Nebraska Hospital Association 340B: The Program, The Environment, A Solution

May 2014



The contents of this presentation are confidential and proprietary to SUNRx, Inc. and may contain material MedImpact considers Trade Secrets. This presentation may not be reproduced, transmitted, published or disclosed to others without SUNRx's prior written authorization.

Background: SUNRx

- Wholly Owned Subsidiary of MedImpact Healthcare Systems, Inc.
- A Leader in 340B, Serving More Than 160 340B Covered Entities
 - Federally Qualified Health Centers (FQHC)
 - Disproportionate Share Hospitals (DSH)
 - Critical Access Hospitals (CAH)
 - Sole Community Hospitals (SCH)
- Solely Dedicated to Maximizing the 340B Contract Pharmacy Model
- An Independent Company
 - No binding ties to wholesalers or chain pharmacies
 - No mail-order pharmacy ownership
- Nationally Recognized
 - 22 State Hospital Associations Preferred 340B Provider

Agenda

- 340B Overview and Environment
 - Defining 340B
 - Current Market Perspective
 - Regulatory Insight and Requirements
- Establishing a Solution

Defining 340B

• Created in 1992 to:

- Expand access to affordable medications for low-income populations
- Enable hospitals to manage savings to better serve the uninsured population

• Eligibility:

- Entities (must be non-profit)
 - Critical Access Hospitals, Federally Qualified Health Centers, Disproportionate Share Hospitals, Critical Access Hospitals, Children's Hospitals and others
- Medications
 - Outpatient drugs only
- Patients
 - Only patients of covered entities

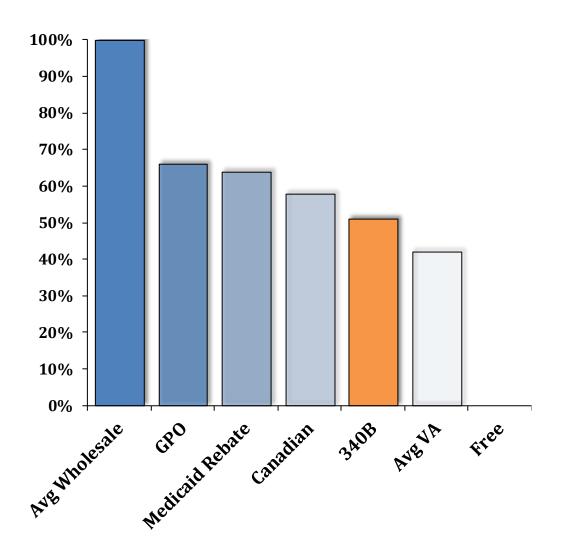
• Oversight Responsibility:

- Health Resources and Services Administration (HRSA)
 - Office of Pharmacy Affairs (OPA)

340B Program Overview

On average, 340B pricing is:

- 51% Lower Than AWP
- 39% Lower Than AMP
- 15% Lower Than GPO



340B: Current Market Perspective

340B Models

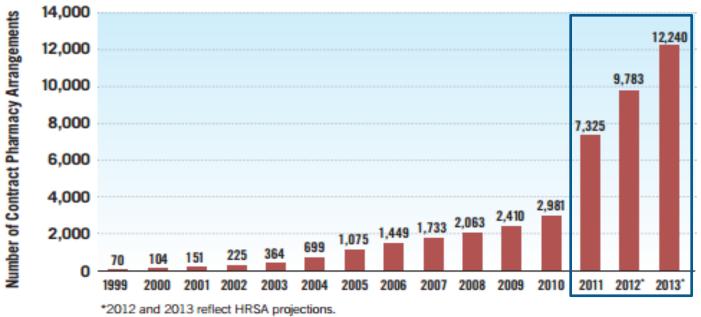
- Contract Pharmacy
 - 340B Administrator Model—Virtual Inventory (i.e., SUNRx)
 - Chain Pharmacy Model (i.e., Walgreens)
- Split Billing (i.e., e-Audit, Sentry, Talyst, MacroHelix)
- Split Billing/Contract Pharmacy (i.e., SUNRx)

Pharmacy Participation

- National Chain Pharmacies (i.e, WAGS, CVS, Rite Aid)
- Regional Chains (Hy-Vee)
- General Merchandising/Food Chains (Walmart, Kroger, HEB, Safeway)
- Independent Pharmacies (including independent chains)

Current Market Perspective: Growth of 340B

Growth in 340B Contract Pharmacy Arrangements, 1999–2013 (as of July of Each Year)



Source: Avalere Health analysis of HRSA 340B contract pharmacy arrangements files.

• This Growth has spurred recent Congressional Scrutiny

- Want assurances that the program continues to meet its original intent
- That contract pharmacies have appropriate oversight

340B: Current Market Perspective

Compliance Approach and Adherence

- Overall responsibility for compliance resides with Covered Entity
- Inconsistency amongst 340B Administrators
 - Program Offerings
 - Fee Schedules
 - Pharmacy Relationships
- Audit Reviews Increase
 - 131 in 2013
 - Findings reported on 51
 - Focus on ensuring the prescription is an "eligible script"
 - Provider Panels
- Manufacturer audits increase
 - Ensure the program is running in accordance with "intent"
- Awaiting "Mega Re-Write"

340B Compliance and Regulatory

© 2014 SUNRx, Inc. All rights reserved.

Regulatory Insight and Environment

- Hospital Eligibility
- Patient Eligibility
- Regulatory Topics
 - Managed Medicaid
 - Facility Registration
 - Program Audits
 - GPO and Orphan Drugs
- 340B Market Conditions

Hospital Eligibility

Covered Entity Type	Non-Profit, Government Contract	DSH Percentage	GPO Exclusion	Orphan Drug Exclusion
DSH Hospitals	Yes	> 11.75%	Yes	No
Critical Access Hospitals*	Yes	No	No	Yes
Children's Hospitals*	Yes	>11.75%	Yes	No
Sole Community Hospitals*	Yes	>8%	No	Yes
Rural Referral Centers*	Yes	>8%	No	Yes

* Added by the Affordable Care Act

Patient Definition

- HRSA Patient Eligibility
 - The covered entity has established a relationship with the individual, such that:
 - 1. The entity <u>maintains records</u> of the individual's health care
 - 2. The prescriber is either <u>employed</u> by the covered entity OR
 - 3. The prescriber provides health care under <u>contractual or</u> <u>other arrangements</u> (e.g., referral for consultation)
 - 4. The <u>responsibility for the care</u> remains with the covered entity
 - Outpatients Only
 - Excludes Fee For Service Medicaid

Managed Medicaid

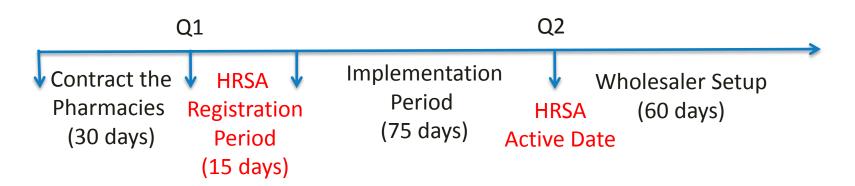
- Two regulations applicable to Managed Medicaid:
 - 1. 340B Regulation
 - Entities must not use 340B for any claim subject to a Medicaid rebate
 - Entity must establishes an arrangement with the state to prevent duplicate discounts
 - 2. Affordable Care Act
 - ACA 2010 gave rebates to States for Managed Medicaid claims
 - Excludes 340B from rebates
 - States are responsible to develop a method to exclude rebates for 340B drugs
- Recommendation
 - Since the burden is on the States to exclude 340B from rebates, entities should contact their states to discuss how to ID 340B claims for rebate purposes
 - Document all conversations with States or Medicaid MCOs

340B Facility and Pharmacy Registration

- HRSA registration periods:
 - New covered entities
 - Off-site facilities
 - Contract pharmacies



Implementation Timeline



150 days Minimum (Up to 210 days)

340B Oversight

- HRSA Audits
 - HRSA conducts audits to assure entities are:
 - Preventing diversion of 340B Drugs (use only for eligible patients)
 - Preventing duplicate discounts (Medicaid rebate + 340B discount)
 - Maintaining readily auditable records
 - Adhering to the GPO and Orphan Drug Exclusions
- Internal Audits
 - HRSA expects entities to perform annual "independent" 340B audits
 - Self Audits—random audits of contract pharmacy claims
 - Self-Reporting of program violations to HRSA
- Annual Facility Recertification—Entities should:
 - Assure that their contacts are up to date on the HRSA website
 - Make sure their OP facilities are registered with HRSA
 - Facilities are on their Medicare Cost Report
 - Contracts are in place and annual audits are conducted

GPO and Orphan Drug Exclusion

• GPO Exclusion

- DSH and Children's Hospitals may NOT purchase any outpatient drugs through a GPO (may use either 340B or WAC for outpatients)
- DSH hospitals must have a split billing system for in-hospital administration
- Orphan Drug Exclusion
 - Cannot use 340B if the use was for the "original orphan diagnosis"
 - Applies to Critical Access, Sole Community and Rural Referral Hospitals
 - Must have a tracking system in place
 - Entities can opt-in or opt-out of using 340B for orphan drugs

340B Market Conditions in 2014

• <u>Factor 1:</u> Impact of the Affordable Care Act

 Insurance Exchanges have underperformed expectations. It is expected that as many as 40 million will remain uninsured.

• Factor 2: Safety Net System Impact

- Reimbursement remains poor for Medicare and Medicaid. Access to participating providers will be difficult—driving patients to safety net facilities such as DSH hospitals.
- 2015 federal budget increases reimbursement to community clinics and become more limited for specialty care.

• Factor 3: HRSA "Mega Reg"

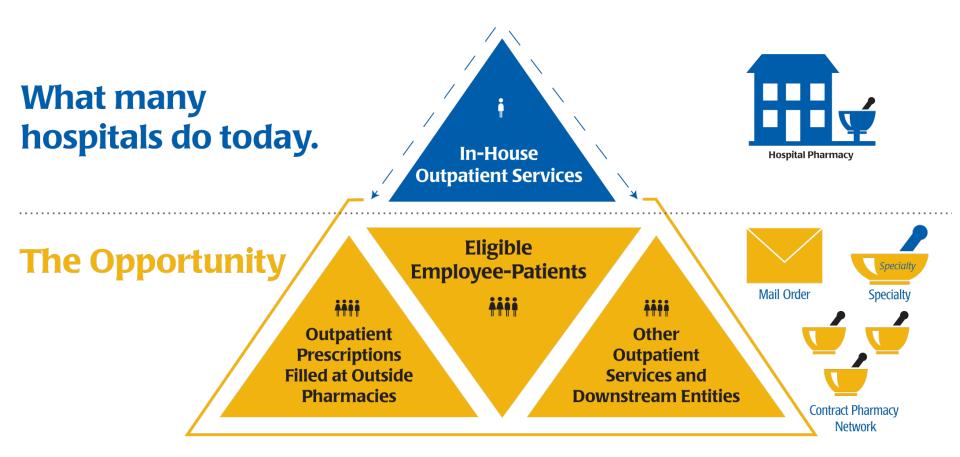
 Widely expected that clarity will be provided surrounding the patient definition, rebates, use of economic benefits, variable dispensing fees, and penalties for violation.

• <u>Conclusion:</u>

- Continued expansion of the 340B industry
- Regulatory clarity coming from the re-write.

Establishing a Solution

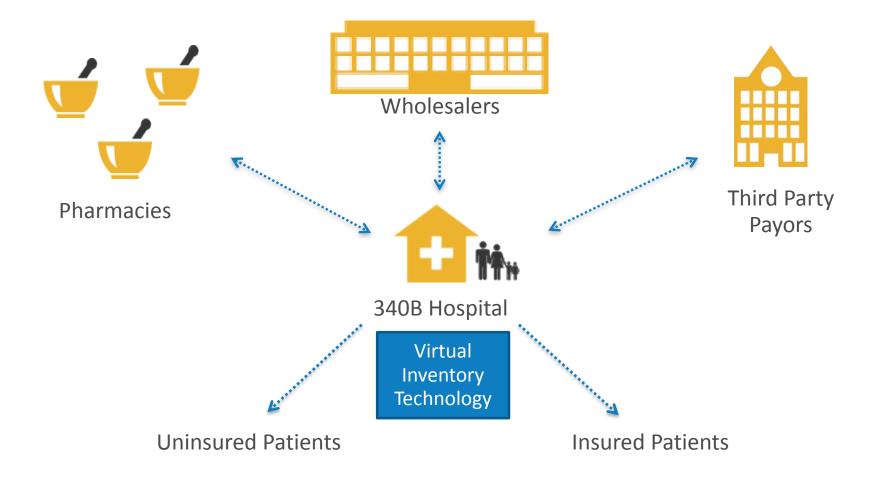
The Hospital 340B Opportunity



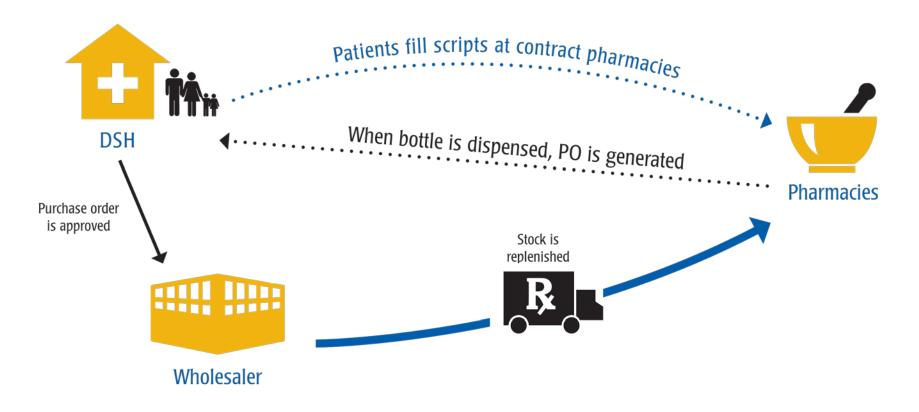
Contract Pharmacies

- Hospitals may set up a contract pharmacy network to serve their patients:
 - Contract pharmacies (all types) supplement your outpatient pharmacy
 - Keep outpatient prescriptions "within the system" that are now being "lost to the community"
 - Convenient pharmacy locations to expand access to the uninsured
 - Working with a pharmacy chain will create efficiencies and greater access
- Pharmacy Contracts
 - Serving both cash and third-party patients
 - Paid a dispensing fee (prefer fixed), and drugs are "replenished" by the hospital (bill-to, ship-to)
 - Strict diversion and inventory control management

340B Program Development and Setup



340B Virtual Inventory



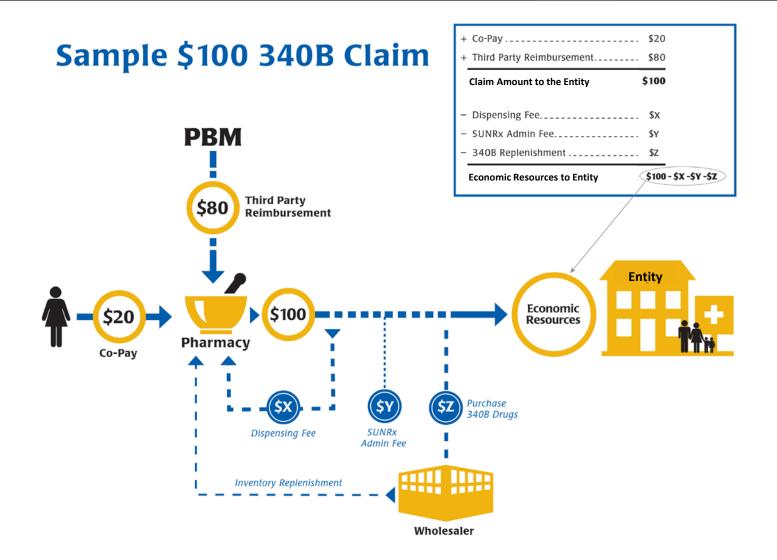
Cash Solution for Uninsured Patients

- Issue 340B prescription cards
- Real-time adjudication
- Determine patient eligibility
- Calculate "lowest price" patient copay
- The Lowest Price...Every Time



• Fact: For nearly 50% of prescriptions 340B is NOT the lowest available price

Third Party Example



Monitoring and Compliance

- Every transaction should be tracked, creating a fully auditable records:
 - Eligibility
 - Medication dispensing history
 - Reversals, re-bills
 - Replenishment orders
 - Pharmacy Receipts

Compliance Reporting

	ventory System					Sector Street Street	in: Virtual In					Profile Lo	
Manage Users	Health Cent	er Pharmacy	Order Manag	pement	Forms	slary Men	sher Enrolling	test.	Inventory 8	tanagem	ent b	ovoices R	ep
Virtual Invent	ory Status												
and a set of the			Health Cen	ter Al				+					
			Locat	ion Al				Ψ.					
			-	Ky Al				20					
			PTARTIN	KY M									
			Sealth	By -Se	sect-				00				
	NDC11	Drug Name	Brand Name	Strengt	h Packi Size	age Trippe 96 Sold		No. Units Sold	HC Inventory	No. On Order	Status	Option	
	00002324030	CYMBALTA 30 HG CAPSULE	CYMBALTA	30 mg	30	80	84		60	60	Pending	Xiew	
	00002751201	HUMALOG MEX. 50/50 VSAL	HUMPHLUG MLA	100 unit/mil (50-50)	10	SUN							
	00002821501	HUMULIN R 100	PERMAN A	100	10	815 East Gate Driv Suite 152				Phot	6: 856-910-777 8: 456-810-705		
			Support on Minist	limmer		Bourt Laurel, NJ 1 Bill Ter Family Hoath Center	Bit Fram: Thamacy			in	f perindja	Dete: 212008-1	215
al trendes Spiller Citizers Hudda Cont	r Planay	Onlar Kanapatai	Francis de Server		inder Dava	Bill Ter Family Health Cente 123 New Hey Austin, Til Contact Isano, Title	Bill Fram: Pharmacy 123 Did Ho Austa, TX			10		Date: 212008 -: non #	215
al investory System	r Plansky	Onler Kesupeni	it Termulary		inder Dava	Bill Ter Family Health Cente 123 Sees Hery Auster, Tit	Bill Fram: Pharmacy 123 Did Ho Austa, TX			100		Dale: 212008 -	275
al trendes Spiller Citizers Hudda Cont	r Banay	Huatth Centor	Tons Family Health Car	~	etter tive	Bill Ter Family Health Cente 123 New Hey Austin, Til Contact Isano, Title	Bill Fram: Pharmacy 123 Did Ho Austa, TX					Date: 212008 -: non #	215
al trendes Spiller Citizers Hudda Cont	а Рыныў	Huatth Consor (Jacattern		~	nder Lava	Bill Te: Family Houth Cente 123 Dees Hey Audin, Te Contact Hame, Tele Contact Enrol Activ	Bill Fram: Pramacy 123 Del Hu Austo, TX	Cuer	19508			Date: 212008 -: non #	
al trendes Spiller Citizers Hudda Cont	r Banay	Huatth Centor	Teas Fanily Hadb Car Snithulis Wederal Circe	~	etter tive	Bit Ter Panity Houth Cente 12) Inee Hey Auste, Te Contact Isane, Tele Contact Deal Adde	Hil Franc Phomacy 123 Del His Austin, TX	(Desc	19804			Date 21000-1 ech X Para Fac Total	
al innology System Clarety Huddh Court	о Рылых	Hatti Center Liccton Thintee/IC Cell	Teas Fanily Hadb Car Snithulis Wederal Circe	tu		Bit Te: Family Houth Cente 23 here Hays Auctor, Te Contact Enel Acov Contact Enel Acov	Bit Free: Paperagy 121 Del His Auste, TX mil Bitty Scale Dependent Bitty Scale Dependent Bitty Scale Dependent Bitty Scale Dependent	Deno 12 Toto 12 Feet Totot	19804			Date: 21000-1 min it There: Tex: 1000 1011 1 -011 1 -011 1	
al investing Spatian		Hatti Cator Gioton Thraevit Casa brog Nase	Teas Fanily Health Car Snithulis Michael Clinic Solitics	64 84		Bit Te Fanity Houth Center 103 New Hey Asala, Te Contact Lane, The Contact Lane, The	Bill Free: Parray 123 Del Hy Auste, TX Mill Stage Scale Despension Seguriting Yes Name	Const 12 Fee Strue	19804			Date: 21008-1 ech # Pare: Fac: 10000 1011	
el trendro Taplice el trens Bradita Cano Meropentic Clans Anti Julico Heroport Hope	ALS TO ME PROPER	Hatti Curtor (Jactori Thiraberdi Cala Shay Burke Kwattoric 13 H	Teas Fanity Hubb Cer Snithule Michae Dine Solies	iter Bere Leo	and Asses	Bit Te Fanily Houth Cente U2 See Hey Ande, TE Contact Lane, Tel Contact Lane, Tel Co	Bit Free: Paperagy 121 Del His Auste, TX mil Bitty Scale Dependent Bitty Scale Dependent Bitty Scale Dependent Bitty Scale Dependent	Const ng Tao ng Fao Taun ui	na			Date: 21000-1 min it There: Tex: 1000 1011 1 -011 1 -011 1	
etwenky tytes etwen insets Coor Hersprok Class Anti-scient Herspication	ITSTONE PLUS ITSTONE MUS	Hatti Cotor Uccon Thinkeyti Casa Brog Russ Averages 11 Suckeytitt 1	Teas Fanty Hult Cen Snitude Medica Cent Solici Solici Hult Smart History	der Ber Seit	Manual Constant	Bit Te Fanily Houth Cente U2 See Hey Ande, TE Contact Lane, Tel Contact Lane, Tel Co	Bit Free: Participation 12:04 Hr Auda, TX 12:04 Hr Auda, TX 12:04 Hole Auda, TX 14:04 Hole Auda, TX	Const ng Tao ng Fao Taun ui	na			Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
d Interley Typica e there therapeutic Class ANTI outtoe Horth Control ANTI outtoe Horth Control ANTI outtoe Horth Control ANTI outtoe Horth Control ANTI outtoe Horth Control	ntstown mens thstown mens thstown mens	Halft Cartor Lactor Transecht Case Brog Bare Koldtacht 15 Buckechter 10	Tess Tanty Hub Ge Solntale Medica Close Solice Soli	for No Sol Sol	Inter Love	Bit Te Fanily Houth Cente U2 See Hey Ande, TE Contact Lane, Tel Contact Lane, Tel Co	Bit Free: Participation 12:04 Hr Auda, TX 12:04 Hr Auda, TX 12:04 Hole Auda, TX 14:04 Hole Auda, TX	Const ng Tao ng Fao Taun ui	na			Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
et trendrog Tipition et there therespecific Class Artify output interpropulations Artify output	ALSTONA, PALPS TESTONA, PALPS TESTONA, PALPS TESTONA, PALPS	Haatti Cantor Laccom Thenajevik Case Borug Bures Suckenster Li Buckenster Li Continents so	Teas Fanty Hubb Car Snithule Michae Cleor Soliton Soliton Soliton Soliton Soliton Soliton Soliton Soliton Soliton Soliton	14 14 15 15 15 15	enter Lovi enter Lovi	Bit Te: Family Hooth Center 123 Here Here Auction Tel Contact Lennes Tele Contact Lennes Tele Contact Lennes Addre Contact Lennes Addre 20 0 0 0 0 0 0 0 0 0	Bit Free: Themacy 120 Dit Hy Audit, TX Million Sector Secto	Const ng Foo ng Foo Down si Foo Rovers Foo Rovers	ngboe nai d	mary	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
d Investig Epities Libers Buddit Cool Therapyolik Class Anti-scole Anti-polar Teol Anti-scole Anti-polar Teol Anti-scole Anti-polar Teol Anti-scole Anti-polar Teol Anti-scole Anti-polar Teol Anti-scole Anti-polar Teol	NETONA PERS TESTENA PERS TESTENA PERS TESTENA PERS TESTENA PERS	нала Солог Сласния Титеречи Сава Колеторов II и Колеторов II и Солалияте со сонтаторов и Амерторов и	Tosso Family Haalth Car Sonthalle Medical Care - Soliton - Soliton	ar 20 50 50 50 50 50 50 50 50 50 50 50 50 50	Market Card	Bit Te Family Houth Cente 123 Inter Hary Acada, TE Contact Errol Actor Contact Errol A	Bit Free: Plasmacy 122 Del Hr Auda, TX mil integ Scali Dapers Helg Scali Dapers Helg Scali Dapers Helg Scali Dapers Helg Free Scales Helg Hart Dapers Helg Free Scales Helg Hart Dapers Helg Free Scales Helg Free	Const ng Foo ng Foo Down si Foo Rovers Foo Rovers	ngboe nai d	mary	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
et trendrog Tipition et there therespecific Class Artify output interpropulations Artify output	NEIDA, NER NEIDA, NER NEIDA, NER NEIDA, NER NEIDA, NER	Hatti Careo Goton Thread-ric Case Brog Bane Averages J Brock Francis Brock Francis Cast Topic Sea Average J	Towar Family Hauffs Car Sambali Macrae Clear Gallers Hanner Hanner Hanner Hanner Hanner Hanner Hanner Hanner Hanner	164 164 164 164 164 164 164 164 164 164	Market Card	Bit Ta: Tanky Houth Cent 10 Hear Hay And Contact Lanes. The Contact Lanes. The Contact Lanes. And 0 0 0 0 0 0 0 0 0 0 0 0 0	Bit Free: Parmay 12: 04 Hv Aven, TX mil Bit Commonweal Parman Bit Commonweal Parman P	Deen ng Poo Sove wi Foo Roven Foo Roven	ngboe nai d	mary	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
Herapach Class Herapach Class Ministry Build Caso Herapach Class Ministry	REIDAL PRIS TEEDAL HIM NUDAL HIM NUDAL HIM NUDAL HIM NUTAL HIM TEEDAL HIM	нала Салон (Асоло Тенареник Сана Клад Калон Алаградска Сан Санарания Алаградска Сан Санарания Алаградска Сан Санарания Алаградска Сан Санарания	Towar Family Haalth Car Sommalia Marcina Chem Soliton	164 164 164 164 164 164 164	of News Crimes Cover States of News Crimes Cover Crimes C	Bit Ta: Tanky Houth Cent 10 Hear Hay And Contact Lanes. The Contact Lanes. The Contact Lanes. And 0 0 0 0 0 0 0 0 0 0 0 0 0	Bit Free: Plasmacy 122 Del Hr Auda, TX mil integ Scali Dapers Helg Scali Dapers Helg Scali Dapers Helg Scali Dapers Helg Free Scales Helg Hart Dapers Helg Free Scales Helg Hart Dapers Helg Free Scales Helg Free	Deen ng Poo Sove wi Foo Roven Foo Roven	ngboe nai d	mary	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
d Intering Spates Charge Mudit Caso Heregenetic Class Antio GLER manipulations Antio GLER manipulations and Spates Antio GLER manipulations and Antio GLER manipulations and Spates Antio GLER manipulations and Antio GLER manipulations antio GLER manipulations antio GLER manipula	12/10/4, FM2/5 112/10/4, FM2/5 102/10/4, FM2/5 102/10/4, FM2/5 102/10/4, FM2/5 102/10/4, FM2/5 102/10/4, FM2/5	Hatt Cantor Gootan Threaden's Cast Bridg Rume Available Cast Bridg Rume Available Cast Cast Tools an Available Cast Cast Tools an Available Cast Cast Tools an Available Cast	Towar Family Haulth Car Sommalia Medicar Care Galace Rome Some Rome Some Rome Some Rome Rome Rome Rome Rome Rome Rome R	No No Sic Cit No Sic Cit No Sic Cit No Sic Cit No Sic Cit No Sic Cit No Sic Cit No Sic Cit Cit Cit Cit Cit Cit Cit Cit Cit Cit		Bit Ta: Tanky Houth Cent 10 Hear Hay And Contact Lanes. The Contact Lanes. The Contact Lanes. And 0 0 0 0 0 0 0 0 0 0 0 0 0	Bit Free: Parmay 12: 04 Hv Aven, TX mil Bit Commonweal Parman Bit Commonweal Parman P	Deen ng Poo Sove wi Foo Roven Foo Roven	ngboe nai d	mary	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
Heropeck Class Heropeck Class Minopeck Class Minopeck Class Minopeck Class Minopeck Class Minopeck Class Minopeck Class Minopeck Class Minopeck Mi	NECTORAL PREPS TESTISMA, PARIS TESTISMA, PARIS TESTISMA, PARIS TESTISMA, PARIS TESTISMA, PARIS TESTISMA, PARIS TESTISMA, PARIS	Hatth Cantor (Jacom Thireperiy) Case (Hong Name Available 11 - Buckkning 11 (Case)Table 11 (Case	Towar Family Haath Car Seminalis Medica Care -Solice -Solice International Care International Care Internati	Nor Nor Sic Con Nor Sic Con Nor Con Con Con Con Con Con Con Con Con Con	A SALANT AND A SALANT A SALANT	Bit Te Pandy Index Center UD Inserting: Audio Té Contact Tanko Té Contact Tanko Ador Contact Tanko A	Bill Free: Pagenay 120 Other Autom, TX 120 Other	Deen ng Poo Sove wi Foo Roven Foo Roven	ngboe nai d	mary	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	3
d Intering Spates Charge Mudit Caso Heregenetic Class Antio GLER manipulations Antio GLER manipulations and Spates Antio GLER manipulations and Antio GLER manipulations and Spates Antio GLER manipulations and Antio GLER manipulations antio GLER manipulations antio GLER manipula	125704, FU25 125704, FU25 125704, FU25 125704, FU25 125704, FU25 125704, FU25 125704, FU25 125704, FU25 125704, FU25	Hatt Cantor Gootan Threaden's Cast Bridg Rume Available Cast Bridg Rume Available Cast Cast Tools an Available Cast Cast Tools an Available Cast Cast Tools an Available Cast	Towe Family Hault Cer Somewis Medica Direc Goles Internet	144 144 144 144 144 144 144 144 144 144		Bit Ta: Tanky Houth Cent 10 Hear Hay And Contact Lanes. The Contact Lanes. The Contact Lanes. And 0 0 0 0 0 0 0 0 0 0 0 0 0	Bit Free: T-20 Cells 120 Cells Autom, TX autom, TX	Deen ng Poo Sove wi Foo Roven Foo Roven	ngboe nai d	mary	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date 21000-1 min # Pase Fac: 201 1 201 2 201 2 201 2 2000-10	1



Dashboard Monitoring

- Program Performance Monitoring:
 - Captured claims by pharmacy
 - Program utilization
 - Financial performance

Marketing Your Program



Conclusion

- Participate in a 340B Program
 - Understand the requirements
 - Engage a partner who will:
 - Maximize the benefit and adhere to compliance
 - Partner with Best Practice Hospitals
 - Utilize Nebraska State Hospital Association relationships

Thank You



© 2014 SUNRx, Inc. All rights reserved