

FILED
March 31, 2016
In the Office of the Clerk of Court
WA State Court of Appeals, Division III

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION THREE

TYLER ARNOLD and JASON)	
SWANSON,)	No. 32055-3-III
)	
Appellants,)	
)	
v.)	
)	UNPUBLISHED OPINION
DEPARTMENT OF HEALTH,)	
)	
Respondent.)	

KORSMO, J. — At issue in this appeal is whether the authority of the Department of Health (DOH) to regulate the unauthorized practice of medicine extends to tattoo artists who use a laser device to remove tattoos. Specifically, does use of a laser device to remove tattoos constitute the practice of medicine? We conclude that DOH had the authority to regulate the device in question and affirm the fines imposed on appellants Tyler Arnold and Jason Swanson.

FACTS

The appellants are licensed tattoo artists who operate tattoo parlors in both the city of Spokane and the city of Spokane Valley. As pertinent here, they also remove tattoos using a Palomar Q-YAG 5 laser device that they acquired in 2008 from a company in

Texas. The two men underwent a one day training in the use of the device by a registered nurse in California.

Someone complained to the DOH in 2009 concerning the use of the Q-YAG 5 device and an investigation ensued. In 2012 DOH sent both Mr. Arnold and Mr. Swanson notices of intent to issue cease and desist orders related to the unauthorized practice of medicine for the use of the Q-YAG 5 device. The charges were contested in an administrative hearing before a Health Law Judge, Jerry Mitchell.

The appellants testified at the hearing and also called an expert, Patrick Clark, to discuss laser devices. Tattoos are created by depositing ink, in particles too large to be absorbed and removed from the body, between layers of the skin. The Q-YAG 5 is a laser device designed to remove tattoos, hair, vascular lesions, and pigmented lesions. It removes tattoos by passing through the upper layer of skin and heating the ink so that it breaks into smaller particles that can be absorbed by the body. Multiple treatment sessions may be required to remove a tattoo.

The operating manual for the Q-YAG 5 indicates that a "complete medical history" should be obtained from the patient and lists some of the specific medical conditions and types of medication that can affect the laser treatment. Administrative Record (AR) at 188-189. The consent and information forms used by the appellants explain the treatment process and some of its possible side effects, and solicit some of the

required medical information from their clientele. AR at 164-173. The consent form also warned that “redness, bleeding, swelling, blistering, and/or very rarely infection or scarring of the areas to be treated” could result. AR at 173.

Judge Mitchell determined that use of the device to remove tattoos did constitute the practice of medicine, finding specifically that the operator’s manual indicated the device should be used “based on the physician’s knowledge and experience, and a physician is responsible for correct diagnosis and for all treatment results.” AR at 219-220. Neither Mr. Arnold nor Mr. Swanson were medically trained. Because lasers penetrate the skin and alter tissue, they are considered medical devices under WAC 246-919-605. AR at 220.

The health law judge ordered both men to permanently cease and desist from using lasers to remove tattoos and fined them \$1,000 each. The judge found that the medical risk to patients was an aggravating factor in assessing punishment, but also found as a mitigating factor that neither man had harmed a patient. AR at 223.

Both men appealed to superior court. The court determined that substantial evidence supported the administrative findings and conclusion that laser tattoo removal constituted the practice of medicine. The case was then timely appealed to this court and argued to a panel.

ANALYSIS

Ultimately, this case turns on the definition of practicing medicine under our statutes. Both parties present very technical arguments. The appellants contend that because their laser only penetrates one layer of skin, but not all layers, it does not penetrate the body. DOH, stringing together its authority to act with wire and duct tape, contends that any penetration of the skin constitutes the practice of medicine. Although the statutory authorization to regulate the use of medical devices could be clearer, we believe DOH has the better of the two arguments.

Under the Washington Administrative Procedure Act, ch. 34.05 RCW, an appellate court will reverse an administrative decision solely for specific, enumerated reasons. RCW 34.05.570. As relevant here, those reasons include the situation where an agency's order is not supported by substantial evidence or is based on an error of law. RCW 34.05.570(3)(d), (e). Like the superior court, this court reviews an administrative determination for substantial evidence and gives de novo review to the conclusions of law. *Heidgerken v. Dep't of Natural Res.*, 99 Wn. App. 380, 384, 993 P.2d 934 (2000).

RCW 18.71.011 defines the practice of medicine. As relevant here, a person practices medicine if he or she: "Severs or penetrates the tissues of human beings." RCW 18.71.011(3). The medical quality assurance commission (MQAC) was created to regulate the practice of medicine by licensed physicians and physician assistants. RCW

18.71.002, .003, 71A.010. To that end, the commission was authorized, inter alia, to

“adopt such rules as are not inconsistent with the laws of this state as may be determined necessary or proper to carry out the purposes of this chapter.” RCW 18.71.017(1).

“Rules, policies, and procedures developed by the commission must promote the delivery of quality health care to the residents of the state of Washington.” RCW 18.71.002.

Among the reasons cited for enacting chapter 18.71 RCW are the “exercise of the police power of the state to protect public health,” and “promote the welfare of the state.” RCW

18.71.003(1). The legislature also recognized that “the health and well-being of the people of this state are of paramount importance.” RCW 18.71.003(2). Accordingly,

“the conduct of members of the medical profession licensed to practice medicine . . . plays a vital role in preserving the health and well-being of the people of the state.”

RCW 18.71.003(3). While the commission regulates physicians, it is the role of the secretary of the DOH to enforce regulations against those who practice without a license.

RCW 18.130.020(10), (12), .040, .190(1).

The MQAC adopted regulations governing the operation of medical lasers by physicians.¹ WAC 246-919-605 governs the use of lasers, light, radiofrequency, and plasma devices (LLRP devices). They are considered “medical devices that: (a) Use a

¹ Comparable regulations governing laser use by physician assistants are found in WAC 246-918-125.

laser . . . to topically penetrate skin and alter human tissue; and (b) Are classified by the federal Food and Drug Administration as prescription devices.” WAC 246-919-605(1).

The regulation then goes on to state:

(2) Because an LLRP device penetrates and alters human tissue, the use of an LLRP device is the practice of medicine under RCW 18.71.011. The use of an LLRP device can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation.

(3) Use of medical devices using any form of energy to penetrate or alter human tissue for a purpose other than the purpose set forth in subsection (1) of this section constitutes surgery and is outside the scope of this section.

WAC 246-919-605.

Ensuing portions of the regulation require physicians to be appropriately trained in the LLRP device, conform to standard medical practice, take a medical history from the patient, examine and diagnose the patient, obtain informed consent to recommended treatment, and provide instructions for both emergency and follow-up care. WAC 246-919-605(4)-(6). A physician, while remaining responsible for the patient’s safety, may delegate the treatment to a properly trained operator in enumerated circumstances. WAC 246-919-605(7)-(10).

The appellants contend both that the health law judge erred in finding that the laser penetrates the skin and alters human tissue, as well as in his legal conclusion that the use of the Q-YAG 5 device to remove tattoos constituted the practice of medicine. Br. of

Appellant at 1. These challenges invoke our review for substantial evidence of the factual findings and de novo consideration of the legal conclusion. RCW 34.05.570(3)(d), (e).

Substantial evidence exists if the evidence is sufficient to persuade a fair-minded rational person of the truth of the evidence. *In re Estate of Jones*, 152 Wn.2d 1, 8, 93 P.3d 147 (2004). Pointing to testimony that the Q-YAG 5 “looks through healthy tissue” to seek out ink, appellants contend that the finding that the device “penetrates the skin” is unsupported by substantial evidence.² Br. of Appellant at 7. This argument relies on definitions of “penetrate” and “skin” that did not have to be accepted by the health law judge.

Appellants’ argument is two-fold—“skin” encompasses all layers of the skin and “penetrates” means piercing through the entire skin. However, the appellants cite no authority suggesting that “skin” must mean all layers of skin cells. Moreover, a common understanding of the word “penetrate” would include merely passing into, rather than completely piercing. *See* WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1670 (1993) (defining “penetrate” as “to pass into or through”).

² Although not assigning error to the finding, appellants make a similar challenge to the finding that “tattoo ink lies beneath the skin.” Br. of Appellant at 6-7. This argument fails for the same reason that its “penetrates the skin” argument fails.

The evidence in the record is more than sufficient to support the finding that use of the Q-YAG 5 device to remove tattoos penetrates the skin. The witnesses at the hearing testified interchangeably that tattoos lie under the dermis or between the layers of skin. In either instance the testimony also indicated that the lasers passed through healthy skin to target those tattoos. Consequently, there is substantial evidence to support the finding of fact that use of the Q-YAG 5 device “penetrates the skin.”

The remaining question³ involves the challenge to the conclusion of law that use of the Q-YAG 5 device to remove tattoos constitutes the practice of medicine. That conclusion necessarily follows from the factual finding that the device “penetrates the skin,” thus satisfying the statutory definition of the practice of medicine—“penetrates the tissues of human beings.” RCW 18.71.011(3).

Additionally, that conclusion is supported by the actual practice of using the device. The Q-YAG 5 is a prescription device subject to federal (and state) regulation as a medical device. The operator is expected to be a health care provider who will take a

³ Because RCW 18.71.011(3) defines practicing medicine in terms of penetrating human tissue, we need not consider the WAC definition of a medical laser device. That said, whether the Q-YAG 5 actually alters human tissue under WAC 246-919-605(1) presents a close question since the device is designed to work solely on the ink, a foreign object in the body. However, the side effects of laser use such as burning or scarring certainly can “alter” bodily tissue even if they do not do so in every case. But, even if the laser did not “alter” human tissue, using the device to penetrate a human body for any other purpose would fall into the category of “surgery” under WAC 246-919-605(3), leaving the appellants subject to even greater regulation.

medical history from the patient, diagnose the patient's condition, select an appropriate treatment, advise the patient of the risks of the treatment, obtain the patient's informed consent to the treatment, and provide any necessary aftercare. The WAC provisions largely parallel the operating instructions. WAC 246-919-605(4)-(6). The appellants' own forms mimic those requirements—they essentially perform the same function and undertake the same responsibilities that a physician using the device would do. An unlicensed person performing medical services is practicing medicine without a license. DOH properly stepped in to prohibit the activity.

While we affirm the issuance of the two cease and desist orders, we make two additional observations. First, the authority to regulate medical devices could be more clearly stated in our statutes so that DOH or the MQAC did not have to make technical arguments tying the devices to the practice of medicine in order to control unauthorized use of prescription devices. Second, the appellants have demonstrated that the Q-YAG 5 device has been safely operated by people who are not in the health care industry to the apparent benefit of the public. Cosmetic treatment is not typically covered by medical insurance and there appears to be a need for a lower cost treatment option. Legislative or administrative consideration of this problem might result in a different approach so that tattoo removal could become available to all who desire it. Nonetheless, purchase of a prescription medical device on the secondary market and operation of the device by those

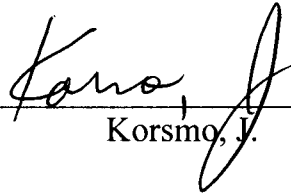
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not subject to health care regulation do present issues of legitimate concern that DOH can regulate for the safety of Washington citizens.

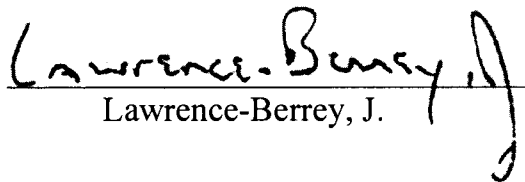
The orders are affirmed.

A majority of the panel has determined this opinion will not be printed in the Washington Appellate Reports, but it will be filed for public record pursuant to RCW 2.06.040.


Korsmo, J.

WE CONCUR:


Siddoway, C.J.


Lawrence-Berrey, J.