US Specialty Pharmacies: A Guide to Mail-Order Providers

By Adrien Laurent, CEO at IntuitionLabs • 11/12/2025 • 45 min read

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vertical integration



Executive Summary

Mail-order specialty pharmacies are a critical component of the U.S. healthcare system's distribution network for high-cost, complex medications. These pharmacies provide specialized services – including careful handling, patient education, and financial assistance – for patients on biologics and other specialty drugs ([1] www.drugchannels.net) ([2] npiprofile.com). In recent years, the specialty pharmacy market has grown explosively; by 2024 U.S. pharmacy dispensing revenues for specialty drugs were about \$265 billion, roughly 39% of all pharmacy revenues ([3] www.drugchannels.net) ([4] www.drugchannels.net). The market is highly concentrated: the top three organizations (CVS Health, Cigna/Express Scripts, and UnitedHealth/Optum) account for roughly two-thirds of specialty drug dispensing revenue ([5] www.drugchannels.net) ([6] www.drugchannels.net). Major mail-order specialty pharmacy providers include PBM-affiliated pharmacies (e.g. Express Scripts

Pharmacy/Accredo, Optum Specialty Pharmacy, CVS Specialty/Aetna), chain-affiliated programs (e.g. Walgreens AllianceRx Prime, Walmart Specialty Pharmacy, Kroger Specialty), health-plan pharmacies (e.g. Kaiser Permanente Mail-Order Pharmacy, CenterWell Specialty Pharmacy in Humana), and large independents (e.g. PANTHERx, BrightSpring's Onco360, SenderraRx). These entities operate nationwide networks of mail-order and hub pharmacies that deliver specialty medications by courier and provide patient support.

Key trends shaping this sector include **vertical integration** (health insurers increasingly owning PBMs and specialty pharmacies), regulatory and reimbursement changes (e.g. 340B program dynamics, Medicare Part D mail-order mandates), and technological innovation (digital prescribing, patient monitoring). Case studies – such as the 2018 Cigna–Express Scripts merger ([7] www.fiercehealthcare.com), UnitedHealth's 2019 acquisition of Diplomat Pharmacy ([8] in.marketscreener.com) ([9] healthcaremedicalpharmaceuticaldirectory.com), and CVS's integration of Aetna's mail-order services – illustrate how strategic consolidations drive the industry. Evidence suggests mail-order specialty services can improve medication adherence and reduce overall costs: for example, most studies find higher adherence with mail-order dispensing ([10] pmc.ncbi.nlm.nih.gov), and one national analysis found Medicare Advantage patients using health-system specialty pharmacies had lower permonth healthcare costs ([11] pmc.ncbi.nlm.nih.gov).

This report provides a comprehensive examination of the mail-order specialty pharmacy sector in the USA, including its history, market structure, key players, business models, regulatory environment, patient outcomes, and future directions. It includes data-driven analysis, example company profiles, and expert insights. All claims are supported with citations from industry reports, peer-reviewed studies, government sources, and trade publications.

Introduction and Background

Mail-order pharmacy refers to pharmacies that dispense medications directly to patients via delivery services rather than in-person pickups. As defined by the U.S. National Plan and Provider Enumeration System (NPPES), a mail-order pharmacy is "a pharmacy whose primary business is to receive prescriptions or other medications and dispense them using common carriers to deliver the medications to patients or their caregivers" ([2] npiprofile.com). Mail-order pharmacies typically counsel patients by phone or email and may store medications centrally, shipping 60- or 90-day supplies. These services have grown with the rise of PBMs (Pharmacy Benefit Managers) and the desire for patient convenience and cost efficiency.

Specialty pharmacy is an area of practice within pharmacy that focuses on high-cost, complex medications often used to treat serious chronic or rare conditions. The Academy of Managed Care Pharmacy (AMCP) defines specialty pharmacy as pharmacies "designed to efficiently deliver medications with special handling, storage,

and distribution requirements" and to "improve clinical and economic outcomes for patients with complex, often chronic and rare conditions" ([1] www.drugchannels.net). In practice, specialty pharmacies dispense biologics, injectables, and other advanced therapies for diseases like cancer, rheumatoid arthritis, multiple sclerosis, HIV/AIDS, and rare genetic disorders. Such medications may require refrigeration, risk management programs (e.g. REMS), patient training in injection or infusion, and close clinical monitoring ([12] healthcaremedicalpharmaceuticaldirectory.com) ([1] www.drugchannels.net). Patients on specialty therapy often need extensive support – from benefit verification to financial assistance – which specialty pharmacies provide alongside medication distribution.

Mail-order specialty pharmacies thus combine both models: they are pharmacies that handle specialty medicines and deliver them by mail. Many of the largest pediatric and adult specialty medicines – including high-cost biologic drugs – are dispensed through mail-order specialty pharmacies. This model emerged as a solution for patients requiring complex therapies to ensure adherence and continuity of care, while also achieving economies of scale in distribution ([1] www.drugchannels.net) ([2] npiprofile.com). Over time, large PBMs and integrated health plans have built extensive specialty pharmacy networks, and independent specialty pharmacy companies have also proliferated. Today, nearly 1,800 U.S. pharmacy locations are accredited as specialty pharmacies by URAC or ACHC, indicating the sector's broad scope ([13] www.drugchannels.net).

As of 2025, mail-order specialty pharmacies are a **major distribution channel** for high-cost drugs in the U.S. The Drug Channels Institute reported that mail-order and specialty pharmacies (together with retail and long-term care pharmacies) dispensed about **\$265 billion** worth of specialty drugs in 2024 ([3]] www.drugchannels.net). This is roughly 39% of all U.S. pharmacy dispensing revenues. That share has grown dramatically from about 24% in 2013, reflecting the increasing prevalence of specialty therapies ([4]] www.drugchannels.net). The market is dominated by a few large pharmacy systems: in 2024 the three largest specialty pharmacy companies (all affiliated with vertically integrated insurers/PBMs) accounted for two-thirds of specialty dispensing revenues ([5]] www.drugchannels.net). Nonetheless, the specialty distribution channel remains diverse, as hospitals, clinics, and independent pharmacies also handle many specialty prescriptions. For example, hospitals and health systems now operate over a quarter of accredited specialty pharmacy locations, leveraging in-house pharmacies to manage specialty therapies ([14]] www.drugchannels.net).

Scope and Objectives. This report aims to catalog the major mail-order specialty pharmacies in the USA and to analyze the industry comprehensively. It includes:

- **Definitions and history** of mail-order and specialty pharmacy.
- Market analysis: size, growth, and share data (using sources like Drug Channels Institute).
- **Profiles of major providers**: including PBM-owned, retail, health plan, and independent specialty pharmacies.
- **Business and operational models**: how mail-order specialty pharmacies function (distribution logistics, insurance processes, patient support).
- Data and research findings: studies on adherence, outcomes, costs, and consumer trends related to mailorder specialty care.
- Case studies: examples of corporate mergers/acquisitions and their impact (e.g. Cigna/Express Scripts, Optum/Diplomat, Walgreens' specialty integration).
- **Regulatory and policy context**: the effect of legislation (e.g. Medicare Part D, state pharmacy laws, 340B program) on specialty pharmacy services.
- Stakeholder perspectives: including payers, providers, patients, and manufacturers.
- Future outlook: emerging trends (digital health, gene therapies, regulatory changes).

• Appendices and tables: summarizing lists of major pharmacies, market share data, and accreditation statistics.

Throughout, we cite data from credible industry reports, peer-reviewed journals, and regulatory sources. For clarity, tables are used to summarize data (e.g., leading specialty pharmacies by revenue), and inline citations support all factual claims.

Mail-Order vs. Specialty Pharmacy: Definitions and Evolution

Defining "Specialty" and "Mail-Order"

The term "specialty drug" generally refers to medications that require special handling or patient management. According to the Academy of Managed Care Pharmacy (AMCP), a specialty drug typically requires "a difficult or unusual process of delivery to the patient (preparation, handling, storage, distribution, REMS programs, etc.) or patient management prior to or following administration" ([15] www.drugchannels.net). Crucially, specialty drugs are often very high cost. Surveys show that most health plans use an average minimum cost threshold of several hundred to over a thousand dollars per month to deem a drug "specialty" ([16] www.drugchannels.net). These can include biologics like monoclonal antibodies, injectables, or oral molecules for rare diseases (e.g. specialty oncology therapies, hepatitis C antivirals, immunoglobulins, enzyme replacements, etc.) ([12] healthcaremedicalpharmaceuticaldirectory.com) ([15] www.drugchannels.net). Under specialty pharmacy benefit coverage, plans may impose higher copayments or specialty tiers.

A "specialty pharmacy" is not a legally defined type of pharmacy but a business model focused on dispensing specialty drugs and managing complex therapy patient populations. The AMCP definition emphasizes that specialty pharmacies are "distinct from traditional pharmacies" because they coordinate many non-dispensing aspects of care (patient education, side-effect management, financial assistance) and deliver medications with special handling requirements ($^{[1]}$ www.drugchannels.net). In practice, a pharmacy qualifies as a specialty pharmacy by choice and accreditation (via URAC or ACHC), offering comprehensive services for chronic complex conditions. Any licensed pharmacy can technically dispense a specialty medication if it accesses the product through wholesale channels ([17] www.drugchannels.net), but specialty pharmacies have become the primary channel for these drugs due to manufacturers and payers building limited networks.

Mail-order pharmacies, by contrast, are defined mainly by their fulfillment model: they dispense medications and ship them to patients' homes rather than operate a retail storefront. The NPPES taxonomy defines a Mail-Order Pharmacy as one that dispenses prescriptions "using common carriers to deliver the medications to patient or their caregivers" ([2] npiprofile.com). Mail-order pharmacies are licensed as such in each state and often focus on 90-day maintenance prescriptions. While retail chains may offer mail-order as an option, traditional "mail-order pharmacy" often refers to centralized facilities run by PBMs or other companies (e.g. Express Scripts Pharmacy, CVS Caremark, etc.).

A mail-order specialty pharmacy combines these concepts: it is a specialty pharmacy that primarily dispenses via mail. In practice, this includes the large PBM-owned specialty pharmacies and many independent specialty pharmacies which ship their products to patients. For example, Express Scripts' Accredo and Optum's CuraScript are specialty pharmacies that fulfill via mail. Many independent specialty pharmacies like PANTHERX or PharMerica also ship to patients nationwide. (Note: Infusion-only specialty providers that deliver medications directly to clinic infusion centers are not usually considered "mail-order," even though they are specialty pharmacies. This report focuses on specialty pharmacies that use mail delivery.)

Historical Context

The origins of mail-order pharmacy trace back decades, initially serving rural or convenience markets. However, its rapid expansion since the 1990s is tied to the rise of PBMs and the push to reduce costs. PBMs discovered that dispensing 90-day supplies via mail could improve adherence and lower per-unit costs. For example, Express Scripts launched large mail-order operations in the 1990s, and many insurers (like Aetna and Cigna) built or acquired mail-order capabilities. Meanwhile, specialty pharmacy emerged in the late 1980s and 1990s as new biological therapies (e.g. interferons for MS/hepatitis, HIV antivirals, cancer drugs) came to market. Initially, manufacturers created "limited distribution networks" for complex therapies to control distribution and provide patient support, and specialty pharmacies systematized the delivery of these drugs to patient homes.

By the 2000s, specialty pharmacies were well-established. Examples of early specialty pharmacy companies include Walgreens' Coram (infusion), Accredo (founded by Express Scripts in 2000), and PharMerica (long-term care specialties). Concurrently, independent specialty pharmacies like Biologics Inc. (founded 1968, now part of Cencora) and Diplomat (1975, now part of UnitedHealth) grew by partnering with provider clinics to ship drugs to patients. The 2010s saw huge consolidation: the ACA era and 340B expansion led hospitals to build in-house specialty pharmacies, while PBMs merged with insurers (e.g. Cigna-Express Scripts, CVS-Aetna, UnitedOptum acquisitions) so that nearly every large insurer ended up owning a mail-order specialty pharmacy.

A turning point was the widespread **vertical integration** of PBMs with payers: by 2020, the three largest specialty pharmacies (CVS-Aetna, Express Scripts-Cigna, and Optum-UnitedHealth) were all part of insurers with captive specialty distribution ([5] www.drugchannels.net) ([18] www.fiercehealthcare.com). For example, Cigna's acquisition of Express Scripts in late 2018 for \$67 billion ([7] www.fiercehealthcare.com) brought together a top insurer and the nation's largest specialty pharmacy. CVS Health similarly completed its merger with Aetna in 2018 and combined Aetna's mail-order with CVS's own specialty network. These moves concentrated specialty dispensing with the payers' own pharmacies, partly to leverage bargaining power and share data.

In parallel, technology and consumer trends fueled mail-order growth. The launch of **Amazon Pharmacy** (via its 2018 acquisition of PillPack) signaled disruption: Amazon enables home delivery of generics and branded medications through a subscription model, and in 2020 expanded to prescription drugs. PBMs responded by "opening" mail networks. For instance, Express Scripts announced in October 2018 that it would allow *all* mail-order pharmacies (including Amazon/PillPack) to access its network ([19] www.beckershospitalreview.com) – a notable shift away from exclusivity enforced by previous litigation. Such developments underscore an evolving landscape where ease of delivery and patient choice are increasingly emphasized.

In summary, mail-order specialty pharmacy has grown from a niche model to a dominant distribution method for many of the most expensive drugs. Its history is intertwined with PBM strategies, insurance consolidation, and regulatory changes. The following sections detail the current state of this sector, its major participants, and its effects on stakeholders.

Market Overview and Key Data

Size and Growth of the Specialty Pharmacy Market

The U.S. specialty pharmacy market is both large and rapidly growing. Drug Channels Institute (DCI) estimates U.S. pharmacy dispensing revenues for specialty drugs reached \$243 billion in 2023 and \$265 billion in 2024 ([20] www.drugchannels.net) ([3] www.drugchannels.net). This represents growth of about 8–9% year-over-year, reflecting new expensive therapies (e.g. gene therapies, new biologics) coming to market. Specialty drugs now



constitute roughly 38–39% of total U.S. pharmacy prescription revenues (^[20] www.drugchannels.net) (^[4] www.drugchannels.net). (For comparison, specialty's share was only about 24% in 2013 (^[4] www.drugchannels.net), illustrating its strong expansion over the last decade.)

This growth is driven by three main factors:

- **Pipeline and approvals**: Numerous new specialty treatments (for cancer, autoimmune diseases, rare conditions) have been approved or are in development, often at very high prices. For example, estimated average annual costs for specialty therapies can exceed \$100,000 per patient ([21] healthcaremedicalpharmaceuticaldirectory.com).
- Payer strategies: Insurers and PBMs often steer patients to mail-order specialty pharmacies to manage utilization. Limited distribution networks (LDNs) set by manufacturers funnel patients to pre-selected pharmacies, often those owned by or contracted with the PBM.
- Aging population: More patients with chronic conditions live longer with specialty medications (e.g. hepatitis C was historically fatal but now curable with specialty antivirals).

By comparison, the entire U.S. retail and mail pharmacy dispensing market (including all drugs) was about \$700 billion in 2023 ([20] www.drugchannels.net). Specialty's \$243B thus approaches two-fifths of that total. Growth in specialty is outpacing traditional drugs; indeed, DCI notes that specialty's share of pharmacy revenue has risen steadily until a slight recent plateau. Factors like the entry of biosimilars and generics are moderating specialty spending growth in 2023–2024 ([22] www.drugchannels.net) ([4] www.drugchannels.net), but the overall trend remains upward.

A detailed breakdown by participant type reveals a concentrated yet diverse market. DCI's analysis of accredited specialty pharmacies (URAC/ACHC) shows about **1,749 unique locations** in 2023 ([13] www.drugchannels.net). Of these, roughly:

- Street pharmacies (about 60%) are chain or independent retail pharmacies that have accreditation to dispense specialty drugs (though many of these locations are not mail-order per se, they may do some mailing).
- Specialty-only/mail hubs (about 40%) are dedicated mail-order or hub pharmacies (often closed-door) operated by PBMs, health systems, wholesalers, or independent specialty companies.

Hospitals and health networks account for about 27% of accredited specialty pharmacies in 2024 ([14] www.drugchannels.net), up from 15% in 2017, reflecting hospital system investment in in-house specialty pharmacies (often driven by 340B program synergies). Independent specialty chains and PBM-owned chains each constitute meaningful shares of locations but capture much larger shares of revenue. DCI finds that the top three companies (CVS Health, Cigna/Express Scripts, UnitedHealth/Optum) capture about two-thirds of specialty drug dispensing revenue ([5] www.drugchannels.net) ([6] www.drugchannels.net). In numerical terms, CVS Specialty (\$73.3B) and Accredo/Freedom Fertility (Express Scripts/Cigna, \$59.5B) alone together accounted for over \$130 billion in revenue in 2023 ([23] www.beckershospitalreview.com). A handful of others (Optum Specialty ~\$32B, Walgreens ~\$8B) fill out the largest slots ([24] www.beckershospitalreview.com).

Table 1 lists the **top specialty pharmacy organizations** by 2023 revenue (including all dispensing settings). These figures come from the DCI/Becker's Hospital Review report ([23] www.beckershospitalreview.com):

Rank	Specialty Pharmacy (Parent Entity)	2023 Specialty Drug Revenue
1	CVS Specialty (CVS Health)	\$73.3 B ([23] www.beckershospitalreview.com)
2	Accredo/Freedom Fertility (Express Scripts/Cigna)	\$59.5 B (^[23] www.beckershospitalreview.com)
3	Other retail/mail/LTC/Specialty pharmacies (aggregate)	\$37.4 B ([23] www.beckershospitalreview.com)



Rank	Specialty Pharmacy (Parent Entity)	2023 Specialty Drug Revenue
4	Optum Specialty Pharmacy (UnitedHealth/OptumRx)	\$32.3 B (^[24] www.beckershospitalreview.com)
5	AllianceRx Walgreens Pharmacy / Walgreens stores	\$ 8.4 B ([25] www.beckershospitalreview.com)
6	CenterWell Specialty Pharmacy (Humana)	\$ 6.2 B ([26] www.beckershospitalreview.com)
7	Onco360 Oncology Pharmacy / CareMed (BrightSpring Health)	\$ 4.6 B ([27] www.beckershospitalreview.com)
8	PANTHERx Specialty Pharmacy (Independently owned)	\$ 3.6 B ([28] www.beckershospitalreview.com)
9	Walmart Specialty Pharmacy / Walmart pharmacies	\$ 3.4 B (^[29] www.beckershospitalreview.com)
10	Kroger Specialty Pharmacy / Kroger pharmacies	\$ 3.2 B ([30] www.beckershospitalreview.com)

Table 1. Top 10 U.S. specialty pharmacies (by 2023 dispensing revenue) ([23] www.beckershospitalreview.com). Values are 2023 revenues for specialty medications (all dispensing settings). "Other retail/mail/LTC" (rank 3) aggregates many smaller providers.

These figures illustrate that while a few players dominate, a long tail of providers makes up the remainder. Ranked #11-15 (not shown) include Centene's Acaria Health, McKesson's Biologics/RxCrossroads, Texas-based SenderraRx, AIDS Healthcare Foundation's AHF Pharmacy, and Navitus's Lumicera ([31] www.beckershospitalreview.com). Beyond that, hundreds of smaller specialty pharmacies and thousands of clinicbased dispensing points operate under various accreditations.

In summary, mail-order specialty pharmacies constitute a major share of the U.S. prescription drug market. The multi-billion-dollar scale of this channel has broad implications: it affects drug pricing negotiations (PBMs' leverage), patient access, and even healthcare outcomes. The following sections examine the key players and business models in detail.

Major Mail-Order Specialty Pharmacy Providers

Given the fragmented landscape, we categorize the principal mail-order specialty pharmacy providers by type. Table 2 (below) highlights representative organizations in each category along with their affiliation and role. It is not exhaustive, but covers the largest and most influential players:

Provider / Program	Type / Owner	Description (Mail-Order Specialty)
Express Scripts Pharmacy (Accredo)	PBM-owned (Cigna/Evernorth)	Major mail-order and specialty pharmacy operations. <i>Accredo Pharmacy</i> is Express Scripts' specialty division handling biologics for chronic illness; <i>Express Scripts Mail</i> (formerly ESI) fills 90-day generics and some specialty. Parent: Cigna/Evernorth after 2018 merger ([7] www.fiercehealthcare.com).
Optum Rx Mail- Order (Optum Specialty)	PBM-owned (UnitedHealth Group/Optum)	UnitedHealth's PBM. Optum acquired Diplomat (2019) and rebranded its specialty arm as <i>Optum Specialty Pharmacy</i> . It services infusions and oral specialty nationwide. Parent: UnitedHealth (Optum) (^[8] in.marketscreener.com) (^[9] healthcaremedicalpharmaceuticaldirectory.com).
CVS Caremark / Aetna Pharmacy	PBM-owned (CVS Health)	CVS's PBM and health plan. Merged with Aetna in 2018. Includes CVS Caremark Mail Order (for generics, 90-day supplies) and CVS Specialty Pharmacy (for specialty drugs). Processes Aetna and other plan patients; also operates Coram infusion branch for IV therapies ([23] www.beckershospitalreview.com).
Walgreens AllianceRx Prime	Joint venture (Walgreens/Prime	Specialty pharmacy network created to serve Blue Cross plans. Formed by Walgreens Boots Alliance and Prime Therapeutics (BCBS-owned PBM).

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Provider / Program	Type / Owner	Description (Mail-Order Specialty)
	Therapeutics)	Dispenses specialty meds via mail and in-store specialty modules. As of 2025,
		covers ~10% specialty volume ([13] www.drugchannels.net).
IngenioRx / Anthem Pharmacy	PBM / health plan (Anthem/BCBS)	Anthem's (BCBS) PBM launched in 2018. IngenioRx operates mail-order and specialty pharmacies. Anthem also has regional generic mail service. Anthem's plans increasingly direct members to IngenioRx for specialty.
CenterWell Specialty Pharmacy (RightSource)	Health plan (Humana)	RightSource by Humana, now rebranded CenterWell, provides mail-order and specialty pharmacy for Humana members. Focus on chronic therapies with adherence support. Pays attention to home delivery for seniors.
Walmart Specialty Pharmacy	Retail chain (Walmart Inc.)	Walmart launched specialty pharmacy services integrated with its retail stores. Offers mail delivery of specialty meds (some via mail, some via store pickups). Partnered in 2022 with UpScriptRx for mail services. Handles both retail and specialty, though specialty revenue is modest ([30] www.beckershospitalreview.com).
Kroger Specialty Pharmacy	Retail/grocery (Kroger Co.)	Kroger's pharmacy division includes specialty. Mail-order network via KrogerRx, focused on specialty immunology and oncology drugs. Dispenses through Kroger and affiliate pharmacies.
Biologics, Inc. / McKesson	Wholesaler-owned (McKesson)	McKesson's specialty pharmacy business, called <i>Biologics/RxCrossroads</i> , handles distribution of limited-distribution specialty products (including gene therapies) and fill/refill programs. Provides hub services for manufacturers.
BrightSpring Health Services (Onco360, CareMed)	Independent chain (BHHC)	BrightSpring (formerly PharMerica) owns <i>Onco360</i> (specialty infusion pharmacy) and <i>CareMed Specialty</i> . Provides mail-order and infusion (through franchised centers). Focuses on oncology and rheumatology injectables.
PANTHERX Specialty Pharmacy	Independent	Founded 2009, concentrated on hepatitis C and specialty meds via mail. Grew rapidly through acquisitions (Holston, others). Services patients nationwide with slow details.
AcariaHealth	Health plan affiliate (Centene Corp.)	Centene's owned specialty pharmacy covers its Medicaid/Medicare members. Dispenses via mail for specialty products (esp. for rare diseases, HIV).
SenderraRx (Blue Cross Texas)	Independent/PBM (Anthem-affiliate)	Specialty pharmacy network for Anthem Advantage plans in Texas. Dispenses specialty and injectables by mail for BCBS members.
Kaiser Permanente Mail Order Pharmacy	Health system (Kaiser Permanente)	Integrated health plan's mail order service for all medications (including specialty) provided to Kaiser members. Focuses on adherence and coordination within Kaiser's system.
Veterans Health Administration (VHA)	Government (VA)	VHA operates its own mail-order pharmacy for veterans, including many specialty meds for VA patients. (Not part of the open market PBM system.)

Table 2. Representative mail-order specialty pharmacy providers in the USA. Each entry includes notable examples and organizational ownership.

This table illustrates the various business models:

- **PBM-owned**: Many insurers own PBMs which in turn operate mail-order specialty pharmacies (e.g. Express Scripts with Accredo, Optum with OptumRx, CVS/Aetna). These combine pharmacy benefit management with an in-house distribution channel ([7] www.fiercehealthcare.com) ([8] in.marketscreener.com).
- **Retail-affiliated**: Traditional pharmacy chains have leveraged mail services or created specialty divisions. Walgreens/BSC created *AllianceRx Prime* in partnership with Prime Therapeutics to serve Blue plans, backed by Walgreens' network ([25] www.beckershospitalreview.com). Retail leaders like Walmart and Kroger



also have specialty programs (though their specialty revenues are smaller relative to their overall pharmacy business ([30] www.beckershospitalreview.com)).

- Health plan-owned: Some integrated delivery systems manage their own mail pharmacies. Kaiser Permanente's well-known mail service fills most prescriptions for Kaiser enrollees, including specialty drugs ([32] kphighlights.kaiserpermanente.org). Humana's specialty pharmacy (formerly RightSource) serves its members with mail delivery and care management. These captive models aim to tie pharmacy use directly into clinical management.
- Independent specialty chains and nonprofits: Companies like PANTHERX, BrightSpring (Onco360/CareMed), and SenderraRx are not owned by PBMs but have grown large by contracting with PBMs or plans. For example, PFSC (BrightSpring) was the parent of Onco360, which was once a leading independent oncology pharmacy ([27] www.beckershospitalreview.com). Nonprofit providers like the AIDS Healthcare Foundation's Pharmacy also dispense large volumes of HIV specialty drugs.

It is important to note that "specialty pharmacy" is not legally exclusive - any pharmacy can dispense a specialty medication. However, many plans restrict certain drugs to designated specialized pharmacies. Mailorder specialty pharmacies often operate closed-door (no retail front), focusing solely on hub operations. Others, like AllianceRx, use "hybrid" models with central mail facilities plus drop-ships in retail stores.

Accreditation and Quality

Ubiquitous accreditation helps standardize services. The two main accrediting bodies are URAC and ACHC. By 2023, nearly 1,800 U.S. pharmacy locations had specialty accreditation ([13] www.drugchannels.net). URAC's recognition means meeting quality measures (e.g. medication management, patient communications, data reporting). For example, URAC-certified pharmacies must show high Medication Possession Ratios (MPRs) and robust patient outreach programs. Accreditation is often required by manufacturers and payers to participate in specialty networks.

Mail-order specialty pharmacies typically use sophisticated dispensing technology and oversight. Many use automated dispensing robots, barcoding, and temperature-controlled systems. Some maintain their own fulfillment centers. For instance, Walgreens describes having four central specialty pharmacies holding multiple national accreditations and nearly 300 community-based specialty locations across the U.S., staffed by ~1,500 specialty pharmacists ([33] www.walgreensbootsalliance.com) ([34] www.walgreensbootsalliance.com). This scale allows Walgreens to handle complex therapies and scattered patient populations.

Business Models and Service Delivery

Mail-order specialty pharmacies provide end-to-end patient services beyond just "filling a script". Key features include:

- Centralized distribution: Most mail-order specialty pharmacies use central fulfillment centers (often off-site/"closed door"). For example, Express Scripts' Accredo and Optum Specialty have large mail-order hubs. Centralization enables handling of temperature-sensitive biologics, complex packaging, and large volume. They often ship via overnight or two-day
- Hub-and-Spoke networks: Many specialty drugs are handled via a hub pharmacy that acts as a coordination center. The hub verifies insurance, obtains prior authorizations, arranges financial assistance, and ships the drug to the end patient (or occasionally to an infusion clinic). For example, Biogen's Spinraza for spinal muscular atrophy uses a dedicated hub that connects physicians to distributor pharmacies.



- Patient management and clinical support: By definition, specialty pharmacies provide education, counseling, and
 monitoring. They often employ nurse educators and pharmacists who regularly call patients about side effects, adherence,
 and labs. For instance, the AMCP definition highlights specialty pharmacists' roles in "patient education...ensur [ing]
 appropriate medication use, promot [ing] adherence" ([35] www.drugchannels.net). Many pharmacies offer adherence
 tools (reminder calls, apps) and coordinate with providers.
- Financial assistance navigation: Because many specialty drugs are extremely costly, specialty pharmacies assist patients with co-pay assistance and foundations. They coordinate manufacturer co-pay cards or patient assistance programs. This is a major component of "navigating financial toxicity" for patients.
- Insurance benefit optimization: Specialty pharmacies routinely conduct benefits investigations to determine whether the drug should be billed through medical benefit or pharmacy benefit**. Decisions here impact coverage and billing. For example, if a therapy is physician-administered (IV), it often goes through medical benefit ('buy-and-bill'). If self-administered, it goes through specialty pharmacy/Pharmacy benefit. Specialty pharmacies ensure claims are routed correctly and coordinate with PBMs.
- **Delivery model**: Typically, patients receive 30- to 90-day supplies shipped to home or clinic. Some pharmacies allow direct router (like FedEx) delivery to the healthcare professional's office for clinic-administered injectables (e.g. oncology injections for self-administration).
- Compliance packaging: Pharmacies may offer packaging (pill organizers, injection kits with syringes pre-filled), though with specialty injectables often prefilled by the manufacturer.

These services differ sharply from a typical retail pharmacy interaction. The additional care coordination of specialty pharmacies is one reason why *studies associate them with improved adherence*. Indeed, multiple analyses find that patients on chronic medication regimens who use mail-order or specialty pharmacies tend to have higher adherence rates than those using retail pharmacies. A systematic literature review found 14 out of 15 studies reported better adherence for mail-order versus retail for chronic meds ([10] pmc.ncbi.nlm.nih.gov). By handling reorders centrally, eliminating frequent trips, and offering reminder services, mail-order specialty pharmacies help patients stay on therapy.

Mail-Order vs. Retail: Comparative Considerations

Mail-order specialty pharmacies extend the traditional mail-order model into high-touch care. Some comparative points:

- Access and Convenience: Mail-order pharmacies deliver directly to patients, which is especially helpful for homebound or rural patients. They often dispense 90-day supplies, reducing refill hassles. Retail pharmacies require physical pick-up or shorter (30-day) fills. However, some retail chains offer mail delivery or drive-through services as well.
- Adherence and Outcomes: As noted, mail-order often improves adherence for chronic meds ([10] pmc.ncbi.nlm.nih.gov). Retail pharmacists may still inadvertently "lose" continuity if patients switch pharmacies. Specialty mail-order pharmacies proactively perform refill outreach, which can boost long-term persistence.
- Personal Interaction: Retail pharmacies allow face-to-face contact, which some patients prefer. Specialty mail-order services compensate with phone consulting. They may lack local presence, but often offer 24/7 pharmacist hotlines.
- Cost and Formulary: PBMs often incentivize mail-order by offering lower copays for 90-day mail orders. Conversely, some insurance plans force patients to use mail-order (or face higher retail costs), which has been controversial. State legislatures have occasionally stepped in to prohibit mandated mail-order except at patient's choice.

Overall, most insurers and employers recommend mail-order for maintenance drugs (including specialty) to manage costs and adherence. As of recent estimates, a substantial portion of specialty drugs in the U.S. are dispensed via mail-order or home delivery networks managed by PBMs or specialty pharmacies ([13] www.drugchannels.net) ([3] www.drugchannels.net).

Market Dynamics and Strategies

Vertical Integration and PBM Dominance

One of the defining features of the specialty pharmacy sector is **vertical integration**. The largest national players combine insurance, PBM, and pharmacy services under one corporate roof. For example:

- CVS Health: After acquiring Caremark (PBM) and Aetna (insurer), all mail-order and specialty pharmacies under CVS (CVS Caremark Mail, CVS Specialty) serve CVS insurance customers and others. CVS Specialty (the specialty pharmacy arm) became the largest player by volume ([23] www.beckershospitalreview.com).
- Cigna/Evernorth: In 2019, Cigna closed its purchase of Express Scripts (\$67B) (^[7] www.fiercehealthcare.com). This merged the former Express Scripts PBM (with its specialty division Accredo) and Cigna's own health plan, creating a specialty pharmacy juggernaut.
- UnitedHealth: United owns OptumRx (PBM) and Optum Specialty. United's Optum acquired Diplomat Pharmacy (nationwide specialty provider) in late 2019 for ~\$320M (^[8] in.marketscreener.com), bolstering its specialty reach and infusion services (^[9] healthcaremedicalpharmaceuticaldirectory.com).
- Humana and Anthem have smaller PBMs but still significant. Anthem's newly-formed IngenioRx (2021) is an example of an insurer creating its own chain to capture specialty prescriptions.

This integration means the dominant payers often process the drug order (PBM) and also fill it (specialty pharmacy). A key consequence is **conflict of interest or market power**: PBM-owned specialty pharmacies often charge themselves lower markups and benefit from spread on brand discounts. Recent FTC findings showed the "Big Three" PBMs (CVS Caremark, Express Scripts, OptumRx) collectively profited over \$7.3 billion by marking up prices of specialty generic drugs for conditions like cancer ([36] www.axios.com). This exemplifies how vertical integration can lead to higher profits that are not entirely transparent to patients or employers. Payers emphasize that integrated ownership also allows for better care coordination and cost control, viewing it as synergies.

By contrast, **independent specialty pharmacies** often sign contracts with multiple PBMs to get patient referrals. They compete by offering personal service or specialized disease expertise. However, they generally command thinner margins as PBMs steer business to their in-house pharmacies. DCI notes that independents have the largest count of locations but a shrinking revenue share ([37] www.drugchannels.net). Many independents have been acquired in recent years (e.g. by hospital systems or larger chains). The net result is that most specialty mail-order volume is steered to PBM-owned chains (two-thirds of revenue ([5] www.drugchannels.net)) even though many independents still exist on the accreditation rolls ([13] www.drugchannels.net).

Reimbursement and Pricing

Specialty pharmacy reimbursement is complex. Under a patient's plan, specialty drugs may be paid from pharmacy benefit or medical benefit depending on route and setting. If covered under medical benefit (e.g. doctor-administered infusion), the drug often excludes the specialty pharmacy altogether (the provider "buys and bills" from hospital/inventory). Specialty pharmacies mainly handle drugs under pharmacy benefit – either self-administered injections or pills. Within the pharmacy benefit, payers often carve out specialty to tier it differently (e.g. 20% coinsurance vs 10% for generics).

PBM-owned specialty pharmacies can realize "spread" in pricing. For example, suppose a specialty drug costs \$100, a manufacturer rebates \$20 to insurer through the PBM, but the PBM pays \$80 to the pharmacy and collects \$100 from the insurer. The \$20 difference is "spread" revenue. In vertically integrated models, the PBM/insurer and pharmacy are the same entity, so this spread accrues in-house, potentially inflating profits ([38] www.drugchannels.net) ([36] www.axios.com). This structure has drawn criticism for lacking transparency.

Additionally, many specialty pharmacies participate in manufacturer copay accumulators and maximizers programs. These limit how manufacturer copay assistance counts toward a patient's deductible. Some PBMs even run programs where a portion of a manufacturer copay (\$X) is retained by the pharmacy or PBM as a service fee, while the patient pays some direct copay. These arrangements (e.g., the "copay of record" issue) drive conflict between patient advocates and PBMs, but are part of the modern specialty pharmacy payment milieu.

Competition and Networks

Because most specialty drugs are dispensed through limited networks, manufacturers and payers wield influence over pharmacy participation. Drug companies often contract with a handful of specialty pharmacies (e.g. through the "limited distribution network" or "wholesale acquisition process") for a given drug, to ensure appropriate support services. Hospitals and health systems have lobbied to expand contracting, since manufacturers' restrictions sometimes disqualify 340B hospitals unless they own the pharmacy doing the dispensing.

Recently, PBMs have begun opening up their networks. The 2018 Express Scripts example ([19] www.beckershospitalreview.com) opened door for more competitors (especially Amazon's PillPack) to join what had been a closed PBM mail network. That change was partly spurred by antitrust litigation and by market pressure. Today, some retailers (CVS, Walmart, Rite Aid) and independent mail-order pharmacies can contract with major PBMs to serve specialty patients, not just the PBM's in-house pharmacy. However, many PBM networks still favor their own pharmacies for dispensing speed and margin.

Price competition among specialty pharmacies themselves is minimal because of third-party payers: patients typically pay coinsurance on the plan's negotiated price, and PBMs or insurers collect the remainder. Thus, pharmacies compete on service and network contracts rather than on transparent price.

Patient Impact, Adherence, and Outcomes

Medication Adherence and Clinical Outcomes

Specialty pharmacy models emphasize adherence, because specialty drugs are only effective if taken regularly and many treat life-threatening conditions. Studies show that mail-order dispensing can significantly improve adherence. For example, a literature review found that in chronic illness, patients receiving meds via mail-order pharmacies had higher medication possession ratios than those using retail pharmacies (14 of 15 studies reviewed showed higher adherence with mail-order) ([10] pmc.ncbi.nlm.nih.gov). The reasons may include fewer refill lapses, automated reminders, and larger supply allotments.

Specialty pharmacies also coordinate closely with clinicians. They may use data from prescription claims and lab reports to intervene if a patient is non-adherent. The goal is to maintain consistent therapy, since lapses in specialty medication can lead to hospitalizations or loss of efficacy. For example, interruption of rheumatoid arthritis injections can cause flares, and missed HIV antivirals can lead to resistance.

Evidence suggests these efforts yield better outcomes and even lower costs. A multicenter study of Medicare Advantage patients showed that users of health-system specialty pharmacies had lower healthcare costs than peers. After one year, average monthly per-patient costs were about \$7,060 for specialty-pharmacy users vs \$8,152 for a matched comparison group ([11] pmc.ncbi.nlm.nih.gov). Although this is one study, it implies that robust specialty pharmacy care (often integrated with clinic providers) can reduce hospitalizations and freestanding office visits, likely by improving disease control.

Patient and Provider Perspectives

From patients' perspective, mail-order specialty can be convenient but has trade-offs. Many patients report satisfaction with home delivery, especially those on complex regimens, disabled patients, or those far from a pharmacy. Specialty pharmacies often provide educational materials and 24/7 support, which many patients find helpful. However, some patients miss face-to-face interaction; minor issues or clarifications can be less convenient by phone. Additionally, shipping errors or delays (rare but possible) can be more critical for lifesustaining meds. Thus, some patients opt for local specialty pharmacies when allowed (e.g. hospital-based specialty pharmacy).

Healthcare providers and infusion centers often view specialty pharmacies as necessary but sometimes problematic. For instance, if a drug is limited by distribution, a provider may need to coordinate with a specific pharmacy for patient meds, which adds administrative burden. A qualitative study of providers noted frustration when patients had to switch pharmacies due to formulary changes or network rules ([39] www.pharmacytimes.com). However, when specialty pharmacies send nurses or educators to clinics, clinicians appreciate that teamwork in monitoring complex therapies.

For pharmacies, the shift to mail-order specialty has eroded revenues in retail settings. Independent drugstores have lobbied for laws preventing insurers from mandating mail-order, arguing for "pharmacy choice." Some states now allow patients to fill 90-day supplies at local pharmacies. The debate continues between supporting community pharmacists and the efficiency benefits of mail-order.

Case Studies and Industry Developments

Several real-world examples illustrate the mail-order specialty pharmacy landscape and its evolution:

Express Scripts and Amazon/PillPack

In 2018, Express Scripts - then the largest PBM - announced it would open its mail-order network to any properly credentialed mail-order pharmacy ([19] www.beckershospitalreview.com). This move came after a lawsuit by PillPack (and two ex-CSX executives behind it) claimed Express Scripts illegally excluded them. Following massive industry pressure (including Amazon's entry into pharmacy), Express Scripts agreed to allow competitors' mail operations. In practice, this meant Amazon's PillPack (acquired in 2018) could start filling prescriptions for Express Scripts members. This case highlights how mail-order networks were previously closed, and how integration of marketplaces is changing access. It also foreshadowed Amazon's 2020 launch of Amazon Pharmacy (retail and mail prescription fulfillment).

Walgreens and Gene/Cell Therapies



In 2024, Walgreens Boots Alliance (WBA) consolidated its specialty assets under Walgreens Specialty Pharmacy. The company invested in a new Gene & Cell Therapy Services center (18,000 sq ft in Pittsburgh) specifically to handle the unique supply chain of CAR-T and gene therapies ([33] www.walgreensbootsalliance.com). Walgreens now boasts four nationwide specialty centers and ~300 communitybased specialty locations ([40] www.walgreensbootsalliance.com) - more than any other retail chain - staffed by thousands of specialist pharmacists and nurses. This strategy is a forward-looking response to expected growth in advanced therapies. It also highlights the blend of retail infrastructure (neighborhood presence) with centralized mail logistics. WBA's press release notes these investments improve patient access and adherence for rare diseases ([41] www.walgreensbootsalliance.com). In effect, Walgreens is building a hub-and-spoke model: centralized hubs ensure handling of new modalities, while local branches maintain patient ties - a hybrid mailand-clinic approach.

UnitedHealth/Optum and Diplomat

On December 9, 2019, UnitedHealth Group's OptumRx entered an agreement to buy Diplomat Pharmacy, Inc. (a publicly traded specialty pharmacy) for roughly \$320 million ([8] in.marketscreener.com). Diplomat, based in Flint, Michigan, was one of the largest independent specialty pharmacies, serving all 50 states with specialty drugs and infusion services ([9] healthcaremedicalpharmaceuticaldirectory.com). Its acquisition gave UnitedHealth extensive new specialty pharmacy capacity and expertise. Optum completed the tender offer in early 2020 ([8] in.marketscreener.com). By merging Diplomat's sites into Optum Specialty, UnitedHealth reinforced its position as a national specialty provider. This case study shows how even "pure-play" specialty firms are being absorbed to achieve scale.

Hospital/Health System Specialty Pharmacy Growth

Hospitals have aggressively built their own specialty pharmacies in recent years. For example, Kaiser Permanente - a fully integrated health system - has one of the largest in-house specialty pharmacies in the country (dispensing millions of specialty scripts annually) ([42] healthy.kaiserpermanente.org). Other systems like UPMC (University of Pittsburgh), UCLA Health, and Providence (with their US Bioservices) operate networks that serve internal patients. This trend relates to 340B concerns: since manufacturer restrictions on outside pharmacies tighten, hospitals use internal pharmacy to capture revenue. Studies from such health systems suggest these integrated specialty programs improve adherence and reduce costs ([11] pmc.ncbi.nlm.nih.gov), For patients of these systems, mail-order from the hospital's own pharmacy is the standard if covered under pharmacy benefit.

Regulatory and Policy Environment

The mail-order specialty model interfaces with several regulatory domains:

• Medicare Part D: Federal guidelines allow Part D plans to require 90-day fills through mail order but must offer an equal plan (same copayment) for fill at a network retail pharmacy. Some Medicare contracts use mandatory mail for maintenance drugs. Amazon Pharmacy RxPass now even includes a \$5/month program open to Medicare members ($^{[43]}$ www.reuters.com). Policy makers have considered whether to encourage or restrict mandatory mail usage.

- 340B Drug Pricing Program: Specialty pharmacies are deeply tied to 340B. Many hospital systems use their acquired specialty pharmacy to dispense for 340B eligible patients, generating higher margins (because they buy at 340B discount but bill full price to payers). Recently, manufacturers have responded by creating exclusive distribution channels (often through manufacturer-owned pharmacies) to limit 340B contract pharmacy growth. The result is a tug-of-war: hospitals build more clinics, while manufacturers limit which pharmacies can dispense certain drugs. These dynamics strengthen hospital-run specialty pharmacies (which take work in-house to remain 340B-eligible) ([14] www.drugchannels.net).
- State laws: Some states have enacted laws to protect pharmacies. For example, certain statutes ban an insurer from requiring a patient to use mail-order or limit the choice of pharmacy network. Others mandate that co-pays at point-of-sale for mail vs retail must be cost-equivalent. This is a response to independent pharmacists' concerns. Each state differs.
- Accreditation and drug regulations: Specialty pharmacies must comply with the same pharmacy laws plus additional requirements. For refrigerated biotech, federal law requires chain-of-custody procedures. For drugs with REMS or risk programs, specialty pharmacies must follow strict patient enrollment procedures, Accreditation organizations (URAC, ACHC) have specialty-specific standards that pharmacies must meet to contract for many specialty products.

In general, the regulatory framework around mail-order specialty pharma is evolving. Increasing scrutiny on PBMs is likely to affect specialty pharmacies, perhaps demanding more transparency in fees and patient costs. Meanwhile, the COVID-19 pandemic accelerated interest in home delivery of all medications, including specialty - regulators temporarily relaxed some restrictions (for example, allowing emergency remote dispensing measures). Going forward, state and federal oversight may adjust to balance innovation (mail delivery convenience) against concerns about market power.

Data Analysis and Evidence

Robust quantitative data on specialty pharmacies can be gleaned from industry reports and studies:

- Market Concentration: As noted, the top three providers dominate revenue share ([5] www.drugchannels.net) ([6] www.drugchannels.net). Drug Channels reports (via DCI) show that, for example, CVS Health and Cigna-Express accounted for roughly 50% of specialty dispensing in 2023 ([23] www.beckershospitalreview.com). This concentration implies that changes affecting one of these (e.g. legal or regulatory) will have outsized market impact.
- Revenue Growth Rates: DCI's data indicate about 8% year-over-year growth from 2023 to 2024 ([3] www.drugchannels.net). Certain segments grew even faster - for example, health system SPs had been growing double digits year-over-year as hospitals rushed into the market. Independent SP revenue growth has slowed as mergers peaked around 2016 ([44] www.drugchannels.net).
- PBM Profitability: Internal analyses suggest specialty drugs now drive a significant portion of PBM profits. In 2024, specialty dispensing accounted for one-third of PBM gross profits ([38] www.drugchannels.net), partially due to spreads and 340B contract revenues. This profit margin incentive partly explains why insurers direct patients into narrow specialty networks.
- Accreditation Trends: The number of accredited specialty pharmacy locations grew more than fivefold from 2015 to 2023 $^{[13]}$ www.drugchannels.net), reflecting industry investment in meeting standards. However, since 2019 this growth has plateaued somewhat, as market consolidation slows new entrants.
- Cost and Utilization: The Hellems et al. study in JMCP (2022) found that among Medicare Advantage patients, use of a health-system specialty pharmacy (where prescriptions and clinic visits are coordinated) correlated with lower total healthcare costs ([11] pmc.ncbi.nlm.nih.gov). Specifically, per-member per-month costs were ~\$7,060 for the specialty pharmacy cohort vs ~\$8,152 for the comparison after one year, a statistically significant difference. (This controlled for patient risk). This suggests integrated specialty care can improve outcomes or substitute less costly services (fewer ER visits/hospitalisations).



- Adherence Statistics: Pharmacy Times notes that nonadherence to medications is a huge issue (30-50% of treatment failures; 125,000 deaths annually in the U.S. can be linked to nonadherence ([45] www.pharmacytimes.com)). While these numbers cover all meds, specialty pharmacy interventions target those very problems: Pharmacy Times estimates up to 30% of prescriptions are never filled ([46] www.pharmacytimes.com). By offering home delivery and support, specialty pharmacies aim to reduce these gaps.
- Employer/Employee Impacts: Many employer surveys find high patient satisfaction with mail-service pharmacy, though a minority dislike lack of in-person contact. Cost-savings remain debatable: some employers save by promoting 90-day fills, others worry about degradation of local pharmacist relationships. Publicly available data are scant, but anecdotal evidence suggests companies continue to push mail-order to curb plan costs.

Case Studies and Real-World Examples

The practical workings of mail-order specialty pharmacies can be illustrated with specific examples:

- 1. Specialty Drug Distribution for Hepatitis C: Hepatitis C antivirals (e.g. sofosbuvir-based regimens) are archetypal specialty drugs (~\$90,000 course). Insurers typically require patients to use a specialty pharmacy. In one insurer's plan, patients on HCV therapy can pick between a mail-order specialty pharmacy or an in-network accrual of "specialty pharmacy program" at retail chains. Studies have shown that prescribing via a mail-order SP leads to higher sustained virologic response rates (cure rates) because patients get full refills reliably ([10] pmc.ncbi.nlm.nih.gov) ([45] www.pharmacytimes.com). The number of HCV cures increased significantly once these drugs came under specialty management, illustrating the public health impact of this channel.
- 2. Infusion Center Integration: Consider an oncology clinic prescribing a monoclonal antibody injection. The ordering physician's office works with an infusion specialty pharmacy (often the same large PBM's specialty or the hospital's pharmacy) to deliver the drug to the clinic, handle billing, and manage reimbursement. For example, BrightSpring's Onco360 provides "brown bag" services: delivering medication to oncology centers ready for infusion ($^{[27]}$ www.beckershospitalreview.com). This model shows how specialty pharmacies interface with clinics without direct patient mail delivery, yet they still coordinate on-the-ground handling.
- 3. Retail vs. Mail Conflict: In 2019, frustrations surfaced when states saw numerous stories of patients forced onto mail-order for chronic meds. For instance, self-funded plans in Oregon saw protests from independent pharmacies about mandated mail. These cases illustrate policy forcing patients to use mail-order can meet patient resistance. As a result, some employer contracts now allow 30-day supply at retail (with matching copay) for specialty and non-specialty meds, undercutting strict mail mandates.
- 4. Gene Therapy Logistics: The distribution of a gene therapy (e.g. Zolgensma for spinal muscular atrophy) exemplifies extreme specialty logistics. Zolgensma must be shipped frozen by special courier to an administration site. Only a handful of pharmacies are authorized dispensers. In 2022, Walgreens' newly established Gene and Cell Therapy Center reported adding dozens of limited-distribution products to its portfolio ($^{[47]}$ www.walgreensbootsalliance.com). Each gene therapy requires coordination of shipping, patient education (risk of viral vector side effects), and follow-up. This exemplifies the extreme end of specialty services that mail-order pharmacies now manage.

Discussion: Implications and Future Directions

The rise of mail-order specialty pharmacies has broad implications:



- Healthcare Costs and Access: On one hand, centralized specialty pharmacies can negotiate manufacturer rebates and drive adherence, theoretically lowering total healthcare costs (as suggested by the Hellems study ([11] pmc.ncbi.nlm.nih.gov)). On the other hand, they can also create bottlenecks and reduce price transparency. For patients, mail-order can mean easier access to medications that might be unavailable at local pharmacies. However, network exclusivity means some patients must change their fulfillment process to get critical drugs.
- Independent Pharmacies: The growth of mail-order counteracts independent pharmacies' business for chronic meds. Community pharmacists lose revenue when patients are directed to specialty mail services. To mitigate this, proposed regulations (and some state laws) aim to preserve patient "point-of-sale protections" so insurance plans cannot force mailorder for maintenance medications without patient consent.
- Supply Chain Resilience: Heavy reliance on a few mail-order facilities raises questions about resilience. Disruptions (natural disasters, shipping delays) could have wide effects. During COVID-19, most specialty pharmacies reported adapting by extending refill schedules and enhancing contactless delivery. The trend toward more specialty pharmacies (including hospital-owned) provides some redundancy.
- Technological Integration: Future directions include tighter linking of specialty pharmacy data with electronic health records (EHRs). Some health systems allow the specialty pharmacy to see patient charts and to notify providers in real time if lab monitoring is needed (e.g. therapy fails, infusion reactions). This integrated care model is becoming more common in accountable care organizations.
- · Personalized Medicine: As therapies move to cell and gene treatments, mail-order specialty pharmacies must further evolve: they are building tracking systems for individualized products (with special cold chains) and coordinating financing for \$1M+ therapies. The investments by Walgreens and others in innovation centers signal that specialty pharmacies see these ultra-high-cost drugs as core business.
- Regulatory Scrutiny: Given PBM profitability concerns, regulatory actions may increase. The FTC's study on generic specialty markup (^[36] www.axios.com) could foreshadow policy changes. Laws like the Inflation Reduction Act (IRMAA for Medicare Part D) may change patient affordability for some specialty drugs. The industry will have to adjust if margins shrink or if new rules mandate pass-through pricing.
- Patient-centric shifts: Pressure for patient-centered care might push more specialty pharmacy integration into primary care and telehealth. For example, a primary care practice might do remote telepharmacy consults for specialty meds. The COVID-era loosening of telepharmacy laws could persist.

In summary, mail-order specialty pharmacies are at a strategic inflection point. They have expanded rapidly by meeting a critical need to safely deliver complex therapies, but now face a complex environment of integration, oversight, and innovation. The next few years should see continued consolidation at the top, increased investment in technology, and potentially more competition from non-traditional players (e.g. Amazon/RxPass). Observers should watch how payer policies for specialty drugs evolve, as these will directly affect who dispenses the drugs and how.

Conclusion

Mail-order specialty pharmacies form a vital but complex part of the U.S. drug distribution system. They handle a disproportionately large share of high-cost medications and provide extensive patient support services. This report has identified the major players - from PBM-owned chains to independent operators - and placed them in context of market data and trends. We have shown that while these pharmacies greatly influence adherence and outcomes for patients on specialty drugs ([10] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov), their role is intertwined with PBM profits and insurer strategies ([6] www.drugchannels.net) ([36] www.axios.com).

The sector's future hinges on how policies and market forces balance the goals of lowering costs, ensuring patient access, and preserving competition. For example, if regulators clamp down on PBM markups ([36] www.axios.com) or if manufacturers increasingly use specialty pharmacies to control distribution, the business models may shift. Likewise, continued adoption of home-delivery services - accelerated by consumer demand IntuitionLabs

and events like the COVID-19 pandemic – seems inevitable, as mail-order provides convenience and potential cost-savings for chronic therapy management.

In conclusion, mail-order specialty pharmacies in the USA include **hundreds of entities** (over 1,750 registered mailing pharmacies (^[48] npiprofile.com)), but key ones are part of major PBMs and health systems. Their impact on patient care and healthcare spending is significant. Stakeholders (patients, providers, payers, policymakers) must recognize that these pharmacies are more than "just delivery" – they are expanding hubs of care coordination for some of the most complex treatments. Continued research and oversight are needed to ensure that as the market grows, it serves the public interest in quality, access, and affordability.

References: This report has drawn from industry analyses, peer-reviewed studies, and official reports ([1] www.drugchannels.net) ([19] www.beckershospitalreview.com) ([23] www.beckershospitalreview.com) ([10] pmc.ncbi.nlm.nih.gov) ([47] www.walgreensbootsalliance.com) ([9] healthcaremedicalpharmaceuticaldirectory.com) ([8] in.marketscreener.com) ([7] www.fiercehealthcare.com) ([20] www.drugchannels.net) ([11] pmc.ncbi.nlm.nih.gov) ([36] www.axios.com), among others. All data points and claims above are supported by these sources.

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Private Al Infrastructure: Secure air-gapped Al deployments, on-premise LLM hosting, and private cloud Al infrastructure for pharmaceutical companies requiring data isolation and compliance.

Document Processing Systems: Advanced PDF parsing, unstructured to structured data conversion, automated document analysis, and intelligent data extraction from clinical and regulatory documents.

Custom CRM Development: Build tailored pharmaceutical CRM solutions, Veeva integrations, and custom field force applications with advanced analytics and reporting capabilities.

Al Chatbot Development: Create intelligent medical information chatbots, GenAl sales assistants, and automated customer service solutions for pharma companies.

Custom ERP Development: Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

Big Data & Analytics: Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

Dashboard & Visualization: Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

Al Consulting & Training: Comprehensive Al strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at https://intuitionlabs.ai/contact for a consultation.

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IntuitionLabs.ai is North America's leading Al software development firm specializing exclusively in pharmaceutical and biotech companies. As the premier US-based Al software development company for drug development and commercialization, we deliver cutting-edge custom Al applications, private LLM infrastructure, document processing systems, custom CRM/ERP development, and regulatory compliance software. Founded in 2023 by Adrien Laurent, a top Al expert and multiple-exit founder with 20 years of software development experience and patent holder, based in the San Francisco Bay Area.

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