

Dispensing Under Standing Protocols: The
Pharmacists' Role in Public Health

*Pharmacists Society of the State
of New York*

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- I have no commercial financial relationships to disclose.
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Objectives

(Pharmacists and Technicians)

At the end of this program you should be able to:

- Review the law of agency as it relates to standing protocols
- List the standing protocols permitted in New York
- Discuss the impact of standing protocols on public health
- Consider other protocols under consideration by the NYS legislature

First question:

- The doctrine of agency law and fiduciary responsibility is created by:
 - A. The legislature
 - B. The courts
 - C. The agencies (executive branch)
 - D. Executive order

Second question:

- Non-patient specific orders for dispensing without prescription include which of the following:

(Select all that apply, “SATA”)

- A. Epinephrine
- B. Post-exposure prophylaxis (PEP) for HIV
- C. Pre-exposure prophylaxis (PreP) for HIV
- D. Naloxone
- E. Limited list of vaccines

Third Question

- Which of the following are reasonable public health outcomes that flow from NPSOs (SATA)?
 - A. herd immunity to a small number of infectious diseases
 - B. improved disease state management
 - C. eliminating infection as a cause of disease
 - D. more rapid treatment of opioid overdose
 - E. more nimble response to patients needs during a public health crisis

Fourth question:

- What other NPSO opportunities might serve patients in New York? (SATA)
 - A. Comprehensive medication management
 - B. Administration of long-acting injections
 - C. Point-of-care testing
 - D. Medical cannabis

Law of “agency”

- A relationship where one party has been given authority to act in place of another
- Based on an agreement between the “principal” and “agent”
 - The agent acts on behalf of the principal taking defined actions as if the principal themselves
 - The agent is a “fiduciary” of the principal
 - Ancient common law doctrine
- Implied or express promises

“Fiduciary”

- Derivative of the agent/principal relationship; one party (agent) is required to put the interests of the other party (principal) in front of their own
 - Strict loyalty (fidelity) to the interests of the principal
 - Principal-centered
 - Defined by the agreement
- A non-patient-specific order (NPSO) satisfies these simple criteria, with one big difference...
- BTW, all professional relationships are fiduciary
 - Patient/client – centered relationship

NPSOs are created by the legislature

- That is, *statute*.
- These are not simply working agreements by two parties in a relationship founded on trust
- They particularly defined by legislative process
- Question: could a prescriber and a pharmacist simply agree on how to help care for patients with chronic disease?

Risk: Professional Misconduct

- Years ago the State Education Department (NYSED) defined any activity that included adjusting medication therapy as “prescribing”, even under the authority of a written agreement defined by objective criteria.
- That is: caring for patients on an agreement with a prescriber would be an action outside the scope of practice could be characterized as “Misconduct” putting the pharmacist license at risk.
- Unless specifically supported by statute.

Non-patient specific orders

- Agreement (aka protocol) between a prescriber and a pharmacist to act on behalf of the prescriber
- Generally, to enable *dispensing* in the absence of a prescription, *actionable monitoring*, and *patient education*
- Based on what is, in essence, a contract with explicit criteria for actions taken by the pharmacist
 - Objective guidelines

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Epinephrine

(Public Health Law §3000-c, Education Law §6807(3))

- Eligible persons/entities
 - Ambulance, ALS, certified 1st responder, EMT
 - Overnight and day camps and employees
 - Schools
 - Sports, entertainment, amusement, government, day care, retail, restaurants
 - Peace officers in towns < 1 million
- Purchase, possess, and use epinephrine auto-injectors for emergency treatment of anaphylaxis
- Designated employees must be properly trained
- Prescribers may issue NPSO to eligible person/entity and pharmacists may dispense

Naloxone

(PHL 3309, 10 NYCRR 80.138)

- “Individuals who are themselves at risk for an overdose or their family members or friends may acquire naloxone in these pharmacies without bringing in a prescription.”
 - https://www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/directories.htm

Opioid overdose prevention

- Opioid Overdose Prevention law (Public Health Law §3309)
 - Originally enacted in 2005, amended twice in 2014, again in 2015, and four times in 2016
- Expands the availability of “opioid antagonist” (naloxone) for individuals at risk of overdose, and those who may witness an overdose

Public Health Law

- PHL section 3309 perhaps more aptly named overdose “rescue” law
- First enacted in 2005, intended to make more readily available. Empowered DoH to establish standards for distribution and oversight, and
 - Administrative liability protection from practicing outside scope for:
 - Acquisition/purchase
 - Possession
 - Use of an opioid antagonist

Expanded mandate for pharmacies in 2016

- Any pharmacy chain with 20 or more locations is required to:
 - Pursue or maintain a non-patient-specific prescription, or
 - Register with DoH as an opioid overdose prevention program
 - NPSO provided by the Harm Reduction Coalition at <https://harmreduction.org/overdose-prevention/nyspharmacies/>

Definition of Pharmacy Practice

- Section 6801: “The practice of the profession of pharmacy is defined as the *administering, preparing, compounding, preserving, or the dispensing* of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority and *collaborative drug therapy management* in accordance with the provisions of [6801-a].”
 - “**administering**” added in 2008, “**CDTM**” in 2011
- Note limitations

Immunizer Bill

- Expanded scope of pharmacy practice in 2008 (first time since 1887)
- Allows licensed pharmacists to execute a “non-patient specific regimen”
 - Must be ordered by an MD or NP

“Administration” (def., §6802)

- “direct application of an immunizing agent to adults”
- “to prevent influenza or pneumococcal, herpes zoster, meningococcal, tetanus, diphtheria, or pertusis”
- “pursuant to a patient specific or non-patient specific order (NPSO)”
- MD or NP practicing in the same or adjoining county
 - Commissioner may issue NPSO for “outbreak” or “imminent threat”
- May administer “medications necessary for emergency treatment of anaphylaxis”

Laws, rules, and regulations prescriptively provide for:

- Training and state certification
- Contents of the NPSO
 - Any portion of a short list of vaccines
 - Includes: influenza, pneumococcal, diphtheria, pertussis, tetanus, meningococcal, herpes zoster (ACIP-approved indications)
 - Excludes: hepatitis A, hepatitis B, MMR, HPV, varicella
 - Anaphylaxis treatment
- Reporting

CDTM

(again §6801)

- “...the administering, preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescription or other legal authority, and **collaborative drug therapy management**...”
 - Definition unchanged from 1887 to 2008
 - CDTM added in 2011

What is CDTM?

- Agreement between physician, pharmacist and patient
- Allows pharmacist to adjust medications, order lab tests and check vital signs

CDTM

- “Services by a pharmacist relating to review, evaluation and management of *drug therapy*”
- “For a specific *disease*”
- “With a voluntarily participating *physician*”
– [NB: *not* a nurse practitioner]
- “In accordance with a written agreement or *protocol*”
- “In accordance with policies, procedures and protocols of the *facility*” (hospital or nursing home with a pharmacy)

CDTM Limitations

- *Only* permitted in hospitals or affiliates, or nursing homes with pharmacies
 - Both Pharmacist/Physician must be employees of facility
- May not diagnose disease
- May not involve controlled substances
- Professional judgment of physician prevails
- Requires voluntary participation of a physician AND patient (consent must be in writing)

CDTM

- May adjust:
 - Drug strength
 - Frequency
 - Route of administration
 - Medication*
 - May order laboratory tests related to drug therapy*
 - Collect/review patient history*
 - Order/Check vital signs*
- (* = only if explicitly stated in the protocol)

Record keeping

- The pharmacist must immediately enter any changes made into the patient's record
 - Must use any reasonable means to contact the patient's other treating physicians that are not in the protocol

Protocol

- Must address a specific disease state
- Must describe nature and scope of permitted activities
- Must describe the documentation process
- Signed/dated by MD and pharmacist including effective dates

Other participation restrictions

- Pharm.D. or Master in clinical pharmacology
 - Plus two years of experience
 - One year must be clinical experience (may be a residency)
 - One year = Minimum 1,680 hours in one calendar year
 - Clinical experience = 15 h/week of drug therapy consultation with a physician (in hospital)
- Other requirements set forth by the department (over)

Additional requirements for pharmacists

8 NYCRR §63.10(c)

- Completed a residency, or board certification
- Meet additional experience requirements (above)
- Application to the Board, individually reviewed

Continuing Education

- Of the CE are required every three years (45 hours total), 5 of these hours must be related to their area of practice outlined in the CDTM protocol (Ed Law, §6827(b)).

Post-exposure prophylaxis (PEP)

- May dispense up to a 7-day starter pack to prevent infection with HIV
 - “Truvada”
- Non-occupational exposure
- Protocol with physician or nurse practitioner
- Regulations in §63.13

Fourth question:

- What other NPSO opportunities might serve patients in New York? (SATA)
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What else *could* be in our scope?

- A lot!
 - Comprehensive medication management (A3867/S5092)
 - Long-acting injection administration (A3830/S4848)
 - Point-of-care testing (A3867/S5092)
 - While we're at it, all other CDC-approved vaccines? (A6511/S5227)
 - Penicillin allergy skin testing

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Questions?

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