CHC/ACT
Community Health Center Association of Connecticut

1484 Highland Avenue / Suite 2
Cheshire, Connecticut / 06410
www.chcact.org

Testimony of

Deb Polun
Chief Strategy Officer
Community Health Center Association of Connecticut (CHC/ACT)

Supporting
Senate Bill 8: An Act Concerning Drug Affordability

Human Services Committee
March 12, 2024

Thank you for the opportunity to provide support for Senate Bill 8, An Act Concerning Drug Affordability.

On behalf of the Community Health Center Association of Connecticut (CHC/ACT), and its sixteen-member community health centers, I want to thank the Committee for its dedication to listening to Connecticut's residents about these important issues. Connecticut's community health centers serve more than 420,000 people each year, providing medical, behavioral health, and dental care in hundreds of locations across the state.

We stand with others in strong support of this bill, and we also have attached additional language that we believe will strengthen the bill by protecting patients' access to low-cost prescription drugs.

This bill provides a robust set of actions that will help our state learn more about the price of prescription drugs and help obtain medications for our state's residents for lower costs. It also sets up a process for community and stakeholder engagement that will inform future policy decisions around prescription drugs.

We urge its support.

Recommended Addition
While the measures included in the bill will help provide affordability and access to prescription medications, CHC/ACT respectfully recommends adding language to protect and strengthen the 340B program in Connecticut. Specifically, to help protect access to deeply discounted 340B prices for uninsured and underinsured patients, CHC/ACT strongly recommends that Connecticut prohibit contract pharmacy restrictions in the 340B program. We have taken the liberty of including suggested language, which is attached to this testimony.

About the 340B Program

The 340B Program was established by the federal government to enable certain health care providers to stretch federal resources to serve more eligible patients and provide more comprehensive services. The entities covered under 340B include federally qualified health centers (FQHCs), Ryan White clinics, certain hospitals, Planned Parenthood, and other safety net providers.

How does the 340B program work? In order to participate in the Medicaid program, pharmaceutical manufacturers agree to provide outpatient drugs to covered entities at significantly reduced prices. Then those providers are reimbursed for the medications by Medicare and commercial insurance at the same price as other, non-340B medications. The revenue is then invested back into the safety net, to expand access to health care services for those most in need.

Until recently, covered entities could either have in-house pharmacies, or could contract with one or more (sometimes several) local pharmacies for their patients to access medications. Some health centers have both an in-house and contract pharmacies.

Another benefit to the program is that the covered entities are able to pass along the savings to their uninsured and underinsured patients, allowing them access to prescription medication that they otherwise may not be able to afford.

It is this second benefit – the ability to help people obtain medication at the lowest possible price – that CHC/ACT and Connecticut's health centers are asking you to protect.

Here are a few examples of commonly prescribed drugs that illustrates the great value that the 340B program brings to the uninsured and underinsured:

Medication	Discounted price through Array Rx	340B price
Advair Disk (inhaler)	$48.06	$25
Levothyroxin (30 day supply)	$126.83	$4
Eliquis (30 day supply)	$305.35	$7.80
Januvia (30 day supply)	$535.30	$0.30
Metformin (30 day supply)	$47.71	$0.30

Recent Changes Impacting the 340B Program and Patients

For thirty years, the 340B program has been recognized as a critical component of the safety net. A few years ago, negative attention was brought to this program because of the actions of a few "bad actor" covered entities – notably not FQHCs, and not in Connecticut.

In the past couple of years, a number of pharmaceutical manufacturers have worked to shrink the 340B program, restricting access to life-saving and life-changing medications by placing limitations on where patients can purchase them at 340B prices.

For example, Amgen recently issued a new policy indicating that covered entities, such as FQHCs, must choose only one "contract pharmacy" location for their patients to purchase their medications, specifically Repatha®, Enbrel®, Otezla®, Aimovig®, Tezspire® and Amjevita®. This action follows similar policy notifications by AstraZeneca, Bayer, Eli Lilly, Merck, and several other manufacturers, all within the past year.

We have attached some of the manufacturer bulletins to our testimony and you can read all of the bulletins at this link.

What this means in practice is that an uninsured FQHC patient who needs a prescription drug does not have a choice in where to pick up that medication.

Compare that uninsured patient to yourself. When you go to the doctor and need a prescription, you will be asked where you would like your prescription to be sent. Now imagine being an uninsured patient that may have taken public transportation to get to your doctor's appointment, then being told to travel 10 miles away to pick up that same prescription that we take for granted. Unlike you or I, they may not be able to go to their local pharmacy, where they have shopped for years. The result of these discriminatory actions by pharmaceutical manufacturers is that the most needy residents in Connecticut, our patients, don't get their medications. Their symptoms become worse, and they may find themselves in the hospital emergency room, adding more cost to the health care system.

CHC/ACT's Proposal

CHC/ACT proposes that Connecticut protect the right of our patients to purchase prescription drugs at 340B prices at any pharmacy contracted with the health center. Notably, this is one of the opportunities identified in the report issued by the 340B Workgroup established in legislation last year.

Many of our FQHCs have multiple sites, so that they can provide health care to people in convenient locations. For example, the Community Health & Wellness Center of Greater Torrington has a site in Torrington, one in Winsted, and will soon open a new site in North Canaan. If you've been to the northwest corner of the state, you know how large and rural it is, with little to no public transportation. Optimus Health Care, a more urban health center, has several sites in Bridgeport, Stamford, Milford, and Stratford. With contract pharmacy restrictions, these health centers – which clearly draw from large geographical areas – must choose one location for their patients to access needed medications. Patients seen in North Canaan may have to travel to Torrington, and those seen in Stamford may have to travel to Bridgeport, to receive affordable medications.

To be clear, these restrictions are already happening. Our patients are already being impacted. And yes, simple medical issues are going untreated because of these unnecessary obstacles being placed in front of the most vulnerable residents of Connecticut.

The current restrictions are hugely limiting for people who already face many barriers to accessing health care and prescription drugs. If patients who have transportation problems, nontraditional work schedules, child care issues, and other challenges are required to travel ten or

twenty or thirty miles or more to pick up a medication at an affordable price, they most likely will simply go without. This will lead to them becoming sicker, impacting their quality of life.

This commonsense proposal will protect people who most need the safety net. It costs the state of Connecticut nothing, ensures people can shop at their local pharmacies – and is one of the most effective ways of enhancing health care affordability for our uninsured and underinsured residents.

Thank you for your consideration and your hard work on behalf of our great state. Please feel free to reach out with any questions: dpolun@chcact.org or 860.667.7820.

Suggested language

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (Effective from passage) **Definitions**. As used in this section and [Section 2]:

(1) "340B drug" means a drug that (A) is a covered outpatient drug within the meaning of 42 U.S.C. § 256b; (B) has been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. § 256b(a)(1); and (C) is purchased by a covered entity. A drug shall be considered purchased if it would have been purchased but for the restriction or limitation described in [Section 2(a)];

(2) "Biologic" has the meaning as defined in section 21a-70d;

(3) "Commissioner" has the meaning as defined in section 19a-1d;

(4) "Covered entity" has the meaning as defined in section 17b-245f;

(5) "Manufacturer" has the meaning as defined in section 21a-70, except that such definition shall include manufacturers of biologics;

(6) "Package" has the meaning as defined in 21 U.S.C. § 360eee(11)(A);

(7) "Pharmacy" has the meaning as defined in section 20-571;

(8) "Third-party logistics provider" has the meaning as defined in section 20-571;

(9) "Wholesaler" or "distributor" has the meaning as defined in section 21a-70.

Section 2. (NEW) (Effective from passage) (a) **Prohibition against interference with 340B drug distribution.** A manufacturer, third party logistics provider, wholesaler, or distributor, or an agent or affiliate of such manufacturer, third party logistics provider, wholesaler, or distributor, shall not, either directly or indirectly:

(1) Deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services; or

(2) Require a covered entity, or a pharmacy that is under contract with a covered entity, to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, or a pharmacy that is under contract with a covered entity, unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

(b) **Enforcement.**

(1) On and after July 1, 2024, if the executive director of the Office of Health Strategy receives information and has a reasonable belief, after evaluating such information, that any manufacturer, third party logistics provider, wholesaler, or distributor, or an agent or affiliate of such manufacturer, third party logistics provider, wholesaler, or distributor has acted in violation of any provision of this section, or rule or regulation adopted thereunder, such manufacturer, third party logistics provider, wholesaler, or distributor, or an agent or affiliate of such manufacturer, third party logistics provider, wholesaler, or distributor shall be subject to a civil penalty of up to fifty thousand dollars. The executive director may issue a notice of violation and civil penalty by first-class mail or personal service. Such notice shall include: (i) A reference to the section of the general statutes, rule or section of the regulations of Connecticut state agencies believed or alleged to have been violated; (ii) a short and plain language statement of the matters asserted or charged; (iii) a description of the activity to cease; (iv) a statement of the amount of the civil penalty or penalties that may be imposed; (v) a statement concerning the right to a hearing; and (vi) a statement that such manufacturer, third party logistics provider, wholesaler, or distributor, or an agent or affiliate of such manufacturer, third party logistics provider, wholesaler, or distributor may, not later than ten business days after receipt of such notice, make a request for a hearing on the matters asserted.

(2) The manufacturer, third party logistics provider, wholesaler, or distributor, or an agent or affiliate of such manufacturer, third party logistics provider, wholesaler, or distributor to whom such notice is provided pursuant to subparagraph (A) of this subdivision may, not later than ten business days after receipt of such notice, make written application to the Office of Health Strategy to request a hearing to demonstrate that such violation did not occur. The failure to make a timely request for a hearing shall result in the issuance of a cease and desist order or civil penalty. All hearings held under this subsection shall be conducted in accordance with the provisions of chapter 54.

(3) Following any hearing before the Office of Health Strategy pursuant to this subdivision, if said office finds, by a preponderance of the evidence, that such any manufacturer, third party logistics provider, wholesaler, or distributor, or an agent or affiliate of such manufacturer, third party logistics provider, wholesaler, or distributor violated or is violating any provision of this subsection, any rule or regulation adopted thereunder or any order issued by said office, said office shall issue a final cease and desist order in addition to any civil penalty said office imposes.

(c) **Non-preemption.** Nothing in this section is to be construed or applied to be in conflict with or less restrictive than:

(1) Applicable federal law and related regulation, including 21 U.S.C. § 355-1; or

(2) Other laws of this state if the state law is compatible with applicable federal law.

Amgen USA Inc.
1 Amgen Center Drive
Thousand Oaks, CA 91320 USA
(805) 447-1000

amgen.com

MODIFIED FEBRUARY 23, 2024 TO REFLECT UPDATE TO AMGEN'S 340B CONTRACT PHARMACY POLICY

Dear Valued Customer,

I am writing to inform you that Amgen Inc. (Amgen) is modifying its policy regarding drugs provided at the 340B price. Effective March 19th, 2024, Amgen's policy will no longer include a separate exception allowing federal grantees – as listed in the HRSA database – to place Bill To / Ship To orders purchased at the 340B price for multiple contract pharmacies. Federal grantees will continue to be eligible to place such orders under the remaining exceptions set forth in Amgen's policy, which will otherwise remain unchanged.

Next Steps

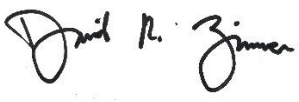
Amgen is utilizing the 340B ESP™ platform to support the contract pharmacy designation process. 340B Grantees that haven't already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have previously registered an account with 340B ESP™ can designate a contract pharmacy in accordance with Amgen's policy by navigating to the Entity Profile tab. Entities that previously made a designation do not have to re-designate.

Grantees who have not previously designated a contract pharmacy must take action by March 5th, 2024 in order for their contract pharmacy designations to take effect on the effective date of the policy.

Grantees may also elect to submit 340B claims through 340B ESP™ for all utilization dispensed through in-house and contract pharmacies.

In support of a smooth transition to our new policy, Grantees should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To orders in advance of the March 19th, 2024 effective date. Subject to the exceptions outlined in Amgen's policy, PHS contracts administered by our wholesalers will no longer support distribution of drugs purchased at the 340B price to 340B contract pharmacies after March 19th, 2024.

Best regards,



David Zimmer
Vice President, US Value & Access

Frequently Asked Questions

Q Which products are subject to Amgen's policy?

A The current policy primarily applies to self-administered, pharmacy benefit Amgen products, specifically Repatha®, Enbrel®, Otezla®, Aimovig®, Tezspire® and Amjevita®.

Q If a covered entity has a contract pharmacy relationship with a pharmacy that is wholly owned or under common ownership with the covered entity's health system, is this pharmacy subject to Amgen's policy?

A Any covered entity may elect to designate any contract pharmacy location registered on the HRSA OPAIS database that is within 40 miles of the covered entity's parent site, or grantee site as listed in the HRSA database, regardless of ownership interest, as its single contract pharmacy location so long as it complies with the claim submission requirements noted below

- Any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location for delivery of 340B-priced drugs within 40 miles of the covered entity parent site, or grantee site as listed in the HRSA database
- A covered entity that does have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy for delivery of 340B-priced drugs if (i) the location of the single contract pharmacy is within 40 miles of the covered entity parent site, or grantee site as listed in the HRSA database and (ii) the covered entity provides claims data for both the in-house pharmacy and the designated single contract pharmacy

Q If a covered entity has an in-house pharmacy that is capable of purchasing and dispensing Amgen drugs, but the entity doesn't currently use it to dispense Amgen drugs, can the entity designate one contract pharmacy instead?

A Yes, under Amgen's policy, a covered entity that has an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy for delivery of 340B priced drugs if (i) the location of the single contract pharmacy is within 40 miles of the covered entity parent site, or grantee site as listed in the HRSA database and (ii) the covered entity provides claims data for both the in-house pharmacy and the designated single contract pharmacy.

Q What happens if a covered entity does not have an in-house pharmacy that is capable of purchasing and dispensing Amgen drugs and does not have a contract pharmacy within the 40-mile radius of the parent site, or grantee site as listed in the HRSA database?

A Amgen will allow the use of a contract pharmacy beyond the 40-mile radius if a covered entity shows that (1) it lacks an in-house pharmacy capable of purchasing and dispensing Amgen's drugs and (2) there is no contract pharmacy capable of purchasing and dispensing Amgen's drugs within a 40-mile radius of the covered entity's parent site, or grantee site as listed on the HRSA database.

Q If a 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy, can the entity designate all locations of the same pharmacy?

A Amgen's policy allows 340B covered entities to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q How can a 340B covered entity change its contract pharmacy designation?

A Covered entities may change their contract pharmacy designation once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database. Changes to the single contract pharmacy can only be made by visiting www.340Besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q Is Amgen requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for Amgen to manage its process with its wholesalers.

Q If the contract pharmacy that a covered entity wants to designate doesn't have a HIN, how can one be obtained?

A Amgen will not register a HIN on behalf of a covered entity. However, if a covered entity needs guidance or more information on how to get a HIN assigned to a contract pharmacy, please reach out to support@340besp.com. If a covered entity tries to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify the covered entity of this requirement and provide instructions for how to obtain a HIN.

Q How does a covered entity ensure that its contract pharmacy designation takes effect on March 19th, 2024?

A For a covered entity's contract pharmacy designation to take effect on March 19th, 2024, its contract pharmacy designation or re-designation needs to be made by March 5th, 2024. After March 5th, please allow 10 business days for the designation to take effect.

Q If a covered entity would like to submit 340B claims for its in-house pharmacy and contract pharmacy and continue purchasing Amgen products at the 340B price, what does the entity need to do to begin submitting claims data?

A 340B covered entities that wish to submit claims data under Amgen's policy can do so by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting claims for Amgen by navigating to the Claims Data Submission tab.

Q What happens if a covered entity does not provide 340B contract pharmacy claims data by the required date?

A If a covered entity elects not to submit claims data for its contract pharmacy, the covered entity can continue receiving 340B-priced products at the covered entity's in-house pharmacy. If the covered entity does not have an in-house pharmacy capable of dispensing products purchased at the 340B price, the covered entity may designate a single contract pharmacy in accordance with Amgen's policy.

Q Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing, once eligibility for our contract pharmacy designation has been processed by our wholesaler?

A All contract pharmacy replenishment orders for all covered entities registered with 340B ESP™ will be honored for prescriptions dispensed to eligible 340B patients within forty-five (45) days of each data submission to 340B ESP™. Please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your initial Amgen claims submission to 340B ESP™.

July 3, 2023

AstraZeneca
1800 Concord Pike
Wilmington, Delaware 19803-2910
T: (800) 456-3669
astrazeneca.com

Dear 340B Covered Entity,

I am writing to inform you that effective August 1, 2023, AstraZeneca will transition the administration of our 340B contract pharmacy program to platform, 340B ESP™. Please note there will be no change to the scope of products subject to our contract pharmacy policy – Oncology and Specialty Pharmacy products remain excluded.

The FAQs below provide a list of impacted brands and appropriate National Drug Codes. Covered entities with an on-site dispensing pharmacy will continue to be able to purchase AstraZeneca product at the 340B price. Covered entities without an on-site dispensing pharmacy, may select a single contract pharmacy location.

As part of this transition all covered entities without an on-site dispensing pharmacy must designate a contract pharmacy using the 340B ESP portal. This applies to covered entities that have already selected a contract pharmacy directly with AstraZeneca.

Covered entities that do not have an on-site pharmacy can make their designations by visiting www.340BESP.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab.

In support of a smooth transition to our new distribution model, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To replenishment orders in advance of the August 1, 2023, effective date.

Covered entities may also submit 340B claims through 340B ESP™ for all utilization. Covered entities that are interested in submitting 340B claims will need to register an account with 340B ESP™ and it is requested that the 340B claims are submitted within 45 days of the dispense date. While it is not a requirement, AstraZeneca encourages covered entities to submit data for program transparency purposes.

If you have questions regarding the change in our 340B distribution model, please contact us at support@340BESP.com.

Sincerely,

Rod Lauzon (Jun 29, 2023 08:22 EDT)

Rod Lauzon
Executive Director, Contract Operations

Frequently Asked Questions

Q: Are Oncology & Specialty products subject to AstraZeneca's Contract Pharmacy policy?

A: No.

Q: Which products are subject to AstraZeneca's Contract Pharmacy policy?

A: AstraZeneca's contract pharmacy policy applies to AIRSUPRA®, BEVESPI AEROSPHERE®, BREZTRI AEROSPHERE™, BRILINTA®, BYDUREON®, BYETTA®, CRESTOR®, DALIRESP®, FARXIGA®, KOMBIGLYZE® XR, LOKELMA™, NEXIUM®, ONGLYZA®, PULMICORT®, QTERN®, SEROQUEL®, SEROQUEL XR®, SYMBICORT®, SYMLIN®, XIGDUO® XR. The NDC list can be found below.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing AstraZeneca's drugs, but my entity doesn't use it to dispense AstraZeneca's drugs. Can my entity designate one contract pharmacy instead?

A: No, under AstraZeneca's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B purchased products to eligible patients then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. No. AstraZeneca's policy allows qualifying 340B covered entities (i.e., covered entities without an on-site pharmacy) to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q. Can my covered entity designate a centralized pharmacy replenishment facility as my single contract pharmacy location?

A. No. Centralized pharmacy replenishment facilities or "central-fill pharmacies" are not eligible to be designated as a single contract pharmacy location for a covered entity. Please refer to the FAQs for a listing of Brands and NDC's above.

Q. How does my covered entity change its contract pharmacy designation and how often can it be changed?

A. 340B covered entities can elect a single contract pharmacy every twelve (12) months or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database. Changes to the single contract pharmacy can only be made by visiting www.340BESP.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q. Is AstraZeneca requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A. Yes, a contract pharmacy must have a HIN assigned to it for a covered entity to designate it as its single contract pharmacy. This information is important for AstraZeneca to manage its process with its wholesalers.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: AstraZeneca will not register a HIN on your behalf, however if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340BESP.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q: My covered entity would like to submit 340B claims for its contract pharmacies. What does our entity need to do to begin submitting 340B claims?

A: 340B covered entities that wish to submit 340B claims under AstraZeneca's policy can do so by registering an account at www.340BESP.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for AstraZeneca by navigating to the Claims Data Submission tab. It is requested that the 340B claims are submitted within 45 days of the dispense date.

Q: Can multiple wholly owned pharmacies be designated as the covered entity's contract pharmacies?

A: Contract pharmacies that are wholly owned by the covered entity (or have common ownership with the entity) will not be able to access 340B pricing unless the covered entity does not have an in-house pharmacy, and the wholly owned pharmacy is designated as the **single** contract pharmacy through the 340B ESP™ platform.

Q: Can child sites also designate a single contract pharmacy relationship?

A: No. All child sites must utilize the parent site's contract pharmacy designation.

Updated 1/1/2024

Product Name	NDC
AIRSUPRA®	
90/80MCG PMDI 120D US	00310-9080-12
BEVESPI AEROSPHERE®	
9/4.8 MCG 120 ACT INHALATION	00310-4600-12
BREZTRI AEROSPHERE®	
160/9/4.8MCG	00310-4616-12
160/9/4.8MCG Inst. Pack	00310-4616-39
BRILINTA®	
TAB 90MG UD Inst. Pack	00186-0777-39
TAB 90MG	00186-0777-60
TAB 60MG	00186-0776-60
BYDUREON®	
BCISE AUTOINJECTOR	00310-6540-04
BYETTA®	
PEN 250MCG/ML	00310-6512-01
PEN 250MCG/ML	00310-6524-01
CRESTOR®	
TAB 5MG	00310-7560-90
TAB 10 MG	00310-7570-90
TAB 20 MG	00310-7580-90
TAB 40 MG	00310-7590-30
DALIRESP®	
TAB 250MCG	00310-0088-28
TAB 250MCG Inst. Pack	00310-0088-39
TAB 500MCG	00310-0095-30
TAB 500MCG	00310-0095-90
FARXIGA®	
TAB 5MG	00310-6205-30
TAB 10MG	00310-6210-30
TAB 10MG Inst. Pack	00310-6210-39
KOMBIGLYZE® XR	
TAB 5MG/500MG	00310-6135-30
TAB 2.5MG/1000MG	00310-6125-60
TAB 5MG/1000MG	00310-6145-30
LOKELMA®	
ORAL SUSPENSION 5G	00310-1105-30
ORAL SUSPENSION 5G Inst. Pack	00310-1105-39
ORAL SUSPENSION 10G	00310-1110-30
ORAL SUSPENSION 10G Inst. Pack	00310-1110-39
NEXIUM®	
CAPS 20MG	00186-5020-31
CAPS 20MG	00186-5020-54
CAPS 40MG	00186-5040-31
CAPS 40MG	00186-5040-54

	IV INJ 40MG/5mL	00186-6040-01
	ORAL SUSPENSION 2.5MG	00186-4025-01
	ORAL SUSPENSION 5MG	00186-4050-01
	ORAL SUSPENSION 10MG	00186-4010-01
	ORAL SUSPENSION 20MG	00186-4020-01
	ORAL SUSPENSION 40MG	00186-4040-01
ONGLYZA®		
	TAB 2.5MG	00310-6100-30
	TAB 2.5MG	00310-6100-90
	TAB 5MG	00310-6105-30
	TAB 5MG	00310-6105-90
PULMICORT®		
	RESPULES 0.25 mg/2 ml	00186-1988-04
	RESPULES 0.5 mg/2 ml	00186-1989-04
	RESPULES 1 mg/2 ml	00186-1990-04
QTERN®		
	TAB 5MG/5MG	00310-6770-30
	TAB 10MG/5MG	00310-6780-30
SEROQUEL®		
	TAB 100MG	00310-0271-10
	TAB 200MG	00310-0272-10
	TAB 25MG	00310-0275-10
	TAB 300 MG	00310-0274-60
	TAB 50 MG	00310-0278-10
	TAB 400 MG	00310-0279-10
SEROQUEL XR®		
	TAB 50 MG	00310-0280-60
	TAB 150 MG	00310-0281-60
	TAB 200 MG	00310-0282-60
	TAB 300 MG	00310-0283-60
	TAB 400 MG	00310-0284-60
SYMBICORT®		
	80/4.5MCG	00186-0372-20
	160/4.5MCG	00186-0370-20
	80/4.5MCG Inst. Pack	00186-0372-28
	160/4.5MCG Inst. Pack	00186-0370-28
SYMLIN®		
	60-PEN 1000mcg/ml	00310-6615-02
	120-PEN 1000mcg/ml	00310-6627-02
XIGDUO® XR		
	TAB 2.5MG/1000MG	00310-6225-60
	TAB 5MG/500MG	00310-6250-30
	TAB 5MG/1000MG	00310-6260-60
	TAB 10MG/500MG	00310-6270-30
	TAB 10MG/1000MG	00310-6280-30

Notice of Reinstatement of Lilly's Prior Contract Pharmacy Limited Distribution System
November 6, 2023

On December 16, 2021, Eli Lilly and Company (Lilly) updated its 340B contract pharmacy limited distribution system to permit an unlimited number of contract pharmacies provided that certain claim-level data was submitted by covered entities to 340BESP.com.

Since that time, Lilly has encountered various issues with the program, such as the following:

- Identification of thousands of duplicate Medicaid discounts, inconsistent with the 340B statute;
- Identification of hundreds of instances where multiple covered entities sought replenishment on the same unit of 340B product;
- Covered entity refusal to investigate Medicaid duplicate discount data;
- Covered entity refusal to issue refunds for agreed-upon Medicaid duplicate discount amounts;
- Underreporting of claim-level data by covered entities, leading to discrepancies between the claims data submitted and the 340B replenishment purchases being requested;
- Covered entity gaming of Lilly's Limited Distribution Program (e.g., misrepresentation of "bill to"/ "ship to" relationships);
- Lack of covered entity accountability for vendors and third-party administrators;
- Covered entity threats of retaliation, litigation, or administrative disputes in response to required "good faith" dispute resolution requests pertaining to contract pharmacy utilization; and
- Unprofessional communications from and conduct by covered entity vendors and third-party administrators.

It is no longer feasible for Lilly to monitor and pursue corrective action for the issues identified above. Therefore, effective November 16, 2023, Lilly is reinstating its previous 340B Contract Pharmacy Limited Distribution System. That program limits distribution of all 340B ceiling priced product:

- To covered entities and their child sites;
- To contract pharmacies wholly owned by the covered entity;
- To unlimited contract pharmacies for "penny priced" insulin products, provided that:
    - The covered entity extends the 340B "penny prices" to eligible patients at the point-of-sale;
    - Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;
    - No insurer or payer is billed for the Lilly insulin dispensed; and,
    - The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

A covered entity without an in-house outpatient pharmacy may designate one contract pharmacy location. Lilly will facilitate bill to / ship orders of 340B priced medicines to that location only. Lilly considers all sites together as one Covered Entity, inclusive on the Parent and Child Sites, or Grantee sites as listed on the HRSA database. Lilly encourages 340B covered entities designating a single contract pharmacy to voluntarily submit limited claims data for their single contract pharmacy transactions for purposes of 340B Program integrity and transparency.

Single Contract Pharmacy Designation

Covered entities that are eligible to designate a single contract pharmacy can do so by registering an account at www.340BESP.com and navigating to the Entity Profile tab. The 340B ESP™ platform is the only way a covered entity can designate its single contract pharmacy location under Lilly's updated policy.

Covered entities that currently have an existing "No In-House" exception with Lilly will need to access 340B ESP™ and designate one contract pharmacy location per Lilly's updated policy. Please complete your single contract pharmacy designation and voluntary data submission by November 13, 2023 to be effective by November 16, 2023.

For covered entities that designate a contract pharmacy after November 13, 2023, please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your designation with 340B ESP™.

Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. Lilly will continue to offer all covered entities its 340B medicines at or below the 340B ceiling price, consistent with the 340B statute. Lilly will also continue to work with all stakeholders to improve program integrity and ensure that the 340B program can be properly and fairly administered going forward.
If you have any questions regarding this notice, please contact Lilly at 340B@lilly.com.

****

Frequently Asked Questions

To get started with Second Sight Solutions' 340B ESP™ platform, follow these simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes about 15 minutes.

2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities. Once your account is set up, the claims upload process takes about 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process, please call Second Sight Solutions at 888-398-5520.

Q1: Which products are subject to Lilly's 340B Distribution Program?

A1: Lilly's 340B program applies to all products (Labeler codes 00002, 00777, 66733).

Q2: If Lilly has already approved a single contract pharmacy exception, do I need to take any action?

A2: Yes. Covered entities that are eligible to designate a single contract pharmacy must register for an account at www.340BESP.com no later than November 13, 2023, to have pricing available by November 16, 2023. Data submission is voluntary.

Q3: If Lilly has already approved an insulin exception, do I need to take any action?

A3: No. Covered entities that have filed, and received approval for, an exception with Lilly as it relates to extending "penny pricing" to eligible patients at the point of sale may continue using unlimited contract pharmacies for "penny priced" insulin products. There is no action required if a covered entity currently has an existing exception in place with Lilly. Contact www.340BESP.com to register for a new insulin exception.

Q4: If Lilly has already approved a wholly owned contract pharmacy exception, do I need to take any action?

A4: No. Contract pharmacies that are wholly owned by the covered entity are not subject to Lilly's 340B Limited Distribution Program. Covered entities may continue using all of their wholly owned contract pharmacies if they have a wholly owned contract pharmacy exception in place. There is no action required if a covered entity currently has an existing wholly owned exception in place with Lilly. Contact www.340BESP.com to register for a new wholly owned exception.

Q5: What will be the effective date for my single contract pharmacy designation?

A5: For covered entities that designate a contract pharmacy after November 13, 2023, please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your designation with 340B ESP™.

Q6: How will Lilly use the 340B claims data that we provide through 340B ESP™?

A6: Data uploaded by 340B covered entities will be used to monitor for and avoid duplicate discounts and to ensure the eligibility of certain contract pharmacy replenishment orders.

Q7: What happens if my organization does not want to provide 340B contract pharmacy claims data?

A7: Submission of claims data is voluntary. All participating 340B covered entities will continue to be able to purchase Lilly medicines at the 340B price when (1) shipped to an address registered on the 340B covered entity database as a parent or child site, or (2) contract pharmacy delivery meets one of the other exceptions recognized in Lilly's Limited Distribution Program. Contact 340B@lilly.com to request information on these exceptions.

Q8: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Lilly's 340B program?

A8: No. Contract pharmacies that are wholly owned by the covered entity are not subject to Lilly's 340B Limited Distribution Program. Covered entities may continue using all of their wholly owned contract pharmacies if they have a wholly owned contract pharmacy exception in place. There is no action required if a covered entity currently has an existing wholly owned exception in place with Lilly. Contact www.340BESP.com to register for a new wholly owned exception.

Q9. I do not have an in-house pharmacy and my 340B covered entity has contract pharmacy arrangements with multiple locations of a pharmacy (e.g. six different CVS pharmacy locations). Can my entity designate all locations of the same pharmacy?

A9. No. The Lilly exception for covered entities without an in-house pharmacy allows covered entities to designate only a single contract pharmacy location. Claims data submission to 340B ESP™ is voluntary for this exception.