## **DECLARATORY RULING OF**

# THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

On August 17, 2023, the Alabama State Board of Medical Examiners ("the Board") considered a request submitted on the behalf of Outpatient Imaging Affiliates, LLC ("OIA") and Diagnostic Health MRI of Gadsden, LLC d/b/a Outpatient Diagnostic Center ("ODC") (collectively "Petitioners") for a declaratory ruling pursuant to Ala. Code § 41-22-11 and Ala. Admin. Code R. 540-X-1-.10, concerning a clinical policy and procedure proposed by ODC to permit the intravenous injection of contrast media by radiologic technologists in Alabama who hold an American Registry of Radiologic Technologists ("ARRT") certification and registration while under the remote supervision of a licensed Alabama physician who is a board-certified radiologist.

## FACTS PRESENTED

Petitioners present the following factual background:

OIA is a national owner and operator of outpatient imaging centers. OIA provides long term management and billing services to its outpatient imaging centers. ODC is a wholly owned subsidiary of OIA. ODC is a provider of medical imaging services that has four facilities located in Alabama (the "Centers"). The Centers are enrolled with Medicare as Independent Diagnostic Testing Facilities ("IDTFs"). The Centers operate under the supervision of licensed Alabama physicians who are board-certified radiologists. All radiologic technologists who perform CT procedures at the Centers hold ARRT credentials as CT technologists in addition to ARRT certification and registration as radiologic technologists. Likewise, all radiologic technologists who perform MRI procedures at the Centers hold ARRT credentials as MRI technologists in addition to ARRT certification and registration as radiologic technologists.

Under the Proposed Policy and Procedure, radiologic technologists performing CT and MRI diagnostic tests that involve intravenous contrast media at a Center would safely administer such contrast media via intravenous injections under the supervision of an Alabama-licensed, board-certified radiologist who is virtually present in the office suite of the Center via A/V real-time communications technology and immediately available to furnish assistance and direction throughout the performance of the procedure. Additionally, under the Proposed Policy and Procedure, an Alabama-licensed RN would be physically present at the Center and available to accept real-time instructions from the supervising radiologist to provide appropriate treatment in response to any adverse reactions that may occur in connection with intravenous contrast media injections performed by radiologic technologists.

Per the Proposed Policy and Procedure, the radiologic technologists would, prior to intravenously administering contrast media to a patient at the Center, review the patient for any contraindications for the administration of contrast media. This would include a review of the patient's available history, the order and diagnosis provided by the ordering physician, and a verbal interview with the patient prior to the intravenous administration of contrast media. Further, to mitigate the risk of adverse reactions to contrast media, the Centers will not allow intravenous contrast media injections to be performed by radiologist technologists without an Alabama-licensed, board-certified radiologist physically present in the office suite of the Center for any of the following patients: (1) patients with a prior allergic-like reaction to contrast media, (2) pediatric patients (i.e., patients under the age of 18), and (3) pregnant patients.

The Centers will also adopt guidelines for the intravenous administration of contrast media as well as the treatment of adverse reactions to contrast media similar to those published by the American College of Radiology (ACR). Moreover, the Centers will be equipped with emergency supplies, including medications and equipment, necessary to respond to adverse reactions to contrast media, and the Centers' clinical staff will hold CPR certification. In addition, the Centers will conduct emergency management onsite training on a regular basis.

# **QUESTION PRESENTED**

May a radiologic technologist who holds ARRT certification and registration administer contrast media via an intravenous injection to a patient in Alabama undergoing a Computed Tomography ("CT") or Magnetic Resonance Imaging ("MRI") diagnostic test pursuant to the order of a physician while (a) such radiologic technologist is under the remote supervision of an Alabama-licensed, board-certified radiologist who is virtually present in the office suite through audio/video ("A/V") real-time communications technology that enables the radiologist to be immediately available to furnish assistance and direction throughout the performance of the procedure and (b) an Alabama-licensed Registered Nurse ("RN") is physically present at the

facility to accept real-time instructions from the supervising radiologist in order to provide appropriate treatment to the patient in the event patient experiences an adverse reaction to the contrast media?

## ANSWER

A radiologic technologist who holds ARRT certification and registration may administer contrast media via an intravenous injection to a patient at an originating site in Alabama undergoing a Computed Tomography ("CT") or Magnetic Resonance Imaging ("MRI") diagnostic test pursuant to the order of a physician only when (a) such radiologic technologist is under the real-time supervision of an Alabama-licensed, board-certified radiologist who is virtually present in the office suite utilizing synchronous audio and visual real-time communications technology that enables the radiologist to observe, direct, and furnish assistance and direction to the radiologic technologist throughout the performance of the procedure; (b) an Alabama-licensed Registered Nurse ("RN"), Certified Registered Nurse Practitioner ("CRNP"), Physician Assistant ("PA"), or non-radiologist physician who is appropriately trained to treat adverse reactions to contrast media is physically present at the originating site whenever contrast media is being administered by intravenous injection to a patient; (c) the originating site facility's policy and procedures includes a modality for the supervising radiologist to provide real-time instructions to the RN, CRNP, PA, or other physician assigned to treat contrast-media reactions; and (d) the originating site facility is equipped with the emergency supplies, equipment, and drugs necessary to treat a contrast media reaction.

#### DISCUSSION

The Board's previously published guidance interpreting applicable law and regulations, issued in a letter dated March 23, 1999, opined:

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There exists no Alabama State Board of Medical Examiners' Rule which addresses the act or task of injecting patients with medication by unlicensed assistive personnel. Consequently, if unlicensed assistive personnel in a physician's office or clinic administer medication by injection to a patient pursuant to delegation by the physician and under the direct supervision of the physician, it is the Board's opinion that no violation of any Board of Medical Examiners Rule has occurred; however, the physician remains responsible for the actions of the employee.<sup>1</sup>

The Board's position when it most recently addressed this issue is that radiologic technologists in Alabama are permitted to administer intravenous contrast media injections pursuant to the order of a physician but only under the direct supervision of the physician, while the physician is immediately physically available on the premises.

There are no provisions in the Medical Practice Act or the Alabama Administrative Code regulations promulgated under the Medical Practice Act addressing whether a physician may conduct direct supervision of unlicensed personnel (e.g., radiologic technologists) injecting patients with contrast media remotely through real-time communications technology that enables the physician to be immediately available to furnish assistance and direction throughout the performance of the procedure. However, in a 2003 letter, the Board opined that [i]njection of any contrast media requires a physician's order and presence."<sup>2</sup> Further, the Board stated that:

The physician who is to respond to the patient's needs and who has consented to be responsible should be immediately physically available (on the premises) when a technician injects contrast media, and injections of contrast media by a technician should be allowed only when the physician is immediately physically available (on the premises).<sup>3</sup>

Accordingly, based on guidance published by the Board when it last had the opportunity to address this question, unlicensed personnel, such as radiologic technologists, in Alabama are permitted to administer contrast media by intravenous injection to a patient pursuant to a

<sup>&</sup>lt;sup>1</sup> Ala. Bd. Of Med. Exam'rs, Opinion Letter on Unlicensed Personnel Giving Injection (Mar. 23, 1999), https://www.albme.gov/uploads/files/1-0399.pdf

<sup>&</sup>lt;sup>2</sup> Ala. Bd. Of Med. Exam'rs, Opinion Letter on Injection of Contrast Media (Jan. 23, 2003), https://www.albme.gov/uploads/files/1-0103.pdf

<sup>&</sup>lt;sup>3</sup> Id.

physician's order while under the direct supervision of the physician. However, under the Board's 2003 interpretation, radiologic technologists are only permitted to perform such intravenous contrast media injections when the supervising physician is immediately physically available on the premises.

#### Current Federal Rules and Accrediting Body Standards Related to Remote Supervision

In light of the Public Health Emergency for COVID-19 (the "PHE"), the Centers of Medicare and Medicaid Services ("CMS") recently amended its regulations governing the level of supervision that is required in order for diagnostic x-ray and other diagnostic tests performed by IDTFs to be payable under the Medicare Physician Fee Schedule. Specifically, CMS temporarily amended the definition of "direct supervision," which is typically required for diagnostic imaging procedures involving contrast media to be payable by Medicare when delivered in an IDTF setting, to include the supervision of a physician who is virtually present in the office suite through A/V real-time communications technology and immediately available to furnish assistance and direction through the performance of the procedure. 5

The ACR has also recently revised its Practice Parameter for the Use of Intravascular Contrast Media (the "ACR Practice Parameter") to allow intravenous contrast media administration to be performed by certified radiologic technologists when, for instance, an RN following a symptom-and sign-driven treatment algorithm is present and immediately available to furnish assistance and direction throughout the performance of the procedure. Under the ACR Practice Parameter, the RN must be under a radiologist's overall direction and control, but the radiologist's presence is not required during the performance of the procedure.<sup>4</sup>

<sup>&</sup>lt;sup>4</sup> Am. Coll. of Radiology & Soc'y for Pediatric Radiology, APR-SPR Practice Parameter for the Use of Intravascular Contrast Media (Revised 2022) at§ II.D., https://www.acr.org/-/media/acr/files/practice-parameters/ivcm.pdf.

# Remote Radiologist Supervision of Contrast Media Administration in Other Jurisdictions

OIA currently operates in 17 states and has communicated to the Board its awareness of approaches to remote radiologist supervision of the intravenous administration contrast media by radiologic technologists similar to its own Proposed Policy and Procedure in Pennsylvania, Kentucky, and the District of Columbia. In these jurisdictions, it is OIA's understanding that radiologists have or are in the process of implementing clinical policies and procedures pursuant to which radiologists conduct remote supervision of diagnostic imaging tests involving contrast media administration by radiologic technologists while a non-radiologist healthcare professional, such as a RN, who is licensed and authorized to administer pharmaceuticals, clinical care, and if needed, basic life support is physically present at the facility. These examples represent a growing acceptance across the country of radiologists conducting direct supervision of radiologic technologists performing intravenous contrast media administration via A/V real-time communications technology.

The positions recently adopted by CMS and the ACR recognize that radiologists can effectively supervise diagnostic imaging tests involving intravascular contrast media under certain circumstances. And the ACR Practice Parameter recognizes that radiologic technologists that hold ARRT certification and registration are competent to perform intravenous contrast media injections under certain levels of radiologist supervision, including under remote radiologist supervision in circumstances like the factual scenario described above. Indeed, the ACR's Manual on Contrast Media states that, subject to the requirements of state law, a radiologic technologist may administer contrast media.<sup>5</sup> The positions adopted by CMS and the ACR are bolstered by the

<sup>&</sup>lt;sup>5</sup> See Am. Coll. Of Radiology, ACR Manual on Contrast Media (2023) at 15, https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast\_Media.pdf.

increasing acceptance of remote radiologist supervision of intravenous contrast media administration by radiologic technologists in other jurisdictions.

## Remote Supervision and Telehealth in Alabama

In 2022, the Alabama Legislature passed Act 2022-302, which established telehealth as a modality for delivering healthcare services rather than a separate field or specialty requiring different qualifications or licenses from the usual practice of medicine. Under Ala. Code § 34-24-701(16), "Telemedicine" is "[a] form of telehealth referring to the provision of medical services by a physician at a distant site to a patient at an originating site via asynchronous or synchronous communications, or other devices that may adequately facilitate and support the appropriate delivery of care." "Telehealth medical services" refers to "[d]igital health, telehealth, telemedicine, and the applicable technologies and devices used in the delivery of telehealth." Ala. Code § 34-24-701(15) The "originating site" is where the patient is located, and the "distant site" is where the physician is located when the telehealth medical services are being delivered. Ala. Code § 34-24-701(5), (10). A physician may provide telehealth medical services from any distant site. Ala. Code § 34-24-703(c).

However, "[a] physician providing telehealth medical services shall owe to the patient the same duty to exercise reasonable care, diligence, and skill as would be applicable if the service or procedures were provided in person." Ala. Code § 34-24-703(a). This duty includes ensuring the safety of the patient. The ACR Practice Parameter states that a radiologist, a non-radiologist physician, an advanced practice provider (PA or CRNP), or an RN who follows a symptom and sign driven treatment algorithm can directly supervise intravenous contrast material administration if he or she is trained in, and periodically demonstrates competence in: "managing acute hypersensitivity and physiologic drug reactions . . . [a]ppropriately administering reassurance,

oxygen, antihistamine, intravenous fluids, beta2-agonist inhaler, epinephrine, [and] position changes . . understanding when to call for assistance and how to activate emergency response systems, [and] Basic Life Support (BLS)."<sup>6</sup> The person supervising the radiologic technologist who is administering the contrast media must, under ACR guidelines, be "in the room or in an adjacent control room" and in a position to "observe the patient during and immediately after the injection," "recognize adverse events related to contrast media injection," and "summon medical assistance as needed."<sup>7</sup>

The Petitioners propose to have a radiologist participating in the administration of intravenous contrast material via a telehealth modality. They further propose to have a licensed and trained healthcare provider physically on site to provide intervention in the case of an adverse event. The Board sees no reason why a radiologist cannot practice telemedicine at Petitioners' originating site when on-site personnel comply with the ACR Practice Parameter described above. Accordingly, it is the opinion of the Board that a radiologist may directly supervise via telemedicine a radiologic technologist who holds ARRT certification and registration and who is administering contrast media via an intravenous injection to a patient at an originating site in Alabama; provided, a non-radiologist physician, an advanced practice provider (PA or CRNP), or an RN who follows a symptom and sign driven treatment algorithm<sup>8</sup> is physically on-site and is equipped and trained to recognize adverse events related to contrast administration and is immediately available to render emergency care.

The Board notes specially that Petitioners state:

<sup>&</sup>lt;sup>6</sup> Am. Coll. of Radiology & Soc'y for Pediatric Radiology, APR-SPR Practice Parameter for the Use of Intravascular Contrast Media (Revised 2022) at 4, https://www.acr.org/-/media/ACR/Files/Practice-Parameters/IVCM.

<sup>&</sup>lt;sup>7</sup> Id.

<sup>&</sup>lt;sup>8</sup> The non-radiologist physician, advanced practice provider, or RN must hold BLS certification and ACLS certification. PALS certification is additionally required for treatment of pediatric patients. *See generally* training requirements for office-based surgical procedures. Ala. Admin. Code R. 540-X-10.

Further, to mitigate the risk of adverse reactions to contrast media, the Centers will not allow intravenous contrast media injections to be performed by radiologist technologists without an Alabama-licensed, board-certified radiologist physically present in the office suite of the Center for any of the following patients: (1) patients with a prior allergic-like reaction to contrast media, (2) pediatric patients (i.e., patients under the age of 18), and (3) pregnant patients.

The scope of the Petitioners' question concerns the supervision of ARRT-certified radiologic technologists. Because the issue exceeds the scope of Petitioners' request, the Board renders no opinion at this time concerning the safety and propriety of administering intravenous contrast media injections to pregnant patients, pediatric patients, or patients with a prior allergic-like reaction to contrast media in an outpatient clinic.

This ruling is based upon the precise facts presented and upon statutes and rules currently in existence. Should any relevant statutes or rules be amended or repealed, this ruling may no longer be valid.

DONE this 17<sup>th</sup> day of August, 2023.

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