

NOTICE OF MEETING

Ohio Hills Health Centers will hold its next regular meeting at 12:00 Noon on Monday, November 18th, 2024, at the Library Annex in Barnesville.

Call in number for Board Meeting:

267-807-9601

PIN number:

810107

AGENDA

CALL TO ORDER – Chairperson

MINUTES OF OCTOBER 21, 2024 – Recording Secretary

CHIEF OPERATING OFFICER'S REPORT - Michael Carpenter

MEDICAL DIRECTOR'S REPORT – Himalaya Patcha, M.D.

DENTAL DIRECTOR'S REPORT – Robert Brewer, DDS

DIRECTOR OF QUALITY & CLINICAL SYSTEMS REPORT – Debbie Fisher, R.N.

DIRECTOR OF OUTREACH AND DEVELOPMENT REPORT – Jan Chambers

DIRECTOR OF REVENUE CYCLE MANAGEMENT REPORT – Dee Stewart

FINANCE COMMITTEE REPORT
INTERIM CHIEF FINANCIAL OFFICER – Matt King

CHIEF EXECUTIVE OFFICER'S REPORT – Jeff Britton

OTHER BUSINESS

ADJOURNMENT

JAB/dm

OHIO HILLS HEALTH CENTERS Minutes of Meeting October 21, 2024

The Ohio Hills Health Centers Board of Trustees held its regular meeting at the ECO Center in St. Clairsville on October 21, 2024.

Call-in Number: 267-807-9601

Passcode: 810107

Present were:

Mr. Brad Hudson, President (Call In)

Mr. Les Tickhill, Vice President (Call In)

Mr. Tim Hall, Barnesville Representative

Mrs. Donna Secrest, Monroe County Representative (Call In)

Mrs. Anita Rogers, Barnesville Representative (Call In)

Mr. Robert Koch, Secretary

Mr. Brent Tisher, Monroe County Representative

Mrs. Deborah Day, Monroe County Representative

Absent was:

Mr. Charles Bardall, Freeport Representative

Mr. Tim McKelvey, Treasurer

Also, present were:

Jeff Britton, Chief Executive Officer

Michael Carpenter, Chief Operating Officer

Matt King, Interim Chief Financial Officer

Debbie Fisher, Director of Quality and Clinical Systems

Dee Stewart, Director of Revenue Cycle Management

Denise McBurney, Recording Secretary

Absent, was:

Himalaya Patcha, M.D., Medical Director

Robert Brewer, DDS, Dental Director

Jan Chambers, Director of Outreach and Development

Meeting called to order by Brad Hudson at 12:05 p.m.

OHHC Board Meeting Minutes Page | 1 October 21, 2024 A quorum being present, Donna Secrest made a motion to approve the minutes of September 23, 2024. Seconded by Anita Rogers.

CHIEF OPERATING OFFICER'S REPORT

1. Call Center

Michael reported on Call Center Statistics from September 2024. There were 6,058 calls received with 5,209 calls answered for an answer rate of 85.98%. The goal is 95%. The average wait time was 55 seconds and the average talk time was 2 minutes and 20 seconds.

2. Operations

Michael reported on new Patient Applications for September 2024. There were 48 applications issued. There were 97 new patient appointments. Breakdown of patient appointments by provider/sites is as follows: OHCC Barnesville Dental – There were 7 applications issued and all were for Dr. Brewer; OHHC Barnesville – There were 42 applications issued and provider information as follows: Ryan=1, Morgan=4, Miles=17, Dr. Patcha=1, Dr. Wooten=11, Jenna=1, Melissa=4, Penny=3; OHHC Belmont Career Center – Shelby Jefferis saw 1 new patient with 51 total medical visits and Dr. Bauer saw 1 new patient with 5 total dental visits. OHHC Caldwell – There was 1 application issued and Dr. Overmiller was the physician; OHHC Freeport Dental – There were 4 applications issued and provider was Dr. Bauer; OHHC Freeport – There were 9 applications issued and provider information as follows: Ryan=7 and Dr. Wooten=2;OHHC Quaker City – There were 6 applications issued with all being patients of Staci; OHHC Woodsfield – There were 26 applications issued and provider information as follows: Dr. Overmiller=9, Jenna=4, Morgan=6, Ryan=7.

3. Construction Project Updates

Michael reported on the third-floor renovation project. Discussions are taking place with WDC architects. A total of \$650,000.00 has been allocated to this project and OHHC has 2 years to spend the allocated dollars.

Michael reported on the Lobby Remodel with the potential option to renovate space for the In-House Pharmacy.

4. Appointment Utilization Scheduling Trends

Michael reported a follow-up for the Board Members on appointment utilization scheduling trends. Every Sunday night he is reviewing the schedules for the future week. Took Friday night's appointment numbers and compiled these. One to four patients are scheduling and getting an appointment in the same week. Currently OHHC providers are averaging 11 patients per provider per day. This will continue to be monitored and update given to the Board Members.

Michael Carpenter requested Board Approval for the Chief Operating Officer's Report.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Robert Koch made a motion to approve the Chief Operating Officers report as presented to the Board. Seconded by Donna Secrest.

RESOLVED, that the motion passed unanimously.

Chief Operating Officers Report – Attached

MEDICAL DIRECTOR'S REPORT - There was no report given by the Medical Director.

DENTAL DIRECTOR'S REPORT – There was no report given by the Dental Director.

DIRECTOR OF QUALITY & CLINICAL SYSTEMS REPORT

1. COVID-19 and Flu Report

Debbie reported on vaccines and testing. For the month of September there were 41 Flu Vaccines administered.

Testing for the month of September:

233 tested for COVID and there were 41 positives with a 18% positivity rate.

Flu report revealed 30 tested; 0 positives; RSV report 0 tested.

2. QI Activities Update

- H3C currently has a roster of 134 patients for the Case Management of Medicare patients who have agreed to participate in the program.
- OACHC-CIN shared savings program is ongoing. We are currently working on measures to increase our profit-sharing money.
- OACHC ACO (Accountable Care Organization) is also a Medicare shared savings program.
 The program encourages promotion of Annual Wellness Visits. We are planning to train our clinical staff on how to perform, encourage these visits throughout the calendar year.
- UDS+FHIR project is ongoing to meet the HRSA required standards of submission in February 2025.
- The annual clinical staff educational training will begin this month. Several training courses
 are planned for our Annual Staff Meeting this month. (Annual Wellness Visit (Medicare),
 Immunization Guidelines, and possible discussion on the Amish culture in Healthcare).
 Presentations are planned by Providers and our Clinical Staff Managers. Robert Koch
 questioned the Amish culture in Healthcare and what we may be planning to do as far as

presentations. The staff members that deal with the Amish need to look at healthcare differently for this group and stated that the only way he was able to get anything accomplished with the Amish was to go through the Bishop.

• PCMH is ongoing with 3 check in's planned for the last Quarter of 2024.

Debbie Fisher requested Board Approval for the Director of Quality & Clinical Systems report.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Anita Rogers made a motion to approve the Director of Quality & Clinical Systems report as presented to the Board. Seconded by Donna Secrest.

RESOLVED, that the motion passed unanimously.

Director of Quality & Clinical Systems Report - Attached

DIRECTOR OF OUTREACH AND DEVELOPMENT REPORT

Michael Carpenter gave an update received from Jan Chambers on the ODH Planning Grant for Bellaire – School Based Health Center. A Business Plan and Community Needs Assessment were submitted last week. OHHC is likely to receive this funding. Jan Chambers has finalized the HRSA Application for the change in scope to add the Bellaire address.

Michael Carpenter requested Board Approval for the Director of Outreach and Development Report.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Les Tickhill made a motion to approve the Director of Outreach and Development Report as presented to the Board. Seconded by Anita Rogers.

RESOLVED, that the motion passed unanimously.

Director of Outreach and Development Report – No formal report attached.

DIRECTOR OF REVENUE CYCLE MANAGEMENT REPORT

Dee report the current month's charges for August were \$584,603.10 and September were \$570,691.42.

OHHC Board Meeting Minutes Page | 4 October 21, 2024 Dee reported the current month's payments for August were \$342,463.17 and September were \$372,799.72.

Dee reported the current month's contractual adjustments for August were \$220,165.61 and September were \$223,571.93.

Dee reported the current month's write-off adjustments were \$12,191.84 for August and \$11,697.04 for September. Write-off adjustments include sliding fee, collection balance transfer, insurance adjustment, small balance, etc.

Dee reported the days in accounts receivable were 45.76 for August and 43.34 for September.

Dee reported we have received some payments from Medicaid regarding some of the issues. There are still some issues not resolved but have been told they are working on them.

Dee Stewart requests Board Approval for the Director of Revenue Cycle Management Report.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Robert Koch made a motion to approve the Director of Revenue Cycle Management Report as presented to the Board. Seconded by Donna Secrest.

RESOLVED, that the motion passed unanimously.

Director of Revenue Cycle Management Report – Attached

CHIEF FINANCIAL OFFICER'S REPORT

Matt reported on information for month ending September 30, 2024. The Balance Sheet and Income Statements (detail and summary) were uploaded to the Board Portal prior to the meeting. Matt indicated that the September finances did improve slightly from the prior month. As you can see from the information from the Portal, there was a \$35,000.00 monthly profit, an indication that we are moving in the right direction. Matt also distributed the monthly bank balances for comparison and analysis.

As mentioned at the last meeting, a majority of the Administrative Team has been watching webinars that focus on FQHC's and how to appropriately maintain documentation (time and effort logs or semi-annual certifications) for the federal grants received by OHHC. Matt his been working with Karen Gilham and Michael Carpenter on developing forms to ensure compliance with these federal regulations/guidelines.

OHHC Board Meeting Minutes Page | 5 October 21, 2024 Matt King requests Board Approval for the Chief Financial Officer's Report.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Anita Rogers made a motion to approve the Chief Financial Officer's Report as presented to the Board. Seconded by Les Tickhill.

RESOLVED, that the motion passed unanimously.

Chief Financial Officer's Report – Attached

CHIEF EXECUTIVE OFFICER'S REPORT

1. 340B Update

Jeff reported no new updates at either state or federal level. Continuing to have weekly meetings with in-house pharmacy consultants. Policy and procedures have been completed and will be presented to the Board at the November Meeting. Meeting has been held with WDC Group architect Chris Widener to finalize the floor plan to reduce construction costs. Estimated construction cost is \$388,000.00. WDC Group Architect, Chris Widener reported there may be room for bids to come in lower. After meeting with WDC Group Michael Carpenter and I met to talk about looking for a temporary location for the In-House Pharmacy due to the only way we can afford this is to borrow money. It will take 12 to 18 months to get this up and running. One solution that we came up with was to utilize the space in my office and the area out in front of my office to temporarily house the In-House Pharmacy. Obviously, this is not the space we need but this would be a relatively inexpensive solution to get revenue generated. This area is secure and would meet the guidelines and we would not have to borrow money. The NPI number has been assigned for the In-House Pharmacy.

2. CARES Program Agreement

Jeff reported the agreement has been signed and Ryan will start working with this program beginning November 1, 2024. The remainder of OHHC Woodsfield staff will see Ryan's patients when Ryan is not in the office.

3. Policy Approvals

Jeff reported on a policy that was inadvertently left out from last month. Policy #2.04 Employment and Termination. Two existing policies were combined to make this one policy. No functional changes. Policy #3.16 Fee Schedule. This policy was significantly changed to reflect the work we recently did for the fee schedule update and the process we will follow in future years when fees are evaluated and updated.

OHHC Board Meeting Minutes Page | 6 October 21, 2024 Jeff requests motion for approval for Policy #2.04 Employment and Termination.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Donna Secrest made a motion to approve Policy #2.04 Employment and Termination as presented to the Board. Seconded by Robert Koch.

RESOLVED, that the motion passed unanimously.

Jeff requests motion to approved Policy #3.16 Fee Schedule.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Donna Secrest made a motion to approve Policy #3.16 Fee Schedule as presented to the Board. Seconded by Robert Koch.

RESOLVED, that the motion passed unanimously.

4. Dentist Search

Jeff reported he did reach out to Dr. Joe Benson and he is still in the decision-making mode as to where he wants to practice. Continuing to work with the Medicus Firm to find a dentist as well.

5. Extra Holiday Time Approval

Jeff reported as you know, in years past I have asked the Board to approve 2 extra paid days off around the holidays in which all OHHC sites were closed those 2 days. If you remember during our previous cost-cutting discussions with the Board, I determined these 2 extra paid days off costs OHHC approximately \$77,000.00 in payroll and lost patient revenue. To help with patient access around the Holidays but still recognize the staff's hard work I am requesting permission to grant all OHHC staff 2 extra paid days off to use at their discretion but within the guidelines of OHHC policy. OHHC will now remain open during those 2 days. Jeff stated he and Michael both received negative feedback regarding this decision. Jeff reported now that OHHC is growing need to make sure our business structure is more like a corporate structure. Jeff reported that both dentists have asked for time off around Thanksgiving and Christmas for 2024. Moving forward, I will be telling the dentists that the expectation will be that one of them will be working through the holidays. Tim Hall completely agrees with the thinking on this but feels this issue needs to be tabled until calendar year 2025. Discussion ensued by Board Members and motion was made by Tim Hall to table this until January of 2025.

OHHC Board Meeting Minutes Page | 7 October 21, 2024

6. OHHC Caldwell

Discussion ensued regarding number of patient seen at the OHHC Caldwell. Michael reported there were 16 patients seen in and that location is only open one day a week from 8:00 to 4:30. Jeff stated if we do not get the extended hours grant for OHHC Caldwell then we will close OHHC Caldwell.

Jeff Britton requests Board Approval for the Chief Executive Officer's Report.

RESOLUTION

Adopted 10/21/2024

WHEREAS, Robert Koch made a motion to approve the Chief Executive Officer's Report as presented to the Board. Seconded by Tim Hall.

RESOLVED, that the motion passed unanimously.

Chief Executive Officer's Report – Attached

BUSINESS:

The next Board Meeting will be held at the Library Annex in Barnesville on November 18, 2024.

ADJOURNMENT

There being no further business motion made to adjourn meeting at 1:25 p.m. by Robert Koch. Seconded by Tim Hall.

Robert Koch, Secretary
Denise McBurney, Recording Secretary

OHHC Board of Trustees October 2024 Report

Call Center

- Call Stats
 - o October 2024
 - 6243 Received
 - 5226 Answered
 - 83.71% Answer Rate Goal of 95%
 - Average Wait Time 50 Seconds
 - Average Talk Time 2 minute 16 seconds

Operations

- New Patient Applications
 - o October 2024
 - New Patient Appointments 91
 - Barnesville Dental 3
 - o Dr. Brewer 3
 - Barnesville 36
 - o Ryan Aston 1
 - o Morgan Stephen 1
 - o Miles Jefferis 12
 - o Dr. Patcha 3
 - o Dr. Wooten 6
 - o Jenna Brown 1
 - o Melissa Huff 7
 - o Penny Shepherd 5
 - Career Center
 - o Shelby Jefferis 1 (43 Total Medical Visits)

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- o Dr. Bauer 7 (24 Total Dental Visits)
- Caldwell 7
 - o Dr. Overmiller 7
- Freeport Dental 4
 - o Dr. Bauer 4
- Freeport 4
 - o Ryan Aston 3
 - o Dr. Wooten 1
- Quaker City -- 10
 - o Staci Fellows 10
- Woodsfield 20
 - o Dr. Overmiller 6
 - o Jenna Brown 2
 - o Morgan Stephen 5
 - o Ryan Gallagher 5
 - o Melissa Huff 2

Construction Projects

- **Construction Updates**
 - o Third Floor Renovation
 - o Lobby Remodel

Denise McBurney

From: Dr. Robert Brewer

Sent: Monday, November 11, 2024 11:16 AM

To: Denise McBurney
Cc: Dr. Robert Brewer

Subject: Dental Director Q4 Report to Board

The following is the Dental Director Q4 Report to the OHHC Board for 11/18/2024:

We are operating at near capacity at both Freeport and Barnesville. There is very little room to expand to new patients with the current facilities and provider levels. We will be offering limited new patient spots at Barnesville beginning in January. Our plan is to begin with one new patient day per months and assess the effect on capacity as we go.

We are continuing to explore ways to get in front of Dental Students to expose them to the opportunities/ advantages of working for an FQHC as a new dentist Our presentation goals are to describe what an FQHC is and then introduce them to the benefits of working with us, especially the student loan repayment opportunities. Recently Casey Edwards and Lori Rockwell went to the WVU Dental Job fair and distributed information. We have applied to do a lunch and learn for the OSU dental students next semester.

The upgrade of the dental imaging software and hardware continues. The goal is to be enable all dental sites to access radiographs, much as we can access patient records, as we prepare for the opening of new dental sites.

Recently we have been working with the call center to review and update protocols for managing and scheduling emergency patients.

Two candidates for dental provider positions have been interviewed. We are waiting to hear back from the pedodontist about his decision and a site visit has been scheduled for the second candidate. Both candidates are finishing education programs with completion dates in May 2025.

Robert A Brewer Jr DDS Dental Director, Dentist Ohio Hills Health Centers 101 East Main Street Barnesville, Ohio 43713 740-239-6447 rbrewer@ohiohillshealth.org



Medical. Dental and Behavioral Health Care

OHHC Board Report

11/18/2024

1. COVID-19 and Flu Report

Vaccines and Testing

• Month of October there were 100 Flu Vaccines administered.

Testing for the month of October

- 177 tested for COVID; 11 positives with a 6% positivity rate.
 **Flu report 63 tested; 0 positive; RSV report 0 tested
- 2. 3rd Qtr Patient Satisfaction Surveys

Medical Patient Satisfaction Summary OHHC: 3rd Quarter 2024

- 806 total Patient surveys sent for visits this quarter: with a return response of > 19 % response rate
- Rating 1 to 5 with overall satisfaction > 4.9 out of 5-star rating
- Additional responses noted being overwhelmingly satisfied with the care provided. One complaint reported that they waited over 1 week to see the provider.

Dental 3rd Quarter Patient Satisfaction Survey Results:

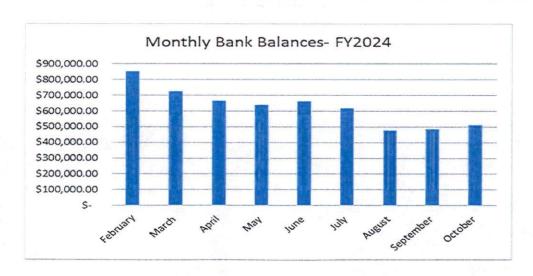
86 total sent to Dental Patients with a return of 15 surveys completed during this quarter. 17% Response Rate.

Comments made: Overall on scale of 1-5; 4.6 for the 3rd Qtr of 2024. This score is slightly lower than previous ratings earlier this year. However, no reported complaints were noted during auditing.

Ohio Hills Health Services Monthly Bank Balances For Fiscal Year Ended January 31, 2025

	February	March	April	 May	June	 July	August	September	October	November	December	January
VesBanco- ICS	\$ 789,571.99	\$ 672,330.55	\$ 614,877.65	\$ 569,257.45	\$ 623,257.45	\$ 549,181.48	\$ 385,038.22	\$ 424,485.33	\$ 428,972.12	•	•	-
WesBanco - CHC	\$ 30,970.66	\$ 23,434.99	\$ 30,689.82	\$ 38,691.68	\$ 12,962.39	\$ 45,916.31	\$ 38,135.40	\$ 23,579.51	\$ 43,753.02			
Citizen's- MFHC	\$ 17,139.17	\$ 12,068.56	\$ 14,676.83	\$ 14,944.81	\$ 20,878.01	\$ 13,763.79	\$ 31,048.57	\$ 17,921.83	\$ 21,400.16	140	-	-
WesBanco- FFHC	\$ 2,186.49	\$ 2,056.18	\$ 856.71	\$ 835.04	\$ 1,480.90	\$ 649.23	\$ 1,078.08	\$ 2,529.96	\$ 2,743.87	-		
Citizen's- QCFHC	\$ 3,446.54	\$ 2,139.98	\$ 1,147.64	\$ 3,657.21	\$ 802.66	\$ 1,098.01	\$ 1,662.76	\$ 4,530.04	\$ 2,309.85		-	12
Community Savings- CFHC	\$ 464.90	\$ 271.49	\$ 495.30	\$ 421.88	\$ 559.86	\$ 377.84	\$ 308.82	\$ 740.42	\$ 797.98			
Woodsfield Savings- SBHC	\$ 1,125.97	\$ 125.97	\$ 229.64	\$ 229.64	\$ 305.86	\$ 155.86	\$ 2,610.54	\$ 4,639.92	\$ 2,193.04	-	-	-
WesBanco- FDP	\$ 8,554.65	\$ 14,371.53	\$ 3,882.40	\$ 10,750.41	\$ 3,335.39	\$ 9,153.43	\$ 17,303.23	\$ 6,431.06	\$ 10,524.42	-		
Citizen's- CFHS	\$ 753.15	\$ 753.15	\$ 753.15	\$ 748.15	\$ 748.15	\$ 748.15	\$ 748.15	\$ 748.15	\$ 748.15			-

TOTALS \$ 854,213.52 \$ 727,552.40 \$ 667,609.14 \$ 639,536.27 \$ 664,330.67 \$ 621,044.10 \$ 477,933.77 \$ 485,606.22 \$ 513,442.61



Ohio Hills Health Services

Balance Sheet 200 - CHC As of 10/31/2024

	Beginning Year Balance	Current Year	YTD Change
Assels			
Current Assets Cash			
Cash in Bank-Operating	33,006.25	43,753.02	10,746.77
ICS - WesBanco	869,484.09	428,972.12	(440,511.97)
Checking-Citizens National	17,525,59	21,400.16	3,874.57
Checking-Caldwell	1,637.48	797.98	(839.50)
Checking-Banc One	1,630.50	2,743.87	1,113.37
Checking-Quaker City	1,286.92	2,309.85	1,022.93
Checking-CFHS	753,15	748.15	(5.00)
Petty Cash	2,900.00	2,980.00	0.00
CD's	124,102.97	124,102,97	0,00
FDP Checking	15,620,45	10,524,42	(5,096.03)
Checking - Belmont Career Center	156.29	2,193.04	2,036.75
Total Cash	1,068,103.69	640,445.58	(427,658.11)
Receivables	0,000,000,00	V 10 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	(127,000.11)
Accounts Receivable	521,369.16	613,407.52	92,038.36
Unposted AR Payments	0.00	(22,547.48)	(22,547.48)
FDP Accounts Receivable	302,848.63	191,201.10	(111,647.53)
Allowance for Doubtful Accounts	(202,000.00)	(202,000,00)	0.00
FDP Allowance for Doubtful Accounts	(130,000.00)	(130,000.00)	0,00
Other Receivable	38,182.73	28,828.47	(9,354.26)
Employee Receivable	28,572.80	27,416.68	(1,156.12)
Employee Receivable - Uniforms	27.76	0.00	(27.76)
Total Receivables	559,001.08	506,306 29	(52,694.79)
Prepaid Assets	14,333.84	0.00	(14,333.84)
Total Current Assets	1,641,438.61	1,146,751.87	(494,686.74)
Investments	10,041,140,01	1,170,733.07	(454,000.74)
Investments	6,342.09	6,342.09	0.00
Total Investments	6,342.09	6,342.09	0.00
Fixed Assets	0,342.09	0,342.09	0,00
. Fumilure & Equipment	1,046,555,51	1,060,543.51	13,988.00
Land	413,208.12	413,208.12	0.00
Building	4,007,851,48	4,007,851.48	0.00
Building Improvements	2,968,033.11	3,022,308.11	54,275.00
Improvements	88,116,91	88,11691	0.00
Accum Dep - Fum. & Equip.	(886,780.94)	(943,821,86)	(57,040.92)
Accum Dep - Building	(616,370.22)	(735,764.13)	(119,393.91)
Accum Dep - Building Improvements	(817,556.13)	(840,966.93)	(23,410.80)
Accum Dep - Improvements	0.00	(36,109.71)	(36,109.71)
ECT H8E Furniture & Equipment	21,849.78	21,849.78	0.00
ARP H8F Furniture & Equipment	122,159.43	122,159.43	0,00
ARP-Capital C&E Construction In Progress	49,943.92	49,943.92	0.00
Roof & Window Replacement Project	22,717.15	567,903.99	545,186,84
Total Fixed Assets	6,419,728.12	6,797,222.62	377,494.50
Intengible Assets	0,117,120.12	0,771,444.02	271,131130
Mayberry Dental Records	209,083.59	209,083.59	0.00
Accum Amortization	(70,856,19)	(81,310.41)	(10,454.22)
Total intangible Assets	138,227.40	127,773.18	(10,454.22)
Total Assets	8,205,736.22	R 078 089 76	(127,646.46)
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Ohlo Hills Health Services

Balance Sheet 200 - CHC As of 10/31/2024

	Beginning Year	G. 14	
	Balance	Current Year	YTD Change
Liabilities			
Accounts Payable	48,053.70	(28,676.76)	(76,730.46)
Accounts Payable Accruals	40,340,33	27,200.00	(13,140.33)
Accrued Payroll	50,642.39	50,642.39	0,00
Accrued Vacation	96,280.62	96,280,62	0.00
Accrued Workers' Comp.	1,966.04	2,439,16	473.12
Note Payable - Short Term	79,055.09	79,055.09	0.00
Notes Pay - Bradfield Bidg	179,325.79	170,304.49	(9,021.30)
USDA Loan Payable	2,809,449.40	2,767,430.07	(42,019.33)
Retirement Plan Payable	175,490.54	261,963.24	86,472.70
USDA Loan Payable - BFDC	72,158.62	63,673.51	(8,485.11)
Deferred Grant Revenue	197,699.11	99,199.11	(98,500.00)
Total Liabilities	3,750,461.63	3,589,510.92	(160,950.71)
Fund Balance			
Fund Balance			
Fund Balance	4,455,274.59	4,455,274,59	0,00
Total Fund Balance	4,455,274.59	4,455,274.59	0.00
Income YTD			
	0.00	33,304.25	33,304.25
Total Income YTD	0.00	33,304.25	33,304.25
Total Fund Balance	4,455,274.59	4,488,578.84	33,304.25
Total Liabilities & Fund Balance	8,205,736.22	8,078,089.76	(127,646.46)

Ohio Hills Health Services Statement of Revenues and Expenditures 200 - CHC

	Current Period Actual	Current Period Budget \$ - Orlginal	Current Period Original Budg Variance	Current Year Actual	YTD Budget \$ - Original	YTD Original Budget Varlance	Prior Year Actual
Revenue							
Revenue-Grant	195,030.60	170,178.83	24,851,77	1,582,262.20	1,531,609.47	50 659 72	E21 600 50
Belmont Career Ctr-Grant Rev	22,613.12	0.00	22,613.12	121,696.43	0.00	50,652.73	.531,609.79
Revenue-Patlent Fees	702,867.50	619,925.24	82,942.26	5,447,963.76		121,696.43	32,856.86
Other Patient Revenue	28,037.53	64,150.58	(36,113.05)	226,096.58	5,579,327.16	(131,363.40)	.172,000.41
Other Revenue	27,847,64	7,519.59	20,328.05	247,479.61	577,355.22	(351,258.64)	632,870.62
Donations Revenue	0.00	2,250.01	(2,250.01)	0.00	67,676.31	179,803.30	343,042,37
Uncollectible Patient Fees	1,040.60	0.00	1,040.60	685.25	20,250,09 0.00	(20,250.09)	1,515,63
Accts Rec System Adj	(287,989.10)	(247,970.17)	(40,018.93)	(2,287,777.43)		685.25	462.96
Interest Income	1,489.51	208.34	1,281.17	19,987.02	(2,231,731.53)	(56,045.90)	081,077.05)
Rental Income	4,890.00	4,715.00	175.00	42,209.00	1,875.06	18,111.96	3,604.46
ECV H80 Grant Revenue	0.00	0.00	0,00	7,924.44	42,435,00 0,00	(226.00)	42,110.00
Roof & Window Rplemnt Proj	0.00	0.00	0.00	545,186.84		7,924.44	118,996.32
Grant Revenue	5.00	0.00	0,00	343,100.04	0.00	545,186.84	0.00
3rd Flor Renovations - Sen Brn Approp	0.00	0.00	0.00	3,430.00	0.00	3,430.00	0,00
Total Revenue	695,827.40	620,977.42	74,849.98	5,957,143.70	5,588,796.78	368,346.92	797,992.37
Expenses							
Wages	364,940. 77	366,703.43	(1,762.66)	3,256,764.28	3,300,330.87	(43,566,59)	.365,550.02
All Other Expenses					, ,	(= , = = = , ,	
Consultant and Contractual	71,974.28	48,856.32	23,117,96	453,785.43	439,706.88	14,078.55	470,177.12
FICA	21,011.72	26,244.90	(5,233.18)	223,589.29	236,204,10	(12,614.81)	236,372.27
State Unemployment	250,52	513.58	(263.06)	7,270.52	4,622,22	2,648.30	4,213.70
Health Insurance	77,493.00	73,175.92	4,317.08	694,526.81	658,583.28	35,943.53	620,822.90
Dental Insurance	2,235.02	2,519.83	(284.81)	18,380.22	22,678,47	(4,298.25)	21,442.13
Workers Comp.	306.90	330,93	(24.03)	4,163.92	2,978,37	1,185.55	4,274.83
Life Insurance	359.22	1,897.59	(1,538.37)	3,135.71	17,078.31	(13,942.60)	13,784.55
Disability Inustance	1,393.34	1,492,24	(98.90)	12,896.93	13,430,16	(533.23)	12,926.13
Retirement	25,598.71	6,821.76	18,776,95	234,644.68	61,395.84	173,248.84	236,752,93
Consumable Supplies	48,818.17	40,092.51	8,725.66	283,939.30	360,832.59	(76,893.29)	380,373.82
Staff Travel-Local	116.30	1,078.56	(962.26)	1,617.94	9,707.04	(8,089.10)	4,850.37
Staff Travel-Out of Town	3,303.06	930.08	2,372.98	11,129.08	8,370.72	2,758.36	8,653.68
Depreciation Expense	26,217.26	0.00	26,217.26	235,955.34	0.00	235,955.34	235,955.34
Amortization Expense	1,161.58	0.00	1,161.58	10,454.22	0.00	10,454.22	10,454 22
Rent	300,00	370.84	(70.84)	2,700.00	3,337.56	(637.56)	16,432.00
Utilities	6,141.91	4,677.99	1,463.92	42,753.31	42,101.91	651.40	39,889.11
Insurance-Malpractice	2,473.26	4,116.59	(1,643.33)	31,208.46	37,049 31	(5,840,85)	26,987.13
Bonding	0.00	356.34	(356.34)	5,199.30	3,207.06	1,992.24	4,666.00
Insurance	7,124.25	2,056.34	5,067.91	21,342.75	18,507.06	2,835.69	19,889.90
Publication, Printing, & Subs.	12,282.68	7,255.64	5,027.04	80,436.07	65,300.76	15,135.31	76,791.06
Maintenance & Repairs	4,906.07	7,115.24	(2,209.17)	97,843,87	64,037.16	33,806.71	69,394.71
Telephone	7,883.30	6,394.73	1,488.57	48,170.37	57,552.57	(9,382.20)	54,202.88
Postage & Freight	1,109.60	776.52	333.08	6,148.25	6,988.68	(840,43)	6,637.00
Interest	5,672.25	5,966.75	(294.50)	52,005.68	53,700.75	(1,695.07)	53,335.26
Recruitment & Retention	2,166.66	2,226.16	(59.50)	17,156.12	20,035.44	(2,879.32)	20,035.44
Real Estate Taxes	0.00	1,177.66	(1,177.66)	20,007.39	10,598.94	9,408.45	13,751.15
Other Taxes	0.00	0.00	0.00	155.37	0.00	155.37	0.00
Legal	1,840.00	2,107.42	(267.42)	7,715.01	18,966.78	(11,251.77)	31,141.00

Ohio Hills Health Services

Statement of Revenues and Expenditures 200 - CHC

	Current Period Actual	Current Perlod Budget \$ - Original	Current Period Original Budg Variance	Current Year Actual	YTD Budget \$ - Original	YTD Original Budget Variance	Prior Year Actual
Accounting	0.00	2,000.00	(2,000.00)	25,000.00	18,000.00	7,000.00	25,000.00
Section 330 (e) Financial Reserve	0.00	1,965.08	(1,965.08)	0.00	17,685.72	(17,685.72)	0.00
Marketing	339.78	1,756.42	(1,416.64)	13,743.83	15,807.78	(2,063.95)	27,242,31
Donations	0,00	0.00	0.00	0.00	0.00	0.00	200.00
ARP H8F Consumable Supplies	0.00	0.00	0.00	0.00	0.00	0.00	257.31
ECV H80 Consumable Supplies	0.00	0.00	0.00	0.00	0.00	0.00	4,523.53
ECV H8G Marketing	0.00	0.00	0,00	0.00	0.00	0.00	49,962 00
Total All Other Expenses	332,478.84	254,273.94	78,204.90	2,667,075,17	2,288,465.46	378,609.71	801,391.78
Total Expenses	697,419.61	620,977.37	76,442.24	5,923,839.45	5,588,796.33	335,043.12	166,941.80
Net Revenue (Expenses)	(1,592.21)	0.05	(1,592.26)	33,304.25	0,45	33,303.80	<u>368,949.43)</u>

Ohio Hills Health Services Summary Statement of Revenues and Expenditures 200 - CHC

20 - Woodsfield

	Current Period Actual	Current Year Actual
Revenue		
Program Income	107,758,32	831,817.86
Other Patient Revenue	16,800.73	90,186,76
Other Revenue	5,363.89	182,361.45
H80 Grant Revenue	62,409.80	509,119.84
Other Grant Revenue	0.00	5,632.76
Total Revenue	192,332,74	1,619,118.67
Expenses		
Personnel	90,674.27	785,348.90
Fringe Benefits	28,963.95	258,955.49
Supplies	19,740.18	78,308.51
Contractual	23,130.20	131,322.62
Other	26,296.02	201,953.71
Depreciation/Amortization	13,586.24	122,276.16
Total Expenses	202,390.86	1,578,165.39
Net Revenue (Expenses)	(10,058.12)	40,953.28

Ohlo Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC

	Current Period Actual	Current Year Actual
Revenue	•	
Program Income	415,919.00	3,160,871.58
Other Patient Revenue	28,037.53	226,096.58
Other Revenue	34,227.15	309,675,63
HBO Grant Revenue	195,030.60	1,582,262.20
Other Grant Revenue	22,613.12	678,237.71
Total Revenue	695,827.40	5,957,143.70
Expenses		
Personnel	364,940.77	3,256,764.28
Fringe Benefits	128,648.43	1,198,608.08
Supplies	48,818.17	283,939.30
Contractual	71,974.28	453,785.43
Olher	55,659.12	484,332.80
Depreciation/Amortization	27,378,84	246,409.56
Total Expenses	697,419.61	5,923,839.45
Net Revenue (Expenses)	(1,592.21)	33,304.25

Ohio Hills Health Services Summary Statement of Revenues and Expenditures 200 - CHC 30 - Freeport From 10/1/2024 Through 10/31/2024

	Current Period Actual	Current Year Actual
Revenue		
Program Income	18,227.82	200,914.68
Other Patient Revenue	80.64	10,060.90
Other Revenue	89.21	12,524.90
H80 Grant Revenue	11,701.84	95,069,56
Other Grant Revenue	<u> </u>	0.00
Total Revenue	30,099.51	318,570,04
Expenses	,	
Personnel	21,799.42	211,234.96
Fringe Benefits	11,057.22	92,015.82
Supplies	6,380.48	24,193.54
Contractual	3,276.22	22,036.24
Other	2,351.09	28,046,44
Depreciation/Amortization	516.11	4,644.99
Total Expenses	45,380.54	382,171.99
Net Revenue (Expenses)	(15,281.03)	(63,601.95)

Ohio Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC 25 - Caldwell

	Current Period Actual	Current Year Actual
Revenue		
Program Income	5,232.63	22,695.50
Other Patient Revenue	120.16	520.35
Other Revenue	44.60	1,284.57
H80 Grant Revenue	5,850.92	47,467.83
Other Grant Revenue	0.00	0.00
Total Revenue	11,248.31	71,968.25
Expenses		
Personnel	5,544.61	42,013,44
Fringe Benefits	2,360.33	16,290.62
Supplies	135.60	3,144.05
Contractual	2,799.21	23,192.83
Other	1,232.45	10,044.29
Depreciation/Amortization	126,75	1,140.75
Total Expenses	12,198.95	95,825.98
Net Revenue (Expenses)	(950,64)	(23,857.73)

Ohlo Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC 45 - Quaker City From 10/1/2024 Through 10/31/2024

	Current Period Actual	Current Year Actual
Revenue		
Program Income	36,242.11	270,614.27
Other Patient Revenue	3,286.85	16,925.78
Other Revenue	124.08	12,625.83
H80 Grant Revenue	11,701.84	95,203.31
Other Grant Revenue	0.00	0.00
Total Revenue	51,354.88	395,369.19
Expenses		
Personnel	22,882.24	186,916.23
Fringe Benefits	13,155.92	92,407.55
Supplies	2,523.65	20,781.30
Contractual	4,212.13	31,138.60
Other	2,269.36	29,256.41
Depredation/Amortization	1,028.60	9,257,40
Total Expenses	46,071.90	369,757.49
Net Revenue (Expenses)	5,282.98	25,611.70

Ohio Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC

40 - Barnesville

	Current Period Actual	Current Year Actual
Revenue		
Program Income	150,580.41	1,057,209.36
Other Patient Revenue	7,749.15	108,402.79
Other Revenue	25,510.38	96,336.20
H80 Grant Revenue	72,161.32	584,379.84
Other Grant Revenue	0.00	550,908.52
Total Revenue	256,001.26	2,397,236,71
Expenses		
Personnel	130,660.36	1,258,735.10
Fringe Benefits	44,967.73	527,568,70
Supplies	6,840.63	69,551.15
Contractual	24,707.55	170,521.89
Other	17,393,57	158,343.50
Depreciation/Amortization	9,010.79	81,097.11
Total Expenses	233,580,63	2,265,817.45
Net Revenue (Expenses)	22,420.63	131,419.26

Ohio Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC

71 - Belmont Career Center - Dental From 10/1/2024 Through 10/31/2024

	Current Period Actual	Current Year Actual
Revenue		
Program Income	4,089.73	10,337.22
Other Grant Revenue	7,808.48	40,736.51
Total Revenue	11,898.21	51,073,73
Expenses		
Personnel Personnel	6,265.27	22,212.20
Fringe Benefits	652,37	3,013,99
Supplies	0.00	10,550.21
Contractual	0.00	0.00
Other	39.18	1,812,58
Total Expenses	6,956.82	37,588,98
Net Revenue (Expenses)	4,941.39	13,484.75

Ohlo Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC $^{\frac{1}{2}}$

70 - OHHC - Belmont Career Center From 10/1/2024 Through 10/31/2024

	Current Period Actual	Current Year Actual
Revenue		
Program Income	4,956.80	25,582.30
Other Grant Revenue	14,804.64	80,959.92
Total Revenue	19,761.44	106,542.22
Expenses		
Personnel	10,995.23	52,599.15
Fringe Benefits	3,707.33	16,149.96
Supplies	7.49	1,327.55
Contractual	95.00	100.00
Other	301.78	1,971.59
Total Expenses	15,106.83	72,148.25
Net Revenue (Expenses)	4,654,61	34,393.97

Ohlo Hills Health Services
Summary Statement of Revenues and Expenditures
200 - CHC

80 - Freeport Dental From 10/1/2024 Through 10/31/2024

	Current Period Actual	Current Year Actual
Revenue		
Program Income	20,286.50	216,542.13
Other Patient Revenue	0.00	0.00
Other Revenue	148.68	2,321.22
H80 Grant Revenue	15,602.44	125,510.91
Other Grant Revenue	0.00	0.00
Total Revenue	<u> 36,037.62</u>	344,374.26
Expenses		
Personnel	27,504.82	242,569.21
Fringe Benefits	8,682.04	66,050.64
Supplies	2,628.01	26,063.99
Contractual	6,243.95	26,536.07
Other	2,474.46	24,889.05
Depreciation/Amortization	1,351.32	12,161.88
Total Expenses	48,884.60	398,270.84
Net Revenue (Expenses)	(12,846.98)	(53,896.58)

Ohio Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC 72 - OHHC - Bellaire From 10/1/2024 Through 10/31/2024

	Current Perlod Actual	Current Year Actual
Expenses		
Contractual	1,500.00	11,000.00
Other	0.00	769.00
Total Expenses	1,500.00	11,769,00
Net Revenue (Expenses)	(1,500.00)	(11,769.00)

Ohio Hills Health Services

Summary Statement of Revenues and Expenditures 200 - CHC

85 - Barnesville Dental From 10/1/2024 Through 10/31/2024

	Current Period Actual	Current Year Actual
Revenue		
Program Income	68,544.68	525,158.26
Other Patient Revenue	0.00	0.00
Other Revenue	2,946.31	2,221.46
H80 Grant Revenue	15,602.44	125,510.91
Other Grant Revenue	0.00	0.00
Total Revenue	87,093.43	652,890.63
Expenses		
Personnel	48,614,55	455,135.09
Fringe Benefits	15,101.54	126,155.31
Supplies	10,562.13	50,019.00
Contractual	6,010.02	37,937.18
Other	3,301.21	27,246.23
Depreciation/Amortization	1,759.03	15,831.27
Total Expenses	85,348.48	712,324.08
Net Revenue (Expenses)	1,744.95	(59,433.45)

OHIO HILLS HEALTH SERVICES 101 East Main Street Barnesville, Ohio 43713

	BOARD APPROVED: 11-18-24 AL MANAGEMENT POLICY	
TITLE: 340B Procedure Manual PAGES: 29	REVISION DATE:	
POLICY NUMBER: 340B.0	EFFECTIVE DATE: 11-18-24	

Purpose: This manual contains the written policies and procedures that Ohio Hills Health Services uses to oversee 340B Program operations, provide oversight of contract pharmacies, and maintain a compliant 340B Program.

Policy 340B.00

- Purpose
- Background
- 340B Policy Statements
- Definitions
- References
- Policy Review, Updates, and Approval

Procedures

- Procedure 340B.01 Covered Entity Eligibility
- Procedure 340B.02 340B Program Enrollment Recertification, and Change Requests
- Procedure 340B.03 340B Eligibility Patient and Health Care Professional Definition
- Procedure 340B.04 Prevention of Duplicate Discounts
- Procedure 340B.05 340B Program Roles and Responsibilities
- Procedure 340B.06 340B Program Education and Competency
- Procedure 340B.07 Inventory Management
- Procedure 340B.08 Contract Pharmacy Operations
- Procedure 340B.09 Referral & Non-Health Center Provider Prescription Eligibility
- Procedure 340B.10 340B Noncompliance/ Material Breach
- Procedure 340B.11 340B Program Compliance Monitoring/Reporting
- Procedure 340B.12 Contract Pharmacy Oversight and Monitoring
- Procedure 340B.13 Prime Vendor Program (PVP) Enrollment and Updates
- Procedure 340B.14 State of Emergency Management

340B.00 – Policy Statements

Purpose: This document defines policies that Ohio Hills Health Services (hereafter, the health center), uses to oversee 340B Program operations, provide oversight of contract pharmacies, and maintain a compliant 340B Program.

Background: Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

The 340B Program is administered by the Federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS). Upon registration on 340B OPAIS (Office of Pharmacy Affairs Information System), the health center:

- Agrees to abide by specific statutory requirements and prohibitions.
- May access 340B drugs.

340B Policy Statements

- The health center complies with all requirements and restrictions of Section 340B of the Public Health Service Act including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. (REFERENCE: Section 340B of Public Health Service Act, 340B Guidelines, 340B Policy Releases).
- The health center uses any savings generated from 340B in accordance with 340B Program intent, "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The health center intends to use 340B savings for staff salaries, employee benefits, expansion of services, patient assistance, and facilities improvements within grant scope.
- The health center meets the requirements of 42 USC §256b(a)(4)(A) to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.
- Per 340B statutory provision "Prohibiting resale of drugs." 42 U.S.C. § 256b(a)(5)(B)., a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."
- The health center has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.
 - o It is the policy of the health center to maintain the ability to track and account for all 340B drugs to prevent diversion. This oversight includes the acquisition, administration, dispensation, and waste of all 340B medications.
 - O The health center remains responsible for ensuring that its contract pharmacy operations comply with all 340B Program requirements, such that the covered entity remains responsible for the 340B drugs it purchases and dispenses through a contract pharmacy. The health center ensures oversight of their contract pharmacy arrangements compliance.
 - o 42 USC §256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. The health center has mechanisms in place to prevent duplicate discounts.
- The health center deems patients seeing prescribers not employed by or contracted with the health center to be eligible to receive 340B medications when sufficient documentation is present within the medical records to demonstrate that the individual is a patient of the covered entity, and the health center maintains an ongoing relationship with the individual.
- The health center has processes in place to maintain compliance with all 340B requirements, including during states of emergency.

- The health center maintains auditable records demonstrating compliance with the 340B Program.
 - o Annually, the health center engages an independent organization to perform external compliance reviews (audits) of its 340B Program, including contract pharmacies.
 - O Documents and records associated with the health center's participation in the 340B Drug Pricing Program are to be kept for three (3) years.
- The health center acknowledges that if there is a breach of the 340B requirements, it may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation. Depending upon the circumstances, the health center may be subject to the payment of interest, reimbursement, penalties, and removal from the list of 340B entities. The health center is responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity with any of the 340B Program requirements.

Definitions:

- Definitions of terms may be found in the <u>Apexus 340B Glossary of Terms</u>.
- Acronym guide may be found in the <u>Apexus Acronym Guide</u>.

References: Each section includes pertinent references to P&Ps, HRSA website, etc.

- Section 340B of Public Health Service Act
- 340B Guidelines
- 340B Policy Releases
- Apexus 340B Glossary of Terms
- Apexus Acronym Guide

Policy Review, Updates, and Approval: These written policies and procedures will be reviewed and approved annually by Ohio Hills Health Services staff, committee, and/or board, and updated whenever there is a clarification or change to the 340B Program requirements.

340B Procedure Manual

340B.01 - Covered Entity Eligibility

SCOPE: Ohio Hills Health Services, (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: The health center must meet the requirements of 42 USC §256b(a)(4)(A) to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

PURPOSE: To ensure the health center's eligibility to participate in the 340B Program.

DEFINITIONS:

- Covered outpatient drug (COPD) as defined in <u>Section 1927(k)</u> of the Social Security Act includes:
 - o All prescription medications where the manufacturer has a pharmaceutical pricing agreement (PPA) in place, including over-the-counter medications ordered by prescription.
 - Biologic products, other than vaccines.
 - o Insulin medications.

PROCEDURE:

- The health center's basis for 340B eligibility is determined by meeting the definition of "federally qualified health center" in section 1905(1)(2)(B) of the Social Security Act.
 - o 340B ID CH050560
 - o HRSA Grant Number H80CS00816
- The term "Federally-qualified health center" means an entity which
 - o Is receiving a grant under section 330 of the Public Health Service Act,
 - O Is receiving funding from such a grant under a contract with the recipient of such a grant, and meets the requirements to receive a grant under section 330 of such Act,
- The health center has identified 340B eligible locations and services where it administers, prescribes, or dispenses 340B drugs as:
 - o All primary or associated locations listed as active in EHB Form 5B.
 - o Associated services, included within scope, defined in EHB Form 5C.
 - o Entity-owned and operated outpatient (in-house) pharmacies and contract pharmacy locations listed as active on 340B OPAIS.
- All new sites added to the health center's approved scope of grant, are deemed 340B eligible once reflected as active on EHB Form 5B. Newly added sites will be registered on 340B OPAIS in the subsequent open registration window.
- The health center maintains auditable records, policies, and procedures related to the definition of covered outpatient drug that are consistent with the 340B statute and Social Security Act.
- The health center ensures that 340B OPAIS is complete, accurate, and correct for all 340B eligible locations (main and associated sites, and contract pharmacies). [Refer to the health center's Policy and Procedure "340B Program Enrollment, Recertification, and Change Request", 340B Manual, Policy 340B.02].
 - o All main/associated site addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.
 - o The health center regularly reviews its 340B OPAIS records [Refer to the health center's Policy and Procedure "340B Program Compliance Monitoring and Reporting", 340B Manual, Policy 340B.11].
- The health center informs HRSA immediately of any changes to its Medicaid information by updating the 340B OPAIS Medicaid Exclusion File within 30 days. The data included in the

Medicaid Exclusion File is provided by covered entities for drugs billed under Medicaid fee-for-service and does not apply to Medicaid managed care organizations.

- The health center carves-in Medicaid reimbursement for entity-owned pharmacy.
- The health center carves-in Medicaid reimbursement for contract pharmacy.
- The health center carves-in/carves-out for Medicaid reimbursement for a limited formulary of 340B clinic administered medications (CADs).
- The health center annually recertifies 340B registration information on 340B OPAIS. [Refer to the health center's Policy and Procedure "340B Program Enrollment, Recertification, and Change Request", 340B Manual, Policy 340B.02].

340B Procedure Manual

340B.02 - Program Enrollment, Recertification, and Change Requests

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: Eligible entities must maintain the accuracy of 340B OPAIS and be actively registered to participate in the 340B Program.

PURPOSE: To ensure that the health center is registered appropriately on 340B OPAIS and maintains accurate records.

References:

- 340B Drug Pricing Program: Grantee Registration Instructions at <u>HRSA OPA Registration</u>
- Registration dates may vary slightly per weekends, holidays, etc.:
 - o January 1-January 15 for an effective start date of April 1
 - o April 1-April 15 for an effective start date of July 1
 - o July 1-July 15 for an effective start date of October 1
 - October 1-October 15 for an effective start date of January 1
- 340B Contract Pharmacy Guidelines

PROCEDURE:

Enrollment

- O The health center is eligible to participate in the 340B Program [Refer to the health center's Policy and Procedure "Covered Entity Eligibility", 340B Manual, Policy 340B.01].
- o The health center identifies upcoming OPAIS registration dates and deadlines.
- o The health center identifies the health center's authorizing official and primary contact.
- o The health center has available the required documents/contracts.
 - 340B ID CH050560
 - HRSA Grant Number H80CS00816
 - IDs for all registered sites listed on <u>340B OPAIS</u>
- o The health center completes registration on <u>340B OPAIS</u>.
- All new sites added to the health center's approved scope of grant, are deemed 340B eligible once reflected as active on EHB form 5B and are registered on 340B OPAIS in the subsequent open registration window.

• Recertification Procedure

- o The health center annually recertifies the health center's information on 340B OPAIS.
- o The health center's Authorizing Official completes the annual recertification by following the directions in the recertification email sent from HRSA prior to the stated deadline.
- o The health center annually recertifies the following information on the HRSA's 340B Database:
 - The authorizing official, along with the primary contact, must perform this procedure at least annually. This should also be done whenever there is a change in site location.
 - HRSA / OPA will send an advanced email notification with preliminary information about the recertification process to the primary contact and authorizing official listed on the HRSA Database.
 - As part of the recertification process, the health center verifies and attests to the accuracy of all information they have listed on 340B OPAIS. This process includes verifying and correcting where needed:
 - EHB Form 5B's listing of active locations to the 340B registrations on OPAIS. For all

- sites, the street address must include the physical address of the location as it is listed on Form 5B.
- Medicaid billing practice information. If the site bills Medicaid for drugs purchased through the 340B Program, the Medicaid numbers, NPI numbers, and states listed on OPAIS must match the billing numbers used by the site.
- Contract pharmacy agreements include all registered locations. Contract pharmacies should be listed with, at minimum, one health center location. If they are listed with one location, they may be used by any of the Grantee Associated sites registered on the database, unless otherwise restricted in the contract agreement.
- Ancillary information including authorizing official, primary contact, billing, and shipping addresses, etc.
- Failure to recertify would result in termination from the 340B Program. The covered entity would not be able to reapply for participation in the program until the next open enrollment period with a start date of the following quarter.
- o The health center submits specific recertification questions to 340b.recertification@hrsa.gov.

Enrollment Procedure: New Associated Sites

- The health center determines that a new service site or facility is eligible to participate in the 340B Program (e.g., due to a change in grant scope).
 - The criteria used include that the service site is identified in the scope of grant, has outpatient drug use, and has patients who meet the 340B patient definition (including provision of services consistent with funding and/or designation status).
- The health center updates the HRSA Electronic Handbook (EHB) to correctly reflect the new service site/facility.
- Once the site/facility is appropriately listed on the EHB as active, the health center's authorizing official completes the online registration process in 340B OPAIS during the registration window.

Enrollment Procedure: New Contract Pharmacies

- The health center has a signed contract pharmacy services agreement between the entity and contract pharmacy prior to registration on 340B OPAIS.
- o Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services
- O The health center's legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.
- The health center has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented. [Refer to the health center's Policy and Procedure "Contract Pharmacy Oversight Management and Monitoring", 340B Manual, Policy 340B.12]
- o The health center's authorizing official or designee completes the online registration during one of four registration windows.
 - Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.
- The health center begins using the contract pharmacy services arrangement only on or after the effective date shown on 340B OPAIS.

Procedure for Changes to the Health Center's Information in 340B OPAIS

- o The health center notifies HRSA immediately of any changes to the health center's grant status or other such changes within the health center.
- o The health center will stop the purchase of 340B drugs as soon as the health center loses 340B Program eligibility (i.e., through a grant status change).
- O The health center's authorizing official will complete the online change request as soon as a change in eligibility is identified.

- The health center will expect changes to be reflected within two weeks of submission of the changes/requests.
- The health center will notify HRSA immediately of any changes to the health center's information on 340B OPAIS. [Refer to the health center's Policy and Procedure "Covered Entity Eligibility", 340B Manual, Policy 340B.01].
- o The health center's authorizing official will complete the online change request as soon as a change in eligibility is identified.
 - The health center will expect changes to be reflected within about 2 weeks of submission of the changes/requests.

Procedure for Changes to the Health Center's Medicaid Exclusion File Information in 340B OPAIS

- The health center notifies HRSA in advance of any changes to Medicaid Fee-For-Service billing practices within the health center's associated sites and entity-owned pharmacies.
- o If electing to carve-in for bill 340B drugs to a state Medicaid agency, the health center will update its OPAIS registration and the Medicaid Exclusion File with the state specific and site billing information including National Provider Identifier (NPI) and Medicaid Billling number (if used by state) in the quarter prior to billing process changes.
 - A change to the MEF may be requested at any time, however changes only take effect the following quarter and only if the change request is received, approved, and processed by the HRSA before the time of the OPAIS snapshot (12:01 am on the 16th day of the month prior to the start of the quarter). Reference: HRSA FAO 1507
 - All changes to Medicaid billing practices will be updated on OPAIS by the 15th of the final month of the quarter before the change is to take effect.
 - OPAIS for the MEF would be completed by June 15th to ensure the information is available for the MEF update pulled by HRSA at the end of the quarter on June 16th.

340B.03 – 340B Eligibility

(Including Patient and Health Care Professional Definitions)

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: Per 340B statutory provision "Prohibiting resale of drugs." 42 U.S.C. § 256b(a)(5)(B)., a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

PURPOSE: The health center ensures that 340B drugs are dispensed/administered/prescribed only to patients of the entity.

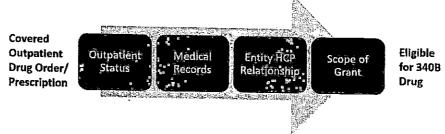
DEFINITIONS:

- Administer: Give medication to an individual, typically in a clinic, based on a health care provider's order.
- Dispense: Provide medication, typically in clinic, based on a health care provider's order to be administered to a patient.
- Outpatient status: All patients seen at the health center for ambulatory care.
- Patient: An individual who has received health care service, in-person or via telehealth, from a health care professional employed by or contracted with the covered entity in the last two years.
- Prescribe: Provide a prescription for a medication to an individual to be filled at an outpatient pharmacy.

ELIGIBILITY:

Patient

- To be considered a patient of the covered entity, i.e. 340B eligible, the patient must have a
 documented encounter, either face-to face or via telemedicine, with a health care professional
 employed by or contracted with the health center within the past two years.
 - To be 340B eligible, the patient is in an outpatient status when the medication is dispensed/administered.



• It is the health center's policy that patients seeing prescribers not employed by or contracted with the health center are eligible to receive 340B medications when sufficient documentation is present within the medical records to demonstrate that the individual is a patient of the covered entity, and the health center maintains an ongoing relationship with the individual.

Health Care Professional

 A health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. o The health center defines health care professionals to include physicians, physician assistants, nurse practitioners, pharmacists, dentists, optometrists, chiropractors, registered nurses, and other professionals licensed to provide healthcare.

Health Care Records

• The health center maintains records of individual's health care. Patient health records are defined by the health center to include all electronic health record (EHR) systems, including traditional EHR systems, shared medical records, and cloud-based portals.

Demonstration of Ongoing Patient Relationship/Responsibility for Care

- Types of elements which add together to support the responsibility for the care provided remains with the covered entity include (but are not limited to):
 - o The patient has had a visit (in person or via telehealth) with the health center within the last 24 months. (Required)
 - Ongoing visits with health center care management e.g. enhanced care management (ECM) & transitional care management (TCM).
 - o Preventative testing and screenings performed by health center.
 - o Medication reconciliation & Medication Therapy Management.
 - o For Non-CE Prescriptions, Including Referral Prescriptions:
 - Consult notes or visit summaries from consulting prescriber are present in the patient's medical record.
 - Shared medical records between the eligible provider and specialist including clinical documentation, consult notes and clinical summary.
 - The medication or consulting prescriber is mentioned in health center visit note.
 - Documentation of the specialist prescription in the patient's medication list.
 - Associated diagnosis is documented in the patient's problem list.

POLICY RATIONALE:

HRSA 1996 Patient Definition Considerations

HRSA 1996 Patient Definition Guidance (FR Doc. 96-27344 October 24, 1996), an individual is a "patient" of a covered entity only if:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; AND
- The individual receives health care services, in-person or via telehealth, (emphasis added) from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; AND
- The individual receives a health care service or range of services from the covered entity which is consistent with the health center scope grant of services.
- An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

340B.04 - Prevention of Medicaid Duplicate Discounts

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: 42 USC §256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

PURPOSE: To ensure that the health center is preventing duplicate discounts.

REFERENCES

Guidance for 340B Drug Claim Submissions:

- Rule 5160-1-60 Ohio Administrative Code | Ohio Laws
- Rule 5160-4-12 Ohio Administrative Code | Ohio Laws
- Rule 5160-9-05 Ohio Administrative Code | Ohio Laws
- Ohio Medicaid Pharmacy Program | Medicaid
- SPBM+Provider+FAQ September+2022.pdf (ohio.gov)

PROCEDURE:

- The health center complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity.
- It is the policy of the health center to not resell, or otherwise transfer, 340B drugs to ineligible patients by adhering to 340B requirements. The health center will not dispense 340B medications to any person that does not meet the health center's patient definition.
- The 340B statute prohibits manufacturers from being subject to providing a discounted 340B price and a Medicaid drug rebate for the same drug, i.e., duplicate discounts. The health center has mechanisms in place to prevent duplicate discounts for both Medicaid Fee-For-Service (FFS) and Medicaid Managed Care (MCO) claims. The health center ensures that drugs purchased under the 340B Program are not subject to a rebate claim by the state Medicaid agency. The health center works closely with State Medicaid agencies to prevent duplicate discounts for Medicaid FFS and MCO claims.

Clinic Administered Drugs

- Medicaid Fee For Service (FFS) Carve-Out: The health center has elected to not purchase drugs for its Medicaid patients through 340B (carve-out).
 - The health center has answered "no" to the question, "Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs?" on 340B OPAIS.
- Medicaid Managed Care (MCO): The health center has elected to not purchase drugs for its MCO patients through 340B (carve-out).

Entity-owned Pharmacies

- Medicaid Fee For Service (FFS) Carve-In: The health center has elected to purchase drugs for its Medicaid patients through 340B (carve-in) and complies with all State and Federal billing requirements to prevent duplicate discounts from occurring.
 - For Medicaid FFS patients, the health center provides and bills 340B drugs, including the required claims modifiers.

- The health center has answered "yes" to the question, "Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs?" on 340B OPAIS and has listed all applicable Medicaid billing numbers and/or NPI on 340B OPAIS and the MEF.
- OHHC will submit a value of "20" in the Submission Clarification Code field (NCPDP field #420-DK) for pharmacy claims.
- OHHC will submit a value of "08" in the Basis of Cost Determination field (NCPDP field #423-DN) for pharmacy claims.
- OHHC will submit the actual acquisition cost (AAC) of the product in the Ingredient Cost Submitted field (NCPDP field #409-D9).
- An FQHC specific professional dispensing fee of \$15.47 is added to the AAC of a drug that is billed to Medicaid FFS.
- Ohio Medicaid FFS reimburses OHHC for 340B purchased drugs per state policy and does not seek manufacturer rebates on drug claims submitted by OHHC.
- AAC values adjust with quarterly 340B pricing updates. In cases where AAC values change from one quarter to another, the submitted AAC value is determined from price file data on the prescription fill date, not the purchase date.
- Medicaid Managed Care (MCO): The health center has elected to purchase drugs for its MCO patients through 340B and complies with all State and Federal billing requirements to prevent duplicate discounts from occurring.
 - Covered entities are required to ensure that drugs purchased under the 340B Program are not subject to a rebate claim by the state Medicaid agency.
 - For Medicaid MCO patients, the health center provides and bills 340B drugs, including the required claims modifiers.
 - OHHC will submit the Usual & Customary (U&C) of the product in the Ingredient Cost Submitted field (NCPDP field #409-D9).
 - OHHC will submit a value of "20" in the Submission Clarification Code field (NCPDP field #420-DK) for pharmacy claims.
 - OHHC will submit a value of "08" in the Basis of Cost Determination field (NCPDP field #423-DN) for pharmacy claims.
 - A list of MCO plan BIN, PCN and group numbers is maintained by the state Medicaid agency.
 - Ohio Medicaid MCO reimburses OHHC for 340B purchased drugs per state policy and does not seek manufacturer rebates on drug claims submitted by OHHC.

Contract Pharmacies

- O Contract Pharmacies are required to carve-out for fee for service Medicaid, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to OPA by the health center.
- o The health center's contract pharmacies will carve-out Medicaid FFS.
- The health center has worked with the states billed on a process to prevent duplicate discounts for Medicaid MCO.
- The health center complies with all payer billing requirements including claims identification methods such as the use of claims modifiers or providing 340B claims files.

340B.05 – Program Stakeholders Roles and Responsibilities

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements.

PURPOSE: To identify the health center's key stakeholders and determine their roles and responsibilities in maintaining 340B Program integrity and compliance.

- The health center's key stakeholders comprise the 340B Oversight Committee, with the authorizing
 official ultimately responsible for 340B program compliance and administration. The 340B
 Oversight Committee meets regularly and may include the following individuals:
 - Chief Executive Officer
 - o Corporate Compliance Officer
 - o Patient Accounts Counselor
 - o Medical Director
 - o Pharmacist In Charge (PIC)
 - o 340B Coordinator
- The 340B Oversight Committee is tasked with the following responsibilities:
 - Responsible for attesting to the compliance of the program through recertification.
 - Account for savings and use of funds to provide care for the patient assistance under the patient assistance agreement, if applicable.
 - o Assure compliance with 340B program with vendors and payers.
 - o Maintain 340B related policy statements and procedures.
 - o Monitor any changes in clinic eligibility/information.
 - o Maintain compliance with purchasing, receiving, and inventory control processes.
 - Ensures compliance with 340B Program requirements for qualified patients, drugs, providers, vendors, payers, and locations.
 - o Design and maintain an internal audit plan of the compliance of the 340B Program.
 - Communicate with medical staff to use effective therapeutic classes that optimize savings with good clinical outcomes.
 - Reviews 340B rules/regulations/guidelines to ensure consistent policies/procedures/oversight throughout the entity.
 - Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
 - Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
 - Oversees the review process of compliance activities, as well as taking corrective actions based on findings. Assess if the results are indicative of a material breach [Refer to the health center's Policy and Procedure "340B Non-Compliance/Material Breach" 340B Manual, Policy 340B.10].
 - Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

o Select third-party entity to conduct independent program audit.

340B.06 - Program Education and Competency

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

PURPOSE: To establish 340B education and competency requirements for the health center's 340B key stakeholders based on their roles and responsibilities in the 340B Program.

- The health center determines the knowledge and educational requirements for each 340B Program role (Refer to the health center's Policy and Procedure "340B Program Stakeholder Roles and Responsibilities" 340B Manual, Policy 340B.05).
- Educational requirements may consist of the following:
 - o Introduction to the 340B Drug Pricing Program
 - Individuals requiring basic 340B knowledge will complete this training upon hire and annually thereafter.
 - o 340B University OnDemand
 - 340B key stakeholders responsible for day-to-day program operation will complete this training upon hire.
 - o 340B University Training & Events
 - 340B key stakeholders responsible for day-to-day program operation may need to complete additional online or in-person training, attend webinars, etc., to stay up to date with 340B program changes.
- The health center provides educational updates and training, as needed (e.g., 340B policy changes, updates in HRSA guidance).
- The health center conducts annual verification of 340B Program competency for key stakeholders responsible for day-to-day program operation.
- The health center conducts annual updates to the health center employees or contracted employees to remain up to date in 340B program changes.
- Training and education records are maintained per organizational policy and available for review.

340B.07 - Inventory Management

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: It is the policy of the health center to maintain the ability to track and account for all 340B drugs to prevent diversion or duplicate discounts. This oversight includes the acquisition, administration, dispensation, and waste of all 340B medications.

PURPOSE: Ensure the proper procurement and inventory management of 340B drugs to maintain the ability to track and account for all 340B drugs to prevent diversion or duplicate discounts. This oversight includes the acquisition, administration, dispensation, and waste of all 340B medications.

BACKGROUND:

- 340B inventory may be procured and managed in the following settings:
 - o Entity-owned pharmacy.
 - o Contract pharmacy.
- All 340B stock is tracked on an 11-digit NDC level.
- Inventory methods for each of the above areas within the entity shall be described within the inventory management policy and procedures.
- The health center uses the following inventory methods:
 - o Entity-owned pharmacy
 - Physically separated 340B and non-340B inventory
 - Contract pharmacy
 - Virtual mixed-use replenishment inventory (i.e., neutral)
- Pharmacists, technicians, and clinicians dispense 340B drugs only to patients meeting all the criteria in the health center's Policy and Procedure "340B Eligibility" [340B Manual, Policy 340B.03].

PROCEDURE:

• Contract Pharmacy Processes

- The health center has a written contract in place for each contract pharmacy location.
- O The contract pharmacies of the health center utilize virtual inventory models and do not hold 340B stock in the pharmacy.
- Processes are in place to ensure that only 340B eligible health center patients receive 340B medications from the contract pharmacy.
- O The contract pharmacies utilize their own retail stock to provide medications to the health center's patients. Once confirmed that the dispensation is qualified for the health center's 340B program, the health center will replenish the pharmacy with 340B stock using a bill-to ship-to arrangement.
- O Though the stock used to replenish the contracted pharmacy is 340B, it is replacing retail stock. Therefore, at the time of shipment, it converts to retail medication (i.e., neutral inventory).
- The health center does not replenish contract pharmacy inventory until the 11-digit NDC accumulation reaches a full package size.
- o The health center, consultants, and third-party administrators all work together to track and confirm the accumulator counts.
- The health center does not bill Medicaid Fee for Service (FFS) for 340B purchased drugs at contract pharmacies and therefore carves-out Medicaid FFS prescriptions from being qualified as 340B eligible.
- o The health center bills Medicaid Managed Care (MCO) for 340B purchased drugs at contract

pharmacies when the pharmacy can comply with state-required billing practices and therefore carves-in Medicaid prescriptions qualifying them as 340B eligible. Pharmacies that cannot comply with state-required billing practices will not qualify MCOs as 340B eligible.

• Entity-Owned Pharmacy Processes:

- The health center provides 340B medications to eligible patients through entity-owned pharmacy services.
- Processes are in place to ensure that only individuals who meet the health center's 340B eligible patient definition receive 340B medications from the entity-owned pharmacy.
- o All inventory dispensations and purchases are tracked within the pharmacy software.
- o Purchase records are maintained electronically in vendor database.
- Pharmacy staff will manually perform a physical inventory once yearly and reconcile inventory as needed.
- o Any disposal of medication is tracked and done in compliance with state and federal laws.
- o The health center carves-in Medicaid (does use 340B purchased drugs) at the entity-owned pharmacy.
- The health center maintains records of 340B related transactions for a period of 3 years in a readily retrievable and auditable format located in secure electronic format. These reports are reviewed by the health center semi-monthly as part of its 340B oversight and compliance program.
- Refer to the health center's Policy and Procedure "Program Compliance Monitoring/Reporting" 340
 Manual, Policy 340B.11 and "Contract Pharmacy Oversight and Monitoring" 340 Manual, Policy
 340B.12.

340B.08 - Contract Pharmacy Operations

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: Covered entity remains responsible for ensuring that its contract pharmacy operations comply with all 340B Program requirements, such that the covered entity remains responsible for the 340B drugs it purchases and dispenses through a contract pharmacy.

PURPOSE: To ensure that the health center remains responsible for all 340B drugs used by its contract pharmacies.

REFERENCE: Federal Register / Vol. 61, No. 165 / Friday, August 23, 1996 / Notices https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

BACKGROUND: The health center has obtained sufficient information from the contract pharmacy contractor to ensure compliance with applicable policy and legal requirements. As a best practice, the signed contract pharmacy services agreements should address the 12-contract pharmacy essential compliance elements: https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf.

- The health center contracts with third party administrators (TPA) to facilitate both the design and implementation of the 340B contract pharmacy program. Contracts are saved electronically in a secure folder.
- The health center has a written contract in place for each contract pharmacy location. Contracts are saved electronically in a secure folder.
- Reference the 340B OPAIS for a current list of contract pharmacies associated with the health center. [340B ID: CH050560]
- The health center registers each contract pharmacy location on the health center's 340B OPAIS prior to the use of 340B drugs at that site.
- The health center uses a replenishment model at an 11-digit NDC level.
- 340B-eligible prescriptions are presented to the contract pharmacy via e-prescribing, hard copy, fax, or phone.
 - o The Contract Pharmacy will verify patient eligibility via TPA eligibility files provided by the health center, including patient encounter data.
 - Updates are made to 340B eligibility data by the health center and TPA at least monthly.
- Contract Pharmacies dispense prescriptions to 340B eligible patients using Contract Pharmacies' non-340B drugs.
- The health center implements a bill-to, ship-to arrangement with the contract pharmacies.
 - o Contract Pharmacies order 340B drugs based on 340B eligible use as determined by TPA accumulator system from the wholesaler.
 - Orders are triggered by package size used and placed by using online system.
 - Invoices are billed to the health center.
- Contract pharmacies receive shipment and verify quantity received with quantity ordered.
 - Identifies inaccuracies.
 - Resolves inaccuracies.
 - o Documents resolution of inaccuracies.
- Contract Pharmacies will notify TPA if Contract Pharmacy doesn't receive 11-digit NDC replenishment order within 1 week of original order fulfillment request.

- The health center reimburses Contract Pharmacy at a pre-negotiated rate for such drugs.
- The health center receives and reviews the invoice for drugs shipped to its contract pharmacies.
- The health center pays invoice to Wholesaler for all 340B drugs.
- Contract Pharmacies provides reports at least monthly to the health center via TPA.
- Contract Pharmacies will adjust claims with supporting documentation when variance or discrepancy has occurred.
 - Contract Pharmacy uses approved methods with knowledge and agreement of the health center regarding reconciliation between inventory and invoices with adjustments as necessary to match changes.
 - Claim adjustments may occur only within 90 days of original billing and with prior notice and approval of entity.
- The health center and Contract Pharmacies have agreed to a procedure for inventory reconciliation if the relationship is terminated by either party. Refer to specific contract for each Contract Pharmacy.
 - The health center works with manufacturers to determine the most appropriate method for handling.
 - o For virtual inventories, the health center pays unreplenished accumulations to Contract Pharmacy at an agreed upon amount specified in contract.
 - The health center and Contract Pharmacy maintain auditable records to ensure the process is transparent to manufacturers and wholesalers.
 - O The procedure may include transferring inventory to an associated covered entity site/ pharmacy that is still 340B registered, credit/rebill, return, or destruction according to state law.
- The health center will not use 340B drugs for Medicaid FFS patients at its contract pharmacies (carve-out). Refer to the health center's policy and procedures "340B Eligibility" 340B Manual, Policy 340B.03 and "Prevention of Duplicate Discounts" 340B Manual, Policy 340B.04.

340B.09 - Referral & Non-Health Center Provider Prescription Eligibility

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: It is the health center's policy to deem prescriptions written by non-health center providers as eligible for the 340B program, if they are written for an individual who is a patient of the covered entity with an ongoing relationship.

PURPOSE: The health center has the following system in place ensures that 340B drugs are dispensed, administered, and prescribed only to patients of the entity.

PROCEDURE:

Ohio Hills Health Services 340B Patient Eligibility Across the Continuum of Care

For an individual's prescriptions written by non-health center prescribers, including referral prescriptions, to qualify as 340B eligible:

- There must be documentation to support the patient-covered entity relationship for the individual receiving the prescription within the health center's EHR.
 - An ongoing patient relationship between the individual and the "covered entity" is required such that the individual continues to meet the patient definition
 - The statutory requirement for 340B eligibility is that the person be a patient of a covered entity and that there is an ongoing patient relationship between the individual and the covered entity.
 - The 340B statute does not require the covered entity to have initiated the healthcare service resulting in the prescription.
- Within the Federally Qualified Health Center model, the Ohio Hills Health Services is responsible
 for the continuum of the patient's health care. This includes ongoing care at the health center for
 patients who have been discharged from the hospital or urgent care.
- Under the Ohio Hills Health Services model, provided by the health center, prescriptions
 resulting from formal referrals or self-referrals, including those to specialists, hospitals,
 emergency departments, or Urgent Care centers are deemed by the health center, in the
 continuum of care, to be 340B eligible, so long as the patient remains active with the entity.
- Best practice is to update patients' medication list to include newly prescribed medications. For an acute condition, updates to the medication list are encouraged but not required (e.g., short-term antibiotics).

Demonstrating Ongoing Patient Relationship/Responsibility for Care

- Types of elements which add together to support the responsibility for the care provided remains with the covered entity include (but are not limited to):
 - The patient has had a visit (in person or via telehealth) with the health center within the last 24 months. (Required)
 - Ongoing visits with health center care management e.g. enhanced care management (ECM) & transitional care management (TCM).
 - Preventative testing and screenings performed by health center.
 - o Medication reconciliation & Medication Therapy Management.
 - Associated diagnosis is documented in the patient's problem list.
 - For Non-CE Prescriptions, Including Referrals Prescriptions:
 - Consult notes or visit summaries from consulting prescriber are present in the patient's medical record.

- Shared medical records between the CE and external prescriber including clinical documentation, consult notes and clinical summary.
- The medication or consulting prescriber is mentioned in health center visit note.
- Documentation of the external prescription in the patient's medication list.

BEST PRACTICES FOR REFERRALS (Encouraged but not required for 340B eligibility)

- The presence of consult note/clinical summary within the patient's medical record does not qualify nor disqualify 340B eligibility.
 - The lack of a consult note should not be a barrier for an eligible patient receiving medication.
- Referral orders for the health center's patients are considered valid with no expiration date if the patient remains active. (See Patient Eligibility Definition)
 - o If the EHR auto-populates referral orders with an expiration date, this does not impact 340B eligibility.
- There may be instances where the dating on the readily retrievable referral falls after the written or fill date of the qualified prescription, this does not impact 340B eligibility.
- In the event a documented referral cannot be readily located within the EHR, the health center staff will verify that the patient remains active with the covered entity and that the health center maintains responsibility of care for the patient (i.e., continues to meet HRSA patient definition) then the care team may update the medical record to document the ongoing referral relationship.
 - When the referral is placed, the health center staff request updated consult notes from the consulting prescriber and update patients' medication list to include newly prescribed medications, if necessary.
 - o For secondary referrals, where the specialist refers the patient to a second specialist, these relationships may also be documented in the medical record under a care coordination referral, so long as the patient continues to meet HRSA patient definition, and the health center maintains responsibility for care.
- Referral orders may be placed with a specific office or provider, but all encounters with the type of
 specialist designated on the referral order are considered valid and 340B eligible (e.g., Referral order
 is to "Dr. Smith Cardiology" or "Community Cardiology". All cardiology encounters are 340B
 eligible.).

340B.10 - Noncompliance/ Material Breach

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: The health center acknowledges that if there is a breach of the 340B requirements, it may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation. Depending upon the circumstances, the health center may be subject to the payment of interest, reimbursement, penalties, and removal from the list of 340B entities. The health center is responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements.

PURPOSE: To define the health center's material breach of 340B compliance and self-disclosure process.

DEFINITIONS:

- Materiality: A convention within auditing/accounting pertaining to the importance/significance of an amount, transaction, and/or discrepancy.
- Threshold: The point that must be exceeded, as defined by the covered entity, resulting in a material breach.

REFERENCE:

- 340B PVP Education Tool: Establishing Material Breach Threshold
- 340B PVP Education Tool: <u>Self-Disclosure to HRSA and Manufacturer Template</u>

- The health center's established threshold of what constitutes a material breach of 340B Program compliance is calculated as a material breach as a discrepancy that results in a negative impact of more than 5% of the total 340B purchases for the fiscal year and does not self-correct within six (6) months.
- The health center ensures that identification of any threshold variations occurs among all its 340B settings, including contract pharmacies.
- The health center will use a \$1,000 minimum nuisance threshold when determining manufacturer repayments.
- The health center 340B Oversight committee reviews potential violations, performs materiality
 assessment, and determines if a material breach has occurred. The committee identifies to whom
 to self-disclose the breach dependent on the materiality determination and corrective action plan
 resolution.
- Management reserves the right to use professional judgement to review issues that may not meet these criteria but may want to be treated as a material breach and disclosed to HRSA.
- Any material breach discovered is required to be disclosed to HRSA as soon as reasonably possible after confirmation of material breach: 340Bselfdisclosure@hrsa.gov.
- The health center maintains records (including all internal/external communication and corrective action plans) of violations, materiality assessment, and resolution to the manufacturer and/or HRSA.

340B.11 - Program Compliance Monitoring/Reporting

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: Covered entities are required to maintain auditable records demonstrating compliance with the 340B Program requirements.

PURPOSE: To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

- The health center develops an internal audit plan adapted by management and an independent consultant.
- The health center uses the following self-audit process to ensure 340B compliance:
 - Once monthly, self-audit report lists are pulled from third party administrators' (TPA) online portals and entity-owned pharmacy software (e.g., EHR or paper logs).
 - For pharmacy claims, these reports include payer, patient name, patient's date of birth, prescription number, physician NPI, physician name, bin number, drug name, date of service, date of approval, quantity, and costs. Reports will be run for each contracted pharmacy TPA and entity-owned pharmacy.
 - Once monthly, the health center completes internal audits of each Contract Pharmacy TPA record. With each TPA's records, 20 random prescriptions will be audited for the following items:
 - The party prescribed the medication meets the eligible patient definition.
 - The prescription is documented in the EHR. (QA/QI Check Does Not Determine Eligibility)
 - The prescription demonstrates that the health center's practice is following the Medicaid billing question on 340B OPAIS.
 - Quarterly and during the annual recertification period, compliance reviews are conducted of the OPAIS database for completeness and accuracy. This review includes:
 - Verifying the accuracy of location listing, Medicaid Exclusion File, and Contact information for the Authorizing Official and Primary Contact.
 - Cross-referencing the OPAIS listing with the Electronic Handbook Form 5B and contract pharmacy agreements to ensure all locations and contract pharmacies listed are 340B eligible and identify if there are registrations or corrections are required.
 - Annually, the health center engages an independent organization to perform external compliance reviews (audits) of its 340B Program including contract pharmacies.
- Documentation Records of each review completed are retained.
 - The results of each review will be reported to the health center 340B Oversight Committee at the next occurring meeting.
 - Assess whether audit results are indicative of a material breach [Refer to the health center's Policy and Procedure "340B Non-Compliance/Material Breach" 340B Manual, Policy 340B.10]
 - o Any changes requiring a 340B OPAIS open enrollment period will then be made in the subsequent period and change requests will be made immediately upon discovery.
 - o If errors or omissions are identified, the PC and AO will make the necessary corrections required to remain compliant.
 - o As needed, issues identified will be reviewed with the Apexus Prime Vendor Program or HRSA

OPA for direction on the appropriate corrective action.

- o Records of any such self-report and corrections will be maintained as auditable records.
- The health center will maintain records of 340B-related transactions for a period of 3 years in a readily retrievable and auditable format located in a secure electronic format.

340B Compliance Review Summary

The 340B compliance review summarizes all activities necessary to ensure comprehensive review of 340B compliance at the health center. The AO and PC are responsible and accountable for overseeing this review process, as well as taking corrective actions based on the findings.

			Area of Focus		
Activity	Frequency (suggested)	Entity Eligibility	Diversion	Duplicate Discount	
Review of all HRSA 340B Database information. Staff responsible: Authorizing Official (AO) / Primary Contact (PC)	Quarterly	X		Discount	
Review of 340B self-audit reports, including internal contract pharmacy compliance audits. Staff responsible: 340B Coordinator	Monthly		X	x	
Update of prescriber and patient eligibility files with TPA/contract pharmacy. Staff responsible: 340B Coordinator	Monthly		X		
Annual 340B Program Compliance Review (Independent External Audit)	Annually	Х	X	X	

340B.12 - Contract Pharmacy Oversight and Monitoring

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: Covered entities are required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records must be maintained to demonstrate compliance with those requirements.

PURPOSE: To ensure that the health center maintains 340B Program integrity and compliance at its contract pharmacies.

REFERENCE: Federal Register / Vol. 75, No. 43 / Friday, March 5, 2010 / Notices (Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services)

- The health center routinely conducts internal reviews of each registered contract pharmacy for compliance with 340B Program requirements. The following elements will be included when conducting self-audits of contract pharmacies to ensure program compliance:
 - The party prescribed the medication meets the eligible patient definition.
 - The prescription is documented in the EHR. (QA/QI Check Does Determine Eligibility)
 - The prescription demonstrates that the health center's practice is following the Medicaid billing question on 340B OPAIS.
 - The 11-digit NDC level is documented for accumulation and/or replenishment of a 340B dispensation or administration (if a virtual inventory is used).
 - The health center can document that no prescriptions were billed to Medicaid unless the contract pharmacy is listed as a carve-in contract pharmacy on 340B OPAIS.
- The health center conducts annual independent audits of each registered contract pharmacy for compliance with the 340B Program requirements.
 - Independent audits will include reviews of:
 - 340B eligibility.
 - 340B registration.
 - Documented policies and procedures.
 - Inventory, ordering, and record keeping practices for all 340B accounts.
 - Review of the listing in the Medicaid Exclusion File and its reflection in actual practices.
 - Testing of claims sample to determine any instance of diversion or duplicate discounts over a set period.
- The health center has mechanisms in place to demonstrate compliance with all state Medicaid billing requirements to prevent duplicate discounts at all sites, including off-site outpatient facilities.
- The health center follows all state practices consistent with state guidance and the health center Medicaid billing numbers/NPI numbers are properly reflected in the Medicaid Exclusion File.
- The health center's 340B Oversight Committee reviews audit results at the next scheduled meeting.
 - The committee will assess if audit results are indicative of a material breach [Refer to the health center's Policy and Procedure "340B Noncompliance/Material Breach" 340B Manual, Policy 340B.10].
- The health center maintains records of 340B-related transactions for a period of 3 years in a readily retrievable and auditable format.

Page 26

340B.13 - Prime Vendor Program (PVP) Enrollment and Updates

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: The purpose of the Prime Vendor Program (PVP) is to improve access to affordable medications for covered entities and their patients.

PURPOSE: Support the health center's participation in the PVP to receive the best 340B product pricing, information, and value-added products.

- **Enrollment in PVP:**
 - The health center completes online 340B Program registration with HRSA.
 - The health center completes online PVP registration (PVP Entity Enrollment).
 - o PVP staff validates information and sends confirmation email to the health center.
 - o The health center logs in to www.340bpvp.com, selects username/password.
- **Update PVP Profile:**
 - o The health center accesses PVP Entity Enrollment.
 - The health center clicks Login in the upper right corner.
 - The health center inputs PVP log-in credentials.
 - In the upper right corner click "My Profile" to access page. https://members.340bpvp.com/webMemberProfileInstructions.aspx.
 - The health center clicks "Continue to My Profile" to access page https://members.340bpvp.com/webMemberProfile.aspx.
 - Find a list of your facilities.
 - Click on the 340B ID number hyperlink to view or change profile information for that
 - Update HRSA Information:
 - Complete the 340B Change Form as detailed above.
 - After 340B OPAIS has been updated, the PVP database will be updated during nightly synchronization.
 - The health center updates the 340B Prime Vendor Program (PVP) Participation Information:
 - Edit The health center's DEA number, distributor and/or contacts.
 - Click submit.

340B.14 - State of Emergency Management

SCOPE: Ohio Hills Health Services (hereafter, the health center) adopts this policy for all personnel, including contracted employees.

POLICY: The health center has processes in place to maintain compliance with all 340B requirements, including during states of emergency.

PURPOSE: To ensure that the health center has processes in place in case of a state of emergency

PROCEDURE:

Health Center 340B Eligibility

During a state of emergency, if additional space is required for expanding the delivery of patient care at a 340B eligible, expanded care delivery location at physical address of the health centers' registered location will be considered 340B eligible. Examples may include but are not limited to conversion of non-clinical areas to patient care areas and expansion into parking lots.

Patient 340B Eligibility

During a state of emergency, patient care may be relocated as required by applicable patient care standards. Patients will still be considered eligible patients, if care is moved outside standard care areas or telehealth practices are utilized, if the patient is registered to the health center.

Health Care Professional Eligibility

o During a state of emergency, where volunteer health professionals are providing health care, documentation should be generated and maintained to make the relationship between the provider and the health center clear and to confirm the health center's responsibility for providing patient care. This documentation should recognize the emergency nature of the situation, the name and address of the volunteer, and his/her relationship to the health center, and should be kept on file by the CE. Additionally, Health Care Providers may work at the CE on a short-term or temporary basis. The Health Care Provider definition will still be in place and all providers, including shortterm or temporary providers, are considered eligible.

Health Record

- During states of emergency, an abbreviated health record will be deemed adequate for purposes of the 340B Program. The record must identify the patient, record the medical evaluation (including any testing, diagnosis, or clinical impressions) and the treatment provided or prescribed. For purposes of 340B Program eligibility, the record may be a single form or note page. It is recorded information that creates a record.
 - In the case of a State of Emergency, HRSA has considered that self-reporting of identity, condition, and history to be adequate for purposes of 340B recordkeeping requirements.
- HRSA recognizes that during a State of Emergency, 340B drug shortages may occur. In this state of emergency health center will continue to ensure it has policies and procedures in place to address the purchase and dispensing of 340B drugs, and it must continue to keep auditable records.

This policy and procedure shall be reviewed and updated consistent with the requirements and standards established by the Board of Trustees and by Health Center management, Federal and State law, regulations, and applicable accrediting and review organizations.

Responsible Parties:	,	
Signature OHHS Board of Trustees President	Date	
Signature OHHS Chief Executive Officer	Date	