FQHC
340B Compliance

State of Maine | 131st Legislature
Joint Standing Committee on Health Coverage, Insurance, and Financial Services
Testimony of Dr. Felicity Homsted on behalf of FQHC 340B Compliance
April 16th, 2025

Neither For, Nor Against:
LD 1018, An Act to Protect Health Care for Rural and Underserved Areas by Prohibiting Discrimination by Participants in a Federal Drug Discount Program
Sponsored by Senator Bailey

Senator Bailey, Representative Mathieson, and members of the Joint Standing Committee on Health Coverage, Insurance, and Financial Services, Dr. Felicity Homsted is the CEO of FQHC 340B Compliance.

- The firm provides 340B consulting services to over 150 covered entities nationwide.
  - This includes 17 Federally Qualified Health Centers and 3 Hospitals in Maine.
- Testimony is offered as a 340B subject matter expert.
- The stance is neutral — neither for, nor against the bill.
- The purpose of the testimony is to explain the 340B Program's legislative and regulatory background and offer broader context for the proposed bill.

340B Program Intent & Use of Savings

- Established in 1992 with bipartisan Congressional support.
- Aims to help safety-net providers (e.g., hospitals, community health centers) serve low-income patients by offering drug price reductions.
- Goal: Stretch federal resources to reach more patients and provide broader services.
- Savings used in two ways:
  - Discounts passed directly to uninsured/underinsured patients to afford medications.
  - Revenue from standard charges reinvested into broader patient services.
- Both methods are recognized as acceptable by HRSA in guidance.

Contract Pharmacy within the 340B Program

- Contract pharmacy concept existed before the 340B Program.
- Statute does not explicitly address how drugs must be dispensed, the prohibition on diversion states: "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."
  - Implies a direct relationship between the patient and the covered entity,
  - Interpreted by HRSA to permit a range of dispensing arrangements, including contract pharmacy.
- At program inception, <5% of covered entities had in-house pharmacies.
- 1996 HRSA guidance supports the use of contract pharmacies to fulfill 340B's purpose.
- Emphasizes that use of external pharmacies is necessary for many covered entities.

Contract Pharmacy Compliance Foundations

- HRSA began exploring contract pharmacy compliance as early as 1993.
- 1995: HRSA received public inquiries on multiple contract pharmacy arrangements.
- 1996 Initial contract pharmacy guidance published
- 2001–2006: HRSA ran multiple contract pharmacy Alternate Methods Demonstrations Projects (AMDP) with 11 entities, included annual auditing for compliance.
- 2007: HRSA requested public comment based on AMDP findings.
- 2010: HRSA issued final guidance allowing multiple contract pharmacy relationships.
- Introduced mandatory annual external audits for entities with multiple contract pharmacies.
- HRSA conducts ~200 covered entity audits annually, reviewing ~6,800 contract pharmacy arrangements.
- Since 2012, about 64,000 contract pharmacy setups have been audited.

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Intersection of Federal and State Law

- Federal law governs 340B pricing; distribution mechanisms fall under State law.
- 1996 HRSA guidance confirms entities can use retail pharmacies as agents under State law.
- Covered entities must still comply with federal diversion and duplicate discount rules.

Growth in the 340B Program

- 2010: Affordable Care Act added 5 new hospital categories to the 340B program.
- Expedited registration led to a 43% increase in participation (from 14,000 to 20,000 sites).
- Growth also driven by:
    - Increased insurance coverage
    - Rising prescription drug prices (up to 15% annually)
    - Growing specialty prescription pipeline
- 340B program growth is multifactorial, coinciding with growth in the overall US drug market.

Manufacturer Restrictions to Contract Pharmacy Distribution

- First seen in 2020 with 4 manufacturers imposing restrictions.
- Currently, 37 manufacturers have placed limitations on contract pharmacy access.
- Restrictions vary by:
    - Type of covered entity affected.
    - Manufacturer's terms.
    - Pathways for restoring access (conditional on participation).

National Landscape

- Over 25% of U.S. states have passed laws similar to Maine's LD 1018 to protect contract pharmacy access.
- 20+ other states introduced similar bills in 2025.
- Some state laws are under litigation but remain upheld.
- PhRMA challenged Arkansas' 2021 law (Act 1103) at the Supreme Court.
    - SCOTUS declined to hear the case on Dec 9, 2024, keeping the 8th Circuit ruling in place, which favored state-level contract pharmacy protections.

Closing Statements

- LD 1018, as written, aligns with existing 340B Statute, Regulations, and Guidance.
- Thorough review indicates the bill remains consistent with the original legislative intent of the 340B Program.

Thank you for considering our comments. Please do not hesitate to contact me directly at Felicity@fqhc340b.com with any follow up questions.

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HEALTH CENTERS

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Senator Bailey, Representative Mathieson, and members of the Joint Standing Committee on Health Coverage, Insurance, and Financial Services, I am Dr. Felicity Homsted, CEO, of FQHC 340B Compliance. FQHC 340B Compliance is a 340B consulting firm serving over one hundred and fifty 340B covered entities across the country, including 17 Federally Qualified Health Centers and 3 Hospitals in Maine. Our company functions as 340B Technical Assistance advisor to the National Association of Community Health Centers.

The first 6 years of my career were spent as a pharmacist at Northern Light's Eastern Maine Medical Center, followed by 6 years as head of pharmacy at Penobscot Community Health Care. In addition to my role as CEO, I serve as Co-Lead investigator for the National Institute on Drug Abuse - Clinical Trials Network, researching Pharmacist-Integrated Collaborative Models of Medication Treatment for Opioid Use Disorder. This research study is based on work started at PCHC that would not have been possible without the 340B Program.

My testimony today is provided in my capacity as a subject matter expert, neither for, nor against the bill, with the intent of shedding light on the 340B Programs' legislative and regulatory history, and to provide a broader context to the proposed bill.

<u>340B Program Intent & Use of Savings</u>
The 340B Program was created in November 1992, with Bipartisan Congressional support. As described in the legislation's accompanying House Report (H.R. REP. 102-384(II) pg.12), the 340B Program was created for certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities ("covered entities") serving low-income patients to receive drug price reductions (42 U.S.C. § 256b (1992)), to *"enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."*

Each 340B covered entity is able to translate 340B discounts on medication prices into access to care through two distinct mechanisms. The first is directly passing along the discounts to uninsured and underinsured patients, helping them afford costly medications. The second is that the safety net provider dispenses the medication at the usual and customary charge and the additional revenue realized is reinvested into providing more comprehensive services beyond just the medications. Both methods result in improved access to care because of the 340B Program. Both methods are acknowledged by HRSA to be acceptable uses of savings (61 FR 43549).

<u>Contract Pharmacy within the 340B Program</u>
The concept of contract pharmacy predates the 340B program. It is important to note that while the 340B Statue does not include a reference to "entity-owned pharmacy" or "contract pharmacy," it does clearly convey that covered entities will be selling medications to patients. The statutory Prohibition on Diversion states, *"a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."* Further to this point, at the time that the 340B Statute was signed into law, less than 5% of the eligible covered entities were known to have entity-owned (in-house) pharmacies. The initial 1996 Contract Pharmacy Guidance published by

Health Resources and Services Administration (HRSA)(61 FR 43549) articulated *"because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program."*

Contract Pharmacy Compliance Foundations

This same guidance document referenced that, as early as 1993, HRSA was working with covered entities already engaged with contracted pharmacies on a limited basis to develop "a workable mechanism for the use of outside pharmacies under arrangements which would decrease the drug diversion potential."

In the initial 1995 request for comment, HRSA received inquiries about the potential for multiple contract pharmacy arrangements (61 FR 43549). Between 2001 and 2006, HRSA worked with 11 different covered entities on an Alternate Methods Demonstrations Project program (AMDP) to assess covered entities' ability to ensure compliance with diversion and duplicate discount prohibitions while engaged with multiple contract pharmacies. These AMDP experiences served as the basis for the 2007 Request for Comment (72 FR 1540) on *"contract pharmacy services arrangements previously limited to the Alternative Methods Demonstration Project program"* i.e. multiple contract pharmacy arrangements. After a three-year review period, HRSA published the 2010 Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, Final Notice (75 FR 1027), formally describing the multiple contract pharmacy relationship in guidance.

Based on the timeline documented in the Federal Register, HRSA spent 17 years validating a methodology to systematize 340B compliance for covered entities engaging with multiple contract pharmacies. The 2010 guidance added compliance expectations of annual external 340B program audits for all covered entities with multiple contract pharmacies.

HRSA conducts 200 audits of covered entities annually, which includes a review of all the entity's contract pharmacy agreements and registrations, sample testing to validate only eligible patients receive 340B medications, and assessment for potential Medicaid duplicate discount violations. On average, just under 7,000 contract pharmacy arrangements are reviewed annually during HRSA 340B audits. Since HRSA began conducting audits in 2012, approximately 64,000 contract pharmacy arrangements have been audited in conjunction with 340B covered entity audits, demonstrating HRSA's ongoing commitment to validating compliance within the multiple contract pharmacy program.

Intersection of Federal and State Law

While the regulation of 340B pricing is dictated in detail within the Federal statute, the 340B statute is silent on the exact mechanism of the sale and distribution of 340B medications to covered entity patients, leaving it to fall under the purview of State laws. Within the 1996 guidance, HRSA agreed with the comment stating as *"a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients,"* re-emphasizing the 340B covered entities' statutory obligations to prevent diversion of 340B drugs to individuals who are not patients and duplication of 340B discounts with Medicaid rebates.

Growth in the 340B Program

While the 2010 contract pharmacy guidance is often cited as the reason for the growth in the 340B Program, during the same month, the Affordable Care Act was signed into law, adding five new categories of hospitals to the 340B program: critical access hospitals, sole community hospitals, rural referral centers, free-standing children's hospitals, and free-standing cancer hospitals. HRSA held an expedited registration period for those hospitals from August 2 to September 27, 2010, and anticipated that the number of entities' participating sites would grow by 43%, from 14,000 to 20,000. Compounding this growth with the increase in access to affordable insurance and the

average annual increase in drug prices (up to 15%) (https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs), the rise in the 340B program is multifactorial.

Manufacturer Restrictions to Contract Pharmacy Distribution

Beginning in September of 2020, pharmaceutical manufacturers began imposing various restrictions on covered entities with respect to accessing 340B medications at contract pharmacies. During the first year, four manufacturers-imposed restrictions. At present, 37 manufacturers have added restrictions, limiting access for 340B covered entities across their contracted pharmacy partners. Each restriction varies by entity type impacted, manufacturer expectations, and the type of access which can be restored through participation with requirements. See attached chart for details.

National Landscape

To date, over a quarter of the states in the country have passed similar bills to LD 1018. Beyond Maine, an additional 20 states introduced bills of this nature this year. While several of these state laws have been involved in litigation with pharmaceutical manufacturers, the laws have held firm thus far. PhRMA requested a Supreme Court challenge to the 9th Circuit's ruling in favor of the Arkansas' contract pharmacy access law (Act 1103, passed in 2021).

In its request for challenge, PhRMA stated *"the Eighth Circuit blessed Arkansas's law, permitting the State to impose its own preferred obligations and enforcement scheme on 340B. The question presented is: Whether the Eighth Circuit erred in holding—in conflict with the decisions of other circuits and this Court—that a State may strip manufacturers of the ability preserved to them by 340B to impose conditions on the use of contract pharmacies as part of the offer to provide 340B-priced drugs and intrude on 340B's centralized enforcement scheme."*

On December 9th, 2024, The Supreme Court declined to hear the case, leaving the 8th Circuit ruling in favor of the Arkansas contract pharmacy access law intact.
https://www.supremecourt.gov/docket/docketfiles/html/public/24-118.html
https://arkleg.state.ar.us/Home/FTPDocument?path=%2FACTS%2F2021R%2FPublic%2FACT1103.pdf
https://340breport.com/legislative-map/contract-pharmacy-protection-bill/

Closing Statements

As stated previously, my testimony is provided in my capacity as a 340B subject matter expert, and is neither for, nor against LD 1018. As written, LD 1018 aligns with current 340B Statute, Regulations, and Guidance and based on a thorough review, the bill has not strayed from the original drafters' legislative intent for the 340B Program.

On behalf of FQHC 340B Compliance, thank you for considering our comments. Please do not hesitate to contact me directly at Felicity@fqhc340b.com with any follow up questions.

Homsted

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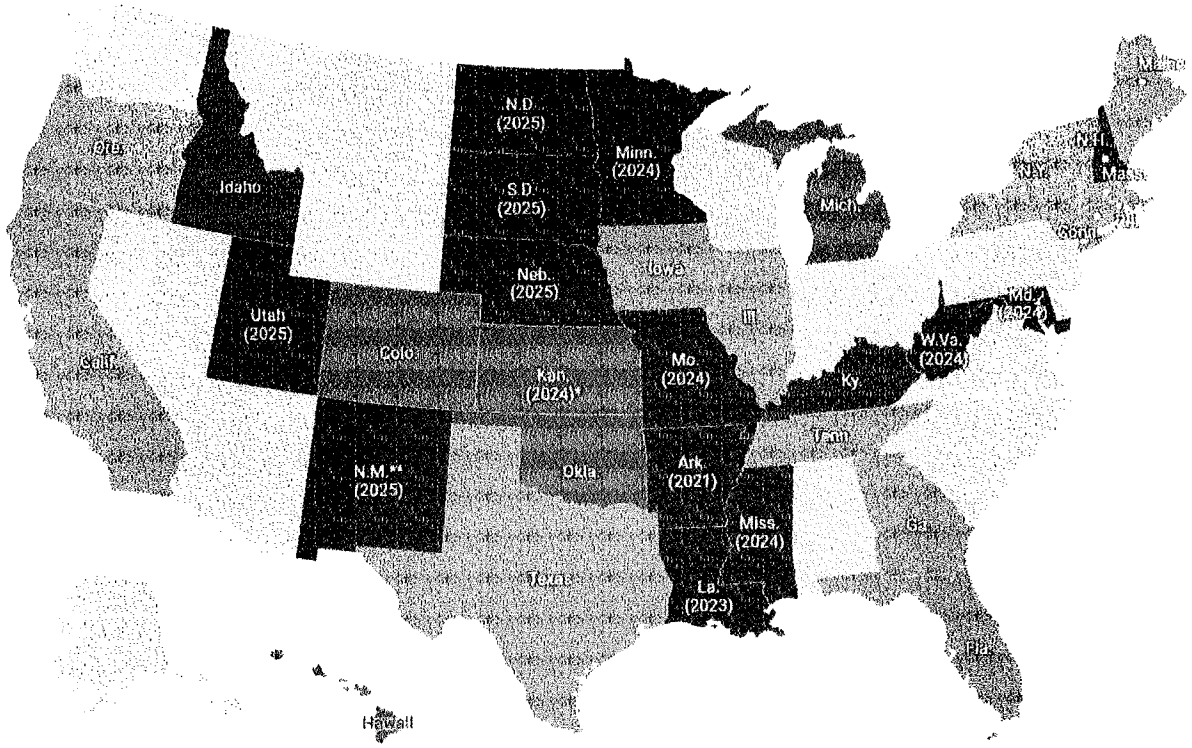
340B REPORT 2025 State Legislation Tracker: Contract Pharmacy Access Bills and Laws

Law passed | Bill introduced in 2025 | Bill cleared first legislative chamber | Bill with state governor | Bill died



*Kansas enacted 340B contract pharmacy access provisions in 2024, but the state attorney general argued in federal court that the law is unenforceable and does not "prohibit or forbid anything."

**New Mexico's bill only applies to community health centers.

Map updated as of April 10, 2025 • Created with Datawrapper

Manufacturer Contract Pharmacy Restrictions (As of 4/3/2025)

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Manufacturer	Restriction	Pricing Restoration Method	State(s) Exempt
AbbVie	Hospital with No EO Rx: 1 CRx (40 miles) + CRx Data Duopa, Imbruvica, Venclexta, Elahere, & Vyalev each designated separately Grantee: **All CRx Data for full restoration;** no designation only option	Hospital No EO Rx: Designation + CRx Data (340B ESP) Grantee: CRx Data (340B ESP)	MD **(CRx Data)** AR, MN, MS, & MO **(No Data)**
Alkermes	No EO Rx: 1 CRx	Designation (340B ESP)	AR, LA, MD, MN, MO, & MS
Amgen	No EO Rx: 1 CRx (40 miles) EO Rx: 1 CRx (40 miles) + EO Rx & CRx Data	No EO Rx: Designation (340B ESP) EO Rx: Designation + EO Rx & CRx Data (340B ESP)	AR, MD, MO, & MS
Astellas *Xtandi & Myrbetriq	No EO Rx: 1 CRx	Designation (340B ESP)	AR, LA, MD, & MS
Astra Zeneca (AZ) *All Except Oncology	No EO Rx: 1 CRx + CRx Data Lynparza, Tagrisso, & Truqap designated separately	Designation + CRx Data (340B ESP)	AR
Bausch	No EO Rx: 1 CRx (40 miles)	Designation (340B ESP)	AR & WV
Bausch + Lomb	No EO Rx: 1 CRx (40 miles)	Designation (340B ESP)	
Bayer	No EO Rx: 1 CRx (40 miles) + CRx Data Adempas designated separately, no 40-mile limit	Designation + CRx Data (340B ESP)	Contact support@340besp.com if state has passed legislation Confirmed: MS
Biogen *Avonex, Plegridy & Zurzuvae	No EO Rx: 1 CRx (40 miles) + CRx Data Zurzuvae designated separately	Designation + CRx Data (340B ESP)	AR, LA, KS, MD, MN, MS, MO, & WV
Boehringer Ingelheim (BI)	No EO Rx: 1 CRx (40 miles) + CRx Data OFEV designated separately, no 40-mile limit	Designation + CRx Data (340B ESP)	AR, LA, MD, MO, & WV
Bristol Myers Squibb (BMS)	No EO Rx: 1 CRx + CRx Data (standard elements + BIN & PCN) Camzyos, Krazati, & IMiDs (Revlimid, Pomalyst, Thalomid) designated separately ***Proposed rebate model****	Designation + CRx Data (340B ESP) IMiDs: Designation (340B ESP) + CRx Data (Secure E-mail)	AR, MD, & MS
Eisai	No EO Rx: 1 CRx	Designation (340B ESP)	AR & LA
Eli Lilly	No EO Rx: 1 CRx + CRx Data CHC entities: 1 CRx per organization, not per associated site ***Proposed rebate model****	Designation + CRx Data (340B ESP) CEs in Exempted States Except WV: CRx Data (340B ESP)	AR, KS, LA, MD, MN, MO, & MS
EMD Serono	No EO Rx: 1 CRx (40 miles) Serostim designated separately & not restricted for Ryan White clinics	Designation (340B ESP)	AR
Exelixis *Cometriq & Cabometyx	No EO Rx: 1 CRx if no CRx Data ***All CRx may be restored with claim submission***	No EO Rx or CRx Data: Designation (340B ESP) Full Restoration: CRx Data (340B ESP)	
Genentech *All except Hemlibra & Evrysdi	No EO Rx: 1 CRx	Designation (340B ESP)	AR
Gilead *Epclusa, Harvoni, Sovaldi, & Vosevi	No EO Rx: 1 CRx if no CRx Data ***All CRx may be restored with claim submission***	No EO Rx or CRx Data: Designation (340B ESP) Full Restoration: Attestation + CRx Data (340B ESP)	
GSK	No EO Rx: 1 CRx Benlysta, Nucala, Zejula, Flolan, & Ojjaara designated separately	Designation (340B ESP)	AR, LA, MD, MN, MO, MS, & WV
Incyte *Opzelura	No EO Rx: 1 CRx (40 miles)	Designation (340B ESP)	
Jazz *Epidiolex	No EO Rx: 1 CRx	Designation (340B ESP)	Any state that has passed legislation
Johnson & Johnson (J&J)	No EO Rx: 1 CRx (40 miles) EO Rx: 1 CRx (40 miles) + EO Rx & CRx Data ***Proposed rebate model****	No EO Rx: Designation (340B ESP) EO Rx: Designation + EO Rx & CRx Data (340B ESP) CEs in Exempted States: CRx Data (340B ESP)	AR, MD, & MS **(CRx Data)**

Attestation: Attest that you will begin uploading data within the next 45 days and pricing is restored based on the attestation.
CRx: Contract pharmacy
Data: Claim Submission
EO Rx: Entity owned pharmacy
LDD: Limited Distribution Drug

Restriction Applies to Hospitals Only | **Restriction Applies to all Covered Entities**

Manufacturer Contract Pharmacy Restrictions (As of 4/3/2025)

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Manufacturer	Restriction	Pricing Restoration Method	State(s) Exempt
Liquidia *Yutrepia	No EO Rx: 1 CRx + CRx Data	Designation + CRx Data (340B ESP)	AR, KS, LA, MD, MN, MS, & WV
Merck	No EO Rx: 1 CRx (40 miles) + CRx Data Winrevair designated separately, no 40-mile limit	Designation (340B ESP) CEs in Exempted States Except SD: CRx Data (340B ESP)	AR, LA, MD, MN, MO, MS, & WV (CRx Data) SD (No Data) – 7/1/25 start
Novartis	No EO Rx: 1 CRx (40 miles) + CRx Data	Designation (340B ESP)	LA, MD. MN, MO, & MS (CRx Data) AR (No Data)
Novo Nordisk *All except Rivfloza	2 CRx (regardless of EO Rx) ***All Grantee CRx may be restored with claim submission***	Designation (340B ESP) Grantee Full Restoration: CRx Data (340B ESP)	AR
Organon	1 CRx + CRx Data (regardless of EO Rx)	Designation + CRx Data (340B ESP) CEs in Exempted States Except WV: CRx Data (340B ESP)	AR, LA, KS, MD, MN, MO, & MS (CRx Data) WV (No Data)
Pfizer *Select products	No EO Rx: 1 CRx Oncology Network designated separately ***All Oncology CRx may be restored with claim submission***	No EO Rx: Designation (340B ESP) Oncology Network Full Restoration: CRx Data (340B ESP)	AR
Sandoz	1 CRx (40 miles) + CRx Data	Designation + CRx Data (340B ESP)	AR & LA
Sanofi	No EO Rx: CAH, DSH, RRC, & SCH: 1 CRx + CRx Data - If CRx in AR, attest or provide evidence of contract language re: maintaining title CHC: 1 CRx per organization, not per associated site ***Proposed rebate model***	CAH, DSH, RRC, & SCH: Designation + CRx Data (340B ESP) CHC: Designation (340B ESP) CEs in MD, MS, & MO: CRx Data (340B ESP)	MD, MO, & MS (CRx Data) AR (No Data, but Hospitals must do 340B ESP Attestation/PSA Upload)
Sobi	No EO Rx: 1 CRx (40 miles)	Designation (340B ESP)	
Sumitomo	No EO Rx: 1 CRx (40 miles) Orgovyx designated separately	Designation (340B ESP) CEs in Exempted States Except WV: CRx Data (340B ESP)	AR, KS, LA, MD, MN, MO, & MS (CRx Data) WV (No Data)
Takeda *Select products	No EO Rx: 1 CRx (40 miles) LDD products designated separately, no 40-mile limit	Designation + CRx Data (340B ESP)	AR
Teva	No EO Rx: 1 CRx (40 miles) + CRx Data	Designation + CRx Data (340B ESP)	AR & LA
UCB	Hospital with No EO Rx: 1 CRx (40 miles) + CRx Data Grantee with No EO Rx: 1 CRx (40 miles)	Hospitals: Designation + CRx Data (340B ESP) Grantees: Designation (340B ESP)	AR
United Therapeutics *All except Adcirca	No EO Rx: 1 CRx if no CRx data ***All CRx may be restored with claim submission***	No EO Rx or Data: Designation (340b@unither.com) Full Restoration: CRx Data (340B ESP)	
Vertex	No EO Rx: 1 CRx	Designation (340B ESP)	AR, KS, LA, MD, MN, MO. MS, & WV
Viatris	No EO Rx: 1 CRx	Designation (340B ESP)	AR, KS, LA, MD, MN, MO, MS, & WV

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CRx: Contract pharmacy
Data: Claim Submission
EO Rx: Entity owned pharmacy
LDD: Limited Distribution Drug

Restriction Applies to Hospitals Only	Restriction Applies to Hospitals and CHCs	Restriction Applies to all Covered Entities