



Annual Meeting & Exposition | Nashville, TN | March 16-19
**LEADING OUR COMMUNITIES
IN PATIENT CARE**

**American Pharmacists Association
House of Delegates – Nashville, TN**

To be completed by the Office of
the Secretary of the House of
Delegates

Item No. 2

Date received 1/7/18

Time received 5:12PM

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Laura Joglekar, on behalf of the 2017-18 Policy Review Committee
(Name)

12/3/17

(Date)

Laura Joglekar (908-507-5295)

(Annual Meeting Contact Number)

APhA Policy Review Committee

(Organization)

Subject: Revisions to the Medication and Medical Device Classification System

Motion: I move, on behalf of the Policy Review Committee, that the following item be ADOPTED to replace existing APhA Policy.

2013 Revisions to the Medication and Medical Device Classification System

1. APhA supports the Food and Drug Administration's (FDA's) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients' relationships with their pharmacists and other health care providers.
2. APhA supports the implementation or modification of state laws to facilitate pharmacists' implementation and provision of services related to a revised drug and medical device classification system.
4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA's approved conditions of safe use.
5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists' input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA's defined conditions of safe use.
6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA's approved conditions of safe use.
7. APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA's defined conditions of safe use within health benefit coverage.

Background:

In certain practice settings pharmacists are qualified to provide clinical intervention as well as input in development of medications as well as medical devices, therefore the policy statement has been updated to include “medical devices”. Over the past few years, FDA is partnering with patients, healthcare professionals and industry to establish modern requirements around various devices (e.g. stents, diagnostics, point of care testing), therefore it is pertinent that APhA continues to support pharmacists who help shape FDA’s policies.

The text below shows the recommended changes and how they affect the existing policy language. New policy language is shown as underlined text and no existing language was recommended for removal.

2013 Revisions to the Medication and Medical Device Classification System

1. APhA supports the Food and Drug Administration’s (FDA’s) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers.
2. APhA supports the implementation or modification of state laws to facilitate pharmacists’ implementation and provision of services related to a revised drug and medical device classification system.
4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA’s approved conditions of safe use.
5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists’ input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA’s defined conditions of safe use.
6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA’s approved conditions of safe use.
7. APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA’s defined conditions of safe use within health benefit coverage.

Existing policy statements 3 and 8 within this policy topic have been recommended to be retained by the 2017-18 Policy Review Committee and therefore have not been included in this new business item.

Current APhA Policy & Bylaws:

N/A

****Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item Content.**

New Business Items are due to the Speaker of the House by **February 14, 2018** (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.