Hospital Not Responsible for Physicians' Lack of Insurance

01-22-20 • alert • katherine leibowitz

Does your clinical trial agreement's (CTA) indemnification provision require the research institution to indemnify for the entire team that it brings to the table or just the institution's employees? If the provision only speaks to the institution's employees, then a recent South Carolina court case serves as a reminder that your CTA may fall short in the remedy department if your study site includes a hospital where the investigators have staff privileges but are not hospital employees.

The case deals with two patients who suffered surgery-related injuries caused by a doctor who had staff privileges at Greenville Health System. McCord v. Laurens Cty. Heath Care Sys., 2020 BL 4711, S.C. App., No 5705, 1/8/20. The court held that the hospital was not responsible for the over $3 million in damages awarded to the patients for the doctor's medical malpractice. This malpractice occurred between December 2008 – May 2009 (Malpractice Period).

During the Malpractice Period, the doctor maintained "claims-made" medical malpractice insurance of $200,000 per claim and $600,000 annual aggregate, with excess coverage in effect, through Joint Underwriting Association (JUA). In July 2009, the doctor switched his malpractice insurance from JUA to MAG Mutual. His insurance from JUA lacked "tail coverage," and he declined "prior acts" coverage from MAG Mutual. When the judgments were rendered for malpractice occurring from December 2008 – May 2009, the doctor's insurance did not cover them.

In the clinical trials context, the looming risk of subject injury means that sponsors need to have their own insurance policies in place along with appropriate indemnification from sites that is backed up with adequate insurance maintained by the sites.

As you know, site structures vary widely across the country. Hospitals frequently have investigators, anesthesiologists, radiologists, pathologists and other physicians on board who are independent contractors rather than hospital employees. While the hospital may have a legal obligation under state law and/or hospital bylaws to require these independent contractor physicians to have insurance, the court acknowledges that "Other courts have rejected attempts to saddle hospitals with a duty to verify its treating physicians are covered by adequate malpractice insurance." Here, the court held that the hospital did not have a duty to ensure that the doctor had malpractice insurance.

In this case, although the doctor did maintain insurance during the Malpractice Period, he changed insurance in a way that left him without coverage for the Malpractice Period, and the court did not find that the hospital should be left holding the bag. In a clinical trial context, if the investigator lacks adequate insurance and the hospital has no duty to ensure that the investigator has adequate insurance, then a court may decide that, as between the injured study subject and the sponsor, the sponsor should be responsible. (That analysis leads to a "joint and several liability" discussion that is beyond the scope of this post.) While the outcome may vary by state and by the facts of the case, the prudent and easiest administrative approach is to require the hospital's indemnification provision in the CTA to cover the entire team that it brings to the table, including its physician contractors. As between the sponsor and the hospital, the hospital is in the best position to address this matter, as the hospital can then turn around and, in its arrangements with its team members, require them

to maintain adequate insurance. Another reason to take this approach is that the hospital typically has a much deeper pocket than an individual doctor.

If you have any questions or would like more information about these developing issues, please contact the following:

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