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American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: _____ Daniel Hussar _____

1/26/16
(Date)

Pennsylvania Pharmacists Association
(Organization)

Subject: Food and Drug Administration (FDA) Authorization for Selected Medications/Dosage Forms to be Available Without a Prescription from a Pharmacist

Motion: Move to adopt the following policy statement language:

APhA urges the FDA to authorize the following medications/dosage forms to be available without a prescription from a pharmacist:

- Naloxone for opioid over dosage
- Epinephrine auto-injectors for severe allergic reactions
- Albuterol for oral inhalation for acute asthma attacks
- Nitroglycerin for sublingual use for symptoms of a heart attack
- Varenicline for smoking cessation
- Nicotine nasal spray for smoking cessation
- Nicotine inhalation system for smoking cessation

Background:

The epidemic of abuse of opioids and the tragedies of deaths from over dosage warrant the most timely availability and use of naloxone. Naloxone is a life-saving intervention but it must be administered as soon as possible following over dosage. On a state-by-state basis pharmacists and others (e.g., police) are being provided the authority to provide and/or use naloxone without a prescription. However, for states to address this matter on an individual basis is a grossly inefficient waste of time, effort, and resources when the FDA is in a position to authorize on a national basis the availability of naloxone without a prescription from a pharmacist.

Similarly, epinephrine, albuterol, and nitroglycerin can be life-saving interventions for urgent medical problems that require immediate availability and use. Pharmacists are the most accessible healthcare professionals and can also provide the needed medications on a timely basis.

The problems resulting from smoking cigarettes are contributing factors to the deaths of more than 440,000 individuals each year in the United States, and represent the country's most important public health challenge. There is an unacceptable irony that cigarettes with their multiple toxins can be purchased by only providing proof of age while there are restrictions (e.g., the need for a prescription) on the availability of products that will help people stop smoking. The risks and consequences of smoking far exceed any risks associated with the use of varenicline, nicotine nasal spray and nicotine inhalation system, and these products should be available without a prescription from a pharmacist.

Current APhA Policy & Bylaws:

2014 Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.
2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.
4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.
5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

(JAPhA 54(4) July/August 2014)(Reviewed 2015)

2005, 1971 Cigarette Sales in Pharmacies

1. APhA recommends that tobacco products not be sold in pharmacies.
2. APhA recommends that state and local pharmacist associations develop similar policy statements for their membership and increase their involvement in public educational programs regarding the health hazards of smoking.
3. APhA recommends that individual pharmacists give particular attention to educating young people on the health hazards of smoking.
4. APhA recommends that APhA-ASP develop projects aimed at educating young people on the health hazards of smoking, such as visiting schools and conducting health education programs.

(JAPhA NS11:270 May 1971) (JAPhA NS45(5):555 September/October 2005) (Reviewed 2009)(Reviewed 2014)

New Business Items are due to the Speaker of the House by **February 3, 2016** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.