PRIOR PRINTER'S NO. 631 PRINTER'S NO. 861

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 569 Session of 2019

INTRODUCED BY LANGERHOLC, K. WARD, GORDNER, YAW, BREWSTER, COSTA, KILLION, WHITE, BROWNE AND HAYWOOD, APRIL 18, 2019

SENATOR BROOKS, HEALTH AND HUMAN SERVICES, AS AMENDED, JUNE 4, 2019

AN ACT

Amending the act of April 14, 1972 (P.L.233, No.64), entitled "An act relating to the manufacture, sale and possession of controlled substances, other drugs, devices and cosmetics; conferring powers on the courts and the secretary and Department of Health, and a newly created Pennsylvania Drug, Device and Cosmetic Board; establishing schedules of controlled substances; providing penalties; requiring registration of persons engaged in the drug trade and for the revocation or suspension of certain licenses and registrations; and repealing an act," providing for dispensing of fentanyl.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, is amended by adding a section to read:

Section 4.1. Dispensing of Fentanyl.--(a) Fentanyl and fentanyl derivatives, as used in section 4(1)(ii)23, shall only be dispensed:

(1) To a patient who is being treated on an in-patient basis or remains in observation status, or during a surgery that takes place in a health care facility as defined in section 103 of the

act of July 19, 1979 (P.L.130, No.48), known as the "Health Care Facilities Act."

(2) For use in palliative or hospice care.

(3) For use in the management of pain associated with cancer.

(4) For use in the management of chronic pain not associated with cancer. In order for this paragraph to apply, the prescriber must:

(i) Document the chronic medical condition in the individual's medical record maintained by the prescriber.

(ii) State the reason why another medication is not appropriate to address the chronic medical condition.

(5) To a patient whose treatment is associated with a medical emergency as documented in the individual's medical record.

(b) In instances where, in the professional medical judgment of the prescriber, TRANSDERMAL fentanyl is required to stabilize <-- an individual's acute medical condition, the prescriber may prescribe no more than a ~~seven-day supply of~~ SINGLE UNIT OF FIVE <-- (5) PATCHES OF TRANSDERMAL fentanyl. In order for this subsection to apply, the prescriber must:

(1) document the acute medical condition in the individual's medical record with the prescriber; and

(2) state the reason why another medication is not appropriate to address the acute medical condition.

(C) A PHARMACIST WHO RECEIVES A PRESCRIPTION FOR TRANSDERMAL <-- FENTANYL SHALL NOT BE REQUIRED TO VERIFY THAT THE DOCUMENTATION REQUIREMENTS FOR PRESCRIBERS UNDER SUBSECTION (B) HAVE BEEN MET. THE PHARMACIST SHALL COMPLY WITH 21 CFR 1306.04 (RELATING TO PURPOSE OF ISSUE OF PRESCRIPTION).

~~(c)~~ (D) The department, in consultation with the Pennsylvania State Police, shall issue an annual report to the General Assembly. The report shall contain the following: <--

(1) Information on the number of overdoses related to fentanyl and the number of overdoses where fentanyl and opioids were present.

(2) Any reduction in the dispensing of fentanyl.

~~(d)~~ (E) This section shall expire two years after the effective date of this section. <--

~~(e)~~ (F) As used in this section, the term "prescriber" shall have the meaning given to it in section 3 of the act of October 27, 2014 (P.L.2911, No.191), known as the "Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act." <--

Section 2. This act shall take effect in 60 days.