Pharmacy Operations Troubleshooting Guide Topic: Mitigating Manufacturer Actions Impacting 340B Financial Savings to Health Centers

July 2021

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Program Alert Notice:

On May 17, 2021 HRSA sent letters to six pharmaceutical manufacturers stating that:

- They were in direct violation of the 340B statute because they refused to ship 340B-priced medications to contract pharmacies
- Shipments to contract pharmacies were to resume immediately
- It was the manufacturers' responsibility to reach out to the 340B entities and pursue "mutually agreed upon refund arrangements" to ensure that all overcharges occurring as the result of their refusal to ship were refunded or credited to 340B entities
- Manufacturers must provide HHS an update on their plans to resume shipping by June 1
- HHS may impose Civil Monetary Penalties should the manufacturers maintain their refusal to ship 340B drugs to contract pharmacies
    - Up to $5,000 per instance of overcharging

While this is great news for the 340B community, there are still many concerns:

- How will CHCs be made whole for savings lost since the issue began, as well as the addition workload placed on the CHCs to find other ways to serve patients who were taking medications involved in the "refusal to ship".
- Even though the manufacturers have been instructed in no uncertain terms to begin shipping immediately, will they do so or will they continue their present actions and seek ligation.

This issue will remain in flux for a while, and we still need to ensure that our patients have access to affordable medications. The following document will assist CHCs in managing this issue until it is fully resolved.

NACHC's 340B/Pharmacy Office Hours 2020-2021 discussion identified a number of promising practices or actions that health centers can take to mitigate the negative financial impact due to manufacturer actions on health center patients and health center 340B savings. These manufacturers include Eli Lilly, AstraZeneca and Sanofi.

This list of health center promising practices is followed by accompanying material and guidance to inform your health center pharmacy operations team:.

1. **Switching patients to drugs that are more affordable and accessible**
   - *Jangus Whitner, PharmD.Primary One Health, Ohio*
2. **Choosing just one contract pharmacy**
   - *Logan Yoho, PharmD, Hopewell Health Centers, Ohio*
   - *Additional information on AZ from a friend of Noddlepod*
3. **Increasing the "capture rate" for your in-house pharmacy.**
   - *Matt Bertsch, PharmD, Sunlife Family Health Centers, Arizona*
4. **Thinking about establishing an in-house pharmacy**
   - *Tim Mallett, RPh, 340Basics, NACHC consultant, and Family Health Center, MI*
5. **Helping patients afford drugs that have suddenly jumped in price.**
   - *Tim Mallett, RPh, 340Basics, NACHC consultant, and Family Health Center, MI*

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Introduction

Beginning in July of 2020 actions taken by some of the pharmaceutical manufacturers may cause a major disruption to health centers who administer the 340B program. Adverse effects may especially exist for those community health centers (CHCs) who rely solely on contract pharmacy arrangements to provide access to affordable medication for their patients. The inability to obtain products from Eli Lilly, Sanofi and Astra Zeneca at contract pharmacies has significantly impacted both patient access and 340B savings, which many CHCs utilize to support a variety of programs within their organizations. In April of 2010, HRSA began allowing all 340B covered entities to contract with multiple pharmacies (75 FR 10272). In fact, health centers are expected to maximize the 340B benefit and utilize every possible source for processing 340B eligible prescriptions.

On May 17,2021, HHS sent letters to the manufacturers who were withholding 340B priced medications from delivery to contract pharmacies. The letter informed these manufacturers that they were out of compliance with the 340B Statute and that they had until June 1, 2021 to provide HHS with a plan for reinstituting deliveries and providing restitution to covered entities (FQHCs) or civil monetary penalties could be implemented. While the actions taken by HHS is very encouraging, there will be ongoing legal battles for a number of months until a full resolution to this problem occurs.

This toolkit has been designed to assist CHCs in maximizing their 340B program when dealing with the manufacturers who have limited distribution of their medications to contract pharmacies. When the suggestions presented here by peer health centers are considered, your CHC may be able to gain the most benefit from 340B program even under the current circumstances. Refer to NACHC's One Pager (Figure 1) to Learn more about how the 340B program works in health centers.

Here's a snapshot of how beneficial the 340B program's savings are to health centers:

Without 340B				**With 340B**			
The FQHC loses $80, all due to the sliding fee discount.	*Sliding Fee Patient*			The FQHC loses only $20. Their net cost for the uninsured patient is reduced $50, and they retain $30 savings on the insured patient.	*Sliding Fee Patient*		
	Drug Cost	$100	**FQHC loses $80**		Drug Cost	$70	**FQHC loses $50**
	Sliding Fee	$20			Sliding Fee	$20	
	Net Cost	$80			Net Cost	$50	
	Insured Patient				*Insured Patient*		
	Drug Cost	$100	**FQHC breaks even**		Drug Cost	$70	**FQHC retains $30 savings**
	Insurance Pays	$100			Insurance Pays	$100	
	Net Cost	$0			Net Savings	$30	

Figure 1 - 340B One-Pager FQHCs Overview (Sept 2020) - https://www.hcadvocacy.org/340b-advocacy/

The landscape of the 340B program and associated regulatory policies are ever-changing. In addition to this publication, visit HRSA's 340B Drug Pricing Program page for the latest updates.

Health Center Pharmacy Operations Promising Practice 1
Substituting Products affected by the Drug Manufacturer attacks on 340B

(Contact: Jangus Whitner, PharmD, BCACP
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Primary One Health, Ohio)

Current List of Affected Products – Lost access to 340B pricing at Contract Pharmacies:

Manufacturer	Effective Date	NDC Labeler Codes *officially announced*	NDC Labeler Codes identified through a price file via 'Name Lookup'
Lilly	9/1/2020	00002 00077 66733	
AstraZeneca	10/1/2020	*Please see attached notice for specific products*	00186 – AstraZeneca Pharmaceuticals 00310 – AstraZeneca Pharmaceuticals
Sanofi	10/1/2020*		00024 – Sanofi-Aventis/-Synthelabo 00039 – Aventis Pharmaceuticals 00066 – Sanofi-Aventis 00068 – Sanofi-Aventis 00075 – Sanofi-Aventis 00088 – Sanofi-Aventis 00955 – Sanofi-Aventis 41167 – Sanofi Pasteur Inc. 49771 – Sanofi-Synthelabo 58468 – Sanofi-Aventis 72733 – Sanofi-Aventis

**Unless the CHC chooses to share their data with ESP/Second Sight Solutions*

Considerations for FQHCs Tackling This:

- **Identify the patients using your cash uninsured prescription assistance programs**
  - Leverage your Third Party Administrator (TPA) Reporting
    - Run reports of claims over the last 3-6 months
    - Filter by uninsured patients
    - Filter by NDC labeler codes affected to identify which uninsured patients are affected
    - Questions to ask yourself:
      - Is the patient still using our prescription assistance program?
        - For example: Does this patient have insurance now? (If yes, then does **not** need immediate attention because they have access to the med)
      - If patient does **not** have insurance and is still an active patient using your prescription assistance program, check their fill history on the claims report
        - When was the last fill? Are they due for a refill soon?
        - Did they get a 90-day supply very recently, e.g. last week? (this may buy you some time in figuring out next steps)

- **Leverage your FQHC's Clinical Pharmacists**
  - Before you make a product substitution recommendation to a PCP, pharmacists can review the patient's chart to recommend the best possible option of the available alternatives, such as:
    - Allergies/intolerances to any of the alternatives
    - Any history of treatment failures
    - Previous attempts at alternatives and why the patient stopped (as it an insurance formulary decision or something more clinically concerning?)
    - Choosing an alternative with a similar delivery device mechanism

- **If you need to switch a patient's medication to one of the available alternatives:**
  - Use the table at the end of this document for guidance in these decisions. (also get a Clinical Pharmacist's input, see above)
  - Message the patient's primary care provider (PCP) notifying her/him of the affected drug and provide him/her with one of the available alternatives.
    - Ask the PCP to include in the electronic prescription notes: "This replaces <insert prev drug's name>" This will ensure the pharmacy is aware to **not** continue trying to fill the old drug
  - Decide who is in charge of contacting the patient of any changes (e.g. the PCP, the PCP's medical assistant, the site nurse, the 340B team, etc.)
    - The last thing we would want is any surprises at the pharmacy for the patient

- **Leverage the help of existing pharmacy partners**
  - If you have a good relationship with your contract pharmacies, consider reaching out for their help in identifying cash uninsured patients currently using your 340B program and also on one of the affected products
    - This can help prospectively identify affected patients.
    - Upon identifying, the pharmacy staff could immediately contact your office or 340B team to get the patient started on the alternative in a timely fashion without delay.
    - Enrolling their help can also supplement the work you did with the TPA reports
  - A good pharmacy partner to start with may be your independent pharmacies

Drug Manufacturer Changes to 340B	Current Medications Affected			Updated 340B options patients can be transitioned to in order to get discounted price			
	"If the patient is on ____" *(from this column)*			Then "switch them to this alternative" *(from this column)*			
	Lilly	AstraZeneca	Sanofi				
Diabetes							
GLP-1 Agonists	Trulicity	Bydureon Byetta	Adlyxin	Victoza Ozempic	[Novo] [Novo]	Rybelsus	[Novo]
GLP-1 + Long-acting insulin (COMBO)			Soliqua	*Xultophy*	*[Novo - but not very cost effective on 340B]*		
DPP-IV inhibitors		Onglyza		Tradjenta Nesina	[BI] [Takeda]	Januvia	[Merck]
DPP-IV Inh + Metformin (COMBO)		Kombiglyze (+XR)		Jentadueto (+ XR) Kazano	[BI] [Takeda]	Janumet (+XR)	[Merck]
SGLT-2 Inhibitors		Farxiga		Jardiance Invokana	[BI] [Janssen]	Steglatro	[Merck]
SGLT-2 Inh + Metformin (COMBO)		Xigduo		Invokamet (+ XR) Synjardy	[Janssen] [BI]	Segluromet	[Merck]
SGLT-2 Inh + DPP-IV (COMBO)	Glyxambi	Qtern		Steglujan	[Merck]		
Long-acting Insulin	Basaglar		Lantus Toujeo	Levemir Tresiba	[Novo] [Novo]	Semglee	[Mylan]
Rapid-acting Insulin	Humalog Insulin Lispro		Admelog Apidra	Novolog	[Novo]		
Intermediate-acting Insulin	Humulin N			Novolin N	[Novo]		
Short-acting Insulin	Humulin-R			Novolin R (Vial &Flexpen)	[Novo]		
Combo Insulin: Intermediate + Short-acting	Humulin 70/30			Novolin 70/30 (Vial & Flexpen)	[Novo]		
Concentrated Short-acting insulin	Humulin-R U-500 Kwikpen & vial			*No alternatives for U-500 concentration available*			
Glucose Evelating Agents	Glucagon 1mg Emergency Kit (NDC: 00002-8031-01)			Glucagen 1mg Hypokit (NDC: 00169-7065-15)			

Please note:

- ****This is NOT all affected products. These are the most commonly used products in primary care for diabetes and respiratory conditions****
- *Tradjenta® and Jardiance® are a joint venture between Boeringer Ingelheim & Lilly, but at this time are not subject to the same Lilly restrictions noted above.*
- *340B prices can change at minimum quarterly. The cost-effective comments may be outdated*

Quick References:

https://www.astrazeneca-us.com/medicines/astrazeneca-medications.html

https://www.sanofi.us/en/products-and-resources/prescription-products

Health Center Pharmacy Operations Promising Practice 2
Choosing a Contract Pharmacy(ies) for Eli Lilly, AstraZeneca and Sanofi

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On May 17, 2021, HRSA sent letters to 6 manufacturers stating that their refusal to ship 340B-priced drugs to contract pharmacies was in direct violation of the 340B statute. HRSA also instructed these manufacturers to immediately begin shipping to contract pharmacies and also to credit CHCs for overcharges. We expect the manufacturers to challenge this in court so there could be some, possibly a significant, delay in seeing the shipments begin. In the meantime, CHCs can follow the process below to set up "single" contract pharmacies where 340B drugs can be shipped until this issue is fully resolved.

When trying to decide on one contract pharmacy, consider the following:

- Utilize your electronic medical record (EMR) and your third party administrator(s) (TPAs) to evaluate the pharmacies with the largest utilization.
  - This may be different for each of the manufacturers. Your TPA should be able to report out the manufacturers (Mfr). For example, Pharmacy A may have the largest utilization of Astra Zeneca drugs and Pharmacy B is the best for Sanofi.
- Consider distance from your site. If the mfr is only allowing one per covered entity (CE), you may want to pick a pharmacy near the middle of your health center's footprint. If the mfr is allowing one contract pharmacy per SITE, you have more freedom to choose the best site regardless of location.
- When choosing a pharmacy, consider things OTHER than 340B.
  - Does the pharmacy provide home deliver? This may expand the number of patients that can access 340B drugs.
  - Does the pharmacy provide other services such as immunizations, durable medical equipment (DME) supplies, or clinical services?
  - Does the pharmacy offer a 340B cash program?
    - Unless you have an in-house pharmacy, you will want to choose a pharmacy that does have the cash program so your uninsured patients can access discounted medications.
- You may also want to involve the site manager(s) and providers. You are probably more likely to get providers to encourage the utilization of the contract pharmacy if they were involved in the decision-making process.
- Some mail order pharmacies are encouraging selecting them as the one contract pharmacy. Consider the items below:
  - This may increase access to contract pharmacies for CHCs with a large footprint.
  - May NOT be a good option for some patients:
    - Transient/Homeless patients may not have a stable address for delivery.
    - Some patients may not have a phone which would be required to access patient counseling.
    - Some elderly patients may not be willing to transition to mail order.
    - Patients may not have access to a debit/credit card to pay copays.
  - Some of these pharmacies do not have cash pay programs.
- If the pharmacy is part of a chain, they may or may not allow one pharmacy to be selected without the others contracted. Speak to your TPA for more details.

Thoughts on Working With AstraZeneca on Multiple Pharmacies

One FQHC's experience with AstraZeneca

- End of September, submitted letter to AZ (on letterhead) stating that we do not have any out-patient, on-site dispensing pharmacies at any of our X locations.
  - Our X 340B eligible Covered Entities are as follows:

340B ID	Covered Entity Sub-Division Name

  - Below are the X Contract Pharmacies we are requesting for the AZ Exception Process:

Pharmacy Name	Pharmacy Address	City, State	ZIP	Pharmacy Phone Number	HIN	DEA Number

Provided the numbers we had at the time.
Followed up later with the full list of HINs.

- Back and forth ensued.
- Got to a place where AZ accepted a small portion of our requested pharmacies, but not all. Received this response: "The rest of the 340B IDs provided are not in our system because wholesalers have not previously sold AstraZeneca products to them. If they purchase in the future, we will add the Covered Entity so they can receive 340B pricing and now have the Contract Pharmacy that will also be added as well. We don't add anyone who can potentially purchase, only once they do purchase."
- Followed up, kindly requesting to explore further. Included a simple pivot table showing recent wholesaler invoices with AZ products, and delivered to those requested contract pharmacy locations.

[Wholesaler Account Number]
[Contract Pharmacy location]
BYETTA
SYMBICORT

- Next communication from AZ was that all of the contract pharmacies were added to the AZ system. Now working with our wholesaler and contract pharmacies to operationalize.
- **Best guess at what worked** = throughout all communications, CE remained very courteous, kill-them-with-kindness, appreciative, never demanding.

Health Center Pharmacy Operations Promising Practice 3
Suggestions and tips for Increasing the Capture Rate for your In-House Pharmacy

(Contact: Matthew Bertsch, PharmD
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Sun Life Family Health Center, Inc., Arizona)

- Migrate to in house pharmacies while honoring patient choice
- Keep up with competitors
  - You are a business – compete!
- Run patient and provider focus groups
  - We have access to the EMR. Call pts/do med recs/change default pharmacies
- Promote to providers and staff
  - They are often the first point of patient contact
- Educate staff on the importance of pharmacy revenue to the bottom line.

Some additional thoughts:

- Place flyers in your waiting rooms and exam rooms promoting the value of your in-house pharmacy
  - Convenient
  - Connected with your provider
  - Significant discounts for eligible patients available
- Your staff are your best advertisement
  - Patient registration walks new patients over to the pharmacy and introduces them to the staff

Health Center Pharmacy Operations Promising Practice 4
Is an In-House Pharmacy Right for My CHC?

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Many Community Health Centers (CHCs) have experienced the value of having their own in-house pharmacy and still more are contemplating the idea. While the thought of operating your own pharmacy may be appealing, there are many factors to consider before ordering medications and opening your doors. Determining if we serve enough patients to be viable, where we place the pharmacy, how our pharmacy impacts the community pharmacies in our area are just some very high-level analysis you need to address before jumping in. This paper will review some of the considerations necessary to determine whether an in-house pharmacy is right for your CHC. To begin, let's look at some pros and cons of the in-house pharmacy.

Pros

- Increased return on your 340B purchased medications over a contract pharmacy
  - X% increase in revenue
  - No dispensing fees
  - No "administrative fees"
    - Sometimes a profit-sharing model
- Better control over patient outcomes
  - Adherence
  - Compliance
- You set the standards for pharmacy care for your patients
- Avoids the issues involved with contract pharmacies
- Can consider an "open door" model, which could increase revenue and attract new patients to the CHC

Cons

- Direct responsibility for pharmacy operations
  - Pharmacy operations are very different from medical, dental, and behavioral health
  - Regulatory concerns
  - Liability
- High start-up costs and effort
  - Design
  - Buildout
  - Inventory
  - TPA services?
  - Hiring and training of staff
  - Additional resources within the CHC
    - Accounting – AR/AP/Payroll
    - HR/Credentialing

Site Selection

While the mission of CHCs is to provide a safety net of medical care for the community (insured, uninsured or underinsured), one first needs to determine the viability of owning and operating a pharmacy. The first step is to run a report out of your EMR of all prescriptions written in a 6-12 month period. The report should include: Date written, medication, quantity, refills, provider, site the prescription was written from and insurance. The first sort should be by site so that you can determine the appropriate location for your pharmacy. Even if the other sites are only a few miles away, the majority of your volume (80-90) will likely be made up of prescriptions written in the site where your pharmacy is located.

Payor Mix

The insurance mix is very key to a successful operation. Ideally, you would need to have 30% or better Medicare Part D and/ Commercial insurance claims. These are the claims that will allow you to gain the most 340B savings as you are able to purchase the medications at 340B prices and bill them to the Pharmacy Benefits Managers (PBMs) at a contracted rate.

When billing Fee For Service (FFS) Medicaid every pharmacy across the country (chain, independent or entity owned) is only reimbursed at Actual Acquisition Cost (AAC) or the National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee (PDF). There is no real opportunity for significant 340B savings here although if you "carve in" (bill FFS using 340B purchased medications) you would lower your Accounts Receivable as the purchase price for the 340B medications will be lower than the retail purchase price.

Whether or not your state allows you to bill the Medicaid Managed Care Organizations (MMCOs) utilizing 340B medications is also a factor to be considered. In most states, FFS claims make up a small percentage (<10%) of the total Medicaid prescriptions written (FFS+MMCO). In states where the CHCs are allowed to bill the MMCOs using 340B medications and retain the savings, a 50% or more Medicaid population is not a significant detriment. You will need to contact your state Medicaid office to find out the policy in your state. If carving in MMCOs is allowed, you then need to know the procedure for identifying the claims so that Medicaid does not seek a manufacturer's rebate on those prescriptions. When a 340B medication is used by the CHC and Medicaid also submits for a rebate, it defined as a Duplicate Discount or colloquially as "double dipping". In this situation, the manufactures provide an up-front price reduction to the CHC and also pay a rebate to Medicaid on the same prescription. It is obviously not fair to the manufacturer to take a financial "hit" twice.

Your percentage of uninsured patients also needs to be considered. There are significant costs involved when owning your own pharmacy and if you are providing greater than 50% of the prescriptions at AAC or below it will be very difficult to provide any income for the CHC. That being said, there are CHCs who do not expect to make any money on their in-house pharmacy and operate it solely to provide access to affordable medications for their uninsured or homeless populations. Some of these sites budget grant and operational dollars to subsidize the pharmacy.

Prescription Volume

The prescription volume required to have a viable pharmacy depends primarily on the payor mix (as described in the last section). You could fill 200 prescriptions a day but if you are only billing insurance for 10 or 15 of those prescriptions you will not succeed financially. There are Ryan White pharmacies that fill fewer than 50 prescriptions a day and are wildly successful. Some CHC pharmacies can be profitable at 70 prescriptions a day or fewer all based on payer mix (<50-60% Part D or Commercial).

Most CHCs average around 50% Medicaid and if your state allows you to carve in the MMCO and be reimbursed at the contracted retail rate your payor mix should be adequate.

Prescription Mix – Brand vs Generic

It is also important to consider the prescribed medication mix. One of the reasons that the Ryan White pharmacy is so successful is that many or most of the medications filled are Brand name and the 340B savings is significant. If there are few Insulins, other brand name diabetic products, inhalers, brand cardio meds or other brand name only medications prescribed, it will be more difficult to provide revenue to the organization. The good news is that you do not need a 50% Brand fill rate to be successful, but you do need some of these medications to realize a larger 340B savings.

Impact on Pharmacies in your Community

Most CHC that do not have an in-house pharmacy have established relationships with various pharmacies in their community. Often these working relationships are with independent pharmacies as they are more apt to work closely with you to best serve your patients. That is not to say that a chain pharmacy cannot be a valued partner, but, more often than not, it is an independent pharmacy that will be a more beneficial partner. Let's say Joe's Pharmacy has been located across the street from your clinic for 15 years and Joe has provided contract pharmacy services for your

patients and offers delivery. If you were to open an in-house pharmacy, the number of prescriptions that Joe would lose could be devastating to his business. You need to do what is best for your CHC and your patients, but you are also members of the community and corporate citizens so you do need to consider how opening your pharmacy may impact other pharmacies that serve your patients. Chain pharmacies tend to be less impacted by the loss of prescriptions and have greater resources than your independent pharmacy owners. The big box stores make much more money on sundry items that they do in their prescription departments.

Pharmacy Location

As any realtor can tell you, the three most important attributes of your home are: Location, Location, and Location. The same can be said about your in-house pharmacy. There are CHCs with pharmacies in their basement, on a second or third floor, behind locked doors in the medical area of their clinic or even across the street. Many of these pharmacies are quite successful. Ideally though, you want your pharmacy to be the first thing patients see when they walk into your clinic and the last thing the see when their visit is complete. This keeps the pharmacy top of mind and even if they do not regularly use your pharmacy, there will be times when, for convenience sake, they will drop off a prescription. This gives your pharmacy staff an opportunity to thoroughly impress the patient and hopefully inspire them to transfer all their prescriptions to you.

Pharmacy Design

I have seen pharmacies as small as 250 sq. ft. but I would never recommend one that small. On average, pharmacies range from 350-1000+ sf. You can process 250-300 prescriptions a day out of 350 sf but if you have the room – take it! Michigan pharmacy rules dictate 10 sf of counter space per pharmacist and that results in a very tight pharmacy. One of the primary reasons to allow space is that accidents happen when people and prescriptions get jammed into too small of an area. You need space to store medications, input prescriptions, fill prescriptions, check and bag prescriptions, store filled prescriptions and counsel patients. When possible, having a private area for counseling is best and that does not always require a "room". Having a portion of your counter or waiting area where private conversations in low tones can occur without others easily overhearing is often sufficient.

Open- or Closed-Door Model

The term closed door, in relation to in-house pharmacy, means that your pharmacy will **only** serve patients of your clinic and not someone who might walk in off the street. This also means that you may **not** fill prescriptions for employee who are not patients or for family members of clinic patients (non-patients). The major advantage of a Closed-Door model is that your inventory would be strictly 340B and there would be no need for a virtual inventory. Your initial inventory costs would be low and the opportunity for accidental diversion would be greatly reduced.

There are many advantages to an Open-Door model but there will also be additional risk and cost involved. Some of the advantages are that you can fill any prescription that comes in the door – employees, family members, clinic neighbors and nearby businesses. Along with that additional business comes additional oversight, auditing, and increased startup cost.

You will need additional space if you choose to operate a dual physical inventory as opposed to a virtual inventory. The virtual inventory will require the services of a Third-Party Administrator (TPA) or special pharmacy software that can manage the accumulation and ordering of 340B medication to replenish your retail stock. Self audits are required regardless of the inventory model you choose but will be even more important since the opportunity for accidental diversion is greater.

The cost of an initial medication order (retail price) can range from $50-60K up to $200k or more. Most initial orders will be in the lower end of that range since most wholesalers offer next day delivery which allows you to keep your inventory volume lower.

One of the primary reasons for choosing to operate an Open-Door pharmacy is the advantage you will have in the area of contracting with insurers/PBMs. Most wholesalers offer a service called a PSAO (Pharmacy Services Administration Organization) which negotiates contracts for all of their pharmacies and can get much better reimbursement rates than when applying as a single pharmacy. PSAOs

will only work with Open Door pharmacies. The improved rates and the fact that the PSAO membership automatically enrolls you in most Medicare Part D and Commercial plans is very real advantage. Unfortunately, there have been many PBMs who have sought out Closed Door 340B pharmacies and either excluded them from their network or force them into contracts which offered reimbursements at 50% or less of those in their standard contract.

Initial Inventory

As mentioned in the previous section, initial inventory costs can vary depending on the 340B pharmacy model you choose. You will want to select a wholesaler early on and begin the application process. Most wholesalers will offer special terms for new pharmacies where your initial order will not have to be paid for up to six months and sometimes at that point you would only pay 1/6 of the cost of the initial order each month until it is paid off. This is something that should be discussed with your wholesaler's representative. Also, it would be appropriate to get proposals from a few wholesalers.

Staffing

This is a significant expense that a CHC needs to consider before moving forward with an in-house pharmacy. You will need to research prevailing salaries in your area for pharmacists and pharmacy technicians. Some states require technicians to be certified and/or licensed so be sure to check with your board of pharmacy. If your projections indicate that you will be filling 50-60 prescriptions a day, it would be best to staff with one pharmacist and one pharmacy technician. As prescription volume grows, so will the need for addition al staff. Once you are consistently filling over 100-125 prescriptions a day you would need to hire and additional pharmacy technician. Most chain store add pharmacists at intervals of 200 prescriptions. In the CHC setting, an additional pharmacist may be required at 150-200 prescriptions a day. There tend to be many more issues requiring the pharmacist's attention with an in-house pharmacy than in an average community pharmacy. Sliding Fee Scales, terminated insurances, lost prescriptions, and insurance coverage issues are just a few of the problems that will occupy your pharmacist's time.

Hours

Many CHCs mirror their pharmacy hours to their clinic hours. This is beneficial as you will already have front desk staff available to provide directions and sign up patients for Sliding Fee programs. You may have security staff in place as well. It is also very convenient for the pharmacy staff to reach out to providers when there are question or insurance issues with new prescription.

Financial Considerations

It is essential to 'count the costs" before jumping into the opening of an in-house pharmacy. The finance department and other clinic leaders should be key members of your feasibility team. Cost that need to be considered would include: construction/remodeling, fixtures (casework, shelving, refrigerator), IT, pharmacy software, pharmacy licensing, PBM applications, pharmacy staff salaries, relief pharmacists, initial medication order, overhead (electric, heat, water, phone, internet), additional liability insurance (general and professional), and uniforms. This list is not exhaustive.

Your feasibility team needs to calculate these costs and determine a breakeven point. Then be prepared to cover many of the ongoing expenses through cash reserves or loans until the breakeven point is reached which can be up to 6 months and sometimes longer.

What is the upside in opening an in-house pharmacy?

After the review of financial considerations (they can be daunting) I feel it is important to close with a reminder of the advantages of having an in-house pharmacy. You will have the opportunity to impact your patient's health in many ways. By providing on site access to medications patients will be more likely to fill and take their prescribed medications. You will be able to provide medications through your Sliding Fee Scale at even better discounts than if the patient used a contract pharmacy. You will have the opportunity to improve both compliance and adherence to medication regimens for your patients. Your pharmacists will be able to solve issues like "medication not covered" rejections or potential interactions quickly because of their immediate

access to your providers. Your patients will truly feel that they are being served within a medical "home" because they can get all the services they need under one roof.

In Conclusion

The purpose of this article was to provide some high-level considerations if your CHC is contemplating operating an in-house pharmacy. Not all CHCs have the provider/prescription volume or space necessary for opening their own pharmacy, but fortunately there are other means for them to gain value from the 340B program (contract pharmacies). Hopefully, you will now have at least a base of information to begin your decision-making process.

Health Center Pharmacy Operations Promising Practice 5 Helping Patients Afford Drugs That Have Suddenly Jumped in Price

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Jangus has provided some great advice on how to switch patients from medications that are no longer available at contract pharmacies. But what if the patient or provider will not switch the medication? What are some other options?

1. Contact the manufacturer's patient assistance program
    a. Sanofi
    https://www.sanofipatientconnection.com/
        i. Can assist up to 400% FPL
    b. Eli Lilly
    https://www.lillycares.com/how-to-apply#check-eligibility
        i. Can assist up to 300-500% FPL
    c. AstraZeneca
    https://www.azandmeapp.com/home.html
        i. Does not provide FPL limits. Must fill out application with total household income to see if you qualify
2. Contact the manufacturer's representative to see if you could get sample medications
3. If there is another CHC nearby with an in-house pharmacy, you may need to suggest that the patient transfer care so that they could obtain their medications through the other CHC's Sliding Fee or EPPAP program.
4. In desperate cases you may choose to utilize some of your 340B savings to purchase the product at retail for the patient

Summary

While the actions of some manufacturers have harmed community health centers, we encourage you to continue utilizing the 340B program to provide discounted medications for your eligible patients and to help extend your federal resources as much as possible, reaching more eligible patients and providing more comprehensive services.

NACHC has the following resources available to assist you:

- Noddlepod – Private chatrooms for health center members to ask questions and share ideas
  - 340B Advocacy
  - 340B Pharmacy Access
- 340B Office Hours – Held the 3rd Thursday of the month at 2 pm eastern time
  - Federal and State 340B updates
  - Focus topic on 340B issues and/or pharmacy operations
- NACHC Training and Technical Assistance
  - Resources are available to assist with 340B issues and pharmacy operations

For assistance or support with any of the aforementioned resources, please contact NACHC's Training and Technical Assistance Division at trainings@nachc.com.

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