BEFORE THE ALABAMA BOARD OF NURSING

IN THE MATTER OF:) PETITION FOR
) DECLARATORY RULING
CALHOUN COMMUNITY COLLEGE)
1 (1.05) and (1.05)	j
Petitioner.)

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-.04 and Section 34-21-1(9) of the <u>Code of Alabama</u> (1975), is it a violation of the Standards of Practice or the Nurse Practice Act for a nursing instructor to supervise nursing students in a clinical setting for the administration of the Covid-19 Vaccination that is not "FDA Approved", only "FDA Emergency Use Authorization"?

FINDINGS OF FACT

- 1. By petition dated March 3, 2021, Calhoun Community College, which operates an approved Alabama nursing education program, by Lynn S. Hogan, DNP, RN, Chair of the Nursing Department and a licensed registered nurse in Alabama, submitted a petition for declaratory ruling.
- 2. Calhoun Community College seeks a declaratory ruling regarding whether a nursing instructor's supervision of nursing students in a clinical setting for the administration of the COVID-19 Vaccination would violate the ABN's statute and rules.
- 3. Calhoun Community College operates ABN-approved nursing education programs offering both LPN and RN-ADN degrees.
- 4. Calhoun Community College has assigned nursing faculty to supervise a clinical group of nursing students in a community setting for the purpose of COVID-19 vaccinations to the public. Some nursing faculty members are refusing the assignment because they have identified an ethical dilemma in administering a vaccine that is not approved by the United States Food and Drug Administration (FDA), but rather authorized under an FDA Emergency Use Authorization (EUA). In support of its request for a declaratory ruling, Calhoun Community College submitted an Attachment which listed citations to various sources with supporting evidence.

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. Calhoun Community College is substantially affected by the Board's rule regarding the practice of professional nursing.

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. Petitioner has satisfied these requirements.
- 2. 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).
- 3. 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).
- 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. 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 lifethreatening 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.

6. On January 27, 2021, the Alabama 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 signa 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. Pursuant to <u>Alabama Board of Nursing Administrative Code</u> § 610-X-6-.04 and Section 34-21-1(9) of the <u>Code of Alabama</u> (1975), it is not a violation of the Alabama Board of Nursing standards of practice or the Nurse Practice Act for a nursing instructor to supervise nursing students in a clinical setting for the administration of the COVID-19 Vaccination that is not "FDA Approved", but only "FDA Emergency Use Authorization," provided that such administration must be pursuant to and in compliance with a standing order from a legally authorized prescriber.
- 2. This declaratory ruling is not intended to address, and should not be construed as addressing, the handling of the "ethical dilemma" identified by nursing faculty.

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

ALABAMA BOARD OF NURSING

PEGGY SELLERS BENSON RN, 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:

CALHOUN COMMUNITY COLLEGE ATTN: LYNN S. HOGAN, DNP, RN 6250 US HIGHWAY 31 NORTH TANNER, AL 35671

ALABAMA BOARD OF NURSING

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

EXECUTIVE OFFICER

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