

MEYA HEALTH

Market Access 101

A GUIDE TO NAVIGATING THE BASICS

Last updated: January 21, 2026

Meya Health, LLC | www.meya.health

This white paper was developed by the Meya Health, LLC team:
Lalitha Priya Chandrashekhar, Michelle DiNicolas, Valerie Henson
Maria Truong, Jennifer Larsen, Jamie DelCane, Ronak Mistry, Katie Hayes

TABLE OF CONTENTS

03 United States (US) Market Access Overview

04 The Evolving Healthcare Landscape

08 US Market Access Stakeholders and Influencers

12 Drug Distribution in the United States

16 FDAMA 114: Engaging Formulary Decision Makers

19 Global Market Access Considerations

22 About Meya Health

23 Our 360° Approach to Access™

24 References

US MARKET ACCESS OVERVIEW

MARKET ACCESS OVERVIEW

Market access, defined as the ability of patients to obtain and benefit from advances in the medical field, is intrinsically linked to the broader goal of improving health outcomes and enhancing patient well-being.[1] It encompasses a complex connection of strategies, policies, and negotiations involving manufacturers, payers, providers, patients, and regulatory bodies. Recognizing the significance of effective market access is imperative for stakeholders across the healthcare spectrum, as it directly impacts the availability, affordability, and utilization of cutting-edge treatments.

Proactive market access strategizing can help manufacturers anticipate challenges related to patient access, pricing, and reimbursement.[2] Demonstrating the value of a treatment to market access stakeholders is crucial to effective communication. Manufacturers must demonstrate the benefits of a treatment in comparison to disease burden.[2] Strategically planning the communication of a pharmaceutical product's value can help companies in negotiations with market access stakeholders.[2] Appropriate reimbursement of a product allows patients to access the treatments they need at a fair price.

This white paper aims to illustrate the multifaceted dimensions of market access, revealing its pivotal role in ensuring that transformative medical breakthroughs reach those who stand to benefit most – the patients.

MARKET ACCESS CHALLENGES: FOCUSING ON PATIENT ACCESS

While manufacturers face several market access hurdles with regards to pricing and regulatory concerns, a patient's ability to access quality healthcare is an essential focus. Social Determinants of Health (SDoH) are pivotal in shaping market access, as they heavily influence health outcomes.[3] SDoH includes patients' neighborhoods, workplaces, and systematic policies that impact day-to-day life.[4] Patients without health insurance, for example, will have barriers to accessing quality care, impacting their overall health. In rural areas with limited access to physicians and healthcare facilities, also known as "healthcare deserts," patients' geographic location directly impacts their health - from identifying symptoms to diagnosing conditions, treatment options, and procedures.[5] It is well established that certain racial and ethnic minority groups have higher rates of illness and death in the US from a series of health conditions when compared to their White counterparts.[6] Poor outcomes within distant populations can result in a higher cost burden to payers. To improve population health, many payers have rolled out specific programs to support health equity initiatives. Availability, affordability, and awareness of treatment can significantly impact the success of a product.[7] Patient centricity in market access conversations and strategy can improve the ability of the individual to obtain high-quality care.[7]

From a population health perspective, poor outcomes can result in a higher cost burden to payers.

THE EVOLVING HEALTHCARE LANDSCAPE

US HEALTHCARE SYSTEM OVERVIEW

The US healthcare system is comprised of a fragmented system of private and public coverage. Approximately 66% of citizens are covered by private health insurance plans while 35% are covered by public health insurance.[8] The main forms of public healthcare coverage are Medicare, Medicaid, CHIP (Children's Health Insurance Program), and military based programs. These federal insurance programs account for over $1 trillion in federal spending.[9] Insurance in the US involves monthly premiums, deductibles, and copayments for care. The US has the highest healthcare spending of any developed nation and tracks behind in healthcare outcomes like maternal mortality and life expectancy at birth.[10] This fragmented system of private and public coverage makes market access for drugs and devices extremely complex.



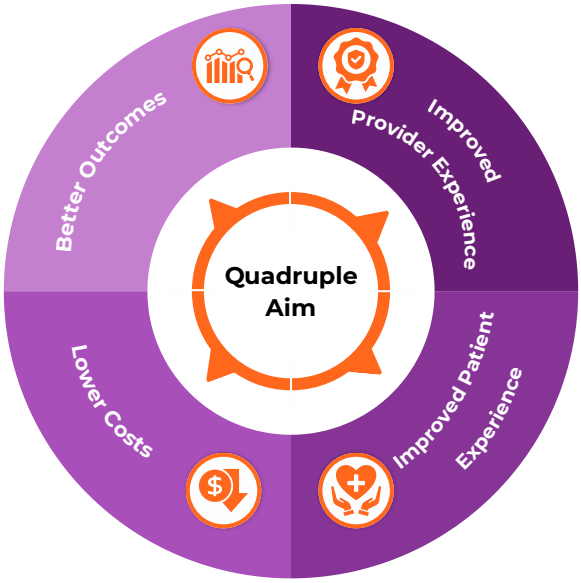
SHIFTING THE VOLUME TO VALUE

The US healthcare system has been consistently trending toward value-based care and away from traditional fee-for-service compensation. This paradigm shift began with the passing of the Affordable Care Act (ACA) in 2010, a response to historically high health care costs.[11,12] The traditional method of compensation provides financial incentives for the quantity of services provided, with no specific attention to the quality of the service or the outcomes. In 2015, the US Department of Health and Human Services (HHS) set a goal for 90% of traditional Medicare payments to be tied to quality or value.[12] Under value-based care, healthcare providers are incentivized to focus on preventive measures, coordinated care, and patient engagement, ultimately aiming to improve health outcomes, while simultaneously reducing costs.[13] This approach not only aligns with the broader goal of achieving better population health, but also fosters a more patient-centric approach to healthcare delivery.[14]

Under value-based care, healthcare providers are incentivized to focus on preventive measures, coordinated care, and patient engagement, ultimately aiming to improve health outcomes, while simultaneously reducing costs.[13]

THE QUADRUPLE AIM

The shift towards value-based care from the traditional focus on clinical outcomes and cost containment has given way to a more holistic approach encapsulated by the Quadruple Aim. This framework expands upon the already established Triple Aim, which is focused on enhancing patient experience, improving population health, and reducing costs, by adding a fourth crucial dimension, the well-being of healthcare providers.[15]



The Quadruple Aim recognizes that the health and satisfaction of those delivering care are linked to the overall quality of care provided. By prioritizing the work-life balance and professional satisfaction of healthcare professionals, the Quadruple Aim sets a higher standard for healthcare excellence.

QUALITY PERFORMANCE MEASURES

The US Agency for Healthcare Research and Quality (AHRQ) identifies three specific types of quality performance measures in healthcare.

These include structural, process, and outcomes measures.[16]

- **Structural Measures:** Highlight efficient processes in provider care, for example, provider to patient ratios
- **Process Measures:** Capture provider services that may improve health, such as the number of people receiving immunizations
- **Outcome Measures:** Quantify the effects of certain medical interventions. Examples include surgical mortality rates, hospital-acquired infection rates, and readmission rates.[16]

QUALITY ORGANIZATIONS THAT ESTABLISH STANDARDS AND METRICS

Several key organizations play pivotal roles in setting and upholding rigorous healthcare standards for health plans, hospitals and HCPs. The National Committee for Quality Assurance (NCQA), the Centers for Medicare & Medicaid Services (CMS), the National Quality Forum (NQF), and the Agency for Healthcare Research and Quality (AHRQ) are instrumental entities in this endeavor.

NCQA: The NCQA stands at the forefront of accrediting and certifying healthcare organizations, health plans, and other healthcare entities. With an emphasis on performance measurement and accountability, the NCQA develops and implements rigorous evaluation criteria.[17] These standards encompass clinical quality, patient experience, and health plan operations, fostering a culture of continuous improvement. This accreditation process enhances transparency, establishes trust among stakeholders, and ultimately leads to improved healthcare outcomes and patient satisfaction.[18,19]

CMS: CMS is largest payer for healthcare services in the United States. Through initiatives like the Hospital Value-Based Purchasing Program (VBP) and the Quality Payment Program (QPP), CMS incentivizes healthcare providers to deliver high-quality, efficient care.

CMS National Quality Strategy Goals



NQF: The NQF is a nonprofit organization with the goal of building healthcare stakeholder consensus for quality measures.[20] These measures span diverse clinical areas, enabling standardized assessments of healthcare performance. The NQF's endorsement process ensures that measures are evidence-based, reliable, and relevant.

AHRQ: The AHRQ is a Department of Health and Human Services agency committed to advancing research and evidence-based practices to enhance the safety and quality of healthcare.[16] Through initiatives like the National Quality Strategy and the Healthcare Effectiveness Data and Information Set (HEDIS), the AHRQ provides critical tools and resources for measuring and improving healthcare quality.[21,22]

CMS VALUE-BASED PROGRAMS

CMS oversees several value-based programs that aim to improve healthcare quality.

These programs include:[18]

- End-Stage Renal Disease Inventive Program
- Hospital Value-Based Purchasing (VPB) Program
- Hospital Readmission Reduction Program (HRRP)
- Value Modifier (VM) Program
- Hospital Acquired Conditions (HAC) Program
- Quality Payment Program (QPP)

The Medicare Shared Savings Program (MSSP) allows providers and suppliers, such as physicians and hospitals, to create an Accountable Care Organization (ACO).[23] An ACO agrees to be held accountable for the quality, cost and experience of care of an assigned Medicare fee-for-service (FFS) beneficiary population.[23] When ACOs enrolled in MSSP provide efficient, coordinated, and high-quality care to patients, they may be eligible to share in the savings they achieve for the Medicare program and the resulting savings can be distributed among the ACO members.

The MSSP allows the CMS payment system to shift from volume to value and outcomes, by providing an alternative payment model that:[23]

- Promotes accountability for a patient population
- Coordinates items and services for Medicare FFS beneficiaries
- Encourages investment in high quality and efficient services

As discussed previously, a focus on quality performance measures places large emphasis on patient experience. This carries through with value-based programs, as patient experience scores account for 25% the hospital Value-Based Purchasing (VBP) total performance scores.[24]

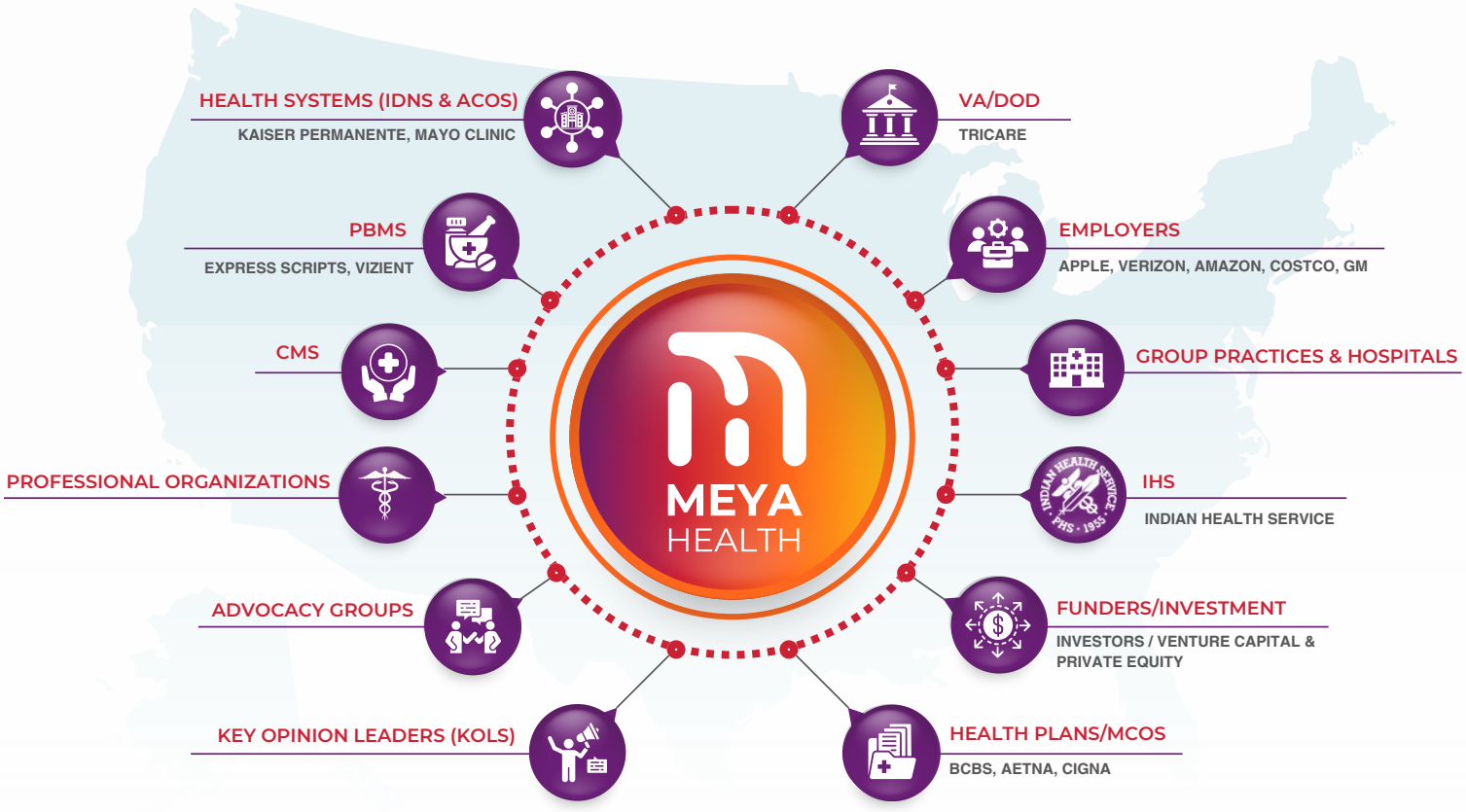


US MARKET ACCESS STAKEHOLDERS AND INFLUENCERS

OVERVIEW

As discussed in the previous section, market access involves interactions between manufacturers, payers, providers, patients, and regulators. Given the complexity of the US healthcare system, there are various stakeholders that collectively shape the accessibility, pricing, and reimbursement of medical products and services. Each stakeholder plays a unique role in shaping market dynamics, and understanding their perspectives is pivotal for successful product adoption, reimbursement, and ultimately, patient access to innovative therapies and treatments.[25]

Each stakeholder plays a unique role in shaping market dynamics, and understanding their perspectives is pivotal for successful product adoption, reimbursement, and ultimately, patient access to innovative therapies and treatments.[25]



COMMERCIAL AND PRIVATE PAYORS

Commercial healthcare payers, primarily for-profit entities, offer insurance coverage in exchange for premiums from individuals, employers, or other groups. They compete in the open market and include major organizations like Aetna, UnitedHealthcare, and Anthem. Serving 66% of citizens, they provide coverage for individuals, families, and through employer-sponsored plans.[8] Commercial payers offer a range of plans with varying coverage levels and cost-sharing options, wielding influence over healthcare delivery and pricing through provider contracts and coverage decisions. Non-profit private payers, like Kaiser Permanente, are driven by a mission to enhance public health and well-being.[26] Non-profit insurance companies may approach coverage and benefits differently.

GOVERNMENT PAYORS

Government-funded payers include Medicare, Medicaid, Children's Health Insurance Program (CHIP), federal/state employee health plans, Indian Health Service (IHS), Tricare and Veterans Health Administration (VHA). These plans are generally funded by federal and state taxes.[25] In 2021, approximately 35% of individuals were covered by Medicare or Medicaid.[27] Government payers are another primary focus for manufacturers, as having products on formulary with government payers can be essential, especially for products targeted towards Medicare-aged individuals.

Medicare: Medicare is a federal health insurance program that provides health care coverage to individuals 65 and older and individuals under 65 with long-term disabilities or end stage renal disease.[25]

Medicaid: Medicaid is a state administered program and eligibility typically includes low-income patients who are pregnant, blind, the caregiver of a child, have a disability, have a household family member with a disability, or be 65 years or older.[28]

Children's Health Insurance Program (CHIP): The Children's Health Insurance Program is a state administered program that provides healthcare coverage for children in low-income families.[29]

Veterans Affairs (VA): VA health care is managed by the US Department of Veterans Affairs and covers those who were active-duty military, naval, or air service and didn't receive a dishonorable discharge.[30]

Tricare: Tricare is managed by the Department of Defense (DoD) and provides healthcare coverage to active-duty military members, retired military members, Guard/Reserves members, Medal of Honor recipients, and the families of beneficiaries.[31]

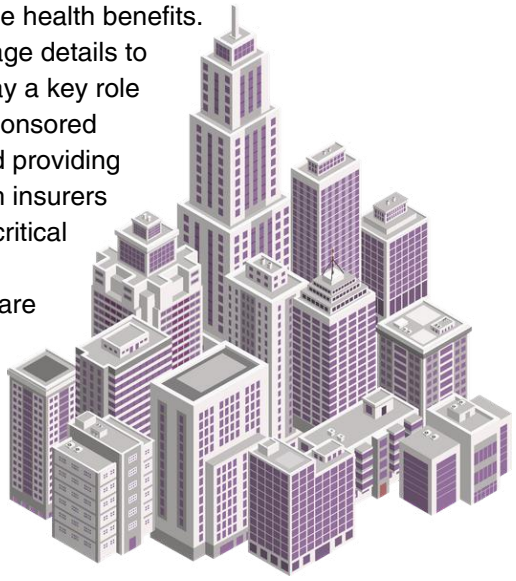
Indian Health Service (IHS): The Indian Health Service is a US Department of Health and Human Services Agency that provides federal health services to American Indians and Alaska Natives.[32]

HEALTH SYSTEMS

Health systems are entities responsible for the ownership and operation of a network comprising one or more healthcare facilities. Such establishments commonly encompass a spectrum of inpatient and outpatient facilities including hospitals, physician groups, health clinics, ambulatory surgery centers, and imaging centers.[33] The primary objective of health systems is to establish a seamless continuum of care for patients. Additionally, these systems possess the capacity to exert influence on physician treatment practices and can wield their substantial market sway to enhance negotiating power for treatments.[33,34] Manufacturers targeting health systems as a network possess the advantage of engaging with hundreds of affiliated providers simultaneously, streamlining the interaction process as opposed to engaging with them individually.[34]

EMPLOYERS

Employers of small and large companies are key decision makers for employee health benefits. Although employers often source out the responsibilities of determining coverage details to third parties such as pharmacy benefit managers or consultants, they often play a key role in the decision-making process.[35,36] Through the administration of employer-sponsored insurance (ESI) plans, employers undertake the responsibility of selecting and providing health insurance options to their workforce, often engaging in negotiations with insurers to delineate the terms and coverage parameters. This process encompasses critical determinations related to premiums, deductibles, copayments, and provider networks, thereby significantly influencing the scope and availability of healthcare services extended to employees and their dependents. It is important for manufacturers to speak directly to employers to educate them on the value of their products and how they can impact the employer's employee health, productivity, and profitability.[37]



PHARMACY BENEFIT MANAGERS (PBMS)

Pharmacy Benefit Managers (PBMs) occupy a pivotal position within the framework of the United States healthcare landscape. These entities serve as intermediaries between pharmaceutical manufacturers, pharmacies, and payers, working to optimize the prescription drug benefit component of health insurance plans.[38] PBMs undertake an array of critical functions, including negotiating drug prices with manufacturers, establishing formularies that dictate which medications are covered, processing and adjudicating prescription claims, and implementing cost-containment strategies.[38] PBMs undertake an array of critical functions, including negotiating drug prices with manufacturers, establishing formularies that dictate which medications are covered, processing and adjudicating prescription claims, and implementing cost-containment strategies.[38] PBMs play a substantial role in driving market competition and exerting downward pressure on drug prices. By leveraging their extensive network and negotiating power, PBMs contribute significantly to cost-effective and accessible pharmaceutical care for millions of Americans. However, it is worth noting that the role of PBMs has been subject to scrutiny, with ongoing debates regarding transparency, pricing practices, and their impact on overall healthcare costs.[39] As such, understanding the multifaceted role of PBMs is imperative for stakeholders seeking to navigate the intricacies of the U.S. pharmaceutical landscape.

GROUP PURCHASING ORGANIZATIONS

Group Purchasing Organizations (GPOs) are entities that help physicians and practices negotiate contracts with manufacturers, distributors, and vendors.[40] These negotiations can lead to cost savings for medical practices and create efficiencies for purchasing supplies. GPOs can leverage the volume of healthcare facilities they represent to negotiate bulk purchases with distributors and manufacturers.[40] Purchasing supplies by using GPOs can streamline the purchasing process of healthcare facilities and create cost savings of up to 18%.[40]

ADVOCACY ORGANIZATIONS

Advocacy organizations play a vital role in determining market access of treatments for specific or rare diseases. Advocacy organizations hold significant influence in policy development, patient support, and disease awareness. These organizations, often non-profit entities, serve as powerful advocates for patients and their families, championing their rights, needs, and interests.[41] In an era of evolving healthcare complexities, advocacy organizations play an instrumental role in filling critical gaps, ensuring that patient voices are heard, and promoting equitable access to quality care. These organizations exert substantial influence on healthcare policy and legislation at local, state, and federal levels. By conducting research, disseminating evidence-based information, and mobilizing grassroots movements, they shape the healthcare agenda, advocating for policies that advance patient interests. Their expertise in specific disease areas equips them with a unique perspective, enabling them to effectively communicate the needs of patients and drive targeted interventions. Examples of such influential advocacy organizations include the National Hemophilia Foundation for hemophilia and the National Organization for Rare Disorders Rare Action Network for rare diseases.[41,42]

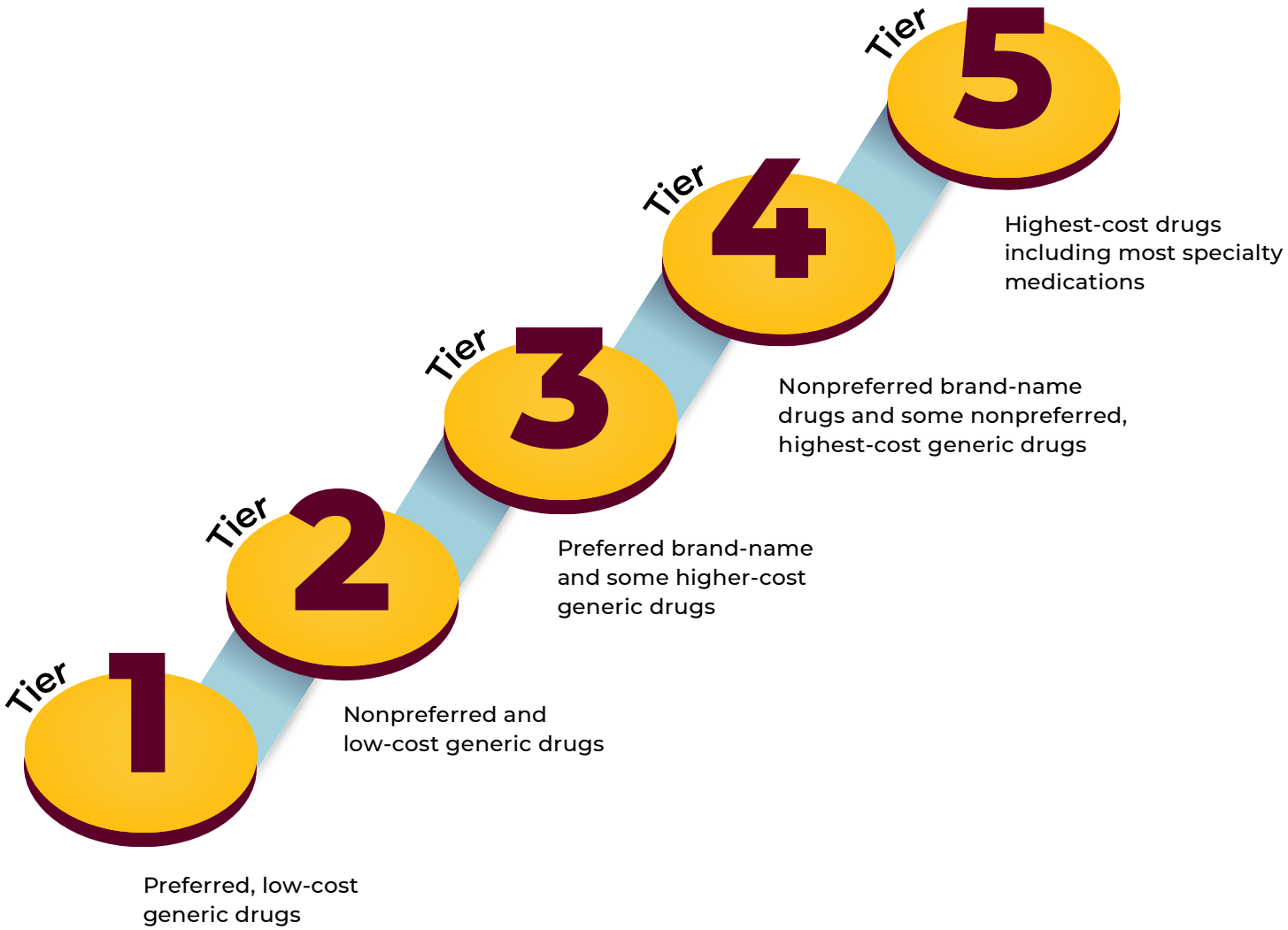


DRUG DISTRIBUTION IN THE UNITED STATES

BENEFIT DESIGN AND FORMULARY TIERS

A formulary is a list of preferred drugs that are covered under a health plan.[43] The primary purpose for a payer to create a formulary is to promote the use of the safest, most effective, and affordable treatment option.[44] This list is often developed by groups, such as a pharmacy and therapeutics (P&T) committee, which is usually comprised of physicians, pharmacists, and other health care providers.[44] Most drugs and related products are reviewed and assigned to a specific "tier," which represents the coverage level the health plan provides.[44] Each plan may divide tiers in different ways and associate different cost amounts with each tier.[45] Often, the more cost-effective agents are placed in the most preferred tier and have the lowest out-of-pocket costs.

Most plans will divide their formularies into 4 to 5 tiers.

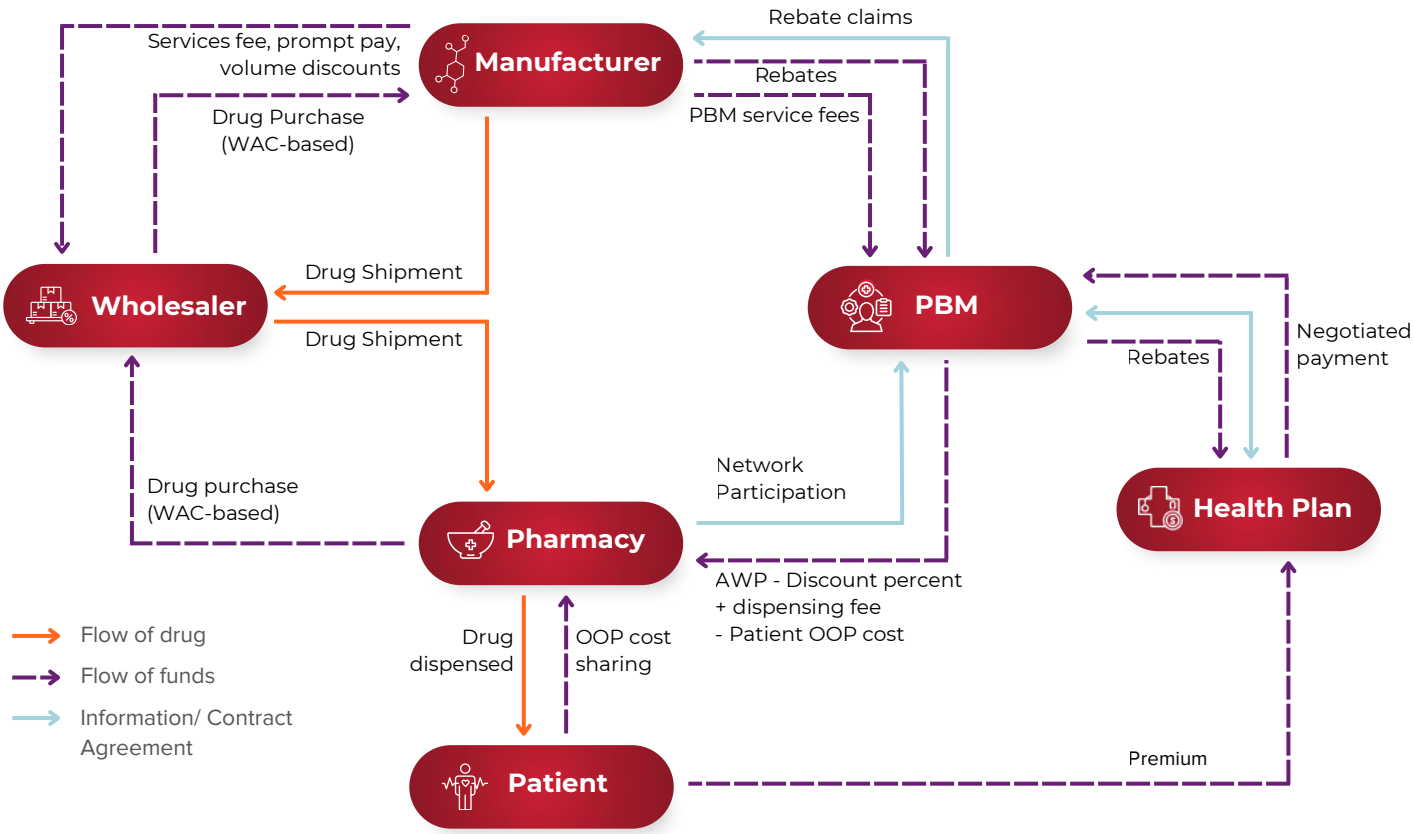


3 ATTRIBUTES OF DRUG DISTRIBUTION IN THE UNITED STATES

Product Flow: With traditional retail products, drug shipments move from manufacturers to wholesalers. Manufacturers manage large-scale production of the drugs and distribute to wholesalers.[47] Wholesalers purchase medications from manufacturers and sell them to customers like pharmacies and hospitals. Pharmacies typically purchase drugs from wholesalers, though they can also be purchased directly from the manufacturer.[47] Once drugs are at a pharmacy, they can be dispensed to patients.

Financial Flow: PMBs negotiate rebates and discounts with drug manufacturers. When a patient purchases a medication that holds a rebate, manufacturers distribute the negotiated amount to a contracted health plan.[48] Pharmacies can submit claims to PBMs for reimbursement at a negotiated rate.[47] Reimbursement from PBMs is usually calculated using the average wholesale price, dispensing fee, and collected patient cost sharing.[47] Patients purchase medications from a pharmacy, and depending on their insurance coverage, they will pay a copay, coinsurance, or the entire cost of the medication.[47]

Contracts: Manufacturers will often contract with wholesalers to guide payment plans and bulk-purchasing agreements.[47] Pharmacies can contract with PBMs to be included in their pharmacy network. This allows the pharmacies to submit claims for the negotiated reimbursement rate mentioned in the previous section. Health plans will also contract with PBMs in order to receive negotiated rebates.[47]



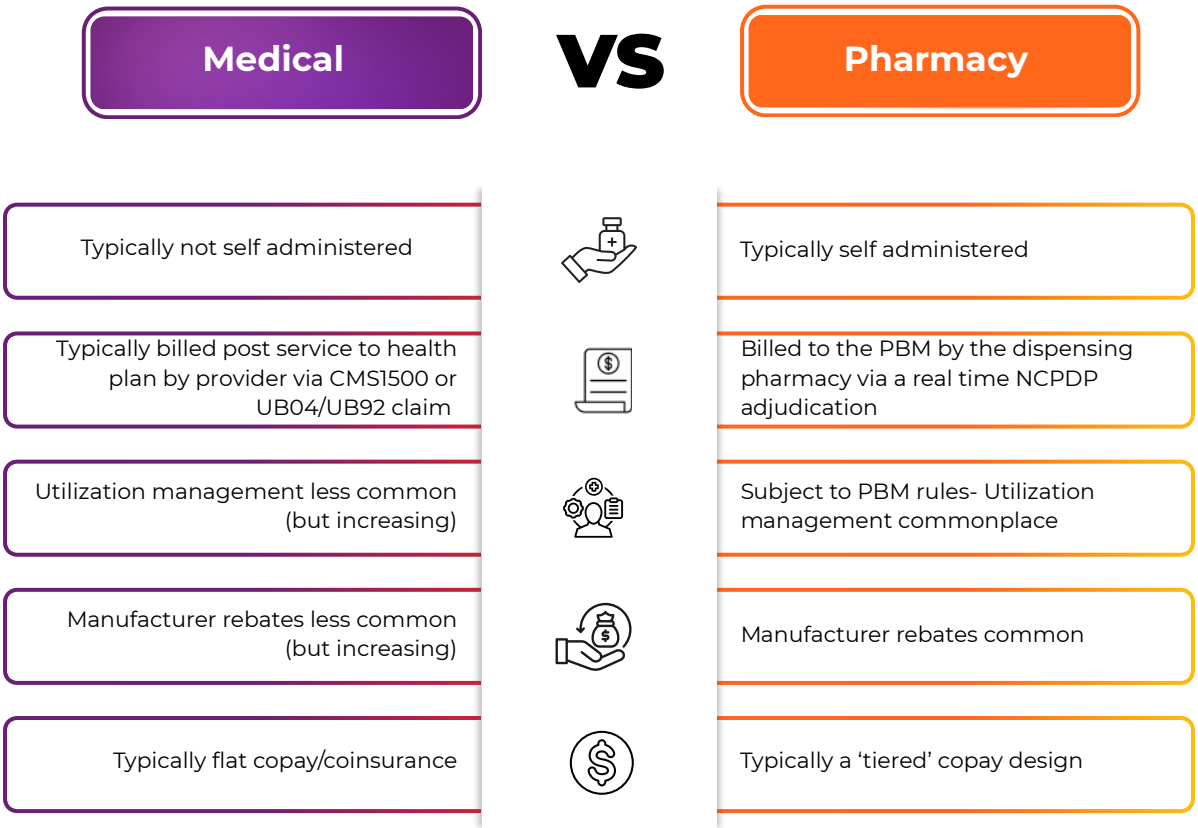
PHARMACY VS MEDICAL BENEFIT

Coverage classifications may be based on mode of administration and medication acquisition. Health plans may classify coverage of drugs as a medical benefit, pharmacy benefit, or both. How drugs are classified can depend on several factors, such as how and where it is administered and how it is acquired.[49]

Drug Administration: Drugs that are considered a pharmacy benefit include medications that are self-administered. For example, insulin, blood pressure medications, and other medications that can be taken in a patient's home.[50]

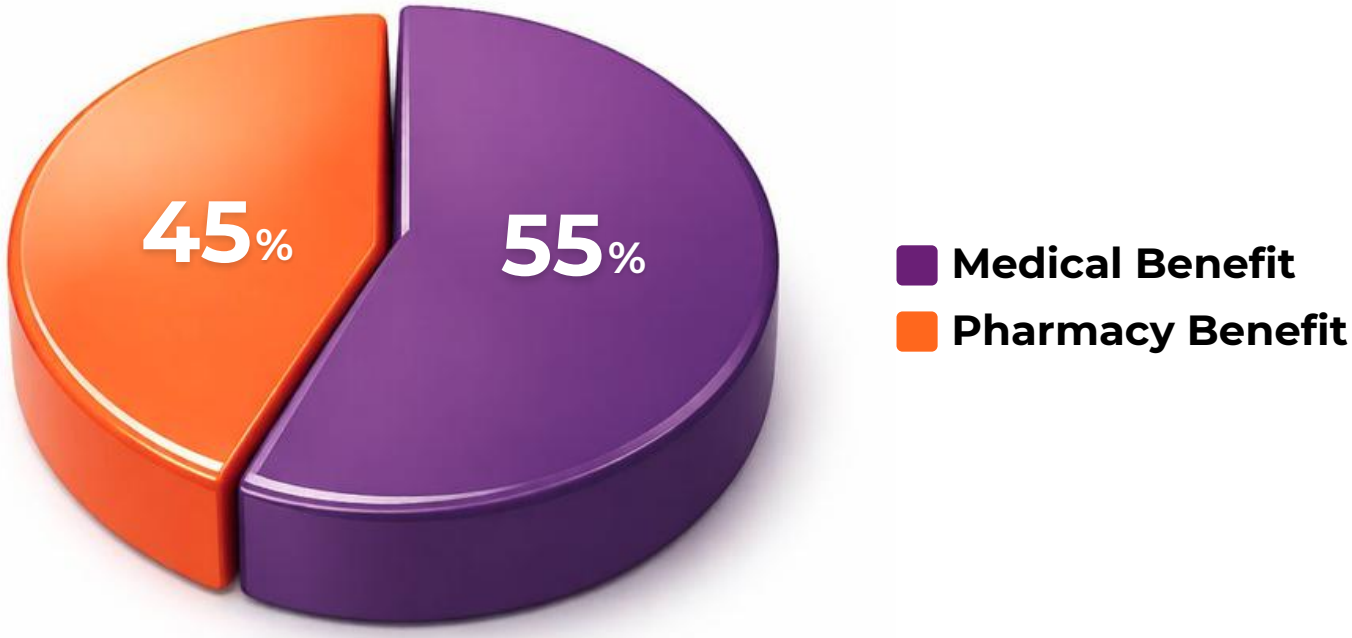
Drug Acquisition: Drugs classified as a medical benefit must be administered in a healthcare setting. These medications involve monitoring by a healthcare professional in an inpatient or outpatient setting.[51]

For drugs covered under a medical benefit, the physician will typically purchase medications for in-office administration and be reimbursed through the buy and bill process. This can include birth control implants, chemo infusions, and certain vaccines.[50]



SPECIALTY DRUGS

Specialty drugs comprise a subgroup of medications that are high-cost oral, injectable, infused, or inhaled medications used to treat complex chronic conditions. These types of drugs are typically highly complex to manufacture and store and are often biologics that are structurally similar to compounds within the body.[52,52] They may require close clinical monitoring due to the potential for severe side effects.[54] Specialty drugs can be covered under a pharmacy benefit, medical benefit, or both, though nearly half of specialty drugs are covered under the medical. benefit.[52,55] Specialty drugs can include medications that treat Crohn's Disease, Cancer, and Hepatitis.[52]





FDAMA 114: ENGAGING FORMULARY DECISION MAKERS

WHAT IS FDAMA 114 AND HCEI?

Market access often requires manufacturers to discuss economic metrics related to health outcomes rather than only focusing on clinical outcomes. The Food and Drug Administration Modernization Act of 1997, commonly referred to as FDAMA 114, was enacted in 1997 as a method of improving the dissemination of health care economic information (HCEI).[56] HCEI involves the economic consequences of a health intervention or a drug's clinical outcomes.[57] FDAMA allows manufacturers to provide payors and formulary committees with information about the value of their treatments. The implementation of FDAMA lowered the level of evidence needed to use HCEI from substantial evidence to competent and reliable scientific evidence (CARSE). Relevant HCEI information under FDAMA includes economic metrics related to health outcomes, for example, cost per Quality of Life Years (QALY).[56]

Despite the frequent use of QALYs in health economics, recent criticism has surfaced highlighting the discriminatory nature of QALY for those with disabilities.[58] The QALY assigned to certain treatments may differ significantly between those with chronic conditions versus those without, as patients with chronic conditions may have a lower threshold of QALY improvement from a medication than patients who are healthy.[58] As a result, the CMS will no longer use QALY as a factor in the Inflation Reduction Act (IRA) maximum fair price negotiations.[59]

The Inflation Reduction Act was enacted in 2022 as a strategy to reduce the rate of inflation. The act aims to address energy costs, carbon emissions, ACA premiums, and out-of-pocket drug costs.[60] The drug cost provision allows Medicare to negotiate the price of drugs covered by Medicare Part D and B with pharmaceutical companies.[61] Companies refusing to participate in these negotiations can be penalized. The maximum fair price of certain drugs established by Medicare negotiations will be published in 2024 and go into effect by 2026.[61] Click here for more information on the IRA.

Market access often requires manufacturers to discuss economic metrics related to health outcomes rather than only focusing on clinical outcomes.

TRADITIONAL VS. FDAMA 114 PROMOTIONAL MATERIALS

Traditional pharmaceutical promotional material utilizes substantial evidence and includes safety/efficacy information meant for a broader audience. FDAMA 114 promotional tools must be based on HCEI related to an approved indication. Evidence used for these materials is based on CARSE.[56] CARSE includes tests, analyses, studies, and other evidence based on the expertise of professionals in the field.[55] The audience of FDAMA-based promotional materials is limited to those with HCEI expertise.[55]

Traditional Promotion	VS	FDAMA 114 Promotion
Proactive		Procative
Traditional safety / efficacy data from label		Based on healthcare economic information (HCEI) related to an approved indication
Broad audience: decision makers for individual patients		Limited audience: payers, formulary decision makers, or similar entity
Evidence based on substantial evidence (RCT)		Evidence based on competent reliable scientific evidence (CARSE)

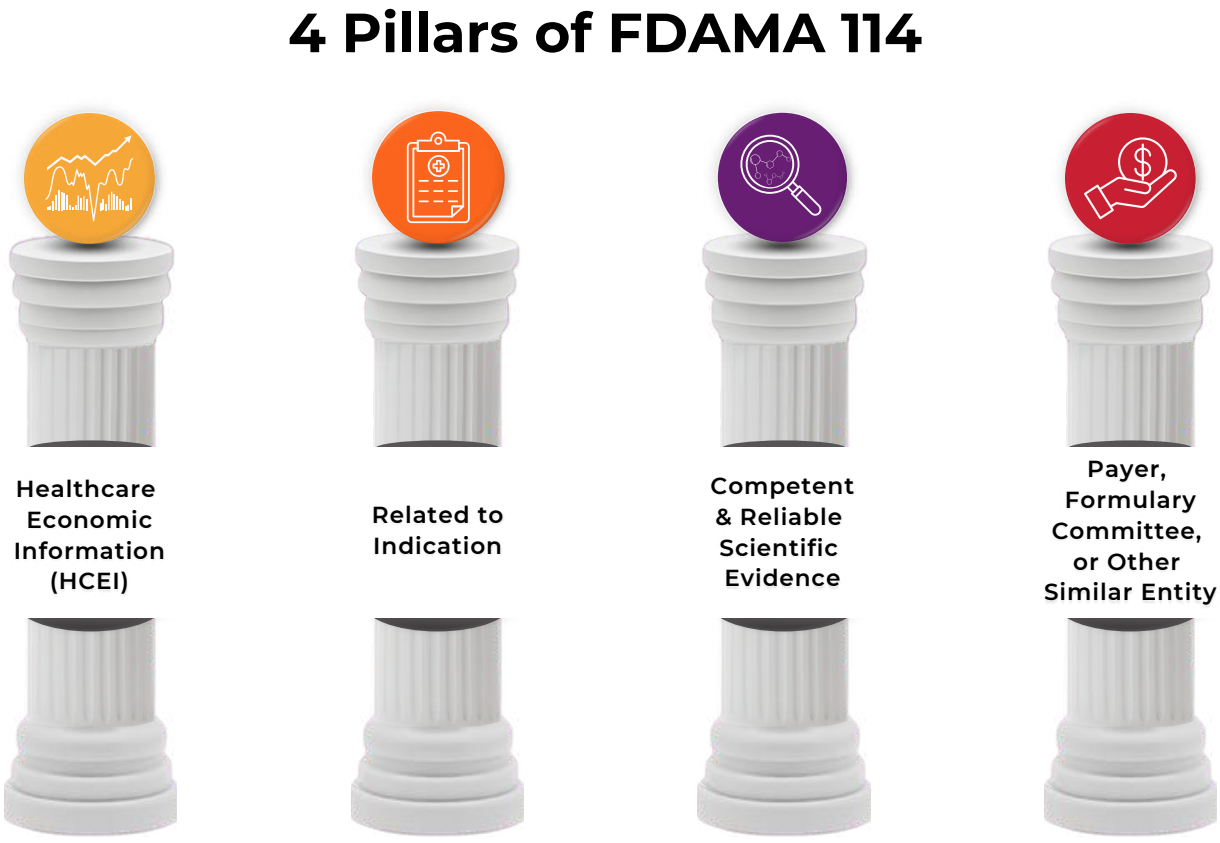


4 PILLARS OF FDAMA 114

FDAMA 114 guidance is based on four pillars[62]:

- Information presented under FDAMA 114 must include HCEI in a manner such as cost-analysis, cost-effective analysis, and cost-benefit analysis
- Information presented under FDAMA 114 must relate to an approved indication and align with the disease or condition, manifestation of the disease or condition, or symptoms associated with the disease or condition for which the drug is approved
- HCEI information presented must be supported by CARSE and truthful, medically accurate, and not misleading
- The audience of FDAMA 114 materials should have an appropriate range of healthcare economic analysis knowledge and expertise needed to interpret HCEI to inform decision-making processes (PBMs and formulary committees)

A recent FDA draft guidance provides recommendations for additional methods of communication between healthcare providers and pharmaceutical companies.[63] The guidance cites real-world data (RWD) and real-world evidence (RWE) as scientifically sound and clinically relevant.[63] The FDA suggests this type of data be shared with healthcare providers under Scientific Information on Unapproved Uses (SIUU) of approved medical products.[63] This updated guidance presents a significant opportunity for manufacturers as the ability to communicate off-label use to clinicians can expand access to patients and improve outcomes for conditions that do not have an approved treatment



GLOBAL MARKET ACCESS CONSIDERATIONS

GLOBAL MARKET ACCESS OVERVIEW

From a global perspective, market access involves a multifaceted interplay of regulatory considerations, healthcare infrastructure, and the preferences and needs of diverse patient populations. Healthcare challenges and landscapes may differ based on the economic development of a nation. Developed markets, like the US, Canada, Australia, and Japan, have high levels of per capita income and are considered highly economically advanced.[64]

Emerging markets, a term used to describe countries with rapid economic growth and less market maturity than developed countries, include countries like China, India, Nigeria, Brazil and Vietnam.[64] Emerging markets may experience a lack of resources and weaker healthcare infrastructure, making it difficult to address the countries' top health issues.[65]

From a global perspective, market access involves a multifaceted interplay of regulatory considerations, healthcare infrastructure, and the preferences and needs of diverse patient populations.

GLOBAL HEALTHCARE LANDSCAPE

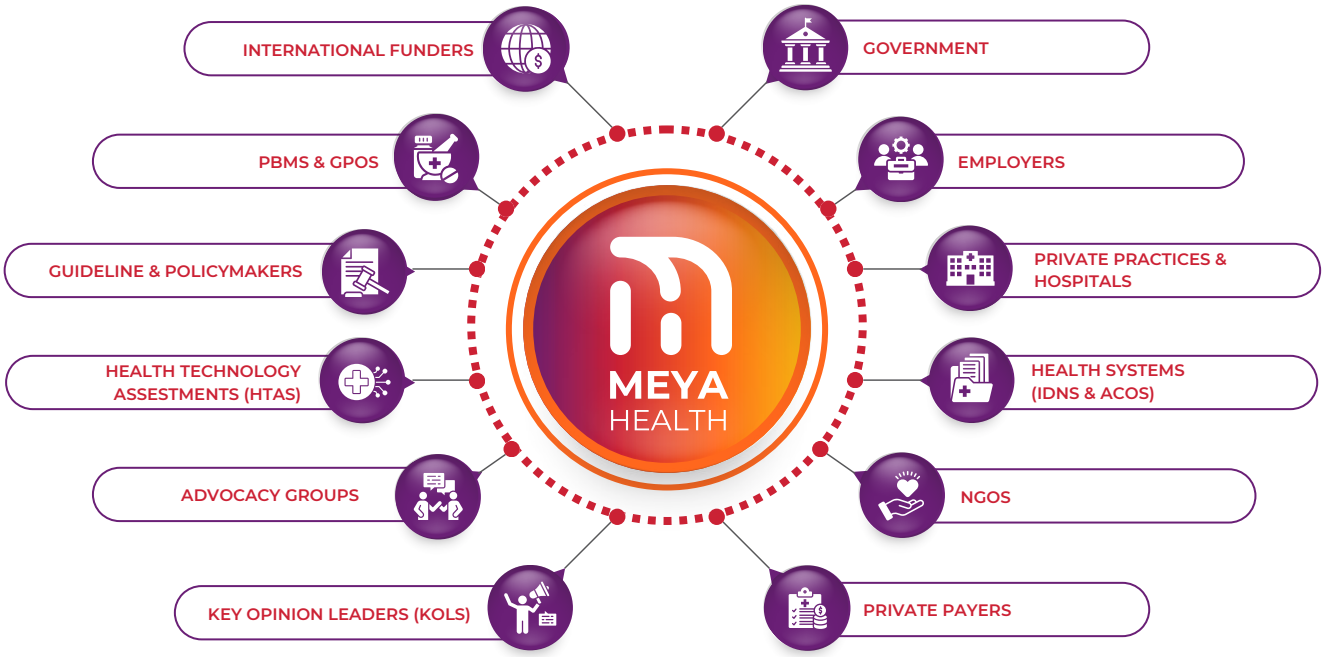
The global health landscape continues to shift due to emerging technologies and evolving healthcare policies. Nations around the world struggle with a wide spectrum of health challenges, from infectious diseases to non-communicable epidemics. This landscape encompasses several factors, including healthcare infrastructure, access to essential services, and health inequities. The COVID-19 pandemic has highlighted the interconnectivity of global health, emphasizing the need for concerted international efforts and public health investments.

Funding and healthcare coverage differ widely across the world compared to the US. All of the developed countries in the world, Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, and the UK, provide universal healthcare coverage, while the US does not.[66] Universal healthcare is typically covered by tax revenue[67] and automatically covers citizens. Many countries with universal healthcare also offer private, voluntary insurance programs.[68] Private healthcare in these nations allows patients to have more choices in providers or facilities and quicker access to care.[68]

Global healthcare systems also differ based on oversight. Decentralized systems, like Switzerland's healthcare system, delegate authority and decision-making to regional or local entities, fostering adaptability and responsiveness to local needs.[69] Centralized systems, like the National Health Service (NHS) in the UK, concentrate authority at a national level, often aiming for uniformity and efficiency in healthcare provision.[67]

GLOBAL MARKET ACCESS STAKEHOLDERS

Like the US landscape, global market access involves various stakeholders including government agencies, advocacy groups, employers, policymakers, and Non-Governmental Organizations (NGOs). The World Health Organization (WHO), a United Nations (UN) agency, spearheads global public health efforts and informs many countries' policy decisions.[70] The WHO is instrumental in guiding countries during international crises. The COVID-19 pandemic, for instance, underscored the pivotal role played by the WHO in coordinating responses, disseminating crucial information, and facilitating global collaboration. NGOs, like Doctors Without Borders, spearhead implementation efforts at the grassroots level, leveraging community-based approaches to bridge gaps in healthcare access and delivery.[70]



DRUG DISTRIBUTION IN THE GLOBAL MARKET

The global pharmaceutical market has experienced significant growth in recent years. For 2022, the total global pharmaceutical market was estimated at $1.48 trillion US dollars.[72] The global specialty drug distribution market size was $2.61 million US dollars in 2021 with projections to reach $74.3 million US dollars by 2031.[73]

Several factors influence drug distribution in the global market, including material shortages, capacity constraints, global regulation, and access to healthcare. These challenges can lead to delays in delivery of essential medications to patients. A prominent issue within the pharmaceutical supply chain is access to materials. Often, a limited quantity of resources and materials can cause bottlenecks in the pharmaceutical supply chain. Pharmaceutical companies also struggle to keep up with the growing demand for their products. This is due to population growth, rising incomes, and increasing access to healthcare. In addition, multinational pharmaceutical companies must adhere to regulatory guidelines of all the countries they supply. This can be a challenge, as each country has its own unique set of regulations. Beyond issues of material shortages and capacity, the delivery process can also be a bottleneck in the pharmaceutical supply chain. This can be caused by a variety of factors, such as packaging shortages, price spikes, and site holdups.[74]

Additionally, an estimated two billion people have no access to essential medicines, effectively shutting them off from the benefits of advances in modern science and medicine. Lack of access to medicines is a complex problem with many causes, including affordability, gaps in local health systems and infrastructures, procurement practices, tax and tariff policies, mark-ups along the supply chain, the strength of national drug regulatory authorities, and the need for safe and secure supply chain management. Medicines account for 20% to 60% of health spending in low- and middle-income countries, compared with 18% in countries belonging to the Organization for Economic Co-operation and Development.[75] Although the US is a world leader in drug discovery and development, most drug manufacturing has moved overseas in recent decades.[76] The high cost of manufacturing drugs forces companies to join complex supply chains, which can put pressure on already fragile infrastructure. Manufacturers often rely on outside suppliers for active pharmaceutical ingredients (APIs) and finished dosage forms (FDFs) to lower costs and increase profits. In fact, 88% of API manufacturing sites and 63% of FDF manufacturing sites are located abroad, mostly in China and India. While this strategy can reduce costs, it can also make it difficult to enforce quality standards and manage sensitive supply chains, which can increase the risk of drug shortages. Changes in the geopolitical situation of foreign API and FDF producers can also disrupt the global supply chain.[77]

Lack of access to medicines is a complex problem with many causes, including affordability, gaps in local health systems and infrastructures, procurement practices, tax and tariff policies, mark-ups along the supply chain, the strength of national drug regulatory authorities, and the need for safe and secure supply chain management.

With all the hurdles faced in drug distribution in global markets, e-commerce integration is making it easier and faster for patients and providers to find and buy the drugs they need. Online demand for healthcare products and services is booming, with the global healthcare e-commerce market projected to hit $435.8 billion in revenue by 2025. This is especially true for pharmaceuticals, which are seeing a surge in online sales in line with the overall growth of e-commerce during the pandemic. E-commerce integration is changing the way pharmaceutical vendors, patients, and providers interact. For patients, e-commerce means the convenience of purchasing and receiving prescription drugs from home. For providers, comprehensive e-commerce platforms provide a way to compare drug prices and availability, enabling informed drug spending and potentially reducing organizational costs.[78]



ABOUT MEYA HEALTH

A STRATEGIC MARKET ACCESS AGENCY

Meya Health is a woman and minority owned strategic communications agency - we specialize in achieving health access goals through medical and value communications strategy. Having transformed the traditional agency model, our approach takes a holistic 360° view that considers the research and clinical development continuum.

We are experts in developing end-to-end communication strategies and tactics for all healthcare stakeholders, from clinical to the general public. We are specialists in the areas of clinical and medical information, population health, health economics, patient outcomes, social determinants of health, racial and other health disparities, and more.

As a full-service strategic market access agency, we focus on leveraging value communication to achieve market access priorities.

80+ BRANDS

55+ INDICATIONS

50+ COMPANIES

37+ US & GLOBAL LAUNCHES

20+ THERAPEUTIC CATEGORIES

10+ YEARS IN BUSINESS

CERTIFICATIONS & AFFILIAITONS

People to Watch
2024

Supplier of the Year
2025

OUR 360° APPROACH TO ACCESS™

TRANFORMING THE TRADITIONAL

We have reimagined the traditional approach by applying a market access lens across the entire product development lifecycle - from clinical to commercialization, launch through post-launch. Our unique approach to access fits into any phase of development, while navigating the medical, legal and regulatory requirements at each.

In an ever-changing market access landscape, we take a proactive stance, anticipating future opportunities and identifying potential challenges. Our distinctive process integrates the market access lens early in development and extends throughout the launch strategy, utilizing landscape analyses and strategic scenario planning to craft a dynamic market access plan.



We specialize in adapting market access plans, tailoring stakeholder-specific messaging to enhance the value proposition based on access opportunities and challenges. Our customized tactical plans, combined with strategic workshops, simplify the value story, creating compelling customer selling propositions.

As a comprehensive agency, we go beyond creating tools and tactics. We equip field teams with adapted tactical plans through a series of strategic workshops, ensuring effective customer engagements. Our proprietary training methodology goes a step further, simulating real-world customer interactions and empowering teams to communicate unique value stories.

This complete view ensures comprehensive, tailored strategies across market access stakeholders.

Our 360° Approach to Access™ involves anticipating challenges, adapting strategic plans, and accomplishing access through wraparound engagement.

Contact MEYA Health to learn more: hello@meya.health

REFERENCES

1. Bunker N. What is Market Access? IQVIA. Published September 2, 2021. Accessed February 2, 2026. https://www.iqvia.com/locations/united-kingdom/blogs/2021/09/what-is-market-access
2. Market Access. Definitive Healthcare. Accessed February 2, 2026. https://www.definitivehc.com/resources/glossary/market-access
3. Hood CM, et al. *Am J Prev Med.* 2016;50(2):129-135.
4. Centers for Disease Control and Prevention. Social Determinants of Health (SDOH). CDC About Priorities. January 17, 2024. https://www.cdc.gov/about/priorities/why-is-addressing-sdoh-important.html. Accessed February 2, 2026.
5. Nguyen A, Chase L. Healthcare Deserts in 2025: Over 80% of the Country Lacks Healthcare Access. GoodRx Research. Published July 15, 2025. Accessed February 2, 2026. https://www.goodrx.com/healthcare-access/research/updated-healthcare-deserts?srsltid=AfmBOopiXrK_UnCFAIUFKKDE4cLPlm4kn8znR89Vxd2pzeK8AB9v2_Ea
6.Baciu A, Negussie Y, Geller A, et al., editors. The State of Health Disparities in the United States. In: Communities in Action: Pathways to Health Equity. National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division. Washington (DC): National Academies Press (US); 2017 Jan 11. Accessed February 2, 2026. https://www.ncbi.nlm.nih.gov/books/NBK425844/
7. Weisel J. The future of market access: a new model for the next normal. prmaconsulting. Published October 18, 2022. Accessed February 2, 2026. https://www.prmaconsulting.com/blog/the-future-of-market-access-a-new-model-for-the-next-normal/
8. Health Insurance Coverage in the United States: 2021. United States Census Bureau. Accessed February 2, 2026. https://www.census.gov/library/publications/2022/demo/p60-278.html
9. Cubanski J, Biniek JF, Neuman T. FAQs on Health Spending, the Federal Budget, and Budget Enforcement Tools. KFF. Published March 20, 2023. Accessed February 2, 2026. https://www.kff.org/medicare/issue-brief/faqs-on-health-spending-the-federal-budget-and-budget-enforcement-tools/
10. Gunja MZ, Gumas ED, Williams RD. U.S. Health Care from a Global Perspective, 2022. The Commonwealth Fund. Published January 31, 2023. Accessed February 2, 2026. https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022
11. Werner RM, Emanuel EJ, Pham HH, Navathe AS. The Future of Value-Based Payment: A Road Map to 2030. Penn LDI. Published February 17, 2021. Accessed February 2, 2026. https://ldi.upenn.edu/our-work/research-updates/the-future-of-value-based-payment-a-road-map-to-2030/
12. Better Care, Smarter Spending, Healthier People: Improving Our Health Care Delivery System. Centers for Medicare and Medicaid Services. Published September 29, 2015. Accessed February 2, 2026. https://www.cms.gov/newsroom/fact-sheets/better-care-smarter-spending-healthier-people-improving-our-health-care-delivery-system-0
13. CMS' Value-Based Programs. Centers for Medicare and Medicaid Services. Updated September 6, 2023. Accessed February 2, 2026. https://www.cms.gov/medicare/quality/value-based-programs
14. Lewis C, Hortsman C, Blumenthal D, Abrams MK. Value-Based Care: What It Is, and Why It's Needed. The Commonwealth Fund. Published February 7, 2023. Accessed February 2, 2026. https://www.commonwealthfund.org/publications/explainer/2023/feb/value-based-care-what-it-is-why-its-needed
15. Learn the Lingo: Key Terms for Navigating The Value-based Care World. American Pharmacists Association. Accessed February 2, 2026. https://www.pharmacist.com/Practice/Practice-Resources/Learn-the-Lingo/
16. Types of Health Care Quality Measures. Agency for Healthcare Research and Quality. Published February 2015. Updated July 2015. Accessed February 2, 2026. https://www.ahrq.gov/talkingquality/measures/types.html
17. About NCQA. National Committee for Quality Assurance. Accessed February 2, 2026. https://www.ncqa.org/about-ncqa/
18. Hospital Value-Based Purchasing. Centers for Medicare and Medicaid Services. Updated September 6, 2032. Accessed February 2, 2026. https://www.cms.gov/medicare/quality/value-based-programs/hospital-purchasing
19. Quality Payment Program. Centers for Medicare and Medicaid Services. Updated October 26, 2023. Accessed February 2, 2026. https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program
20. NQF's History. National Quality Forum. Accessed February 2, 2026. https://www.qualityforum.org/about_nqf/history/
21. National Quality Strategy Fact Sheet. Agency for Healthcare Research and Quality. Updated January 2017. Accessed February 2, 2026. https://www.ahrq.gov/sites/default/files/wysiwyg/nqsfactsheet_2017.pdf
22. Major Health Plan Quality Measurement Sets. Agency for Healthcare Quality. Accessed February 2, 2026. https://www.ahrq.gov/talkingquality/measures/setting/health-plan/measurement-sets.html
23. Shared Savings Program. Centers for Medicare and Medicaid Services. Accessed February 2, 2026. https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos
24. Chiu N, et al. JAMA Health Forum. 2022;3(7):e221956.
25. Tikkanen R, Osborn R, Mossialos E, Djordjevic A, Wharton GA. United States. The Commonwealth Fund. Published June 5, 2020. Accessed February 2, 2026. https://www.commonwealthfund.org/international-health-policy-center/countries/united-states
26. Our Impact in Georgia. Kaiser Permanente. Accessed February 2, 2026. https://about.kaiserpermanente.org/content/internet/kp/kpcomms/en/commitments-and-impact/public-policy/our-impact/news-perspectives-on-public-policy-georgia.html

27. Health Insurance Coverage of the Total Population. KFF. Accessed February 2, 2026. https://www.kff.org/other/state-indicator/total-population/
28. Texas Medicaid. Benefits.gov. Accessed February 2, 2026. https://www.benefits.gov/benefit/1640
29. Children's Health Insurance Program (CHIP). Medicaid. Accessed February 2, 2026. https://www.medicaid.gov/chip/index.html
30. Eligibility for VA health care. US Department of Veterans Affairs. Published September 30, 2023. Accessed February 2, 2026. https://www.va.gov/health-care/eligibility/
31. TRICARE Health Insurance Explained. Military Benefit Association. Published May 2021. Accessed February 2, 2026. https://www.militarybenefit.org/get-educated/tricare-health-insurance/
32. Agency Overview. Indian Health Service. Accessed February 2, 2026. https://www.ihs.gov/aboutihs/overview/
33. Integrated Delivery Network. Definitive Healthcare. Accessed February 2, 2026. https://www.definitivehc.com/resources/glossary/integrated-delivery-network
34. Martin R. Integrated Delivery Networks. IQVIA. Accessed February 2, 2026. https://www.iqvia.com/-/media/iqvia/pdfs/us/us-location-site/market-access/integrated-delivery-networks.pdf
35. Quilici E. Market Access: Employers as Barriers to Value. PharmExec.com. Published December 17, 2019. Accessed February 2, 2026. https://www.pharmexec.com/view/market-access-employers-barriers-value
36. Whaley CM, Sachdev G, Bartlett M, Bai G. It's Time For Employers To Bring Health Care Decisions In-House. HealthAffairs. Published September 22, 2022. Accessed February 2, 2026. https://www.healthaffairs.org/content/forefront/s-time-employers-bring-health-care-decisions-in-house#:~:text=Bringing%20health%20care%20decisions%20in,purchasing%20ecosystem%20and%20information%20disadvantage.
37. Kenton W. What Is Absenteeism? Definition, Causes, and Costs for Business. Investopedia. Updated December 22, 2022. Accessed February 2, 2026. https://www.investopedia.com/terms/a/absenteeism.asp
38. Pharmacy Benefit Managers and Their Role in Drug Spending. Published April 22, 2019. Accessed February 2, 2026. The CommonwealthFund. https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending
39. Middlemen are often standing between patients and their medicines. PhRMA. Accessed February 2, 2026. https://phrma.org/Middlemen
40. FAQ. Healthcare Supply Chain Association. Accessed February 2, 2026. https://supplychainassociation.org/about-us/faq/
41. Public Policy Positions. National Organization for Rare Disorders. Published December 28, 2022. Accessed February 2, 2026. https://rarediseases.org/driving-policy/public-policy-positions/
42. Advocacy. National Bleeding Disorders Foundation. Accessed February 2, 2026. https://www.hemophilia.org/advocacy
43. What is a Pharmacy Benefit Manager and How Does a PBM Impact the Pharmacy Benefits Ecosystem? Truveris. Published February 17, 2021. Accessed February 2, 2026. https://truveris.com/what-is-a-pharmacy-benefit-manager-pbm-and-how-does-a-pbm-impact-the-pharmacy-benefits-ecosystem/
44. Formulary Management. Academy of Managed Care Pharmacy. Published July 18, 2019. Accessed February 2, 2026. https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management
45. What Medicare Part D drug plans cover. Medicare. Accessed November 8, 2023. https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover
46. Understanding Drug Tiers. Humana. Accessed February 2, 2026. https://www.humana.com/pharmacy/medication-information/understanding-drug-tiers
47. West M, Nam D, Getachew B, Grady L, Frieder M. Follow the Pill: Understanding the Prescription Drug Supply Chain. Avalere. Published May 20, 2020. Accessed February 2, 2026. https://avalere.com/insights/follow-the-pill-understanding-the-prescription-drug-supply-chain
48. The reality of drug rebates: What they are, how they work, and the value they bring. Evernorth. Published September 6, 2023. Accessed February 2, 2026. https://www.evernorth.com/articles/reality-drug-rebates-what-they-are-how-they-work-and-value-they-bring
49. McCain J. The Importance of a Thorough Benefits Investigation to Help Navigate Medical vs Pharmacy Benefit. National Association of Medication Access & Patient Advocacy. Accessed February 2, 2026. https://namapa.org/medical-vs-pharmacy-benefit
50. Is My Prescription a Pharmacy or Medical Benefit? Blue Cross Blue Shield of Texas. Published April 24, 2023. Accessed February 2, 2026. https://connect.bcbstx.com/understanding-benefits/b/weblog/posts/pharmacy-benefit-vs-medical-benefit
51. Levine AA, et al. J Manag Care Spec Pharm. 2023;29(6):10.18553/jmcp.2023.29.6.607.
52. Specialty Pharmacy Drug List. Magellan Rx Management. Accessed February 2, 2026. https://magellanrx.com/member/external/commercial/common/doc/en-us/MRx_Formulary_Specialty.pdf
53. Emerging trends in the specialty drug industry. Elsevier. Accessed February 2, 2026. https://www.elsevier.com/clinical-solutions/insights/resources/insights-articles/drug-information/emerging-trends-in-the-specialty-drug-industry
54. Specialty Pharmaceuticals. Academy of Managed Care Pharmacy. Published July 18, 2019. Accessed February 2, 2026. https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/specialty-pharmaceuticals
55. Medical vs Pharmacy Benefit. Specialty Drug Resource. Accessed February 2, 2026. https://www.specialtydrugresource.com/coverage-landscape-overview/medical-vs-pharmacy-benefit
56. AMCP Partnership Forum: FDAMA Section 114—Improving the Exchange of Health Care Economic Data. J Manag Care Spec Pharm. 2016;22(7):826-831.
57. Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities Questions and Answers. Food and Drug Administration. Published June 2018. Accessed February 2, 2026. https://www.fda.gov/media/133620/download
58. Smith WS. The U.S. shouldn't use the "QALY" in drug cost-effectiveness reviews. STAT. Published February 22, 2019. Accessed February 2, 2026. https://www.statnews.com/2019/02/22/qaly-drug-effectiveness-reviews/

59. Cubanski J. FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program. KFF. Published August 8, 2023. Accessed February 2, 2026. https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/
60. Summary: The Inflation Reduction Act of 2022. Senate.gov. Accessed February 2, 2026. https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_one_page_summary.pdf
61. Cubanski J, Neuman T, Freed M. Explaining the Prescription Drug Provisions in the Inflation Reduction Act. KFF. Published January 24, 2023. Accessed February 2, 2026. https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/
62. Niyazov A, Lenci D. Communicating Healthcare Economic and Pre-approval Information With Healthcare Decision-Makers: Opportunities Following the 21st Century Cures Act and FDA Guidance. Front Public Health. 2018;6:304. Published 2018 Nov 14. doi:10.3389/fpubh.2018.00304
63. Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers Guidance for Industry. Food and Drug Administration. Published October 2023. Accessed February 2, 2026. https://www.fda.gov/media/173172/download
64. What is the difference between a developed, emerging, and frontier market?. Nasdaq. Published May 11, 2012. Accessed February 2, 2026. https://www.nasdaq.com/articles/what-difference-between-developed-emerging-and-frontier-market-2012-05-11
65. Mor N. Lessons for Developing Countries From Outlier Country Health Systems. Front Public Health. 2022;10:870210. doi:10.3389/fpubh.2022.870210
66. NEW INTERNATIONAL STUDY: U.S. Health System Ranks Last Among 11 Countries; Many Americans Struggle to Afford Care as Income Inequality Widens. Commonwealth Fund. Published August 4, 2021. Accessed February 2, 2026. https://www.commonwealthfund.org/press-release/2021/new-international-study-us-health-system-ranks-last-among-11-countries-many
67. Tikkanen R, Osborn R, Mossialos, Djordjevic A, Wharton GA. England. The Commonwealth Fund. Published June 5, 2020. Accessed February 2, 2026. https://www.commonwealthfund.org/international-health-policy-center/countries/england#universal-coverage
68. Considering Single Payer Proposals in U.S.: Lessons from Abroad. The Commonwealth Fund. Published April 11, 2019. AccessedFebruary 2, 2026. https://www.commonwealthfund.org/publications/2019/apr/considering-single-payer-proposals-lessons-from-abroad
69. Tikkanen R, Osborn R, Mossialos, Djordjevic A, Wharton GA. Switzerland. The Commonwealth Fund. Published June 5, 2020. Accessed February 2, 2026. https://www.commonwealthfund.org/international-health-policy-center/countries/switzerland#universal-coverage
70. About WHO. World Health Organization. Accessed February 2, 2026. https://www.who.int/about
71. Moss K. NGO Engagement in U.S. Global Health Efforts: U.S.-Based NGOs Receiving USG Support Through USAID KFF. Published December 15, 2014. Accessed February 2, 2026. https://www.kff.org/report-section/us-ngos-in-global-health-report/
72. Mikulic M. Revenue of the worldwide pharmaceutical market from 2001 to 2022. Statista. Published August 29, 2023. Accessed February 2, 2026. https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/
73. Speciality Drug Distribution Market Report Overview. Business Research Insights. Published October 30, 2023. Accessed February 2, 2026. https://www.businessresearchinsights.com/market-reports/specialty-drug-distribution-market-100865
74. Salib V. Reimagining the Global Pharmaceutical Supply Chain. PharmaNews Intelligence. Published November 14, 2022. Accessed February 2, 2026. https://pharmanewsintel.com/features/reimagining-the-global-pharmaceutical-supply-chain
75. Access to medicines: making market forces serve the poor. World Health Organization. Published May 11, 2017. Accessed February 2, 2026. https://www.who.int/publications/m/item/access-to-medicines-making-market-forces-serve-the-poor
76. Research C for DE and. Safeguarding Pharmaceutical Supply Chains in a Global Economy. Food and Drug Administration. Published November 1, 2019. Accessed February 2, 2026. https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019
77. Jacob EC. Factors Involved in U.S. Generic Drug Shortages. US Pharmacist. Published June 18, 2020. Accessed February 2, 2026. https://www.uspharmacist.com/article/factors-involved-in-us-generic-drug-shortages
78. MacDonald K. The Future Of Pharmaceutical E-Commerce. Published September 14, 2021. Accessed February 2, 2026. https://www.forbes.com/sites/forbestechcouncil/2021/09/14/the-future-of-pharmaceutical-e-commerce/?sh=2fbf9f0e462d