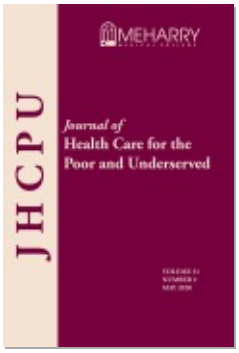
Strengthening the U. S. Medication Safety Net by Connecting Abundance to Need



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Strengthening the U. S. Medication Safety Net by Connecting Abundance to Need

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Abstract: Cost-related medication non-adherence (CRN) is a major population health concern in the United States, especially for patients with chronic conditions. It is associated with disease progression and increases the likelihood of emergency department utilization and hospitalization, thereby increasing overall health care expenditures. In this paper, we describe the prescription medication safety net in the United States and assess its reliability. We also introduce Dispensary of Hope (DoH), a charitable medication distribution network, as a reliable medication access program that is capable of filling gaps in medication coverage for low-income and uninsured Americans. Our critical assessment of the medication safety net in the United States suggests that an expansion of DoH could reduce CRN in the United States, improve chronic illness care, and help health systems achieve the triple aim of improving patient experiences and population health while reducing cost.

Key words: Charitable medication distribution, medication access, medication safety net, patient assistance program, low income, underinsured, uninsured, vulnerable populations, population health.

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Background

Cost-related medication non-adherence (CRN) is a major population health concern in the United States (U.S.).[1–3] Dimensions of CRN include not filling a prescription, delaying filling a prescription, taking less medicine than prescribed, or skipping medication doses due to cost concerns.[3] The prevalence of CRN has been estimated to be as high as 23% among adults in the U.S.[2] Americans with limited or no prescription coverage have considerable challenges with medication access and CRN among uninsured working-age adults is nearly double the rate among the general adult population.[2] Cost related medication non-adherence impedes chronic illness care, complicates or exacerbates disease states, and increases unnecessary emergency department utilization. Thus, CRN has been linked with the rise in health care expenditures.[4–6] Poor medication adherence results in between $100 and $300 billion in avoidable health care costs annually in the U.S.[7] Improving medication access for underinsured and uninsured individuals can be an important step towards achieving the triple aim of improving patient experiences and overall population health while reducing health care costs.[8]

Long-term medication access is essential for people with chronic conditions in order to slow disease progression and reduce complications. Individuals managing chronic conditions without adequate insurance often depend on safety-net providers for their medical care and medication needs.[9] The Institute of Medicine defines the health care safety net as "those providers that organize and deliver a significant level of health care and other related services to uninsured, Medicaid, and other vulnerable patients."[10[p3]] The supply of affordable medications is insufficient to meet demand at safety-net clinics and the lack of affordable medications ranks among the top resource constraints facing these clinics.[11] Gaps in the medication safety net are significant and the need for reliable medication assistance programs cannot be overemphasized. In this paper, we describe the current state of America's prescription medication safety net, assess its reliability, and highlight the opportunity to make it more reliable through charitable medication distribution.

Composition and limitations of America's prescription medication safety net.

Major sources of medication for the U.S. health care safety net are discussed below, with a focus on national programs.

Medicaid. Medicaid is the largest provider of prescription benefits to low income populations. Although the Patient Protection and Affordable Care Act (ACA) significantly decreased the number of uninsured patients,[12] more than 28 million Americans still did not have health insurance in 2018.[13] Those covered by Medicaid in many states typically face monthly limits on the number of reimbursable prescriptions.[14] This gap in coverage contributes to the existing need for prescription medications that falls on safety-net providers. To meet these needs, safety-net providers offer medication access programs that rely on donated medication samples; the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program; pharmaceutical manufacturer-sponsored patient assistance programs (PAPs); and more recently, charitable medication

distributors. These sources of input for medication access programs are highlighted below.

Medication samples. Over half of the annual marketing budget of pharmaceutical manufacturers is spent on free samples to physicians.[15] Drug samples can help patients avoid treatment delays and could be an effective stop-gap measure for patients waiting to be approved for other assistance programs.[16] However, it has been found that uninsured Americans were less likely than their insured counterparts to receive free drug samples, with the exception of those on Medicaid.[17] It is also noteworthy that medication samples are of limited value for addressing the needs of vulnerable patients.[16] First, free samples are not practical for the ongoing management of chronic diseases, as there is no guarantee of a consistent supply. Second, sampled products are often expensive new releases, which can be problematic when there is no long-term maintenance plan for vulnerable patients, especially in those instances when less expensive alternatives are available. Third, free samples can influence provider prescribing practices in a manner that is misaligned with the interests of patients or the health care system if such medications are more expensive or less effective than existing alternatives.[15,18,19] Individuals receiving medication samples have been found to have subsequent higher prescription expenditures than their counterparts.[20] Hence, medication samples should be considered more of a marketing and sales tool than a component of the medication safety net.[17]

Health Resources and Services Administration's 340B drug pricing program. The 340B program, established by the U.S. Congress in 1992, allows safety-net organizations to generate revenue by purchasing medications from pharmaceutical manufacturers at discounted prices while receiving payer reimbursements at standard rates.[21,22] Through 340B, eligible organizations are able to purchase and redistribute prescription and nonprescription medications for outpatients at significantly reduced costs.[23,24] Eligible health centers (federally qualified health centers—FQHCs; FQHC Look-Alikes; Native Hawaiian Health Centers; Indian Health Centers; and Ryan White HIV/AIDS Program Grantees); hospitals (Children's Hospitals, Critical Access Hospitals, Disproportionate Share Hospitals, Free Standing Cancer Hospitals, Rural Referral Centers, and Sole Community Hospitals); and specialized clinics (Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics)[25] receive discounts of between 20% to 50% of the listed drug price.[26] The 340B program is a vital source of medications for safety-net providers,[9] but it has significant limitations. First, hospitals receive the majority of 340B discounted drugs; however, they are not required to pass on savings to patients[27] and evidence suggests that a number of hospitals fail to do so.[28] Second, the discounts on medications offered via 340B may not be enough for the very poor to afford them. Third, eligibility criteria for the 340B program are complicated. In addition to belonging to the aforementioned hospital types,[25] most hospitals must demonstrate that the proportion of patients covered by Medicaid, or by both Medicare and the Supplemental Security Income program exceeds 11.75%.[26] It has been suggested that the strict and complicated requirements disqualified more than half of nonprofit and public general acute-care hospitals from participating in the 340B program in 2015.[29] Fourth, because of existing discounts via the Medicaid drug rebate program, Medicaid patients are not eligible for 340B programs.[27] Hence, Medicaid patients who

exceed their prescription benefit limits cannot obtain additional medications through this program. Fifth, changes to the 340B program by the U.S. Department of Health and Human Services (HHS) effective January 2018 resulted in a 27% cut in Medicare Part B reimbursement to hospitals for 340B discounted drugs.[30] Although a Federal judge issued an injunction in December 2018 halting implementation of the policy, the government continues to pursue avenues to scale back the 340B program. Significant reduction in 340B savings for hospitals will leave them with even fewer resources with which to provide medication assistance to patients.

Pharmaceutical manufacturer-sponsored patient assistance programs (PAPs). Pharmaceutical manufacturers, at their discretion have programs that provide prescription drugs to low income patients without prescription benefit coverage.[31,32] The drugs available in PAPs are based solely on corporate discretion. Most PAPs offer brand-name medications[16] and deliver them to patients through their health care providers.[33]

Data from a few recent studies indicate that PAPs are associated with improvement in patient outcomes[32] and health system savings on indigent care.[34–36] However, PAPs have multiple limitations that raise serious questions about their overall value to the prescription medication safety net.[33,37–40] First, most PAPs provide access to only one or two specific drugs, resulting in little support to the medication safety net.[33] Second, PAP application processes are complex and resource intensive because patient eligibility criteria can vary across manufacturers and each medication request requires a separate application. These administrative burdens can tax safety net providers and limit their ability to access medications via these programs.[33] Finally, PAPs can be burdensome to patients as they may have to wait two to six weeks to receive medications and/or cover the shipping fees[31] or copays[33].

Direct charity and retail discount programs. A number of organizations outside of the federal government and pharmaceutical manufacturers are attempting to provide medication access to vulnerable patients. Rx Outreach is a faith-based, charitable mail order pharmacy based in St. Louis, Missouri, with a mission to deliver affordable medications to low-income individuals regardless of their insurance status. Rx Outreach provides prescription medications for common chronic conditions such as asthma, diabetes, and hypertension, at highly discounted prices to individuals meeting income eligibility requirements.[41] It has the capacity to send prescriptions to patients in all 50 states and some U.S. territories,[42] allowing them to reach low-income individuals living in rural and remote areas.

Some pharmacy chains across the country offer generic drugs at discounted prices, often through membership programs, some of which have associated membership fees. Walmart's Prescription Program, for example, offers selected generic prescriptions at a discounted rate of $4 for a 30-day supply. Some hospitals have charity care funds through which they cover discharge prescriptions for patients in need.

Charitable medication distribution networks. The limited access to medications experienced by uninsured patients is not necessarily a function of scarcity. There is an abundance of medications in the U.S. as it has been estimated that the value of unexpired medications wasted each year could be as much as $5 billion to $10 billion.[43,44] Medication surpluses can be a function of multiple factors including variations in projected versus actual sales, new competition for a product, changes in formularies and

other uncertainties in the marketplace. Besides pharmaceutical manufacturers, surplus medications also accumulate at the health care facility level, such as hospitals and skilled nursing facilities. These surplus medications are usually destroyed; however, charitable medication distributors have developed a new drug supply model that preserves and redirects surplus medications to meet the needs of vulnerable patients. State-level laws that have been enacted in the last two decades have created an enabling environment for such drug donation and reuse.[45]

There are two models of charitable medication distribution in the U.S. The first type of charitable medication distribution is one in which the distributor simply serves as a matching platform to connect random donors with random recipients without taking responsibility for collecting, distributing, or accounting for the use of the medications. SIRUM, a non-profit organization based in Palo Alto, California, may be the largest organization using the matching platform model as it operates on a national scale. Many state-level drug donation and reuse programs rely on SIRUM's platform to keep their programs operational;[45] donors and recipients use SIRUM's platform to find and connect with each other. Eligible donors and recipients vary by state according to local laws. At this time, SIRUM only processes medications from organizational donors (e.g., manufacturers, wholesalers, pharmacies, skilled nursing facilities, assisted living communities, and hospitals) but offers to help individuals donate medications through its partner nonprofit organizations.[46] Eligible recipients include individuals, community clinics (e.g., FQHCs, free clinics), charitable pharmacies, and wholesalers, depending on the state.[47] The second type of charitable medication distribution, which can be regarded as a distribution network model, is one where the distributor establishes contracts with donors (e.g., pharmaceutical manufacturers) and dispensing sites (health care institutions) to meet the medication needs of vulnerable patients. In this arrangement, the distributor assumes responsibility for collecting, collating, and distributing the donated medications to the dispensing sites. Americares (through its USAccess Program),[48] Direct Relief (through its Replenishment Program),[49] and the Dispensary of Hope (DoH)[50] are three large nonprofit organizations that use a distribution network model. Americares and Direct Relief are global health organizations that provide health care assistance (including medications) to the poor as well as emergency medical assistance during disasters across the world.[48,51] DoH has a sole mission to provide medication support to the U.S. health care safety net.

Dispensary of Hope (DoH). DoH is based in Nashville, Tennessee and is licensed as a wholesale pharmaceutical distributor to receive and distribute excess medications in all states in the U.S.. Currently, DoH has over 200 dispensing sites in 34 states.[52] The organization is growing rapidly and plans to continue its expansion to ensure capacity to deliver a consistent supply of essential medications to low-income and uninsured people on a national scale.[53] It contracts with pharmaceutical manufacturers for three kinds of donations: excess medications (shorter-dated products that would otherwise be destroyed), scheduled donation of specified medications as part of the manufacturer's corporate social responsibility, and specific medications requested by DoH as necessary to fill gaps in its inventory.[54] DoH receives and inventories these donations and coordinates distribution to its partners across the U.S. who dispense them to low-income and uninsured patients at no cost. The DoH affiliated dispensing sites vary and include

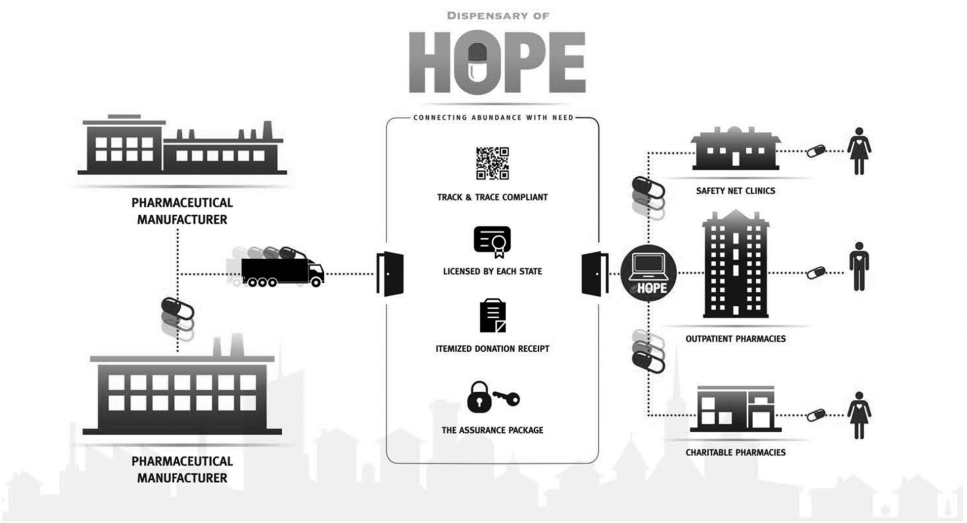

Figure 1. The Dispensary of Hope (DoH) chartiable medication distribution model.[a]
Note:[a]
Pharmaceutical Manufacturers donate their excess inventory and offer other planned donations to meet patient needs. Dispensary of Hope aggregates donations, authenticates and enrolls dispensing sites, and ensures safe distribution and responsible use of donated medications (i.e., The Assurance Package). Lastly, Dispensary Sites (safety net clinics, outpatient pharmacies, and charitable pharmacies) verify income and insurance status, enroll patients, and dispense medications free of charge to qualified patients.
Source: Dispensary of Hope.

charitable pharmacies, outpatient pharmacies, and safety-net clinics that contract with DoH to be part of its distribution network. Sites pay a flat annual subscription fee which helps defray the administrative costs of running the program and distributing medications. Within the scope of the inventory, participating sites are able to order an unlimited amount of medications as necessary to meet the needs of their low income and uninsured patients. Figure 1 illustrates the DoH model, including the functions of key players. The DoH eligibility criteria for patients and for health care organizations are listed in Table 1. Organizations seeking to become a DoH dispensing site are able to contact DoH by completing a form on the page titled "Become a Dispensing Site" on DoH's website.[55] Completing this request form is the first step in an onboarding process that involves discussions, a formal application, site visits, signing of agreement, training on DoH's online ordering platform, and initiation of the partnership (Personal Interview with DoH's Chief Development Officer, 12/13/2019).

DoH's distribution network advances medication access programs in key ways. First, a clinically-driven, comprehensive formulary with over 400 drugs is utilized in sourcing medications from manufacturer donors, including medications in demand for treating common illnesses.[44] An appropriate drug formulary is essential to running a successful medication access program.[16] The DoH pharmacy team uses clinical evidence and guidelines, as well as analytics from inventory analysis and medication requests to develop its formulary which focuses on primary care conditions. Second, the DoH model guarantees some consistency in medication access. The dispensing

Table 1.

DISPENSARY OF HOPE'S (DOH) ELIGIBILITY CRITERIA FOR PATIENTS AND FOR HEALTH CARE FACILITIES

Patients[a]	Health care facility
1. To qualify, patients have to meet two basic criteria: a. Be uninsured, and b. Have income at or less than 200% of the federal poverty level (FPL). 2. Dispensary of Hope (DoH) seeks to complement, not replace existing programs. Hence eligibility for other prescription benefit options (e.g. Medicaid) need to be excluded before tapping into DoH resources. Examples of eligible patients who might be considered for DoH medications: a. Patients who are in a waiting period for insurance coverage. b. Patients who might be ineligible for other medication assistance programs. c. Patients who are in between jobs and are uninsured. d. Patients being discharged from the hospital who are identified as at risk of not filling discharge prescriptions and potentially becoming readmitted.	Requirements to participate in the Dispensary of Hope network: 1. 501(c)(3) organization or owned by a 501(c)(3) hospital/health system. 2. Having a pharmacy licensed to fulfill ambulatory patient prescriptions. 3. Capability to manage an inventory of DoH drugs, including ability to carry out segregation and tracking. 4. Commitment to qualify patients to receive prescriptions filled from the DoH inventory. 5. Agreement to dispense DoH drugs to patients free of charge.

Note
[a]The pharmacy or clinic is responsible for determining patient eligibility using the criteria set by DoH.
Source: internal documents provided by the Dispensary of Hope.

sites can order unlimited supplies of medications from DoH inventory to meet ongoing needs of patients. This means that eligible patients can reliably obtain free medications from their local clinic or pharmacy (the dispensing site) for as long as they need them, without interruption. This would help address the pervasive problem of CRN in the U.S.[1–3] Third, DoH is accountable for the use of donated medications by its affiliated dispensing sites. It contracts with and maintains a relationship with each affiliated dispensing site, and has a supply chain system through which it distributes and monitors use of medication by its dispensing sites. The sites also agree to accountability with use of the medications, which is monitored through site visits, annual self-assessments of their policies and procedures, and regular audits of inventory and compliance.

DoH's medication access model is well aligned with all dimensions of the Triple

Aim.[8] First, the DoH model improves patients' experience of care as the medication recipients do not have to go through a complex application process. The pharmacist at the patient's local clinic or pharmacy (i.e., the dispensing site) determines eligibility by following a simple local qualification process that evaluates insurance status, income level, and existing medication coverage. Once completed, the pharmacist simply fills the patient's prescription from the onsite DoH inventory on the spot, including ongoing refills. Thus, a second advantage is that DoH's model avoids unnecessary delays in obtaining needed medications as may be experienced with other programs that require shipping (e.g., PAPs and Rx Outreach). Third, unlike other programs that have out-of-pocket costs for patients (e.g., discounted medication prices as with 340B or Rx Outreach, and shipping fee or copays as with some PAPs),[31,33] the DoH model has no patient-related charges, thereby eliminating cost barriers to medication access.

DoH's model improves the health of populations and reduces the cost of health care, thereby benefitting the dispensing health care facilities as well. DoH provides a sustainable path to improving medication access, and hopefully improving adherence for vulnerable patients. This would be expected to result in improved health outcomes, including a reduction in complications, emergency care utilization, and hospital admissions/readmissions,[4–6] thus leading to a reduction in uncompensated care for its partner health care organizations and systems. Early results of the impact of DoH adoption on health care utilization and outcomes are promising. A pre-post study of a group of patients that benefited from the DoH program in 2014 showed a 37% decrease in hospitalizations, a 20% decrease in average cost per hospitalization episode, a 3% decrease in emergency department (ED) visits, and a 54% decrease in ED cost per visit.[44] The DoH program also yielded a 3:1 return on investment.[44] These results suggest that providing reliable medication access to vulnerable patients yields benefits for patients and health systems alike. Thus, DoH can play an important role in the population health strategy of its partner health care institutions.

The DoH model also provides benefits for the partnering pharmaceutical manufacturer donors. DOH provides a coordinated approach to providing charity care and enhances the corporate social responsibility profile of its manufacturer partners. It also addresses the problem of excess inventory that must be destroyed,[43,44] thereby reducing costs to pharmaceutical manufacturers and positively affecting their environmental footprint. Many of the donations are also tax deductible, conferring additional economic advantages to the donors.

Despite the strength of its addition to the prescription medication safety net in the U.S., DoH is not without limitations. First, DoH serves the low-income and uninsured but does not address the persisting problem of underinsurance that is estimated to affect more than one-third of low-income adults in the U.S.[56] Second, although DoH has a robust inventory with over 300 medications for common primary care conditions at any given time (correspondence with DoH's Director of Pharmaceutical Services, 12/06/2019), it does not meet all of the possible chronic medication needs of low-income and uninsured patients. Third, despite its growing network, DoH currently has no presence in about one-third of states in the U.S., and only patients with access to its over 200 sites can benefit from the program at this time. If patients cannot physically get to a DoH dispensing site, they likely will not be able to benefit from the program

unless a DoH site offers mail order for their patients. Fourth, since it depends on the ability of its pharmaceutical manufacturer donors to follow through with their commitments, it can experience fluctuations in the availability of some of the medications in its inventory.

Reliability of America's Prescription Medication Safety Net

The ultimate test of the reliability of a safety-net system for prescription medications in the U.S. is the ongoing ability of low-income patients without prescription benefit coverage, or with limited prescription coverage, to receive medically necessary prescriptions when needed, for as long as necessary, and without undue complexities or delays, despite their inability or limited ability to pay. Box 1 provides a comparison of key aspects of various programs that anchor the prescription medication safety-net system. Medicaid is excluded from the comparison since the focus is on programs that fill the coverage gaps left by Medicaid. As shown in Box 1, most programs within the current prescription medication safety-net system fail to deliver on one or more of the assessed dimensions of reliability. Although medication samples and random charitable medication matching programs (e.g., SIRUM) come at no cost to patients, they are too arbitrary to be reliable sources of medication. Additionally, PAPs are too limited in scope to meet the bulk of medication needs for uninsured individuals.[33] Importantly, 340B and DoH offer consistent supply of medications for covered patients; whereas DoH medications come at no cost to the recipients, 340B medications are not free but may be available at discounted prices. Furthermore, 340B's design may result in cost savings from the program accruing to hospitals but not to vulnerable patients (Box 1). From the comparison in Box 1, one can infer that DoH is a promising addition to medication access programs in the U.S. as it has a model that can overcome some of the challenges of other programs. However, DoH has its own limitations as outlined previously, and medication access remains a puzzle and multiple programs must be cobbled together by safety-net providers to ensure full coverage to meet patients' needs.

Overall, most of the medication access programs exclude patients with insurance, so underinsured patients may be particularly at risk if they are unable to meet all of their medication needs through their insurer. Rx Outreach's model can be an important medication source for the underinsured, as well as uninsured patients not reached by free and reliable sources like DoH. However, although Rx Outreach's prices are steeply discounted, it is not free and the very poor may not be able to pay the discounted prices. The coverage gap for the underinsured deserves attention as medication access programs across the U.S. continue their efforts to meet the medication needs of low income Americans.

Conclusion.

In this paper we sought to describe the composition and assess the reliability of America's prescription medication safety net. We find that the U.S. prescription medication safety net consists of government-run programs (Medicaid, 340B, and state-level drug donation and reuse programs), pharmaceutical manufacturer-initiated programs

Box 1.

COMPARISON OF MEDICATION ACCESS PROGRAMS ON MEASURES OF RELIABILITY[a]

Medication source	Scope (coverage)	Consistency	Cost to patient	Patient inclusion/exclusion criteria
Medication samples	Limited and arbitrary	Inconsistent supply	Free	Open to any patient, at the discretion of the provider
HRSA 340B drug pricing program	A broad set of prescription and non-prescription medications	Consistent supply	Patient pays discounted prices if the 340B participating organization passes on the savings to patients[b]	Patients do not need to be poor or uninsured; with the exception of Medicaid patients, any patient that receives regular medical care at the 340B participating organization is eligible. A lot of safety net health care providers are not eligible to participate in 340B, hence their low income patients cannot benefit from the program
Pharmaceutical manufacturer-sponsored patient assistance programs (PAPs)	Majority cover only one or two medications	Limited information but patients are likely able to continue receiving the approved medications if they remain eligible	Some charge copays and/or shipping fees	Eligibility varies by manufacturer. Generally for low income and uninsured but excludes underinsured patients, including those on Medicaid
Charitable medication matching platforms: e.g. SIRUM	Arbitrary	Inconsistent supply	Free	Open to any patient, at the discretion of the receiving facility or provider

(*continued on p. 513*)

Box 1. (*continued*)

Medication source	Scope (coverage)	Consistency	Cost to patient	Patient inclusion/exclusion criteria
Charitable medication distribution networks: e.g., Dispensary of Hope (DoH)	DoH's inventory has over 300 commonly prescribed medications	Consistent medication coverage: patients can get unending refills so long as they remain eligible. Providers can place unlimited orders to meet patient demands	Free	DoH's medications are available to low income and uninsured patients but excludes underinsured patients, including those on Medicaid
Direct charity and retail discount programs: e.g., Rx Outreach	Rx Outreach's Inventory has over 300 commonly prescribed medications for chronic illnesses	Consistent medication coverage so long as the patient remains eligible	Discounted prices billed directly to the patient	Rx Outreach's medications are available to low income patients irrespective of insurance status

Note

[a]The authors define reliability in this context as the ongoing ability of low income and uninsured or underinsured patients to receive medically necessary prescriptions when needed, for as long as necessary, and without undue complexities or delays, despite their inability or limited ability to pay.

[b]Although hospitals receive the majority of 340B discounted drugs, there is no requirement for hospitals to pass on 340B savings to patients (Conti & Bach, 2013).

DoH= Dispensary of Hope

(medication samples and PAPs), direct charity and retail discount programs (e.g., Rx Outreach), and charitable medication distribution networks (e.g., DoH). Although gaps persist in the medication safety net, especially for the underinsured, DoH is a promising addition to the system as it has a reliable model that can consistently deliver access to common medications for low-income and uninsured patients at no cost to the patients. Improved medication access through DoH and other medication access programs will help address the population health problem of CRN, which affects more than 40% of uninsured American working-age adults,[2] and help health systems achieve the triple aim of improved patient experiences and population health while reducing costs.[8]

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