

Office of the Attorney General

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MIKE HILGERS ATTORNEY GENERAL

LESLIE S. DONLEY
ASSISTANT ATTORNEY GENERAL

August 9, 2024

Via email at Raimundo Tigris

RE: Public Record Matter Involving the University of Nebraska (Nebraska Public

Health Laboratory)
Our File No. 20241137

Dear Mr. Tigris:

This letter is in response to your petition received by this office on July 17, 2024. You have requested the assistance of the Attorney General in obtaining CLIA¹ lab validation for certain tests performed at the Nebraska Public Health Laboratory (NPHL). On July 25, we discussed your petition with Jaclyn Klintoe, Director of University Records/Associate General Counsel, for the University of Nebraska (University). At our request, Ms. Klintoe provided us an analysis of the University's position relating to the requested records. On August 1, we informed you that our response would be delayed as we needed more time to consider the matter. We have now completed our review. We considered your petition under the provisions of the Nebraska Public Records Statutes (NPRS), Neb. Rev. Stat. §§ 84-712 through 84-712.09 (2014, Cum. Supp. 2022), amended 2024 Neb. Laws LB 43. Our findings in this matter are set forth below.

RELEVANTS FACTS

In an email sent to the NPHL on May 20, 2024, you requested the following records:

The CLIA lab validation for the following tests on the NPHL test menu (https://www.nphl.org/index.cfm/test-directory/ [nphl.org]):

We understand that Congress enacted the Clinical Laboratory Improvement Amendments (CLIA) in 1988 to "establish[] authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where or by whom the test was performed." See https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/6064bk.pdf.

Ebolavirus
Burkholderia pseudomallei
Smallpox
Lead, Filter Paper Blood Spot (LEADBS)
Lead, Capillary Whole Blood (LEDCAP)
Lead, Venous Whole Blood (LEDVEN)

You clarified you were "requesting the **documentation that the clinical laboratory maintains on file** to ensure compliance with '42 CFR § 493.1253 - Standard: Establishment and verification of performance specifications." (Your emphasis.)

Ms. Klintoe responded to your request on May 29, providing you copies of the University of Nebraska Medical Center's "CLIA Certificate of Accreditation" and the "CAP Certificate of Accreditation." Following a delay during which the University personnel assessed your request, Ms. Klintoe denied your request on July 3, asserting that responsive documents "are quality assurance materials protected by Nebraska's statutory peer review privilege" After further inquiries by you, Ms. Klintoe clarified on July 18 that the denial was based on provisions in the Health Care Quality Improvement Act (HCQIA),² specifically § 71-7912 relating to the confidentiality of peer review records. She stated that "the University's position is that the quality control documents requested are protected by the peer review privilege, as they are records of the peer review committee within the meaning of the Nebraska law, and are not subject to disclosure under the public records laws of Nebraska."

Your petition informs us that U.S. labs that report individual results to patients or their doctors are "clinical labs." These labs are subject to the requirements in 42 CFR 493. The NPHL is considered a clinical lab and "holds a high-complexity CLIA laboratory license via a Certificate of Accreditation." You indicate that clinical labs are required to have "test validation" on file for each test run by that lab as prescribed by 42 CFR 493.1253. You state that "[t]his is mundane, technical information that is maintained on file for the purpose of ensuring that diagnostic tests are appropriate for use with patients." You further state that these records "are typically composed by laboratory staff . . . and then approved by the CLIA Laboratory Director."

You disagree with the University's position that the requested records are protected under the HCQIA.³ You argue that "[a] plain review of 71-7910 indicates that peer review does not apply to the test validation activity of NPHL, i.e. professional credentialing and ongoing quality review do not pertain [to] test validation conducted under 42 CFR 493.1253." You acknowledge that the activities conducted for quality control and assurance purposes required in 42 CFR 493.1256 [Standard: Control

Neb. Rev. Stat. §§ 71-7904 to 71-7913 (2018, Cum. Supp. 2022).

We acknowledge the confusion caused by the reference to a repealed statute in the denial letter.

Procedures] could be construed "as 'quality review' under § 71-7910," but conclude that "71-7912 cannot apply."

Ms. Klintoe informs us that the validation documents contain "parameters around precision, accuracy, sensitivity, specificity (including interfering substances), calibration, and quality control." A NPHL medial director "evaluates the data for acceptability for use as a clinical diagnostic test." Ms. Klintoe states that "NPHL's laboratory quality committee also oversees the Lab's quality management and ensures that these validations and verifications are completed."

In support of the University's position that § 71-7912 applies to the requested records, Ms. Klintoe represents:

The Lab's laboratory quality committee is a peer review committee within the meaning of Neb. Rev. Stat. § 71-7910(1)(a) and its confirmation that laboratory validation materials are completed and current for accreditation purposes is a peer review activity as defined in § 71-7909. The definition of peer review explicitly captures the "compliance of a hospital . . . or other health care facility operated by a health care provider . . . with applicable laws, rules, and regulations." § 71-7909. Here, federal regulation (CFR § 493.1253) requires that a lab operating like NPHL maintain specific accreditation status. Therefore, the documents used by NPHL's laboratory quality committee to ensure federal regulatory compliance with CFR § 493.1253 are peer review committee records within the meaning of Nebraska law and are subject to the presumption of confidentiality contained in § 71-7912. See Neb. Rev. Stat. § 71-7912 ("The . . . records . . . of a peer review committee shall be held in confidence . . . [.]").

DISCUSSION

Public records in Nebraska "include all records and documents, regardless of physical form, of or belonging to this state, any county, city, village, political subdivision, or tax-supported district in this state, or any agency, branch, department, board, bureau, commission, council, subunit, or committee of any of the foregoing." Neb. Rev. Stat. § 84-712.01(1) (2014). While access to public records is broad, it is not absolute. The NPRS allow access "[e]xcept as otherwise expressly provided by statute" (§ 84-712(1)) or "[e]xcept when any other statute expressly provides that particular information or records shall not be made public" (§ 84-712.01(1)). "A statute qualifies as an 'other statute' under § 84-712(1) when the plain language of a statute makes it clear that a record, or portions thereof, is exempt from disclosure in response to a public records request." State ex rel. BH Media Group, Inc. v. Frakes, 305 Neb. 780, 794, 943 N.W.2d 231, 243-44 (2020). The burden of showing that a statutory exception applies to disclosure of particular records rests upon the custodian of those records. Id. at 788, 943 N.W.2d at 240; Aksamit Resource Mgmt. LLC v. Neb. Pub. Power Dist., 299 Neb. 114, 123, 907 N.W.2d 301, 308 (2018).

Three statutes in the HCQIA are pertinent to our discussion. First, Neb. Rev. Stat. § 71-7909 defines "peer review" as

the procedure by which health care providers evaluate the quality and efficiency of services ordered or performed by other health care providers, including practice analysis, inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review, root cause analysis, claims review, underwriting assistance, and the compliance of a hospital, nursing home, or other health care facility operated by a health care provider with the standards set by an association of health care providers and with applicable laws, rules, and regulations.

Peer review committees are defined in § 71-7910(1), which provides:

- (1) Peer review committee means a utilization review committee, quality assessment committee, performance improvement committee, tissue committee, credentialing committee, or other committee established by a professional health care service entity or by the governing board of a facility which is a health care provider that does either of the following:
- (a) Conducts professional credentialing or quality review activities involving the competence of, professional conduct of, or quality of care provided by a health care provider, including both an individual who provides health care and an entity that provides health care; or
- (b) Conducts any other attendant hearing process initiated as a result of a peer review committee's recommendations or actions.

The confidentiality provision relied on by the University as its basis to deny you access to the validation records states, in part:

(1) The proceedings, records, minutes, and reports of a peer review committee shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action. No person who attends a meeting of a peer review committee, works for or on behalf of a peer review committee, provides information to a peer review committee, or participates in a peer review activity as an officer, director, employee, or member of a professional health care service entity or an officer, director, employee, or member of the governing board of a facility which is a health care provider shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings or activities of the peer review committee or as to any findings, recommendations, evaluations, opinions, or other actions of the peer review committee or any members thereof.

* * *

(3) A health care provider or individual claiming the privileges under this section has the burden of proving that the communications and documents are protected.

Neb. Rev. Stat. § 71-7912 (emphasis added).

We have carefully considered the parties' respective positions in conjunction with the statutes cited above. In our view, the University has met its burden to protect the confidentiality of the records at issue. Ms. Klintoe represents that the NPHL laboratory quality committee is a peer review committee as contemplated in § 71-7910(1)(a). The committee oversees the NPHL's "quality management and ensures . . . validations and verification are completed." The committee's oversight constitutes a peer review activity under § 71-7909, which expressly includes "compliance . . . with applicable laws, rules, and regulations." She asserts that CFR § 493.1253 requires NPHL to maintain specific accreditation, and that the documents used by the committee to ensure regulatory compliance are peer review records. Accordingly, those records are confidential under § 71-7912. We agree. Moreover, while you argue that the NPHL's test validation activity does not apply to "peer review," you acknowledged that certain activities performed pursuant to 42 CFR § 493.1256 could be viewed as "quality review under § 71-7910."

In Nebraska, statutory language is to be given its plain and ordinary meaning; an appellate court will not resort to interpretation to ascertain the meaning of statutory words which are plain, direct, and unambiguous. *Farmers Cooperative v. State*, 296 Neb. 347, 893 N.W.2d 728 (2017). The plain language in § 71-7912 makes peer review committee records *confidential*, not subject to discovery nor to be offered as evidence in civil actions. Thus, § 71-7912 is an "other statute" that the University may continue to rely on to protect the confidentiality of the validation records at issue.

CONCLUSION

For the reasons explained above, we conclude that the requested CLIA lab validation for certain tests performed by the NPHL are confidential records pursuant to § 71-7912. Since the University did not unlawfully deny your records request, no further action by this office is warranted and we are closing this file.

If you disagree with our analysis, you may wish to discuss this matter with your private attorney to determine what additional remedies may be available to you under the NPRS.

Sincerely,

MIKE HILGERS Attorney General

Leslie S. Donley

Assistant Attorney General

c: Jaclyn Klintoe (via email only)

49-3602-31