

340B DRUG PRICING PROGRAM MANUFACTURER REBATE MODEL PILOT AGREEMENT

Agreement Number:	340B-PILOT-2024-5544-REV1
Program Type:	HRSA 340B Rebate Model Pilot Program
HRSA Pilot Notice:	FR-2024-340B-PILOT
Effective Date:	October 1, 2024
Pilot Termination Date:	September 30, 2027 (or earlier per HRSA notice)
Agreement Version:	1.1 (Revised)

PARTIES

Manufacturer: BioPharma Solutions LLC
Address: 3500 Research Parkway, Cambridge, MA 02142
HRSA Registration: MFR-340B-88776
DEA License: BB1234567
Contact: 340B Compliance Office, 340b-compliance@biopharmaso.com

Covered Entity: Community Health Network of Greater Detroit
Address: 1200 Health Plaza, Detroit, MI 48201
340B ID: 340B-MI-DET-99887
Entity Type: Federally Qualified Health Center (FQHC)
HRSA Registration Status: Active, renewed annually
Parent Organization: Detroit Community Health Alliance

RECITALS AND BACKGROUND

A. HRSA 340B Program. The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program under Section 340B of the Public Health Service Act, which requires pharmaceutical manufacturers to provide outpatient drugs at discounted ceiling prices to eligible covered entities.

B. Pilot Program Structure. HRSA has established a Rebate Model Pilot Program whereby manufacturers may transition from providing upfront 340B ceiling price discounts to a rebate model for specified covered outpatient drugs.

C. Voluntary Participation. Covered Entity voluntarily elects to participate in this pilot program for eligible drugs manufactured by BioPharma Solutions. Manufacturer agrees to provide retrospective rebates in lieu of upfront ceiling price discounts for covered drugs during the pilot period.

D. Compliance Obligations. Both parties acknowledge heightened compliance obligations under this pilot structure, including duplicate discount prevention, data security for protected health information (PHI), and detailed claims substantiation.

ARTICLE 1: COVERED DRUGS AND NDC LISTING

1.1 Pilot-Eligible Drugs. The following drugs manufactured by BioPharma Solutions are eligible for rebate under this pilot agreement:

NDC-11	Drug Name	Strength	Form	Package	WAC Price
65432-100-11	ImmunoVax	50mg	Injectable vial	10mL	\$4,850.00
65432-100-12	ImmunoVax	100mg	Injectable vial	20mL	\$9,250.00
65432-200-22	CardioPro	25mg	Tablet	90ct bottle	\$1,240.00
65432-200-23	CardioPro	50mg	Tablet	90ct bottle	\$1,890.00
65432-300-33	OncoPulse	200mg	Injectable	50mL vial	\$12,500.00
65432-400-44	DiabetEase	10mg/mL	Injectable pen	3mL pen	\$685.00
65432-400-45	DiabetEase	10mg/mL	Injectable vial	10mL vial	\$1,950.00
65432-500-55	PainAway XR	100mg	ER Capsule	60ct bottle	\$425.00
65432-500-56	PainAway XR	200mg	ER Capsule	60ct bottle	\$780.00
65432-600-66	InfectShield	500mg	IV solution	250mL bag	\$2,100.00

1.2 Wholesale Acquisition Cost (WAC). WAC prices listed above are current as of October 1, 2024. Manufacturer shall update Covered Entity with WAC changes quarterly via written notice and portal update.

1.3 340B Ceiling Price Calculation. HRSA-published 340B ceiling prices for each NDC shall be accessible via HRSA's 340B OPAIS system. Manufacturer shall ensure ceiling prices are updated timely and accurately per HRSA requirements.

ARTICLE 2: REBATE CALCULATION METHODOLOGY

2.1 Rebate Formula. For each qualifying dispense, the rebate amount shall be calculated as:

$$\text{Rebate Per Unit} = (\text{WAC Price} - \text{340B Ceiling Price}) \times \text{Quantity Dispensed}$$

2.2 Current 340B Ceiling Prices (Q4 2024). The following ceiling prices apply to rebate calculations for October-December 2024 claims:

NDC-11	Drug Name / Strength	WAC Price	340B Ceiling	Rebate/Unit
65432-100-11	ImmunoVax 50mg vial	\$4,850.00	\$1,215.00	\$3,635.00
65432-100-12	ImmunoVax 100mg vial	\$9,250.00	\$2,320.00	\$6,930.00
65432-200-22	CardioPro 25mg (90ct)	\$1,240.00	\$310.00	\$930.00
65432-200-23	CardioPro 50mg (90ct)	\$1,890.00	\$472.50	\$1,417.50
65432-300-33	OncoPulse 200mg vial	\$12,500.00	\$3,125.00	\$9,375.00
65432-400-44	DiabetEase 3mL pen	\$685.00	\$171.25	\$513.75
65432-400-45	DiabetEase 10mL vial	\$1,950.00	\$487.50	\$1,462.50
65432-500-55	PainAway XR 100mg	\$425.00	\$106.25	\$318.75
65432-500-56	PainAway XR 200mg	\$780.00	\$195.00	\$585.00
65432-600-66	InfectShield 250mL	\$2,100.00	\$525.00	\$1,575.00

2.3 Quarterly Ceiling Price Updates. HRSA updates 340B ceiling prices quarterly. Manufacturer shall notify Covered Entity of ceiling price changes within five (5) business days of HRSA publication. New ceiling prices apply prospectively from their HRSA-designated effective date.

2.4 Unit of Measure. Rebate calculations shall be based on the package size as listed in the NDC database. Partial packages shall not be prorated; rebates apply only to complete package dispensing units.

ARTICLE 3: DUPLICATE DISCOUNT PREVENTION REQUIREMENTS

3.1 Statutory Prohibition. Federal law prohibits manufacturers from providing both a 340B discount and a Medicaid drug rebate for the same drug. 42 U.S.C. § 256b(a)(5)(A). Covered Entity shall implement comprehensive processes to prevent such duplicate discounts.

3.2 Medicaid Fee-for-Service Exclusion. The State of Michigan is a 340B Medicaid carve-out state. All drugs dispensed to patients with Michigan Medicaid fee-for-service (FFS) coverage are EXCLUDED from 340B program participation and therefore EXCLUDED from this rebate agreement.

Covered Entity shall:

- (a) Identify Medicaid FFS beneficiaries prior to dispense using State Medicaid verification systems
- (b) Flag Medicaid FFS dispenses in pharmacy system to prevent 340B claims
- (c) Exclude all Michigan Medicaid FFS dispenses from quarterly rebate claim submissions
- (d) Maintain auditable documentation of exclusion methodology

3.3 Medicaid Managed Care. Michigan Medicaid managed care dispenses ARE eligible for 340B rebates under this agreement, as Michigan does not carve out Medicaid MCOs from 340B. Covered Entity shall distinguish between FFS and MCO coverage when processing claims.

3.4 Medicare Part D Exclusion. All Medicare Part D covered outpatient drugs are excluded from this rebate program per CMS guidance prohibiting manufacturer rebates on Part D drugs dispensed through 340B program. This includes:

- Medicare Part D primary coverage
- Medicare Advantage Part D (MA-PD) plans
- Medicare Part D Low-Income Subsidy (LIS) beneficiaries

3.5 Contract Pharmacy 340B Discount Check. For drugs dispensed through Covered Entity's contract pharmacy arrangements (identified in Section 5.3), Covered Entity shall verify that NO upfront 340B ceiling price discount was applied at point of sale/purchase. If 340B ceiling price was applied at purchase, the dispense is INELIGIBLE for rebate under this pilot program to prevent duplicate discounting.

3.6 Manufacturer Copay Assistance Programs. Dispenses where manufacturer-sponsored copay cards or patient assistance programs were utilized are EXCLUDED from rebate claims to prevent stacking of financial assistance programs.

3.7 Documentation Requirements. Covered Entity shall maintain the following documentation for all claimed dispenses:

Documentation Type	Retention Period	Audit Access
Payer verification records	7 years	Within 15 days of request
Medicaid FFS exclusion logs	7 years	Within 15 days of request
340B eligibility determinations	7 years	Within 15 days of request
Contract pharmacy TPA records	7 years	Within 15 days of request
Duplicate discount prevention procedures	Duration + 3 years	Within 30 days of request

ARTICLE 4: CLAIMS SUBMISSION PROCEDURES AND REQUIREMENTS

4.1 Submission Frequency. Covered Entity shall submit rebate claims on a quarterly basis according to the following schedule:

Quarter	Coverage Period	Claim Due Date	Expected Payment Date
Q4 2024	Oct 1 - Dec 31, 2024	February 14, 2025	April 14, 2025 (60 days)
Q1 2025	Jan 1 - Mar 31, 2025	May 15, 2025	July 14, 2025
Q2 2025	Apr 1 - Jun 30, 2025	August 14, 2025	October 13, 2025
Q3 2025	Jul 1 - Sep 30, 2025	November 14, 2025	January 13, 2026
Q4 2025	Oct 1 - Dec 31, 2025	February 13, 2026	April 14, 2026

4.2 Claim Submission Portal. All claims must be submitted electronically via Manufacturer's secure 340B rebate portal at <https://340b-rebates.biopharmaso.com>. Portal access credentials shall be provided to Covered Entity's designated 340B Program Administrator within ten (10) business days of agreement execution.

4.3 Required Data Elements. Each claim submission must include the following data elements for each dispense:

Minimum Required PHI Data Set (per HRSA pilot requirements):

- De-identified patient token (hashed patient ID, no SSN or name)
- Date of service / dispense date
- NDC-11 code
- Quantity dispensed
- Prescriber NPI number
- Dispense location (340B ID or contract pharmacy ID)
- Payer class (Commercial / Medicare Part B / Medicaid MCO / Self-Pay / Other)
- 340B eligibility flag (Y/N)
- Duplicate discount certification (attestation of no Medicaid FFS, no Part D, no double discount)

4.4 PHI Security and HIPAA Compliance. All protected health information (PHI) transmitted under this Agreement shall be handled in accordance with:

- HIPAA Privacy Rule (45 CFR Part 160 and Part 164, Subpart E)
- HIPAA Security Rule (45 CFR Part 164, Subpart C)
- Minimum necessary standard for data disclosure
- Data encryption in transit (TLS 1.3 minimum) and at rest (AES-256)

Covered Entity shall execute Manufacturer's Business Associate Agreement (BAA) prior to first data transmission. Manufacturer agrees to use PHI solely for rebate adjudication, audit, and HRSA reporting purposes.

4.5 Data Minimization. Covered Entity shall transmit ONLY the minimum PHI elements required by HRSA pilot program guidelines. Specifically:

- DO NOT submit: patient names, Social Security numbers, dates of birth, addresses, or detailed diagnosis codes
- DO submit: de-identified patient tokens using irreversible cryptographic hashing
- Tokenization algorithm: SHA-256 with facility-specific salt

ARTICLE 5: COVERED ENTITY SITES AND CONTRACT PHARMACIES

5.1 Owned/Operated Sites. The following sites owned and operated by Covered Entity are registered with HRSA as 340B-eligible locations:

Site Name	Address	340B ID	Site Type
Main Health Center	1200 Health Plaza, Detroit, MI	340B-MI-DET-99887	Parent FQHC
East Side Clinic	450 Gratiot Ave, Detroit, MI	340B-MI-DET-99888	FQHC Child Site
West Community Health	2100 Grand River, Detroit, MI	340B-MI-DET-99889	FQHC Child Site
North Wellness Center	3300 Woodward Ave, Detroit, MI	340B-MI-DET-99890	FQHC Child Site
In-House Pharmacy (Main)	1200 Health Plaza, Detroit, MI	340B-MI-DET-99887-PH	On-Site Pharmacy

5.2 HRSA Registration Maintenance. Covered Entity shall maintain active HRSA 340B registration for all sites listed above and notify Manufacturer within fifteen (15) days of any:

- Registration terminations or suspensions
- Addition of new child sites
- Changes in parent entity ownership or structure
- Annual recertification submissions to HRSA

5.3 Contract Pharmacy Arrangements. Covered Entity maintains contract pharmacy relationships with the following pharmacies registered in HRSA 340B database:

Pharmacy Name	NCPDP ID	340B Contract ID	TPA Name
Detroit Community Pharmacy	1234567	CP-99887-001	Wellcare Pharmacy Services
Motor City Rx	2345678	CP-99887-002	Wellcare Pharmacy Services
HealthPlus Pharmacy Network	3456789	CP-99887-003	Wellcare Pharmacy Services

Contract pharmacy dispenses are eligible for rebate under this pilot program ONLY IF:

- (a) Pharmacy is registered in HRSA 340B database as contract pharmacy for Covered Entity
- (b) Drug was purchased at WAC (NOT at 340B ceiling price)
- (c) Patient eligibility was verified per Covered Entity's TPA protocols
- (d) All duplicate discount prevention measures were applied

ARTICLE 6: REBATE PAYMENT TERMS AND REMITTANCE

6.1 Payment Timeline. Manufacturer shall remit rebate payments within sixty (60) calendar days of receiving complete and accurate quarterly claim submissions. Payment shall be made via wire transfer or ACH to Covered Entity's designated bank account.

6.2 Banking Information. Covered Entity's payment details:

Bank Name: First National Bank of Michigan
Routing Number: 072000805
Account Number: 4455667788
Account Name: Community Health Network 340B Rebate Account

6.3 Claim Adjudication and Denials. Manufacturer shall complete claim adjudication within forty-five (45) days of submission. If any dispenses are denied, Manufacturer shall provide detailed denial report specifying:

- Claim line numbers denied
- Specific denial reason codes
- Supporting explanation and corrective action needed
- Process for resubmission of corrected claims

Common denial reasons include:

- NDC not eligible under pilot program
- Duplicate claim (already submitted in prior quarter)
- Medicaid FFS patient (excluded per Section 3.2)
- Medicare Part D coverage (excluded per Section 3.4)
- Missing required data elements
- 340B ID not active in HRSA database on date of service
- Contract pharmacy not registered for date of dispense

6.4 Payment Reconciliation. Each payment shall be accompanied by detailed remittance advice showing:

- Total claim amount submitted
- Total approved amount
- Total denied amount
- Line-by-line claim status
- Payment reference number for Covered Entity accounting

6.5 Late Payment Interest. If Manufacturer fails to remit payment within seventy-five (75) days of claim submission (allowing 15-day grace period), interest shall accrue on unpaid amounts at a rate of Federal Reserve Prime Rate plus one percent (1%), calculated daily.

ARTICLE 7: AUDIT RIGHTS, HRSA OVERSIGHT, AND COMPLIANCE

7.1 Manufacturer Audit Rights. Manufacturer may audit Covered Entity's rebate claims, dispense records, and duplicate discount prevention procedures upon forty-five (45) days advance written notice. Audits shall:

- Occur no more than once per calendar year unless fraud suspected
- Be conducted during normal business hours
- Preserve patient privacy per HIPAA requirements
- Be limited to records directly related to claimed rebates

7.2 HRSA Program Integrity Audits. Both parties acknowledge that HRSA may audit Covered Entity's 340B program compliance and this rebate pilot arrangement at any time. Covered Entity shall:

- Cooperate fully with HRSA auditors and provide requested records
- Notify Manufacturer within five (5) days of receiving HRSA audit notice
- Share audit findings with Manufacturer within thirty (30) days of completion

7.3 OIG and State Oversight. Covered Entity acknowledges potential oversight from:

- HHS Office of Inspector General (OIG)
- Government Accountability Office (GAO)
- Michigan Department of Health and Human Services
- Other federal or state agencies

7.4 Record Retention. Covered Entity shall maintain all records related to this Agreement for minimum of six (6) years following the end of each contract year, including:

- Dispense records and prescription files
- Payer verification documentation
- Patient eligibility determinations
- 340B purchase invoices and audit trails
- Claim submissions and payment records
- Duplicate discount prevention logs
- Contract pharmacy TPA records

7.5 Audit Findings and Remediation. If audit reveals rebate overpayments exceeding two percent (2%) of total rebates paid:

- Covered Entity shall reimburse overpayments within sixty (60) days
- Covered Entity shall implement corrective action plan
- Manufacturer may require enhanced claims documentation for subsequent quarters
- Repeated violations may result in agreement termination

ARTICLE 8: TERM, TERMINATION, AND PILOT PROGRAM SUNSET

8.1 Pilot Program Term. This Agreement is effective October 1, 2024 and continues until the earlier of:

- (a) September 30, 2027 (scheduled pilot end date), OR
- (b) Date HRSA publishes Federal Register notice terminating the pilot program

8.2 Transition Back to Standard 340B Pricing. Upon pilot program termination:

- Manufacturer shall resume providing upfront 340B ceiling price discounts within thirty (30) days
- Covered Entity retains rights to rebates on all dispenses through termination date
- Final claims for last pilot quarter due within standard 45-day timeframe
- No retroactive adjustment of prior quarters upon pilot termination

8.3 Voluntary Withdrawal. Either party may withdraw from pilot program participation with ninety (90) days advance written notice to the other party and to HRSA. Withdrawal requires:

- Written notice to HRSA 340B Program Office
- Completion of all pending claim cycles
- Final reconciliation of accounts

8.4 Termination for HRSA Non-Compliance. Manufacturer may immediately terminate if:

- Covered Entity loses 340B program eligibility
- HRSA suspends Covered Entity from 340B program
- Material violation of duplicate discount prevention requirements
- Submission of fraudulent claims

ARTICLE 9: REVISION HISTORY

Version 1.0 (October 1, 2024): Original agreement executed.

Version 1.1 (December 1, 2024): Updated Section 4.1 to clarify Q4 2024 claim due date as February 14, 2025 (accounting for 45-day submission window plus year-end processing delays). Added explicit Medicare Part D exclusion language to Section 3.4 per HRSA clarification memo dated November 15, 2024.

ARTICLE 10: DISPUTE RESOLUTION AND GOVERNING LAW

10.1 Good Faith Negotiations. Disputes shall be resolved through good-faith negotiations between designated representatives within thirty (30) days of written notice.

10.2 HRSA Guidance. If dispute involves interpretation of HRSA 340B program requirements, parties shall jointly request written guidance from HRSA Office of Pharmacy Affairs before pursuing other remedies.

10.3 Arbitration. Unresolved disputes shall be submitted to binding arbitration under American Arbitration Association Commercial Rules in Boston, Massachusetts.

10.4 Governing Law. This Agreement is governed by federal 340B statute and regulations. To the extent not preempted by federal law, Massachusetts state law applies.

IN WITNESS WHEREOF, authorized representatives execute this Agreement:

BIOPHARMA SOLUTIONS LLC

COMMUNITY HEALTH NETWORK

By: _____

Name: Dr. Amanda Foster

Title: VP, Government Pricing

Date: October 1, 2024

By: _____

Name: Marcus Johnson

Title: Executive Director

Date: October 1, 2024

EXHIBIT A: 340B REBATE PROGRAM CONTACTS

Manufacturer 340B Compliance Office:

Email: 340b-rebates@biopharmaso.com

Phone: 1-877-340-DRUG (1-877-340-3784)

Portal: <https://340b-rebates.biopharmaso.com>

Mailing: BioPharma Solutions 340B Department, PO Box 8800, Cambridge, MA 02142

Covered Entity 340B Program Administrator:

Name: Sarah Thompson, PharmD

Title: Director of 340B Program Compliance

Email: sthompson@chndetroit.org

Phone: (313) 555-0145

Address: 1200 Health Plaza, Suite 400, Detroit, MI 48201

HRSA 340B Program Contact:

Office of Pharmacy Affairs (OPA)

Email: OPACustomerService@hrsa.gov

Phone: 1-888-723-7361

Website: www.hrsa.gov/opa