BEHIND-THE-COUNTER DRUGS\(^1\)

**Background:**

While several other countries currently have a version of a behind-the-counter (BTC) class of drugs, the FDA is unclear if it has the authority to establish a BTC classification of medications. The establishment of a BTC class of drugs could help improve patient care by removing potential barriers to access.

**AMCP Position:**

The Academy of Managed Care Pharmacy (AMCP) supports the establishment of a third class of drugs (BTC) that would allow consumers, with the intervention of a pharmacist, to purchase certain medications without a prescription, assuming the following conditions are met:

1. Medications selected for BTC status must provide a benefit to the public.
2. Decisions on which drugs are selected for BTC status must be based on clinical effectiveness and safety.
3. Standardized processes for ordering and dispensing of BTC drugs must be established.
4. Pharmacists must be required to perform clinical evaluation and interventions before dispensing BTC drugs.
5. Pharmacist training requirements must be based on knowledge and skills required to interpret objective clinical data and to apply selection criteria in order to dispense BTC products.
6. Patient health information must be protected.
7. Program oversight requirements must be developed.

**Talking Points:**

- **Provide FDA authority to regulate** – FDA should be able to develop regulations to allow and govern a BTC classification of medications.

- **Develop policies regarding compensation for services** – Policies regarding compensation for pharmacist services would need to be developed by private and public payers in collaboration with the pharmacy profession, including treatment of flexible spending accounts, health reimbursement accounts, and health savings accounts.

- **Ensures safe access to medication** - The establishment of a BTC classification would grant patients access to necessary medications without the need for an appointment with a prescriber and can be dispensed safely, assuming the above conditions are met. Pharmacists are also generally more available to patients than prescribers, either in the retail or community setting, or available via telephone or over the internet.
Ease the burden on physicians and other prescribers – As more Americans gain access to the health care delivery system, demand for services from authorizing prescribers is expected to rise. Establishing a BTC classification could help to increase patient access to care by allowing pharmacists to act as the primary points of contact for certain diseases and conditions.

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