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ADVANCE SHEET HEADNOTE
October 14, 2014

2014 CO 73

No. 13SA124, Simpson v. Cedar Springs Hosp., Inc. – Quality Management Privilege.

In this original C.A.R. 21 proceeding, the supreme court holds that the trial court erred in finding that a hospital must have "authoritative" documentation of approval by the Colorado Department of Public Health and Environment ("CDPHE") for the quality management privilege under section 25-3-109, C.R.S. (2014) to apply. The supreme court holds that because the hospital maintained a CDPHE license at all relevant times, its quality management program was necessarily approved by CDPHE, and the documents from its quality management committee meetings are therefore covered by the quality management privilege. The supreme court makes this rule absolute, and remands to the district court for further proceedings consistent with this opinion.

The Supreme Court of the State of Colorado

2 East 14th Avenue • Denver, Colorado 80203

2014 CO 73

Supreme Court Case No. 13SA124

Original Proceeding Pursuant to C.A.R. 21 El Paso County District Court, Case No. 10CV2481 Honorable David A. Gilbert, Judge

Plaintiff:

Scott R. Simpson,

v.

Defendants:

Cedar Springs Hospital, Inc., a Delaware Corporation, d/b/a Cedar Springs Behavioral Health System; Roger Dwight Pumphrey, M.D.; and Charles J. Peck, M.D.

Rule Made Absolute

en banc October 14, 2014

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JUSTICE EID delivered the Opinion of the Court. JUSTICE MÁRQUEZ dissents.

- Petitioner-Defendant Cedar Springs Hospital, Inc. ("Cedar Springs") petitioned this Court under C.A.R. 21 to issue a rule to show cause challenging the trial court's order that it produce materials related to quality management. In the underlying medical malpractice case, Respondent-Plaintiff Scott R. Simpson ("Simpson") sought to obtain the minutes from meetings of two Cedar Springs quality management committees. Cedar Springs refused to produce these documents, asserting that they were protected by the quality management privilege set forth in section 25-3-109, C.R.S. (2014). This privilege covers "records, reports, or other information of a licensed or certified health care facility that are part of a quality management program." § 25-3-109(3) (emphasis added). Section 25-3-109(2) defines "quality management program" as one that is "approved by" the Colorado Department of Public Health and Environment ("CDPHE").
- Before the trial court, Simpson argued that Cedar Springs failed to show that its quality management program was "approved by" CDPHE because it failed to show that its program complied with all CDPHE regulations. In particular, Simpson pointed to a letter from CDPHE stating that Cedar Springs' quality management plan "has been approved," and adding "[p]lease submit a schedule for implementation of the plan within 90 days." A CDPHE regulation requires facilities to submit "a schedule for [quality management] plan implementation" within 90 days of receiving written notice that its plan has been approved. 6 Code Colo. Regs. 1011-1:II-3.1.1(9) (2014). According to Simpson, because Cedar Springs failed to produce evidence that it submitted such an

implementation schedule in response to the letter, its program could not be deemed "approved."

- Tequired to maintain a CDPHE license, and because Cedar Springs was licensed by CDPHE throughout all relevant periods, its quality management program was necessarily approved by CDPHE.
- The trial court agreed with Simpson, reasoning that licensure was insufficient to demonstrate that facilities "complied with what they are required to comply with," and stating that such facilities should have "authoritative" documentation "immediately in place" confirming that their quality management plans were properly implemented.
- We now make our rule absolute. Under the trial court's rationale, every privilege determination would entail a top-down compliance review of the facility claiming the privilege. The statutory scheme, however, tasks CDPHE—not the trial court—with ensuring that a licensed facility's quality management complies with applicable CDPHE regulations. Moreover, the trial court's reasoning misperceives the purpose of the quality management privilege, which is to promote frank and honest discussion about quality management, not to act as a backstop for regulatory compliance. We hold that because a quality management program is required in order to be licensed by CDPHE, and because Cedar Springs was licensed by CDPHE during all relevant periods, its quality management program is necessarily "approved" by CDPHE. Therefore, the documents here were created as part of a quality management

program approved by CDPHE and are protected by the quality management privilege.

Accordingly, we conclude that the trial court erred in ordering that they be produced.

T.

- In 2008, Simpson sought treatment at Cedar Springs for depression, anxiety, and panic attacks. He was given a course of treatment and administered various medications. Simpson alleges that these medications resulted in complications including a toxic acquired brain injury, temporal lobe brain epilepsy, vestibular damage, and central nervous system damage. Simpson brought a medical malpractice suit against Cedar Springs and psychiatrists Dr. Roger Pumphrey and Dr. Charles Peck,¹ alleging that they negligently prescribed inappropriate medications, inadequately monitored him, and failed to take corrective action when he had negative reactions.
- Initial depositions included that of Jodi Mattson, Cedar Springs' Director of Nursing. She testified that the Pharmacy and Therapeutics Committee and the Performance Improvement Committee maintained minutes of their meetings and their review of adverse drug reactions. After Mattson's deposition, Simpson served a request for production on Cedar Springs, asking for "a copy of [the Pharmacy and Therapeutics Committee's and the Performance Improvement Committee's] minutes from January 1, 2008 to present, as well as any such document[s] in any way pertaining to Scott Simpson."

¹ Simpson dismissed his claims against Dr. Peck, and Dr. Pumphrey did not participate in this C.A.R. 21 proceeding.

- Cedar Springs responded to this request by stating that the information was subject to the quality management privilege pursuant to section 25-3-109, which makes privileged records, reports, or other information of a licensed health care facility that are part of a CDPHE-approved quality management program. Cedar Springs argued that because it was licensed by CDPHE, its quality management program was necessarily approved by CDPHE. It was undisputed that Cedar Springs was initially licensed, and that its license was repeatedly renewed throughout the period relevant to this case.
- Cedar Springs also produced a privilege log and a supplemental privilege log providing details about the requested documents. The supplemental privilege log stated,

[the meetings] were conducted pursuant to a Performance Improvement Plan . . . as part of Cedar Springs' quality management program as identified in the Performance Improvement Plan. Cedar Springs is approved by [CDPHE]. Accordingly, the actions of the Committee, particularly as reflected in the minutes of meetings conducted as part of a Performance Improvement Plan, are privileged.

Simpson filed a motion seeking in camera review and production of seventeen sets of minutes from the supplemental privilege log. Simpson argued that the minutes were discoverable because, in order for a quality management program to be deemed "approved" by CDPHE, a facility had to demonstrate that its quality management program was in compliance with all applicable CDPHE regulations. In particular, Simpson argued that the quality management program was not in compliance with 6 Code Colo. Regs. 1011-1:II-3.1.1(9), which requires a facility to submit to CDPHE "a

schedule for [quality management] plan implementation not to exceed 90 days after the date the facility receives written notice of [CDPHE's] approval of the plan."

- Cedar Springs produced a letter from CDPHE dated October 14, 2003, stating that "your [quality management] plan has been approved. Please submit a schedule for implementation of the plan within 90 days of commencing operation." Simpson argued that because Cedar Springs had produced no evidence that it had submitted an implementation schedule within 90 days, the quality management program could not be deemed "approved."
- In addition, Simpson argued that Cedar Springs was not in compliance with another CDPHE regulation requiring that it submit to CDPHE "a description of" a "permanent and substantive change in its quality management plan." 6 Code Colo. Regs. 1011-1:II-3.1.4. Simpson argued that Cedar Springs made such a change in 2008 and failed to produce evidence that it had submitted the change to CDPHE.
- The trial court agreed with Simpson with regard to the implementation plan and ordered that the documents be produced for in camera review. The court stated that it was "not convinced that just because the facility is reissued a license, it demonstrates that they have necessarily complied with what they are required to comply with in order to ensure that their quality management program maintains a certain privilege."

 The court also stated that it was denying the privilege in this case in order to encourage facilities such as Cedar Springs to have "authoritative" documentation "immediately in place" confirming that their quality management plans are properly implemented. The

trial court did not address Simpson's alternative argument regarding Cedar Springs' alleged failure to submit to CDPHE changes it made to the plan in 2008.

¶14 This C.A.R. 21 proceeding followed.

II.

This case requires us to determine whether the documents sought by Simpson are covered by the quality management privilege as defined by section 25-3-109. Questions of privilege are particularly appropriate for review under C.A.R. 21 because an erroneous disclosure of privileged information may cause harm that cannot be remedied on appeal. Ortega v. Colo. Permanente Med. Grp., P.C., 265 P.3d 444, 447 (Colo. 2011). Because this case requires us to interpret the statutory definition of "quality management program," we employ a de novo standard of review. Smith v. Exec. Custom Homes, Inc., 230 P.3d 1186, 1189 (Colo. 2010).

The quality management privilege is governed by section 25-3-109, entitled "Quality management functions – confidentiality and immunity." According to the legislature, "the implementation of quality management functions to evaluate and improve patient and resident care is essential to the operation of health care facilities licensed or certified by the" CDPHE. § 25-3-109(1). The legislature has further declared that, given the importance of quality management, "it is necessary that the collection of information and data by such licensed or certified health care facilities be reasonably unfettered so a complete and thorough evaluation and improvement of the quality of patient and resident care can be accomplished." <u>Id.</u> To this end, the legislature has deemed "confidential" any "records, reports, or other information of a licensed or

certified health care facility that are part of a quality management program." § 25-3-109(3). Such information "shall not be subject to subpoena or discoverable or admissible as evidence in any civil or administrative proceeding." § 25-3-109(4). In other words, it is covered by the quality management privilege.

Breaking down the statutory requirements, the quality management privilege applies to (1) "records, reports, or other information" (2) of a "licensed or certified health care facility" (3) that are "part of" (4) a "quality management program." § 25-3-109(3). No one disputes that the documents sought by Simpson—that is, minutes of meetings of the Pharmacy and Therapeutics Committee and the Performance Improvement Committee—are "records, reports, or other information." Nor does anyone dispute that they are records of a "licensed or certified health care facility," that is, Cedar Springs. Finally, no one disputes that the records were created as "part of" Cedar Springs' quality management program.² The only question in this case is

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² This case is thus distinguishable from Zander v. Craig Hospital, 267 F.R.D. 653 (D. Colo. 2010) ("Zander I") and Zander v. Craig Hospital, 743 F. Supp. 2d 1225 (D. Colo. 2010) ("Zander II"). There, the court held that only information created as part of a facility's quality management program—not "every word uttered by a licensed health care professional . . . following a procedure or treatment"—would be covered by the privilege. Zander I, 267 F.R.D. at 661. It is in this context that the court stated that only statements made in "compl[iance]" with a facility's quality management program would be covered by the privilege. Id.; see also Zander II, 743 F. Supp. 2d at 1234–35 (holding that documents created as part of the facility's quality management program were privileged, whereas documents created as part of physician's independent investigation were not). In this case, no one disputes that the minutes in question were created as part of Cedar Springs' quality management program, specifically the Pharmacy and Therapeutics Committee and the Performance Improvement Committee. There is therefore no need for us to determine the scope of the privilege as to whether documents were created as "part" of a quality management program.

whether Cedar Springs' program meets the statutory definition of "quality management program," which is one that has been approved by CDPHE.

¶18 Section 25-3-109(2) defines a "quality management program" as

a program which includes quality assurance and risk management activities, the peer review of licensed heath care professionals not otherwise provided for [in another statutory provision], and <u>other quality management functions which are described by a facility in a quality management program approved by the department of public health and environment.</u>

(Emphasis added.)³ This definition of a quality management program is somewhat circular, defining such a program in relation to the functions of such a program as described by the facility. The definition does, however, provide an additional guidance—namely, that the quality management program to which the privilege applies is one that is "approved by" CDPHE.

Cedar Springs argues that because a quality management program is required to maintain a CDPHE license, and because Cedar Springs was licensed by CDPHE throughout all relevant periods, its quality management program is necessarily "approved" by CDPHE. In contrast, Simpson argues, and the trial court held, that licensure is not sufficient to show that a program has been "approved." We agree with Cedar Springs, and hold that if a facility is licensed by CDPHE, its quality management program is an "approved" program under the statutory definition.

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³ The parties and the trial court have focused on the third phrase of section 25-3-109(2). We do as well, and do not consider whether the documents in question might have been produced in conjunction with the first two phrases.

CDPHE regulations require that all licensed facilities "establish a quality ¶20 management program . . . that complies with" an extensive list of requirements. 6 Code Colo. Regs. 1011-1:II-3.1. CDPHE oversees this regulatory compliance through regular fitness reviews. 1011-1:II-2.8.1 (CDPHE "shall review [a facility's] fitness to conduct or maintain a licensed operation"). As part of these fitness reviews, CDPHE "shall determine by on-site inspection or other appropriate investigation [the facility's] compliance with applicable statutes and regulations." <u>Id.</u>; see also 1011-1:II-2.11.1 ("The Department . . . shall have the right to enter upon and into the premises of any licensee or applicant for a license in order to determine the state of compliance with the law and regulations"). Particularly relevant to this case, fitness reviews include consideration of the facility's "quality improvement plans, other quality improvement documentation as may be appropriate, and accreditation reports." 1011-1:II-2.8.1(E). If for some reason CDPHE determines that a licensed facility's quality management program is not in compliance with applicable regulations, it has broad discretion in taking action against the facility. 1011-1:II-2.9.3 ("A license issued by the Department may be revoked, suspended, annulled, limited, or modified at any time during the license term because of a licensee's failure to comply with any of the applicable statutes or regulations "). Therefore, under CDPHE regulations, a facility may maintain its license only if it has established a quality management program approved by CDPHE.

As applied here, there is no dispute that Cedar Springs has maintained a CDPHE license at all relevant times. Its quality management program was therefore approved

by CDPHE, and the documents sought by Simpson that were produced as part of that program are privileged.⁴

In arguing that licensure is not sufficient to demonstrate CDPHE approval, Simpson contends that Cedar Springs' privilege claim must fail because it has not demonstrated that its quality management program is in compliance with all CDPHE regulations. In particular, Simpson points to a regulation requiring facilities to submit "a schedule for [quality management program] plan implementation" within 90 days of receiving written notice that its plan has been approved. 6 Code Colo. Regs. 1011-1:II-3.1.1(9). Simpson relies upon a 2003 letter from CDPHE stating that Cedar Springs' quality management plan "has been approved," and adding "[p]lease submit a schedule for implementation of the plan within 90 days." According to Simpson, because Cedar Springs failed to produce evidence that it submitted such an implementation schedule in response to the letter, its program cannot be deemed "approved" under the statutory definition.

We disagree with Simpson's argument, as well as the trial court's rationale adopting it, for two reasons. First, as made clear by the regulatory regime discussed

⁴ Simpson points to the fact that a new facility must submit to CDPHE for approval a plan for its quality management program within 90 days of receiving a license, 6 Code Colo. Regs. 1011-1:II-3.1.1, positing that possession of a license alone may not demonstrate regulatory compliance during the approval period. See 6 Code Colo. Regs. 1011-1:II- 3.1.2 (CDPHE may return the submitted plan to the facility with "specific reasons for disapproval" and a schedule for resubmission). However, in this case, because there is no dispute that Cedar Springs was initially licensed, and that its license was repeatedly renewed throughout the period relevant to this case, we need not address the potential application of the privilege within the approval period.

above, CDPHE—not the trial court—is the entity tasked with ensuring that a licensed facility's quality management program complies with applicable regulations. Indeed, we find nothing in the privilege statute or regulations to suggest that the trial court must find that a facility is in compliance with all CDPHE regulations in order for the quality management privilege to attach. On the contrary, the privilege attaches to "records, reports, or other information of a licensed or certified health care facility that are part of a quality management program" that has been "approved by [CDPHE]." § 25-3-109(2)–(3) (emphasis added). Under Simpson's argument and the trial court's rationale, every privilege determination would entail a top-down compliance review of the facility claiming the privilege. We do not believe such a review is contemplated or permitted by the statutory scheme.

On a similar note, Simpson's argument misperceives the purpose of the quality management privilege. The legislature recognized the privilege because, as noted above, "it is necessary that the collection of information and data by such licensed or certified health care facilities be reasonably unfettered so a complete and thorough evaluation and improvement of the quality of patient and resident care can be accomplished." § 25-3-109(1). In other words, quality management teams must be able to speak openly and honestly about the quality of services delivered in order for those services to be improved. There is nothing in the statutory scheme to suggest that a privilege determination should be used as a backstop for regulatory compliance. Indeed, the privilege is designed to encourage frank and open discussion about quality

management, not to punish a facility for failure to have approval documentation "immediately in place," as suggested by the trial court.

Simpson also contends that the privilege cannot attach in this case because Cedar Springs failed to show that its quality management program was in compliance with another CDPHE regulation requiring that it submit to CDPHE "a description of" a "permanent and substantive change in its quality management plan." 6 Code Colo. Regs. 1011-1:II-3.1.4. Simpson argues that Cedar Springs made such a change in 2008 and failed to produce evidence that it had submitted it to CDPHE. Although the trial court did not address this alternative argument in its ruling, we find it unpersuasive for the reasons stated above—namely, that the privilege determination is not a regulatory compliance review. In other words, determining whether a facility has submitted "permanent and substantive [plan] change[s]" to CDPHE is part of the ongoing licensure process, not a prerequisite to application of the privilege.

In sum, we hold that because Cedar Springs is licensed by CDPHE, it has an "approved" quality management program. The documents in question were therefore created as part of "a quality management program" as defined by statute. Accordingly, the documents are covered by the quality management privilege, and the trial court erred in ordering that they be produced.

III.

¶27 For the above reasons, we make the rule absolute and remand this case to the district court for further proceedings consistent with this opinion.

JUSTICE MÁRQUEZ dissents.

JUSTICE MÁRQUEZ, dissenting.

- Today, the majority concludes that because Cedar Springs Hospital remained licensed by the Colorado Department of Public Health and Environment ("CDPHE") during all relevant periods, CDPHE necessarily "approved" the hospital's quality management program, and therefore, documents created as part of the program were protected by the quality management privilege under section 25-3-109, C.R.S. (2014). I generally agree that ongoing licensure implies CDPHE approval of a hospital's quality management program. Such an inference is justified, however, only where CDPHE is actually aware of the components of the hospital's program.
- In this case, such an inference is unwarranted because it is undisputed that Cedar Springs made permanent changes to its quality management plan in 2008 (prior to Simpson's treatment) that it did not report to CDPHE. Although CDPHE regulations require a facility to report only "permanent and substantive" changes to its quality management plan prior to implementation, 6 Code Colo. Regs. 1011-1:II-3.1.4 (2014), Cedar Springs has failed to show that the permanent changes it made to the quality management plan in 2008 were not substantive. Its bare assertions that such changes were non-substantive do not, in my view, establish that the changes would not have impacted CDPHE's approval of the hospital's program. If the changes were indeed patently non-substantive, then a court should be able to make that determination. However, Cedar Springs neither produced nor identified the purportedly non-substantive changes made in 2008 and instead argued that Simpson failed to show that the hospital made substantive changes that it should have reported. The statutory

privilege at issue is a powerful one, and Cedar Springs had the burden to establish it was entitled to that privilege. Cedar Springs' argument turns this burden on its head.

In my view, a hospital that relies on ongoing licensure as evidence of the Department's continued approval of its quality management program must establish that it notified the Department of changes made to the quality management plan—or otherwise establish that it did not need to report the changes made. Here, Cedar Springs failed to meet this (minimal) burden because it neither submitted a description of its 2008 plan changes to CDPHE nor otherwise established that the 2008 changes were non-substantive and therefore did not have to be reported. Accordingly, I respectfully dissent.

I.

Simpson initially requested production of the minutes from meetings of two Cedar Springs quality management committees. Cedar Springs argued that such documents were protected by the quality management privilege under section 25-3-109.

Notably, Cedar Springs argued that because the hospital remained licensed, CDPHE necessarily had approved its quality management program. Simpson eventually moved for in camera review and production of certain minutes from Cedar Springs' supplemental privilege log, arguing that a quality management program can be "approved" by CDPHE only if it complies with CDPHE regulations, and Cedar Springs had failed to comply with a CDPHE regulation requiring the facility to submit a schedule for plan implementation. The court granted Simpson's motion, reasoning that Cedar Springs had failed to meet its burden to show that the privilege applied.

Following an in camera inspection of the meeting minutes, the court ordered the hospital to release the records to Simpson.

Based on a review of the minutes produced, Simpson requested additional documents, including a minutes notebook for 2008. Cedar Springs moved for reconsideration of the trial court's earlier ruling ordering in camera review and production of the minutes. Specifically, Cedar Springs sought reconsideration of the trial court's ruling that the quality management privilege was inapplicable and produced, for the first time, a letter from CDPHE dated October 14, 2003, stating that Cedar Springs' "plan has been approved." Cedar Springs asked the court to rule that the quality management privilege applied to bar Simpson from introducing the previously disclosed minutes at trial and to preclude Simpson from further discovery of quality management documents, including the minutes notebook for 2008.

In response to Cedar Springs' motion for reconsideration, Simpson pointed out that the newly disclosed October 2003 approval letter from CDPHE expressly informed Cedar Springs that "permanent and substantive changes in your plan must be reported to the Department prior to implementation." Simpson also established that Cedar Springs had made changes to its quality management plan in January 2008,¹ yet had failed to submit a description of such changes to CDPHE prior to implementation. In its reply in support of its motion for reconsideration, Cedar Springs did not show that it

¹ The quality management plan document reflects that it was issued in July 2001 and later revised in January 2008.

had reported such changes to CDPHE or that it was not required to report the changes. Indeed, it did not even identify what changes it had made to the plan in 2008.

II.

- The quality management privilege covers "records, reports, or other information of a licensed or certified heath care facility that are part of a quality management program." § 25-3-109(3). As the majority notes, the statutory definition of a "quality management program" is somewhat circular, see maj. op. ¶ 18, but such a program must be "approved by" CDPHE. § 25-3-109(2). Relevant here, CDPHE regulations require a facility that makes a "permanent and substantive change" to its quality management plan to submit a description of the change to the Department prior to implementation. 6 Code Colo. Regs. 1011-1-II-3.1.4. The Department shall notify the facility if the change fails to meet regulatory requirements. Id.
- The party claiming a statutory privilege has the burden of proving its applicability. Hartmann v. Nordin, 147 P.3d 43, 51 (Colo. 2006). In this case, Cedar Springs had the burden to show the documents at issue were part of an approved quality management program and therefore exempt from discovery. Cedar Springs argued that the hospital's continued licensure established that CDPHE approved its quality management program. It further asserted that the 2008 changes to its quality management plan were non-substantive and, therefore, it need not have reported them to CDPHE.
- I have no quarrel with the general notion that where CDPHE licenses a facility, it is reasonable to infer that the facility's quality management program is "approved" by

the Department. See maj. op. ¶¶ 19-21. Such an inference is justified, however, only because we assume that the Department has before it all information necessary to determine whether a program complies with applicable regulations. See id. at ¶ 20. In my view, such an inference is unwarranted in this case. It is undisputed that Cedar Springs made permanent changes to its quality management plan following CDPHE's initial approval, yet Cedar Springs failed to establish either that CDPHE was made aware of those changes or, alternatively, that such changes were non-substantive (and therefore not required to be reported to CDPHE for its consideration).² Under these circumstances, we cannot properly infer that ongoing licensure of the hospital reflects CDPHE approval of Cedar Springs' quality management program. Consequently, in my opinion, Cedar Springs did not meet its burden to show it was entitled to the protection of the quality management privilege.

III.

The quality management privilege is a powerful and important one, and Cedar Springs had the burden to establish it was entitled to the privilege. In my view, a hospital that relies on CDPHE licensure as evidence of the Department's continued approval of its quality management program must at least establish that it notified the Department of reportable changes made to the quality management plan—or otherwise

² Cedar Springs could have met this minimal burden by establishing that it had submitted the 2008 changes to CDPHE, or by presenting the actual changes made or a copy of the original 2001 plan for comparison. If indeed the changes were patently non-substantive, as Cedar Springs claimed, then the non-substantive nature of such changes should be readily determinable by a trial court.

establish that changes made to its program were not required to be reported. Because Cedar Springs did not meet its (minimal) burden in this case, I respectfully dissent.