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Pharma DTP Risk Checklist

The 4P Framework for Direct-to-Patient Programs

A structured review of the operational, legal, pricing, and compliance risks most pharma teams underestimate before launching a DTP program.

EVIDION ADVISORY

Commercial Strategy & Execution - Risk Management

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ABOUT THIS CHECKLIST

How to Use

This checklist maps the full risk explosure landscape across the 4Ps of marketing: Product, Price, Place, and Promotion.

Work through each section with your commercial, legal, supply chain, and compliance leads.

Check

You have a documented plan or policy in place for this area.

GAP

This is an open risk that remains undecided or without clear direction.

Sharpest Watch Out

Items flagged as the sharpest watch outs are the underlying questions that **MUST** be addressed to provide clear directionon all other aspects of the program.

THE 4P RISK MAP - PART 1

Product

When you ship directly to patients, you're no longer moving pallets. You're moving individual units to thousands of addresses — which means you suddenly carry the responsibilities of a retailer.

You become accountable for unit-level inventory, product recalls, and patient-facing returns.

Whether you decide to hire third-party logistics partners (3PL) or handle them yourself, make sure you evaluate each of the topics in this chapter.

Product

- [ ] **Unit-Level Serialization or Lot-Level Traceability**

  How will you track inventory? With multiple lots on a pallet and dozens of units per lot, what is the best way to decrement inventory so you can ensure supply of each SKU? Will you be able to quickly detect diversion or counterfeit product?

- [ ] **Product Recall Infrastructure**

  If there's a quality issue or a product recall, you need to be able to contact each customer, except now you're not just calling the distributor; you're responsible for getting the message to the end user. Can you identify and contact each affected patient directly? Do you have the systems & protocols in place?

- [ ] **Returns and Reverse Logistics**

  If patients no longer want their prescription, what is your plan? Will you have them return the product? Do you have a documented patient returns process & mapped reverse logistics flow?

Product

☐ **Property Tax Calculations**

Where you warehouse the product inventory is also an important consideration for financial reasons. Each state has its own property tax calculation and contracting a 3PL in Kentucky vs. Illinois can result in millions of dollars of savings. Have you assessed your financial exposure?

Sharpest Watch-Out: PRIVACY

Pharmaceutical manufacturers have historically been exceptionally careful with the collection and retention of patient-level Protected Health Information (PHI) to avoid massive legal penalties, prevent severe reputational damage, and maintain the integrity of competitive clinical research. In fact, most pharma companies avoid entering any PHI into their systems and will spend millions of dollars with third-party agencies and vendors to de-identify, anonymize, encrypt, and protect PHI.

But now you need to be able to ship product directly to a patient's home and call them in the case of a recall. How will you be able to do this on a 1:1 patient-level without being able to identify the patient?

THE 4P RISK MAP - PART 2

Price

DTP turns pricing into a patient decision-making moment — and simultaneously raises the stakes with payers and government price reporting requirements.

Your DTP price doesn't exist in a vacuum: it interacts with contracted payer rates, Best Price calculations, and Medicaid rebate obligations.

It effectively becomes your "manufacturer suggested retail price" and provides price transparency to every stakeholder involved.

Price

- [ ] **Patient Willingness-to-Buy**

  Choosing your DTP price must start with your patient's willingness to buy. If the price is set too high and patients aren't interested, then it will become obvious that the program wasn't set up to actually help patients and the company may get blamed for being disingenuous.

  If the price is too low and patients get a better price from your DTP program than through your insurer, you are likely cannibalizing your more profitable channel.

- [ ] **Payer Contract Review**

  If your DTP price is below your commercial net price (i.e. patients are getting a bigger rebate than payers), commercial payers may interpret the pricing action as a breach of contract. In their minds, you are inducing patients to do business with you instead of them by offering a better price. This could trigger penalties or renegotiation demands.

  Even if your DTP price is equivalent to your commercial net price, you should still review your payer contracts because many of them have a "non-solicitation clause" that forbids you do business directly with any of their customers.

Price

- [ ] **Government Price Reporting**

  Government price calculations are all based on your commercial net price, so by offering an even lower price, you may be triggering updates to your ASP, AMP, and Best Price calculations. Has your government pricing team assessed the impact before launch?

- [ ] **Antitrust/Anticompetitive Risk**

  Setting prices below cost or significantly below competitors may be perceived as a strategy to drive rivals out of the business with the intent of raising prices later. To be considered illegal, the federal trade commission generally require proof that you can likely monopolize the market, giving you the power to subsequently raise prices to high levels later. Have your forecasting and finance teams assessed the potential changes in market share? Make sure to document this assessment and ensure your DTP price is re-evaluated each year.

Price

- [ ] **Patient Affordabiliity Strategy**

  Will you offer copay assistance or patient assistance programs for DTP? If so, do those programs interact with your existing patient support infrastructure? Do you have controls to prevent duplicate discounting? Or the controls to ensure patients pick the optimal program for them? For example, if a commercial patient could be leveraging a $10/month copay card instead of using your $50/month DTP program, how will you help them choose the right program for them?

- [ ] **Not Billable to Insurers**

  To ensure you don't violate the AKS, your DTP price needs to be available to ALL comers and these claims cannot be submitted to any insurer, especially any Federal healthcare program. This means that individuals obtain the product without using their Medicare Part D benefit and therefore the amount they pay to your DTP program does not count toward their Part D deductible or true-out-of-pocket.

  This is where you'll need to be very careful about how you write the Terms & Conditions or else patients won't understand the long-term impact of what they might be giving up.

Price

Sharpest Watch-Out: CANNIBALIZATION

Federal Anti-Kickback Statute requires that your DTP price needs to be made available to all-comers, but do you really want everyone to buy at your DTP price? How do you set up eligibility criteria and terms & conditions to ensure you don't cannibalize other sales channels? And how do you communicate it clearly?

THE 4P RISK MAP - PART 3

Place

Place represents your business model – it determines where and how patients pay for and receive the product.

Depending on how accessible your product needs to be, you could go with a centralized (single mail-order pharmacy) or a distributed model (multiple pharmacies).

Remember that the moment you own the distribution channel, you own the operational risk that comes with it so don't undervalue the operational excellence required to make a DTP program work.

Place

- [ ] **Speed & Availability**

  What type of product are you building the DTP program for? Can patients wait for this treatment? Or does it need to have same-day accessibility? Does it need provider-administration or monitoring? The answers to this question will determine how you build your business model.

- [ ] **Ownership Model**

  Who should take financial title (i.e. ownership) of the product? Will it be set up as Consignment where the manufacturer retains ownership until the retailer sells the item? Or will it be set up more like Dropshipping, where the manufacturer technically sells the product, but a third-party supplier handles inventory and shipping? Or could you leverage traditional Resale and have the pharmacy purchase inventory upfront and keep 100% of the revenue from final sale? How does each model impact Best Price and the dependencies from the Pricing section above?

Place

- [ ] **Title Transfer to Patient**

  At what point does financial title (i.e. ownership) transfer from the manufacturer to the patient? Will it be at the point when product is shipped out the door? Or the point when product reaches the patient? This affects your liability exposure, insurance requirements, and returns policy.

- [ ] **State Licensing & Distribution Permits**

  Shipping product directly to patients may require wholesale distributor licenses or pharmacy licenses in certain states, Has your legal team mapped the requirements?

- [ ] **Sales Tax Compliance**

  While pharmaceutical drugs are generally not subject to state sales tax, there are 5-6 states where specific counties, cities, or municipalities charge varying percentages. Reporting requirements vary significantly by sales tax nexus, but all require the sales tax to be calculated & collected at point-of-sale. Do you have the systems, protocols, and reporting mechanisms in place?

Place

☐ **Vendor Quality Agreements**

Any third-party logistics provider handling your product needs a quality agreement and the more you add, the harder it is to enforce consistent service levels. Supply chain & transportation logistics get tougher too, as you may need inventory to be sent form one to another in case of outages. Do you have documented service level agreements and oversight processes for these partners?

⚠ **Sharpest Watch-Out: STEERING**

Federal Anti-Kickback Statute requires that you don't use your DTP program to induce patients to choose a particular provider or pharmacy, but do you really want to make the DTP price available at all of your commercial pharmacies? If not, how do you communicate and transfer prescriptions into your DTP program without angering existing pharmacy customers?

THE 4P RISK MAP - PART 4

Promotion

Promotion is the most legally sensitive area of DTP.

Federal Anti-Kickback Statute is meant to prevent financial incentives from improperly influencing medical decisions — and violation is a criminal offense, not just a compliance issue. Plus, you're risking the rest of your business from being excluded from federal programs like Medicare.

Promotion

- [ ] **Clinical Decision-Making vs. Patient Support**

  Patient support services must be clearly separated from promotional content to drive prescriber-demand. Many pharma manufacturers interpret this differently – some will require a rep to clearly end the clinical sale before starting any education on patient support and others will go as far as setting up completely different sales forces to execute on this messaging. Some may go to the extreme and tell you to not even call this “promotion.” Consider the preferences of your company before designing any content.

- [ ] **Audience Segmentation**

  Promoting broadly can blur the lines of demand generation vs. patient support, so regulatory teams will likely be restrictive about who you can tell about your DTP program. Many manufacturers believe these programs should only be marketed to patients already taking your drug (that way, the clinical decision-making has already occurred). If this is the case for you, then patient journey & patient segmentation exercises should be completed before you start any messaging work.

Promotion

- [ ] **Media Buys & Digital Marketing**

  If you can't promote broadly due to this AKS concern, then you can't develop media plans like traditional consumer marketers where you target consumers as general groups (i.e. age/gender/interests). Somehow you must show that your programmatic banner ads are targeting people you KNOW are patients (without having the data to PROVE that they are patients). Collecting first-party data through CRM campaigns and completing market research with existing patients will help you figure this one out, but you may still need to participate in a significant number of negotiations with your med-legal-regulatory review team.

- [ ] **Messaging Strategy**

  What you say about your DTP program needs to also be carefully considered. Your message isn't only going to be delivered to your patients & doctors; it will also inadvertently get into the hands of your competitors, payers, wholesalers and pharmacies. It is important to work with your creative agencies to design messaging with these other stakeholders in mind and maybe even include their care-abouts into the creative brief.

Promotion

Sharpest Watch Out: INDUCEMENT

If your DTP program becomes “the reason doctors prescribe your drug,” you’re in Anti-Kickback Statute territory. Even if you don’t mean for the DTP program to become a key feature of your product offering, legal cases are often made based on perception and optics.

Where you place the DTP messaging on promotional assets, how it’s delivered by your field representatives, and even how you compensate them to deliver the message needs to be carefully considered.

EVIDION

Operators who have built what others only advise on

Evidion Advisory helps pharma, biotech & vendor teams design & execute patient support programs that work in practice,

not just on paper.

Let's chat

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