

ALERT

COVID-19 Questions: Does Your PBM Agreement Hold Answers?

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Wiley's Health Care Group has decades of experience in the negotiation and administration of Pharmacy Benefit Manager (PBM) Agreements on behalf of our health plan clients. While COVID-19 is new to all of us, a well-constructed PBM Agreement may hold the answer to many of the questions that are now emerging. Quickly becoming familiar with the many contract tools that might be at your disposal will be key to efficiently and effectively managing your pharmacy benefit and PBM contract. The alert below identifies some of these areas. Our team is available to assist and support you working through these issues during this challenging time.

The worldwide spread of the novel coronavirus, COVID-19 (COVID-19) is likely to result in ever escalating strains on the pharmaceutical supply chains. Health plans may find themselves challenged to deliver their members both new COVID-19 drugs as they become available, and equally, if not more importantly, deliver existing pharmaceuticals unrelated to COVID-19 that are now in short supply as a result of restrictions on shipments and impacts on the manufacturing work force. According to a 2019 U.S. Food and Drug Administration (FDA) report, 88% of the active pharmaceutical ingredients used in drugs for the U.S. market are manufactured overseas. The FDA has been closely monitoring drug supplies for potential disruptions or shortages in the U.S. and, as a result, pharmaceutical manufacturers must notify the FDA of anticipated supply disruptions. The first drug shortage was reported at the end of February.

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Practice Areas

Health Care
Pharmacy Benefit Manager (PBM)
Contracting

WHAT DOES IT MEAN FOR HEALTH PLANS: Health plans have a full plate managing the myriad impacts of COVID-19 on their employees, provider communities, and members. Fortunately, on the pharmaceutical benefit front, plans have an industry partner upon whom they should be able to rely: their PBM. Health plans should reach out to their PBMs to coordinate and collaborate regarding the impacts of COVID-19 on delivery of pharmaceuticals to members, but not without first evaluating their PBM agreements. While no contract can anticipate every possible scenario, a well-drafted PBM agreement will anticipate and address certain key areas that may be helpful in managing your pharmaceutical benefit and PBM in the months ahead.

Some key PBM contract provisions to review and questions to answer include:

Contract performance. You and your customers have come to expect a certain level of service from your PBM. Has your business team evaluated whether the PBM will be able to meet performance guarantees if there is a drug or labor shortage? And what contingencies and remedies are contractually directed if they do not?

Have you considered whether COVID-19 is considered a force majeure event under the PBM agreement? If it is, what steps is the PBM required to take in such an event? And, what can the health plan do if the PBM refuses to, or cannot, perform?

Drug prices. Although some manufacturers are pledging to hold prices stable, drug shortages and increased demand tend to drive increased pricing. Do the financial guarantees in your PBM agreement protect your plan if the prices of key ingredients increase? If utilization migrates based on drug availability, how will your rebates be impacted? Has your financial team analyzed any financial guarantees your plan has made to employer groups or other accounts and whether your plan can meet them? What conditions allow the PBM to exclude drugs impacted by a shortage from financial guarantees?

Formularies. Additions and deletions from the formulary may be needed on a more frequent basis if drugs are in short supply. Have you discussed whether the PBM allows for off-cycle changes to the formulary? Will the PBM's P&T committee expedite approval of therapeutic substitutions to make up for drug shortages, and what role does your health plan play?

New drugs and vaccines. Pharmaceutical manufacturers have already begun testing investigational drugs and vaccines. How are such new-to-market drugs addressed in your PBM agreement? What financial guarantees, especially price protections, does your PBM agreement provide for new drugs? What pricing obligations do you have vis-à-vis your employer group contracts and how are new drugs to be priced under these agreements?

Impact on distribution channels. Have you discussed with your PBM how it can supplement retail network pharmacies if they experience drug inventory shortages? Is your PBM agreement flexible enough to allow mail order or specialty drug distribution from alternative sites should supply in the retail chain run low or in the event that the workforce at a primary mail order location is impacted by the virus? Have you discussed with the PBM what steps it will take if the mail order and/or specialty pharmacies are unable to maintain an adequate supply of drugs?

Exclusivity and delegated services. We have already seen the impacts of workforce shortages in China. During a labor or supply disruption, how will exclusivity and delegation provisions in your agreement impact your ability to move segments of the PBM's functions inhouse or to another contractor (e.g., customer service, drug purchasing, mail order and specialty drug dispensing)?

Disaster recovery and business continuity plans. A Disaster Recovery and/or Business Continuity Plan usually provides for an infrastructure redundancy back-up plan. Does your PBM agreement provide you visibility into those Disaster Recovery and Business Continuity Plans (Plans)? When are these Plans triggered? Has your PBM developed Plans specific to the COVID-19 outbreak and possible drug and workforce shortages that may result? Have you discussed it with them to ensure it aligns with your corporate approach to the issue?

Clinical services and cost management programs. Does your PBM anticipate that certain cost management programs may need to be paused to accommodate drug shortages? Are there clinical services that need to be revised or put on hold (e.g., in-person evaluations)? If so, which programs may need to be altered and paused, and how will the PBM and your health plan handle ongoing obligations to members and employer group health plans?

Visit our COVID-19 Resource Center