BEFORE THE ALABAMA BOARD OF NURSING

IN THE MATTER OF:)	PETITION FOR
)	DECLARATORY RULING
CHRYSTAL FOURNIER, 1-179881 (Active))	
VICKIE HALE-BROWN, 1-044703 (Active))	
)	
Petitioners.)	

DECLARATORY RULING

COMES NOW the Alabama Board of Nursing, by and through its Executive Officer Peggy Sellers Benson, RN, MSHA, MSN, NE-BC, and issues the following ruling:

QUESTION PRESENTED

Pursuant to <u>Alabama Board of Nursing Administrative Code</u> § 610-X-6-.07, is it within the scope of practice for a Registered Nurse to administer an unapproved COVID-19 vaccination authorized only for emergency use and to supervise nursing students administering an unapproved COVID-19 vaccination authorized only for emergency use?

FINDINGS OF FACT

- 1. By petition dated March 10, 2021, Petitioners submitted a petition for declaratory ruling. Petitioners are licensed registered nurses in Alabama who serve as nursing instructors for Calhoun Community College.
- 2. Petitioners seek a declaratory ruling regarding whether it is within the scope of practice of a registered nurse to administer the COVID-19 vaccination which has an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), and to supervise nursing students administering a COVID-19 vaccination which has an EUA from the FDA.
- 3. As nursing faculty, Petitioners have been assigned to supervise a group of nursing students in administering the COVID-19 vaccination. Petitioners have declined to accept this assignment, citing their sincerely held ethical dilemma regarding administration of the COVID-19 vaccine that does not have FDA approval, but only an EUA from the FDA. Petitioners have submitted a timeline of events surrounding this assignment, as well as a June 2015 document produced by the American Nurses Association entitled "Risk and Responsibility in Providing Nursing Care."

JURISDICTION

Pursuant to Section 41-22-11 of the <u>Code of Alabama</u> (1975), the Alabama Board of Nursing has jurisdiction to issue declaratory rulings with respect to the validity of a rule, with respect to the applicability to any person, property or state of facts of any rule or statute enforceable by it, or with respect to the meaning and scope of any order of the agency, if a written petition for declaratory ruling is filed by a person who states with specificity the reason why the person is substantially affected by the rule at issue. See also <u>Alabama Board of Nursing Administrative Code</u> § 610-X-1-.09. Petitioners are substantially affected by the Board's rule regarding medication administration.

CONCLUSIONS OF LAW

- 1. A petition for declaratory ruling to the Alabama Board of Nursing should state the name and address of the petitioner, a statement of facts sufficient to show that the petitioner is substantially affected by the rule, and identification of the rule, statute or order and the reasons for the questions. <u>Alabama Board of Nursing Administrative Code</u> § 610-X-1-.09. Petitioners have satisfied these requirements.
- 2. The practice of professional nursing includes the promotion of health and prevention of illness and executing medical regimens according to approved medical protocols and standing orders, including administering medications and treatments prescribed by a legally authorized prescriber. Alabama Board of Nursing Administrative Code § 610-X-6-.04(1)(d) and (g).
- 3. The standards of practice regarding medication administration for a registered nurse are set forth in <u>Alabama Board of Nursing Administrative Code</u> § 610-X-6-.07. Nothing in this rule prohibits nurses from administering COVID-19 vaccinations available under and FDA EUA.
- 4. Nursing students enrolled in an approved school of nursing may perform nursing skills incident to their course of study (e.g. clinicals). Ala. Code § 34-21-6. Administration of medications is a nursing skill, and as such may be performed by nursing students under the supervision of clinical supervisors or assigned clinical faculty.
- 5. Clinical learning experiences shall be supervised by a registered nurse with knowledge of educational strategies and subject matter, and who is experienced in the clinical technologies essential to the safe practice of nursing. The clinical supervisor or assigned clinical faculty shall hold an active unencumbered Alabama RN license or a multistate RN license. The clinical supervisor or assigned clinical faculty shall be readily accessible to assign or prescribe a course of action, provide procedural guidance, direction, and evaluation for students engaged in the clinical learning experience. Alabama Board of Nursing Administrative Code § 610-X-3-.02(14)(a), (b), and (c).
- 6. According to the FDA, "An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives." (https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained, last accessed March 11, 2021). COVID-19 vaccinations which have received an EUA are authorized by the FDA for use during the public health emergency, despite not having completed the regular FDA approval process.
- 7. On January 27, 2021, Alabama's State Health Officer issued a Standing Order for Health Care Worker Volunteers Administering COVID-19 Vaccinations. The order covers the administration of the COVID-19 vaccine by volunteers in Alabama state and local public health sponsored clinics. The order specifically covers "nursing students who have completed skills competency for vaccine administration and who have a university instructor or delegate present with them at the clinic site." Among other requirements, the Standing Order requires that patients be provided with a current copy of the Emergency Use Authorization (EUA) Fact Sheet for Recipients and Care Givers or Vaccine Information Statement (VIS) for the COVID-19 vaccine they will be receiving, and requires that the patient sign a consent form after reviewing the EUA

Fact Sheet or the VIS. The Centers for Disease Control also has developed form standing orders for use by medical directors or other authorized practitioners.

RULING

The Petition for a Declaratory Ruling is hereby granted, and the Alabama Board of Nursing hereby rules as follows:

- 1. It is within the scope of practice for a Registered Nurse to administer a COVID-19 vaccination which has received Emergency Use Authorization from the United States Food and Drug Administration, provided that such administration must be pursuant to and in compliance with a standing order from a legally authorized prescriber.
- 2. It is within the scope of practice of a Registered Nurse to supervise nursing students in administering a COVID-19 vaccination which has received Emergency Use Authorization from the United States Food and Drug Administration, provided that such administration must be pursuant to and in compliance with a standing order from a legally authorized prescriber.
- 3. This declaratory ruling is not intended to address, and should not be construed as addressing, the handling of petitioners' self-described "sincerely held ethical dilemma."

DONE and **ORDERED** on this the 19th day of March, 2021.

ALABAMA BOARD OF NURSING

PEGGY SELLERS BENSONRN, MSHA, MSN, NE-BC

EXECUTIVE OFFICER

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 22nd day of March, 2021, a true and correct copy of the foregoing Declaratory Ruling was served by forwarding the same by United States certified mail, postage prepaid, and addressed as follows:

VICKIE HALE-BROWN, DNP, MSN, RN 22 TRAILING VINE HARVEST AL 35749

CHRYSTAL FOURNIER, RN, FNP-BC 506 FERRY ST NE DECATUR AL 35601

ALABAMA BOARD OF NURSING

PEGGY S BENSON, RN, MSHA, MSN, NE-BC

EXECUTIVE OFFICER

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