

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

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| Elias Karkalas, M.D., | : | |
| Petitioner | : | |
| | : | |
| v. | : | |
| | : | |
| Department of State, Bureau of | : | |
| Professional and Occupational | : | |
| Affairs, State Board of Medicine, | : | No. 1932 C.D. 2012 |
| Respondent | : | Submitted: May 3, 2013 |

BEFORE: HONORABLE BONNIE BRIGANCE LEADBETTER, Judge
HONORABLE PATRICIA A. McCULLOUGH, Judge
HONORABLE ANNE E. COVEY, Judge

OPINION BY
JUDGE COVEY

FILED: June 11, 2013

Elias Karkalas, M.D. (Karkalas) petitions this Court for review of the Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine’s (Board) September 17, 2012 order imposing a \$2,500.00 civil penalty and requiring him to complete 10 hours of continuing education in the area of medical recordkeeping. The issue for this Court’s review is whether the Board erred as a matter of law when it interpreted Section 16.95(a) of the Board’s Regulations¹ (the Regulation) to require a physician providing prescription review services to a commercial company to have continuing access to and control over his patients’ medical records. We affirm.

The facts in this case are undisputed. Karkalas has held a license to practice medicine and surgery in Pennsylvania since 1981. In 2009, Karkalas contracted with Health Solutions Network, Inc. (HSN), a commercial company also known as a clearinghouse, to review online prescription requests. Pursuant to his

¹ 49 Pa. Code § 16.95(a).

contract, Karkalas filled prescription requests based upon HSN's customers' online questionnaires which provided information such as the reason for the request, medical history, and other prescribed medications being taken.

Between July 21, 2009 and September 3, 2009, Karkalas wrote 28 prescriptions for 28 HSN customers for the drug Butalbital. HSN maintained in its secure computer database all related questionnaire information of the individuals for whom Karkalas had written the prescriptions. Karkalas had full access to the online database and could contact an HSN custodian of records for further assistance in accessing patient records. During his contract with HSN and until late fall 2011, Karkalas kept his prescription records only on HSN's centralized database. He did not print or otherwise personally retain prescription records or patient questionnaires. Further, he did not maintain in his office any records, independent files, or even patient names pertaining to the online prescriptions.

At some point in 2011, HSN terminated its contract with Karkalas and discontinued his access to the online database. As a result, Karkalas was unable to obtain the records relating to the prescriptions he had written through HSN. HSN ultimately provided Karkalas with patient records evidencing that, in 2009, he had authorized 28 prescriptions for Butalbital through HSN. However, Karkalas could not verify the accuracy of the records. In the fall of 2011, upon realizing that he might not have access to documents and medical records generated for and maintained by clearinghouses for whom he performed services, Karkalas began to maintain his own records in a secure database in his office.

On April 14, 2011, the Board issued an Order to Show Cause alleging 2,499 counts that Karkalas had violated the Medical Practice Act of 1985² (Act) and the Regulation. The Order to Show Cause specifically alleged that Karkalas had

² Act of December 20, 1985, P.L. 457, No. 112, *as amended*, 63 P.S. §§ 422.1 - 422.51a.

engaged in unprofessional conduct, in that he failed to maintain medical records for 2,499 patients subjecting him to disciplinary action under Section 41(6) of the Act³ for violation of the Regulation.

At a March 27, 2012 hearing, the Board issued an amended Order to Show Cause reducing the number of counts to 28. The parties stipulated to the essential facts of the case and the sole issue. On May 14, 2012, the hearing examiner issued her report and order finding that Karkalas had violated the Regulation, and she imposed disciplinary action under Section 41(6) of the Act.

On May 24, 2012, the Board issued a notice of intent to review. On September 17, 2012, the Board issued its order adopting the hearing examiner's findings of fact, concluding that Karkalas had violated the Regulation when he failed to maintain access to and control over his patients' medical records. The Board issued its order imposing a \$2,500.00 civil penalty, and further required Karkalas to complete 10 hours of continuing education in the area of medical recordkeeping. Karkalas appealed to this Court.⁴

Karkalas argues that the Board erred when it held that he violated the Regulation. He claims that the Regulation does not require a physician "to have perpetual 'access to' and 'control over' [a patient's] medical records." Karkalas Br. at 10. He contends that the Board's interpretation of the Regulation ignores the realities of modern medical practice in that many physicians are employed by healthcare systems, hospitals or group practices where the employers and not the physicians maintain patient medical records. Because physicians are generally not

³ 63 P.S. § 422.41(6). This section authorizes the Board to impose disciplinary or corrective measures for violation of the Board's Regulations.

⁴ "This Court's standard of review of a decision of the State Board of Medicine is limited to determining whether necessary findings of fact are supported by substantial evidence in [the] record and whether there was [an] error of law or constitutional violation." *Perez-Rocha v. Bureau of Prof'l & Occupational Affairs, State Bd. of Med.*, 933 A.2d 1102, 1106 n.4 (Pa. Cmwlth. 2007).

permitted to take patient medical records with them when they leave employment, Karkalas asserts that if the Board's interpretation of the Regulation is permitted to stand, the aforementioned trade practices will result in countless physicians violating the Regulation. Accordingly, he argues the Board's interpretation of the Regulation must be erroneous. We disagree.

It is well-established that:

[i]n reviewing an administrative agency's interpretation of its own regulations, courts are governed by a two step analysis. First, in construing administrative regulations, the ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation. Second, the regulations must be consistent with the statute under which they are promulgated.

Commonwealth v. Forbes Health Sys., 492 Pa. 77, 81, 422 A.2d 480, 482 (1980) (citations and quotation marks omitted).

Section 16.95 of the Board's Regulations states, in relevant part:

(a) A physician shall maintain medical records for patients which accurately, legibly and completely reflect the evaluation and treatment of the patient. The components of the records are not required to be maintained at a single location. Entries in the medical record shall be made in a timely manner.

....

(e) A patient's medical record shall be retained by a physician for at least 7 years from the date of the last medical service for which a medical record entry is required. The medical record for a minor patient shall be retained until 1 year after the minor patient reaches majority, even if this means that the physician retains the record for a period of more than 7 years.

(f) The components of a patient's medical record, which are prepared by a physician or his agent and which are retained by a health care facility regulated by the Federal

government, or by the Department of Health or the Department of Public Welfare are considered to be a part of the patient's medical record which is required to be maintained by a physician, but are otherwise exempt from the requirements in subsections (a) -- (e). . . .

49 Pa. Code § 16.95.

As to the first part of the analysis, the Board asserts that its interpretation of the Regulation is not erroneous and is consistent with the Regulation's language. The relevant portion of the Regulation requires a physician to “**maintain** medical records for patients.” 49 Pa. Code § 16.95(a) (emphasis added). The Board contends that its interpretation of the word “maintain” as requiring a physician to have “access to and control over medical records,” is consistent with *Black's Law Dictionary* 965 (7th ed. 1999) which defines the word “maintain” to mean “to continue in possession of” and “to care for.”⁵

“Where a term is not defined, we are instructed that ‘[w]ords and phrases shall be construed according to rules of grammar and according to their common and approved usage.’ 1 Pa.C.S. § 1903(a). Moreover, in ascertaining the common and approved usage or meaning of a word, we may resort to the dictionary.” *St. Ignatius Nursing Home v. Dep't of Pub. Welfare*, 918 A.2d 838, 845 (Pa. Cmwlth. 2007). Because we agree that the Board's interpretation is not plainly erroneous and is consistent with the plain language of the Regulation as well as consistent with the aforementioned dictionary definition, we conclude that part one of the analysis has been met.

In regards to part two of the analysis, the Board notes that the Regulation is consistent with the statute under which it was promulgated. As authorized by

⁵ The Board acknowledges that a physician is not required to keep all components of a patient's medical record in one place, but must continue to have access to and control over the record for at least 7 years, as required under Section 16.95(e) of the Board's Regulations, 49 Pa. Code § 16.95(e).

Section 8 of the Act, “[t]he [B]oard, in the exercise of its duties under this act, shall have the power to adopt such regulations as are reasonably necessary to carry out the purposes of this act.” 63 P.S. § 422.8. This Court has stated that the purpose of the Act is “to provide for the proper licensing of practitioners by [a] duly constituted Board[] which could, by administrative regulation, establish standards of care and conduct by practitioners.” *Pa. Med. Soc’y v. State Bd. of Med.*, 546 A.2d 720, 723 (Pa. Cmwlth. 1988). Given this purpose, we agree that the Regulation is consistent with the Act, as it establishes standards of care and conduct for physicians.

As the Board correctly points out, Karkalas’ argument regarding the impact of the Board’s interpretation on modern medical practice is without merit.⁶ Section 16.95(f) of the Board’s Regulations⁷ specifically addresses Karkalas’ concerns by exempting those components of a patient’s medical record retained by a health care facility from the requirements of Section 16.95(a) of the Board’s Regulations.⁸

Because we conclude that the Board’s interpretation is not “plainly erroneous or inconsistent with the [R]egulation,” and is consistent with the Act, we hold that the Board properly found that Karkalas violated the Regulation, and

⁶ Karkalas’ maintenance of his own secure patient record database since the fall of 2011 demonstrates that the Board’s interpretation of its Regulation does not render physicians’ services to clearinghouses untenable merely by requiring those physicians to maintain access to and control over their patients’ medical records.

⁷ 49 Pa. Code § 16.95(f).

⁸ Karkalas did not discuss or otherwise mention Section 16.95(f) of the Board’s Regulations in his brief. However, the Board referenced that section in its responsive brief to address Karkalas’ argument on the impact of the Board’s interpretation upon the practice of medicine. Thereafter, for the first time, Karkalas argued in his reply brief that HSN should be considered a “health care facility” as described in Section 16.95(f) of the Board’s Regulations, and pursuant to that section, the records in HSN’s possession should have been exempted from the requirements of Section 16.95(a) of the Board’s Regulations. “[A]dditional arguments not raised in appellee’s brief may not be raised in a reply brief” *Firman v. Dep’t of State, State Bd. of Med.*, 697 A.2d 291, 297 n.11 (Pa. Cmwlth. 1997). Because Karkalas first raised these issues in his reply brief, they are waived.

imposed disciplinary action under Section 41(6) of the Act. *Forbes Health Sys.*, 492 Pa. at 81, 422 A.2d at 482.

For all of the above reasons, the Board's order is affirmed.

ANNE E. COVEY, Judge

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ORDER

AND NOW, this 11th day of June, 2013, the Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine's September 17, 2012 order is affirmed.

ANNE E. COVEY, Judge