

NORTH CAROLINA
WAKE COUNTY

BEFORE THE NORTH CAROLINA
BOARD OF FUNERAL SERVICE
RULING NO. D17-001

In the matter of:

Mary Rose Browder and SCI Shared
Resources, LLC,

Petitioners.

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**DECLARATORY
RULING**

THIS CAUSE comes before the North Carolina Board of Funeral Service (hereinafter the "Board") pursuant to North Carolina General Statute § 150B-4 and 21 NCAC 34A .0108, at its offices at 1033 Wade Avenue, Suite 108, in Raleigh, North Carolina, with a quorum present.

PROCEDURAL HISTORY

Mary Rose Browder, who serves as corporate counsel for SCI Shared Resources, LLC (hereinafter "Petitioners"), filed a request for declaratory ruling on April 7, 2017 (hereinafter the "Request"). Due to the Board's regular meeting schedule, Petitioners agreed to waive the time requirement, pursuant to of 21 NCAC 34A .0108(a)(3), for the Board to consider the Request. Accordingly, the Board considered Petitioners' Request on May 10, 2017, on which date the Board's next regularly scheduled meeting for the purpose of conducting the Board's business was held. The Board voted at its meeting on May 10, 2017 to grant the Request and to issue a declaratory ruling. Due to the Board's regular meeting schedule, Petitioners also agreed to waive the time requirement, pursuant to 21 NCAC 34A .0108(b), for the Board to issue a declaratory ruling. Accordingly, the Board agreed to issue a declaratory ruling in response to the Request at its meeting on July 11-12, 2017, on which dates the Board's next regularly scheduled meeting would be held.

QUESTION

Would it be a violation of the Board's governing statutes and rules if a funeral establishment and/or crematory who receives into its care a dead human body containing a leadless pacemaker causes the body to be cremated without first removing the leadless pacemaker?

RULING

Pursuant to North Carolina General Statute Chapter 150B-4(a), an agency, upon request from a person aggrieved, shall issue a declaratory ruling concerning the validity of a rule or the application of a statute or rule to a particular set of facts. This ruling is based solely on the facts provided to the Board and to the extent the Board can glean pertinent facts necessary to apply the statutes and regulations under its jurisdiction. Pursuant to In re Ford, this Declaratory Ruling and Petitioners' request for declaratory ruling only shall constitute the record for judicial review. See 52 N.C. App. 569, 572 (1981). The Board is charged by the North Carolina General Assembly with enforcing Chapter 90, Article 13A of the North Carolina General Statutes. See N.C. Gen. Stat. §§ 90-210.18A(a) & 90-210.23(a), (i).

Based on information provided to the Board, Petitioner Mary Rose Browder serves as corporate counsel for Petitioner SCI Shared Resources, LLC, a limited liability company with ownership and management interests in several affiliate funeral establishments and crematories licensed and regulated by the Board. Petitioners are seeking the Board's opinion as to whether cremating or causing to be cremated a dead human body containing a leadless pacemaker without first removing the leadless pacemaker may violate Chapter

90, Article 13A, of the North Carolina General Statutes and, therefore, subject a licensee to disciplinary action.

As an initial matter, the Board finds that Petitioners qualify as a “person aggrieved” for purposes of making this declaratory ruling. Petitioner Mary Rose Browder serves as corporate counsel for Petitioner SCI Shared Resources, LLC, a limited liability company with ownership and management interests in several funeral establishments and crematories licensed and regulated by the Board. As such, funeral establishments and/or crematories owned Petitioner SCI Shared Resources, LLC could be subject to disciplinary action if any of its owners, partners, managers, members, officers, agents, or employees violated any provision of [Article 13A] or any regulations of the Board. N.C. Gen. Stat. § 90-210.25(d)(4).

Turning to the substance of Petitioners’ Request, the Board relies upon the following statutes in issuing this ruling. First, N.C. Gen. Stat. § 90-210.129(d) makes it unlawful to knowingly cremate a deceased human body that contains an implanted pacemaker “or other hazardous implant or condition in place”:

No body shall knowingly be cremated with a pacemaker or defibrillator or other potentially hazardous implant or condition in place. The authorizing agent for the cremation of the human remains shall be responsible for taking all necessary steps to ensure that any pacemaker or defibrillator or other potentially hazardous implant or condition is removed or corrected prior to cremation. If an authorizing agent informs the funeral director and the crematory licensee on the cremation authorization form of the presence of a pacemaker or defibrillator or other potentially hazardous implant or condition in the human remains, then the funeral director shall be responsible for ensuring that all necessary steps have been taken to remove the pacemaker or defibrillator or other potentially hazardous implant or to correct the hazardous condition before delivering the human remains to the crematory.

Second, N.C. Gen. Stat. § 90-210.125(a)(9) provides that a cremation authorization form shall contain, among other items: “[a] representation that the human remains do not contain a pacemaker or any other material or implant that may be potentially hazardous to the person performing the cremation.” The Board interprets these statutes together to mean that only those pacemakers that “may be potentially hazardous to the person performing the cremation” shall be required to be removed prior to performing the cremation.

N.C. Gen. Stat. § 90-210.125(a)(9) has not been amended by the North Carolina General Assembly since 2003, while N.C. Gen. Stat. § 90-210.129(d) has not been amended by the North Carolina General Assembly since 2008. At the time the applicable statutes were enacted, existing technology did not contemplate the possibility of a leadless pacemaker. Rather, the accepted industry standard prior to the advent of recent technology was that a pacemaker would contain leads, or wires that deliver energy to the heart muscle. It was generally accepted that, due to the risk of a leads pacemaker exploding due to high temperatures as part of the cremation process, said pacemakers should be removed prior to cremation. Since the applicable statutes were most recently amended, however, medical device and technology companies have developed—and the Federal Drug Administration (hereinafter “FDA”) has approved—at least one brand of “leadless” pacemakers. The Board is aware of ballistics research purporting to show that, for the leadless pacemaker brand already approved by the FDA, little or no risk of explosion of a leadless pacemaker was noted. In response to this issue and to ensure the protection of public health, safety and welfare, the Board submitted proposed legislative changes to N.C. Gen. Stat. § 90-210.125(a)(9) and N.C. Gen. Stat. § 90-210.129(d) to the North Carolina General Assembly in February 2017 that, if enacted, would address the recent advancements in

pacemaker technology. In the interim, licensees may find themselves in a quandary regarding how to properly prepare and cremate dead human bodies containing leadless pacemakers in a manner that is compliant with the Board's applicable statutes and rules.

Petitioners have stated that leadless pacemakers are inserted into the heart through a vein and can be removed by a physician using a similar intra-vein procedure. The manner of placement of these pacemakers into the heart, however, causes any removal of the same to be a more invasive procedure than the removal of a leads pacemaker. If funeral establishments and/or crematories regulated by the Board are required to adhere to the letter of N.C. Gen. Stat. § 90-210.129(d) and N.C. Gen. Stat. § 90-210.125(a)(9), they then must be prepared to perform, and consumers must be prepared to pay for, this invasive procedure to occur prior to cremation.

In light of the foregoing, the Board holds that a funeral establishment and/or crematory licensed by the Board must determine prior to cremation whether a dead human body contains a pacemaker. If the pacemaker contains leads, then the Board will deem it an actionable violation of N.C. Gen. Stat. § 90-210.129(d) and N.C. Gen. Stat. § 90-210.125(a)(9) to cremate the body without first removing the pacemaker. If a funeral establishment and/or crematory has confirmed prior to cremation that a dead human body contains a leadless pacemaker approved by the FDA or other government agency so authorized, the Board will not deem it an actionable violation of N.C. Gen. Stat. § 90-210.129(d) and N.C. Gen. Stat. § 90-210.125(a)(9) to cremate the dead human body without first removing the leadless pacemaker. The Board expressly declines to provide any opinion as to potential safety, health, or other risks that the funeral establishment and/or crematory assumes when cremating a dead human body containing a leadless pacemaker.

EFFECT OF RULING

This ruling is binding on Petitioners and the Board consistent with North Carolina General Statute section 150B-4(a).

Issued by the North Carolina Board of Funeral Service, this the 11th day of July, 2017.

THE NORTH CAROLINA BOARD OF
FUNERAL SERVICE


By: Charles J. Graves
Charles J. Graves
Board President

CERTIFICATE OF SERVICE

I hereby certify that a copy of the aforementioned Declaratory Ruling was sent by certified U.S. Mail, Return Receipt Requested, postage prepaid to:

Mary Rose Browder
SCI Shared Resources, LLC
29 Allen Parkway
Houston, TX 77019

This, the 12th day of July, 2017.


~~Christina D. Cress~~ Christina Cress McLaurin
General Counsel