



EBOOK

FROM PRE-APPROVAL TO POST-LAUNCH

END-TO-END COMMERCIALIZATION GUIDE FOR SPECIALTY PHARMA

Insights from professionals with hands-on experience navigating the complexity of specialty pharma commercialization — government pricing, patient support, distribution, and post-launch optimization.

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FOREWORD

The history of the pharmaceutical industry is a story of extraordinary innovation. Today, that progress is accelerating with advances in specialty pharmaceuticals, rare disease therapies, oncology, and cell and gene therapy, which are pushing the boundaries of what is possible. But scientific breakthroughs alone don't save lives. The path from approval to patient access requires a coordinated, strategic approach to commercialization.

Together, Two Labs and Riparian have had the opportunity to work alongside specialty pharma manufacturers at nearly every stage of commercialization, and one thing we've seen repeatedly is that government pricing, patient support, specialty pharmacy strategy, and post-launch optimization cannot be approached in isolation. Decisions made in one area often have implications for another. As regulatory requirements tighten and access pathways become more complex, manufacturers need a commercialization strategy that connects these functions rather than treating them as separate workstreams.

This eBook is a practical guide through four of the most critical components of the commercialization process for specialty treatments. Each chapter reflects conversations we've had with manufacturers navigating these challenges and the hard-won insights that came from helping them through it. We hope it helps you build a more connected commercialization strategy, one that supports patient access, strengthens launch readiness, and positions your product for long-term success.

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Two Labs partners with pharmaceutical manufacturers to deliver customized commercial solutions to help bring their products to market and maintain compliance across the product lifecycle through industry expertise, integration, and strategic implementation.

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Chapter 1:

PRICING PRESSURE IS RESHAPING COMMERCIAL STRATEGY

Pricing a specialty therapy isn't just about numbers; it's a high-stakes balancing act. Manufacturers must establish pricing that reflects the innovation and value of their therapies while navigating payer pushback, government compliance, and patient affordability.

To gain access to federal markets, participation in government programs such as Medicaid, Medicare, and 340B introduces significant operational and financial complexity. Evolving reporting requirements, inflation-based penalties, and expanding Drug Price Transparency (DPT) laws mean that even minor missteps can result in significant financial exposure and regulatory risk.

Successfully navigating this environment requires more than strategy alone. It demands precision, foresight, and a deep understanding of how pricing decisions have cascading impacts across government programs.

Navigating Complex Pricing Models for Specialty Drugs

Manufacturers face a complex landscape when navigating government pricing programs for specialty drugs, where the channel mix differs from the standard construct of the wholesaler/chargeback model upon which these federal programs were initially designed. Rebates, fees, and discounts offered to specialty distributors and specialty pharmacies (SP) have unique characteristics that can significantly affect manufacturer liability under federal programs.

Programs like the Medicaid Drug Rebate Program (MDRP) and the 340B Drug Pricing Program each carry significant penalties for non-compliance and yet require nuanced, precise calculations with reconciliation to financial reporting documents, quarterly/ annual submissions, and compliance with unique data definitions and filters.

To best support these efforts, manufacturers must consider the following in their pricing models:

- > Gross-to-Net (GTN) Adjustments
- > Inflationary Penalties
- > Market Segmentation

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Strategies for Specialty
Pharma to Navigate
Government Pricing >

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Comparison of Key Government Pricing Programs			
Program	Purpose	Submission Requirements	Penalties for Non-Compliance
Medicaid Drug Rebate	Establishes mandatory rebates to the states for purchases by Medicaid patients	Quarterly/annual reporting of AMP and BP	\$10,000/day for late filings; additional fraud penalties for inaccurate submissions, potential suspension or debarment
340B Drug Pricing	Upfront discounts available to certain safety net providers ("covered entities"), including DSH Hospitals	Quarterly reporting of the 340B price on a two-quarter lag	Civil monetary penalties for overcharges
Medicare Part B/D	Reimbursement for outpatient drugs for Medicare patients through a rebate or reimbursement to providers that administer drugs	Quarterly reporting of ASP	Monetary penalties and suspension or exclusion from programs
FSS/VA	Upfront negotiated discount to federal agencies that purchase drugs; some agencies have an additional mandatory discount	Quarterly and annual NFAMP; annual confirmation of tracking the customer ratio	\$10,000 for each invoice if pricing is inaccurate; penalties for late submission; potential suspension or debarment

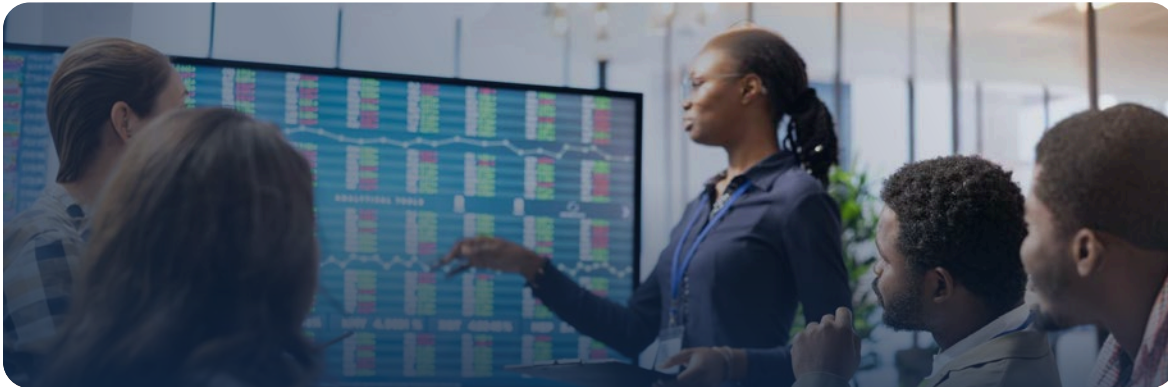
Aligning Pricing Strategy with Long-Term Market Access

Securing reimbursement for specialty drugs requires a proactive approach to justify value while addressing payer concerns.

To successfully gain coverage, manufacturers should consider the following:

- Engage Payers Early
- Consider the Advantages of Value-Based Agreements (VBAs)
- Use Data-Driven Evidence

While these approaches can strengthen market access, they must be implemented with a clear understanding of how they influence government pricing reporting and compliance obligations.



Impact of Government Policies on Specialty Pharma Pricing

Policy changes continue to reshape the government pricing landscape, increasing both scrutiny and financial risk for manufacturers.

The Inflation Reduction Act (IRA), for example, introduces new pricing pressures through Medicare drug price negotiations, inflation-based rebates, and manufacturer financial contributions. At the same time, state-level DPT laws require detailed disclosures related to pricing decisions, including development, manufacturing, and commercialization costs.

These evolving requirements create additional complexity in several key areas:

- **Government Program Adjustments:** Changes across Medicaid, Medicare, and 340B alter rebate obligations and pricing calculations, increasing the risk of misalignment if not proactively managed
- **Transparency Requirements:** State-level reporting laws expand the scope of required disclosures, adding administrative burden while increasing visibility into pricing strategies
- **Regulatory Interdependencies:** Strategic decisions that target one market can have unintended consequences across multiple federal programs, underscoring the need for an integrated, coordinated approach

Successfully navigating these pressures requires more than pricing discipline. As market access becomes more tied to affordability, reimbursement, and treatment continuity, manufacturers must ensure patients can successfully navigate the path to therapy.

Manufacturers that integrate government program planning into pricing strategy before key commercial decisions are finalized are better positioned to manage compliance risk, strengthen market access, and support long-term commercialization success.

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Chapter 2:

PATIENT SUPPORT HAS BECOME A COMMERCIAL IMPERATIVE

A breakthrough therapy delivers results only if patients can access and maintain it. Across all therapeutic areas, the path from prescription to getting on and staying on therapy involves steps like reimbursement review, prior authorizations, financial navigation, and patient education.

In specialty and rare disease markets—where therapies are high-touch and high-cost—each step becomes more sensitive. Even small inefficiencies in benefit verification, documentation, or patient engagement can delay therapy and reduce adherence.

If Patient Support Programs (PSPs) are not properly structured, manufacturers may experience delayed treatment initiation, inconsistent reimbursement outcomes, provider friction, and variability in launch performance. But a thoughtfully designed support infrastructure transforms patient services from a transactional function into a strategic driver of access, experience, and commercial predictability.

From Access Support to Strategic Advantage

Comprehensive Patient Support Programs operate at the intersection of patient experience and commercialization strategy. More than operational infrastructure, their design shapes how patients navigate access pathways and how effectively manufacturers gain visibility into performance across the treatment journey.

At Two Labs, we believe patient services are grounded in structured processes, defined KPIs, and routine review mechanisms.

Designing for Scale, Compliance, and Real-World Performance

PSPs must adapt as markets and payer policies evolve and regulations change. Site-of-care models are expanding beyond centers of excellence. Program design must anticipate and respond to these shifts.

Two Labs works with manufacturers early to create scalable, patient-centered support before launch. This includes:

PSP Component	Purpose
Benefit Verification	Confirm coverage
Prior Authorization Support	Reduce access delays
Financial Assistance	Improve affordability
Case Management	Coordinate patient journey
Adherence Support	Improve persistence



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However, reaching launch is just the beginning of the program lifecycle. Ongoing assessment and optimization are essential for long-term success.

Structured Evaluation and Post-Launch Optimization

Following implementation, structured program reviews provide a framework for continued evaluation. These assessments may examine:

- **Benefit verification turnaround patterns**
- **Prior authorization and appeal trends**
- **Case throughput and backlog indicators**
- **Escalation trends**
- **Documentation practices and audit preparedness**
- **Training alignment and quality monitoring findings**
- **Customer satisfaction insights**

Programs that are routinely evaluated and recalibrated are better positioned to remain aligned with evolving market, regulatory, and payer landscapes.

The Human Element: Training and Quality as Core Infrastructure

Process design, technology, and performance metrics are essential components of a successful PSP. However, long-term program effectiveness also depends on the people who deliver support day-to-day.

Even strong models need consistent evaluation and ongoing upskilling. In complex reimbursement environments, variability in case management practices can affect documentation quality, escalation handling, and provider experience.

Comprehensive training and structured quality oversight are foundational to the success of the PSP, driving operational excellence and ensuring that patients and providers receive the high-quality support they depend on.

By combining training, call simulations, and ongoing quality monitoring, manufacturers maintain operational consistency over time.

High-performing Patient Support Programs take time to establish but are crucial for a product's future. As therapies become more complex, investing early in structured, tailored support and regular program evaluations positions manufacturers for consistency and stakeholder trust. Patient services go beyond access—they include advocacy, education, and treatment experience.

Delivering this level of support, however, depends heavily on the specialty pharma infrastructure established before launch.

Building PSPs that remain effective as therapies scale requires ongoing evaluation, operational discipline, and a deep understanding of evolving access dynamics.

A Lifecycle Approach to Patient Services

High-performing Patient Support Programs follow a deliberate lifecycle:



PRE-LAUNCH

- Model design and workflow mapping
- SOP development and documentation standards
- KPI definition aligned with commercial goals
- Employee training programs and certification



LAUNCH

- Real-time performance monitoring
- Early trend analysis
- Rapid issue resolution and escalation management



POST-LAUNCH OPTIMIZATION

- Structured health checks
- Data-driven workflow refinements
- Landscape adaptation
- Scalable infrastructure planning
- Ongoing quality monitoring
- Upskilling and continued employee development

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Chapter 3:

SPECIALTY PHARMACY STRATEGY SHAPES THE PATIENT EXPERIENCE

Pre-launch specialty pharmacy selection is one of the most important commercial decisions you will make. This decision will determine how quickly patients access therapy, how smoothly prescribers navigate reimbursement, how much visibility you have into your own data, and how your brand is experienced in the market from day one.

It influences GTN performance, payer dynamics, operational scalability, and compliance exposure. Once contracts are signed and workflows are built, changing course becomes complex, disruptive, and highly visible.

With the right strategic alignment and disciplined implementation, specialty pharmacy strategy can become a powerful accelerant for launch success.

Start With Strategy: Defining Your Pre-Launch SP Model

Before evaluating specialty pharmacies, issuing a Request for Proposal (RFP), or comparing infrastructure capabilities, manufacturers should align internally on foundational strategic questions. Without alignment on these questions, selection becomes reactive. The objective is not to choose the largest or most recognizable partner, but the one aligned with your commercial strategy and access environment.

Foundational Questions	Strategic Considerations
What is the patient experience we are designing?	- Is speed to therapy the top priority? - Does this population require white-glove onboarding? - Will patients need financial navigation support? - How complex is treatment initiation? - What level of adherence monitoring is expected?
What level of channel control do we need?	- How critical is real-time data transparency? - Do we need centralized escalation pathways? - How tightly must inventory flow be managed?
Is this exclusive, limited, or open distribution?	- What is the optimal balance between access and control? - How complex will data aggregation become?
How complex will payer coverage be?	- Will extensive prior authorizations be required? - Are appeals and exceptions expected to be frequent? - Is coverage primarily a medical or a pharmacy benefit?
What data do we require?	- What reporting cadence will leadership expect? - What metrics must be visible in the first 30/60/90 days? - Do we require patient-level visibility?



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Scale vs. Depth: Choosing the Right SP Model

Large national specialty pharmacies offer infrastructure, established payer relationships, geographic reach, and operational capacity. Their integration with major PBMs can streamline access and support scalability.

Mid-sized specialty pharmacies often bring therapy expertise, operational agility, and closer manufacturer alignment. In targeted markets, that depth can strengthen onboarding and issue resolution.

The right model depends on the realities of the product and the access landscape. Several critical factors must be evaluated, including:



Misalignment introduces friction, including slower time to therapy, increased operational escalations, and unnecessary strain on providers and internal teams. Alignment, by contrast, stabilizes the launch environment and allows access processes to perform as intended from day one.

Defining KPIs Before Contracting

Performance expectations should be defined before contracts are signed. Aligning on KPIs during the pre-launch phase establishes clear standards, transparency, and accountability.

These metrics directly influence commercial performance:



Contracts should reinforce these expectations through clearly defined service levels, reporting cadence, data standards, inventory management expectations, and structured exit clauses.

Defining performance and contractual accountability at the same time protects the launch from preventable volatility.

Specialty Pharmacy Selection Criteria

Selecting specialty pharmacies requires a structured evaluation framework. Infrastructure scale alone does not determine alignment with a launch strategy.

Manufacturers should evaluate:



CLINICAL
EXPERTISE



REIMBURSEMENT
CAPABILITY



DATA
MATURITY



OPERATIONAL
EXECUTION



GOVERNANCE
ALIGNMENT

A disciplined Request for Information (RFI) or RFP process supported by cross-functional scoring strengthens decision quality. The objective is alignment between the partner's capability and the product's clinical, operational, and reimbursement realities.

Common Reasons Manufacturers Utilize Specialty Pharmacies	
Specialty Pharmacy Need	How an SP Supports
High-cost therapies	Supports reimbursement navigation, affordability programs, and financial assistance coordination
Complex treatment regimens	Provides patient education, adherence support, and clinical monitoring
Limited patient populations	Offers specialized expertise and focused patient management
Prior authorization requirements	Works with providers and payers to facilitate access and reduce delays
REMS requirements	Supports compliance with program requirements and patient monitoring obligations
Temperature-sensitive products	Provides specialized storage, handling, and distribution capabilities
Limited distribution strategies	Helps manufacturers maintain visibility, control, and oversight of product distribution

Turning Strategy Into Execution

The **implementation phase** is where launch readiness is validated. Selecting a specialty pharmacy partner is only half of the work. True readiness requires structured pressure testing before the first prescription is written.

Effective **pre-launch implementation** begins with a disciplined process and timeline. Weekly governance workstreams create alignment between manufacturer and specialty pharmacy teams, ensuring operational and clinical training, adherence program development, and patient services integration are aligned before launch.

Mock patient journey testing allows teams to simulate real-world referral, benefit investigation, prior authorization, and dispensing workflows. These simulations expose operational gaps while there is still time to correct them.

Escalation pathway mapping is equally important. Clear ownership, defined resolution timelines, and documented communication channels prevent access issues from lingering.

Care team training must also align with brand positioning and patient experience expectations. The specialty pharmacy team frequently becomes a primary operational touchpoint for patients and providers, influencing how the therapy is experienced in the market.

Specialty pharmacy is not simply a distribution decision. It is a commercial strategy lever. When selected and implemented with discipline, it accelerates patient access, stabilizes early launch performance, and strengthens prescriber trust.



TIME TO THERAPY



PROVIDER EXPERIENCE



DATA VISIBILITY



GTN PERFORMANCE



OPERATIONAL SCALABILITY



LAUNCH STABILITY

As products move from launch into the realities of the market, maintaining performance requires ongoing optimization across trade, distribution, operations, and access strategy.

The most successful launch models are built on thoughtful planning, rigorous implementation, and alignment between commercial strategy and operational execution.

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Chapter 4:

CONNECTING STRATEGY TO POST-LAUNCH PERFORMANCE

Bringing a drug to market is a significant milestone, marking the culmination of years of clinical development, regulatory planning, and cross-functional coordination, all converging in a single moment: launch day.

While launch is a significant achievement, it does not guarantee commercial success. Once a product enters the market, strategies are tested by real-world conditions that often challenge initial assumptions. Demand may differ from forecasts, inventory can become misaligned, and payer or access barriers may delay patient uptake.

A strong launch plan alone does not ensure sustained success. As these conditions unfold, gaps between strategy and execution emerge, affecting access, channel performance, and commercial outcomes. Organizations that identify and address these gaps early, while aligning trade, distribution, and operational execution, are better positioned for ongoing performance and reliable patient access.



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The Shift from Launch Readiness to Commercial Performance

Pre-launch planning is designed to create a controlled and predictable model. Teams define distribution strategy, establish trade agreements, and align operational processes based on expected demand and channel behavior.

After launch, that model becomes dynamic and interdependent. Performance is no longer driven by planning assumptions, but by how the system operates under real conditions.

Organizations that perform well in this phase recognize that commercialization is not a fixed model. It is a system that requires continuous evaluation and adjustment.

Several factors begin to reshape performance:

- > Real-world demand patterns that differ from forecasts
- > Variability in channel performance across wholesalers, specialty distributors, and SPs
- > Evolving payer and provider dynamics that influence access and reimbursement
- > Operational strain as volume scales across distribution and fulfillment networks

Why Post-Launch Optimization Matters

If post-launch optimization is not actively managed, gaps in execution can quickly translate into measurable commercial impact. Misalignment across trade and distribution can raise costs, erode margins, and reduce efficiency. Poor inventory positioning can create imbalances or product delays, while gaps across partners can slow patient access and create inconsistent provider experiences.

These are not isolated operational challenges. They directly affect:

- > Revenue realization and financial performance
- > Patient access and therapy adoption
- > Channel efficiency and partner performance

Where Post-Launch Optimization Breaks Down

Even well-designed commercial models encounter friction once exposed to real-world conditions. Across manufacturers, four consistent pressure points emerge.



Turning Strategy into Results

Even when organizations recognize post-launch challenges, many struggle to implement a coordinated response. Trade, distribution, operations, and data are often managed in silos, creating gaps between strategy and execution.

As a result, well-designed strategies fail to translate into consistent outcomes once exposed to real-world conditions.

Organizations that sustain commercial success treat post-launch as a continuous performance management system, focusing on aligning execution across all components of the commercial model.

They consistently:

- ✓ Evaluate distribution performance and partner effectiveness
- ✓ Align trade strategy with real-world utilization and channel economics
- ✓ Adapt operations as demand and access dynamics evolve
- ✓ Use integrated data to guide decision-making
- ✓ Plan for lifecycle transitions well in advance

Most importantly, they connect these functions. Trade, distribution, operations, and data operate as a coordinated system rather than independent workstreams. Organizations that connect strategy to execution gain greater control over performance, enabling faster decision-making, more consistent access, and stronger commercial outcomes over time.



Organizations that connect strategy to execution gain greater control over performance, faster decision-making, and more consistent patient access.

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FINAL NOTES

THE FUTURE OF SPECIALTY PHARMA COMMERCIALIZATION

The frameworks in this guide are a starting point. But frameworks don't execute. People do. Partners do. Systems do.

Every chapter of this guide exists because the path from approval to patient access is full of decisions that compound. Pricing strategy affects government compliance. Patient support design affects provider experience. Specialty pharmacy selection affects launch performance. Post-launch optimization affects everything.

As specialty pharma continues to evolve, commercial success will depend on how effectively those pieces work together — not how well each operates on its own.

The manufacturers who get this right aren't the ones who execute each function perfectly in isolation. They're the ones who build a commercialization model where every decision informs the next, and where the right partners are in the room before the hard questions surface.

The question isn't whether commercialization is becoming more complex. We know that it is. Pipeline growth in cell and gene therapy, rare disease, and oncology means manufacturers are bringing increasingly sophisticated therapies to market at an accelerating pace. As those products mature, the commercial challenges don't diminish; they compound. Pricing obligations grow more intricate, government reporting requirements become more demanding, and gross-to-net pressures intensify as payer dynamics shift. The question is whether your strategy is built to perform when that complexity becomes reality.

Two Labs and Riparian, part of Envision Pharma Group, have helped manufacturers navigate every stage covered in this guide. Not as outside advisors looking in, but as hands-on partners who understand what breaks, what holds, and what it takes to build an end-to-end commercialization model that performs in the real world.

The path from approval to access is complex, but you don't have to navigate it alone.

We're ready to help.

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PRE-LAUNCH READINESS QUICK CHECK

IS YOUR LAUNCH PLAN READY FOR REAL-WORLD COMPLEXITY?

Successful commercialization depends on more than completing individual workstreams. Decisions involving licensing, compliance, distribution, patient services, prescriber access, and pricing are interconnected. A delay or misalignment in one area can create downstream consequences across the launch plan. **Use this checklist to identify where additional attention may be needed.**

Licensing and Distribution

- Is your state licensing sequence aligned with your anticipated approval date, 3PL selection, and target launch states? ☐ Yes ☐ In Progress ☐ No
- Would the licenses required to ship product be in place if approval occurred earlier than expected? ☐ Yes ☐ In Progress ☐ No

Compliance

- Are DSCSA master data, GTIN structure, barcode design, procedures, and trading-partner integrations on track? ☐ Yes ☐ In Progress ☐ No
- Do you have a response strategy if FDA raises the possibility of a REMS before approval? ☐ Yes ☐ In Progress ☐ No

Channel and Trade Operations

- Has your distribution model been validated against the patient journey, site of care, payer mix, and dispensing requirements? ☐ Yes ☐ In Progress ☐ No
- Are ownership, monitoring, and escalation processes defined for inventory, orders, chargebacks, and unexpected demand? ☐ Yes ☐ In Progress ☐ No

Patient Services

- Are hub workflows, business rules, SOPs, call guides, and employee training ready for launch? ☐ Yes ☐ In Progress ☐ No
- Have realistic call simulations tested how teams will manage complex patient, provider, and payer scenarios? ☐ Yes ☐ In Progress ☐ No

Prescriber and Reimbursement Visibility

- Are compendia submissions, NDC information, labeling, packaging, and pricing activities reverse-timed from launch? ☐ Yes ☐ In Progress ☐ No
- Will the product be visible in the EHR and e-prescribing systems most commonly used by your prescribers? ☐ Yes ☐ In Progress ☐ No

Cross-Functional Readiness

- Is there one integrated roadmap showing dependencies across commercial, compliance, access, operational, and patient-support workstreams? ☐ Yes ☐ In Progress ☐ No
- Have the decisions being made today been evaluated for their potential impact six to twelve months from now? ☐ Yes ☐ In Progress ☐ No



What Your Answers May Be Telling You

A single **NO** matters when it involves time-sensitive activities such as state licensing, REMS planning, DSCSA implementation, or compendia submissions.

Multiple gaps across connected areas may signal a broader integration problem rather than an isolated workstream issue. Two Labs can help you identify where timing is becoming critical and where early action can prevent downstream disruption.

This checklist provides a basic starting point. Complete the full online assessment to get:

- Guidance for each workstream
- The commercial and patient-access implications of identified gaps
- Cross-functional dependencies to watch
- A readiness score and recommended next steps

TAKE THE COMPLETE PRE-LAUNCH READINESS ASSESSMENT

GLOSSARY

340B Drug Pricing Program

A federal drug discount program administered by the Health Resources and Services Administration (HRSA). It requires manufacturers to sell outpatient drugs at deep statutory discounts to hospitals and clinics that serve high volumes of low-income and uninsured patients. Manufacturers participating in Medicaid must also sign a Pharmaceutical Pricing Agreement obligating them to offer covered outpatient drugs to designated "covered entities" — including disproportionate share hospitals, federally qualified health centers, critical access hospitals, children's hospitals, free-standing cancer hospitals, and Ryan White HIV/AIDS Program grantees — at or below a statutory 340B ceiling price, calculated using AMP minus the Medicaid unit rebate amount (URA). Effective January 1, 2027, HRSA's 340B Rebate Model Pilot Program lets participating manufacturers replace the upfront discount with a back-end rebate on drugs carrying a Medicare Maximum Fair Price for 2026 and 2027.

Drug Price Transparency (DPT)

Federal and state proposals aimed at increasing the transparency of drug pricing, such as the proposed Drug-Price Transparency for Consumers Act of 2025 and state-level laws. These measures generally require drug manufacturers, Pharmacy Benefit Managers (PBMs), and health plans to report pricing data and often aim to make information on price increases, costs, and rebates available to the public and policymakers. Some proposals focus on making drug price information more accessible to consumers, such as including prices in direct-to-consumer advertising.

Gross-to-Net (GTN) Adjustments

Deductions from gross sales at list price, typically WAC, used to determine a manufacturer's net revenue. Common components include commercial and PBM rebates, Medicaid rebates, 340B discounts, Medicare Part D discounts and inflation rebates, chargebacks, distribution fees, GPO fees, federal pricing obligations, prompt-pay and cash discounts, copay assistance, coupons, returns, and other government pricing liabilities. Because many liabilities settle months after the sale, they are first estimated and later trued up, making forecast accuracy a major financial risk. This risk is especially high in specialty pharma, where gross-to-net gaps are wider and small forecasting errors can materially affect results.

Inflation Reduction Act (IRA)

Federal legislation (P.L. 117-169), enacted August 16, 2022, that made the most significant U.S. drug pricing changes in two decades. Key pharmaceutical provisions include Medicare Drug Price Negotiation, Part B and Part D inflation rebates, Part D benefit redesign with an annual out-of-pocket cap (\$2,000 in 2025; \$2,100 in 2026, indexed thereafter), replacement of the Coverage Gap Discount Program with the Manufacturer Discount Program, a \$35 monthly insulin cost-sharing cap, and no cost-sharing for recommended adult vaccines. CMS sets a Maximum Fair Price (MFP) for selected high-expenditure, single-source drugs without generic or biosimilar competition. Negotiated prices apply to 10 drugs in 2026, 15 more in 2027 and 2028, and 20 more annually thereafter; the program covers Part D drugs in 2026–2027 before expanding to Part B.

Inflationary Penalties

Rebates triggered when a manufacturer raises a drug's price faster than general inflation, measured by CPI-U. Two regimes apply:

- a. Under MDRP, the additional CPI rebate applies to single-source and innovator multiple-source drugs since 1991 and to non-innovator multiple-source drugs since Q1 2017. It compares current AMP to baseline AMP indexed by CPI-U, adding any excess to the basic rebate.
- b. Under the IRA, separate Medicare Part B and Part D inflation rebates require payment to the Medicare Supplementary Medical Insurance Trust Fund when prices exceed CPI-U benchmarks. Part B rebates use ASP and are calculated quarterly; Part D rebates use AMP over 12-month periods beginning October 1.

Medicaid Drug Rebate Program (MDRP)

A federal-state program requiring pharmaceutical manufacturers to sign a National Drug Rebate Agreement with CMS and pay quarterly rebates to state Medicaid agencies for federal Medicaid payment and Medicare Part B coverage of outpatient drugs. Manufacturers must also enter 340B and Federal Supply Schedule (FSS) agreements and report Average Manufacturer Price (AMP) monthly and quarterly and Best Price quarterly. For single-source and innovator multiple-source drugs, the basic rebate is generally the greater of 23.1% of AMP or the difference between AMP and Best Price, plus inflation-based rebates when price increases exceed inflation. As of January 1, 2024, the statutory cap limiting Medicaid rebates to 100% of AMP was eliminated, allowing rebates to exceed AMP.

Medicare vs. Medicaid

Medicare – a federally governed program applied for at a local Social Security office. It is for people aged 65 years and older, people who are permanently disabled and cannot work, and people of any age who have kidney failure or long-term kidney disease.

Medicaid – a state-governed program applied for at the State's Medicaid agency. It is for low-income: pregnant women, children under the age of 19, people 65 and over, people who are blind, people who are disabled, and people who need nursing home care.

Patient Support Program

A program that may be offered by a drug manufacturer to provide personalized support (including financial support) to patients to improve health outcomes. It serves as a central point of contact for the manufacturer for supporting the patient journey with high-touch drugs and/or as a reimbursement center of excellence to guide reimbursement or perform benefit investigation/verification and deliver on Patient Assistance Programs (e.g., PAP Free Drug, Bridge/Quick Start Programs).

Ship to targets: Hubs do not ship commercial products. Leading Hubs may have non-commercial dispensing pharmacy licenses as part of their offering to ship Free Drug (eg. PAP product) directly to patients.

Other Services:

- Reimbursement Access Support
- Clinical/Adherence

Pharmacy Benefit Manager (PBM)

Manages pharmacy benefit plans on behalf of insurers and third-party payers, including, e.g., negotiation of network pharmacy discounts, drug manufacturer rebate contracts, and formulary management

REMS (Risk Evaluation and Mitigation Strategies)

A strategy to manage a known or potential serious risk associated with a drug or biological product. A REMS will be required if the Food and Drug Administration (FDA) determines that a REMS is necessary to ensure the benefits of the drug or biological product outweigh its risks. A REMS can include a Medication Guide, Patient Package Insert, a communication plan, elements to ensure safe use, and an implementation system. This resource center contains information for pharmacists, patients, and other healthcare professionals about REMS, and the specific requirements for drugs that require a REMS.

RFP (Request for Proposal)

Issued at an early stage in a procurement process, where an invitation is presented for suppliers, often through a bidding process, to submit a proposal on a specific commodity or service. The RFP process brings structure to the procurement decision and is meant to allow the risks and benefits to be identified clearly upfront.

Specialty Distributor

Specialty distributors ship products primarily to physician offices and clinics, hospitals, IDNs, and academic institutions. They support alternate site markets using a buy-and-bill model, purchasing products from manufacturers, and reselling them to providers who administer therapy and bill patients or payers directly. Depending on the commercial structure, the distributor may or may not take title to the drug. While specialty distributors typically do not service traditional retail classes of trade, there are select therapeutic categories where distribution into retail settings may occur, such as seasonal vaccines (e.g., influenza) or public-health-driven therapies (e.g., COVID treatments). These scenarios are exception-based and driven by product characteristics, access requirements, and manufacturer strategy. Specialty distributors primarily support manufacturers that require a limited distribution model.

This approach is commonly used for therapies targeting small, highly specialized patient populations, including orphan or rare diseases, where prescribing is concentrated among a limited number of specialist providers or centers of excellence. Additional drivers for limited distribution include high product cost, complex handling requirements such as cold-chain or frozen storage, short dating, constrained supply, and heightened risk of diversion or loss. By concentrating distribution through a limited number of specialty distributors, manufacturers can maintain tighter control over inventory flow, improve demand forecasting and compliance oversight, enhance visibility into product movement, and better align distribution with clinical pathways and reimbursement models. Through close coordination with treating providers, specialty distributors also enable just-in-time delivery to ensure product arrives at the site of care in alignment with the patient's visit.

Specialty Pharmacy

Focuses on dispensing specialty medications, which are typically high-cost, high-complexity drugs used to treat chronic, rare, or complex conditions. These medications often require:

- Special handling or administration (e.g., injectable, infusion, temperature-controlled).
- Patient education and support for adherence and side-effect management.
- Prior authorization and insurance coordination due to high cost.
- Clinical monitoring to ensure safety and effectiveness.

Specialty pharmacies often provide comprehensive patient care services, such as:

- 24/7 clinical support
- Medication therapy management
- Coordination with prescribers and payers
- Assistance with financial support programs