

MARYLAND OVERDOSE RESPONSE PROGRAM: IMPLEMENTATION OF NALOXONE STANDING ORDERS

*BHA Naloxone Conference
September 2, 2015*

Michael Baier
Overdose Prevention Director
Department of Health and Mental Hygiene
Behavioral Health Administration
michael.baier@maryland.gov
410-402-8643



Overview

- Why standing orders?
- Standing orders under SB516, 2015
- Potential models of standing order implementation
- Proposed BHA requirements and documentation

Why Standing Orders?

- ORP law did not provide alternative to existing Rx/dispensing protocols; focused primarily on training/certification process
- Typically Rx is “patient”-specific
- No existing legal authority for practitioners to delegate dispensing
- Practitioner must be physically present to Rx/dispense
- Practitioner time is expensive; volunteers hard to find

SB516, 2015

- Developed by overdose advocacy coalition coordinated by UM Law Drug Policy Clinic
- Reconciled w/ ORP-specific sections of SB757 (DHMH departmental)
- Does not require that DHMH adopt regulations for any section to become effective
- **Effective October 1, 2015**

SB516: Standing Orders

- Definition: “written instruction for the prescribing and dispensing of naloxone to certificate holders”
- May be issued by a:
 - Licensed physician, or
 - Advanced practice nurse w/ prescribing authority

WHO:

- Is employed by DHMH or a local health department
or
- Supervises or conducts ORP trainings

SB516: Standing Orders, ctd.

A physician or APN who issues a standing order may **DELEGATE** dispensing to:

- Licensed registered nurse who is:
 - Employed by a LHD, **and**
 - Has completed a DHMH-approved training course
- Employee or volunteer of the authorized entity who is authorized to conduct ORP trainings

A licensed healthcare professional w/ dispensing authority (i.e. pharmacist) may dispense under a standing or issued by a **physician**

Key Points

- **Only** ORP certificate holders can be prescribed/dispensed naloxone under standing order
- Standing order authority does not replace, but ***supplements***, existing physician/NP authority to Rx/dispense to cert holders
- Written standing order = “blanket” non-person-specific Rx to potentially any ORP cert holder
- Practitioner delegates dispensing authority, ***NOT*** prescribing authority

Other SB516 Issues

- Naloxone dispensers exempt from any requirement to have dispensing permit
- Immunities for physicians, nurses & pharmacists from disciplinary & civil action presumably extend to standing order prescribing and dispensing
- Entity employee/volunteer dispensing under standing order not considered to be practicing medicine, registered nursing or pharmacy

LHD Nurse Dispensing

- SB626, 2015: Requirements for LHD RN dispensing of naloxone & other drugs
- Requires LHD-employed RN to:
 - complete DHMH training course developed w/ boards of nursing & pharmacy
 - comply with formulary approved by new nurse dispensing committee
 - maintain confidentiality of patient records
 - comply with DHMH drug storage and inventory policies
- Prescriber must be LHD employee

SB516/SB626 Overlap

- **CAVEAT:** Intradepartmental discussions continue on resolving overlap; stay tuned....
- SB626 addresses dispensing on receipt of Rx, not specifically under standing order
- LHD RNs that meet SB626 criteria for dispensing should be covered under standing orders w/o extra requirements
- Possibility covered naloxone formulations limited by nurse dispensing committee

Standing Order Models

Three potential models:

1. ORP “All in One”: Entity provides training & naloxone dispensing via prescriber delegates
2. ORP/pharmacy partnership: Entity provides training, dispensing from partner pharmacies
3. Jurisdiction-wide standing order for pharmacist dispensing

ORP “All in One”

- Entity’s physician/APN (employee or volunteer) issues standing order
- Entity’s trainers (employees/volunteers or LHD RNs) delegated dispensing authority by prescriber
- Trainers train, issue certificates and dispense once cert issued to trainee
- Trainers responsible for following dispensing protocols
- Could facilitate direct outreach model or simply make classroom trainings more efficient

ORP/Pharmacy Partnership

- Entity's physician (employee or volunteer) issues standing order
- Entity's trainers (employees/volunteers) train and issue certificates
- Entity partners with one or more pharmacists who dispense under standing order to cert holders
- Pharmacist could bring naloxone to training site or entity directs trainees to pharmacy

Jurisdictional

- DHMH or LHD physician (employee) issues statewide or jurisdiction-specific standing order
- All or some pharmacists within jurisdiction of standing order authorized to dispense to cert holders
- SB516 does not require pharmacist to perform any additional actions before dispensing, doesn't prevent prescriber from requiring something extra

Potential Models Summary

- May be other “hybrid” standing order models
- Much depends on practitioner interpretation of & comfort with legal authority
- Health occupations licensing boards have authority to set parameters on licensee practice
- BHA authority primarily focused on entities, not practitioners; some standing order authorities outside of entity operations

Proposed BHA Requirements & Documentation

Regulations

- Not required by SB516
- Need to strike balance between providing helpful structure and unduly creating barriers to implementation
- “Wait & see” approach:
 - Make technical edits to regs to match statute
 - Defer any additional standing order structure until experience demonstrates necessity
 - Develop ORP policies & documentation to provide initial structure in lieu of regs

Documentation

- BHA developing standing order forms specific to “all in one” and partner pharmacy models
- “All in one” documentation will rely heavily on entity’s dispensing protocols
- Partner pharmacy form will be more prescriptive in dispensing instructions to pharmacists
- More investigation needed RE jurisdictional standing order
- All forms required to be submitted to BHA

Dispensing Protocols

- COMAR 10.47.08.03A(5): Dispensing protocols required part of entity application if entity intends to dispense
- Thinking about an “all in one” standing order model?
TIME TO REVISIT YOUR DISPENSING PROTOCOLS!
- BHA revising dispensing protocol guidance document
- Due to variation among entities, BHA does not require a specific protocol or format
- However, many prescription drug dispensing requirements apply regardless of setting

Things to Consider Including in Dispensing Protocols

- Who specifically may dispense under standing order?
- Which naloxone formulation(s) and related supplies may be dispensed? Are there factors that dictate dispensing one form or another?
- How will naloxone be stored prior to dispensing?
- How will naloxone and supplies be labelled in accordance with applicable laws?
- How will dispenser document dispensing?
- Who can be dispensed naloxone? Any ORP cert holder? Only those certified by the entity? Only specific individuals?

Supervisory Agreements

- H-G Article § 13-3104(d): Entity employees/volunteers who conduct trainings must be supervised by physician, APN or pharmacist in accordance w/ written agreement b/t practitioner and entity
- Must cover:
 - Procedures for providing training
 - Info on how trainer will be trained
 - Standards for documentation of training delivery
- **Perfect opportunity to document plan for training/oversight of employees/volunteers on dispensing protocols**

Next Steps

- BHA working with Office of the Attorney General to finalize standing order documentation, dispensing protocol guidance and general implementation guide
- Goal to have all documentation complete by October 1
- Provide technical assistance to ORP entities and affiliated practitioners with implementing standing orders
- Notify entities of success stories through ORP listserv
- Provide further guidance on implementation of jurisdictional standing orders

Final Non-Standing Order- Related Issue

SB516:

(1) ANY LICENSED HEALTH CARE PROVIDER WHO HAS PRESCRIBING AUTHORITY MAY PRESCRIBE NALOXONE TO A PATIENT WHO IS BELIEVED BY THE LICENSED HEALTH CARE PROVIDER TO BE AT RISK OF EXPERIENCING AN OPIOID OVERDOSE OR IN A POSITION TO ASSIST AN INDIVIDUAL AT RISK OF EXPERIENCING AN OPIOID OVERDOSE.

(2) A PATIENT WHO RECEIVES A NALOXONE PRESCRIPTION UNDER PARAGRAPH (1) OF THIS SUBSECTION IS NOT SUBJECT TO THE (ORP) TRAINING REQUIREMENTS UNDER § 13-3104(D) OF THIS SUBTITLE.

Questions?

Michael Baier

Overdose Prevention Director

Department of Health and Mental Hygiene

Behavioral Health Administration

michael.baier@maryland.gov

410-402-8643