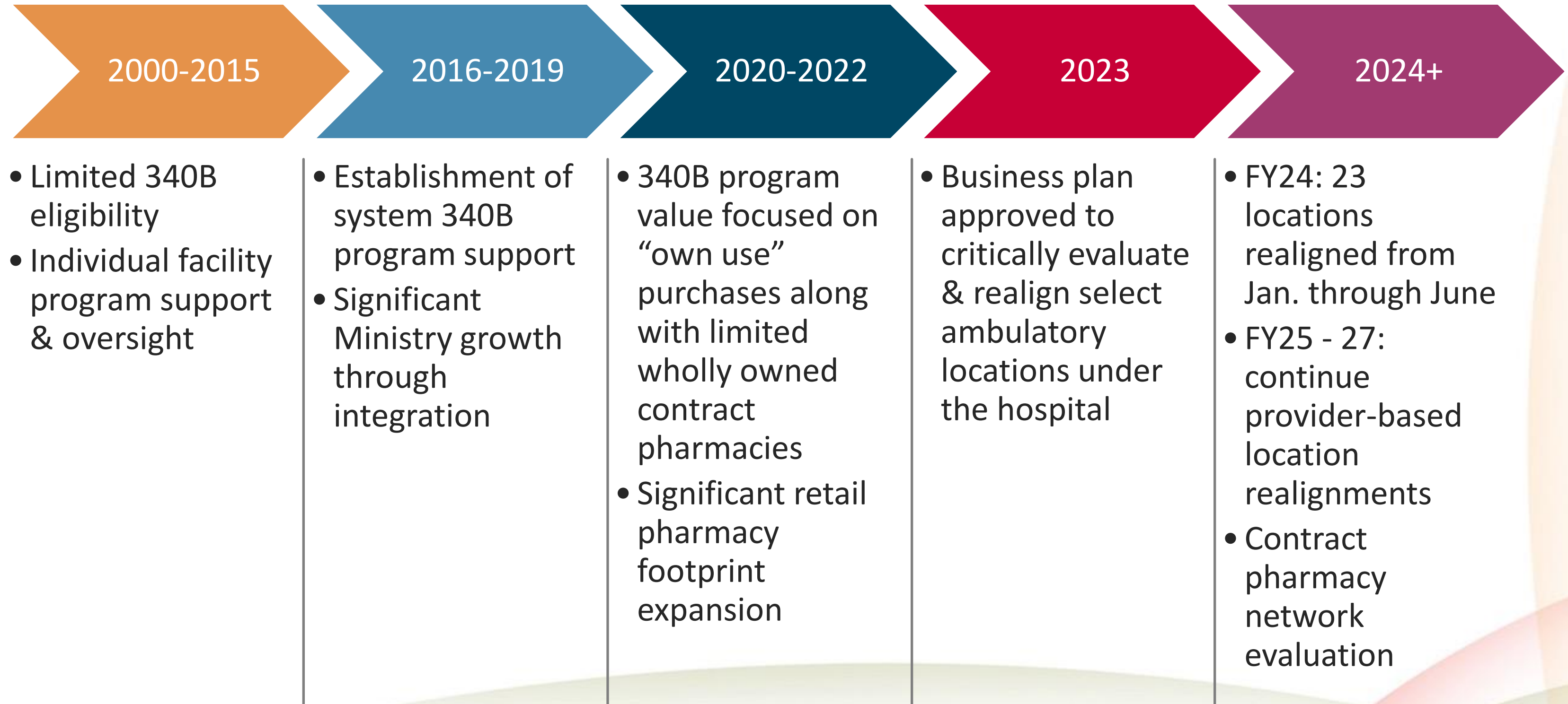
340B Journey to Date



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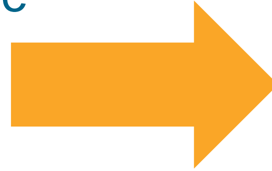
340B Program Expansion

Why transition from Clinic to HOD?

- To be eligible to participate in 340B, an offsite, outpatient facility must be reimbursable on a hospital's filed Medicare Cost Report.
- Converting to HOD transfers ownership to associate outpatient costs & charges as evidenced on the hospital filed Medicare Cost Report.



Procurement Savings for Buy & Bill model (infusion & procedural areas)

Internal & External Contract Pharmacy Expansion

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Program Strategy

Strategy & Principles

- ✓ Scalable billing model that is fully compliant from the start
- ✓ Minimize possible impact to patients
- ✓ Continue to use Ambulatory EHR / Epic tools
- ✓ HODs must appear on FY24 Medicare Cost Reports to be eligible for 340B pricing in FY25
- ✓ Savings will begin in FY25
- ✓ Strategic regrouping around a more focused FY24 approach

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Primary Guiding Principles

Strategy & Principles, *cont.*

- ✓ Improve patient care, access, experience & throughput
- ✓ Avoid significant increases in patient expenses or additional charges
- ✓ Physicians to continue to utilize tools they are familiar with
- ✓ Retain clinic culture & strengthen relationships with hospital partners
- ✓ Increase medication adherence & access through expansion of pharmacy benefit advisory services
- ✓ Maintain or improve performance in risk-based contracts
- ✓ Provide more consistent guidance & experience for infusion options

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340B Program Expansion
Change Impact

Minimal clinic impact that will return meaningful & tangible benefits to the Ministry

Who is impacted?

Physicians / APPs*

Roomers

Schedulers

*APPs - Advanced Practice Providers
** RVU - Relative Value Unit

- ✓ No anticipated RVU changes
- ✓ Minimal training required
- ✓ Medical receptionists will remain at the clinics
- ✓ Staffing changes to be evaluated & adjusted as needed over time

340B Program Expansion

Our Approach

Use of Hybrid vs. Traditional Billing Model

- All financial activity resides on Hospital Billing (HB) side of Epic
- Housing financial activity within HB allows us to leverage existing infrastructure
    - 340B Modifier Build
    - HOD on/off campus modifier build
    - 3M core grouper (Medicare claims editing)
- Recommended approach avoids duplication of infrastructure build & maintenance in Professional Billing (PB) space
- Proposed model addresses key legal & compliance risks surfaced to date
- Uniform charging
- Mandatory claims submission requirements
- Wisconsin Physician Services (WPS) directive that claims should present in similar fashion regardless of filing order (primary vs. secondary)

Physicians work in ambulatory Epic module to document

Billing starts and stays within HB

Charge router funnels all charges to HB to the appropriate claim form

Secondary claims follow secondary payor rules and required claim forms

340B Program Expansion, *cont.*

Hybrid Model Projected Impact on Patients by Payor Category

	Commercial	Medicare with no Secondary	Medicare and Medicare Advantage with Secondary	Medicare Advantage no Secondary	Medicaid
Copay	No Change / No Impact	There is no cap on Medicare out of pocket (20% out of pocket after Deductible)	No Change / No Impact	E&M slightly Higher Copay. Procedure may have larger impact. If plan doesn't pay, then could revert to self pay liability	No Change / No Impact
Deductible	No Change / No Impact	There is no cap of Medicare out of pocket	No Change / No Impact	If plan doesn't pay, then could revert to self pay liability	No Change / No Impact

- No changes or impacts for Commercial, Medicare with good Supplemental and Medicaid Patients
- For patients with straight Medicare and those with poor Supplemental Plans, Mercy will work with the patients to convert to supplemental plans with better coverage
- Majority of impacted patients (approx. 60%) could qualify for some type of financial assistance from Mercy
- Copays for procedures might be higher in 2024

Headwinds & Hurdles to Overcome

- Ongoing pharma restrictions for contract pharmacies
- Increased regulatory environment under the hospital
  - The Joint Commission (TJC) / Center for Medicare and Medicaid Services (CMS)/ Board of Pharmacy / Department of Health
  - Sterile compounding
- Re-evaluation of historical hospital policies / processes
- Electronic Health Record (EHR) rebuild required
- Complex billing requirements & revenue cycle
- Physician / provider workflow
- Perceived loss of clinic culture
- Variety of 340B facility types (DSH, RRC, CAH, SCH)

Resources Needs / Team Members / Stakeholders

- Epic / EHR rebuild
- Revenue cycle
- 340B program management / pharmacy leadership
- Dedicated operational leadership
- Formal project management support
- Compliance & Legal
- Environment of Care / facilities / signage
- Operational engagement & focus
- Analytical resources
- Use of consultants: Insource vs. outsource?

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Operational Considerations

One size does not fit all:

- Must customize (even clinics/HOD locations)
- Must understand current practice
- Consider how HOD rules will affect workflow

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Operational Considerations, *cont.*

Joint Commission & CMS Standards

- Pharmacy medication order entry/verification

  vs.
- Provider supervised administration
- Building infrastructure to be HOD compliant
- Hospital-based policies & procedures

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Operational Considerations, *cont.*

White Bagging vs. Brown vs. Clear

- Clinics allowed white & brown bagging
- How to transition to clear bagging
- Alternatives to white bagging
- Communication to patients & providers

Brown Bagging: Medication is sent **to the patient,** and they **bring it** to the provider.

White Bagging: Medication is sent **from a specialty pharmacy to the provider** for the patient.

Clear Bagging: Medication is provided **by the health system's pharmacy** and sent to the provider for the patient.

Operational Considerations, *cont.*

Medication ordering & procurement

- Must come from hospital pharmacy or contracted pharmacy
- Clinic physicians may or may not have hospital credentials & privileges
- Prior Authorization: Must attain new PA for government plans

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Operational Considerations, *cont.*

Billing Compliance

- Must document as medication administration, not as a chart note
- Hybrid billing
    - Clinic
    - Hospital-based
- Potential delay in billing & reimbursement

340B Considerations

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Set Expectation to Eligibility

Keep CFO & other leaders aware that converting a clinic to an HOD does not always equate to immediate 340B savings.

- Clinic within the four walls
- Requires child site registration
- Intersection of both potentially within a specialty

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Potential Timeline to Eligibility

Newly converted clinic not within the four walls

- Timeline will vary based on when conversion takes place compared to your fiscal year (FY)
- Converted in first month of FY
  - 22 Months (based on July 1 – June 30 FY)
- Last month of FY
  - 10 months to a 340B participating start date
- Consider an expedited Medicare cost report filing if applicable to your FY & HRSA's registration periods

Opportunity Assessment

Current 340B landscape MFR restrictions

Educate on risks based on restrictions

Build a robust data model/ use a consultant

Entity-owned Wholly-owned contract pharmacy

Buy & bill

vs.

clear bagging options

Messaging

Make it about the patient benefit

Get leadership support early on to develop direct patient benefit initiatives.

- Compliance
- Legal
- Care Coordinators
- Government Relations/Advocacy

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Mitigate Risk

- EHR / Third Party Administrator (TPA) setup
- Billing modifiers
- Utilization capture
- Drug procurement
- Contract pharmacy registrations
- Medicare Cost Report (MCR) flow of expense & revenues
- Set yourself up for success so all the conversion efforts aren't delayed to reach savings

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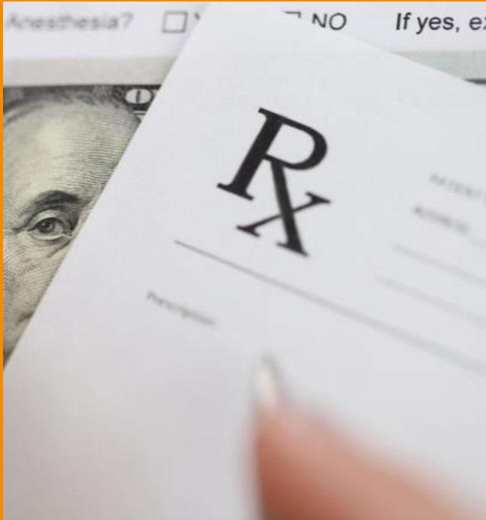
Assessment Question #1



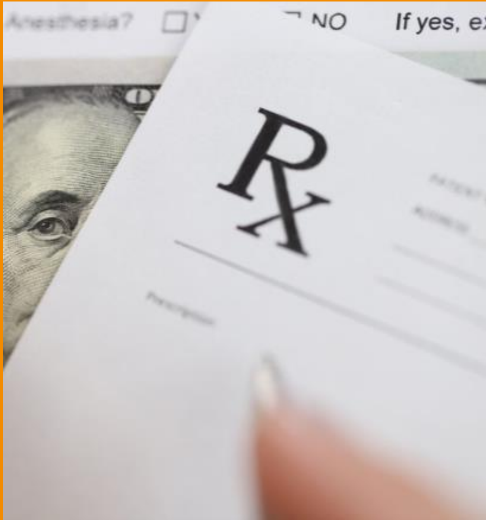
Which of the following is a rationale to convert a clinic to a hospital-based department?

A. Maintain or improve performance in risk-based contracts

B. Provide more consistent guidance & experience for infusion options

C. 340B opportunity

D. All of the above



Answer: Question # 1

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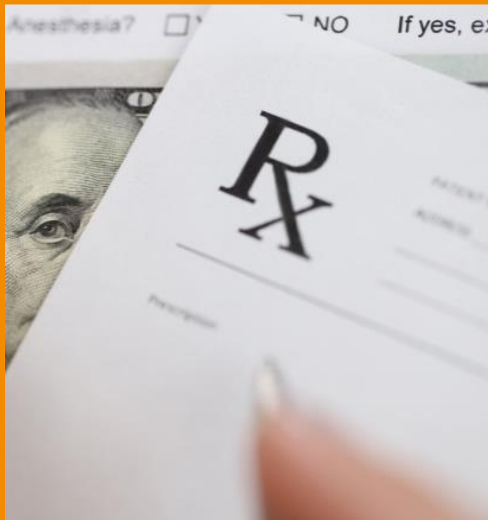
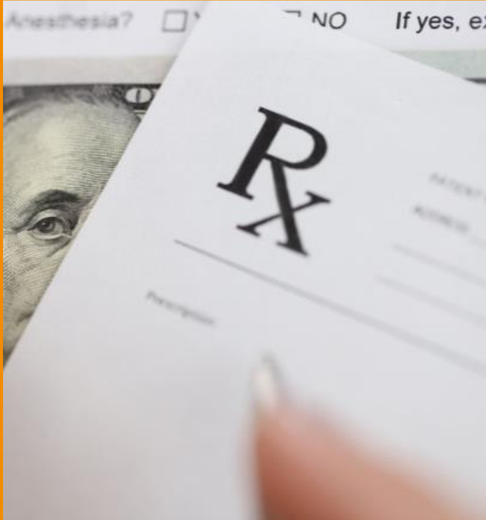
Assessment Question #2



Which of the following aspects should be considered regarding billing when converting from a clinic to a hospital-based department?

A. Potential hybrid billing setup
B. Impact to patient 's out of pocket
C. Flow of expense and revenues to the MCR
D. All of the above

Answer: Question #2



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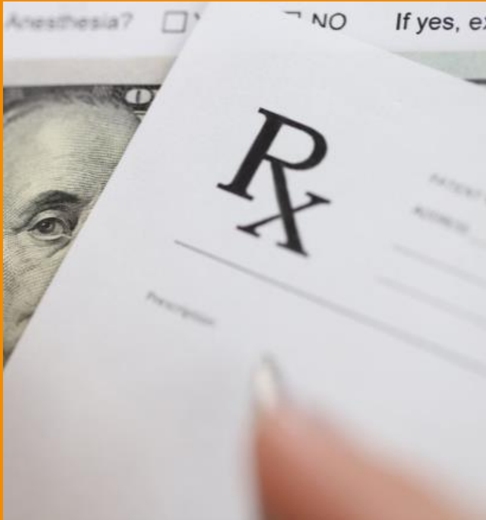

Following HRSA's current guidance on 340B child site registration requirements, how long may it take for a newly converted HOD location to have 340B eligibility?

A. Up to 22 months

B. Next Quarter

C. 1 month

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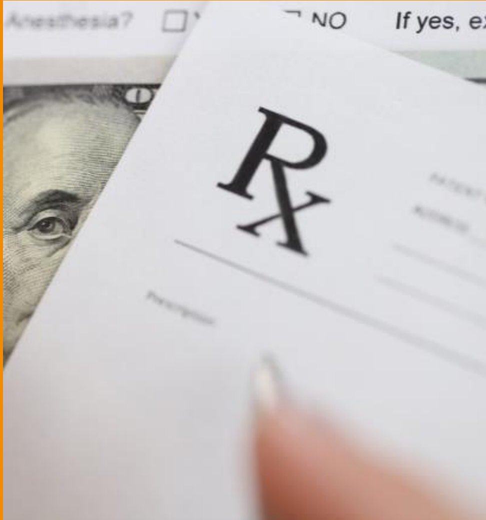
Answer: Question #3



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References

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