Oregon HFMA Winter Conference

Salem, OR

February 16, 2012

Macro Helix
Turning R_x into ROI

Meeting Agenda

- 340B Overview
- Applying for 340B
- Audit and Compliance Considerations
- Optimization/Savings Enhancements
- Contracted Retail Pharmacy
- Contact Information

Macro Helix
Turning R_x into ROI

340B Program Overview

- The 340B drug discount program is a section of the Veterans Health Care Act of 1992 which requires pharmaceutical manufacturers whose drugs are covered by Medicaid to provide discounts on outpatient covered drugs purchased by specific public health services and government-supported facilities (called covered entities) that serve the nation's most vulnerable patient populations.
- Qualified hospitals (DSH, CAHs, RRCs, and SCHs) can receive discounts based on the utilization of pharmaceuticals by covered outpatients. Retrospective procurement is used to realize the discounts based on this utilization.
- The program is administered by the Office of Pharmacy Affairs ("OPA"). The OPA and drug manufacturers have the right to conduct compliance audits of participating facilities. A clear audit trail must be created to remain in compliance with the regulations of the program.

Macro Helix
Turning R_x into ROI

Eligible Hospitals

340B participation is limited to only certain non-profit and government affiliated hospitals.

DSH Hospitals – traditional acute care hospitals that can demonstrate a DSH Adjustment Factor greater than 11.75% on the most recently filed Medicare Cost Report.

Children's Hospitals – pediatric hospitals with a 3300-series Medicare provider number that can perform a DSH calculation based on worksheet S-3 and demonstrate a result greater than 11.75%.

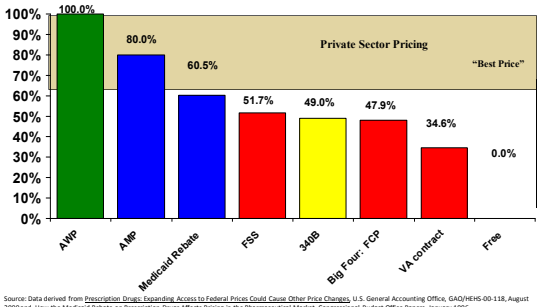
Sole Community Hospitals – hospitals with Sole Community designation that can demonstrate a DSH Adjustment Factor greater than 8.0% on the most recently filed Medicare Cost Report.

Rural Referral Centers – hospitals with Rural Referral Center designation that can demonstrate a DSH Adjustment Factor greater than 8.0% on the most recently filed Medicare Cost Report.

Critical Access Hospitals - All Critical Access Hospitals, regardless of DSH values.

Macro Helix
Turning R_x into ROI

340B Pricing



Source: Data derived from Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes, U.S. General Accounting Office, GAO/HEHS-00-118, August 2000 and How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Market, Congressional Budget Office Papers, January 1996.

340B Pricing

- The 340B price cannot exceed AMP minus the Medicaid "rebate percentage"
  - Brand Name 340B Price: Lower between (AMP – 15%) & best price
  - Generic 340B Price: (AMP – 11%)
  - Actual calculations are not publicly available
- 340B discount is an average of 20-30% off of typical GPO pricing
  - 49% discount off of AWP
- Drug manufacturers that participate in the Medicaid Program are required to offer 340B pricing
- Apexus (340B Prime Vendor) negotiates sub-ceiling prices
- Inpatient pricing is available, but not mandated

Macro Helix
Turning R_x into ROI

340B and the Medicare Cost Report

The Medicare Cost Report plays a critical role in determining 340B eligibility and cost savings.

Eligibility – for non-CAH hospitals, Worksheet E, Part A line 4.03 identifies the DSH Adjustment factor. Hospitals must demonstrate a DSH Adjustment factor of greater than 11.75% for DSH hospitals or greater than 8% for SCH and RRC hospitals.

Qualified Locations – once enrolled, 340B drugs can only be used in reimbursable cost centers as determined by Worksheet A. Retail pharmacy prescriptions are qualified for 340B if they relate to care provided to the patient in a reimbursable cost center on Worksheet A.

Page 7

Macro Helix *Turning R_x into ROI*

Applying for 340B

Hospitals applying for 340B status must submit the following documents:

1. 340B Registration Document
   - Identifies hospital name and location
   - Point of contact
   - DSH Adjustment factor or other eligibility criteria
   - Medicaid billing status
2. Group Purchasing Organization non-Participation Agreement (not applicable for CAHs)
   - Effectively makes 340B an "all or nothing" program
   - Any non-340B outpatient drug procurement must occur at WAC pricing
3. Outpatient facility registration
   - Required for off-site locations
   - Optional for points of patient service at the same physical address as the main hospital
4. Indigent Care Agreement Attestation (not applicable for government owned facilities)
   - Must be signed by hospital and public official
   - Submission of the actual agreement is not required
5. DSH Adjustment Factor Verification (not applicable for CAHs)
   - Worksheet E, Part A; or
   - An official document from Dept. of HHS
   - An independent auditor's statement of the calculated DSH factor

Page 8

Macro Helix *Turning R_x into ROI*

340B Patient Definition

An individual is a "patient" of a covered entity, and eligible for 340B drugs only if:

- the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
- the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity;
- An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting;

Page 9

Macro Helix *Turning R_x into ROI*

340B Patient Definition (in plain English)

In order for a patient to be eligible for 340B in a hospital setting they must:

1. Be an outpatient at the time the drug is administered.
2. Receive the drug in a reimbursable cost center on Worksheet A.
3. Receive the care from an employed or contracted clinician.
4. Have a record at the hospital of the care provided.

In order for a patient to be eligible for 340B in a retail pharmacy setting they must:

1. Have received care from the hospital in a reimbursable cost center on Worksheet A.
2. The drug must be related to the care provided by the hospital (responsibility for the care)
3. Receive the care from an employed or contracted clinician.
4. Have a record at the hospital of the care provided.

Macro Helix
Turning R_x into ROI

340B Qualified Drug Utilization

- Drug must be administered to a qualified patient (per patient definition on previous slide)
- 340B is for outpatient use only
- Drugs must be administered in a hospital point of service that would qualify as a "reimbursable cost center" on a Medicare cost report
  - 100% hospital owned (i.e. joint ventures are not eligible)
  - Non-profit (i.e. for profit subsidiaries are not eligible)
  - Same tax ID number as the hospital
- Outpatient facilities (Physician clinics, surgery centers, etc.)
  - Ownership of inventory
  - Proximate relationship
  - Employed Physicians

Macro Helix
Turning R_x into ROI

340B in Operation

- Hospital must file application for 340B status with the Office of Pharmacy Affairs
  - New hospitals are admitted to the 340B at the beginning of each quarter
- Separate 340B account(s) is established with existing drug wholesaler
  - Purchasing system remains the same
  - New account contains 340B prices
    - "Cost Minus" is applied to 340B purchases
- Pharmacy Buyer purchases eligible drugs on 340B account and all other drugs on GPO account
- Wholesaler delivers drugs from both purchase orders
  - Separate invoices for each account
- Drugs purchased direct from a manufacturer can be obtained at 340B prices
- No need for separate inventory if tracking system is in place

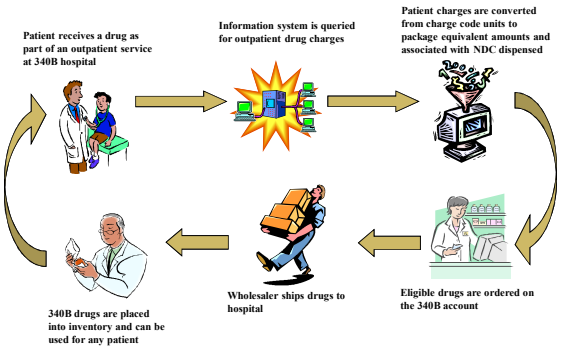
Macro Helix
Turning R_x into ROI

Tracking Requirements

- Hospital must be able to prove that the drugs purchased on the 340B account were administered to an outpatient in an eligible point of service
- Patient level detail
- Identify qualified patients
  - Patient Type, Status, and/or Point of Service
- The 340B program should be implemented in all qualified outpatient points of service
  - Both "Mixed" & "Clean" areas
- Two options:
  - Separate 340B Inventory
  - Retrospective Purchasing

Macro Helix
Turning R_x into ROI

340B Virtual Inventory Process



Factors that Affect 340B Savings

- Drug Usage/Product Mix
- Provider Based Point of Service Requirements
- Medicaid Billing Requirements
- Direct Contracts and Nominal Pricing
- Formulary Management
- Outpatient and Inpatient Mix
- Data System Capabilities
- Others

Macro Helix
Turning R_x into ROI

Orphan Drug Exclusion

Orphan drugs are defined by the FDA as a medications used to treat diseases that occur rarely (less than 200,000 cases) or where is no hope for recovery of development costs, so there is little financial incentive for industry to develop them.

Orphan drugs are controlled by the FDA's Office of Orphan Products Development (OOPD).

Currently the orphan drug list contains over 300 different medications including some well know therapies:

- Avastin – $6.5B annual sales
- Botox - $1.3B annual sales
- Neupogen - $1.4B annual sales
- Novoseven - $1.3B annual sales
- Rituxan - $5.7B annual sales
- Remicade - $6.0B annual sales

NOTE: Annual sales estimated from company financial reports and other publicly available data
Orphan Drug listing can be searched at: http://www.accessdata.fda.gov/scripts/opdlisting/oopd

Macro Helix
Turning R_x into ROI

Orphan Drug Exclusion

The Health Reform Reconciliation Bill specifically excludes Orphan Drugs from 340B "covered outpatient drugs" for entity types granted 340B status as a result of the Health Reform Legislation.

For newly eligible entity types, 340B savings can be affected by 20% to 60% as a result of the inability to realize cost savings on orphan drugs.

Proposed regulations will mitigate the impact of the orphan drug exclusion by:

- Permitting orphan drug purchases on 340B for patients treated for a non-orphan disease (i.e. Remicaide for use with rheumatoid arthritis)
- Prohibiting orphan drug purchases on 340B for patients treated for the orphan disease (i.e. Remicaide for Chrohn's disease)

Macro Helix
Turning R_x into ROI

Medicaid and 340B

The legislation that created 340B specifically exempts a pharmaceutical manufacturer from having to provide a 340B price to a provider and a rebate to a Medicaid program on the same transaction.

- Most state Medicaid programs including Iowa and Nebraska now require providers to bill for outpatient drugs using both the applicable HCPCS code and the actual NDC administered to the patient.
  - NDC billing is mandated for all Medicaid programs by the Deficit Reduction Act of 2005
- State Medicaid programs are collecting the NDC information for outpatient drugs to facilitate rebate collection from pharmaceutical manufacturers.
- In most states, providers are required to either carve-out Medicaid or adjust billing to reflect actual 340B acquisition cost.

Macro Helix
Turning R_x into ROI

Audit Process and Regulations Overview

Macro Helix
Turning R_x into ROI

Audit Trail

All participating hospitals **MUST** maintain an audit trail for **ALL** 340B purchases. Data required for the audit trail includes:

- 340B purchase history
- GPO purchase history
- Patient billing records including patient classification (IP/OP)
- List of eligible points of service and DSH Adjustment factor calculation
- Specifications used to define outpatient utilization query
- CDM to NDC Crosswalk
- Policies and Procedures

All 340B enrolled entities agreed to be subject to audits at the time that they joined the program. Audits can be requested by the Office of Pharmacy Affairs **AND** by pharmaceutical manufacturers.

Macro Helix
Turning R_x into ROI

Key Compliance Risks

340B has been added to the OIG work plan and the OIG has issued several memos discussing the need for additional regulation of the 340B program.

As a result of ballooning 340B enrollment, pharmaceutical manufacturers have seen revenue erosion on many drugs.

Key compliance risks associated with the 340B program include:

- Diversion
- Over purchasing of 340B drugs
- Cherry picking
- Lack of audit trail
- Failure to identify qualified vs. non-qualified patients
- Failure to identify qualified vs. non-qualified points of service
- Inadequate CDM to NDC crosswalk maintenance

Macro Helix
Turning R_x into ROI

Ensuring Long-Term 340B Compliance

1. Convene key stakeholders periodically to review 340B in the larger context of your organization.
2. Establish regular maintenance of 340B data, CDM-NDC crosswalk.
3. Don't over rely on 340B split billing software. All 340B software requires validation and end-user input.**
4. Regularly review 340B savings compared to overall drug spend and patient volumes. Investigate any divergence in savings and patient volumes.
5. Approach IT system changes and wholesaler/GPO changes carefully.
6. Monitor changing regulations at the federal and state levels. Watch your Medicaid program's rule carefully.

Macro Helix *Turning R_x into ROI*

Recertification Process

The Office of Pharmacy Affairs has begun sending advance notices of required recertification of 340B eligibility to participating 340B entities.

The actual recertification process will occur annually starting in the Spring of 2012 and will incorporate:

- Emailed recertification instructions. Emails will be sent to the registered contact person(s) on the Office of Pharmacy Affairs entity database.
- Provider confirmation/attestation of continued eligibility for 340B participation.
- Online submission with possible hard copy submission of supporting documentation.
- Disenrollment for providers failing to respond or unable to demonstrate continued 340B eligibility.

To prepare for recertification, 340B entities should:

1. Ensure OPA contact information is up-to-date.
2. Validate that all locations are registered and Medicaid carve-in/out option is accurate.

Macro Helix *Turning R_x into ROI*

340B Program Audits

340B Program audits have been discussed continuously for many years, however, with the program's expansion, it appears that audits will start to occur in 2012. Audits can come from two sources:

1. Office of Pharmacy Affairs – areas of focus likely to include:
   - Program Eligibility Confirmation
   - Medicaid Duplicate Discount Verification
   - Eligible vs. Ineligible Site Identification and Segregation
   - GPO Exclusion Compliance (as applicable)
2. Drug Manufacturers – area of focus likely to include:
   - Drug specific tracking, accumulation, and replenishment
   - Eligible patient/Eligible prescription identification
   - Inpatient/Outpatient segregation including out to in conversions
   - NDC to NDC replenishment

Macro Helix *Turning R_x into ROI*

Optimizing 340B Savings

Macro Helix
Turning R_x into ROI

Tips and Tricks

Long term 340B maximization is a continuous process. A well run 340B program will:

1. Maintain adequate audit trails for manufacturer or OPA inquiries
2. Increase 340B savings year-over-year in conjunction with volume growth and price inflation
3. Leverage 340B pricing in retail, home care, and niche areas
4. Incorporate pharmacy leadership into managed care contracting processes and utilize 340B where appropriate as a mechanism to drive other volumes into the hospital
5. Seek additional cost savings and revenue enhancements each year
   - Physician recruitment and retention
   - Strategic expansion and partnerships
   - Coordination of care with state and local agencies

Macro Helix
Turning R_x into ROI

Most Commonly Overlooked 340B Opportunities

The most commonly overlooked 340B opportunities include:

- Direct purchases – as a 340B entity, you are entitled to 340B pricing regardless of the vendor
- Non-pharmacy purchases – blood bank, central supply, radiology, etc.
  - Albumin, Factors, Suprane, Magnevist, Tisseel, etc.
- Bundled charges – gases, kits, contrast media, etc.
- Take home, indigent drugs, and no-charge items – floor stock, ER take-home packs, indigent patient drug programs, etc.
- Non-pharmacy charge codes – drugs purchased by pharmacy but billed using a non-pharmacy CDM code.
- Off-site provider-based settings – seasonal clinics, travelling nursing stations, other clinics
- New drugs, misc. drug code items
- O/P to I/P conversions – emergency department, cath lab, surgery, etc.
- "Inpatient DSH" pricing (as applicable)
- Drug selection based on new pricing structure – brand name items may provide the lowest price in certain categories

Macro Helix
Turning R_x into ROI

Recommendations for Long-Term Optimization

1. Conduct annual review/planning meetings including pharmacy, finance, reimbursement, internal audit, administration, and other relevant stakeholders.
2. Incorporate 340B into the hospital's internal audit work plan.
3. Validate the maintenance of the CDM to NDC crosswalk. Perform random testing and validation monthly.
4. Review 340B savings monthly and report to administration quarterly. Identify and investigate trends and anomalies.
5. After any system change (new wholesaler, information system, billing process, etc.) evaluate the impact on 340B processes and savings.
6. Validate utilization data sources and queries each year.
7. Review legislative changes no less than every year.

Macro Helix *Turning R_x into ROI*

Cost Savings in Retail Pharmacies

Macro Helix *Turning R_x into ROI*

340B Regulatory Requirements

- All 340B enrolled entities are entitled to utilize 340B at all pharmacies and patient care areas that appear on the Medicare Cost Report as reimbursable cost centers.
  - Includes central, satellite, home care, retail, and other pharmacies
- All enrolled entities are further permitted to utilize contract pharmacies which act as the covered entity's agent in the dispensing of 340B drugs.
  - The contract pharmacy agreement must:
    - Identify the specific pharmacies (physical addresses) covered by the contract
    - Incorporate a "bill-to-ship-to" arrangement where the covered entity retains responsibility for payment for 340B inventory
    - Clearly define the fee structure and avoid paying the contracted pharmacy on the basis of individual patient profitability
    - Hold both parties responsible and liable for any non-compliance with 340B regulations

See Federal Register Vol. 61, No. 165, 8/23/96, Pg. 43549 – 43556
Vol. 75, No. 43, 3/5/10, Pg. 10272 - 10279

Macro Helix *Turning R_x into ROI*

Operationalizing a 340B Contract Pharmacy

- The most common type of retail pharmacy is the "Open Door" variety which means they fill all valid prescriptions
- 340B in this type of pharmacy requires a two part test on all prescriptions:
  1. Did the customer in the pharmacy receive a health service from the 340B covered entity within the preceding 12 months?
  2. Was the health service proximal to the prescription filled?

     (i.e. a hospital chest pain patient filling a blood pressure medication would be deemed qualified whereas the same patient filling a prescription for a skin rash would not because the prescription isn't proximal to the service provided by the 340B hospital)
- Refill and referral prescriptions can be eligible (Morford Letter)
- 340B inventory must be invoiced to the enrolled hospital
- Revenue pass through and dispensing fees must be calculated, tracked, and paid per the contract terms

Macro Helix *Turning R_x into ROI*

Benefits of a Contract Retail Pharmacy

- Prescriptions are filled in the usual manner

  340B use is invisible to customers
- Reimbursement is unaffected for non-Medicaid prescriptions

  Medicaid is subject to rebate/duplicate discount limitations or carve-out for 340B inventory only
- Cost savings can be achieved for all qualified patients

  Opportunity for win/win with local pharmacies
- Cost savings is realized and revenue is received by the hospital without any additional investments in personnel, equipment, or infrastructure

Macro Helix *Turning R_x into ROI*

Inventory Management Options

Inventory management in an open-door retail environment can be structured in one of three ways:

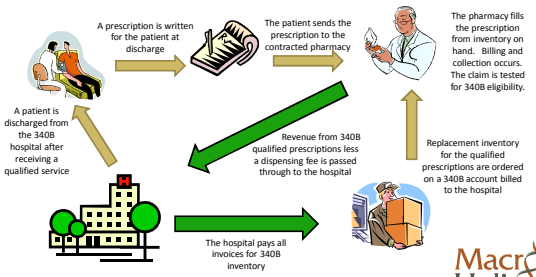
Virtual Replenishment Inventory – prescriptions are filled using existing stock, 340B eligibility is determined after dispense and replacement inventory is ordered on the 340B account.

Separate Inventory – prescriptions are filled from one of two inventories. Pharmacy staff determine 340B eligibility at the time of dispense and select the correct inventory to utilize for the prescription.

Specialized/Custom – inventory processes can be adapted to mail order, central fill, specialty drug, shared stock, or other needs as necessary.

Macro Helix *Turning R_x into ROI*

Retail Pharmacy Inventory Process



Macro Helix
Turning R_x into ROI

Contract Pharmacy from the Pharmacy's Perspective

The biggest challenge associated with 340B from the retail pharmacy's perspective is inventory management.

- Inventory "swell" is a common occurrence due to the replenishment model used with most contract pharmacies.
  - Consider split-billing when possible.
  - Integrate 340B ordering into existing perpetual processes (i.e. CIM, etc.)
  - Pro-actively return excess inventory whenever possible.
- Understand the impact of 340B on cash flow and coordinate in advance with your 340B entity partner.
  - Plan for initial payments to the hospital to be spread over a period of time.
  - Regularly purchase C2's on 340B when possible.
  - Consider smaller package sizes when appropriate (especially for oral solid generics)

Macro Helix
Turning R_x into ROI

Example Prescription

Stand Alone Pharmacy:	
Prescription Reimbursement:	$50
Pharmacy's Ingredient Cost:	$41
Pharmacy Margin:	**$9**
Hospital Revenue:	$0
Hospital's Ingredient Cost:	$0
Hospital Margin:	$0
Total System Margin:	**$9**

Contracted Pharmacy Structure:	
Prescription Reimbursement:	$50
Pharmacy's Ingredient Cost:	$0
Dispensing Fee Received	$14
Pharmacy Margin:	**$14**
Hospital Revenue ($50 less $14):	$36
Hospital's 340B Ingredient Cost:	$26
Hospital Margin:	$10
Total System Margin:	**$24**

Macro Helix
Turning R_x into ROI

Compliance Considerations

340B use in a retail pharmacy has a heightened risk of non-compliance. Specific areas of concern include:

1. Misidentification of 340B eligible prescriptions
2. Inaccurate 340B ordering and/or drug diversion
3. Medicaid over-billing

Manufacturer inquires were increasingly common in 2011. We have observed manufacturers investigate:

1. Patient definition interpretation and enforcement
2. Medicaid rebate vs. 340B duplicate discount
3. Facility eligibility
4. Retroactive savings recovery objections

Macro Helix
Turning R_x into ROI

Appendix

Macro Helix
Turning R_x into ROI

340B Links

- The Office of Pharmacy Affairs' website for the 340B program.
  - www.hrsa.gov/opa/
- The Office of Pharmacy Affair's Covered Entity Database. The database contains all of the entities participating in the 340B program.
  - http://opanet.hrsa.gov/opa/CE/CEExtract.aspx
- The Safety Net Hospitals for Pharmaceutical Access.
  - www.safetynetrx.org
- Prime Vendor Program managed by Apexus.
  - www.340bpvp.com/home.asp

Macro Helix
Turning R_x into ROI

Contact Information

Julie Crozier
(972) 333-5028
jcrozier@macrohelix.com

Macro Helix
Turning R_x into ROI