VERMONT SUPERIOR COURT
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CIVIL DIVISION
Case No. 416-12-16 Wmcv

Mayotte et al vs. Brattleboro Memorial Hospital, et al.

Decision on Defendants' Motion *in Limine* to Exclude Evidence of Post-Care Inspection and Policy Changes (Motion 57)

By motion filed February 24, 2020, Defendants moved to preclude Plaintiffs from introducing evidence at trial relating to an inspection by the State Division of Licensing and Protection ("DLP"), the report resulting from that inspection, and any subsequent corrective action taken by Brattleboro Memorial Hospital ("BMH"). Plaintiffs opposed the motion, and Defendants filed a reply brief. The court heard oral argument on March 11, 2022.

The events giving rise to this medical malpractice action occurred in March 2015. In June 2015, the DLP conducted an unannounced site visit at BMH and identified a federal regulatory violation pertaining to "Quality Assurance and Performance Improvement" for patient safety. The document Defendants seek to exclude resulted from the DLP inspection. It is completed on a form from the federal Department of Health and Human Services; it references federal regulatory provisions pertaining to patient safety and includes DLP's conclusions and a plan of correction ("DLP report"). The DLP report says the agency's conclusions are based on staff interviews and a record review.

The DLP report relates to how BMH handled its obligations under federal law to measure, analyze, and track the adverse event that is the subject of this case. The report says that BMH "failed to utilize their established event reporting system to collect information related to an adverse patient outcome and analyze the cause in an effort to identify opportunities for improvement and implement preventative actions." DLP Report at 2. The report states that the patient's medical problems placed her at "high risk during pregnancy," briefly describes the circumstances of her discharge from the Birthing Center, and refers to an "unanticipated home delivery with serious complications and harm resulting." *Id.* The DLP concluded that: "Despite the negative outcome for the patient, staff failed to complete an event report and conduct a [Root Cause Analysis] to investigate the incident in accordance with the hospital's Incident Reporting policy." *Id.* The report says that hospital staff confirmed that an event report should have been completed but had not been done; that there had not yet been an internal investigation to identify "any possible areas for improvement"; and that they were still waiting for a peer review to be completed. *Id.* at 3.

The second part of the DLP report is BMH's three-page plan of correction to address the regulatory violations described above.[1] Among other things, it lists completion dates for various actions, including a root cause analysis on the "adverse outcome case" and the "response to adverse event;" peer review; revisions to the incident reporting policy "to ensure reporting and tracking of adverse events;" revisions to the root cause analysis policy, risk management plan, performance improvement plan, chart location policy, chain of command policy, scope of practice for Certified Nurse Midwives, and peer review process; reorganization of risk management duties "to allow for more oversight"; presentation of the case to a "Quality Patient Safety Committee"; and assessment of the peer review process by consultants.

BMH subsequently performed a root cause analysis, conducted peer review, and revised some policies. The court previously ruled, pursuant to 26 V.S.A. §§ 1441–1443, that documents relating to the root cause analysis and peer review are privileged and not subject to discovery. See Decision and Order dated August 27, 2019.

Defendants' position is that the entire DLP report is irrelevant because it pertains to the timeliness of BMH's internal response to the case after the events occurred, not the care BMH provided Ms. Mayotte. To the extent it could be relevant, Defendants contend the report is more prejudicial than probative, "because it would improperly suggest to the jury that the inspection necessarily means that BMH did something wrong in caring for Ms. Mayotte." Motion at 2. Finally, Defendants say the policy changes are inadmissible subsequent remedial measures under V.R.E. 407.

Plaintiffs maintain the DLP report and correction plan are "highly probative of disputed facts in this case," and that the report is not unfairly prejudicial or protected by privilege. Opp. at 1. Further, Plaintiffs argue that V.R.E. 407's bar to the admission of evidence of subsequent remedial measures does not apply because the evidence falls outside Rule 407 or will be used for a purpose that is an exception to Rule 407.

Specifically, Plaintiffs would like to be able to use the report's statement that the incident at issue was an "adverse event" pursuant to 18 V.S.A. § 1912(1), because they say this is in dispute, and the report may be needed for impeachment. The court concludes that this statement has very little probative value, and it is unlikely to be needed at trial for impeachment.

Title 18 is part of the state regulatory framework for hospitals; it contains rules for a patient's bill of rights, licensing, privacy, and a system for tracking and improving patient safety. Section 1915 requires hospitals, among other things, to have internal polices for tracking and analyzing "reportable adverse events, adverse events, and near misses," to in fact report such adverse events to the Department, and to provide the Department with its causal analysis and correction plan for each reportable adverse event. 18 V.S.A. § 1915.

Section §1912(1) defines an adverse event as "any untoward incident, therapeutic misadventure, iatrogenic injury, or other undesirable occurrence directly associated with care or services provided by a health care provider or health care facility." 18 V.S.A. § 1912(1). Clearly, this definition includes

[1] The court does not know who created or is responsible for the content of the provider's plan of correction.

events that are not caused by medical negligence. Defendants also correctly point out that the DLP report does not refer to Title 18.

Rather, the form refers to § 482.21 of Title 42 of the Code of Federal Regulations, pertaining to quality assessment and performance improvement at hospitals that receive Medicaid and Medicare federal funding. These regulations implement the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21 *et seq*. The specific regulations mentioned on the form, § 482.21(a), (c)(2), and (e)(3), require a hospital, among other things, to measure, analyze, and track quality indicators, including "adverse patient events"; track medical errors and adverse patient events, analyze their causes, implement preventive actions; and establish clear expectations for safety. 42 C.F.R. § 482.21.[2]

Suffice it to say, the DLP's report indicates BMH inadequately handled its internal, post-care analysis and tracking of the adverse event that is the subject of this litigation. There is no express finding that this was a "reportable adverse event" under Title 18, which would mean BMH was required to report the event to regulatory authorities.

Importantly, Plaintiffs have not demonstrated how BMH's handling of its internal quality assurance protocols after this incident has any relevance to the ultimate question of negligence. The State's definition of "adverse event" is broad and has little relationship to the question of malpractice. The court has not found any definition of "adverse patient event" in the federal framework, but certainly has no reason to conclude that it is any less broad than the Vermont definition. The DLP investigation and report indicates that the hospital had some deficiencies in its internal procedures for measuring, reporting, and tracking an adverse outcome or event. Yet it contains no information about whether the hospital made a medical error in providing care to Ms. Mayotte.

Therefore, the report's statement that there was an adverse event is only relevant to the question of whether something undesirable occurred. This is not contested.

Any limited probative value of this statement must be weighed against the risk that the DLP report will confuse the jury, cause unnecessary delay, be unfairly prejudicial, or result in the needless presentation of evidence. V.R.E. 403.

Because Defendants acknowledged at oral argument that this was an "adverse event," and refer to it as a "mal-occurrence" in their brief, it is very unlikely this information will be needed for impeachment at trial. It does not appear to be in dispute. Based on these admissions, the court believes that this finding will be cumulative and unnecessary.

Also, it would take considerable time and effort for the parties to explain this report to the jury in any coherent way. Defendants have a legitimate concern about creating a "trial within a trial" if the plaintiffs are permitted to do so. In order for the jury to be able to understand the meaning of this report, they would have to be told in some detail about the systems of state and federal regulation that mandate hospitals to analyze and track adverse patient events of all kinds, those caused by negligence and otherwise. The defense is also reasonable in having concerns that if the jury is told of the

[2] An "event report" constituting "patient safety work product" issued pursuant to these rules is privileged, subject to certain exceptions. 42 U.S.C. § 299b-22; *Univ. of Kentucky v. Bunnell*, 532 S.W.3d 658, 666 (Ky. Ct. App. 2017), as modified (Oct. 30, 2017).

hospital's duty to conduct root cause analysis and peer review, they will wonder about the outcomes of those analyses. For important policy reasons that information is privileged and confidential, as the court previously ruled. The lack of information and explanation would be likely to cause a jury confusion, or lead them to believe that the hospital was hiding something. References to regulatory violations by the hospital could suggest to the jury that the government believes BMH did something wrong. The very limited probative value of this evidence does not outweigh the risk of unfair prejudice.

The court makes a similar determination with respect to the other information in the DLP report. Plaintiffs believe it is significant that the report refers to Ms. Mayotte's pregnancy as "high risk" because Defendants have said the question of whether a patient is "high risk" is complicated and not binary. Again, Plaintiffs want to be able to use the report for impeachment. At argument, Defendants noted that two experts will testify at trial that Ms. Mayotte was at high risk. Further, the court understands that the regulator's basis for indicating this was a high-risk pregnancy comes from the patient's medical records, and perhaps staff interviews. These medical records and expert testimony will be better evidence of Ms. Mayotte's condition and the risks related to her pregnancy and birth. This report's reference to high-risk pregnancy has minimal probative value, if any, and it is likely to add nothing to the primary evidence offered at trial.

The report states that there was a "negative outcome for the patient" and that she had experienced an "unanticipated home delivery with serious complications and harm resulting." Plaintiffs say these facts are in dispute. Defendants contend that the fact of harm associated with this delivery is not in dispute; the question is whether the harm was caused by Defendants' breach of the standard of care. Further, these statements are certain to duplicate other evidence.

The parties also disagree about whether the plan of correction contains relevant and probative evidence that survives Rule 403 balancing, and, if it does, whether it would have to be excluded under Rule 407 as evidence of subsequent remedial measures.

The plan of correction refers to several policy revisions to be undertaken by the hospital, including a "chart location policy." Plaintiffs view the reference to chart location policy to be significant because they contend nurses caring for Ms. Mayotte did not have access to some of her prenatal records. Plaintiffs say this document shows BMH had "a professional duty to ensure that the providers at the birthing center had access to Jessica Mayotte's prenatal records . . . and prove it was feasible to make that happen." Opp. at 4. Or, they say, it could be used to impeach any defense witnesses who suggest the records were available at the birthing center.

Defendants contend the reference to "chart location policy" is in fact a misnomer and that there was no revision to a chart location policy. Rather, they say this refers to a policy regarding tracking, record keeping, and storage, which is attached as Exhibit D to their reply. The policy says, "Records will be developed for each educational activity, stored to ensure retrieval, and kept confidential." The document does not expressly reference a policy regarding the location of a patient chart, but rather appears to pertain to the continuing education of nurses. Thus, the reference to revisions of a chart location policy appears to be irrelevant, and potentially misleading.

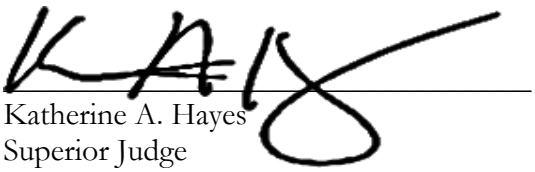
Plaintiffs also want to admit the reference to a revision to the scope of practice for certified nurse midwives. Plaintiffs' theory is that this shows the midwives had a professional duty to Ms. Mayotte to abide by BMH guidelines on the scope of care. Again, this broad reference to revising the scope of

practice is unlikely to be probative of anything. If the midwives' duty to abide by BMH guidelines is a contested issue at trial, the court may revisit this issue.

In sum, the DLP report is, at best, minimally probative with respect to the question of Defendants' negligence, but is very likely to cause confusion, delay, or unfair prejudice to Defendants. Many of the statements contained in the report are also cumulative or undisputed. Under Rules 401 and 403, the report should not be admitted at trial for purposes of impeachment or otherwise.

The motion in limine to exclude the report is therefore granted. While the court believes this evidence is very unlikely to be admitted for any purpose based on the parties' submissions in this motion, the court recognizes that the unexpected can occur at trial. For that reason, the motion is granted without prejudice to Plaintiffs seeking permission to use the report for impeachment purposes during the course of the trial based on significantly different facts or circumstances arising at trial.

It is so ordered.



Katherine A. Hayes
Superior Judge
April 11, 2022