

Federal Drug Discount Program Critical for Oregon's Health

Studying the Impact of the 340B Drug Discount Program on Four Federally Qualified Health Centers in Oregon



Pharmaceutical Policy Experts

Rx|X Consulting, LLC provides policy research and analytics, program evaluation, and compliance services to clients in the pharmaceutical policy marketplace. Founded in 2009 by Madeline Carpinelli Wallack and Suzanne Herzog, Rx|X has worked with federal and state governments, 340B covered entities, pharmaceutical companies, law firms and advocacy organizations to develop solutions to challenging regulatory and compliance issues. The expertise of the founding directors comes from their senior level experience with the federal Department of Health and Human Services' principal oversight agency, the US Office of Inspector General, and through their ongoing engagements with a range of clients operating at the intersection of pharmacy and government.

The Rx|X team has been engaged in the analysis and understanding of public policy and economics of the pharmaceutical marketplace over the last 15 years. They are recognized leaders in the 340B Drug Discount and Medicaid Drug Rebate Programs, frequently speak at national conferences, and have a significant body of influential reports.

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Executive Summary

Study Objectives

This study was commissioned by the Oregon Primary Care Association to:

- Highlight the importance of the 340B Drug Pricing Program to Oregon’s federally qualified health centers (FQHCs), and
- Evaluate the impact of a proposal from the Oregon Health Authority that would require FQHCs and their contracted partner retail pharmacies to bill Coordinated Care Organizations (CCOs) for the actual acquisition cost of 340B drugs, instead of accepting the contracted reimbursement rate. Any difference between the cost of the drugs and the contracted rate would be passed back to CCOs.

Rx|X carried out the study using a sample of four Oregon FQHCs. During December 2013, qualitative and quantitative data was collected from:

- Central City Concern’s Old Town Clinic (Portland),
- Virginia Garcia Memorial Health Center (Beaverton, Hillsboro, McMinnville and Cornelius),
- Siskiyou Community Health Center (Grants Pass and Cave Junction), and
- Northwest Human Services (Salem and Monmouth).

Importance of the 340B Program to Oregon’s FQHCs

The 340B Program was created by the U.S. Congress in 1992 to help lower the cost of drugs to certain safety-net providers, called covered entities. These providers include FQHCs, public hospitals and other federal grantees. The 340B Program requires manufacturers to provide discounts on certain drugs purchased by qualified covered entities.

FQHCs purchase drugs from participating manufacturers at discounted 340B prices for eligible patients and accept contracted reimbursement rates for the drugs from Medicaid Managed Care Organizations (and, more recently, CCOs, which cover about 90 percent of Oregon’s Medicaid members). The discount does not always provide an advantage, since in some cases the reimbursement rate has been lower than the purchase price. When the reimbursement rate exceeds the purchase price, FQHCs have generally retained the difference and used these savings to benefit patients.

This is in keeping with the original intent of the 340B Program, which permits covered entities to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

This study found that Oregon’s FQHCs use the funding to carry out the federal intent in a variety of ways. All are designed to increase access and provide additional

services for the vulnerable and underserved. The type and extent of assistance is dictated largely by the needs of the FQHC's community.

Examples include:

- Financial assistance to patients unable to afford their prescriptions.
- Clinical pharmacy services, such as disease management programs or medication therapy management.
- Student residencies and/or internships to provide additional pharmacy services to patients.
- Outreach programs.
- Additional healthcare services, such as dental or behavioral health services.
- Registration of patients for manufacturer patient assistance programs.

FQHCs rely on the 340B funding to offset the costs of providing these and other important (yet unreimbursed) services. And as safety-net community providers, FQHCs use the funding to benefit all patients of the community, indirectly passing savings to the state as a whole.

Impact Of a Potential Mandated 340B Acquisition Pass-Through to the State

The Oregon Health Authority (OHA) is considering a requirement that FQHCs and their contracted partner retail pharmacies bill CCOs only for the actual acquisition cost of 340B drugs, instead of accepting the contracted reimbursement rate. Any difference between the cost of the drugs and the contracted rate would be passed back to CCOs.

The study found that the proposed new mandate, or other additional regulations and restrictions on drug purchasing and/or billing, could lead to reduced access to pharmacies and services for Oregonians. Also, the sustainability of FQHC-retail pharmacy partnerships would be uncertain.

Conclusion

The study concluded that the 340B Program has been critical in supporting the Oregon safety net for many years. Policies that shift cost savings to the State may not actually be effective and could adversely impact patient care. FQHCs and CCOs should be permitted maximum flexibility to collaborate on program design and cost savings, to keep the focus on innovation and improving health outcomes.

Background

Study Objectives

This report was commissioned by the Oregon Primary Care Association to highlight the importance of the 340B Drug Pricing Program to federally qualified health centers (FQHCs) in the state and to evaluate the impact that a potential mandated 340B actual acquisition cost billing requirement might have on the services and resources of these centers.

The 340B Drug Pricing Program

The 340B Program was created by the U.S. Congress in 1992 to help lower the cost of drugs to certain safety net providers, called covered entities, which include FQHCs, certain hospitals and other federal grantees. The 340B Program requires manufacturers to provide discounts on drugs purchased by covered entities.

Because these entities serve the uninsured, under-insured and publically insured, they traditionally receive no or low payment for drugs from patients or insurers. The 340B Program lessens the impact of inadequate payment by reducing the acquisition cost of drugs by 25 to 50 percent and allowing for program savings in instances where patients are insured.

But Congress created the 340B program as a means to do more than provide drugs to low-income people. The original intent of the legislation was to permit covered entities to: “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹

In August 2013, 29 U.S. senators, including Jeff Merkley of Oregon, and 84 U.S. representatives, including Peter DeFazio and Suzanne Bonamici of Oregon, signed bipartisan letters supporting the original intent of the 340B program. “Given the significant economic pressures on these safety net providers, any threat to these savings means that these community-based programs are at great risk.”²

Several studies have documented the value of the 340B Program to covered entities. A 2011 study by the National Association of Community Health Centers found that almost all surveyed respondents used 340B savings to enhance the health centers’ ability to serve the uninsured or underinsured.³ Many FQHCs report 340B savings as vital to providing comprehensive services and would be unable to provide the current level of services without the program. Similarly, a 2011 study by the Government Accountability Office (GAO) found that 340B entities interviewed reported using their 340B savings to support or expand access to services.⁴

The Health Resources and Services Administration’s Office of Pharmacy Affairs (OPA) oversees the 340B Program. OPA reminds entities that with the important benefits

of the drug discount comes significant responsibility. Entities must ensure that only qualified patients receive drugs purchased using the discount. Further, if the entity provides a 340B-discounted drug to a Medicaid beneficiary, the state Medicaid agency must be properly notified so that it will not request a Medicaid drug rebate. This requirement is in place to prevent pharmaceutical manufacturers from offering a “duplicate discount”—or both an upfront price reduction through 340B and a Medicaid rebate—on the same drug.

OPA verifies entity eligibility and requires attestation of program compliance through an annual recertification process. OPA conducts a number of entity audits each year. Manufacturers also perform 340B entity audits to review compliance related to their products.

340B Billing to Medicaid Managed Care Organizations

In Oregon, Medicaid patient benefits can either be administered by the state or by Medicaid Managed Care Organizations (MCOs). The state oversees fee-for-service (FFS) benefits for patients, while MCOs coordinate benefits much like private insurance plans. Current Oregon Health Authority (OHA) rules require that for Medicaid fee-for-service patients: “340B covered entities and federally qualified health centers or their contracted agents that fill Medicaid patient prescriptions with drugs purchased at the prices authorized under Section 340B of the Public Health Service Act must bill Medicaid for the actual acquisition cost.”⁵

During 2013, the Oregon Primary Care Association and individual State legislators conferred on the extent to which this requirement would apply to MCOs/Coordinated Care Organizations (CCOs). In Oregon, CCOs are local health entities that deliver health care and coverage for people enrolled in the Oregon Health Plan (Medicaid). The CCOs act as Oregon’s version of an ACO. Oregon has 16 CCOs, covering approximately 90 percent of Medicaid members.⁶

OHA has published provider notices in support of applying the FFS reimbursement rate to MCOs/CCOs. Covered entities have disputed the legality of this policy and have raised several questions about the practicality of this requirement and its impact on entity operations.

Before the Patient Protection and Affordable Health Care Act (PPACA), MCOs were not eligible for mandatory manufacturer rebates under the Medicaid Drug Rebate Program (MDRP). 340B entities were permitted to acquire drugs at 340B prices, accept the contracted reimbursement rate from the MCOs, and retain the difference, since no duplicate discount provisions applied. These program savings have been instrumental in the development of integrated pharmacy services and other health care benefits offered to patients of 340B entities over several years.

In 2010, the Affordable Care Act (ACA) extended the federal rebate program to MCOs, thereby creating uncertainty for 340B covered entities' billing practices and program income. 340B covered entities have processes for passing through the 340B price for Medicaid fee-for-service, including all behavioral health drugs, but the pass-through for MCO claims is complicated by the involvement of Pharmacy Benefit Managers (PBMs) and other third-party administrators that oversee the execution of the MCO contracts.

Project Overview

Purpose & Methodology

The purpose of this study is to provide information on how the 340B program is used by FQHCs and to explain the potential impact of a policy requiring FQHCs to bill CCOs at actual acquisition cost for 340B drugs.

Rx|X carried out the study using a sample of four Oregon FQHCs. During December 2013, qualitative and quantitative data was collected from:

- Central City Concern's Old Town Clinic (Portland),
- Virginia Garcia Memorial Health Center (Beaverton, Hillsboro, McMinnville and Cornelius),
- Siskiyou Community Health Center (Grants Pass and Cave Junction), and
- Northwest Human Services (Salem and Monmouth).

Rx|X interviewed clinic directors, pharmacy directors and pharmacy staff. Discussion focused on the importance of 340B, the manner in which 340B program savings were used to support the clinics' services, and the potential impact of the proposed actual acquisition cost billing requirement. Following the discussion, Rx|X requested further quantitative documentation detailing the clinics' services, including data on the volume, type and annual/monthly expenditure on drugs per site, payer mix, staffing and cost of special programs. Where available, Rx|X reviewed the number of CCO patients receiving specialized services from the clinic. Rx|X relied on the data as reported by the FQHCs.

Due to the variability of data retained and reported by the FQHCs and the differences in services offered at each, Rx|X was unable to combine the data reported by the FQHCs and make conclusions based on uniform information. Instead, data is reported individually for each.

The two types of data collected - qualitative and quantitative - are presented as both individual case study profiles and integrated into overall findings and observations.

FQHCs and 340B: An Overview

FQHCs provide patient-centered care to members of the community, regardless of ability to pay. As local providers, each FQHC can target its services and outreach to best serve the needs of its own community. The legislation creating CCOs defers decision-making to providers like FQHCs, stating, "Communities and regions are accountable for improving the health of their communities and regions, reducing avoidable health gaps among different cultural groups and managing health care resources."⁷

Each FQHC uses its 340B savings to benefit its unique community and patient population. This flexibility of the 340B program is a key benefit, allowing savings to be best targeted and utilized by those providers on the front lines of providing care.

In accordance with the statutory intent of the 340B Program, FQHCs generally use 340B savings to provide increased access and additional services. For example, all four FQHCs included in the case studies provide financial assistance to patients unable to afford their prescriptions. The extent of assistance varies and is largely dictated by the needs of the FQHC's community.

Similarly, all four FQHCs reported using 340B services to increase services, but the types of services varied depending on the needs of the community. Some FQHCs used 340B savings to provide clinical pharmacy services, such as disease management programs or medication therapy management. Other FQHCs used 340B savings to offset outreach programs and provide additional healthcare services, such as dental or behavioral health services.

In addition, use of 340B savings at the FQHC level allowed the clinics to leverage their savings to provide even greater impact. Some FQHCs used 340B savings to help register patients for manufacturer patient assistance programs or fund student residencies and/or internships to provide additional pharmacy services to patients.

The descriptions of each of the four clinics featured in the following sections highlight the unique ways in which 340B savings are utilized to best serve each FQHC's specific community. For additional information, see Appendix A for snapshots of services offered at each clinic.

Leveraging 340B Savings: Central City Concern Old Town Clinic

Old Town Clinic Profile

Central City Concern’s Old Town Clinic provides integrated healthcare services to single adults and families in the Portland metro area, many of whom are experiencing homelessness. Its mission is “to provide comprehensive solutions to end homelessness and achieve self-sufficiency.” The clinic uses the team-based model of care. Pharmacists serve as key members of the provider team, along with primary care providers and behaviorists, completing an intake for all new patients.

Funding Key Pharmacy Residency Partnerships

Central City Concern’s Old Town Clinic is able to leverage its 340B savings to increase its pharmacy services through a residency program with the Oregon State University (OSU) College of Pharmacy. The Old Town Clinic reported using its 340B savings to support a

CCC’s Old Town Clinic – Dedicated Space

The pharmacy team is able to provide personalized pharmacy services in a number of physical spaces specialized for patient encounters. The Central City pharmacy team indicated that the three sit-down spaces, one standing space and one private room are conducive to the provision of individualized patient counseling. According to the clinic director, this dedicated space would not be possible without 340B savings.

portion of the costs of two post-graduate elective residencies for care management of diabetic patients. The total cost of this program is \$93,000 per year and the application of 340B savings toward this purpose is essential. Through this partnership, the clinic is able to increase the value of its 340B savings to reach more patients and provide more comprehensive services.

For example, as part of their care management of diabetic patients, post-graduate pharmacy residents offered individual and group diabetes self-management education to patients

(both CCO and non-CCO) enrolled in the pharmacist-managed disease management program for underserved populations. They also provided individual follow-up visits to assess optimal therapy and peer-support groups.

Offsetting Costs of Serving the Uninsured

Old Town Clinic’s in-house pharmacy fills about half of the prescriptions written from the clinic. With approximately half its patients uninsured, the pharmacy works with patients on a sliding-fee scale, with the majority of patients receiving their prescriptions at no cost. The pharmacy team estimates a net cost to the clinic of \$3,000 a week. Its 340B savings offset this cost and allow the clinic to help patients obtain their drugs and provide personalized service to improve medication adherence.

Providing Personalized Pharmacy Services

When working with patients, the pharmacists at the Old Town Clinic provide one-on-one services starting with a comprehensive medication therapy management review.

Patients bring in current medications, which are reviewed by the pharmacist. The pharmacist then synchronizes medications, follows up with the provider, reviews the patient's chart and discusses the medication with the patient. This personalized service allows the patient and pharmacist to work as partners in developing a medication plan. This is a vital step for improving medication adherence, especially given many Old Town Clinic patients have low health literacy and are in need of assistance.

Pharmacists routinely work on a four-week rotation schedule to fill prescriptions before the refill date and identify any changes in medication. This process allows the Old Town Clinic to alert patients regarding one pick-up date for all drug refills at the same time, reducing the number of trips the individual must make to the pharmacy. For patients who cannot open traditional prescription bottles, the Old Town Clinic provides bubble packaging to improve patient medication adherence.

Leveraging 340B Savings: Virginia Garcia Memorial Health Center

Virginia Garcia Profile

Virginia Garcia Memorial Health Center (Virginia Garcia) provides comprehensive and culturally appropriate primary health care to the communities of Washington and Yamhill counties with a special emphasis on migrant and seasonal farm workers and others with barriers to receiving care. Through its on-site pharmacies, clinical pharmacists serve as integral team members under the medical home model. Virginia

Virginia Garcia's Return to Stock Project

Instead of returning medications that are not picked up, pharmacy students identify medications for hypertension and antibiotics that have not been picked. Patients are contacted to inform them that medications are waiting. In the first trial of this project the students had great success at reaching patients who subsequently picked up their medications, showing an improvement in blood pressure control versus patients who did not pick up their medications.

Garcia's in-house pharmacists work with patients on an individual level, helping to reduce barriers and improve health literacy. They have a full-time clinical pharmacy technician who does all the scheduling, follow up and outreach. Savings from the 340B program fund this position.

Reducing Patient Costs

Virginia Garcia pharmacists advise patients on both clinical matters as well as administrative issues, such as how to best pay for drugs. This type of patient counseling is time consuming and not typically offered at retail settings. Because almost 50 percent of Virginia Garcia's patients are uninsured, the center uses 340B savings to provide drugs at a nominal fee, never turning away patients for their inability to pay.

Through its Indigent Medical Assistance Program, Virginia Garcia leverages its 340B savings to help patients register for manufacturer patient assistance programs, which help patients receive the drugs they need at little/no cost from the manufacturer. These programs can help stretch pharmacy dollars but require staff resources to help guide patients through the complicated registration process.

Investing in Health Literacy

Virginia Garcia's patient population includes many undocumented workers with low health literacy. The center has successfully recruited bilingual pharmacists and pharmacy technicians and has used 340B program savings to dedicate the time and resources needed to provide translation services and to spend sufficient time with these patients. They work with patients to explain clinical issues and determine ways that patients and Virginia Garcia can reduce drug costs.

Focusing on Services for Specific Disease States

The pharmacists and pharmacy technicians at Virginia Garcia target high risk/high utilizers and partner with local CCOs to identify patients who may benefit from appointments with a clinical pharmacist. In addition, pharmacists have collaborative

practice agreements for the following chronic conditions: diabetes, hypertension, hyperlipidemia, smoking cessation, depression, anxiety and psychiatric medication monitoring. These collaborative practice agreements allow pharmacists to start, stop or modify therapy for the referred conditions and to order lab monitoring necessary to improve disease state outcomes and medication safety.

Leveraging 340B Savings: Siskiyou Community Health Center

Siskiyou Profile

Siskiyou Community Health Center (Siskiyou) provides patient-centered care to help manage patients' individual family and wellness needs through its clinics in Grants Pass and Cave Junction. Siskiyou carries out its mission to build healthy communities by providing multiple outreach programs throughout the region.

For patients unable to afford their medications, Siskiyou offers a \$4 formulary for commonly used medications, similar to programs offered by larger chains. In addition, Siskiyou offers a voucher program to offset the cost for those unable to pay.

Integrating Pharmacists into the Primary Care Model

The in-house pharmacist is an integrated member of the primary care team and sees patients at a crucial point - during the medical visit at the clinic. The pharmacist is able to work in real time with the clinician during the visit, a benefit not available with traditional retail pharmacies. The pharmacist has access to the medical record, providing additional resources to ensure quality care.

Supporting Community Demands

At its main clinic in Grants Pass, Siskiyou offers family practice, OB/GYN, mental health services, lab services, dental services and an in-house pharmacy. The Cave Junction clinic is currently undergoing an expansion, funded in part through 340B savings, that will provide more dental and mental health services and a second 340B pharmacy. Because of the success of the psychiatric nurse practitioner at the primary site, a second in-house psychiatric nurse practitioner will be added to the Cave Junction location by mid-2014.

Siskiyou's Outreach Program

The Outreach Program invests significant amounts of time cultivating trusting relationships with families in the community. As a result of these relationships, an Outreach Program patient approached Siskiyou staff concerning her grandmother who was diabetic and did not have the financial means to purchase necessary medical treatment. Because she was unable to afford medication, she was using her cat's insulin for her own medical needs. Upon hearing this story Siskiyou staff provided the granddaughter with information on Siskiyou's sliding scale and referred them to a primary care provider in Cave Junction. This Outreach Program referral resulted in the grandmother receiving appropriate medical care to address her health condition.

Providing Mental and Oral Health Services

To fulfill its mission to provide multiple outreach programs throughout the community, Siskiyou uses its 340B savings to subsidize its school-based clinics and dental services. A mobile dental unit visits schools for preventive care and exams. Siskiyou also provides an in-home baby check following the birth of a child, with outreach on parenting skills.

Siskiyou's in-house pharmacy and behavioral health services are elements of its integrated medical home model. In other clinical settings, a patient may leave

with a referral to a behavioral health professional or a prescription, and the clinic provider has no way of knowing if the patient will use the referral or fill the prescription. Through its in-house pharmacy, Siskiyou can get medications to the patient right away, encouraging adherence. And their in-house psychiatric nurse practitioner has worked successfully with the pharmacist to create starter medication packs to get patients on the appropriate medication from the first visit.

Leveraging 340B Savings: Northwest Human Services

Northwest Human Services Profile

Northwest Human Services comprehensive medical, dental, mental health and social services through clinics in Salem and Monmouth.

Northwest Human Services provides a number of outreach services, including a Crisis Hotline, Homeless Outreach and Advocacy Project (HOAP), Homes Offering Shelter to Teens (HOST), Street Outreach Program (SOP), transitional living program, dental services, mental health services and comprehensive primary care. The diversity of populations targeted by Northwest Human Services through these programs includes the homeless (including teens), populations transitioning to being housed, the developmentally disabled and those living with mental illness. These often-overlooked populations will likely not be covered under Medicaid expansion or the health insurance exchange because of their instability or inability to obtain coverage on their own, yet Northwest Human Services remains committed to caring for them.

NWHS – Pharmacy Services

The lack of an in-house pharmacy does not prevent personalized pharmacy services from NWHS's on-staff pharmacist. These services identify affordable options and improve patient outcomes. As one example, even though a patient had insurance, it was cheaper to charge the patient the 340B cost than to process the claim and charge the branded copay. This diligence in monitoring both clinical choices and cost was also recently applied when a patient starting chemotherapy needed a new reflux medication that would not interact with her chemotherapy drugs. The pharmacist was able to identify the best option for safety, efficacy and cost.

Improving Pharmacy Access

Northwest Human Services uses contract pharmacy arrangements to access 340B pricing and improve pharmaceutical access for its patients. Through its voucher program, Northwest Human Services pays 100 percent of a drug's cost for patients who are without a home, uninsured and unable to pay. For patients whose incomes are less than 200 percent of the federal poverty level, Northwest Human Services passes the entire 340B discount to the patient. In addition, the 340B program has allowed Northwest Human Services to provide mail order pharmacy options, improving access for elderly patients in particular.

Northwest Human Services pharmacists serve an administrative function to ensure that contract pharmacy relationships are functioning appropriately and work to educate providers and patients regarding the available pharmacy options.

Offering Free Clinical Pharmacy Services

Through the use of its 340B savings, Northwest Human Services provides clinical pharmacy services at the request of providers and responds to direct requests from patients. Although Northwest Human Services does not offer in-house pharmacy services, with 340B savings, it is able to maintain a pharmacist as part of the provider care team.

An important role of the clinical pharmacist on staff is to review and analyze 340B pricing to efficiently establish the formulary and help providers prescribe the most affordable options for patients. This work helps reduce costs for both patients and clinics and improves patient medication adherence. Northwest Human Services also uses its 340B savings to allow the pharmacist to counsel providers on 340B prices and coverage.

Collective Findings Across Health Centers

Summary of Findings

The data collected from each of the four health centers revealed three common findings, detailed below.

1. Health centers are best equipped to manage and allocate 340B savings based on the demands of the communities they serve.
2. Health centers provide important clinical pharmacy services to all patients, despite a lack of payment. The services require professional time and resources and result in improved health outcomes but are neither reimbursed nor revenue-generating.
3. Restrictions on how clinics can purchase or bill for drugs could reduce services for contract and in-house pharmacies, ultimately harming patients.

1. Health Centers Best Equipped to Allocate Savings

FQHCs are community organizations, governed by and for the people served. For a health center to receive FQHC status and grants, a majority of the members of its board must be patients of the center. Thanks to this local control, FQHC services reflect the most critical needs of the community. In addition, FQHCs see patients within their communities regardless of their ability to pay. As these uninsured patients transition to Medicaid as a result of health reform, FQHCs are in the best position to serve these patients as well as any remaining uninsured. Through its direct use of 340B savings and commitment to serving their communities, an FQHC can efficiently turn 340B savings into community benefits.

Savings from the 340B Program are used optimally when they are retained by the FQHC. Any policy that shifts 340B savings away from an FQHC will dilute the savings and compromise patient services. The Oregon Health Authority's (OHA) proposed mandated actual acquisition cost billing requirement seems to assume that the difference between the 340B price and a CCO's contracted rate will either bolster the State Medicaid's pharmacy budget or be invested in the CCO network for better coordination of benefits. However, this belief rests on two important yet flawed assumptions. First, it assumes that the savings from CCO claims are passed directly from the FQHC to the State or the CCO. However, this is not the case. Specifically:

- Unlike fee-for-service claims, there is no direct pass-through of savings from a CCO claim. When most CCO claims are adjudicated, they must travel through a Pharmacy Benefit Manager (PBM), where a negotiated percentage of the savings is retained, before reaching the CCO. The figure below illustrates the indirect pass through of 340B savings for CCO organizations.



OHA cannot guarantee that CCOs would realize savings from the pass-through for a number of reasons. First, the PBMs would have to agree to pass the savings to the CCOs, thus reducing the benefit to the State. Second, over the last few years, PBMs have been negotiating reduced payments to entities that participate in 340B as part of a strategy to indirectly benefit from 340B programs. Third, the State is not a party in any of the CCO contract negotiations, making them unable to control what happens to the savings.

The second flawed assumption is that the reimbursement rate for most, if not all, CCO claims, would be significantly reduced by a mandatory 340B pass-through. Again, this assumption is inaccurate. Specifically:

- Certain categories of prescription medications—including high-cost behavioral health drugs and heavily utilized generic medications—are already subject to pricing discounts through existing cost containment strategies, such as the behavioral health pass-through on drugs that are on a Maximum Allowable Charge (MAC) list. For these claims, the savings already in place reduce the benefit that the State or CCOs would realize from a mandated 340B pass-through.
- Behavioral health medications dispensed to both fee-for-service and CCO covered patients are reimbursed by the State at the 340B acquisition price plus a \$10 dispensing fee. These drugs are commonly used and can be very high-cost. At Siskiyou, for example, two common drugs provided during the first 11 months of 2013 were the anti-depressant Pristiq and Lamotrigine, a bi-polar medication. Lamotrigine is relatively inexpensive at \$0.32 retail cost per unit and a \$0.05 340B cost per unit, but with 38,610 dispensed, the difference in the ingredient cost equates to \$10,586.86 to the State. Similarly, in the first 11 months of 2013, Siskiyou acquired Pristiq at an estimated 340B acquisition cost of \$1,448.23, while the estimated retail cost was \$3,597.49, resulting in a difference in the ingredient cost of \$2,149.26 to the State.
- In addition to mental health drugs reimbursed directly by the State, for multi-source medications on a maximum allowable cost (MAC) list, the reimbursement is already capped, thus reducing the potential impact of a 340B

acquisition cost pass-through. According to the pharmacy director at Virginia Garcia, approximately 20 percent of their dispensed drugs are subject to a MAC, which can sometimes be less than the acquisition cost of the drug, even at the 340B price.

As safety-net community providers, FQHCs use 340B savings to benefit all patients of the community directly (regardless of payer), indirectly passing savings to the State as a whole. As patients transition from uninsured to receiving Medicaid coverage through FFS or CCOs, FQHCs can leverage their existing community relationships to continue to serve these patients. In addition - though it is not possible to pinpoint how the need for these services will evolve as parallel health care policies unfold – for a certain contingent of patients, health care needs will always exceed their insurance coverage. FQHCs are needed to fill these coverage gaps with affordable, accessible care.

FQHCs use 340B savings to provide medications to the uninsured and those unable to pay. Although the methods varied, each of the four FQHCs in this study provided medications at little to no cost to those patients unable to pay. Further, the four FQHCs all reported using 340B savings to further stretch resources and ensure that patients get the medications they need. Specific examples include:

- More than half of prescriptions dispensed at Central City Concern’s Old Town Clinic in 2013 were for uninsured patients. Of the 90,361 prescriptions dispensed in 2013, 46,712 were provided to the uninsured.
- Virginia Garcia Memorial Health Center leveraged its 340B savings to provide 2,058 prescriptions through patient assistance programs (PAPs) in 2013. PAPs are manufacturer programs that offer access to medications. However, they often have eligibility requirements and registration processes that are difficult for patients to navigate. By using pharmacy staff, funded by 340B, Virginia Garcia Memorial Health Center is able to increase its use of PAPs and stretch resources further.
- Almost half (48 percent) of prescriptions filled at the Siskiyou Community Health Center pharmacy were on the \$4 formulary. Based on Siskiyou data from the first 11 months of 2013, approximately 48 percent of prescriptions were filled with the \$4 formulary. Of the 35,926 total prescriptions dispensed, 17,120 were \$4 list drugs. Siskiyou uses a \$4 formulary to make commonly prescribed medications more affordable for all patients. When Siskiyou dispenses a medication from this formulary to a CCO patient, the CCO is only billed \$4. As with all patients, when acquisition costs are higher than \$4, Siskiyou incurs a loss on these prescriptions.

- Northwest Human Services uses a voucher program to help provide access to necessary medications for patients without the ability to pay. In the past year, Northwest Human Services provided more than \$115,337 in 340B drugs to patients at no cost through its voucher program. Vouchers are for patients who are without a home, uninsured and unable to pay. According to NWHS, the pharmacy relies on 340B income to offset the cost of the voucher program.

2. 340B Savings Offset Costs of Vital, Unreimbursed Services

Since the program's inception, 340B has provided each of the four clinics with varying degrees of income needed to develop and sustain a wide variety of innovative patient care services. Integrated clinical pharmacy services offer one example. Not only do CCO beneficiaries receive the basic services for free, but additionally, use of integrated pharmacy services has been shown to reduce health care expenditures overall.

The four clinics use 340B program income to fund different services and clinical positions that best serve the needs of their patients at no additional cost. Without the program income, these services or additional staff would not be available. Specifically:

- One of the most-cited clinical pharmacy services is **medication therapy management (MTM)**. In MTM, pharmacists evaluate a patient's entire medication list, including over-the-counter and herbal products. This can be a time-consuming process for pharmacists, as many patients use dozens of medications, over-the-counter products, and herbal supplements. Pharmacists determine whether any drug therapy problems exist, such as duplicate therapy (two different medications fulfilling the same purpose), inadequate or excessive dosage, or drug-drug interaction. Again, by communicating these findings with prescribers, pharmacists advocate for the needs of their patients, reduce the complexity of a patient's therapy, and save money for the health care system.
- Another key clinical pharmacy service provided is **medication reconciliation**. Through this process, pharmacists gather a complete list of medications the patient is taking, including any over-the-counter and herbal products. The pharmacist must pay careful attention to detail, verifying exactly when, how and why the patient uses each product. Pharmacists may have to cross-reference multiple sources—including patient or family recall, previous pharmacies the patient has used, and hospital or nursing home records—to compile a complete and accurate medication list.

Medication reconciliation is an important aspect of care for any new patient, especially those with complex medication regimens. By establishing a reliable baseline of what the patient has been taking, pharmacists help the health care team better understand the patient's needs going forward. Often, the pharmacist finds that the patient may be taking several products in a manner different from that intended by the prescriber.

A pharmacist may even combine medication reconciliation with medication therapy management. After the accurate medication list is completed, a pharmacist may review it for potential drug therapy problems and bring those concerns to the attention of the prescriber.

- **Disease state management** is another valuable clinical pharmacy service that pharmacists provide. For patients with certain chronic medical conditions, such as diabetes, asthma, depression and hypertension (high blood pressure), pharmacists work closely with patients and primary care providers to ensure that medications are working as intended to help the patient reach health care goals. A typical disease state management appointment may range from 15 minutes to an hour or more. In this setting, pharmacists review the patient's medication regimen, identify any potential side effects, and assess whether the disease is getting better or worse, based on findings such as changes in symptoms or laboratory markers.

Disease state management adds value to the health care system because pharmacists are uniquely trained to identify and prevent adverse drug events. If a patient is not receiving full benefit from a medication, if they are experiencing side effects, or if a potentially dangerous drug-drug interaction is possible, the pharmacist can inform the prescriber and recommend appropriate action. This service improves outcomes and lowers health care costs, as several studies have demonstrated (see Appendix B).

Each of the four FQHCs in this study provides uncompensated services – MTM, medication reconciliation, disease state management and/or others - that contribute to CCO savings for patients. Examples:

- With 340B savings, pharmacists at Old Town Clinic's in-house pharmacy are able to offer MTM, continuity of care services, increased patient encounters and a specialized program focused on anticoagulation monitoring at no additional cost to patients or CCOs. Pharmacists provided \$22,728 in 2013 in uncompensated time to improve outcomes and reduce overall patient costs.

- Old Town Clinic saved CareOregon an estimated \$11,490 as a result of improved outcomes from medication management programs.ⁱ MTM, such as that provided in person by Old Town’s pharmacists, has been shown to reduce health care expenditures by an average of \$383 per patient.⁸ Old Town tracked the visits of CareOregon patients in the last six months of 2013 and identified 30 unique patients. Taking the average expenditure reduction of \$383 per patient, the estimated reduction in health expenditures is \$11,490 annually.
- Anticoagulation monitoring services provided to CCO beneficiaries further save money for the state. Many patients at risk for a serious clotting event, such as a heart attack or stroke, are placed on medications called anticoagulants to prevent clot formation. For patients on anticoagulant medications, clinics may offer specialized monitoring services, often managed by a pharmacist. Studies have found that patients in pharmacist-led anticoagulation clinics realized improved health outcomes, resulting in savings of approximately \$1,620 per patient annually. Using this estimate, for the 83 unique CareOregon patients receiving non-reimbursed anticoagulation monitoring in the last six months of 2013, the total value in reduced costs equals \$134,508 annually. (See Appendix B for additional information on the literature regarding the impact and savings from disease state monitoring.)
- Virginia Garcia provides pharmacist-led disease state management programs for several chronic conditions, including diabetes, asthma, depression and hypertension. Many studies have examined the role of the pharmacist in optimizing outcomes and reducing direct medical costs, such as those associated with physician visits, emergency department utilization and hospitalizations. Based on these studies and the estimates for savings at the clinic, it is clear that pharmacist-managed disease management offers a substantial return on investment. By fronting the initial cost of clinical pharmacist services, Virginia Garcia is able to save money for the patients of two CCOs.

Patients often have multiple chronic conditions, so the number of patients in the table below may not be unique. Therefore, a net savings cannot be presented. However, using estimates from the literature and the number of patients who received the targeted disease counseling, we can present an indication of the overall magnitude of value provided through this intervention.

ⁱ CareOregon is former managed care organization that is now one of seven Risk Accepting Entity (RAE) members of the Health Share CCO. The distinction between a RAE and a CCO is irrelevant for the purpose of this analysis and beyond the scope of this report.

Disease Management Services Provided to CareOregon/Tuality Health Alliance Patients at Virginia Garcia Memorial Clinic⁹

	Number of Patients	Estimated Savings per Patient*	Total Annual Estimated Savings
Diabetes	91	\$2,600	\$236,600
Asthma	15	\$725	\$10,875
Depression	20	\$983	\$19,660

**For a narrative of the supporting literature for the savings per patient, please see Appendix B.*

- Data from Siskiyou show that 21 percent of patients receiving pharmacist-led behavioral health interventions were members of CCOs. In 2009, Siskiyou added a Behavioral Health Department to supplement the increasing number of patients requiring mental health services. Patients that present with serious mental health issues have an increased risk of experiencing other health issues, such as obesity, diabetes and hyperlipidemia.¹⁰
- Siskiyou also reports using 340B savings to expand pharmacy access to patients at its Cave Junction clinic through the opening of a new 340B in-house pharmacy. The clinic is located in Southern Oregon's rural Illinois Valley, where geographic and financial barriers hinder patient access to vital health resources. The addition of the 340B pharmacy at the Cave Junction clinic will allow patients to access medications using the center's sliding fee scale and vouchers.
- According to Northwest Human Services, income from the 340B program helped its recent expansion to a medical home model, including the addition of a psychologist, clinical pharmacist, behaviorist and health instigator. The patient-centered medical home model is a key component of Oregon's health reform movement but carries an annualized cost of \$154,770. Savings from the 340B program are important to maintaining service levels.
- In addition, 29 percent of Northwest Human Services pharmacy patients were uninsured in 2013. Although some of these patients may gain insurance through Medicaid expansion, Northwest Human Services' provision of free and reduced cost medications to these individuals stabilizes this population of potential Medicaid patients, which will reduce future Medicaid costs.

3. Restrictions on Drug Purchasing/Billing Could Reduce Access & Services

A mandated 340B pass-through for CCO claims would pose two important challenges for covered entities. First, the administrative challenge of claim identification and the corresponding reduction in savings would be a costly burden that would threaten the viability of FQHC in-house pharmacies and discourage retail pharmacies from participating in contract relationships with FQHCs.

Second, this policy would likely shift resources from FQHCs to CCOs in the design of care delivery programs and pharmacy services. While CCOs and FQHCs have launched partnerships and pilots, patient care programs originate with the FQHCs. If money were shifted to CCOs, it is likely that each CCO would be responsible for choosing the specific set of services its patients should receive. This change would place an additional burden on FQHC pharmacists when seeing patients.

Specifically, the providers at FQHCs who wanted to offer a specific service to a patient would first have to spend extra time and effort verifying that such a service was in alignment with the patient's unique CCO plan. This would be a particular burden for FQHCs that contract with multiple CCOs.

Each CCO is unique, as is each FQHC. A mandate from the State that forces every CCO to partner with every FQHC will not be effective, because the actors in local communities best know if/how it is appropriate to partner on the delivery of pharmacy services. On the other hand, allowing CCOs and FQHCs the flexibility to collaborate when warranted and the freedom to act independently is ultimately in the best interests of patients.

Difficulties with a mandate include:

- In-house pharmacy operations at FQHCs are already vulnerable and would be difficult to maintain without 340B program income. According to interviewees from the three clinics that deliver in-house pharmacy services, operations run on 340B program savings. Clinical pharmacy services do not generate revenue for the FQHC but are crucial to fulfilling the health centers' missions and for improving the health outcomes of their patients, who would not otherwise have access to such individual attention. FQHCs have come to rely on 340B savings where possible to offset the costs of delivering such services.

For example, Virginia Garcia's four in-house pharmacies operated at a combined net loss of \$25,000 in 2013. Additional administrative requirements, plus the loss of 340B savings, would make it difficult or impossible to provide pharmacy services on site and to provide easy access to customized pharmacy services and pharmacy products for patients.

- If contract pharmacies were required to pass through the 340B price to CCOs, the sustainability of FQHC-retail pharmacy partnerships would be uncertain. Contracted partnerships between FQHCs and retail pharmacies can be a useful way for FQHCs to increase patients' access to prescription medications. Contract pharmacies in the community can form close working relationships with FQHCs and improve their understanding of patient needs. For example, Northwest Human Services has a pharmacist who works regularly with its contract pharmacies to ensure patient access and the success of the program.

In addition, covered entities often use contract pharmacy relationships to help patients receive the medications they need at little or no cost. For example, Northwest Human Services has a voucher program that covers 100 percent of the drug cost for patients unable to pay. In 2013, this program provided over \$115,000 worth of 340B drugs to patients. Similarly, for patients with incomes over 200 percent of the Federal Poverty Level, Northwest Human Services passes the entire 340B discount to the patient, allowing patients to purchase medications at a reduced cost.

- Contract pharmacy fees likely exceed the proposed reimbursement of actual acquisition cost plus a small dispensing fee. 340B covered entities can contract with retail pharmacies to dispense 340B drugs, improving access within the community. However, these relationships often increase the cost of the program, with the covered entity paying the contract pharmacy dispensing and administrative fees. These fees, which allow contract pharmacies to increase access, would not be captured through payment limited to the 340B acquisition cost.

According to Northwest Human Services, each 340B-eligible prescription costs the clinic approximately \$22 in administrative costs. As such, they only manage to break even if the reimbursement equals the actual acquisition cost plus \$22. If a CCO actual acquisition cost-billing rule is enacted, contract pharmacy relationships may not be cost-effective, leaving covered entities to eliminate contract pharmacy relationships. This could have a particularly negative impact on older patients in rural areas, such as those who rely on Northwest Human Services' 340B contract pharmacy mail order option. For many of these individuals, their options for accessing discounted drugs are scarce and this contracted program is essential for obtaining the drugs they need.

- Shifting clinical program design responsibilities to the CCO, rather than the FQHC, could create an unintended incentive to align pharmacy services with reimbursement over needs. With the status quo care delivery system, the 340B program allows individual FQHCs the flexibility to allocate resources as appropriate for their unique patient populations. An FQHC tailors its services to meet its patient needs, offers that service to patients (often at no or minimal charge), and demonstrates the value of that service to CCOs.

If CCOs are to recoup 340B savings from the FQHCs, the apparent intention is that CCOs, rather than FQHCs, would assume responsibility for determining which patient care services their patients should receive.

Currently, FQHCs use 340B income to offset the cost of filling coverage gaps in patient care services. Without it, FQHCs will only be able to provide CCO beneficiaries with the services that are specified—and paid for—by CCOs. FQHCs will lose the flexibility to offer services to patients for whom that specific care service is not covered. For FQHCs serving multiple CCOs, this will mean spending valuable time checking patient’s specific CCO coverage before caring for patients, causing undue delays in patient care.

All of the FQHCs in this study reported contracting with more than one CCO. For example, Northwest Human Services contracts with Willamette Valley Community Health Plan and Yamhill County Care Organization. Virginia Garcia contracts with Yamhill County Care Organization, Health Share and Family Care.

FQHCs are incubators of innovation in patient care. Individual FQHCs, not CCOs, are the direct providers of care on the front lines and, as such, have the truest sense of their patients’ unique needs in a way not available to CCOs. For example, CCOs do not have the same access to the day-to-day health needs of their patients.

Therefore, local FQHCs are best equipped to identify and advocate for appropriate services for their patients. The current status quo model aligns with the intent of the CCO model to “provide an opportunity for frontline care providers to have a voice in their workplace in order to effectively advocate for quality care.”¹¹

Conclusion

It is clear from the experiences reported from these four health centers that the 340B Program has been critical in supporting the Oregon safety net for many years. Policies that shift cost savings to the State and/or CCOs may not be effective and could adversely impact patient care. FQHCs and CCOs should be permitted maximum flexibility to collaborate on program design and cost savings, so as to keep the focus on innovation and improving health outcomes.

Appendix A: Snapshots of the 4 FQHCs

The next four pages provide snapshots of the missions, services offered, and impact of 340B Program viability.

Central City Concern: Old Town Clinic

Diabetes care and anticoagulation management for uninsured and high-risk patients

AT A GLANCE

Clinic location(s): Portland, OR

Primary focus:

- Primary and naturopathic services
- Holistic approach to wellness, including job placement and housing services
- Pharmacist-managed diabetes and anticoagulation care
- Payment on sliding scale

Patients served annually: 6,664

Homeless served annually: 6,228

% Medicaid/CHIP: 31.1%

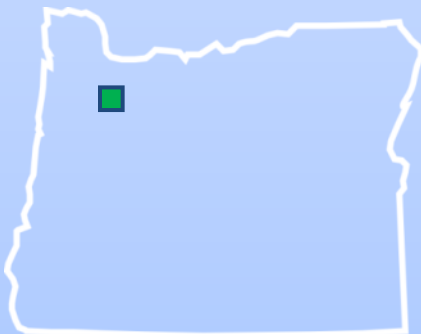
% Uninsured: 48.6%

% Below 100% of poverty line: 90.2%

Pharmacy service delivery model:

In-house

“Old Town Clinic provides compassionate health care to people who might not otherwise get care, treating them with dignity and respect”



■ 340B registered clinic

All data reported from 2012 calendar year unless otherwise noted.

Mission

Central City Concern was established in 1979 (originally as Burnside Consortium) to care for the needs of a growing population in the Portland metropolitan area suffering with alcohol dependence, poverty, and inadequate housing. The mission has expanded to provide holistic support through addiction recovery services, housing, and income (via employment or assistance programs) for individuals and their families. Imperative to this support structure is Central City Concern’s Old Town Clinic, which provides convenient, comprehensive care to low-income and homeless populations regardless of ability to pay for services.

Services Offered

At the Old Town Clinic, patients have access to a full range of primary care services in one location. Services include:

- Preventative wellness visits
- Cancer screenings, including colorectal and cervical cancer
- Treatment of injuries and minor office procedures
- Tobacco cessation counseling
- Connection to mental health and chemical dependency services
- Holistic naturopathic and wellbeing services, including yoga, acupuncture, and aromatherapy programs
- Intensive pharmacist-led anticoagulation management with weekly or bi-weekly medication monitoring
- Diabetes care offered through partnership with Oregon State University College of Pharmacy

Unique to Old Town Clinic is its sliding scale fee system, in which patients are charged reduced rates based on ability to pay. No patient is turned away from care due to inability to pay for services. Because of this innovative approach, Old Town Clinic is able to prevent costly emergency department visits and ensure access to necessary health services.

Impact of 340B on Program Viability

Old Town Clinic operates an in-house pharmacy that fills approximately 50% of the clinic’s prescriptions, often to patients without insurance. The clinic estimates that it waives \$3000/week in medication acquisition costs alone. This weekly loss would be unsustainable if not for the 340B program. Without 340B support, the poorest patients that Old Town Clinic serves would be unable to receive their life-sustaining medications and medical services. These patients would be forced to rely upon emergency departments, a far more costly option for routine care.

Additionally, 340B funding is reinvested in the clinic to support the salaries of a clinical pharmacist and post-graduate pharmacy resident, both of whom are actively involved in diabetes care and anticoagulation management. Many of the patients receiving these services have low literacy levels, and without personal support from pharmacists, would be unable to adhere to complex medication regimens, leading to further emergency department utilization and higher costs.

Virginia Garcia Memorial Health Center

Dental care and health literacy for a growing population of children and migrant workers

AT A GLANCE

Clinic location(s): Cornelius, Beaverton, McMinnville, and Hillsboro, OR
School-based sites in Tigard, Forest Grove, Willamina, and Hillsboro, OR

Primary focus:

- Comprehensive dental care for children and new mothers
- Culturally appropriate health education for migrant and seasonal farmworkers
- Pharmacist-led medication management and counseling for frequent clinic visitors

Patients served annually: 35,849

Agricultural workers served annually: 6,673

School-based served annually: 1,300

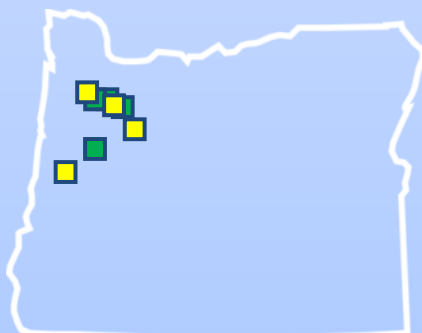
% Medicaid/CHIP: 49.7%

% Uninsured: 39.0%

% Below 100% of poverty line: 80.6%

Pharmacy service delivery model: In-house

"[Virginia Garcia provides] high-quality, comprehensive, and culturally appropriate primary health care"



- 340B registered clinic
- 340B registered school-based health center

All data reported from 2012 calendar year unless otherwise noted.

Mission

In 1975, a young girl named Virginia Garcia tragically died of complications from what should have been an easily treatable minor foot wound. A daughter to migrant workers, Virginia and her family were unable to access the care they needed for her treatment. After the girl's death, Virginia Garcia Memorial Health Center (Virginia Garcia) was founded with a mission to meet the health care needs for migrant workers and their families.

Services Offered

Through Virginia Garcia, patients have access to a wide range of primary care services and education programs. These services include:

- Special focus on migrant and seasonal farmworkers through Migrant Camp Outreach Program
- Insurance open enrollment fairs for children and seasonal farmworkers
- Comprehensive dental services and unique pilot programs:
 - Dental screenings and complete dental treatment for children ages 0-21, regardless of insurance status
 - **OB Dental Program** and **Baby Days**: Early childhood hygiene and disease prevention strategies for new and expectant mothers
 - **First Tooth Project**: Disease prevention education for dentists statewide; particularly important for dentists in rural areas who would otherwise be unable to access such training
- Partnership through Care Oregon to provide frequent clinic visitors with one-on-one medication management with a clinical pharmacist
- Integration of behavioral health specialists into primary care appointments to improve access to care and remove cultural stigma of mental health services

Virginia Garcia is continually growing and serving patients in creative ways. A fourth school-based health center opened in Hillsboro in March 2013. In March 2014, a new clinic will open in Newberg and a dental clinic will come to Hillsboro.

Impact of 340B on Program Viability

The majority of Virginia Garcia patients—over 60%, according to 2012 HRSA data—do not speak English as their native language. Therefore, it takes extra time for the pharmacy team to provide thorough medication reconciliation and culturally appropriate medication counseling. The team also spends extra time to engage patients with assistance programs to make medications more affordable.

Virginia Garcia participates in the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC). In this model, teams nationwide join in discussions about successes and challenges at their practice sites and engage in intensive learning sessions. PSPC involvement has been proven to improve outcomes and reduce adverse drug events, but participation requires time and financial resources.

Virginia Garcia leverages finances judiciously, including grants from Care Oregon and other partners, to help make its services feasible. 340B is also a vital piece of the financial picture for Virginia Garcia's rapidly expanding program. 340B income finances the salaries of a 0.85 FTE clinical pharmacist and a clinical pharmacy technician, and it contributes to supporting the clinic's programs as a whole.

Siskiyou Community Health Center

Interprofessional collaboration toward comprehensive primary care for children and families

AT A GLANCE

Clinic location(s): Grants Pass, OR and Cave Junction, OR

Primary focus:

- Prenatal, newborn, and early childhood support and education
- Behavioral health programs and medication “starter packs”
- Dental care through clinic, schools, and Mobile CareVan
- Close collaboration between clinic practitioners and on-site laboratory and pharmacy services

Patients served annually: 10,873

School-based served annually: 891

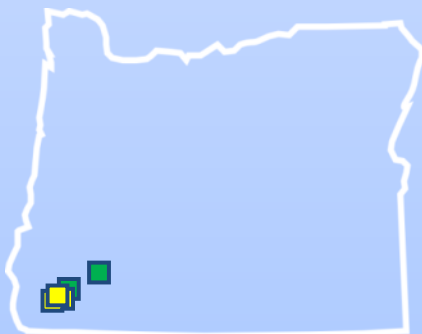
% Medicaid/CHIP: 37.9%

% Uninsured: 37.0%

% Below 100% of poverty line: 66.0%

Pharmacy service delivery model: In-house (Grants Pass)

“SCHC continues to follow its mission to build healthy communities by providing an affordable solution for quality health care”



■ 340B registered clinic

■ 340B registered school-based health center

All data reported from 2012 calendar year unless otherwise noted.

Mission

Siskiyou Community Health Center (SCHC) was founded in 1973 through the efforts of volunteers in the Illinois Valley community. With humble beginnings in an old farmhouse, the program has expanded over the years into a Federally Qualified Health Center (FQHC), now complete with an on-site pharmacy and laboratory as of 2010. SCHC continues to explore innovative ways to serve its patients and fulfill its mission of building healthy communities.

Services Offered

Patients at SCHC are offered programs and services to meet their needs at all stages of life, with a particular emphasis on care for children and families. SCHC services include:

- School-based community health centers
- **Chronic Disease Management Program:** targets diabetes, hypertension, heart disease, and arthritis
- Lifestyle counseling for tobacco cessation, nutrition, and physical activity
- Anticoagulation Clinic
- Behavioral health program featuring individual counseling and use of neurofeedback technology
- Collaboration between pharmacy and psychiatric nurse practitioners to prepare convenient behavioral medication “starter packs” to increase medication adherence
- Participation in Oregon ContraceptiveCare (CCare), offering free and reduced-cost contraceptives, annual exams, sexual health education, and sexually transmitted infection diagnosis and treatment
- Prenatal and newborn care through the following:
 - Prenatal wellness checks and education
 - **Project Baby Check** and **Healthy Start:** Education and support services for parents of children ages birth – kindergarten
- Innovative dental service programs:
 - **“Kids Smile”:** school-based dental prevention program
 - **Mobile CareVan:** limited dental exams, cavity treatment, and simple tooth extractions
- \$4 formulary for select prescription medications at Grants Pass pharmacy
- Voucher program for select prescriptions

Impact of 340B on Program Viability

SCHC plans to use 340B income to expand pharmacy services to the Cave Junction clinic. Expansion is in progress and will be complete by summer 2014. This will make medications much more accessible; patients in Cave Junction currently have to travel 60 miles round-trip to Grants Pass for their prescriptions. The primary care home in Cave Junction will also benefit from the expertise of an on-site pharmacist to answer medication questions and enhance care transitions. Expansion of pharmacy services to Cave Junction is dependent on 340B income.

340B also helps fund the prescription voucher and \$4 formulary programs. Without the \$4 formulary, SCHC would have to bill higher prices to managed care organizations and ultimately the state Medicaid agency for these claims. 340B investment on the clinic level keeps health care accessible and affordable for all.

Northwest Human Services

Housing assistance, crisis support, and medical services for youth and mentally ill adults

AT A GLANCE

Clinic location(s): Salem, OR and Monmouth, OR

Primary focus:

- Crisis and information hotline
- Housing services and life skill development for youth and mentally ill adults
- Voucher program for prescription medications for homeless patients
- RxAlign program for customized medications adherence programs and increased 340B utilization

Patients served annually: 12,309

Homeless patients served annually: 1,769

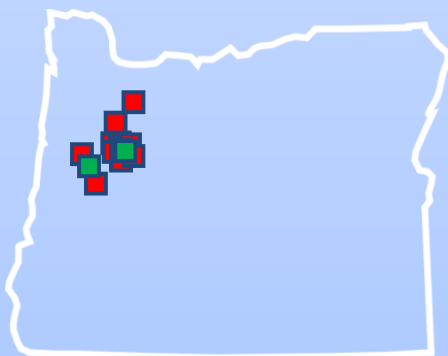
% Medicaid/CHIP: 45.1%

% Uninsured: 28.6%

% Below 100% of poverty line: 73.3%

Pharmacy service delivery model: Contract

“As long as there is need in our community, we will continue to be a safety net providing health care and social services.”



■ 340B registered clinic

■ Contract pharmacy

All data reported from 2012 calendar year unless otherwise noted.

Mission

Northwest Human Services was originally founded in 1970 as a temporary crisis call center. The number of calls received vastly outpaced expectations, and the crisis hotline quickly became established as a vital support structure for the local community. In the years that followed, the program continued to grow to its current form, adding more services as needs in the community were realized. Northwest Human Services today provides a holistic approach to wellness including medical, dental, mental health, and social services.

Services Offered

Community members utilize Northwest Human Services for a variety of medical and personal assistance needs, including:

- **Homeless Outreach and Advocacy Project (HOAP):** specifically aimed toward providing mentally ill adults with vital resources including psychiatric medication management, substance abuse counseling, life skills support, hygiene, food, and shelter
- **Homes Offering Shelter to Teens (HOST) Youth and Family program:**
 - Basic shelter services and street outreach
 - Transitional Living Program (TLP) to prepare youth with savings program and independent living skills necessary to establish their own permanent residence using their own income
- 24/7 crisis and information hotline offered in English and Spanish to provide community members with trauma counseling, suicide intervention, and emergency financial and prescription assistance for life-sustaining medications
- Medical and dental clinics with patient-centered primary care home (PCPCH) model, including recent addition of behavioralist to clinic staff
- Clinical pharmacist services for comprehensive medication management, adherence programs, and 340B pricing information
- Voucher program to help homeless patients cover costs of prescription medications and avoid emergency department utilization

Northwest Human Services uses its unique programs to improve healthcare access for patients with barriers to care, including mental illness, homelessness, disability, English as a second language, and lack of transportation.

Impact of 340B on Program Viability

340B income is reinvested directly into Northwest Human Services' overall budget, which supports the wide variety of programs listed above. As one example, the prescription medication voucher program would be impossible without 340B.

340B also covers the salary of the clinical pharmacist on staff at Northwest Human Services. In addition to providing medication management for patients, the clinical pharmacist offers 340B pricing education to fellow providers within the primary care home. He also personally developed the RxAlign program used by Northwest Human Services. Through RxAlign, the pharmacist provides customized solutions to improve clinical outcomes for patients and increase the clinic's 340B utilization, both of which lead directly to more cost-effective patient care.

Appendix B: Support for Estimated Savings for Pharmacists' Interventions in Disease State Management

INR/Anticoagulation

Close monitoring is particularly vital for the widely used anticoagulant warfarin. Every few weeks, a blood draw is needed to determine whether a laboratory value called the INR (international normalized ratio) is within the recommended safe range. If an INR is too low, the patient is at risk for a clot. On the other hand, an elevated INR poses a risk for serious internal bleeding. The INR changes in response to warfarin dose. Pharmacists are specially trained to interpret INR results and determine whether the appropriate warfarin dose is being administered to prevent clots while, at the same time, avoiding a dangerous bleed.

Patients in pharmacist-led anticoagulation clinics had fewer major to fatal bleeding events (1.6% versus 3.9%), fewer thromboembolic events (3.3% versus 11.8%), fewer warfarin-related hospitalizations (5% versus 19%), and fewer emergency department visits, both warfarin-related (6% versus 22%) and warfarin-unrelated (46.8% versus 168%) than their counterparts receiving standard care. It has been estimated that these improved outcomes saved \$162,058 per 100 patients annually.¹²

Diabetes Management

For diabetes management, the widely cited Asheville Project found that the diabetes management program saved money for payers. Within one year, insurance claims per patient per year decreased by \$2,704 from baseline, even when factoring in the cost of the pharmacist's time and the increase in number of diabetes medication claims.¹³

In Buffalo, New York, the MedSense project was built on a similar model, with pharmacists providing diabetes management in collaboration with primary providers. MedSense corroborated the findings of the Asheville project and found an average cost savings of \$2,547 per patient in the first year of implementation.¹⁴

Asthma

In addition to its work in demonstrating the value of diabetes disease state management, the Asheville Project also examined outcomes from pharmacist-led asthma interventions and found improvement in all outcome measures. Fifty-five percent of patients improved in asthma severity classification, and patients reported significant improvements in quality of life. Annual emergency department utilization decreased from 13.9% of patients at baseline to only 3.2% of patients after five years of

follow-up. The patients also had fewer hospitalizations. After five years of follow-up, annual direct medical costs per patient had decreased by \$725 from baseline.¹⁵

Depression

Findings from Project ImPACT: Depression, released in 2011, demonstrated that pharmacists can also add substantial value when caring for patients with depression. At the initial patient intake visit, the pharmacist performed a comprehensive health history, gathering information about the patient's mental status, stressors and mental health history. The pharmacist also administered the baseline PHQ-9 assessment and collected information about the patient's medications. At each follow-up visit, the pharmacist discussed treatment goals, administered a PHQ-9, assessed the patient's medication regimen and formulated a treatment plan.

After one year, 80% of study participants showed improvement in their PHQ-9 scores over baseline, and 56% had achieved remission (PHQ-9 score <5). Economic outcomes were also improved. Annual health care expenditures decreased by an average of \$983 per patient in the study, despite the cost of the pharmacist intervention and increased prescription drug utilization.¹⁶

Appendix C: References

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- ¹ H.R. Rep. No. 102-384(II), at 12 (1992).
- ² Letters are available online: http://www.snhpa.org/files/340B_draft_052313.pdf and http://www.snhpa.org/files/senate_signon_letters.pdf
- ³ National Association of Community Health Centers (NACHC), “NACHC Study: Benefits of the 340B Drug Pricing Program for Health Centers,” May 2011. Available online at: <http://www.nachc.com/client/documents/5.11%20NACHC%20study%20on%20340B%20benefits.pdf>
- ⁴ Government Accountability Office (GAO), “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (GAO-11-836),” September 2011. Available online at: <http://www.gao.gov/assets/330/323702.pdf>
- ⁵ Oregon Health Authority Pharmaceutical Services Administrative Rule, Chapter 410, Division 121, Effective February 21, 2013, Section 410-121-0155: Reimbursement.
- ⁶ The list of the 16 coordinated care organizations approved for Oregon Health Plan is available here: <http://www.oregon.gov/oha/OHPB/Pages/health-reform/certification/index.aspx>.
- ⁷ Oregon House Bill 3650, Section 1(3)(d).
- ⁸ Wakefield MK. Special report to the Senate Appropriations Committee on advancing clinical pharmacy services in programs funded by the Health Resources and Services Administration and its Safety-Net Partners. U.S. Department of Health and Human Services Health Resources and Services Administration. Available at <http://www.hrsa.gov/publichealth/clinical/patientsafety/clinicalpharmacyservices.pdf>. Accessed January 8, 2014.
- ⁹ The number of patients only includes those CareOregon/Tuality Health Alliance patients not yet enrolled in ICCT.
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