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RULE ADOPTION

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

ADDITION OF SINCALIDE, A SYNTHETIC CHOLECYSTOKININ, TO LIST OF APPROVED NON-RADIOACTIVE MATERIALS LICENSED NUCLEAR MEDICINE TECHNOLOGISTS MAY ADMINISTER

Adopted Amendment: N.J.A.C. 13:35-6.20

Proposed: September 3, 2002 at 34 N.J.R. 3058(a).

Adopted: December 10, 2002 by the State Board of Medical Examiners, William V. Harrer, M.D., President.

Filed: June 20, 2003 as R.2003 d.286, with a substantive change not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:9-2 and 45:1-15.1.

Effective Date: July 21, 2003.

Expiration Date: September 20, 2004.

Summary of Public Comments and Agency Responses:

The Board received written comments from the following individuals or representatives of organizations:

1. Henry J. Powsner, M.D., Chairman, Commission on Radiation Protection, New Jersey Department of Environmental Protection, Division of Environmental Safety, Health and Analytical Programs.
2. Robert S. Rigolosi, President, Medical Society of New Jersey.

COMMENT: The commenters support the adopted amendment because it will improve patient care by ensuring the timely administration of "Kinevak (CCK)" during nuclear medicine procedures and allow physicians and nurses to perform other essential tasks.

RESPONSE: The Board thanks the commenters and agrees that the adopted rule will greatly improve patient care.

COMMENT: A commenter states that the adopted amendment specifically permits administration of "Kinevak (CCK)" which is a brand name of synthetic cholecystokinin. The commenter states that the rule as written would only permit Kinevak to be administered by a licensed nuclear medicine technologist. The commenter adds that there is currently a shortage of Kinevak and that they expect the manufacturer to resume production in early 2003. The commenter states that a number of nuclear medicine departments are presently using Sincalide, the generic name of synthetic cholecystokinin, which is prepared by some compounding pharmacies. The commenter recommends that the language of the adopted rule be amended to replace Kinevak with Sincalide, a synthetic cholecystokinin. The revised language would permit all forms of cholecystokinin to be administered by a licensed nuclear medicine technologist.

RESPONSE: The Board agrees with the commenter's suggestion and has made the technical change upon adoption. The change in the rule reflects the lack of availability of "Kinevak" and permits licensed nuclear medicine technologists to administer the same drug in its generic or brand name form.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendment does not involve any Federal standards or requirements.

Full text of the adoption follows:

<< **NJ ADC 13:35-6.20** >>

13:35-6.20 Physician delegation of tasks to radiologic technologists and nuclear medicine technologists

(a)-(l) (No change.)

(m) A physician may direct the LNMT to administer, under direct physician supervision, nonradioactive pharmaceuticals as follows:

1.-4. (No change.)

5. Vitamin B-12;

6. Intravenous flush solutions such as saline or heparin; and

7. <<-Kinevac (CCK)->> <<+Sincalide, a synthetic cholecystokin+>>.

(n)-(p) (No change.)