



"We put CARE back into Healthcare"

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Connecting Communities to Care: Bridging the Gap Between Donated Medications and Free Clinics Across the US

February 14, 2019

Executive Summary:

NITE Foundation dba SanRio Health is a non-profit 501(c)(3) charitable organization founded in 2017, dedicated to providing free or lower cost pharmaceutical drugs and medical devices to independent pharmacies, non-profit clinics and hospitals, and non-profit care centers that provide care to the medically underserved, which includes children, veterans, homeless, elderly and those in poverty.

Our Mission is to reduce the cost of pharmaceuticals and medical devices to patients in medically underserved, low income, and rural areas where patients are less likely to have access to affordable care. By facilitating the flow of free or lower cost medications to providers, we want to create opportunities for everyone to have affordable medication access regardless of their financial abilities. We are bringing CARE back to Healthcare.

As a pharmaceutical wholesaler we will be receiving donations from manufacturers and other distributors and partnering with providers who are able to distribute these products directly to patients in need. Our goal is to increase access to costly lifesaving medications through our distribution partners throughout the country.





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INTRODUCTION:

Every year 75 million Americans struggle to afford prescription medications. ^[1]

Every year the price of medications increases, forcing more and more people to decide between lifesaving medications or putting food on their table.

Every year up to seven BILLION dollars' worth of medications expire or are discarded. ^[2]

The healthcare system in the United States IS broken.

We NEED better practices in place to help redirect these resources to those in need. SanRio Health's Mission is to facilitate the flow of these critical medications to those medically underserved. By serving as the conduit between the manufacturers and providers that care for the medically underserved, we believe we can make a difference in the lives of those struggling to afford their medications.

Our objective is to illustrate how critical it is to make changes in our healthcare system and how we intend to bridge the gap between manufacturers and providers to make medications more affordable and more accessible to those in need.

Over the next few pages, we will review the current landscape of our nation's healthcare, the benefits to helping provide affordable medications, and our role in driving this change.



Get
Involved





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BACKGROUND/PROBLEM STATEMENT:

Currently, our healthcare system is unable to provide for all of the Americans who need access to care and affordable medications. This is only expected to get worse. Since the start of the Affordable Care Act, free and charitable clinics have seen a 20% overall decrease in funding whereas, there has been a 40% increase in the demand for services that free and charitable clinics provide. ^[3] By 2024, 35 million Americans are expected to be uninsured creating a further burden on our healthcare system.

A survey of patients that are deemed "seriously ill" by the Commonwealth Fund, Harvard T.H. Chan School of Public Health, and the NY Times ^[4] reported that 62% of patients felt confused and helpless about their health care, 57% have difficulty paying their bills, and 53% faced financial ruin. Even among those with health insurance, 31% couldn't pay for their hospital bills and 27% were unable to afford their medications. Of these seriously ill patients with insurance, 36% used up most or all of their savings, while 21% were unable to afford basic necessities such as food, heat, and housing.

EVEN WITH INSURANCE, A SERIOUS ILLNESS CAN MEAN FINANCIAL DISTRESS

	INSURED	NOT
Used up all or most of your savings	36%	57%
Contacted by a collection agency	29%	58%
Unable to pay for basic necessities like food, heat, or housing	21%	51%
Borrowed money or got a loan or another mortgage on their home	13%	14%
Unable to buy health insurance because of having that medical or health	9%	31%
Declared bankruptcy	4%	4%

Source: Seriously Sick? Don't Count on Insurance Being Enough; New York Times; OCT 17, 2018; Page A13

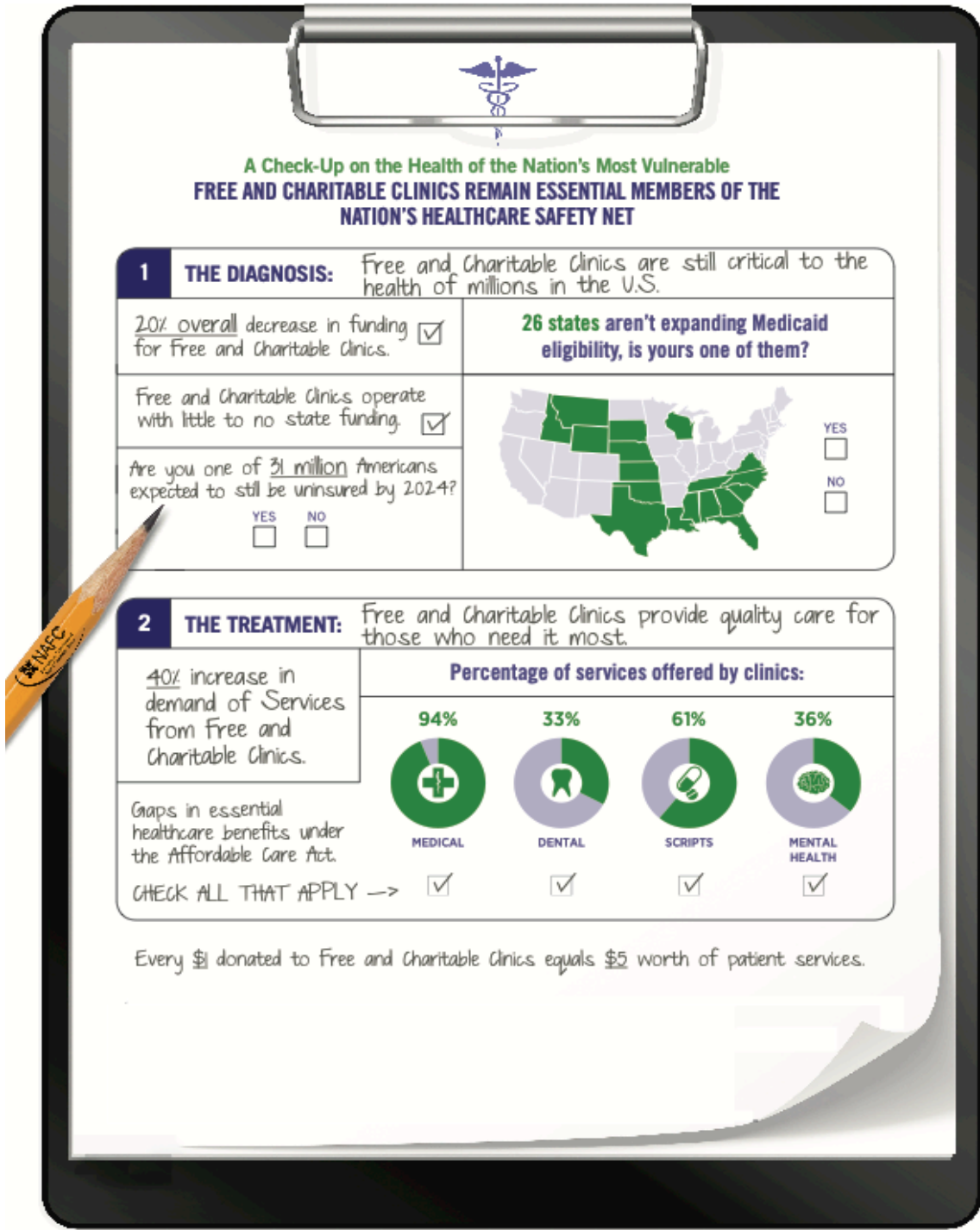


Figure 1 NAFC. 2014. America's Free and Charitable Clinics: Vital Support For 30 Million Uninsured Americans.
<https://www.nafcclinics.org/sites/default/files/NAFC%20Infographic%20%26%20Report%20Feb%20202015%20small.pdf>



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Studies also show that half or more patients with chronic diseases do not take their medications as prescribed. Annually, non-adherence to medications or suboptimal therapy leads to 275,689 deaths and costs up to \$528 billion dollars. ^[5] This is happening even though we are seeing \$billions of medications wasted.

DRUG PRICES ARE GETTING HIGHER – BRAND DRUGS ARE THE CULPRIT

Rising brand drug prices are behind the increase in prescription drug spending and patient costs. In 2017, brand drugs accounted for only 10 percent of prescriptions dispensed, but more than 77 percent of total spending. ^[6] Conversely, generics made up 89 percent of prescriptions, but only 26 percent of spending. And while brand companies highlight that they are “limiting” year-over-year price increases to less than 10 percent, such price increases are nonetheless many times the rate of inflation and responsible for significant increases in the real cost of brand drugs. These brand drug prices increasingly create significantly larger burdens on patients and payers.

As brand drug prices continue to rise, the health care system faces rising costs. This is seen in the rapid explosion of specialty medicine development. In 2018, expensive specialty medicines used for only 2 to 3 percent of patients are anticipated to account for approximately 50 percent of all spending on prescription drugs, 2 which accounted for more than \$400 billion in 2017.³

Brand drug manufacturers, payers and providers have sought creative mechanisms to use the savings created by generics to shield consumers from the high prices of brand drugs. Generic substitution automatically provides patients with lower-cost alternatives that are the same as the brand. Unfortunately, recent formulary design trends increasingly subject generic medicines to higher cost sharing to reduce brand drug cost sharing. ^[7] Because of high brand drug prices, patients face increasingly higher out-of-pocket costs for all of their medicines.



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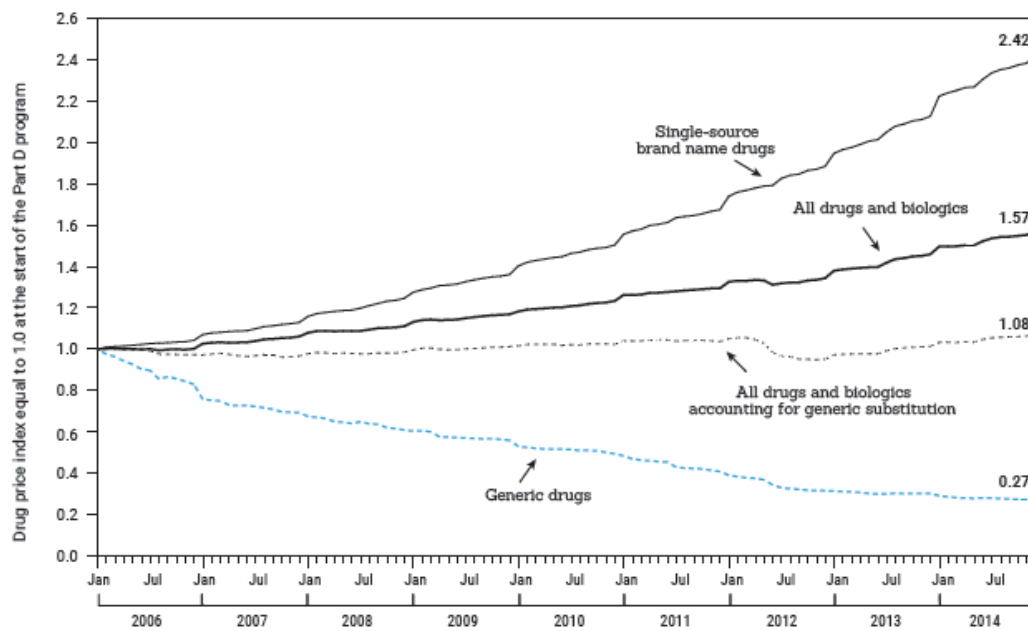
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Price Increases for Brand-Name Drugs Are Overwhelming the Effects of Using Lower-Priced Generics



Note: Chain-weighted Fisher price indexes.

Source: MedPAC report to the Congress: Medicare Payment Policy. Status Report on the Medicare Prescription Drug Program (Part D). March 15th, 2017.



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UNSUSTAINABLE DEFLATION:

Just a decade ago there were multiple wholesalers and pharmacies that contracted with generic manufacturers for the purchase of prescription drugs. Over the past few years, rapid consolidation has whittled down the number of buyers so that today three large buying consortia control 90% of all drug purchases for the retail market.

As this consolidation on the buyers' side has occurred, the number of manufacturers supplying generics has increased, with each company getting a slimmer share of the market.

The market imbalance has resulted in more than two years of price deflation in the generic market and has driven companies to execute portfolio optimization strategies for the products they sell. In many cases today, generic companies are deciding not to launch new approvals and even opting to exit the markets where drugs are priced as commodities with razor-thin margins. Not only does this threaten sustainability of the industry, it lowers the number of competitors in the market, which could lead to drug shortages and increased prices.

Savings In Jeopardy

MARKET IMBALANCE

Too Few Buyers Hold Too Much Power

Walgreens Boots Alliance
AmerisourceBergen
EXPRESS SCRIPTS®
Econdisc
RED OAK SOURCING
CardinalHealth
CVS caremark
ClarusONE Sourcing Services
MCKESSON
Walmart

Three Large Buying Consortia Control **90 Percent** of the Market

Source: Fein, Adam J. Fein. The 2016-2017 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, September 2016.



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ANTI-COMPETITIVE ABUSES – BRAND MONOPOLIES INFLATE PRICING:

Competition from generic drugs brings down drug prices. Yet every year we see increasing anti-competitive activity by brand drug companies to obstruct generic competition and thereby extend the marketing monopoly for their high-priced brand drugs. Manipulation of FDA safety programs to block generic drug development, renting sovereign immunity to circumvent patent laws, and filing sham citizen petitions to derail generic approvals are among the schemes used to gain unwarranted market protection

Unless these practices are stopped, consumers and patients will never see any meaningful relief at the pharmacy counter. Everybody wins when our prescription drug system operates as designed, with the brand and generic industries working in tandem:

- Brand companies get patents that provide a period of market exclusivity during which they recoup their development expense and earn profits for future investment in new drugs.
- And when those patents expire, generic companies introduce lower-priced competing versions that drive down costs.

When this equilibrium is skewed by anti-competitive behavior, patients suffer by losing access to affordable medicine they need to live healthier lives.

Helping patients afford their medications will increase adherence, decrease mortality and overall healthcare costs by decreasing further interventions, hospitalizations and unnecessary readmissions.

SOLUTION:

The solution is to provide free or lower cost medications to those in need by using 501(c)(3) tax credits to leverage manufacturer relationships, receive donations of both much needed and excess medications and, facilitate the redirection of these medications to those who need it most.



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HOW WILL WE ACHIEVE OUR MISSION?

By building relationships with manufacturers and authorized distributors to obtain medications either via donation or discounted rates, we can pass those medications on to providers that care for the medically underserved.

- Acquire licensing in all 50 US states to be authorized to distribute FDA Approved prescription drugs and devices.
 - We are currently licensed in Arizona, Connecticut, Minnesota, New Hampshire, and Texas.
 - We are currently authorized to distribute in Hawaii and Pennsylvania – they do not require out-of-state wholesalers to be licensed in their state.
- Appropriate selection of clinics.
 - We will work with clinics whose mission aligns with ours.
 - We will work to make sure that each clinic we partner with to provide free or discounted medications does their due diligence and has policies and procedures in place to make sure the help goes only to those in need – i.e. Uninsured, Underinsured, TANF, or have limited or no access to Primary, Specialty, or Prescription health care.
 - There are over 1,400 Free and Charitable Clinics operating in the U.S. through the NAFC (National Association of Free and Charitable Clinics). In the states we are licensed, we can help as many of those clinics.
- Building manufacturer relationships.
 - We will contact manufacturers and open a dialog about donating medications or money to our cause.
 - It does not have to be a one-time donation, we will try to keep an open donation cycle with them so that we can acquire the much-needed medications on a regular basis throughout the year.
 - As a licensed Wholesaler, we also can purchase the much-needed medications at the standard WAC (Wholesale Acquisition Cost) and then donate or provide at a low cost those medications to clinics, as needed.
- Creating programs to help the homeless or underserved.
 - Using donated OTC items (first aid kits) and toiletries, we can provide "health care bags" to homeless patients visiting our partnered free clinics to keep them healthy and safer on the streets.



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HOW DOES THIS BENEFIT THE MANUFACTURER?

In partnering with manufacturers, they would receive benefits in the form of tax credits, reduced waste, increased manufacturing efficiency, and a better public image.

- Manufacturers can donate up to 50% of their Adjusted Gross Income to a Qualified Charitable Organization to help decrease their tax burdens.
 - The tax credits are given for the Fair Market Value of any medication donated. For FDA approved prescription drugs and devices, the value will be set at 2x the "Cost Basis" for the medication, or WAC whichever is less
 - The tax credit is a 1:1 reduction of taxes owed to the US Government – essentially a redirection of the tax money to the non-profit.
- Manufacturers can decrease their wasted medications.
 - Every year manufacturers produce excess medications to cover their inventory in case of emergency or raw materials shortage.
 - \$7 Billion worth of medications are wasted or destroyed yearly as a result of this excess production strategy.
 - Manufacturers can become more efficient and cost effective if they clear up their inventory space and donate these excess supplies instead of letting them sit there and become expired.
- Improve the quality of care and reduce healthcare inequality for the millions of vulnerable and socially disadvantaged patients who seek care, while increasing their social contributions and public image.

HOW DOES THIS BENEFIT THE CLINICS AND PATIENTS?

By providing access to additional free and low-cost medications, the clinics we help serve will be able to increase the programs they offer, offer additional programs currently not offered, increase the types or classes of medications they fill. As a result, we will be able to help increase patient medication adherence, decrease healthcare costs, and increase the quality of life of our fellow man.

- Benefit to Clinics
 - Currently, every clinic must buy a certain amount of prescription drugs each year. This amount depends on what drugs are currently being donated to them.
 - Clinics need basic types of medications for most patient illnesses such as Hypertension, Diabetes, Heart Disease, Cancer, and Asthma.

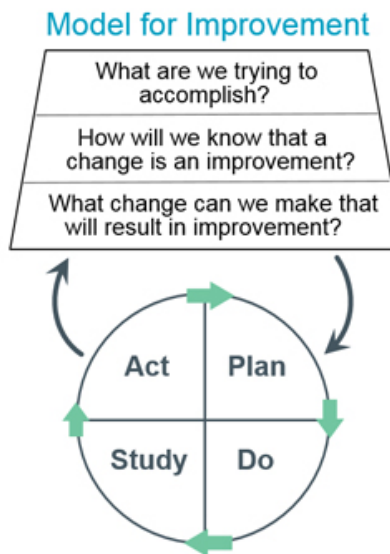


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- These drugs are oftentimes not donated so, the clinics must purchase these drugs at full price from a normal wholesaler.
- We can decrease the costs associated with purchasing these drugs, by either donating them at no cost to the clinic or charging a small fee per bottle to cover operating expenses, i.e. Shipping Costs, Overhead, etc...
- Expanded Services
 - By reducing the costs to purchase medications, clinics can use this money that has been historically set aside for this purpose on expanding and strengthening current programs.
 - We can offer medications that clinics may not be able to receive regularly which, can increase the number and types of medications the clinic can provide to patients.
- New Services
 - The reduced cost of medications for the clinic may also enable them to provide totally new programs that they previously lacked funding for.
- Benefit to Patients
 - Many Americans struggle to pay monthly bills or afford quality healthcare. Nearly 18% of adults report that they skip their medications as prescribed because of cost. As a result, this leads to an increase in healthcare costs as patients have more hospital readmissions, or increased doctor visits.
 - Patients deserve to receive medical care with dignity and compassion – treated with care and respected as human beings.
 - The ability to receive medications at no cost so that they can spend money on basic necessities for their families.
 - Patients who are regularly seen by a medical professional are more likely to be screened for serious diseases and conditions.
 - For some patients this is the only way they would be able to receive health care and medications.

MODEL FOR IMPROVEMENT:



The Model for Improvement,* developed by Associates in Process Improvement, is a simple yet powerful tool for accelerating improvement. The model is not meant to replace change models that organizations may already be using, but rather to accelerate improvement. This model has been used very successfully by hundreds of health care organizations in many countries to improve many different health care processes and outcomes.

The model has two parts:

- Three fundamental questions, which can be addressed in any order.
- The Plan-Do-Study-Act (PDSA) cycle** to test changes in real work settings. The PDSA cycle guides the test of a change to determine if the change is an improvement.

**The Plan-Do-Study-Act (PDSA) cycle was originally developed by Walter A. Shewhart as the Plan-Do-Check-Act (PDCA) cycle. W. Edwards Deming modified Shewhart's cycle to PDSA, replacing "Check" with "Study." [See Deming WE. [The New Economics for Industry, Government, and Education](#). Cambridge, MA: The MIT Press; 2000.]

WHAT WE ARE TRYING TO ACCOMPLISH:



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- We obtain donations from manufacturers and other benefactors to obtain the much-needed medications.
- We donate or charge a reduced price to the local free clinics, independent pharmacies, non-profit clinics and hospitals and non-profit providers to enhance, expand or create new services to those in need.
- The recipient provides the medications to those in need using their program models for defining poverty, etc.
- The benefit is that those who normally would not be able to afford their medications would now be able to, i.e. children, veterans, those in poverty, working poor, homeless, elderly thus, causing a decrease in mortality and overall health care costs by decreasing further interventions, hospitalizations and unnecessary readmissions.

HOW WILL WE KNOW A CHANGE IS AN IMPROVEMENT?

We will know a change is an improvement when the recipients are able to serve more patients, they are able to enhance their current programs and provide new programs to those they serve.

WHAT CHANGE CAN WE MAKE THAT WILL RESULT IN IMPROVEMENT?

The change we can make that will result in improvement is providing free or low-cost medication to the recipients who will provide those medications to patients who normally would not be able to take their medications due to the exorbitant cost.

CONCLUSION:

Our objective is to illustrate how critical it is to make changes in our healthcare system and how we intend to bridge the gap between manufacturers and providers to make medications more affordable and more accessible to those in need.

Our future solution is to expand to all 50 states wherein we are able to help alleviate much of the medication costs to those individuals and families who need it the most, i.e., children, veterans, homeless, elderly and those in poverty. We will provide backpack care bundles of donated first aid and personal care items to homeless patients in our contracted free clinics. We also envision becoming a major supplier of medications to areas hit hard by disasters by acting as a conduit for manufacturers to donate needed



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medications. We provide a valuable resource and avenue for medication manufacturers and distributors to donate their excess medication inventory.

By serving as the conduit between the manufacturers and providers that care for the medically underserved, we believe we can make a difference in the lives of those struggling to afford their medications.

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