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LS Prime® Feature: Known Critical Facts Reporting Requirements

Did you know?

What is "reasonable" in the eyes of a jury? Should your insurance coverage turn on this question? Most life science insurers subscribe to the "reasonableness" standard when determining whether known circumstances, prior acts, or expected or intended events are excluded under their policies.

In the life sciences context, it is not always possible for a policyholder to know whether an adverse event or "circumstance" could "reasonably" result in a claim. If a claim does later arise, the policyholder must convince the carrier—and, if coverage is disputed, a court—that the adverse event could not "reasonably" have resulted in a claim.

How is LS Prime® different?

LS Prime® (a non-admitted policy) is the only life sciences policy that takes all the guesswork out of reporting. LS Prime® has eliminated the Known Circumstances Exclusion with its "reasonableness" language and replaced it with the **KNOWN CRITICAL FACTS REPORTING REQUIREMENT:** a requirement based upon concrete, objective, easily understandable **critical facts**.

Built into the policy, **critical facts** tell the policyholder what they need to report to us. If a **critical fact** takes place and is known to top level management or its insurance or legal department, then—and only then—need the prospective policyholder notify us of the event. This eliminates the need for a policyholder—and its agent—to evaluate what is "reasonable" or risk losing coverage. It also eliminates the reams of unnecessary paperwork and inconsequential circumstance documentation that policyholders must gather and send to their carriers pre-binding and upon renewal.

See reverse side for how this coverage works and Claims Examples

1. The suspension of a **clinical trial** for safety reasons or non-compliance
2. A **Class I Product Recall**
3. The addition of a black box warning
4. An **adverse event** that is both severe—such as one that causes death or requires hospitalization—and that results in a label change
5. A defect in a product that would lead to a **severe adverse event** with continued use

Who needs this Coverage?

- Medical Device Manufacturer
- Contract Research Organization (CRO)
- Medical Device Component Manufacturer
- Dietary Supplement Manufacturer
- Biotech / Pharmaceutical Manufacturer
- Cosmetic Drug Manufacturer
- Contract Manufacturing Organization (CMO)
- Medical Food Manufacturer
- Contract Sales Organization (CSO)

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How does this coverage work?

A policyholder approaching Berkley Life Sciences for new coverage would report all known **critical facts** to the underwriter during the underwriting process. If the policyholder seeks coverage for claims resulting from these known **critical facts**, the underwriter would determine whether to add an endorsement to the policy providing coverage for the known **critical facts**.

Renewal with Berkley Life Sciences is even easier. Upon renewal, the policyholder need only update the underwriters as to any new known **critical facts** taking place after the initial coverage date. Coverage for these **critical facts** is then automatic: the new **critical facts** do not need to be scheduled on renewal.

Known Critical Facts Reporting Requirements Claims Examples:

Liquid Pain Medication: Prior to policy binding, a policyholder discovers that vials containing its liquid pharmaceutical product may not have been properly sterilized. Although there is no indication that the potential failure to sterilize would cause serious injury, the policyholder initiates a Class II Product Recall. The company does not report the recall to its carrier pre-binding. After the recall is initiated a patient is exposed to tainted medication allegedly caused by improper sterilization of the vials, and makes a claim for damages. Most product liability policies would deny this claim because the policyholder should have "reasonably" believed the recall could result in a claim. This is not the case with LS Prime®. Because the Class II Product Recall was not a known **critical fact**, there is no pre-binding reporting requirement under LS Prime®.

Tissue Sealant Device: The insured manufactures a tissue sealant device used to close wounds during surgery. Pre-binding, adverse event reports are received by the FDA that a number of patients who underwent surgery where the device was used sustained post-surgery infections. The FDA determines that there is no product label change necessary. The company does not report the adverse events to its carrier. After the policy is bound, a patient makes a claim for damages, alleging that he received an infection from the use of the sealant device. Most product liability policies would consider this a "known circumstance" and deny the claim. LS Prime® is different. Since the adverse event was not a **serious adverse event**, and no product label change was necessary, it would not be considered a known **critical fact**. There is no pre-binding reporting requirement for this event under LS Prime®.

Cancer Drug: A policyholder is conducting a clinical trial for a new cancer drug. Prior to binding the policyholder discovers that one batch of the drug has an abnormally high level of an inactive ingredient, but no injuries have been reported. The policyholder does not report the event to the carrier. The batch of drugs is replaced with one that contains the accurate levels of ingredients and the trial continues. After the trial is completed several patients claim that they were injured as a result of the high levels of inactive ingredient in the first batch. Most product liability policies would deny these claims because the policyholder should have "reasonably" believed that the high levels could have resulted in a claim. Under LS Prime®, however, the policyholder's failure to report the circumstance would not preclude coverage.