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No Doctor, No Problem: The Benefits of Innovation Expanding OTC Drug Access

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Christopher Stomberg, PhD – November 2025

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Executive Summary

This study examines how innovation in patient access to treatment without a prescription could address critical patient needs. Notable disparities in healthcare access and outcomes persist across both geographic areas and socio-economic groups in the US. Some gaps in healthcare service and outcomes may be bridged by extending access to more medicines without the need for a prescription. However, the range of candidate medicines available for switching to OTC status historically has been limited by the ability of patients to interpret product labeling and make appropriate self-selection decisions. Recent regulatory changes allowing companies to leverage new technologies and innovate new ways to aid the patient self-selection process may pave the way to better access to needed medications. While retail pharmacies bridge some of these gaps, non-traditional retail sources for medicines, such as dollar stores, may also play an important role because they are often located where healthcare access challenges are greatest. Broadening the range of treatments available via the OTC pathway is therefore likely to have a beneficial impact in areas otherwise experiencing health care access challenges, particularly if non-traditional outlets are included in the retail mix.

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1. Introduction

Inadequate access to healthcare is a significant public health concern. According to the Health Resources and Services Administration (HRSA), 76 million Americans (one in five) live in a primary care Health Professional Shortage Area (HPSA).[1] Some of these shortage areas have earned the nickname "medical deserts" in academic studies;[2] in the US, they are particularly concentrated in rural areas and the South. HRSA forecasts indicate the shortage situation is unlikely to improve in the foreseeable future.

Difficulties booking office visits, long wait times, inadequate insurance coverage, and travel can be obstacles to obtaining needed prescription medications. Innovations in remote physician access, such as telehealth visits, may address some, but not all, of these issues. On the insurance side of the equation, the trend toward high deductible health plans has placed a greater financial burden on patients by increasing out-of-pocket costs for prescription medications—particularly within low-income households.[3] Higher patient burdens lead to lower prescription medication utilization and worse medical outcomes.[4] These combined trends can make it harder for many Americans to access needed medications via the traditional prescription pathway.

The broad availability of OTC medications at retail locations beyond pharmacies can be crucial—especially in areas that are pharmacy deserts, where the local dollar store could be the only store around.[5] Recent regulatory changes have opened the door to innovation in how companies aid patient self-selection decisions.

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[1] "Health Workforce Shortage Areas," *Health Resources & Services Administration*, *US Department of Health & Human Services*, accessed 10 January 2025, available at https://data.hrsa.gov/topics/health-workforce/shortage-areas. ("Health Workforce Shortage Areas").

[2] Brînzac, Monica, et al., "Defining Medical Deserts—An International Consensus-Building Exercise," *European Journal of Public Health*, Vol. 33, No. 5, 2023, p. 785–788.

[3] Abdus, Salam, "Financial Burdens of Out-of-Pocket Prescription Drug Expenditures Under High-Deductible Health Plans," *Journal of General Internal Medicine,* Vol. 36, No. 9, 2020, p. 2903–05.

[4] Shrank, William, et al., "The Epidemiology of Prescriptions Abandoned at the Pharmacy," *Annals of Internal Medicine*, Vol 153, No. 10, 2010, p. 633–640.

[5] "Featuring a wide variety of dollar general OTC products, we make it easy and affordable to maintain your health without a prescription." See "Medicine Cabinet," *Dollar General*, accessed 14 February 2025, available at https://www.dollargeneral.com/c/health/medicine-cabinet.

That innovation will likely further benefit patients by making a broader range of therapies available via this pathway.

I begin this paper by reviewing the trends and geography of healthcare access in the US. The most important trend in healthcare delivery is that the growth in demand for healthcare services through population growth and aging will outpace the growth in supply of physicians. But access issues are also geographical in nature. I show access issues are particularly concentrated in rural areas and in the South. A review of statistics on insurance coverage, savings rates, and rising costs of prescription medication demonstrates financial access may be a significant barrier to adequate healthcare in lower-income groups. My analysis also links HPSA data aggregated to the county level with data on pharmacy and dollar store locations. I demonstrate that in counties with higher rates of health professional shortages for primary care, per-capita pharmacy access is in general not any worse than in counties with better overall healthcare access. Though this statistic does not account for the greater driving distances typical of rural areas, it does indicate retail locations can have a role in alleviating access issues. Because OTC medicines can be obtained in any retail setting, I also link the HPSA data to the locations of a dollar store chain that sells OTC products. I find areas with a high fraction of the population in HPSAs have nearly five times higher per-capita access to that chain's stores than areas with a low fraction of the population in HPSAs. This indicates, via greater OTC access, retail chains (like dollar stores) that cater to rural and lower-income populations may be ideally situated to address some of the healthcare gaps in HPSAs.

These findings suggest broadening the range of medicines that can be obtained without a prescription at retail locations may be particularly helpful for populations located in areas of primary care shortage.

2. Healthcare Access

2.1. Health Professional Shortages

In areas where health professionals are in short supply, access to a variety of healthcare services can be adversely affected, including the prescribing of necessary medications. HPSAs can be designated for either primary, dental, or mental health professionals and are based on the following criteria:

- Geographic: "A shortage of providers for an entire group of people within a defined geographic area."
- Population: "A shortage of providers for a specific group of people within a defined geographic area."
- Facility: Certain medical facilities may be automatically designated as shortage areas, and others may be designated based on a shortage of providers.[6]

State Primary Care Offices are responsible for submitting applications for the designation of an HPSA. HPSA applications may include data such as clinical practice activity, provider practice locations, and demographic data. States have an incentive to provide these data and apply for HPSA designations because a variety of federal programs, such as the National Health Service Corps (NHSC), rely on these designations to distribute resources. The HRSA is ultimately charged with evaluating and approving or rejecting the applications.[7] The overall process of HPSA evaluation and designation has been going through a modernization over the last 10 or so years.[8]

As noted in the introduction, the HRSA reports 76 million Americans live in a HPSA for primary care, with more than 13,000 additional practitioners needed to resolve these shortages.[9] However, health access issues in the US are not limited to primary care. HRSA also reports 60 million Americans reside in HPSAs for dental health, and more than 10,000 practitioners would be needed to resolve those shortfalls.[10] Similarly, HRSA reports 122 million people reside in HPSAs for mental health, and over 6,000 additional practitioners would be needed resolve those shortfalls.[11]

These shortages appear unlikely to improve. As depicted in

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[6] "What Is Shortage Designation?" *Health Resources & Services Administration, US Department of Health & Human Services*, June 2023, accessed 25 June 2024, available at https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation#hpsas.

[7] "Reviewing Shortage Designation Applications," *Health Resources & Services Administration, US Department of Health & Human Services*, August 2022, accessed 25 June 2024, available at https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation/reviewing-applications.

[8] "Understanding the Shortage Designation Modernization Project," *Health Resources & Services Administration, US Department of Health & Human Services*, August 2022, accessed 25 June 2024, available at https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation/modernization-project.

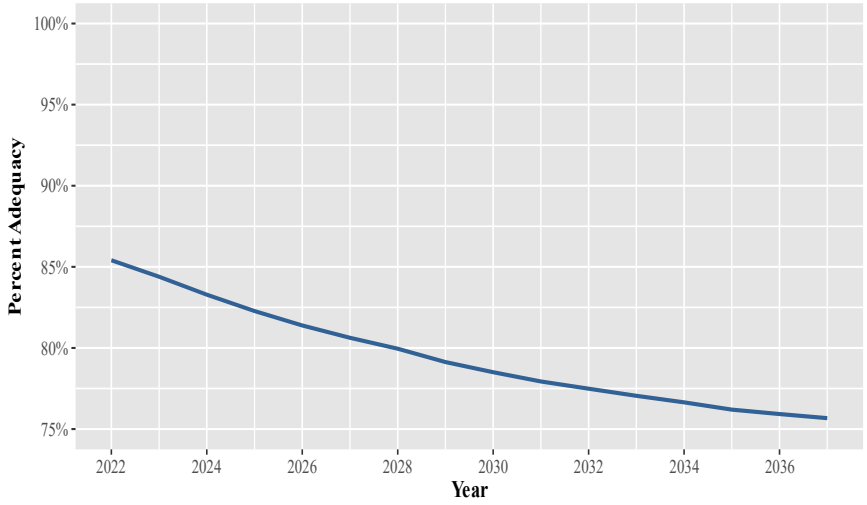
[9] "Health Workforce Shortage Areas."

[10] Id.

[11] Id.

Figure 1, the national average supply of primary care physicians relative to demand was approximately 85% in 2022 and is projected to fall through 2037.

Figure 1: HRSA Total US Primary Care Percent Adequacy, 2022–2037



Source: "Workforce Projections (Workforce_Projections_FullData.xlsx)," *Health Resources and Services Administration, US Department of Health and Human Services*, November 2024, accessed 8 January 2025, available at https://data.hrsa.gov/data/download.

2.2. Demand for and Supply of Physicians

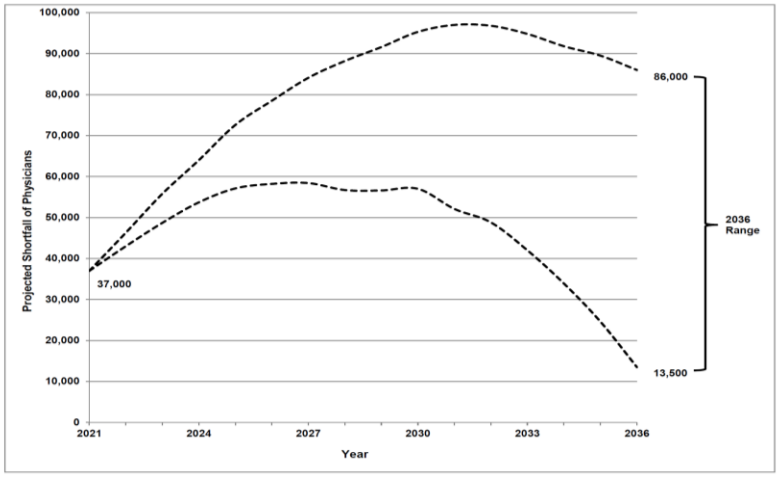
Shortages in any market are generally the result of an excess in demand relative to available supply. Here, physician shortages refer to an excess of demand for healthcare services relative to the available supply of physicians. Among the consequences of a shortfall in physicians is a potential shortfall in available prescribers. A 2024 report published by the Association of American Medical Colleges (AAMC) states: "We continue to project physician demand will grow faster than supply under most of the scenarios modeled...."[12] Largely corroborating the HRSA forecasts, the AAMC projects a worsening of physician shortages through 2030. The AAMC, however, projects possible

[12] "The Complexities of Physician Supply and Demand: Projections From 2021 to 2036," *Association of American Medical Colleges*, March 2024, accessed 25 June 2024, p. 55, available at https://www.aamc.org/media/75236/download?attachment. (AAMC Report).

improvements after 2030 (as shown in **Figure 2**). In particular, this report projects that by 2036 there will be:

- A shortage of between 20,200 and 40,400 primary care physicians;[13]
- A shortage across non-primary care specialties of up to 46,200 physicians;[14] and
- A total shortfall between 13,500 and 86,000 physicians.[15]

Figure 2: Total Projected Physician Shortfall Range, 2021–2036[16]



Demand growth is a key contributor to expected shortages, driven primarily by the growth and overall aging of the US population. The AAMC report projects a population growth of 8.4% between 2021 and 2036. In this same time period, the 65-and-older population is projected to increase by 34.1%, and the 75-and-older population is expected to increase by 54.7%. The older the population, the more medical care required, increasing physician demand.[17]

Several factors contribute to projected physician supply shortfalls in the US. One of these is supply bottlenecks in graduate medical

[13] Ibid.

[14] Id, p. 3–4, Exhibits 6, 8, 10, and 12. The projected shortage of non-primary care specialties comprises the sum of shortages for medical specialist physicians, surgeons, primary-care-trained hospitalists, and other specialist physicians.

[15] Id, p. 55.

[16] Id, Exhibit ES-1.

[17] Id, p. 32–34.

education (GME) positions.[18] Each year, over 4,000 doctors graduate from medical school but are unable to obtain GME positions to become licensed physicians.[19] Most of these medical residencies are funded by the federal government. In 2018, 86% of medical residencies were funded by Medicare, Medicaid, and the VA; 2% were funded by hospitals and philanthropists; and the remainder of funding came from state matching of Medicaid funds.[20] As of 2020, Medicare funded approximately $10 billion of the $15 billion total funding for GMEs. However, Medicare's ability to fund GME positions is limited; the 1997 Balanced Budget Act set a cap on the number of GME positions that can receive direct funding from the Centers for Medicare and Medicaid Services.[21] While the Consolidated Appropriations Act of 2021 allows for 1,000 additional GME positions above this cap (phased in over several years), this is not sufficient to give all doctors graduating from medical school GME positions.[22] Indeed, *The New York Times* reports there are as many as 10,000 doctors who have graduated from medical school and consistently apply to GME programs but are rejected and, as a result, are unable to become practicing physicians, despite demand for their labor.[23]

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[18] A GME position is required for all graduates to become physicians.

[19] Ahmed, Harris and J. Carmody, "On the Looming Physician Shortage and Strategic Expansion of Graduate Medical Education," *Cureus*, Vol. 12, No. 7, 2020.

[20] See, e.g., Martinez, Ramon, "State-Supported Physician Residency Programs," *MOST Policy Initiative*, accessed 15 November 2024, available at https://mostpolicyinitiative.org/science-note/state-supported-physician-residency-programs/. Medicare has been funding graduate medical education since the 1960s, but this funding was initially intended to be temporary. Medicare funding covers direct expenses (e.g., salaries and admin costs) and indirect expenses (additional costs of patient care that come from having a GME program). Direct funding is determined based on a set formula with three variables: (1) weighted resident count, (2) a per-resident dollar amount specific to the hospital, and (3) proportion of the hospitals inpatient days that were from Medicare patients. Indirect funding is mostly given on a per-Medicare patient discharge basis (see, e.g., "GME Financing," *Graduate Medical Education that Meets the Nation's Health Needs*, ed. Jill Eden, Donald Berwick, and Gail Wilensky, *National Academies Press*, 2014.).

[21] Ahmed, Harris and J. Carmody, 2020.

[22] "Frequently Asked Questions on Section 126 of the Consolidated Appropriations Act (CAA), 2021," *Centers for Medicare & Medicaid Services*, accessed 9 July 2024, available at https://www.cms.gov/files/document/frequently-asked-questions-section-126.pdf.

[23] Goldberg, Emma, "*'I Am Worth It:'* Why Thousands of Doctors in America Can't Get a Job," *The New York Times*, 19 February 2021, updated 20 July 2021, accessed 9 July 2024, available at https://www.nytimes.com/2021/02/19/health/medical-school-residency-doctors.html.

Notably, the AAMC's shortage projections assume investments in GME continue to grow as the Consolidated Appropriations Act of 2021 funds an additional 200 GME positions each year between 2023 and 2027. In addition, states and hospitals have recently begun funding additional GME positions. The AAMC report notes that if GME investments do not continue to grow, then "the projected shortfalls would be much more severe" and would "closely resembl[e] those presented in the 2021 report, which projected a shortfall of up to 124,000 physicians by 2034."[24]

Another factor negatively affecting the supply of physicians is the rate at which physicians exit the profession. The overall aging of the population has supply-side impacts as well, with it being "very likely that more than a third of currently active physicians will retire within the next decade."[25] Another source of physician exit is burnout, which has been estimated at more than 50% over the past 20 years.[26] A substantial and persistent problem in the physician workforce, burnout is more common among younger physicians and high-performing physicians. Younger physicians experiencing burnout may leave the healthcare workforce altogether, opting for alternative careers with lower stress levels. The effects of this are longer-lasting than early retirement—the healthcare workforce loses many years of potential service from these young workers, as opposed to the loss of just a few years from older workers retiring. Moreover, as high-performing employees leave, the overall quality of care deteriorates.[27] Among physicians experiencing burnout who continue practicing, overall medical care worsens, and the risk of medical errors increases.[28]

Common reasons for burnout include too much bureaucracy, large amounts of time spent using electronic systems, and long working hours.[29] Unsurprisingly, the COVID-19 pandemic exacerbated issues related to burnout. A 2022 paper compared results of a survey given to physicians in 2020 and 2021 and found several metrics of burnout had increased substantially. In particular, mean

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[24] Specifically, the difference between projections with no growth and 1% annual growth (beyond the growth resulting from the Consolidated Appropriations Act of 2021) is a supply of 41,000 physicians by 2036. See AAMC Report, p. vi, 3.

[25] Id, p. viii.

[26] Bhardwaj, Anish, "COVID-19 Pandemic and Physician Burnout: Ramifications for Healthcare Workforce in the United States," *Journal of Healthcare Leadership*, Vol. 14, 2022, p. 91–97.

[27] Ibid.

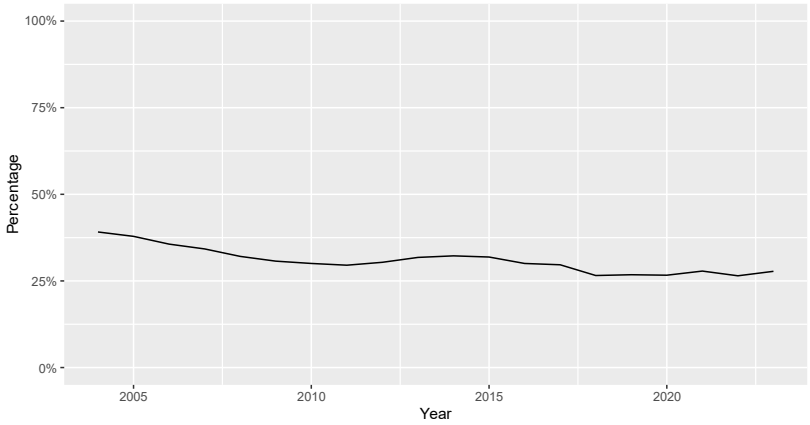
[28] Yates, Scott, "Physician Stress and Burnout," *The American Journal of Medicine*, Vol. 133, No. 2, 2020, p. 160–164.

[29] Ibid.

emotional exhaustion scores increased by 38.6%; mean depersonalization scores increased by 60.7%; and, while only 38.2% of physicians had one or more manifestations of burnout in 2020, 62.8% did in 2021.[30]

Shortfalls in the supply of primary care physicians also fit into a long-developing shift from physicians practicing primary care to focusing on specialties, largely beginning after World War II. As of 2023, only 28% of practicing physicians in the US were in general internal medicine, family medicine, or pediatrics. This is much lower than the proportion of general practitioners in other western nations.[31] Indeed, data from the Bureau of Labor Statistics show that even in the past two decades, the proportion of physicians and surgeons that are generalists has declined substantially, from almost 40% in 2004 to less than 28% in 2023. See **Figure 3**.

Figure 3: Proportion of Physicians and Surgeons That Are General Physicians, 2004–2023



Note: I define general physicians as comprising the following occupations: family and general practitioners, family medicine physicians, general internal medicine physicians, general internists, and general pediatricians.

Source: "Occupational Employment and Wage Statistics Tables" 2004–2023 National Data, *US Bureau of Labor*

[30] Shanafelt, Tait, et al., "Changes in Burnout and Satisfaction with Work-Life Integration in Physicians During the First 2 Years of the COVID-19 Pandemic," *Mayo Clinical Proceedings,* Vol. 97, No. 12, 2022, p. 2248–2258.

[31] Dalen, James, et al., "Where Have the Generalists Gone? They Became Specialists, then Subspecialists," *The American Journal of Medicine*, Vol. 130, No. 7, 2017, p. 766–768.

Statistics, accessed 31 July 2024, available at https://www.bls.gov/oes/tables.htm.

This shift from general care to specialization is often theorized to be due to the higher salaries specialization offers—especially amid the increasingly large amounts of debt doctors take out in medical school. This shift may also represent a belief that specialties offer preferable lifestyles.[32] It should be noted, however, that while the share of physicians pursuing careers in primary care has declined, the number of primary care physicians per capita has remained relatively stable.[33] This, however, does not address the aging of the US population and the growing healthcare demand stemming from that trend.

2.3. Are Nurse Practitioners and Telehealth a Solution?

Nure practitioners (NPs) may be thought of as a solution to physician shortages. If the ability to get an appointment with an NP is not constrained as it is with physicians, then getting access to healthcare resources (including prescription drugs) through NPs may be a solution. Indeed, the supply of advance practice registered nurses (APRNs) and physician associates (PAs) has grown substantially in recent years, and the professions are expected to grow by 40% and 28%, respectively, in the next decade. Since APRNs and PAs may be able to provide care (including prescribing medication) that would otherwise require physicians, they may be able to satisfy some of the excess demand for physician services.[34]

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[32] Dalen, et al., 2017.

[33] "Occupational Employment and Wage Statistics Tables" 2004–2023 National Data, *US Bureau of Labor Statistics*, accessed 31 July 2024, available at https://www.bls.gov/oes/tables.htm; "Annual Estimates of the Resident Population for the United States, Regions, States, District of Columbia and Puerto Rico: April 1, 2020 to July 1, 2024 (NST-EST2024-POP)," *US Census Bureau, Population Division*, December 2024, accessed 28 January 2025, available at https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-total.html; "Annual Estimates of the Resident Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2019 (NST-EST2019-01)," *US Census Bureau, Population Division*, December 2019, accessed 11 February 2025; and "Intercensal Estimates of the Resident Population by Sex and Age for the United States: April 1, 2000 to July 1, 2010 (US-EST00INT-01)," *US Census Bureau, Population Division*, September 2011, accessed 11 February 2025, available at https://www.census.gov/data/tables/time-series/demo/popest/intercensal-2000-2010-national.html.

[34] AAMC Report, p. 35–36.

The treatment authority of NPs is not, however, equivalent to physicians, and they are not perfectly substitutable as prescribers. State laws for NPs can be categorized as full practice, reduced practice, or restricted practice. The American Association of Nurse Practitioners defines these categories as:

- Full Practice: "State practice and licensure laws permit all NPs to evaluate patients; diagnose, order and interpret diagnostic tests; and initiate and manage treatments, including prescribing medications and controlled substances, under the exclusive licensure authority of the state board of nursing. This is the model recommended by the National Academy of Medicine, formerly called the Institute of Medicine, and the National Council of State Boards of Nursing."
- Reduced Practice: "State practice and licensure laws reduce the ability of NPs to engage in at least one element of NP practice. State law requires a career-long regulated collaborative agreement with another health provider in order for the NP to provide patient care, or it limits the setting of one or more elements of NP practice."
- Restricted Practice: "State practice and licensure laws restrict the ability of NPs to engage in at least one element of NP practice. State law requires career-long supervision, delegation or team management by another health provider in order for the NP to provide patient care."[35]

As of October 2024, 27 states and Washington, DC, are full practice; 12 are reduced practice; and 11 are restricted practice.[36] Even beyond the limitations in reduced and restricted practice states, there are a number of barriers preventing NPs from prescribing, and generally practicing, to the same extent a physician can.[37] States have recently been acting to expand NPs'

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[35] "State Practice Environment," *American Association of Nurse Practitioners*, October 2024, accessed 11 February 2025, available at https://www.aanp.org/advocacy/state/state-practice-environment.

[36] Id.

[37] Many states have transitioned to practice periods in which newly graduated NPs must practice under the supervision of an experienced physician or NP. Federal regulations and institutional and organizational rules also limit NPs' ability to practice. For example, NPs may lack privileges in a hospital setting, and physician co-signature may be required for prescriptions. Many of these barriers differ across, and even within, geographies. When required, collaborative practice agreements may be expensive to maintain and present financial barriers to NPs' ability to care for patients. See, e.g., Kleinpell, Ruth, et

ability to practice independently, with several states expanding NP scope of practice, including their ability to independently prescribe certain medications.[38]

Similarly, although telehealth has expanded significantly since the COVID-19 pandemic, it is not a universal solution for physician shortages. These services rely heavily on another resource that is also often difficult to access in HPSAs: high speed digital communications. For example, a recent study published by Sidecar Health found that 34 million people live in locations considered primary care deserts that also have poor access to the broadband necessary for reliable telehealth visits.[39]

While these trends are likely to ease access issues in states that have delegated broader prescribing power to NPs and expanded digital networks in rural areas, even universal adoption of these measures may not overcome the challenges of geography.

3. The Geographic and Economic Dimensions of Health Outcomes and Access

3.1. The Geography of Outcomes

It has long been known health outcomes are not identical across the US. Important geographic concentrations exist not only in specific disease categories but in overall mortality rates, even after

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al., "Addressing Barriers to APRN Practice: Policy and Regulatory Implications During COVID-19," *Journal of Nursing Regulation,* Vol. 14, No. 1, 2023, p. 13–20.

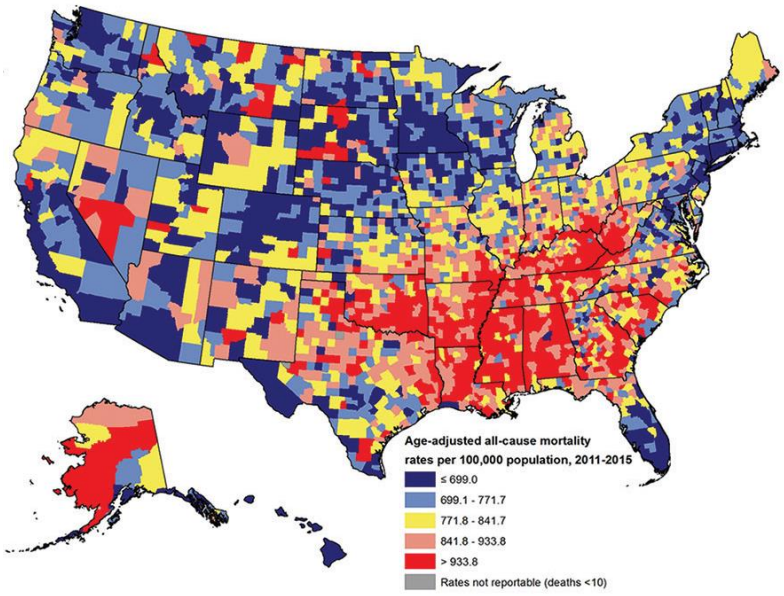
[38] See, e.g., Diaz-Camacho, Vicky, "Kansas Joins 25 Other States by Expanding Access to Nurse Practitioners," *Flatland*, 19 April 2022, accessed 14 February 2025, available at https://flatlandkc.org/news-issues/kansas-joins-25-other-states-by-expanding-access-to-nurse-practitioners/; Gero, Justin, "Delaware Becomes the Latest Full Practice Authority State, *National Nurse-Led Care Consortium*, 5 August 2021, accessed 14 February 2025, available at https://nurseledcare.phmc.org/advocacy/policy-blog/item/1100-delaware-becomes-the-latest-full-practice-authority-state.html; "State of New York Grants Full and Direct Access to Nurse Practitioners," *American Association of Nurse Practitioners*, 11 April 2022, accessed 14 February 2025, available at https://www.aanp.org/news-feed/state-of-new-york-grants-full-and-direct-access-to-nurse-practitioners; and "Utah Becomes 27th State with Full Practice Authority," *National Nurse-Led Care Consortium*, 20 March 2023, accessed 14 February 2025, available at https://nurseledcare.phmc.org/advocacy/policy-blog/item/1412:utah-becomes-27th-state-with-full-practice-authority.html.

[39] Caldwell, Nicole, "State-by-State Breakdown of the More than 34 Million Living in Primary Care Deserts with Limited Telehealth Access," *Sidecar Health*, 2 February 2022, accessed 17 October 2024, available at https://sidecarhealth.com/blog/state-by-state-breakdown-of-the-more-than-34-million-living-in-primary-care-deserts-with-limited-telehealth-access/.

accounting for differences in the average age of the local population.

In a 2017 research paper, the authors mapped age-adjusted all-cause mortality rates by county during the 2011–2015 time period.[40] In reviewing this map, included as **Figure 4**, a clear pattern emerges. While counties in large parts of the Northeast, Upper Midwest, and West experienced all-cause mortality equal to or below 699 per 100,000 population (dark blue), a large fraction of counties in the South and parts of the Southeast, Oklahoma, and Nevada experienced all-cause mortality at least 33% higher (red).

Figure 4: Age-Adjusted Mortality Rates by County, 2011–2015[41]



This pattern is repeated for cardiovascular disease (CVD) mortality, as shown in **Figure 5**. In fact, CVD mortality in the counties depicted in red is at least 47% higher than in counties depicted in dark blue. Mortality across other conditions is also correlated with geographic region. For example, mortality rates from cancer are higher in the Eastern US, and mortality rates from diabetes are higher in the Southeast, Southwest, and Appalachia.[42]

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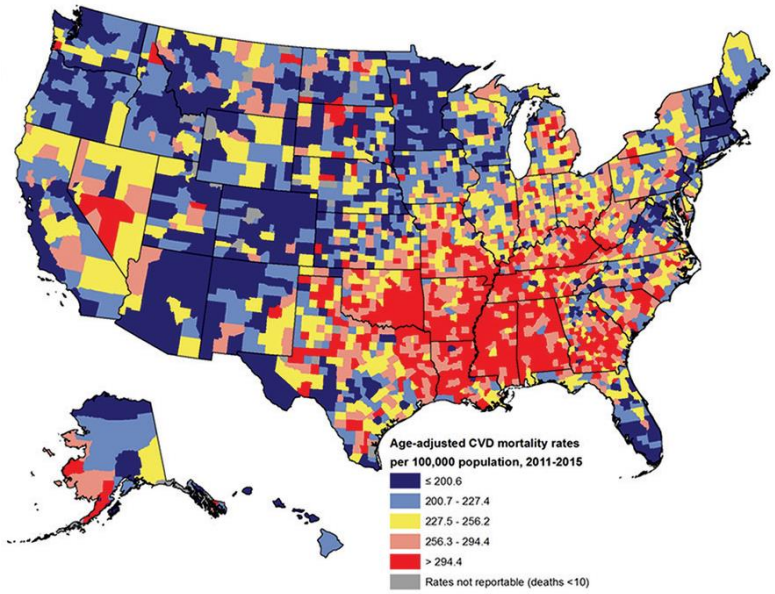
[40] Singh, Gopal, et al., "Social Determinants of Health in the United States: Addressing Major Health Inequality Trends for the Nation, 1935-2016," *International Journal of MCH and AIDS*, Vol. 6, No. 2, 2017, p. 139–164, Figure 14. (Singh, et al., 2017).

[41] Id, Figure 14.

[42] Id, p. 149–151, Figures 16, 18.

Overall, the study finds the prevalence of chronic conditions is higher in rural areas. For example, people in non-metropolitan areas have a 42% higher relative risk of heart disease and a 16% higher relative risk of diabetes compared to people in large metropolitan areas.[43]

Figure 5: Age-Adjusted Cardiovascular Mortality Rates by County, 2011–2015[44]



Disparities in health outcomes are also correlated with socio-economic status. The relative risk for chronic conditions, such as heart disease and diabetes, is significantly higher for people with lower educational attainment, lower income, and lower employment status. People with a family income of less than $35,000 are more than twice as likely to have diabetes than people in families with incomes over $100,000. They are also 49% more likely to have heart disease. Someone with less than a high school education is more than twice as likely to have diabetes as someone with a college degree or higher.[45]

Disparities in health outcomes and access to healthcare also exist across racial and ethnic groups. For example, the Centers for Disease Control (CDC) reports racial and ethnic minorities have higher rates of illness and mortality for diabetes, hypertension,

[43] Id, Table 2.

[44] Id, Figure 15.

[45] Id, Table 2.

obesity, and other diseases.[46] As another example, the recent COVID-19 pandemic disproportionately affected Black, Hispanic, and native populations and caused a more substantial decrease in life expectancy for these groups compared to the white population.[47]

A recent report by the Commonwealth Fund found "substantial health and healthcare disparities exist between white and Black, Hispanic, and American Indian and Alaska Native (AIAN) communities in nearly all states."[48] Racial and ethnic disparities in healthcare and health outcomes have several drivers, including a disproportionate lack of high-quality healthcare in many minority communities, discrimination, and a variety of historical federal and state policies.[49]

These patterns suggest geography alone may not explain differences in outcomes. Socio-economic patterns (that may align with certain geographies) are important as well.

3.2. The Geography of Physician Access

The shortage of healthcare professionals is a nationwide issue, but it is far from uniformly distributed. In fact, counties that have a higher percentage of their population residing in HRSA-defined shortage area geographies tend to have poorer health outcomes, such as higher all-cause mortality. This suggests a treatment gap exists in these areas. It also highlights the need for alternative treatment pathways. OTC drugs that do not require access to traditional patient care sites can be one of those pathways because they leverage the resources available in (often rural) places where traditional medical treatment facilities and practitioners may be absent.

In **Figure 6**, I color code the proportion of each county's population that resides in a HPSA for primary care, based on data

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[46] "Racism and Health," *Centers for Disease Control*, 20 June 2024, accessed 15 November 2024, available at https://www.cdc.gov/minority-health/racism-health/?CDC_AAref_Val=https://www.cdc.gov/minorityhealth/racism-disparities/index.html.

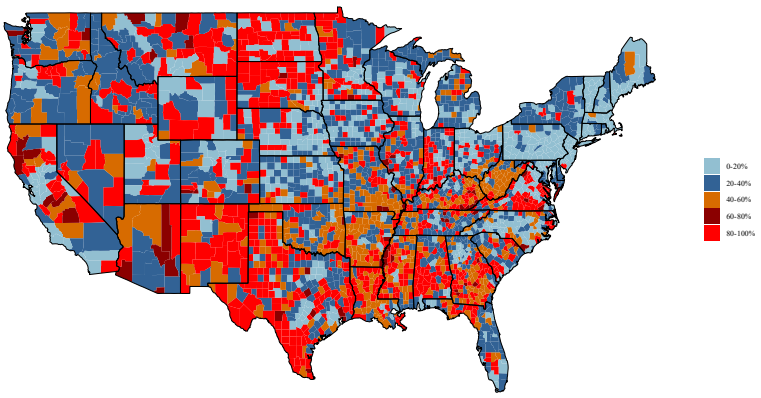
[47] "Advancing Racial Equity in U.S. Health Care," *The Commonwealth Fund*, 18 April 2024, accessed 3 June 2024, available at https://www.commonwealthfund.org/publications/fund-reports/2024/apr/advancing-racial-equity-us-health-care. ("Advancing Racial Equity," 2024).

[48] Id.

[49] Id.

obtained from HRSA.[50] The areas with access challenges (e.g., counties with more than 60% of their populations living in an HPSA) are geographically clustered and track the aforementioned outcomes data relatively closely. Many counties in the Northeast appear to have a relatively low proportion of their population residing in shortage areas, while counties in the South, Southeast, and Appalachia have some of the highest proportions of their populations in HPSAs. In many instances, these HPSAs coincide with counties with the highest all-cause mortality statistics in **Figure 4**.

Figure 6: Proportion of Population in Primary Care HPSA by County



Notes: 1) The proportion of the population in a primary care HPSA is calculated by summing the HPSA population for each county and dividing it by the total population in each county. The HPSA population is the number of people served by an HPSA as of 9 January 2025 and is from HRSA. The total population is from the 2023 County Population Estimates. 2021 County Population Estimates data are used for Connecticut to align with other data sources, as Connecticut recently changed its county designations. 2023 County Population Estimates data include new Connecticut county designations that do not align with old county designations. 2021 County Population Estimates data include old Connecticut county designations, which are used in HPSA data.

[50] HRSA's HPSA Primary Care data are updated daily. The information provided in this chart was downloaded on 9 January 2025.

2) In cases in which an HPSA designation crosses county lines, the HPSA population is distributed evenly across those counties.

3) I exclude HPSAs with a status of "Withdrawn." This is in line with HRSA's methodology. See, "Health Workforce Shortage Areas."

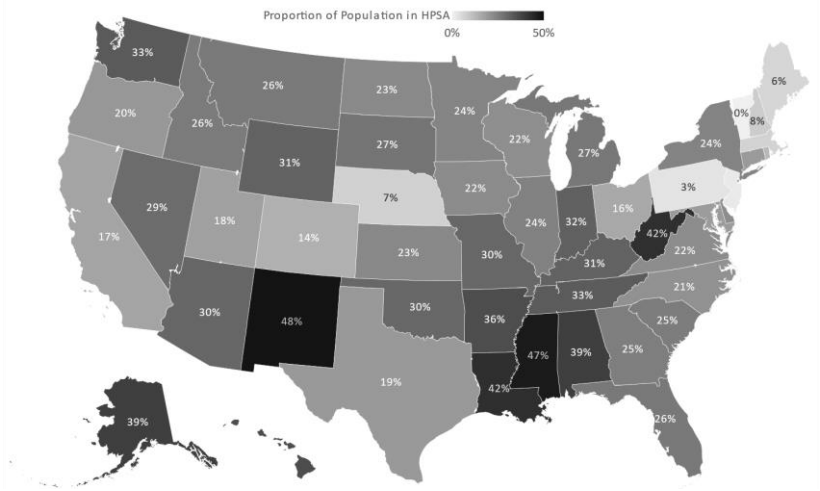
4) I exclude the following HPSA facilities that are automatically designated as HPSAs: federally qualified health center; federally qualified health center look-alike; Indian health service, Tribal health, and urban Indian health organizations; rural health clinic; and other Facility. This is in line with HRSA's methodology. See "What Is Shortage Designation," 2023 and "Designated Health Professional Shortage Areas Statistics: First Quarter of Fiscal Year 2025 Designated HPSA Quarterly Summary," *Bureau of Health Workforce, Health Resources and Services Administration (HRSA), US Department of Health & Human Services*, 31 December 2024, accessed 9 January 2025, p. 14, available at https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport.

Sources: "All HPSAs - CSV," *Health Resources and Services Administration, US Department of Health & Human Services*, accessed 9 January 2025, available at https://data.hrsa.gov/data/download?data=SHORT#SHORT; "7/1/2023 County Population Estimates (co-est2023-alldata.csv)," *United States Census Bureau*, March 2024, accessed 21 January 2025, available at https://www.census.gov/data/tables/time-series/demo/popest/2020s-counties-total.html; and "7/1/2021 County Population Estimates (co-est2021-alldata.csv)," *United States Census Bureau*, March 2022, accessed 21 January 2025, available at https://www2.census.gov/programs-surveys/popest/datasets/2020-2021/counties/totals/.

Aggregating these data on a state level, shown in **Figure 7**, highlights the broad disparities. For example, while almost half of New Mexico's population lives in a shortage area, almost none of

Vermont's population does.[51] There can also be substantial differences between states near each other. For example, only 7% of Nebraska's population is in an HPSA, but it is surrounded by states with two to three times the proportion of population in HPSAs. Although some variation in access may be explained by an urban versus rural split, there also are contradictions to this story. For example, 26% of Floridians reside in HPSAs compared to only 6% of Maine residents, even though Florida has almost 10 times the population density of Maine.[52] The connection between HPSAs and outcomes is also not always direct. For example, even though most counties in New Mexico have more than 80% of their populations located in HPSAs, CVD mortality in many of those counties is relatively low.

Figure 7: Proportion of Population in Primary Care HPSA by State



Notes: 1) The proportion of the population in a primary care HPSA is calculated by summing the HPSA population for each state and dividing it by the total population in each state. The HPSA population is the number of people served by an HPSA as of 9 January 2025 and is from HRSA. The total population is from the Census Bureau as of 1 July 2024.

[51] Vermont does have some population in shortage areas, but the percentage is close to zero.

[52] See "Population Density by State—Residents per Square Mile," *Datapandas*, accessed 18 October 2024, available at https://www.datapandas.org/ranking/population-density-by-state.

2) I exclude HPSAs with a status of "Withdrawn." This is in line with HRSA's methodology. See, "Health Workforce Shortage Areas."

3) I exclude the following HPSA facilities that are automatically designated as HPSAs: federally qualified health center; federally qualified health center look-alike; Indian health service, Tribal health, and urban Indian health organizations; rural health clinic; and other facility. This is in line with HRSA's methodology. See Note 4 to **Figure 6**.

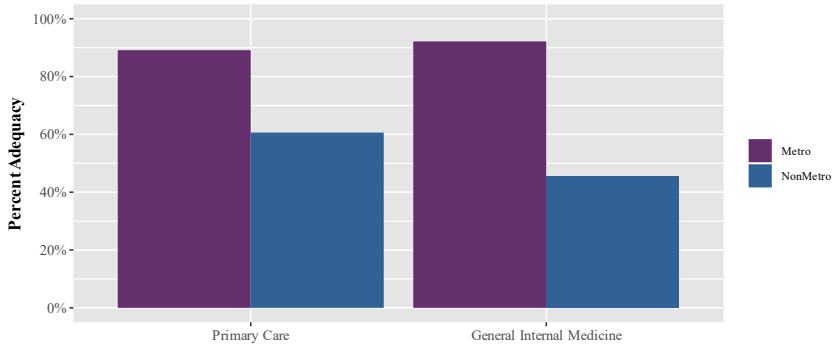
Sources: "All HPSAs - CSV" and "Annual Estimates of the Resident Population for the United States, Regions, States, District of Columbia and Puerto Rico: April 1, 2020 to July 1, 2024 (NST-EST2024-POP)," December 2024.

These figures demonstrate that, while geography is clearly important, no single determinant fully explains the geographical variation in health professional shortages.[53] This may be due to the unique and varied demographics, cultures, governments, and other systems that may not be strictly geographical in nature.

Nevertheless, a few broad geographical patterns emerge from the HPSA data. The first is that rural areas have a substantially lower physician supply adequacy rate (measured by supply of physicians within a geography divided by HRSA's estimated demand for physicians within that area). I examine these rates for primary care physicians overall and for general internal medicine physicians, which is a profession within the primary care category. In **Figure 8**, I compare metropolitan (metro) and nonmetropolitan (nonmetro) areas. While the adequacy rate for primary care physicians in metro areas is almost 90%, it is closer to 60% in nonmetro areas. The adequacy rate for general internal physicians in metro areas (over 92%) is similar to that of primary care physicians in metro areas. However, in nonmetro areas the adequacy rate for general internal physicians is well below 50%. That is, doubling the number of general internal medicine physicians in nonmetro areas would still not be sufficient to eliminate HRSA-identified shortages.

[53] Literature on the topic of physician shortages has identified variation within individual states and even within individual cities. See, e.g., Ahmed, Harris and J. Carmody, 2020.

Figure 8: US General Physicians Percent Adequacy by Rurality, 2022



Note: Primary care physicians comprise family medicine physicians, general internal medicine physicians, geriatrics physicians, and pediatrics physicians.

Source: "Workforce Projections (Workforce_Projections_FullData.xlsx)," 2024.

Health disparities between those living in rural and urban areas have been well-documented in literature. Those living in rural areas experience worse healthcare and health outcomes on average. A 2015 paper pinpointed several reasons for this, including:

- Cultural perceptions and stigmas on seeking healthcare;
- Difficulty with transportation to health facilities;
- Lack of available services in close proximity; and
- Lack of internet access, which is increasingly used to access health services.[54]

In addition, physicians are less likely to locate to rural areas. To a large extent, this can be explained by the tendency of physicians to practice where they received their medical education or completed their residency and that medical schools and residencies are generally in urban or suburban areas.[55] Likewise, the economics of setting up a general practice in a rural geography with a geographically dispersed population of potential patients is

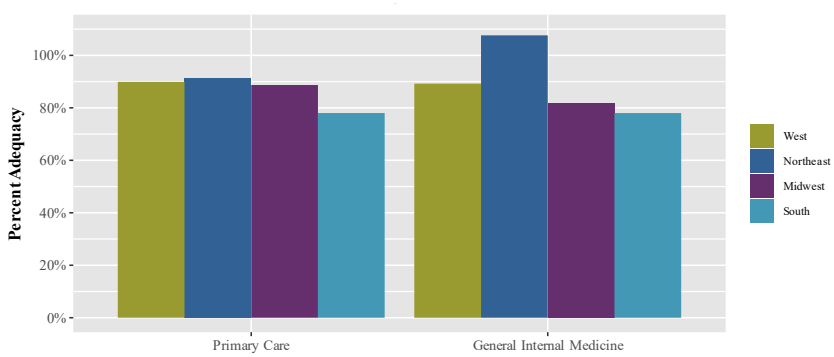
[54] Douthit, N., et al., "Exposing Some Important Barriers to Health Care Access in the Rural USA," *Public Health*, Vol. 129, No. 6, 2015, p. 611–620.

[55] Nielsen, M., et al., "Addressing Rural Health Challenges Head On," *Missouri Medicine*, Vol. 114, No. 5, 2017, p. 363–366.

unlikely to be as attractive as practicing in an urban location. The consequence, however, is disproportionate physician shortages in rural areas, as seen in **Figure 8**.

Broad regional shortage trends also emerge in primary care categories, as shown in **Figure 9**. In the Northeast and West, the primary care adequacy rate is at least 90%. In the South, it is below 80%. The disparities are even greater for general internal medicine, where the adequacy rate is over 100% in the Northeast and 78% in the South.

Figure 9: Primary Care and General Internal Medicine Physicians: Percent Adequacy by Region, 2022

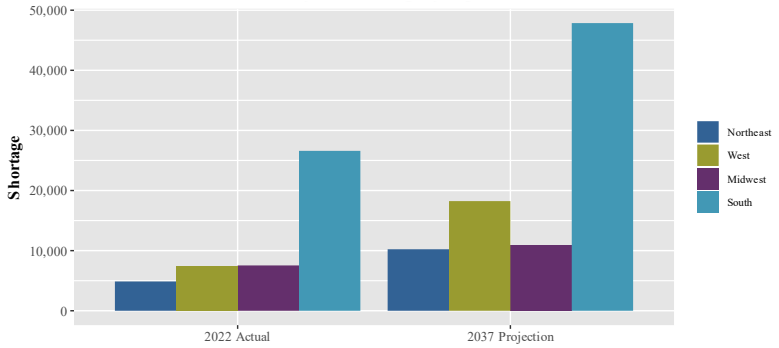


Note: Primary care physicians comprise family medicine physicians, general internal medicine physicians, geriatrics physicians, and pediatrics physicians.

Source: "Workforce Projections (Workforce_Projections_FullData.xlsx)," 2024.

The scale of the shortfall in the South becomes evident when expressed in terms of the number of physicians needed to make up the shortfalls. **Figure 10** reveals HRSA estimated a shortfall of over 26,000 primary care physicians in the South in 2022. That is roughly five times more than the estimated shortfall in the Northeast region during the same period. HRSA has predicted the shortfall in the South will grow to nearly 48,000 physicians by 2037.

Figure 10: Primary Care Physicians: HRSA Estimated Shortage by Region



Source: "Workforce Projections (Workforce_Projections_FullData.xlsx)," 2024.

3.3. Other Access Considerations

There are other access issues facing patients in the US. For example, a 2021 study using National Health Interview Survey (NHIS) data noted disparities in access to healthcare across racial and ethnic groups. Compared to the white population, Black and Hispanic populations have higher rates of being uninsured, and the Hispanic population has a higher rate of people without a usual source of care.[56] In addition, the CDC has acknowledged that "people from some racial and ethnic minority groups…are more likely to face multiple barriers to accessing healthcare."[57]

Lower-income individuals also face hurdles to access. In **Figure 11**, I compare the proportion of the population that had to delay care due to cost across income levels based on NHIS data. The clear message in these data is that low-income individuals reported delaying care at a rate three to four times greater than high-income individuals. This pattern is robust over a 20-year period despite substantial changes in healthcare coverage, such as those introduced by the Affordable Care Act.

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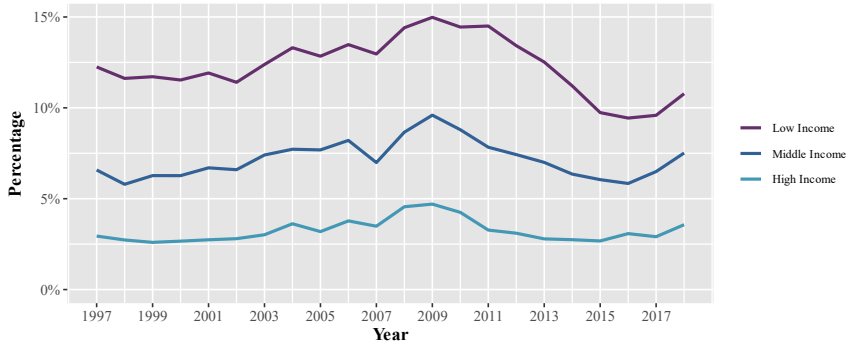
[56] Mahajan, Shiwani, et al., "Trends in Differences in Health Status and Health Care Access and Affordability by Race and Ethnicity in the United States, 1999–2018," *JAMA*, Vol. 326, No. 7, 2021, p. 637–648.

[57] "What Is Health Equity?," *Centers for Disease Control*, 1 July 2022, accessed 8 July 2024, available at https://www.cdc.gov/healthequity/whatis/index.html.

Figure 11: Proportion of Population That Delayed Care Due to Cost by Income, 1997–2018



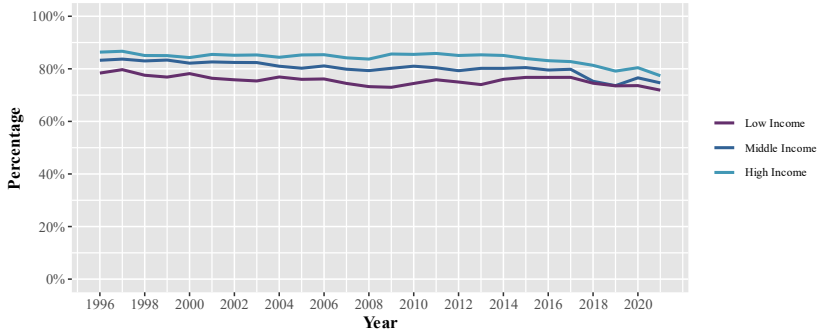
Note: Low, middle, and high income are defined as 0–200%, 200–500%, and over 500% of the poverty line, respectively.

Source: Lynn A. Blewett, Julia A. Rivera Drew, Miriam L. King, Kari C.W. Williams, Daniel Backman, Annie Chen, and Stephanie Richards, "IPUMS Health Surveys: National Health Interview Survey, Version 7.4 [dataset]," *IPUMS*, 2024, available at https://doi.org/10.18128/D070.V7.4.

Turning to Medical Expenditure Panel Survey (MEPS) data, I find a consistent difference over time in access to a "usual place" for medical care between high-income and low-income individuals (**Figure 12**).[58] As of 2021, over one-quarter of low-income individuals did not have a usual place for medical care. Importantly, the proportion of people with a usual place for medical care has decreased over time at all income levels.

[58] Blewett, et al., 2024.

Figure 12: Proportion of Population with a Usual Place for Medical Care by Income, 1996–2021



Note: Low, middle, and high income are defined as 0–200%, 200–500%, and over 500% of the poverty line, respectively.

Source: Blewett, et al., 2024.

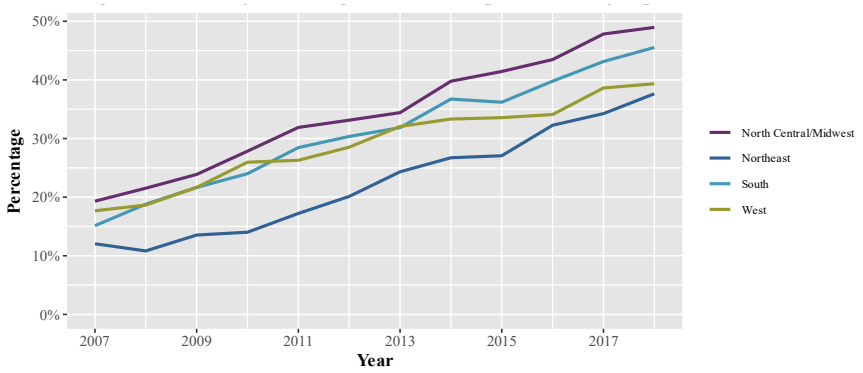
The pattern of access by income level may be related to insurance coverage. In particular, high deductible health plans (HDHPs) are becoming increasingly prevalent. As **Figure 13** indicates, the percentage of privately insured patients covered under HDHPs has risen steadily across all regions. There is also regional disparity in the adoption of HDHPs. For example, HDHP enrollment in the South rose from roughly 15% to over 45% in the 10 years from 2007 to 2017. In the Midwest, it rose from under 20% to nearly 50% during the same period. Patients in the West and Northeast were less likely to be covered under HDHPs but followed a similar trend.

HDHPs are often viewed as a method to counter increasing healthcare costs by incentivizing patient cost-saving behavior.[59] The theory behind these plans is rooted in the idea that, if patients are shielded from the incremental costs of the healthcare they consume, they will over-use the resources, which in turn will drive prices up. Increasing patient out-of-pocket costs during an extended deductible window is intended to make consumers more price sensitive, preferring to seek less frequent and less expensive treatments.

[59] Wooldridge, Scott, "HDHP Enrollment Reaches More than 50% of American Private-Sector Workers," *BenefitsPRO*, 20 February 2023, accessed 22 May 2024, available at https://www.benefitspro.com/2023/02/20/hdhp-enrollment-reaches-more-than-50-of-american-private-sector-workers/?slreturn=20240522151603.

This theory appears to hold in practice. A recent mental health study indicated the impact of HDHPs on service utilization is significant: Primary care visits drop by 5–6%, mental health office visits drop by up to 18%, inpatient hospital admissions drop by up to 19%, and prescription drug fills drop by up to 4%.[60] But, while these plans appear to successfully reduce costs and consumption, not all of this is necessarily positive for patients. A separate study also found HDHPs reduce the overall use of health services and, as a result, reduce healthcare costs. While this study documented reductions in services characterized as "inappropriate," such as seeking emergency care for non-emergency needs, it also documented reductions in preventative care and other medical services characterized as "appropriate."[61]

Figure 13: Proportion of Privately Insured Population with HDHPs by Region, 2007–2018



Source: Blewett, et al., 2024.

There are potential income disparities in how HDHPs affect patient decisions. More than 30% of the low-income population is covered under HDHPs.[62] According to the Bureau of Labor Statistics (BLS), the median HDHP deductible for private industry workers

[60] Fronstin, Paul, and Christopher Roebuck, "How Do High-Deductible Health Plans Affect Use of Health Care Services and Spending Among Enrollees with Mental Health Disorders?," *Employee Benefit Research Institute,* Issue Brief, No. 555, 10 March 2022, Figure 10.

[61] Agarwal, Rajender, et al., "High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Needed Preventative Services," *Health Affairs*, Vol. 36, No. 10, 2017, p. 1762–1768.

[62] Blewett, et al., 2024.

in the US was $2,500 in 2023.[63] Higher-income patients may have the ability to take advantage of pre-tax Health Savings Accounts (HSAs) and Flexible Spending Accounts (FSAs) to ease the burden of out-of-pocket costs. Workers with lower incomes may not have such access. According to the BLS, only 19% of workers in the lowest wage quartile had access to HSAs in 2023, compared to 57% in the highest wage quartile.[64]

In any case, access to the tax advantages of an HSA is likely moot for lower-income households. According to the Federal Reserve Board of Governors, median household savings in 2022 were just $900 for the bottom 20% of households by income. Even for households in the 20–40th percentile income category, median savings were $2,550.[65] Given that the median deductible limit for HDHPs is $2,500, these households have barely enough savings on hand should they need to meet this deductible limit. A medical event could quickly outstrip household savings and force hard decisions between seeking physician services and providing food and shelter.

A recent paper using NHIS data also found the Black population enrolled in HDHPs tended to have lower incomes than the white population enrolled in HDHPs. While the wealth of Black HDHP enrollees was not significantly different from the Black population not enrolled, the white population enrolled was on average wealthier than the white population not enrolled.[66] As the negative effects of HDHPs are more pronounced for lower income individuals due to the relative inability to self-insure, this could exacerbate existing racial disparities in health outcomes and access to healthcare.

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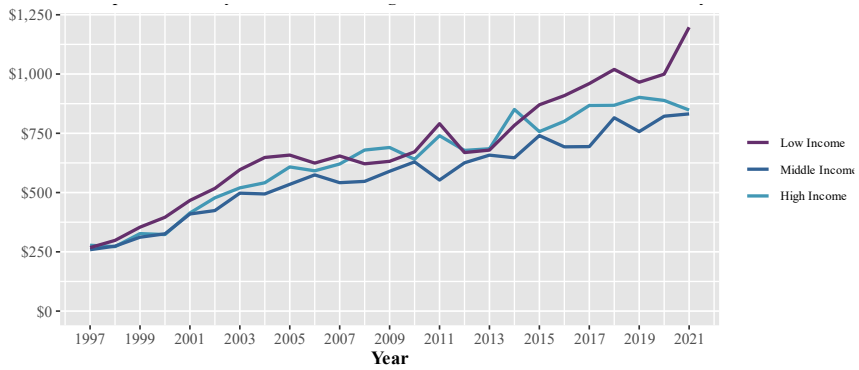
[63] "High Deductible Health Plans and Health Savings Accounts," *US Bureau of Labor Statistics*, 11 April 2024, accessed 9 November 2024, available at https://www.bls.gov/ebs/factsheets/high-deductible-health-plans-and-health-savings-accounts.htm. ("BLS HDHP Statistics," 2024).

[64] Id.

[65] Meanwhile, households in the top two income deciles had median savings of $33,800 and $111,600, respectively. I measure savings here as the amount held in transaction accounts, since that is likely to represent liquid funds that are available for medical expenses. This is as opposed to, for example, money held in retirement accounts, which is not easily accessible. See "Survey of Consumer Finances (SCF)," *Board of Governors of the Federal Reserve System*, 2 November 2023, accessed 9 November 2024, available at https://www.federalreserve.gov/econres/scf/dataviz/scf/table/#series:Transaction_Accounts;demographic:inccat;population:all;units:median.

[66] Zewde, Naomi, "Racial Wealth Inequality and Access to Care with High-Deductible Health Insurance," *AEA Papers and Proceedings*, Vol. 114, 2024, p. 180–185.

Figure 14: Per Capita Total Direct Payments Made During the Year for Prescribed Medications by Income, 1997–2021



Note: Low, middle, and high income are defined as 0–200%, 200–500%, and over 500% of the poverty line, respectively.

Source: Blewett, et al., 2024.

Finally, it is important to recognize the costs borne by households for prescription medication have been rising in tandem with HDHP adoption. **Figure 14** (based on annual MEPS data) shows direct payments made for prescribed medication increased more than three-fold between 1997 and 2021.[67] Importantly, low-income individuals have seen faster growth in their prescription drug costs and now spend more per capita for these medications than higher income groups.

4. Over-the-Counter Medication as a Potential Solution

OTC medicines can be transformative for the millions of people living in areas with low access to traditional healthcare resources. In pharmacy deserts in particular, the broad availability of OTC medications at retail locations beyond pharmacies can be crucial. In those places, the local dollar store might be the only store around.[68] While the transition to OTC status has historically led to substantial consumer benefits, a common challenge to receiving FDA approval for a switch to OTC status has been demonstrating patients can properly self-select products based on package labeling alone. Recent regulatory changes have opened the door to

[67] Figure 14 includes all costs made directly for prescription medication, which includes costs that are not made directly by the patient (e.g., payments made by insurance).

[68] See "Medicine Cabinet," 2024.

innovation in how companies can aid patients in making self-selection decisions. These changes will likely further benefit US consumers (particularly those in healthcare deserts) by enhancing access to a broader range of treatments.

4.1. OTC Benefits and Considerations

Currently, many medications cannot be dispensed in an OTC setting. Those that have made the switch are available to patients as and when needed without requiring input from a prescriber (who may be scarce in many parts of the country). Typically, a prescription drug may switch to OTC status, referred to as a Prescription-to-Nonprescription switch (Rx-to-OTC switch), through the FDA's New Drug Application (NDA) process.[69] Since 1976, over 100 ingredients, indications, or dosage strengths have undergone the Rx-to-OTC switch, including commonly used products such as ibuprofen.[70] Previous research has documented the success of Rx-to-OTC switches. One study found the introduction of the first OTC drug in a class increased drug overall class-level utilization by an average of 30%.[71] Another study found that between 2009 and 2016, a period during which four ingredients used to treat allergies underwent an Rx-to-OTC switch, more people with allergies used OTC medication and fewer used prescription medication. In addition, fewer people with allergies visited a healthcare professional, saving patients the cost and time burden of doctor visits.[72]

Substantive literature has developed around evaluating the benefits and risks of OTC switches for specific drug classes. In the context

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[69] "Prescription-to-Nonprescription (Rx-to-OTC) Switches," *US Food & Drug Administration*, 28 June 2022, accessed 18 June 2024, available at https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches.

[70] "FAQs About Rx-to-OTC Switch," *Consumer Healthcare Products Association (CHPA)*, accessed 26 June 2024, available at https://www.chpa.org/about-consumer-healthcare/faqs/faqs-about-rx-otc-switch#:~:text=How%20many%20medicines%20available%20today,products%20on%20the%20market%20today and "Ingredients & Dosages Transferred from Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975," *Consumer Healthcare Products Association (CHPA)*, 23 August 2023, accessed 26 June 2024, p. 1–3, available at https://www.chpa.org/sites/default/files/media/docs/2023-08/switch%20list%20updated%20Aug%2023_2023.pdf.

[71] Stomberg, Christopher, Tomas Philipson, Margaret Albaugh, and Neeraj Sood, "Utilization Effects of Rx-OTC Switches and Implications for Future Switches," *Health*, 05, 10, 2013 p. 1667–80, available at https://doi.org/10.4236/health.2013.510225.

[72] "Assessing Consumer Benefits of Allergy Rx-to-OTC Switches," *Nielsen and Consumer Health Products Association (CHPA)*, 2017, p. 2–4.

of OTC second-generation non-sedating antihistamines, Brass (2004) articulated specific tradeoffs, for example, between greater treatment access and potential sub-optimal treatment choices made by patients without the aid of a physician.[73] The first OTC second-generation antihistamine product (Claritin) was approved by the FDA in 2002.[74] Several drugs in the statin class of cholesterol-lowering drugs were evaluated for switch to OTC status.[75] However, no drug in the statin class has been approved for OTC status. More recent examples include OPill, the first oral contraceptive approved for OTC access (approved July 2023), and Narcan, an over-the-counter preparation of naloxone for treating acute opioid overdose (approved March 2023).[76] Prior to OPill's launch, one study demonstrated access to an OTC oral contraceptive would substantially reduce the rate of unintended pregnancy relative to baseline contraception use in a study population. This was largely driven by women switching from less effective methods, including no birth control (35% of study participants).[77] The considerations driving Narcan OTC approval

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[73] Brass, Eric P., "Implications of a Switch from Prescription to Over-the-Counter Status for Allergy Drugs," *Current Allergy and Asthma Reports*, 4, 3, p. 245–50, available at https://doi.org/10.1007/s11882-004-0033-1.

[74] "Prescription to Nonprescription Switch List," *Food and Drug Administration*, accessed 20 September 2024, available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/prescription-nonprescription-switch-list.

[75] Brass, Eric P., "Consumer Behavior in the Setting of Over-the-Counter Statin Availability: Lessons from the Consumer Use Study of OTC Mevacor," *The American Journal of Cardiology* 94, 9, p. 22–29, available at https://doi.org/10.1016/j.amjcard.2004.07.051 (CUSTOM); Brass, Eric P., et al., "Can Consumers Self-Select for Appropriate Use of an Over-the-Counter Statin? The Self Evaluation of Lovastatin to Enhance Cholesterol Treatment Study," *The American Journal of Cardiology*, 101, 10, 2008, p 1448–55, available at https://doi.org/10.1016/j.amjcard.2008.01.020 (SELECT); Brass, Eric P., Shannon E. Allen, and Jeffrey M. Melin, "Potential Impact on Cardiovascular Public Health of Over-the-Counter Statin Availability," *The American Journal of Cardiology*, 97, 6, 2006, p. 851–56, available at https://doi.org/10.1016/j.amjcard.2005.10.022; and Stomberg, Christopher, Margaret Albaugh, Saul Shiffman, and Neeraj Sood, "A Cost-Effectiveness Analysis of Over-the-Counter Statins," *The American Journal of Managed Care*, 22, 5, 2016, e175–184.

[76] "FDA Approves First Nonprescription Daily Oral Contraceptive," accessed 20 March 2025, available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive,; "FDA Approves First Over-the-Counter Naloxone Nasal Spray," accessed 20 March 2025, available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spraym; and "Prescription to Nonprescription Switch List," 2024.

[77] See, e.g., Guillard, Hélène, Irene Laurora, Stephanie Sober, Artin Karapet, Eric P Brass, and Anna Glasier, "Modeling the Potential Benefit of an Over-the-Counter Progestin-Only Pill in Preventing Unintended Pregnancies in the U.S." *Contraception*,

related largely to access to this rescue medication for opioid overdose. While a complex patchwork of state and local laws had the intended effect of enhancing access to prescription-only naloxone, it also caused confusion among providers that limited uptake.[78] A pre-OTC switch study predicted that converting naloxone to OTC status would likely lead to a substantial increase in sales.[79] This indeed happened: A survey of pharmacies in North Carolina found same-day naloxone availability increased from 42% prior to the OTC switch to 58% within six to nine months post OTC switch.[80]

These examples point to some of the consumer benefits of OTC switch. However, one of the key hurdles in the FDA approval process for OTC products is the demonstration that patients would be able to achieve a satisfactory level of treatment self-selection based on product labeling. To this end, the FDA requires label comprehension studies to demonstrate patients in a realistic retail setting can appropriately select treatment.[81] For some therapeutic classes, such as statins, it has proven difficult for companies to generate label comprehension results that met the FDA's criteria for OTC switch.[82] For example, a second label comprehension trial (SELECT) was run to test improvements on labeling used in the first OTC lovastatin label comprehension study (CUSTOM). While these changes improved trial outcomes, lovastatin was nevertheless not approved for OTC switch. Subsequent research has demonstrated the time and effort patients devote to understanding OTC product labeling may be driven by auxiliary influences such

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117, January 2023, p. 7–12, available at https://doi.org/10.1016/j.contraception.2022.10.006.

[78] Evoy, Kirk E., Lucas G. Hill, and Corey S. Davis, "Considering the Potential Benefits of Over-the-Counter Naloxone." *Integrated Pharmacy Research and Practice*, Volume 10, February 2021, p. 13–21, available at https://doi.org/10.2147/IPRP.S244709.

[79] Murphy, Sean M., Jake R. Morgan, Philip J. Jeng, and Bruce R. Schackman, "Will Converting Naloxone to Over-the-Counter Status Increase Pharmacy Sales?" *Health Services Research*, 54, 4, 2019, p. 764–72, available at https://doi.org/10.1111/1475-6773.13125.

[80] Marley, Grace T., Izabela E. Annis, Kathleen L. Egan, Paul Delamater, and Delesha M. Carpenter, "Naloxone Availability and Cost After Transition to an Over-the-Counter Product," *JAMA Health Forum*, 5, 7, 2024, e241920, available at https://doi.org/10.1001/jamahealthforum.2024.1920.

[81] "Guidance for Industry: Label Comprehension Studies for Nonprescription Drug Products," *US Food and Drug Administration*, August 2010, accessed 13 February 2025, available at https://www.fda.gov/media/75626/download?attachment.

[82] See, e.g., Pray, Stephen, and Gabriel Pray, "New Statin Risks and the Battle for OTC Status," *US Pharmacist*, Vol. 40, No. 2, 2015, p. 12–15.

as consumer characteristics (e.g., need for cognition) and package information besides the Drug Facts label (e.g., brand name).[83]

These hurdles suggest innovating the OTC pathway to provide tools to aid consumer decision making beyond the product label could broaden the range of available medication and further reduce hurdles for patients to access treatment. The FDA recognized this possibility in issuing a rule allowing for what it calls a "Nonprescription Drug Product with an Additional Condition for Nonprescription Use" (ACNU).[84] In issuing this new rule, the FDA stated: "FDA recognizes the potential benefit of providing consumers with access to additional types of nonprescription drug products, such as some drug products that are currently available only by prescription."[85] From a healthcare system perspective, opening an innovative pathway like this could improve outcomes for millions of patients who do not currently have good healthcare access via traditional pathways.

Much of the benefit of OTC products can be framed as cost savings. Demonstrating this can require more than simply reviewing sticker prices. In addition to the out-of-pocket cost of a prescription drug, there is also the cost of the physician visit required to obtain a prescription. Time costs are also a substantial part of the equation. For each treatment event, time is required for identifying in-network physicians, booking appointments, traveling to and from appointments, waiting in the office, traveling to the pharmacy, navigating insurance coverage afterwards, and any number of other time-consuming activities. Moreover, the inflexibility of physician schedules and pharmacy hours can cause lost work time (which can be costly) and delays in starting treatment. Even at price parity compared to a prescription drug, an OTC equivalent can be considerably cheaper because it avoids most of these hidden costs of prescription drugs. One estimate put clinical cost savings from the availability of OTC medication (such as the time costs) at $94.8 billion annually. Annual potential

[83] Catlin, Jesse R., Cornelia Pechmann, and Eric P. Brass, "The Influence of Need for Cognition and Principal Display Panel Factors on Over-the-Counter Drug Facts Label Comprehension," *Health Communication*, 27, 3, 2012, p. 264–72, available athttps://doi.org/10.1080/10410236.2011.578335.

[84] See FDA Final ACNU Rule, 26 December 2024, accessed 14 February 2025, available at https://www.federalregister.gov/documents/2024/12/26/2024-30261/nonprescription-drug-product-with-an-additional-condition-for-nonprescription-use.

[85] Id, p. 105290.

productivity gains, such as those from avoided appointments, are estimated at $34 billion.[86]

Beyond cost savings, OTC medications are also more available than prescription drugs because they are sold at various retail stores, as opposed to only at pharmacies.[87] Particularly in areas lacking good access to healthcare resources, being able to go to a local store to obtain appropriate treatment can be a significant benefit.

4.2. Retail as a Valuable Point of Contact in Underserved Areas

Doctors, particularly in rural areas, are expected to become even more scarce. OTC products can be especially important because they can be obtained even where pharmacies are scarce, for example from convenience stores, dollar stores, and online retailers. Patients in HPSAs are therefore likely to benefit disproportionately when there is a larger pool of medications available as OTC products.

Pharmacies are often one of the first places consumers turn for their non-prescription medications. As of 2019, there were over 60,000 pharmacies across the US.[88] In **Figure 15**, I plot pharmacy frequency by county based on data from a recent research paper.[89] One pattern that emerges from this analysis is that some areas with a relatively high per capita pharmacy concentration also have relatively high populations located in HPSAs. HPSAs that have a relatively high pharmacy density may particularly benefit from enhanced OTC access. For example, higher per-capita pharmacy densities appear in eastern Kentucky, West Virginia, counties along the southern portion of the Mississippi River, and an axis along the western edges of the Midwest. These areas contain many counties with over 40% of their populations in HPSAs. Likewise, areas in the northern Midwest and Northeast generally have a

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[86] "OTC Sales Statistics," *Consumer Health Products Association (CHPA)*, accessed 19 August 2024, available at https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics.

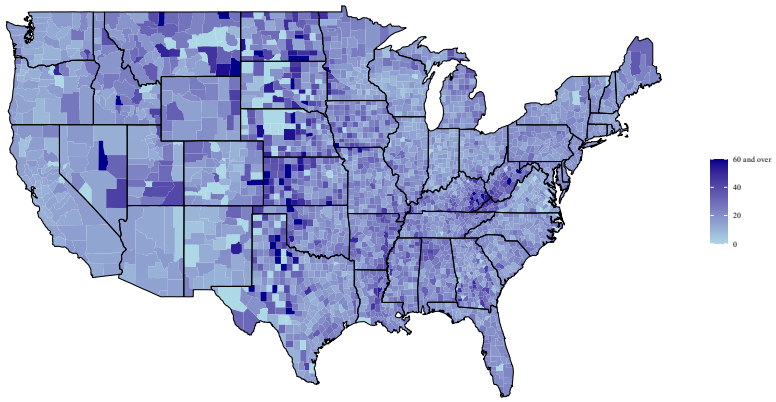
[87] Schneider, Heinz, et al., "White Paper on the Benefits of OTC Medicines in the United States," *Pharmacy Today*, October 2010, p. 68–79, at p. 68.

[88] "Understanding Differences Between the Number of Pharmacies Reported by NCPA and NCPDP," *Pharmaceutical Care Management Association*, September 2021, accessed 14 November 2024, p. 6, available at https://www.pcmanet.org/wp-content/uploads/2022/02/Understanding-Differences-Between-The-Number-of-Pharmacies-Reported-by-NCPA-and-NCPDP-2.pdf.

[89] Wittenauer, Rachel, et al., "Locations and Characteristics of Pharmacy Deserts in the United States: A Geospatial Study," *Health Affairs Scholar*, Vol. 2, No. 4, 2024.

lower fraction of their populations in HPSAs and also tend to have lower per-capita pharmacy densities compared to areas in the South and Appalachia.

Figure 15: Pharmacies per 100k Population by County



Source: "tractdata_dataframe.rds," in Wittenauer, et al. (2024), Supplementary Data, accessed 7 October 2024, available at https://github.com/rwitten1/Pharmacy-Deserts-Analysis.

Per-capita pharmacy figures do not fully reflect accessibility due to typically greater distances and lower overall population density in rural areas. The Wittenauer, et al. (2024) study took distances into account and estimated that 15.8 million people in the US live in pharmacy deserts, defined as low-income areas with low access to a pharmacy. Removing the low-income requirement, 34 million adults live in areas with low access to pharmacies. They also found pharmacy deserts are located in urban and rural areas more often than in suburban areas, and on average, people who are non-Hispanic Black, American Indian or Alaskan native, or Hispanic white are more likely to live in a pharmacy desert. These findings suggest retail pharmacies may not always provide a viable solution for reliably accessing OTC drugs.[90]

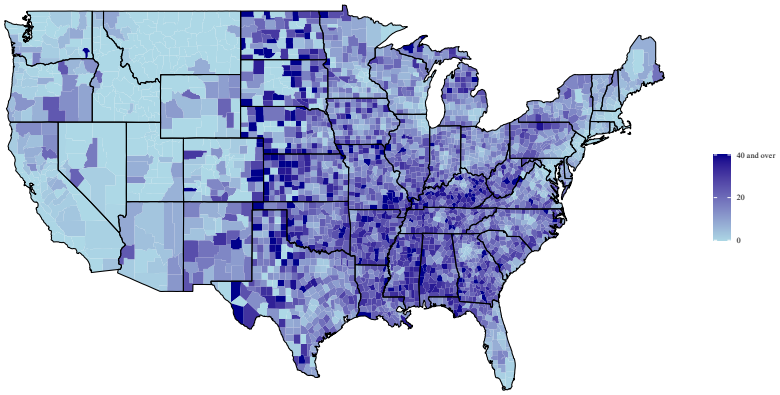
For this reason, I turn to another type of retail outlet commonly found in rural areas that also carries OTC products: dollar stores. It is possible to map dollar store locations using a dataset obtained from the Department of Agriculture's Supplemental Nutrition Assistance Program (SNAP), formerly referred to as food stamps. This dataset provides the location of retail stores that honor food

[90] Wittenauer, et al., 2024, p. 2.

support for customers receiving government subsidies. I focus on dollar stores because they are a prevalent form of retail that services SNAP recipients and promotes OTC medication offerings.[91] I obtained "Dollar General" store locations through the SNAP website and plotted their frequency by county across the United States (**Figure 16**).

This map illustrates the potential importance of these alternative types of retail locations for addressing healthcare access issues. Dollar General locates its stores predominantly in locations that are rural and in counties with large populations in HPSAs—much more so than retail pharmacies do. The local dollar store could, for many people in these pharmacy deserts, become part of the solution to some of the gaps in their healthcare access.

Figure 16: Dollar General Stores per 100k Population by County



Note: Population is from the 2023 County Population Estimates. 2021 County Population Estimates data are used for Connecticut to align with SNAP Retailer Location data, as Connecticut recently changed its county designations. 2023 County Population Estimates data include new Connecticut county designations that do not align with old county designations. 2021 County Population Estimates data include old Connecticut county designations, which are used in SNAP Retailer Location data.

Sources: "SNAP Retailer Location Data," *US Department of Agriculture, Food and Nutrition Service*, accessed 21 January 2025, available at https://usda-snap-retailers-usda-fns.hub.arcgis.com/datasets/8b260f9a10b0459aa441ad8588c2251c/explore?location=2.512396%2C-

[91] See "Medicine Cabinet," 2024.

14.737150%2C2.90; “7/1/2023 County Population Estimates (co-est2023-alldata.csv),” 2024; and “7/1/2021 County Population Estimates (co-est2021-alldata.csv),” 2022.

To demonstrate how important these retail locations can be, I arranged counties into five groups by the fraction of their population located in HPSAs (

Table 1). There are, for example, 805 counties with the lowest fraction (0–20%) of their populations in HPSAs. These counties are nevertheless populous and contain over 170 million residents overall. At the other end of the scale, there are 818 counties with the highest fraction (80–100%) of their populations in HPSAs. Despite there being more counties in this lowest healthcare access group, they contain less than one-tenth (17 million) of the country's population.

The figures in this table make clear the number of retail pharmacies per capita is roughly the same in counties with a high fraction of population in HPSAs (17.8) compared with counties with the best healthcare access (17.5). This corroborates the patterns visible in the county-by-county map. This does not account for the distances people may be required to travel to visit pharmacies in a low-population density area, which is why Wittenauer, et al. (2024) nevertheless labeled many of these areas as "pharmacy deserts."

Our analysis of Dollar General store locations tells a different story. These stores are disproportionately located in the counties that have the most profound exposure to health professional shortages. The per-capita number of Dollar General stores located in low-access counties (16.4) is almost five times the average in high-access counties (3.5). This suggests retail locations like dollar stores may be ideally situated to act as a conduit for OTC medications and other healthcare inputs that could address the needs of populations residing in HPSAs.

Table 1: Statistics for Retail Access by Proportion of Population in Primary Care HPSA

Proportion of Population in Primary Care HPSA	Counties	Population (Million)	Pharmacies per 100k Population	Dollar General Stores per 100k Population
0–20%	805	173.0	17.5	3.5
20–40%	930	113.4	18.6	7.0
40–60%	517	26.2	22.6	12.9
60–80%	73	5.5	21.2	6.5
80–100%	818	16.7	17.8	16.4

Notes: 1) Population is from the 2023 County Population Estimates. 2021 County Population Estimates data are used for Connecticut to align with other data sources, as Connecticut recently changed its county designations. 2023 County Population Estimates data include new Connecticut county designations that do not align with old county designations. 2021 County Population Estimates data include old Connecticut county designations, which are used in HPSA data, SNAP Retailer Location data, and Wittenauer, et al. (2024) supplementary data.

2) Pharmacies per 100k Population is calculated using the number of pharmacies and population by county from the Wittenauer, et al. (2024) supplementary data.

3) Dollar General Stores per 100k Population is calculated using the number of Dollar General stores from the SNAP Retailer Locator Data and population data from the 2023 and 2021 County Population Estimates. See Note 1.

Sources: "All HPSAs – CSV;" "7/1/2023 County Population Estimates (co-est2023-alldata.csv)," 2024; "7/1/2021 County Population Estimates (co-est2021-alldata.csv)," 2022; "tractdata_dataframe.rds," in Wittenauer, et al., 2024; and "SNAP Retailer Location Data," 2025.

5. Conclusion

This study focuses on the geographic and economic dimensions of healthcare access in the US. Notable disparities in healthcare

access remain across both geographic areas and socio-economic groups in the US. These findings suggest innovations that broaden the range of treatments that can be obtained without a prescription may be particularly helpful for those populations located in HPSAs or lacking the economic resources to utilize traditional medical services.