340B:

Toolkit for Responding to Recent Threats

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Introduction to 340B Response Toolkit

Purpose

The purpose of this 340B Response Toolkit is to support health centers, PCAs, and HCCNs in their efforts to repudiate and press against recent efforts that would undermine the value of the 340B program for their medically-underserved patients. It is structured by development (e.g., Executive Order, refusal to send 340B-priced drugs to contract pharmacies) and contains documents intended for both internal and external use. The items for internal use include Talking Points and FAQs; those for external use include a template for a letter to Congress, and a draft press release.

THIS DOCUMENT MUST BE CONSIDERED the foundational document for NACHC membership's use in our initial stage of promoting the benefits of 340B to Capitol Hill, the media, and others. You can anticipate emails, memoranda, and other forms of updates as events unfold. Also, NACHC is mindful that there are anti-trust issues to which we must be sensitive.

Summary of Recent 340B Developments

Several recent developments are threatening core elements of health centers' 340B programs, including the contract pharmacy model and the ability to retain savings on drugs dispensed to Medicare and privately-insured patients. These developments include:

- On July 1, drug manufacturer **Eli Lilly** posted a notice on the HRSA webpage stating that they will no longer allow certain dosages of Cialis, if purchased by a 340B provider at the 340B price, to be delivered to contract pharmacies. The following week, **HRSA** stated in a press interview that they lack the authority to stop Lilly from taking this action.
- In early July, drug manufacturer **Merck** sent a letter to all 340B providers requesting them to submit data every two weeks about every Merck drug that was dispensed by a contract pharmacy. Merck stated that there would be much more severe consequences if 340B providers refused to submit this data.
- On July 24, the President issued an **Executive Order (EO)** instructing HRSA – to the extent allowable by statute – refuse to provide 330 grant fund to health centers who charge low-income patients more than the 340B price for insulin or EpiPens. When announcing this Executive Order, both the President and HHS Secretary Alex Azar spoke disparagingly about health centers, implying that they benefit from 340B at the expense of their low-income patients.
- On July 27, drug manufacturer **Sanofi** sent a letter to all 340B providers requesting that they submit the same data as Merck (except for Sanofi), and stating explicitly that if a 340B provider did not comply, they would refuse to permit any Sanofi drugs to be shipped to its contract pharmacies.

- **Bausch Health** has begun implementing a "direct distribution" structure, which requires 340B providers to purchase certain drugs from directly from Bausch's preferred wholesaler if they want to receive the 340B price.

Potential Impact

As these developments have occurred, NACHC staff have consulted regularly with our 340B Strategic Advisory Group, and our 340B Workgroup. (The 340B Strategic Advisory Group consists of 12 CEOs and pharmacists from PCAs and health centers, all of whom have deep expertise in 340B issues; this includes two former and one incoming Chair of the NACHC Board. The 340B Workgroup is a much larger group which reports to NACHC's Health Policy Committee.) Based on these discussions, it is our view that if these developments are allowed to continue unchecked, they will spread rapidly to encompass most manufacturers, most drugs, and all pharmacies (both in-house and contract). This will likely lead to the end of:

- 340B pricing for drugs shipped to contract pharmacies
- health centers' ability to retain 340B savings on any drugs dispensed to Medicare or privately-insured patients.

We have also concluded that the root of all these policy issues is the 340B statute, which:

- Lacks key programmatic details and protections
- Gives HRSA very little enforcement authority.

Three-Part Strategy

In consultation with the 340B Strategic Advisory Group and the 340B, NACHC has developed a three-prong strategy for responding to these developments. These prongs are:

- **Legal:** Exploring legal approaches to block the Administration's and manufacturers' actions. NACHC is working closely with Feldesman-Tucker to research options.
- **Legislative:** Working to amend the 340B statute to prohibit discriminatory contracting and ensure health centers' on-going ability to use multiple contract pharmacies.
- **Public Relations/ Outreach**: Reaching out to the Hill, to manufacturers, the media, and potential allies (e.g., independent pharmacies) to educate them about developments and request their support in blocking them.

This toolkit is intended to assist with PR/ outreach activities.

Executive Order on 340B and Health Centers

Talking Points

Summary:

- Health centers don't need an Executive Order to make them provide low-income patients with access to affordable medications and other medical services. That's what they do – and have done -- every day since they were created over 50 years ago. That's their mission.

- By attempting to fix a problem that doesn't exist, the EO creates new problems that are inconsistent with its stated goal of expanding access to affordable drugs:
  - Many diabetic patients would end up paying more for their insulin. Depending on the type of insulin a patient needs, the 340B price could be far above what health centers currently charge low-income patients. For example, the 340B price for inhaled insulin is hundreds of dollars. Health centers currently discount this price for low-income patients, but would be prohibited from doing so under the EO.
  - Many diabetic patients would face dramatic fluctuations in how much they pay for insulin from one calendar quarter to the next. It is not unusual for the 340B price for a one-month supply of a particular brand of insulin to be one penny during one quarter, and over $100 in another quarter. Thus, under the EO a low-income patient's cost for insulin could switch from 3 cents to over $300 in just 3 months.
  - To keep charges affordable for low-income patients, health centers would seek to put these patients on the type of insulin with the lowest 340B price. As 340B prices change quarterly, this could require changing patients' insulin prescriptions quarterly. This would create a significant administrative burden for health center staff, and potential clinical complications for patients.

General:

- Health centers nationally were blindsided by the Trump Administration's Executive Order (EO) on Community Health Centers and 340B.
  - The EO requires FQHCs to provide insulin and EpiPens to low-income patients at 340B price, and specifically mentions penny pricing.
  - The Administration never discussed this EO with any health centers, nor have they ever raised any concerns about how health centers use their 340B savings.

- Health centers don't need an Executive Order to make them provide low-income patients with access to affordable medications and other medical services. That's what they do – and have done -- every day since they were created in 1965. That's their mission.

- Far more concerning than the EO itself, was the President's comment that FQHCs "are charging their poorest patients massive, full prices."

- Nothing could be further than the truth. As safety net providers committed to ensuring affordable access for all, health centers are already part of the solution to unaffordable drug prices – not the problem

- By law, regulation, and mission, every penny that health centers save through 340B discounts is used either to make medication affordable for low-income patients, or to support other activities that expand access to care.

- Members of Congress from both parties have repeatedly highlighted health centers as excellent stewards of the 340B program, using the savings it generated as Congress intended — "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Try to avoid discussions of whether the EO is enforceable. If pressed, say:

- *Our lawyers do not see how this EO could be enforced under current law.*
- *If it were enforced, the impact would be the opposite of its stated goal. Many patients would end up paying more for drugs, and it would create significant administrative burdens for both providers and patients.*

Try to avoid discussions of penny pricing. If pressed, say:

- *Drug prices vary dramatically from one calendar quarter to the next, and across different formulations of the same drug. For example:*
  - *This quarter, the 340B price for some types of insulin may be a penny, but for other types of insulin the price is hundreds of dollars.*
  - *Drugs that are penny-priced this quarter may be much more expensive next quarter. Health centers seek to keep the drug prices affordable despite these swings.*
  - *Penny pricing only occurs when the manufacturer increases the sticker price of a drug much faster than inflation.*

Executive Order on 340B and Health Centers

NACHC Statement

July 24, 2020

The Community Health Center mission is to ensure access to affordable, high-quality care for all people, regardless of ability to pay — and that includes pharmaceuticals. We are proud that Health and Human Services Secretary Alex Azar has in the past noted their longstanding "track record of delivering quality care at a significantly lower cost," a task made possible by programs such as 340B.

The 340B program gives small, community-based non-profits like health centers access to discounts that they could not negotiate on their own. By law, regulation, and mission, every penny that health centers save through 340B discounts is used either to make medication affordable for low-income patients, or to support other activities that expand access to care. We cannot underscore enough how vitally important such discounts are as health centers battle COVID-19 on the frontlines of hot zones across America.

Health centers are accountable and transparent in how they apply resources to patient care. Members of Congress from both parties have repeatedly highlighted health centers as excellent stewards of the 340B program, using the savings it generated as Congress intended — "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Health centers are not charging low-income patients "massive, full prices" for pharmaceuticals. Indeed, health center staff are putting their lives on the line every day to protect vulnerable populations from the spread of COVID-19.

Let's be clear: health centers support actions to make drug prices affordable, especially for life-savings medicines such as insulin and EpiPens. As safety net providers committed to ensuring affordable access for all, health centers are already part of the solution – not the problem.

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Executive Order on 340B and Health Centers

FAQs

General

What does the Executive Order (EO) say?

The Executive Order, entitled "Access to Affordable Life-Saving Medications" was issued on July 24, roughly an hour after the conclusion of the President's press conference announcing this and other EOs around drug pricing. The EO, which impacts only FQHCs (no other types of 340B providers):

- discusses how some types of insulin and EpiPens are current available under "penny pricing" (an explanation of penny pricing is included below),
- states that uninsured American should be able "to purchase these pharmaceuticals from an FQHC at a price that aligns with the cost at which the FQHC acquired the medication" and that
- "to the extent allowable by law", future grants under Section 330 should be "conditioned" on health centers' charging low-income uninsured and underinsured persons no more than the 340B prices for insulin and EpiPens.

Is the EO enforceable?

Both NACHC and our legal counsel agree that HRSA lacks the authority to enforce the Executive Order. Nonetheless, HRSA may still seek to enforce the EO either by regulation or guidance, and the optics of challenging its enforceability might be less-than-ideal. For that reason, NACHC prefers to focus on the fact that enforcing the EO would be counter-productive to the goal of expanding access to affordable drugs, rather than debating the EO's enforceability.

Why would enforcing the Executive Order be counter to the goal of increasing access to affordable medications for low-income uninsured patients?

By attempting to fix a problem that doesn't exist, the EO creates new problems that are inconsistent with its stated goal of expanding access to affordable drugs:

- Many diabetic patients would end up paying more for their insulin. Depending on the type of insulin a patient needs, the 340B price could be far above what health centers currently charge low-income patients. For example, the 340B price for inhaled insulin is hundreds of dollars. Health centers currently discount this price for low-income patients, but would be prohibited from doing so under the EO.
- Many diabetic patients would face dramatic fluctuations in how much they pay for insulin from one calendar quarter to the next. It is not unusual for the 340B price for a

one-month supply of a particular brand of insulin to be one penny during one quarter, and over $100 in another quarter. Thus, under the EO a low-income patient's cost for insulin could switch from 3 cents to over $300 in just 3 months.

- To keep charges affordable for low-income patients, health centers would seek to put these patients on the type of insulin with the lowest 340B price. As 340B prices change quarterly, this could require changing patients' insulin prescriptions quarterly. This would create a significant administrative burden for health center staff, and potential clinical complications for patients.

Should health centers make any changes <u>now</u> to how much they charge low-income uninsured patients for insulin and EpiPens?

No. There should be no need for health centers to change how much they charge low-income uninsured patients for insulin or EpiPens -- even if those drugs are currently penny-priced. The health center mission -- to provide access to affordable care regardless of ability to pay -- ensures that health centers are already complying with the "spirit" of the EO.

<u>Penny Pricing</u>

Why is the 340B price for some drugs only one penny?

If a health center pays only one penny for a drug, it is because the manufacturer has raised the drug's price much faster than the rate of inflation. The standard 340B price is either 13% or 23% below the Average Manufacturer Price (AMP.) However, if a manufacturer raises a drug's price faster than inflation, then the 340B discount is increased. This reduction – called an "inflation penalty" -- is meant to discourage manufacturers from raising prices too fast.

In the event that a drug price rises significantly faster than inflation, the inflation penalty can exceed the standard 340B price. In these situations, the drug's price would be negative, so rather than forcing manufacturers to pay FQHCs for these drugs, HRSA sets the 340B price at one penny. Thus, when a health center pays a penny for a drug, it indicates that the manufacturer raised the drug's regular price much faster than inflation.

How can a FQHC charge $5 for a drug that it purchased for one penny?

When a patient picks up a drug at a pharmacy, there are two costs involved – the cost of the drug itself, and the cost of the costs to dispense it (e.g., pharmacy staff time, supplies, overhead), called the professional dispensing fee. Thus, in the case of a penny-priced drug sold for $5.00, the cost of the drug is one cent, and the dispensing fee is $4.99. (Note that the typical dispensing fee paid by Medicaid to health center pharmacies ranges $10 to $13 for a 30-day prescription, so this $5 charge still represents a loss for the health center.)

Do you pay only a penny for insulin?

340B prices vary dramatically from one calendar quarter to the next, and across different versions of the same drug. During some quarters, the 340B price for some types of insulin may be only a penny, because the manufacturer recently increased their sticker price much faster than inflation. However, during that same quarter, the 340B price for other types of insulin could be hundreds of dollars. Also, a drug that costs a penny during one quarter can cost significantly more the next quarter.

The health center mission is to enable low-income patients to access insulin and all other prescribed drugs at affordable prices, despite the variations in sticker prices. This means charging low-income patients amounts that are affordable and predictable, regardless of which drugs they need or how those drugs' prices are changing.

Merck & Sanofi Data Requests

Talking Points

Summary:

- Health centers remain willing to make good faith efforts to help prevent duplicate discounts for drugs dispensed to ***Medicaid*** patients.
- However, if health centers were to provide Merck and Sanofi with the data they have requested on 340B-priced drugs dispensed to ***Medicare and commercially-insured patients***, it would quickly end the ability for health centers to retain any 340B savings on these drugs.
    - Merck and Sanofi have explicitly stated that they will use this data in a manner that will lead to discriminatory contracting.
- Assuming that other manufacturers follow Merck and Sanofi's lead, and extend the request to in-house pharmacies, this would force most health centers to eliminate both their entire pharmaceutical programs and other services supported with 340B savings.

General:

- Two major drug manufacturers – Merck and Sanofi – are requesting that all health centers (and other 340B providers) submit information on all their drugs that were purchased under 340B and dispensed via contract pharmacies.
    - The request includes not just drugs dispensed to Medicaid patients, but also those dispensed to Medicare and commercial patients.
    - For those 340B providers who do not comply:
        - Merck has threatened "substantially more burdensome" action.
        - Sanofi states that it will no longer allow 340B-priced drugs to be shipped to contract pharmacies as of October 1, 2020.

- As always, health centers remain willing to make good faith efforts to avoid duplicate discounts on drugs dispensed to Medicaid patients, as this is expected under the 340B statute.

- However, Merck and Sanofi's request for data on 340B-priced drugs dispensed to Medicare and commercial patients:
    - is a significant overreach that is not justified under the statute, or for any reason related to 340B program integrity.
    - will lead to a significant expansion of discriminatory contracting, further reducing or eliminating health centers' ability to retain any 340B savings on these drugs.

- Both Merck and Sanofi explicitly state that they will use data on drugs dispensed to Medicare and commercial patients to reduce the amount they pay in ***voluntary*** discounts negotiated with Pharmaceutical Benefits Managers (PBMs.)
    - Recent history clearly shows that when PBMs are denied manufacturer discounts on 340B drugs, they respond by extracting those discounts from the 340B providers through discriminatory contracts. In this way, the 340B savings that Congress meant to accrue to health centers are transferred to the PBM.

    - Thus, Merck and Sanofi are expecting health centers to undertake a significant administrative burden in order to help the manufacturers pay less in voluntary discounts to PBMs – even though the health centers, and not the PBMs, are the ones who will ultimately lose the benefit of the drug discounts.

    - Health centers are under no obligation to assist manufacturers in reducing the discounts they voluntarily provide PBMs, and it is clearly against their best interests – and Congressional intent for the 340B program – to do so.

Merck & Sanofi Data Requests

FAQs

What is NACHC's biggest concern about providing the data requested by Merck and Sanofi?

NACHC's largest concern is that providing data on 340B-priced drugs dispensed to Medicare and privately-insured patients will lead to a significant expansion of discriminatory contracting, further reducing health centers' ability to retain any 340B savings on these drugs.

Merck's letter states that it wants to "ensure it isn't paying… duplicate discounts on Medicare Part D and commercial utilization" Sanofi indicates a similar intent, stating "manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 340B program." Both statements clearly indicate that the manufacturers plan to ensure that they do not offer discounts to Pharmaceutical Benefits Managers (PBMs) for drugs purchased under 340B.

As past experience has clearly indicated, this type of manufacturer action generally leads to "discriminatory contracting" on the part of the PBM – meaning that the PBM pays less for the 340B drug to make up for the discount they are not getting from the manufacturer. Eventually, this results in the health center losing the benefit of the 340B savings mandated by Congress.

How would sending data on Medicare and commercial insurance lead to less 340B savings for health centers?

Here is a simplified example of how this would work:

- Say the Average Manufacturer Price (AMP) for a brand-name "Drug X" is $100, and the 340B price is $77.00. Pharmaceutical Benefits Managers (PBMs) reimburses pharmacies the AMP ($100) for each unit of Drug X they dispense.
- To entice a PBM to purchase large quantities of Drug X, the manufacturer offers the PBM an *after-the-fact* rebate of 25% for each unit of Drug X purchased. This rebate lowers the PBM's *net* price for Drug X to $75. ($100 paid to the pharmacy, minus $25 rebate from the manufacturer.)
- As a result of the data request to 340B contract pharmacies, the manufacturer learns that some units of Drug X were sold at the 340B price of $77.
- The manufacturer refuses to pay the PBM the 25% after-the-fact rebate for those units of Drug X purchased at the 340B price, arguing that they already provided a discount on those drugs.
- To make up for the "lost" manufacturer rebate, the PBM reduces reimbursement for those drugs purchased under 340B from $100 to $75. In this way, the PBM "stays whole" as its net price for Drug X remains $75. However, the health center (or other 340B provider) has lost the benefit of the 340B discount, as it is now being reimbursed $75 for a drug for which it paid $77.

Thus, receiving data on 340B-priced drugs directly from 340B providers will make it much easier for manufacturers to deny rebates to the PBMs for those drugs, which in turn makes it much more likely that PBMs will engage in discriminatory contracting practices. In other words, ***providing this data to manufacturers makes it highly unlikely that health centers will be able to retain 340B savings on these drugs.***

Is there a difference between the request for data on drugs dispensed to Medicaid patients, versus data on drugs dispensed to Medicare and privately-insured patients?

Yes, there is an important difference. The 340B statute clearly prohibits "duplicate discounts" under Medicaid -- meaning that a unit of a drug cannot be subject to both the 340B discount and a Medicaid rebate. ***HRSA expects health centers – and all other 340B providers – to engage in "good faith efforts" to avoid duplicate discounts under Medicaid***. This includes both preventing them from occurring, and rectifying any that are identified after-the-fact. As discussed below, there are many ways that health centers can make a "good faith effort" to avoid duplicate discounts under Medicaid.

In recent years, manufacturers and PBMs have begun using the term "duplicate discounts" in a much broader sense, to include any time a drug purchased under 340B is subject to a voluntary discount negotiated between the manufacturer and PBM (or other parties in the drug supply and payment chain.) Manufacturers are increasingly reluctant to offer voluntary discounts to PBMs for drugs purchased under 340B for Medicare and privately-insured patients, claiming that doing so would constitute a "duplicate discount." However, unlike under Medicaid, there is no statutory restriction that prevents manufacturers from providing both a 340B discount and a voluntary PBM discount on the same drug. To the contrary, manufacturers voluntarily negotiate discounts with PBMs.

As 340B providers are not required to help manufacturers determine when to pay voluntary discounts, they are under no legal obligation to make any effort to provide manufacturers with the necessary data. Also, as discussed above, providing that data would likely lead to further reductions in their ability to retain 340B savings on drugs dispensed to Medicare and privately insured patients.

What other concerns does NACHC have about Merck and Sanofi's requests?

Beyond the concerns about loss of 340B savings, we also expect that the requested data would provide Merck and Sanofi with a competitive advantage, as it would provide insights into how their products are being prescribed, by whom, and where.

Our legal counsel has indicated that we are not required to make any efforts to avoid duplicate discounts on drugs dispensed under Medicaid managed care. Do you agree?

We agree that 340B providers may not *technically* be required to make efforts to avoid duplicate discounts on drugs dispensed under Medicaid managed care, as it can be argued that the statute places that responsibility on State Medicaid program and Managed Care Organizations (MCOs). However, NACHC strongly encourages health centers to cooperate with *reasonable* efforts to avoid such discounts and follow any state directives, as part of their commitment to be good stewards of the 340B program. Having said that, we do not think that Merck and Sanofi's requests are reasonable ways to address this issue.

What are some examples of "good faith efforts" health centers can make to help prevent duplicate discounts under Medicaid?

There are many ways that health centers can demonstrate a "good faith effort" to prevent and rectify duplicate discounts under Medicaid. These include:

- Working directly with your state on a methodology to avoid duplicate discounts.
- Conducting regular self-audits and self-disclosures
- Working collaboratively with Kalderos (a private organization that investigates potential duplicate discounts that may have occurred in the past)

How does NACHC recommend that health centers respond to Merck and Sanofi's requests?

For legal reasons, *NACHC cannot advise FQHCs on if or how to respond to Merck's and Sanofi's requests.* However, we are sharing (under separate cover) an informational memo prepared by our legal counsel, Feldesman Tucker. We can also share the following information:

There are three general options to consider:

1. Comply with the manufacturers' request by their stated deadlines
2. Wait to see how the situation evolves
3. Decide not to provide the requested data..

Health centers choosing options 2 or 3 should also decide whether to contact the manufacturers directly to alert them to their decision, or to simply allow the deadlines to pass without a response.

- HRSA expects FQHCs to make a "good faith effort" to work with manufacturers to avoid duplicate discounts under Medicaid. However, there is no requirement anywhere that FQHCs provide information on drugs dispensed to Medicare and privately-insured patients.
- FQHCs are not legally required to respond to agree to either Merck or Sanofi's requests. However, failing to send any response to Merck and Sanofi (aka ignoring the letters) might be viewed as failing to make a good faith effort to assist with avoiding duplicate discounts under Medicaid.
- There are many ways that FQHCs can work "in good faith" to avoid duplicate Medicaid discounts that would be much less burdensome and more reasonable than what Merck

and Sanofi are requesting. (See discussion above.) Merck and Sanofi might not be aware of these options, or of other procedures you use to avoid duplicate Medicaid discounts .

- As discussed above, NACHC is very concerned about how giving manufacturers data on drugs dispensed to Medicare and privately-insured patients will impact the FQHCs' ability to retain 340B savings.

Merck & Sanofi Data Requests

NACHC Letter to Merck

NATIONAL ASSOCIATION OF Community Health Centers

August 7, 2020

Mr. Phil Rinnander
Executive Director, Global Human Health US Finance Lead
Customer Contract Management
Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
Kenilworth, NJ 07033

(Sent via Email phil_rinnander@merck.com)

Dear Mr. Rinnander:

On behalf of our nation's 1400 Federal Qualified Health Centers (FQHCs, or health centers) and the nearly 30 million medically-underserved patients they serve, I am writing to express my serious concerns about your request for data on 340B-priced drugs dispensed to health center patients via contract pharmacies. I am also requesting a meeting to discuss alternative approaches for avoiding duplicate discounts, as well as strategies to prevent third parties from accessing the financial benefits of the 340B discounts intended for health centers.

Background on FQHCs and 340B Program Integrity:

FQHCs are the backbone of the nation's primary care safety net. As mission-driven organizations, FQHCs intentionally seek to care for medically-underserved and vulnerable populations, and to ensure that these individuals can access affordable, high-quality health care regardless of their ability to pay. With roughly 14,000 sites nationally, FQHCs care for nearly 30 million vulnerable individuals, including persons experiencing homelessness, migrant and seasonal farmworkers, and resident of public housing. Nationally, one of every three persons living in poverty and one of every five persons in rural areas receives care from their local FQHC.

Each FQHC is governed by its own patients. Almost 70% of FQHC patients have incomes below the Federal Poverty Level (FPL); if uninsured or underinsured, these individuals pay no more than a nominal fee for health care services. Another 23% of FQHC patients have incomes

between 101% and 200% FPL; if uninsured or underinsured, they are charged based on a sliding fee scale. Almost one-quarter of FQHC patients have no insurance, and almost half have Medicaid. As small, community-based organizations, FQHCs lack the negotiating power possessed by many other entities involved the health care. As a result, the discounts provided by the 340B program are critical to FQHCs' ability to offer their patients access to affordable pharmaceuticals and other services.

Across the nation, FQHCs are committed to being good stewards of the 340B program. By law, regulation, and mission, every penny that health centers save through 340B discounts is used either to make medication affordable for low-income patients, or to support other activities that expand access to care for their medically-underserved patient population. Members of Congress from both parties have repeatedly highlighted FQHCs as excellent stewards of the 340B program, praising them for using 340B savings as Congress intended — "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." We cannot overstate how vitally important such discounts are to FQHCs' efforts as health centers battle COVID-19 on the frontlines of hot zones across America.

As part of their stewardship of this critical program, FQHCs are committed to avoiding both diversion and duplicate Medicaid discounts. Their proactive efforts to prevent diversion and duplicate Medicaid discounts from ever occurring include:

- Implementing policies and procedures designed to prevent diversion and duplicate Medicaid discounts, based on guidance from Apexus.
- Collaborating with State Medicaid agencies, managed care organizations, and contract pharmacies to develop and adopt measure to avoid duplicate Medicaid discounts.
- Hiring third-party administrators with expertise in avoiding diversion and duplicate discounts to administer their 340B programs. For example, TPAs can block all Medicaid claims unless the state has provided guidance on avoiding duplicate discounts.
- Training staff on compliance information provided by HRSA, Apexus, and NACHC (e.g., the NACHC 340B Manual for Health Centers)
- Participating in monthly national webinars on 340B compliance, and/or in-person compliance trainings held at least four times a year at the national level.

In addition to these proactive measures, FQHCs also engage in several retrospective activities to identify and correct any diversion or duplicate discounts that may have occurred. These efforts include:

- Regular self-audits (either monthly or quarterly, depending on the health center)
- Annual external audits.
- Making good faith efforts to voluntarily collaborate with state and private (e.g., Kalderos) efforts to identify duplicate Medicaid discounts.

As an added layer of program integrity, FQHCs are also subject to:

- HRSA 340B audits
- Manufacturer audits, provided that the manufacturer has demonstrated reasonable cause and received HRSA prior approval of their audit work plan.

With this background about FQHCs' on-going commitment to 340B program integrity, we will now outline our concerns about your data requests, first addressing Medicaid and then Medicare and commercial insurance.

Data on Drugs Dispensed to Medicaid Patients

As good stewards of the 340B program, FQHCs are committed to doing their part to prevent duplicate discounts on drugs dispensed to Medicaid patients. As outlined above, FQHCs currently engage in a range of efforts designed to prevent and rectify such duplicate discounts, including – but not limited to -- making good faith efforts to cooperate with outside organizations who share the same program integrity goal. However, Merck's recent request for data on Medicaid drugs would require much more than a "good faith effort" on the part of FQHCs, for the following reasons:

1. **Merck is placing the same expectations on all 340B providers, without consideration of providers' commitment to program integrity or specific evidence of duplicate discounts.** Merck is making the identical request of every 340B provider in the country, regardless of what types of program integrity protections they have in place, or whether they have ever been found to have been involved in duplicate discounts. To the extent that duplicate discounts with Medicaid might be occurring, they are likely to be concentrated among specific providers, provider types, and/or states. Merck's one-size-fits-all approach is unfair to FQHCs and other providers who have strong histories of compliance and who utilize rigorous systems to ensure program integrity.

2. **The amount of data being requested is massive, and would constitute a significant administrative burden for FQHCs.** Merck's request for Medicaid data far exceeds what can be considered a "good faith effort". As you know, Merck is requesting bi-weekly reports on every 340B-priced Merck drug dispensed to every Medicaid patient at every contract pharmacy associated with every FQHC in the country. While uploading this data to the ESP portal may be relatively easy, collecting it would be a major undertaking for FQHC pharmacy staff.

3. **The requested data would give Merck a competitive advantage.** The requested data would provide Merck with valuable insights into which drugs are prescribed, by whom, where, and when -- insights that would certainly be useful from a competitive perspective. Given the breadth and one-size-fits-all nature of Merck's request, it seems reasonable to assume that the data will be used in this fashion. It is inappropriate to ask an FQHC to undertake onerous reporting processes to provide data that will be used for

competitive purposes, particularly without documented evidence that the FQHC was involved with duplicate Medicaid discounts.

As previously stated, FQHCs remain willing to engage in "good faith efforts" to identify and rectify duplicate Medicaid discounts, and we would be happy to discuss less burdensome and more targeted ways that FQHCs could collaborate with Merck to achieve this goal. However, it is not appropriate to ask FQHCs to engage in an onerous reporting process to hunt for potential duplicate Medicaid discounts when there is no evidence or history to suggest that they are responsible for such discounts -- and when their efforts will provide a competitive advantage to the organization demanding the data.

Data on Drugs Dispensed to Medicare and Commercially Insured Patients

Your letter states that Merck wants to "ensure it isn't paying… duplicate discounts on Medicare Part D and commercial utilization". We read this statement as indicating that you do not want to pay voluntary discounts to Pharmaceutical Benefits Managers (PBMs) for drugs purchased under 340B.

We have two concerns about the request for data on Medicare and commercial insured patients. Unlike in the Medicaid program, the rebates that Merck provides to PBMs for Medicare Part D and commercial drugs are purely voluntary; they are not required under 340B or any other statute. As such, there are no 340B program integrity issues involved with these rebates, and FQHCs are under no obligation to support Merck's efforts to avoid paying them. It is inappropriate to expect FQHCs to engage in an onerous reporting process to provide Merck with data that will be used for its financial gain, independent of any 340B requirements.

Our second -- and more important concern -- is that providing this data will accelerate the difficulties that FQHCs already face in "holding onto" the discounts that Congress intended (and drug manufacturers provide) for them. In recent years, FQHCs have faced a dramatic and worrisome expansion of what we call "discriminatory contracting." This term refers to contracting practices used by third parties, such as PBMs and insurers, to effectively transfer the benefit of 340B savings from the FQHC to themselves. For example, a PBM will pay the FQHC significantly less for a drug simply because it was purchased under 340B than they would otherwise. In this way, the benefit of the 340B discount is transferred from the FQHC to the PBM.

The expansion of discriminatory contracting under 340B is a major concern for FQHCs across the country, as it is rapidly eroding their ability to retain the benefit of 340B discounts, and in turn, their ability to affordable pharmaceutical and other services to their low-income patients. Unfortunately, at present there are no legal restrictions that prevent PBMs (or other groups) from engaging in discriminatory contracting. Our concern is that if Merck uses data submitted by FQHCs to reduce rebates to PBMs, the PBMs will make up for the shortfall by reducing reimbursement to the FQHCs. As a result, Merck will still be providing 340B discounts, but FQHC will no longer be benefitting from them. In other words, complying with Merck's request for data on Medicare and commercial patients will undermine the benefit of the 340B

program for FQHCs, threatening their on-going ability to offer affordable pharmaceuticals and other services for their low-income, medically-vulnerable patients.

Request to Meet to Discuss Alternative Approaches

My staff and I would welcome an opportunity to discuss alternative approaches that could meet Merck's needs without further eroding FQHCs' ability to retain 340B savings, or placing undue burdens on their staff. For example, we have several ideas around duplicate Medicaid discounts that we would be happy to share, and we would appreciate your insights on how to address discriminatory contracting. To schedule a meeting, or to request further information, please contact NACHC's Chief Strategy Officer, Steve Carey, at scarey@nachc.org, or our Senior Policy Advisor, Colleen Meiman, at cmeiman@nachc.org.

/S/

Eli Lilly's & Sanofi's Refusal to Ship 340B Drugs to Contract Pharmacies

Talking Points

Summary:

- By refusing to ship 340B-priced drugs to contract pharmacies, Eli Lilly and Sanofi are violating both the 340B and 330 statutes.
    - The 340B statute requires manufacturers to see 340B-priced drugs to all eligible providers, regardless of where they are shipped
    - The 330 statute explicitly states that health centers may provide services -- including pharmacy services -- via contract.

- If allowed to proceed, these manufacturers' actions will force health centers to completely stop offering services through contract pharmacies. The end of contract pharmacies will dramatically decrease the ability of health center patients to access affordable medications and other services.

General

- Two major drug manufacturers – Eli Lilly and Sanofi – are taking actions to prevent drugs purchased at the 340B price from being shipped to contract pharmacies.
    - Effective July 1, Eli Lilly has stopped allowing certain doses of Cialis to be shipped to contract pharmacies if they were purchased under 340B.
    - Sanofi has stated that it will stop allowing any 340B-priced drugs to be shipped to contract pharmacies if the health center (or other 340B provider) fails to submit data that would enable Sanofi to reduce the voluntary discounts it provides to PBMs.
    - HRSA currently contends that they lack the authority necessary to require manufacturers to ship 340B-priced drugs to contract pharmacies.

- These actions are a clear violation of **both** the 340B and 330 statutes:

- There is no provision in the 340B statute that:
    - allows manufacturers to deny 340B pricing to a health center or other 340B provider, or
    - requires that a drug purchased by a 340B provider be shipped only to locations that the manufacturer has approved.

- The rules governing the health center program both allow and expect health centers to make 340B-priced medications available to their patients via contract pharmacies.

- The statute that created the health center program states in the first sentence that health centers may provide services – including pharmaceutical services -- via contract.
- To ensure that Federal grant funds are used as efficiently as possible, health centers are prohibited from paying more than the 340B price for pharmaceuticals.

- If allowed to proceed, these manufacturers' actions will force health centers to stop using contract pharmacies, as they cannot afford to provide pharmaceutical services without access to 340B pricing. The loss of contract pharmacies will dramatically decrease the ability of health center patients to access affordable medications and other services.
  - Contract pharmacies dispense over 50% of the drugs provided to health center patients.
  - Contract pharmacies expand the ability of health center patients to access affordable medications in three ways:
    - **Geographic:** For health centers that cover a large service area, or whose patients have limited transportation options, contract pharmacies enable patients to access affordable medications closer to home.
    - **Hours:** Contract pharmacies can provide pharmaceutical access during nights and weekends. For health centers' in-house pharmacies, it is rarely feasible -- either financially or logistically – to provide this type of coverage.
    - **Capacity:** Many health centers lack the financial or professional capacity to operate their own pharmacies, so without contract pharmacies their patients would have no access to affordable pharmaceuticals.

Eli Lilly's & Sanofi's Refusal to Ship 340B Drugs to Contract Pharmacies

FAQs

Is what Eli Lilly and Sanofi are proposing legal?

NACHC and other 340B provider groups do not think that it is legal for manufacturers to refuse to allow 340B-priced drugs purchased by 340B providers to be shipped to contract pharmacies. Specifically, there is no provision in the 340B statute that:

- allows manufacturers to deny 340B pricing to a health center or other 340B provider, or
- requires that a drug purchased by a 340B provider be shipped only to locations that the manufacturer has approved.

However, in response to Lilly's initial announcement, HRSA stated publicly that it lacks the authority to force manufacturers to ship 340B-priced to contract pharmacies.

Do health centers have protections around contract pharmacies that other 340B providers do not?

Yes. The first line of the 330 statute states that health center may provide services directly, via cooperative agreement, or by contract. This includes pharmaceutical services. To the best of our knowledge, health centers are the only type of 340B provider that have this type of language in their authorizing statute.

Eli Lilly is only restricting access to certain doses of Cialis at contract pharmacies. Given that it's only one drug, should we be concerned?

Yes. It is our view that Cialis was the "camel's nose under the tent" for Eli Lilly, and that now HRSA has announced that they will not stop them, Lilly will likely expand this policy to other drugs. Unless they are stopped, we expect other manufacturers to follow suit – as Sanofi has already done.

All Manufacturer Issues

Template for Letter to Lawmakers

Community Health Centers are recognized by lawmakers as judicious, fair, and honest stewards of the 340B program. However, many lawmakers are not fully aware of the program, and how health centers use the savings to benefit our patients.

Please consider using this template below – modifying/tailoring it to reflect your relationship with the elected official and inserting any data you think would be more personal, etc.

Your letterhead

Dear (Congressman/Congresswoman/Senator):

Fundamental services we have been providing to our patients in (insert city, town, area) are at risk and we cannot compete with big Pharma's attacks on programs benefiting vulnerable populations.

I am writing to request your assistance in addressing recent actions by drug manufacturers Eli Lilly, Merck, and Sanofi that seriously threaten health center's on-going ability to provide our low-income and medically-vulnerable patients with access to affordable medications and other critical services, including *briefly name 1-2 services that are supported with your 340B savings.*

Give background about your health center – e.g., location, number of patients served, patient demographics, fact that you treat everyone regardless of ability to pay and charge on a sliding fee scale based on income.

As a Federally Qualified Health Center (FQHC), *name of health center* is eligible to participate in the 340B drug discount program. The 340B program requires drug manufacturers who participate in Medicaid and Medicare to provide discounts on the price of outpatient pharmaceuticals purchased by "safety net" providers, such as *name of your health center* and other FQHCs. The 340B program is central to our ability to offer affordable pharmaceuticals to our low-income patients who are uninsured or underinsured; by reducing how much we would otherwise spend on drugs, it frees up other funds to support critical services such as *give examples of activities you fund with your 340B savings.*

In early July, drug manufacturer Eli Lilly announced that it would no longer allow certain drugs purchased at the 340B price by 340B-eligible providers to be delivered to "contract pharmacies, meaning pharmacies that are not owned by the 340B provider. A few days later, drug manufacturer Merck sent a letter to all 340B providers instructing them to submit extensive data bi-weekly on all Merck drugs dispensed by contract pharmacies. Later in the month, drug manufacturer Sanofi announced that effective October 1, it will refuse to allow any drugs

purchased at the 340B price by 340B-eligible providers to be delivered to contract pharmacies, unless the 340B provider submits the same type of data that Merck is requesting. In response to these developments, the Health Resources and Services Administration (HRSA) in HHS announced that it lacks the authority necessary to stop the manufacturers' actions.

These manufacturer actions violate both Section 330 and Section 340B of the Public Health Service statute. More importantly, these actions fundamentally threaten health centers' ability to continue providing our medically-underserved patients with access to affordable pharmaceuticals and other services. Specifically:

- Eli Lilly and Sanofi's refusal to ship 340B-priced drugs to contract pharmacies violates both the 340B statute and the health center authorizing statute. The 340B statute requires manufacturers to see 340B-priced drugs to all eligible providers, regardless of where they are shipped. The health center authorizing statute (Section 330 of the Public Health Service Act) explicitly states that health centers may provide services -- including pharmacy services -- via contract.
- Eli Lilly and Sanofi are threatening the ability of health center patients to access affordable pharmaceuticals at contract pharmacies. Health centers rely on contract pharmacies to make pharmaceuticals more accessible to their patients, both geographically and in terms of hours of operations. *Give examples of why you use contract pharmacies – e.g., more accessible for patients in terms of distance, night/weekend hours, access to public transportation.* Nationally, roughly half of drugs that FQHCs dispense to their nearly 30 million medically underserved patients are dispensed via contract pharmacies. If allowed to proceed, these manufacturers' actions will force health centers to completely stop offering services through contract pharmacies. The end of contract pharmacies will dramatically decrease the ability of health center patients to access affordable medications and other services.
- Merck and Sanofi's requests for data on Medicare and privately-insured patients:
    - **Are intended to save the manufacturer money, rather than ensure 340B compliance.** Both manufacturers state that they will use the requested data to avoid paying discounts to Pharmaceutical Benefits Managers (PBMs) for drugs purchased under 340B. However, manufacturer discounts to PBMs are completely independent from 340B and are offered on an entirely voluntary basis, generally as an incentive to increase the PBMs' purchases of a particular drug. It is inappropriate to force health centers to undertake an onerous reporting process, completely unrelated to 340B compliance, simply to save manufacturers money.
    - Will strip health centers of the benefit of the 340B savings mandated by Congress, undermining their ability to provide affordable pharmaceuticals and other services to their low-income patients. Providing this data will almost certainly cause health centers to lose the benefit the 340B discounts that Congress intended for them. In recent years, FQHCs have faced a dramatic and worrisome expansion of "discriminatory contracting" – meaning practices used by third parties, such as PBMs and insurers, to effectively transfer the benefit of 340B savings from the FQHC to themselves. (For example, a PBM will pay the

FQHC only its actual purchase price for a drug – thereby capturing the benefit of the 340B savings for itself at the expense of the health center.) The manufacturers have been clear that they will use this data to deny voluntary discounts to PBMs – and recent history is clear that PBMs will respond to this "shortfall" by reducing reimbursement for to the health center. Thus, complying with Merck's and Sanofi's request for data on Medicare and commercial patients will strip the 340B benefits away from health centers, undermining their ability to continue providing affordable pharmaceuticals and other services for their low-income, vulnerable patients.

On behalf of the (insert number of employees) caring for (insert number of patients) we are asking you for 3 actions. Please:

1. **Committee Contact** (if letter to the House: Chairman Pallone and Ranking Member Walden) (if letter to Senate: Chairman Alexander and Ranking Member Murray) to express your grave concerns about the implications of big pharma's actions;

2. **Leadership Contact** (if letter to House: Speaker Pelosi and Republican Leader McCarthy) (if letter to Senate: Majority Leader McConnell and Democratic Leader Schumer) expressing the same as above;

3. **Industry Contact**: Engage via letter or phone call anyone with whom your office has a contact at Merck, Eli Lilly, Sanofi, and Pharma to express your concern about the risk of their actions on your community's low-income and vulnerable populations.

Health center doctors, nurses, and other staff do the best we can with what we have. This unprecedented attack from industry and certain others is unfair, unwarranted, and harmful to the needs of vulnerable patients.

We hope we can count on you to follow through on these points above. Please let us know what you are willing to do and contact me if I can answer any questions. I can be reached at (e-mail and phone).

Sincerely,

Name

Title

All Manufacturer Issues

Draft Press Release

For Immediate Release: August XX 2020

340B Savings Under Assault by Big Pharma / Health Centers Could Not Offer Low Cost Drugs and Other Services to Low-Income Patients

Millions of Americans served by the nation's Community Health Centers depend on life-saving medications provided at a reduced cost under the embattled 340B program. The discounted medicines have been a lifeline for low-income, uninsured and chronically ill patients for nearly 30 years, especially during the COVID-19 pandemic and the economic downturn. But mounting pressure from pharmaceutical manufacturers, Pharmaceutical Benefits Managers (PBMs), and the federal government threatens to dismantle the program hailed as a means to stretch federal resources as far as possible to help vulnerable populations.

SUGGESTED QUOTE "By law, regulation, and mission, every penny that health centers save through 340B discounts is used either to make medication affordable for low-income patients, or to support other activities that expand access to care. We cannot underscore enough how vitally important such discounts are as health centers battle COVID-19 on the frontlines of hot zones across America. Health centers have a proud tradition of accountability and transparency in how they apply resources to patient care. They are part of the solution – not the problem."

Health centers receive discounts under 340B from drug manufacturers on medications dispensed to their patients through participating pharmacies. By reducing how much health centers pay for drugs, these discounts help health centers make drugs affordable for low-income under-insured and uninsured patients. The discounts also free up resources that health centers can use to support other services that expand access to health care. Members of Congress from both parties have repeatedly highlighted health centers as excellent stewards of the 340B program, using the savings it generates as lawmakers intended while maintaining a strong focus on program integrity.

Many in the health center community are speaking out in support of 340B, including providers and uninsured patients who recognize that without access to 340B discounts, most health centers would be unable to offer affordable pharmaceuticals to their low income patients, or to maintain other services that are supported with 340B savings.

SUGGESTED QUOTE FROM PROVIDER:

"Each health center board of directors is made up of patients from the health center and members of its community. This community-led model ensures every decision put into action is for the good of the population it serves. Many of these decisions are made possible by 340B savings. To think that health centers would do anything other than use 340B savings to benefit their patients is to not understand what a health center is and the reason they exist."

SUGGESTED QUOTE FROM PATIENT'

"I was recently laid off from my job due to COVID-19 and am a diabetic. I have no insurance. Without my health center and the 340B program, I would not be able to afford insulin to keep my blood sugar levels in check. I am grateful my health center provides life-saving medications at an affordable cost for people like me."

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