Legal Perspectives on Pharmacist Prescribing and Pharmacy in the Information Age

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Objectives

Upon completion of the program, attendees should be able to:

- Explain the continuum of pharmacist prescribing activities from dependent to independent prescribing
- List at least two jurisdictions where pharmacists are authorized to independently prescribe contraceptives
- Identify key elements of a collaborative practice agreement in Connecticut
- Assess how technology may change patient demand and the delivery of patient care services and the future of pharmacist prescribing authority

Perspectives

- Let's chat about the following statements:
  - Pharmacists are an underused resource
  - Pharmacists are an essential element of an effective, interdisciplinary healthcare team
  - Pharmacists can improve patient outcomes in ways that other healthcare professionals cannot
  - Pharmacist-provided patient care services are the future of pharmacy
  - Pharmacist-provided patient care services can improve health and reduce costs for care
  - Pharmacist-provided patient care services are valuable and should be reimbursed like other healthcare services

Pharmacist Patient Care Services

- Drug utilization review (DUR)
  - Also known as Drug Utilization Evaluation (DUE) or Medication Utilization Evaluation (MUE)
  - Can be prospective, concurrent, retrospective
  - Usually in institutional setting, but can also be mandated by government payor (e.g., Medicaid)
- Medication Reconciliation
  - 2005 National Patient Safety Goal #8 of TJC
  - Initial focus on transitions of care (hospital admission, intra-hospital transfer, discharge)
  - Resource intensive (e.g., clinical pharmacists)
    - Technology solutions have not panned out
    - Patient engagement may be a factor
- Medication Therapy Management
  - Includes: assessments treatment plan formulation; selecting, initiating, monitoring, administering meds; monitoring/evaluation of patient response; comprehensive medication review; documentation & communication with other healthcare team members; patient education & adherence support; care coordination
- Collaborative Practice Agreements
  - Expansion of scope of practice usually authorized by statute
  - May limit types of providers that may collaborate

Note: all of these are patient-specific, and reimbursement/resource allocation is an issue*

Expand Pharmacist Prescribing Authority?

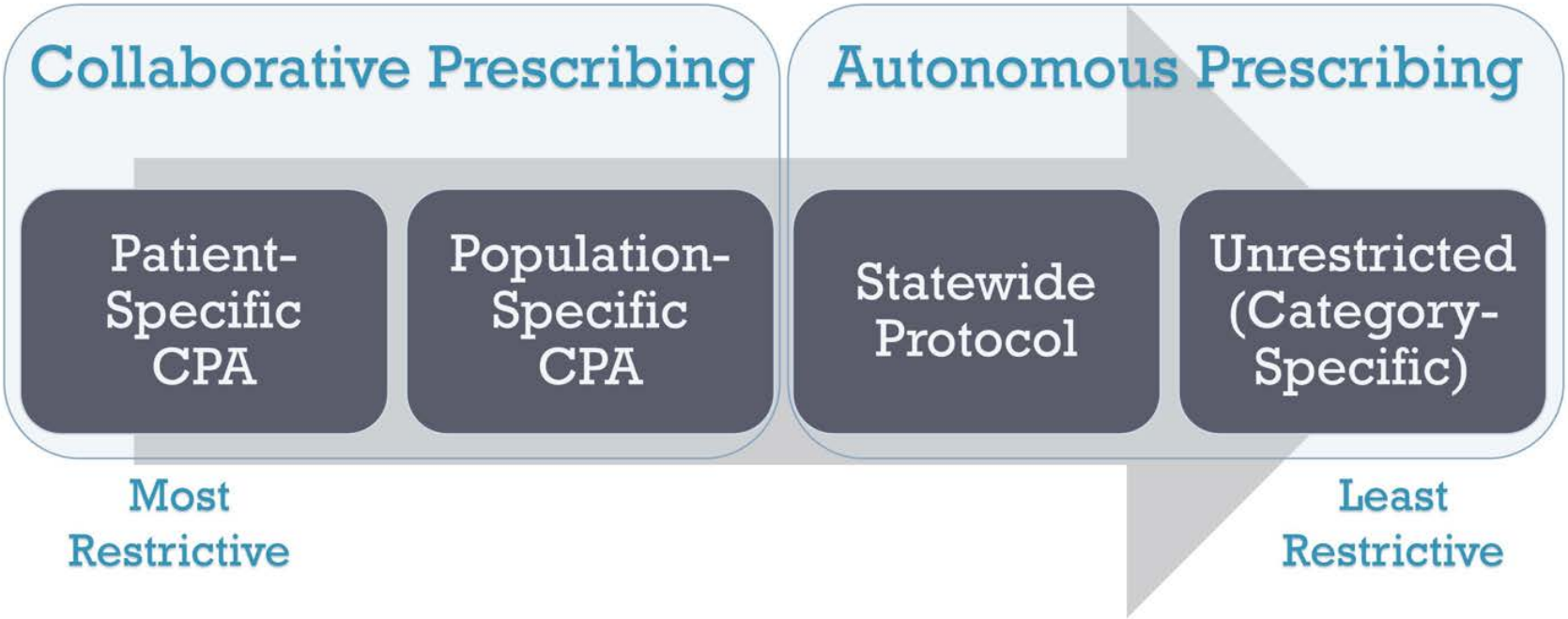
- What might be accomplished by giving pharmacists the authority to prescribe?
- Patient-centered potential effects
  - Improved patient outcomes
  - Better patient education and adherence
  - Decreased adverse drug events (increased patient safety)
  - Increased patient access to medicines
- Pharmacist-centered potential effects
  - Better use of pharmacists' skills and training
  - Professional autonomy
  - Increased reimbursement opportunities
  - Better integration into interdisciplinary healthcare team
  - Increased liability, need for higher limits on professional liability insurance
  - Reimbursement not clear; May have to separate prescribing services from dispensing services (anti-referral issues)

Would Expanded Prescribing Authority Stop with Pharmacists?

- Some peer reviewed literature (and other countries) refer to pharmacist prescribing as “nonmedical prescribing”
  - In some countries and other states, “nonmedical prescribing” authority is also extended to:
    - Nurses (not just APRNs)
    - Optometrists
    - EMTs/Paramedics
    - Psychiatrists
    - Dieticians
    - Physiotherapists
    - Radiographers
    - Social workers

Spectrum of Pharmacist Prescribing Authority

- Dependent prescribing (the "physician-extender" model because authority to prescribe is delegated by the authorized prescriber, and may be setting specific).
  - Patient-specific (most-restrictive)
  - Population-specific
    - Connecticut examples: APRN prescribing (through "collaboration agreement") and PA prescribing (through "delegation agreement")
- Independent (autonomous) prescribing (the "statutory" or "scope of practice" model because prescribing authority is granted by law)
  - Statewide "protocol"
    - Connecticut example: pharmacist prescribing of naloxone
  - Unrestricted (but usually category specific)



Source: https://naspa.us/resource/swp/

Significant Hurdles to Pharmacist Prescribing

- Responsibilities and accountability
  - Who does diagnoses of patient?
    - Medical collaborator (physician, APRN)
    - Questionnaire
  - What about additional assessments?
    - Does pharmacist assess only response to medications for diagnosed condition or also other, undiagnosed conditions?
- Coordination of care
  - Polypharmacy and medication reconciliation
- Risk Management / Professional Liability
- Reimbursement
  - Anti-kickback and anti-referral laws
  - Separation of functions (i.e., dispensing from prescribing)

CURRENT PRESCRIBING AUTHORITY IN CONNECTICUT

Prescribing Practitioner

[CGS 20-571 & CGS 21a-250]

- An individual licensed by
  - the State of Connecticut, any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States
  - who is authorized to issue a prescription
  - within the scope of the individual's practice

Connecticut Prescribing Practitioners

[CGS 20-127; CGS 20-633c; CGS 21a-250; 21a-252]

- Physician (MD)
  - Examples: psychiatrist (*not psychologist*); ophthalmologist
- Osteopath (DO)
- Dentist (DDS, DMD)
- Podiatrist (DPM)
- Veterinarian (DVM, VMD)
- Certain nurses:
  - Advanced Practice Registered Nurse (APRN)
  - Certified Registered Nurse Anesthetist (CRNA)
  - Nurse-Midwife (APRN)
    - NOT registered nurses (RN); not licensed practical nurse (LPN)
- Physician Assistant (PA)
- Optometrist (OD) – but not nonemergency oral glaucoma drugs
- Pharmacist (BS, PharmD)
  - opioid antagonist; collaborative drug therapy management

APRN Prescriptive Authority

[CGS 20-87a; CGS 20-101c; CGS 21a-252(e)]

- Setting. APRN may prescribe and dispense in all practice settings
  - Except APRN with *current certification from American Association of Nurse Anesthetists – CRNA* - prescribing during surgery may do so *only if* physician medically directing the prescriptive activity is physically present
- Controlled drugs. APRN may (within scope of practice) prescribe all CII-CV and legend drugs
  - If under written collaborative agreement with a CT licensed physician, collaborative agreement must specify level of CII & CIII that can be prescribed
  - After 3 years & 2,000 hours of practice under a collaborative agreement, APRN may practice independently (*i.e.*, without written collaborative agreement)
- Samples. May request, sign for, receive & dispense professional samples
- Rx Content. No co-signature necessary - but APRN's prescription form must contain name, address and phone of APRN. Name of collaborating MD (if any) allowed but not required
- Administration of order by others. May cause the same to be administered by an RN or LPN under APRN's direction and supervision

Physician Assistant Prescriptive Authority

[CGS 20-12d; CGS 21a-252(g)]

- Setting. May prescribe in all practice settings provided it is within scope of practice - no physician co-signature needed
- Controlled Substances.
  - PA may prescribe all CII-CV and legend drugs pursuant to written "delegation agreement" between PA and supervising physician licensed to practice in CT
  - CII/CIII – Although no co-signature needed, supervising MD must document approval of CII/CIII in medical record in accordance with the delegation agreement
- Rx Content. Rx form used by PA **must have** PA's signature, name, address & license number (supervising MD's name, address, license & phone number no longer needed) – PA shall sign & print name on all orders
- Samples. May request, sign for, receive & dispense professional samples
- Administration of order by others. May cause the prescribed drug to be administered by APRN, RN or LPN acting under a physician's direction

Not (yet) Allowed to Prescribe in Connecticut

- Clinical Nurse Specialist (CSN, RN)
  - Unless qualified as APRN (a/k/a NP), may not prescribe
- Psychologist (PhD, PsyD)
  - In some states (but not CT), psychologists have limited prescribing authority
- Emergency Medical Technician / Paramedic
- Chiropractor (DC)
- Optician (no drugs; may design, fit and verify eyeglasses based on prescription written by ophthalmologist or optometrist)
- Naturopathic physician (ND)

PRESCRIBING AND DISPENSING OF NALOXONE

Pharmacist Prescribing of Naloxone

[CGS 20-633c]

- Pharmacist may prescribe opioid antagonist if
  - Pharmacist is trained and certified by DCP-approved program
  - Prescribing is done in good faith
  - Pharmacist provides training in the administration of the opioid antagonist to the person to whom the drug is dispensed
  - Pharmacist maintains record of dispensing and training

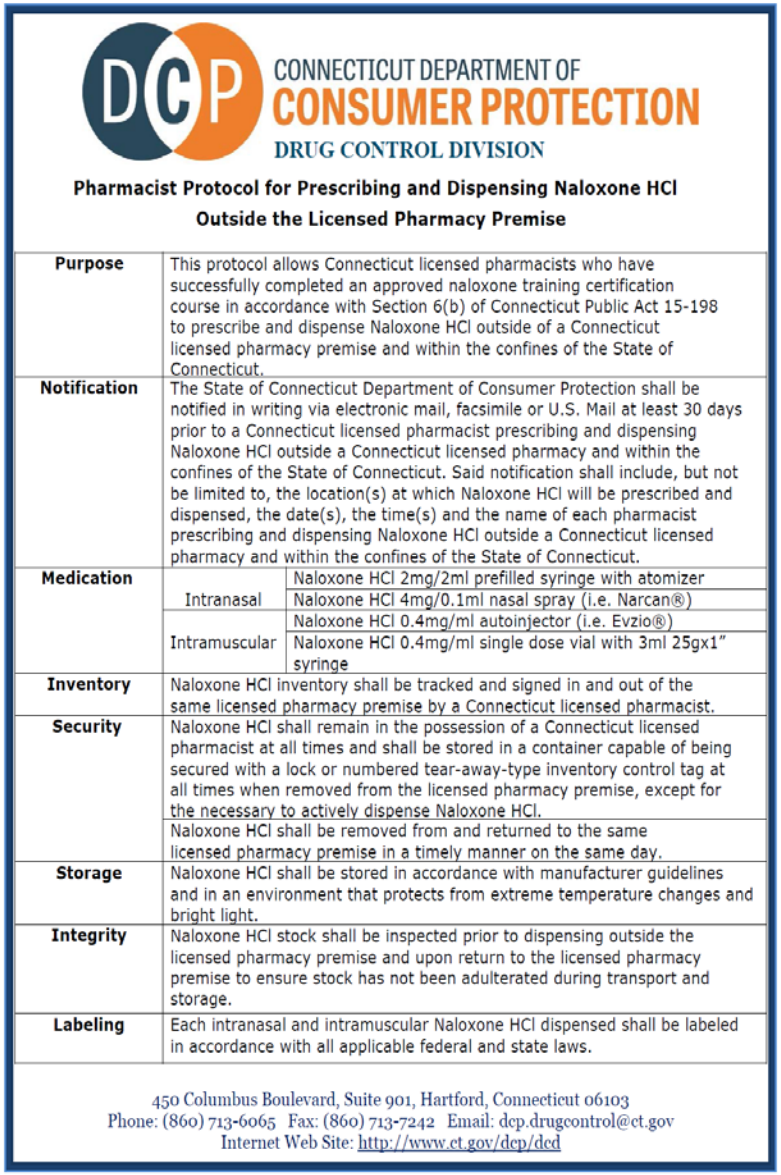
- Prescribing pharmacist :
  - May NOT delegate or direct anyone else to prescribe the opioid antagonist
  - May NOT have someone else train on the administration of the opioid antagonist

Dispensing Opioid Antagonist by Protocol Standing Order
[CGS 20-633d]

- Pharmacy and prescriber may enter into an agreement for a "medical protocol standing order" to dispense opioid antagonist
  - Opioid antagonist must be FDA approved
  - Only in intranasal delivery system or auto-injection (no IM with syringes and vial)
  - May dispense to person at risk, or family, friend or other person in a position to assist person at risk of overdose
  - Pharmacy must provide DCP with copy of each medical protocol standing order agreement
- Pharmacist dispensing under protocol must:
  - be trained and certified by program approved by DCP
  - provide training on administration to person that drug is dispensed to
  - maintain record of dispensing and training of "patient"
  - Send copy of dispensing record to prescriber with medical protocol standing order agreement with pharmacy

Naloxone and Standard of Care/Immunity [CGS 17a-714a]

- Licensed health care professional who may legally prescribe opioid antagonist (naloxone) may prescribe or dispense to "any individual" and:
  - Not be civilly or criminally liable for subsequent use of opioid antagonist
  - Deemed not to have violated standard of care
- Licensed health care professional may administer opioid antagonist to treat or prevent overdose and:
  - Not be civilly or criminally liable for administration of opioid antagonist
  - Deemed not to have violated standard of care
    - BUT there is uncertainty whether the pharmacist has to be acting within scope of employment
- A good Samaritan acting in good faith and with reasonable care (and who is not a licensed healthcare professional acting in ordinary course of employment) may administer opioid antagonist and:
  - Not be civilly or criminally liable for administration of opioid antagonist
- As of 10/01/2017, each city/town in Connecticut should have an emergency medical services plan to equip medical emergency first responders with opioid antagonist and train on administration
  - Training on administration must be approved by DPH



CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION
DRUG CONTROL DIVISION

Pharmacist Protocol for Prescribing and Dispensing Naloxone HCl Outside the Licensed Pharmacy Premise

Purpose	This protocol allows Connecticut licensed pharmacists who have successfully completed an approved naloxone training certification course in accordance with Section 6(b) of Connecticut Public Act 15-198 to prescribe and dispense Naloxone HCl outside of a Connecticut licensed pharmacy premise and within the confines of the State of Connecticut.	
Notification	The State of Connecticut Department of Consumer Protection shall be notified in writing via electronic mail, facsimile or U.S. Mail at least 30 days prior to a Connecticut licensed pharmacist prescribing and dispensing Naloxone HCl outside a Connecticut licensed pharmacy and within the confines of the State of Connecticut. Said notification shall include, but not be limited to, the location(s) at which Naloxone HCl will be prescribed and dispensed, the date(s), the time(s) and the name of each pharmacist prescribing and dispensing Naloxone HCl outside a Connecticut licensed pharmacy and within the confines of the State of Connecticut.	
Medication	Intranasal	Naloxone HCl 2mg/2ml prefilled syringe with atomizer
		Naloxone HCl 4mg/0.1ml nasal spray (i.e. Narcan®)
	Intramuscular	Naloxone HCl 0.4mg/ml autoinjector (i.e. Evzio®)
		Naloxone HCl 0.4mg/ml single dose vial with 3ml 25gx1" syringe
Inventory	Naloxone HCl inventory shall be tracked and signed in and out of the same licensed pharmacy premise by a Connecticut licensed pharmacist.	
Security	Naloxone HCl shall remain in the possession of a Connecticut licensed pharmacist at all times and shall be stored in a container capable of being secured with a lock or numbered tear-away-type inventory control tag at all times when removed from the licensed pharmacy premise, except for the necessary to actively dispense Naloxone HCl.	
	Naloxone HCl shall be removed from and returned to the same licensed pharmacy premise in a timely manner on the same day.	
Storage	Naloxone HCl shall be stored in accordance with manufacturer guidelines and in an environment that protects from extreme temperature changes and bright light.	
Integrity	Naloxone HCl stock shall be inspected prior to dispensing outside the licensed pharmacy premise and upon return to the licensed pharmacy premise to ensure stock has not been adulterated during transport and storage.	
Labeling	Each intranasal and intramuscular Naloxone HCl dispensed shall be labeled in accordance with all applicable federal and state laws.	

450 Columbus Boulevard, Suite 901, Hartford, Connecticut 06103
Phone: (860) 713-6065 Fax: (860) 713-7242 Email: dcp.drugcontrol@ct.gov
Internet Web Site: http://www.ct.gov/dcp/dcd

https://portal.ct.gov/DCP/Drug-Control-Division/Drug-Control/Opioid-Overdose-Information-for-Pharmacists

COLLABORATIVE DRUG THERAPY MANAGEMENT

Hallmarks of Collaborative Practice Agreement

- Enabled by statue/regulation, flexible by agreement
- Formal relationship between pharmacist and medical provider (physician, APRN, other)
  - Voluntary collaboration of interdisciplinary team
- May use:
  - Patient-specific protocol
  - Disease/condition of certain patient population
- Contains appropriate communication processes for coordination of care

- Typical characteristics
  - Post-diagnosis initiation and monitoring of drug therapy
  - Usually addresses chronic disease states or conditions
  - Pharmacist's expertise may address polypharmacy issues

Other Key Elements of Collaborative Practice

- Statutory/regulatory elements
  - Healthcare provider participants (e.g., Only physician prescribers; all prescribers)
  - Structure of relationship (e.g., 1:1 physician/pharmacist, or groups of physicians/pharmacists)
  - Populations served (e.g., single patient/agreement; populations/per agreement)
  - Authorized services (e.g., initiate, modify, terminate/deprescribe drug therapy; test ordering & interpretation; administration of meds)
  - Requirements & restrictions (e.g., reporting; documentation; limitations; licensing body oversight)
- "Contractual" elements & safeguards
  - Pharmacist and physician determine (and document) scope of pharmacist services
  - List actual participants (prescriber/pharmacist)
  - Identify required training/competencies/continuing education
  - Identify specific patients or patient populations
  - Specify disease states, services, protocols/clinical guidelines, documentation processes
  - Specify term (period) of collaborative practice agreement (e.g., one year)
  - Address liability insurance issues

Pharmacist Collaborative Drug Therapy Management

[CGS 20-631 to 20-631a; RCSA 20-631-1 to 20-631-3]

- To qualify, pharmacist must be one of the following:
  - BS with 10 years of experience, or PharmD
  - Certified by
    - Board of Pharmaceutical Specialties or
    - Commission for Certification in Geriatric Pharmacy
  - Credentialed in disease state management by National Institute for Standards in Pharmacist Credentialing
  - In a pharmacy residency accredited by ASHP
  - Successfully completed disease state management certification program approved by ACPE

Pharmacist Collaborative Drug Therapy Management

[CGS 20-631 to 20-631a; RCSA 20-631-1 to 20-631-3]

- If qualified, must have a CDTM agreement with a Connecticut licensed physician** that includes:
  - Types of prescriptive authority decisions pharmacist is allowed to make (initiate, continue, modify)
  - Patients who are eligible for treatment
  - Types of diseases/drugs/drug categories involved
  - Procedures, decision criteria, plans and guidelines for therapeutic decisions (especially to initiate or modify drug therapy)
  - Required training
  - Plan for periodic review, feedback & quality assurance
  - Procedures

Legislation (SB 931) in the current (2019) session of the General Assembly is proposing to expand this to include APRNs (but not Pas)

Pharmacist Collaborative Drug Therapy Management

[CGS 20-631 to 20-631a; RCSA 20-631-1 to 20-631-3]

- In addition to CDTM agreement, must have patient-specific written protocol that includes (at a minimum):
  - Specific drug(s) managed by pharmacist
  - Terms & conditions to initiate, modify or discontinue
  - Conditions/events that pharmacist must report to physician
  - Lab tests that may be ordered by pharmacist
  - Drugs that may be administered by pharmacist
- Pharmacist must report patient's drug therapy management to physician at least every 30 days
- Physician must have physician-patient relationship with the patient
  - Patient does NOT need to consent to collaboration with pharmacist

PHARMACIST PRESCRIBING IN OTHER JURISDICTIONS

Contraception

- As of February 2019, the following United States jurisdictions allow pharmacists to prescribe oral contraceptives
  - California
  - Colorado
  - District of Columbia
  - Hawaii
  - Idaho
  - Maryland
  - New Mexico
  - Oregon
  - Tennessee
  - Washington
- The following jurisdictions allow pharmacists to dispense oral contraceptives under a standing order or a consulting agreement without requiring the patient have an in-person medical exam first:
  - New Hampshire
  - Ohio
  - Utah
  - West Virginia

Pharmacist Prescribing of Contraception

- Of the jurisdictions that have adopted pharmacist prescribing for contraception, the details vary:
  - Most use a self-screening tool (questionnaire) to assess patient suitability/eligibility
  - Most are restricted only to "self-administered" oral contraceptives
    - Some allow for other forms of contraceptives
  - Prescriptive authority also varies
    - Some require collaborative practice agreement
    - Some are under statewide protocols and guidelines
  - Minimum age requirements may apply
  - Prior prescription from medical provider may be required
  - Prescribing may be for limited supply
  - Pharmacist prescribing may or may not be compensable
- Almost all jurisdictions require additional training or continuing education

Smoking Cessation

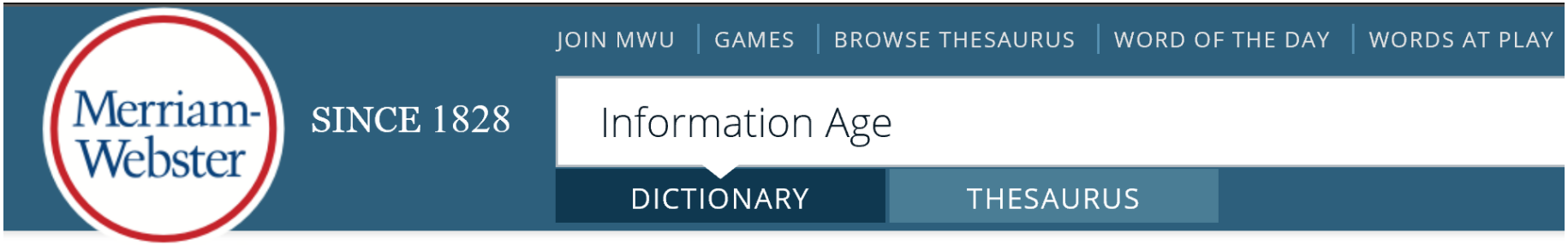
- Colorado has a "collaborative practice statewide protocol" for pharmacists to provide smoking cessation services to patients, including prescribed medication
  - Pharmacists must be trained (completion of ACPE smoking cessation program)
  - Pharmacist services must also include "educational component" that provides counseling on medication therapies and cessation strategies, and referral to specific sources under the Colorado Quit Line Program
  - Pharmacist uses a screening tool to assess each patient
  - Protocol excludes certain patients (e.g., under 18, pregnant, history of: seizure disorder, eating disorder, mental illness, others)
  - Pharmacist must communicate with patient's PCP; if patient does not have PCP, must provide patient with written record of medications/devices furnished

Saskatchewan, Canada (UTIs)

- Saskatchewan, Canada allows pharmacists to assess and prescribe antibiotics for urinary tract infections (UTIs)
  - Initial diagnosis must be made by physician or nurse practitioner (not the pharmacist)
  - Setting: community/retail pharmacists
  - Training: pharmacist must follow established guidelines; training is part of pharmacist education and licensure
  - Restrictions: pharmacist may not prescribe for
    - pregnant woman
    - males
    - immunocompromised patients (e.g., chemo)
    - other circumstances outside guidelines
  - Reimbursement: pharmacy may charge for the assessment in addition to the prescribed medication

Strep and Flu

- Point of care testing used in Canada (rapid strep test) and based on result of test, pharmacists were referring for treatment
  - Pharmacists had also advocated for ability to prescribe antibiotics for treatment
- Controversial – "negative" test results were missing strep infection in children
  - Nova Scotia College of Pharmacists said that POC testing for strep, without referring patient to consult with primary care provider (physician or nurse practitioner) does not meet standard of care for diagnosing children
    - Contrary to practice guidelines established by Infectious Disease Society of America
  - Alberta and British Columbia Colleges of Pharmacists implemented practice standards and guidelines on POC testing for strep



Information Age noun

variants: *or* **information age**

Definition of *Information Age*

: the modern age regarded as a time in which information has become a commodity that is quickly and widely disseminated and easily available especially through the use of computer technology

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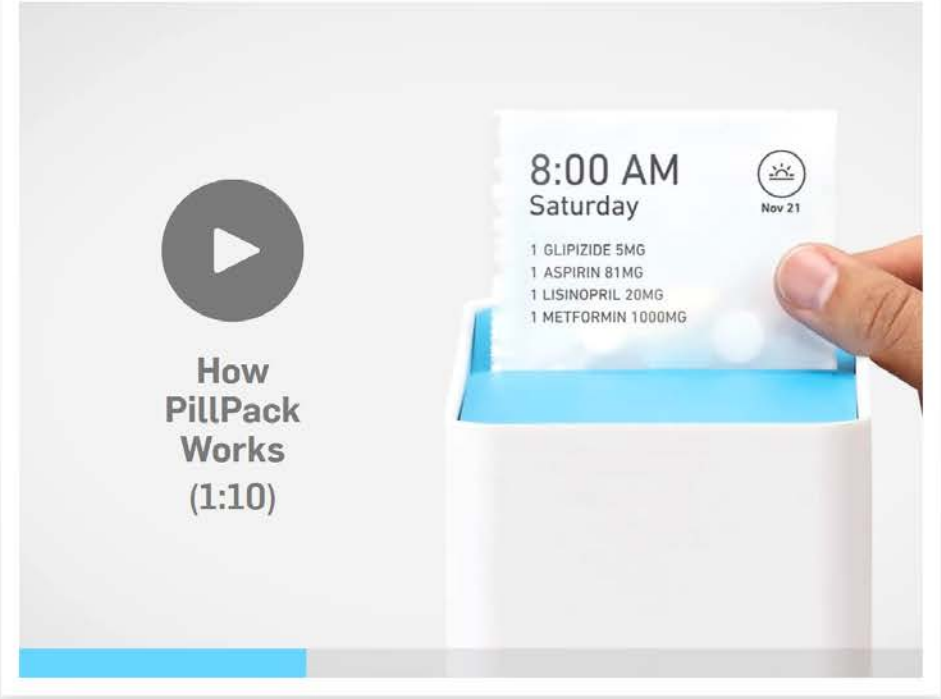

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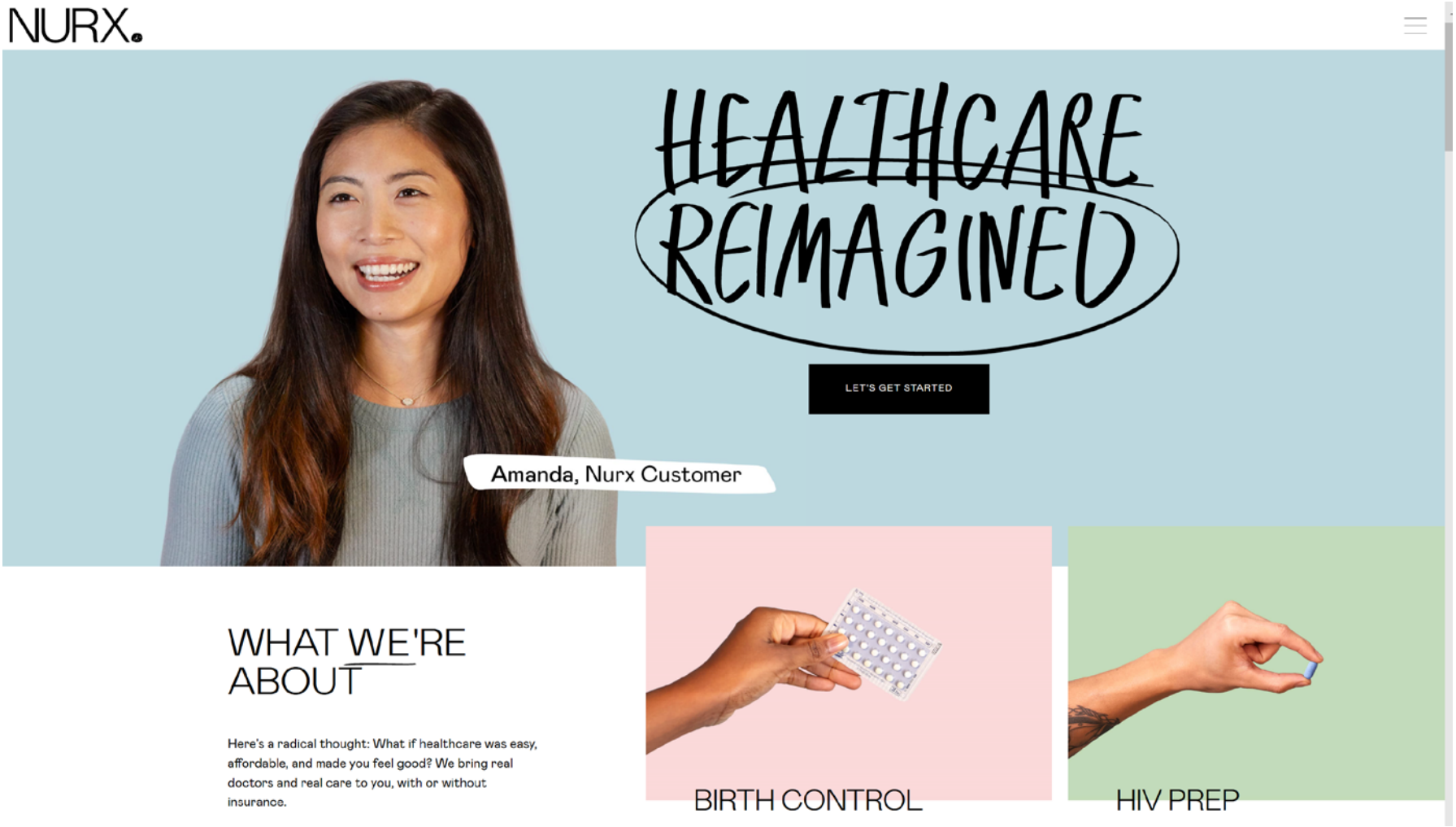

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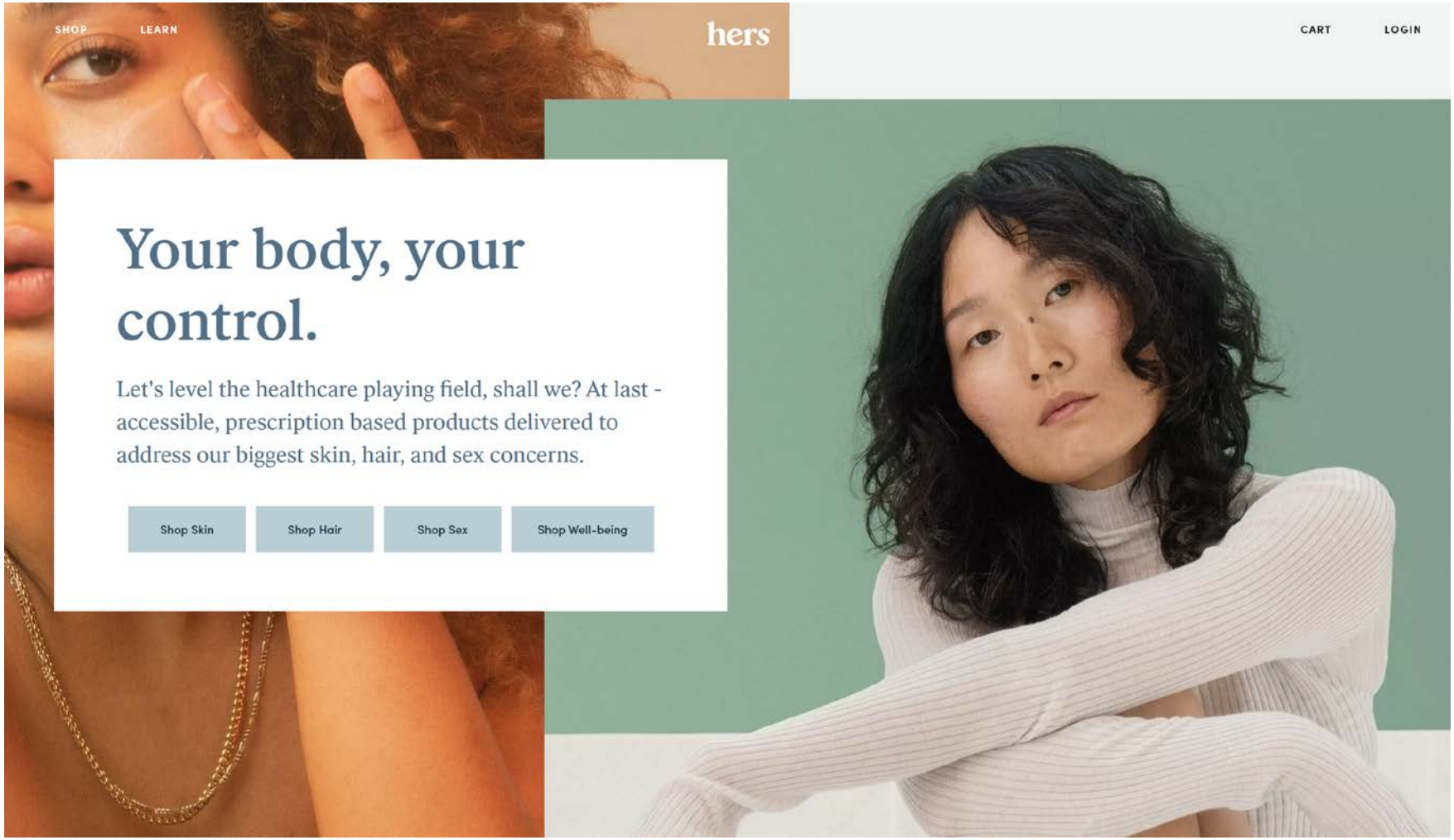

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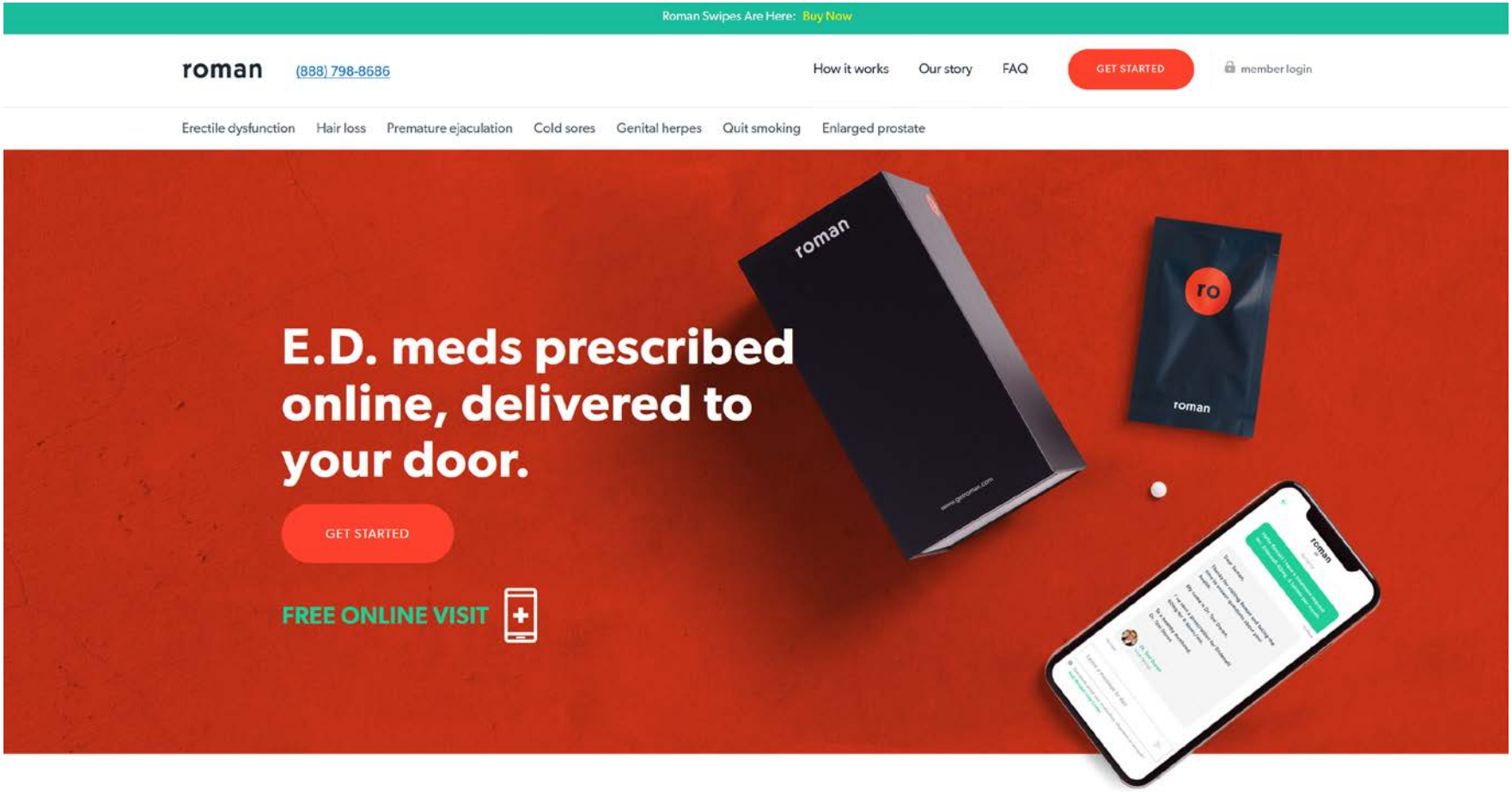
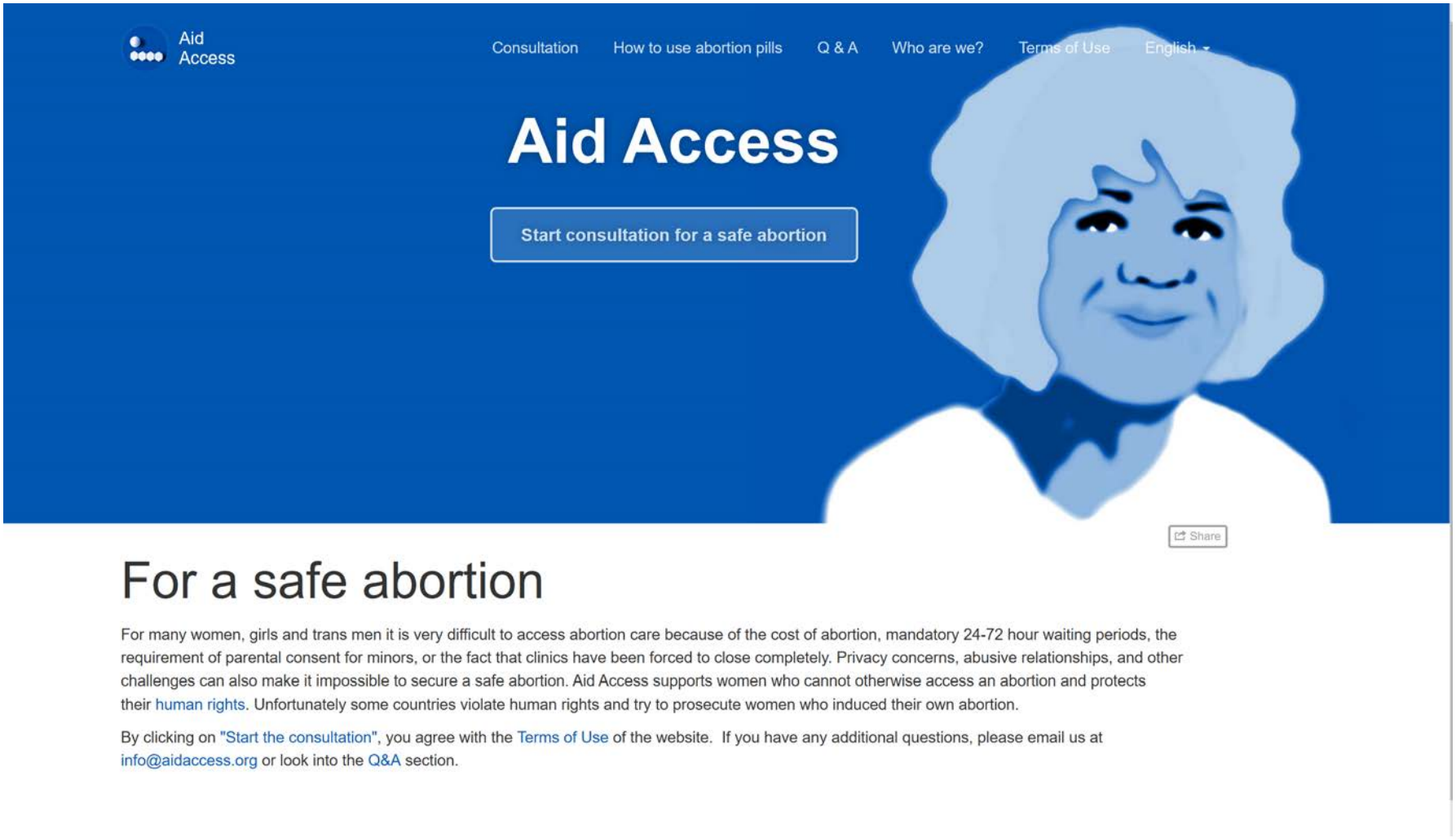


www.getroman.com



https://aidaccess.org/

ctpost News Sports UConn Nation I nt Living

Yale to offer emergency contraception via vending machine

By Register Staff Updated 11:05 am EST, Thursday, November 29, 2018

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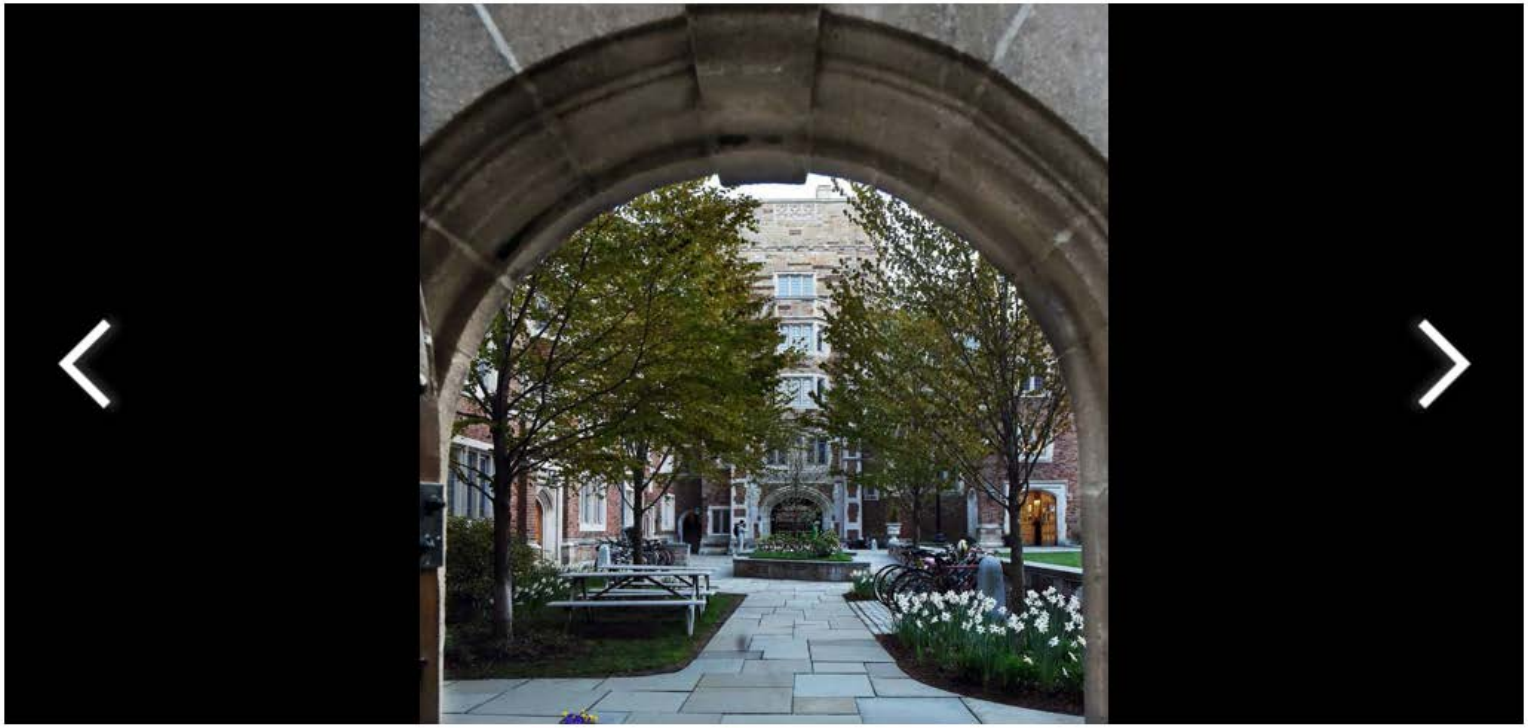


Photo: Catherine Avalone / Hearst Connecticut Media File Photo

IMAGE 1 OF 7

Yale University

In Connecticut, **nonlegend** drugs may not be sold or dispensed by a vending machine

[RCSA 20-576-31]

Telehealth in Connecticut

[CGS 21a-249(c)(5); CGS 19a-906] – New as of 07/01/2018

- Telehealth provider is prohibited from prescribing CI, CII or CIII controlled substances via telehealth (i.e., no prescribing without in-person examination) EXCEPT:
  - May prescribe via telehealth a CII or CIII (other than an opioid) for the treatment of a psychiatric disability or substance use disorder (including medication-assisted treatment) in accordance with Ryan Haight Online Pharmacy Consumer Protection Act (21 USC 829(e))
  - If prescribing under the exception, practitioner MUST use electronic prescribing (no waiver permitted)
- This prohibition does not apply using telehealth for hospital inpatient
- CIV, V, and non-controls are unrestricted (may be prescribed via telehealth visit only)
- Pharmacist can be a telehealth provider

Where is the future of Pharmacy Practice?

- Dispenser
- Gatekeeper
- Drug information expert
- Patient advocate
- Clinician
- Prescriber
- Diagnostician
- Educator

Questions?

Connecticut General Statutes Section 20-631.
Collaborative drug therapy management agreements between pharmacists and physicians. Scope. Pharmacist competency requirements. Regulations.

(a) Except as provided in section 20-631b, one or more pharmacists licensed under this chapter who are determined competent in accordance with regulations adopted pursuant to subsection (d) of this section may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients. In order to enter into a written protocol-based collaborative drug therapy management agreement, such physician shall have established a physician-patient relationship with the patient who will receive collaborative drug therapy. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist. For purposes of this subsection, a "physician-patient relationship" is a relationship based on (1) the patient making a medical complaint, (2) the patient providing a medical history, (3) the patient receiving a physical examination, and (4) a logical connection existing between the medical complaint, the medical history, the physical examination and any drug prescribed for the patient.

(b) A collaborative drug therapy management agreement may authorize a pharmacist to implement, modify or discontinue a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of such discontinuance no later than twenty-four hours from the time of such discontinuance. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified or discontinued, (3) the conditions and events upon which the pharmacist is required to notify the physician, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report at least every thirty days to the physician regarding the patient's drug therapy management. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) A pharmacist shall be responsible for demonstrating, in accordance with regulations adopted pursuant to subsection (d) of this section, the competence necessary for participation in each drug therapy management agreement into which such pharmacist enters.

(d) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, shall adopt regulations, in accordance with chapter 54, concerning competency requirements for participation in a written protocol-based collaborative drug therapy management agreement described in subsection (a) of this section, the minimum content of the collaborative drug therapy management agreement and the written protocol and such other matters said commissioners deem necessary to carry out the purpose of this section.

(P.A. 02-41, S. 1; P.A. 03-164, S. 1; June 30 Sp. Sess. P.A. 03-6, S. 146(c), (d); P.A. 04-169, S. 17; 04-189, S. 1; P.A. 05-217, S. 1; P.A. 10-117, S. 91.)

Agency
Department of Consumer Protection

Subject
Collaborative Drug Therapy Management

Inclusive Sections
§§ 20-631-1—20-631-3

CONTENTS

Collaborative Drug Therapy Management

Sec. 20-631-1. Competency requirements

To qualify for participation in a collaborative drug therapy management agreement, a pharmacist shall be licensed in this state and shall meet at least one of the following qualifications:

(1) Bachelor of Science degree in pharmacy with 10 years of clinical experience, or a Pharm.D. degree;

(2) Certification by the Board of Pharmaceutical Specialties;

(3) Certification by the Commission for Certification in Geriatric Pharmacy;

(4) A credential in disease state management from the National Institute for Standards in Pharmacist Credentialing;

(5) Pharmacy residency accredited by the American Society of Health-System Pharmacists; or

(6) Completion of a disease state management certification program approved by the Accreditation Council for Pharmacy Education.

(Effective January 2, 2013)

Sec. 20-631-2. Content of a collaborative drug therapy management agreement

A collaborative drug therapy management agreement shall include:

(1) The types of prescriptive authority decisions the pharmacist may make (e.g., initiation, continuation or modification);

(2) Patients who are eligible for treatment;

(3) The types of diseases, drugs, or drug categories involved (there are no limitations on disease states or conditions);

(4) The procedures, decision criteria, plans, or guidelines the pharmacist is to follow when making therapeutic decisions, particularly when initiating or modifying drug therapy;

(5) Required training;

(6) A plan for periodic review, feedback and quality assurance; and

(7) Procedures for documenting prescribing decisions.

(Effective January 2, 2013)

Sec. 20-631-3. Content of patient protocol

A written protocol for a specific patient established pursuant to a collaborative drug therapy management agreement shall include, but need not be limited to, the following:

(1) The specific drug or drugs to be managed by the pharmacist;

(2) The terms and conditions under which drug therapy may be implemented, modified or discontinued;

(3) The conditions and events that the pharmacist is required to report to the physician;

(4) The laboratory tests that may be ordered by the pharmacist; and

(5) The drugs that may be administered by the pharmacist.

(Effective January 2, 2013)

PSNet
PATIENT SAFETY NETWORK

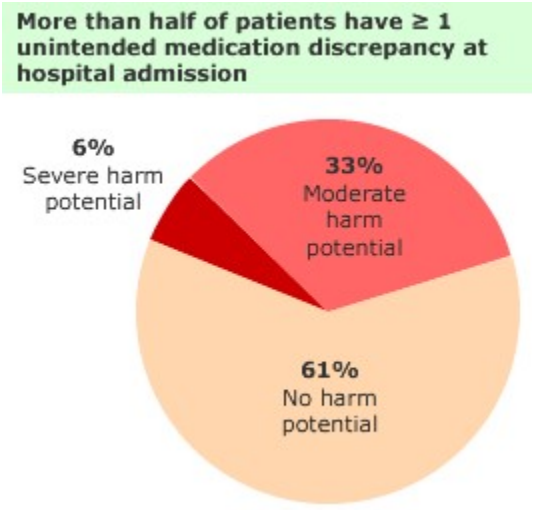
Patient Safety Primer Last Updated: January 2019

Medication Reconciliation

Background

Patients often receive new medications or have changes made to their existing medications at times of transitions in care—upon hospital admission, transfer from one unit to another during hospitalization, or discharge from the hospital to home or another facility. Although most of these changes are intentional, unintended changes occur frequently for a variety of reasons. For example, hospital-based clinicians might not be able to easily access patients' complete pre-admission medication lists, or may be unaware of recent medication changes. As a result, the new medication regimen prescribed at the time of discharge may inadvertently omit needed medications, unnecessarily duplicate existing therapies, or contain incorrect dosages. These discrepancies place patients at risk for adverse drug events (ADEs), which have been shown to be one of the most common types of adverse events after hospital discharge. Medication reconciliation refers to the process of avoiding such inadvertent inconsistencies across transitions in care by reviewing the patient's complete medication regimen at the time of admission,

transfer, and discharge and comparing it with the regimen being considered for the new setting of care.



Source: Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. Arch Intern Med. 2005;165:424-429. [go to PubMed]

Accomplishing Medication Reconciliation

The evidence supporting patient benefits from reconciling medications is relatively scanty. Most medication reconciliation interventions have focused on attempting to prevent medication errors at hospital admission or discharge, but the most effective and generalizable strategies remain unclear. A 2016 systematic review found evidence that pharmacist-led processes could prevent medication discrepancies and potential ADEs at hospital admission, in-hospital transitions of care (such as transfer into or out of the intensive care unit), and at hospital discharge. A 2013 systematic review published as part of the AHRQ *Making Health Care Safer II* report also found that pharmacist engagement in medication reconciliation prevented discrepancies and potential ADEs after discharge. However, both the actual clinical effect of

medication discrepancies after discharge appears to be small, and therefore, medication reconciliation alone does not reduce readmissions or other adverse events after discharge.

Information technology solutions are being widely studied, but their effect on preventing medication discrepancies and improving clinical outcomes is similarly unclear. A 2016 systematic review found that electronic tools often lacked the functionality to accurately reconcile medications, perhaps explaining why medication discrepancies persist even in organizations with fully integrated electronic medical records. Several studies have also investigated the role of enhanced patient engagement in medication reconciliation in the outpatient setting and after hospital discharge. These efforts are promising but also lack evidence regarding the impact on medication error rates.

Medication reconciliation has therefore become an example of a safety intervention that has been effective in research settings but has been difficult to implement successfully in general practice. A 2016 commentary identified the major reasons for difficulty achieving safety improvements via medication reconciliation. They include the resource intensive nature of interventions such as clinical pharmacists, which disincentivizes organizations from investing in medication reconciliation; the alterations to clinical workflow that result from interventions, which creates inefficiencies and confusion regarding the best possible medication history; and conflict between medication reconciliation and other system quality improvement priorities, such as patient flow improvement. The commentary provides recommendations for

organizations, clinicians, and researchers on how to better implement and evaluate medication reconciliation interventions.

Current Context

Medication reconciliation was named as 2005 National Patient Safety Goal #8 by the Joint Commission. The Joint Commission's announcement called on organizations to "accurately and completely reconcile medications across the continuum of care." In 2006, accredited organizations were required to "implement a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient" and to communicate "a complete list of the patient's medications to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization."

The Joint Commission suspended scoring of medication reconciliation during on-site accreditation surveys between 2009 and 2011. This policy change was made in recognition of the lack of proven strategies for accomplishing medication reconciliation. As of July 2011, medication reconciliation has been incorporated into National Patient Safety Goal #3, "Improving the safety of using medications." This National Patient Safety Goal requires that organizations "maintain and communicate accurate medication information" and "compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies."

Editor's Picks

JOURNAL ARTICLE › STUDY

Incidence of clinically relevant medication errors in the era of electronically prepopulated medication reconciliation forms: a retrospective chart review.

Stockton KR, Wickham ME, Lai S, et al. CMAJ Open. 2017;5:E345-E353.

CASE

A Pill Organizing Plight

JOURNAL ARTICLE › COMMENTARY

The problem with medication reconciliation.

Pevnick JM, Shane R, Schnipper JL. BMJ Qual Saf. 2016;25:726-730.

TOOLS/TOOLKIT › TOOLKIT

MARQUIS Medication Reconciliation Resource Center.

Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS). Philadelpha, PA: Society for Hospital Medicine.

JOURNAL ARTICLE › STUDY

Engaging patients in medication reconciliation via a patient portal following hospital discharge.

Heyworth L, Paquin AM, Clark J, et al. J Am Med Inform Assoc. 2014;21:e157-e162.

JOURNAL ARTICLE › REVIEW

Medication reconciliation during transitions of care as a patient safety strategy: a systematic review.

Kwan JL, Lo L, Sampson M, Shojania KG. Ann Intern Med. 2013;158(5 Pt 2):397-403.

TOOLS/TOOLKIT › TOOLKIT

Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation.

Gleason KM, Brake H, Agramonte V, Perfetti C. Rockville, MD: Agency for Healthcare Research and Quality; Revised August 2012. AHRQ Publication No. 11(12)-0059.

JOURNAL ARTICLE › STUDY

Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial.

Kripalani S, Roumie CL, Dalal AK, et al; PILL-CVD (Pharmacist Intervention for Low Literacy in Cardiovascular Disease) Study Group. Ann Intern Med. 2012;157:1-10.

JOURNAL ARTICLE › REVIEW

Hospital-based medication reconciliation practices: a systematic review.

Mueller SK, Sponsler KC, Kripalani S, Schnipper JL. Arch Intern Med. 2012;172:1057-1069.

JOURNAL ARTICLE › STUDY

Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases.

Bell CM, Brener SS, Gunraj N, et al. JAMA. 2011;306:840-847.

CASE

Reconciling Records

CASE

Medication Reconciliation Pitfalls

JOURNAL ARTICLE › STUDY

Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events: a cluster-randomized trial.

Schnipper JL, Hamann C, Ndumele CD, et al. Arch Intern Med. 2009;169:771-780.

CASE

Medication Reconciliation Victory After an Avoidable Error

CASE

Hospital Admission Due to High-Dose Methotrexate Drug Interaction

WEB RESOURCE › MULTI-USE WEBSITE

National Patient Safety Goals.

Oakbrook Terrace, IL: The Joint Commission; 2018.

PERSPECTIVE

Integrating Multiple Medication Decision Support Systems: How Will We Make It All Work?

CASE

Medication Reconciliation: Whose Job Is It?

JOURNAL ARTICLE › STUDY

Role of pharmacist counseling in preventing adverse drug events after hospitalization.

Schnipper JL, Kirwin JL, Cotugno MC, et al. Arch Intern Med. 2006;166:565-571.

CASE

Reconciling Doses

JOURNAL ARTICLE › STUDY

Unintended medication discrepancies at the time of hospital admission.

Cornish PL, Knowles SR, Marchesano R, et al. Arch Intern Med. 2005;165:424-429.

Report of the Task Force on Pharmacist Prescriptive Authority

NOTE: The NABP Executive Committee accepted the report and appreciated the research and discussion of the Task Force. However, the Executive Committee concluded that the recommendations do not adequately address the Task Force charge regarding pharmacist prescriptive authority. In response, the Executive Committee will engage in additional research to develop specific recommendations for states to establish and recognize pharmacist prescriptive authority.

Members Present:

Dennis Wiesner (TX), *chair;* Kerstin Arnold (TX); Tom Bender (NJ); Tim Fensky (MA); Cathy Hanna (KY); Virginia "Giny" Herold (CA); Leo Lariviere (RI); Cathy Lew (OR); Mike Podgurski (PA); Joyce Tipton (TX); Cynthia Warriner (VA).

Others Present:

James DeVita, *Executive Committee liaison*; Krystalyn Weaver (NASPA); Robert Braylock, PharmD/MBA candidate (University of Findlay College of Pharmacy), *guests;* Carmen Catizone; Eileen Lewalski; Maureen Schanck; Angie Rutkowski, *NABP staff.*

Introduction:

The Task Force on Pharmacist Prescriptive Authority met September 1-2, 2015, at NABP Headquarters. This task force was established in response to Resolution 111-4-15, Task Force on Pharmacist Prescriptive Authority, which was approved by the NABP membership at the Association's 111th Annual Meeting in May 2015.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing state laws and regulations addressing pharmacists' prescriptive authority and relevant NABP *Model Act* language.
2. Recommend revisions, if necessary, to the NABP *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing this issue.
3. Propose key messages that should be conveyed to boards of pharmacy, key stakeholders, and the public about the patient care benefits of granting pharmacists limited prescriptive authority.

Recommendation 1: NABP Should Support Pharmacists Having Limited Ability to Initiate, Modify, and Terminate Drug Therapy.

The task force recommends that NABP support pharmacists having limited ability to initiate, modify, and terminate drug therapy under certain circumstances including, but not limited to collaborative practice agreements and state protocols.

Background:

The task force members discussed how the health care delivery landscape is constantly changing and the fact that we are entering a time when there is an emphasis on expanding accessible, affordable, and quality health care. Members agreed that health care professionals should be encouraged to practice at the highest level possible for their profession as long as proper safeguards are in place; this would include pharmacists who are trained and competent in drug therapy and who are vastly underutilized in most health care delivery systems. Members pointed out that pharmacists, who are the most accessible health care team member, may be the key to reaching patients with health care services that they may not otherwise receive or have difficulty accessing.

The task force discussed how some states like California and Oregon have implemented new laws and updated existing laws and rules to allow for pharmacists to initiate, modify, and terminate drug therapy in limited circumstances, while other states have expanded their collaborative practice guidelines and statewide protocols to allow for pharmacists to be more actively involved in managing drug therapy. Members agreed that, with the projected demand on the current health care delivery model, the need and opportunity for pharmacists' involvement in health care delivery has never been greater.

The task force members were resolute in their belief that today's pharmacists, with more clinical opportunities and training, are needed to provide more for patients while continuing to dispense medication. This is grounded on the knowledge that pharmacists are now impacting more lives and reaching more individuals through such means as community pharmacist immunizations, antimicrobial stewardships, diabetes clinics, and warfarin clinics than would have ever been possible before pharmacists entered the clinical arena. Pharmacists working in the Indian Health Services and the Veterans Health Administration have demonstrated positive impact on patient outcomes for decades and are a valued member of the health care team. These benefits include "improved patient access to physicians, improved continuity of care and more comprehensive medication management," to name a few.[1]

Recommendation 2: NABP Should Amend the Model Act.

The task force recommends that NABP amend the Model Act. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

[1] Ragan, A. Case Study: *The Advancement of Clinical Pharmacist Prescribing Privileges.* Bethesda, MD: American Society of Health-System Pharmacists; n.d.

Article I

Title, Purpose, and Definitions

Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means the interpretation, evaluation, and implementation of Medical Orders; the accepting, processing, or Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and Administration of immunizations; and other approved patient care services such as the initiation of Drug therapy; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

(See comment list.)

Comments

Section 104. Comment.

The definition of the "Practice of Pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms "must perform" and "is responsible for" intends to allow delegation of tasks to Certified Pharmacy Technicians or Pharmacy Technicians.

Pharmacy is a dynamic profession and a broad definition of the practice will permit the Board to make necessary changes from time to time to meet the changing practice. Such changes may be affected by new or amended rules, which would be promulgated pursuant to the requirements of the State Administrative Procedures Act, affording all interested parties an opportunity to review and comment on any proposed rules.

NABP recognizes that protection of the public health should extend across state borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the "Practice of Pharmacy."

In the interest of public health and patient access to timely, efficient, and quality care, it is warranted to ensure that the definition of the "Practice of Pharmacy" includes pharmacists with the legislative and regulatory authority to initiate medication therapy based upon the following specific parameters. The development of the parameters should include all stakeholders needed to appropriately define and confine the authority within the pharmacist's education and expertise. (Examples where a pharmacist could potentially initiate medication therapy include public health and preventative medications such as, but not limited to, naloxone, hormonal contraceptives, and travel medications.)
The following factors should be considered in the development of parameters:

1. No diagnosis required or is easily assessed
2. Formulary or protocol (such as regional, Board, or State-established)
3. Communications and feedback is required between pharmacist, patient, and primary care provider where one exists or referral by pharmacist to primary care provider and/ or appropriate practitioner, if necessary.

Section 105. Definitions.

…

(u) "Collaborative Pharmacy Practice" is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction and collaboration with one or more Practitioners ~~under protocol and in collaboration with Practitioner(s)~~ to provide patient care services to achieve optimal medication use and desired patient outcomes.

(v) "Collaborative Pharmacy Practice Agreement" is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice as defined by law and the Rules of the Board.

…

(b4) "Medical Order" means a lawful order of a Practitioner that may or may not include a Prescription Drug Order.

…

(w4) "Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement" means those duties and limitations of duties placed upon one or more Pharmacists by the collaborating Practitioner or Practitioners, the Board, and applicable law, and includes the limitations implied by the scope of practice of the collaborating Practitioner or Practitioners.

…

(f5) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.

…

(j5) "Prescription Drug Order" means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, where a valid Patient-Practitioner relationship exists, that is communicated to a Pharmacist in a licensed Pharmacy.

…

Model Rules for the Practice of Pharmacy

…

Section 5. Pharmacist Care

…

(d) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

(i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(ii) the types of decisions that the Pharmacist is allowed to make. ~~may include:~~

~~(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;~~

~~(B) a detailed description of the methods, procedures, decision criteria, and plan the Pharmacist is to follow when conducting allowed activities; and~~

~~(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made.~~

(iii) a process for generating any necessary medical orders, including prescription orders, required to initiate allowed activities.

(iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(~~i~~v) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
(vi) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
(vii) a provision that allows either party to cancel the Agreement by written notification;
(viii) an effective date; ~~and~~
(~~viii~~ix) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing~~.~~; and
(x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(3~~4~~) ~~Initiation of the Collaborative Pharmacy Practice Agreement~~
~~The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.~~

(4) Documentation of Pharmacist activities
Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to receive~~d~~ it. Documentation of allowed activities shall be considered Protected Health Information.

~~(5) Review~~
~~At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.~~

Background:

Krystalyn Weaver from National Alliance of State Pharmacy Associations (NASPA) presented to the task force members trends in collaborative practice authority and recommendations from NASPA's Collaborative Practice Workgroup, which included NABP observation. Included in the discussion was the fact that state collaborative practice statute and regulations are highly variable between states. Krystalyn also explained that there is variability in how related terms such as protocol are defined. The NASPA workgroup recommended that the framework for collaborative practice agreements should consider the pharmacist's education and training while keeping patient safety and best interest paramount.

The task force members concluded that NABP should encourage state boards of pharmacy to review current requirements for collaborative practice agreements and revise requirements to remove barriers that may have previously prevented the greater acceptance and wider adoption of collaborative practices between physicians and pharmacists. It was agreed that state collaborative practice laws and rules should be broad in scope to allow varying degrees of collaboration and should not interfere with the extent of collaboration between a pharmacist and other health care providers.

In regard to collaborative practice laws and rules, the task force members stressed that states should not impede, among other things, pharmacists from collaborating with multiple providers, the ability of a pharmacist to initiate drug therapy, the administration and interpretation of tests, the number of patients and disease states that can be treated per collaborative practice agreement, and the types of drugs that a pharmacist can initiate, discontinue or modify within a collaborative practice agreement. As has been demonstrated by pharmacists working in the Indian Health Service and other federal health care systems, the depth and scope of collaborative practice should be determined by the pharmacist and prescriber entering into a collaboration.

Recommendation 3: NABP Should Support Key Messages Pertaining to Pharmacists' Role in Providing Health Care

The task force recommends that NABP support the following key messages pertaining to pharmacists' role in providing health care:

1. Expand pharmacists' role, consistent with their education and training, on health care teams to increase patient access to quality health care.
2. Pharmacists continue efforts to enter into collaborative agreements with practitioners to improve outcomes by increasing patient access to timely and efficient care.
3. States continue to implement and expand collaboratively developed initiatives to provide for limited pharmacists' prescriptive authority through formularies and protocols.
4. Pharmacists gain provider status in support of efforts to improve access to pharmacist care.
5. Educate the public and other stakeholders on the expanding role of pharmacists in health care.

Background:

Members conveyed how pharmacists have long provided the public with advice on over-the-counter (OTC) products as part of their role as medication experts. With the implementation of robotics and technology to assist with the dispensing functions and the public demand for more access to primary care, the pharmacist is well positioned to provide increased patient-centered services and an expanded role in patients' drug therapy. Being that the pharmacist is the most accessible health care provider and hospital emergency departments are often burdened with patients having a noncritical need for drug therapy, the task force recommends that boards of pharmacy and departments of health support pharmacists' initiatives to provide timely drug therapy in circumstances such as preventative medicine where patient access to drug therapy is warranted yet not deemed critical. This is already the case in certain states and counties where regulations have been instituted to allow pharmacists to deliver travel medications, nicotine replacements, hormonal contraceptives, naloxone, Antibiotic therapy for the treatment of Lyme disease, and, if warranted, following a pharmacist administered swab test to detect influenza and streptococcal infections.

The task force agreed that states can assist timely access to drug therapy by approving statewide protocols or state approved formulary whereby a pharmacist can furnish certain drugs to a patient when the pharmacist demonstrates adequate training and or obtains the required certification. The task force also called on support from FDA and other stakeholders for implementation of a third class of drugs beyond OTC and prescription only medication that may offer patients access

to certain medications only after consultation with a pharmacist. Some examples could include methylprednisolone dose pack for poison ivy exposure or other topical agents for dermatitis. Members determined that this third class of drugs would be appropriate for conditions that are either self-diagnosed or easily diagnosed.

In order to facilitate employer support and pharmacists' incentive to provide services beyond their historic role in drug delivery, the task force deemed it imperative that pharmacists gain provider status for reimbursement purposes. Provider status is the vehicle by which clinical pharmacy services will systematically be offered by pharmacists to patients on a consistent basis. Members stressed that by achieving provider status, establishing a payment system for clinical services offered by pharmacists should ensue.

With millions of individuals entering the health care system as a result of the Affordable Care Act, there is a need for increased access to care. Currently there is a lack of primary care physicians (PCPs), which requires the health care industry's attention. According to a report published by the Association of American Medical Colleges, the projected shortage of PCPs by 2025 will range from 12,500 to 31,100.[2] With such a shortage, other members of the health care team, such as pharmacists, must help bridge the gap. While members of the pharmacy profession are aware of the potential role of pharmacists in health care delivery, further education must be provided to the general public and other stakeholders about the benefits of pharmacists' interventions. Informing the public and stakeholders about these potential benefits will lead to an appreciation and utilization of the expertise of pharmacists to help advance health and wellness, improve outcomes, and increase patient safety.

[2] IHS Inc., *The Complexities of Physician Supply and Demand: Projections from 2013 to 2025.* Washington, DC: Association of American Medical Colleges; 2015.

May 2019 | Fact Sheet

Oral Contraceptive Pills

For over 50 years, American women have relied on oral contraceptive pills to prevent pregnancy. Oral contraceptives are now the most widely used form of contraception and are also commonly used to manage other health conditions. In the U.S., daily oral contraceptive pills have traditionally only been available with a prescription, but current legislative and advocacy efforts in some states have focused on broadening access to oral contraceptives by eliminating the requirement that women first have an in-person clinical visit. This factsheet provides an overview of oral contraception, discusses private insurance and Medicaid coverage, and reviews emerging strategies to promote and expand women's access to oral contraceptives.

Background

In 1960, the Food and Drug Administration (FDA) approved the sale of Enovid for use as the first oral contraceptive. Controversial from its earliest days, in 1965, the Supreme Court ruling in *Griswold v Connecticut* upheld married women's rights to contraception, followed in 1972 by the Supreme Court's decision in *Eisenstadt v Baird* which extended the right to single, unmarried individuals.[1]

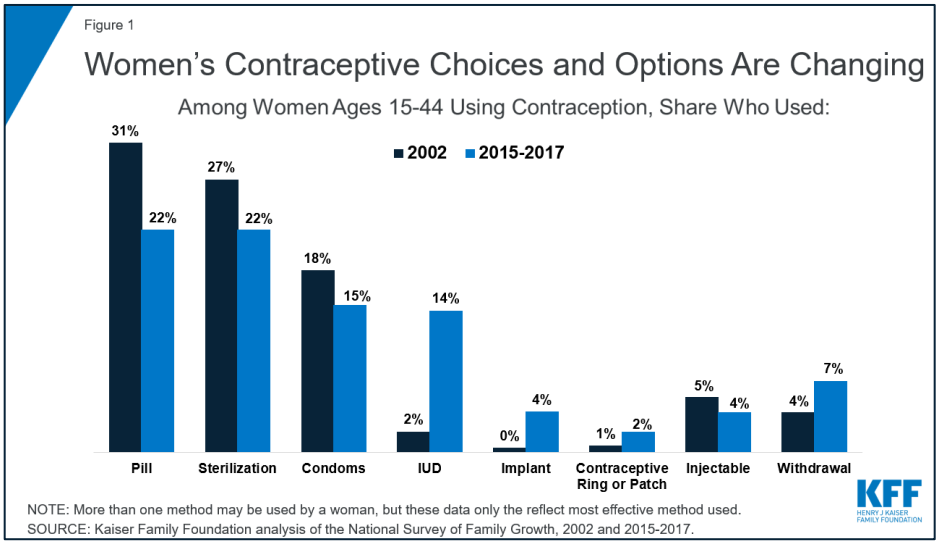
Oral contraceptive pills (OCP) consist of the hormones progestin and estrogen, or only progestin, and must be taken orally once per day in order to prevent pregnancy. Currently, there are three different types available on the market: the combination pill, the progestin-only pill, and the continuous use pill. The three formulations vary in their chemical hormonal composition as well as regimen for use (**Table 1**). Different brands further add to the diversity of OCP available by altering the type and/or dose of hormones. Emergency contraceptive pills are also a type of OCP, consisting of the progestin levonorgestrel, but are not intended for daily use. Rather, they are used to prevent pregnancy after unprotected sex.

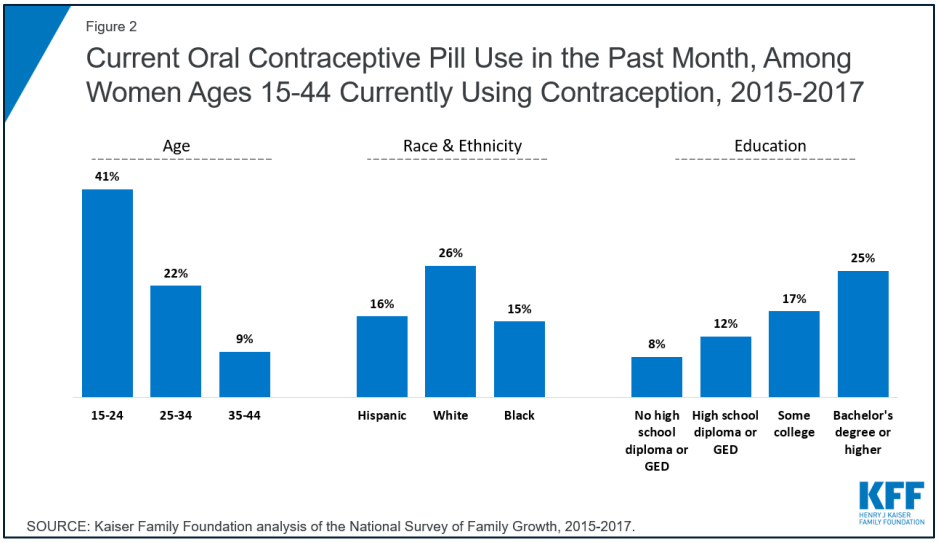
Table 1: Types, Composition and Regimen for Daily Oral Contraceptive Pills

Type and Composition	Regimen
Combined Pill:[2] Consists of estrogen and progestin *Examples*: Yaz, Yasmin, Loestrin (iron-containing)	**21-day packs:** 1 pill per day for 21 days, followed by 7 days of nonuse for menstruation **28-day packs:** 21 or 24 hormonal pills (brand dependent). The remaining pills either contain estrogen only or do not have hormones.
Progestin Only: Consists of progestin *Examples*: Norenthindrone (Micronor), Norgestrel	**28 day packs:**all pills are active. Suggested to be taken daily at the same time within a three hour window.
Extended/Continuous Use:[3] Consists of estrogen and progestin *Examples*: Seasonale, Seasonique, Lybrel	**91-day packs**:84 days of active hormone pills followed by 7 inactive pills,and/or low dose estrogen (results in 4 periods/ year) **365 day pack**: consist of 365 hormonal pills; no inactive pills.

Both the combined and progestin-only pills are highly effective with perfect use, with a failure rate (rate at which women become pregnant while using the contraceptive) less than 1%. However, the failure rate with "typical use" is 9%,[4] which accounts for inconsistent or incorrect use.

The pill was the first FDA-approved contraceptive to be used in the U.S., and is still the most commonly used form of contraception. In 2015-2017, the most recent years for which there are national data, slightly less than a quarter (22%) of women age 15-44 who currently use contraception reported using the pill as their method of choice, a decline from 31% in 2002[5] (**Figure 1**). At the same time, there has been a rise in use of intrauterine devices (IUDs), which have been promoted by several medical groups in recent years.





Among women who use any form of contraception, OCP use is higher among younger women, and decreases with age. White women are more likely to use OCP than Hispanic or Black women. OCP use increases with higher educational attainment (**Figure 2**).

OCPs are primarily used for pregnancy prevention, but they can also be used to address other health conditions, particularly menstrual-related disorders such as menstrual pain, irregular menstruation, fibroids, endometriosis-related pain, and menstrual-related migraines. Use of combined pills for acne has been formally approved by the FDA for specific brands.[6] While most (86%) women who use OCP take them to prevent pregnancy, 14% use them solely for non-contraceptive reasons.[7]

Oral contraceptives are safe for most women.[8] Possible side effects include headache, nausea, breast tenderness, and breakthrough bleeding. The combined hormonal pills may be associated with a small increased risk of deep vein thrombosis, heart attack and stroke for some women.[9] Findings from one

study suggest small increases in the likelihood of first depression diagnosis with the use of hormonal contraception, including both oral combined and progestin-only pills.[10]

Insurance Coverage and Financing of Oral Contraceptives

While OCP have been available since the mid 1960's, they were not always covered by insurance plans in the same way as other prescriptions drugs. In the early 1990's this became the focus of legislative action, first at the state and then the federal level. State legislatures began passing "contraceptive equity" laws which typically required that plans offering prescription drug coverage also cover contraceptives on the same terms as other prescriptions. Some state laws went further to require that plans cover all FDA-approved contraceptives. However, these state laws only applied to plans that were regulated by the state, but not self-funded or self-insured plans, which cover most workers with employer-sponsored insurance and are federally regulated through ERISA.[11] Furthermore, these laws did not address cost sharing, and one study found that between 1996 and 2006, women paid 56% of the cost of OCP under their private insurance plan.[12] Minimum coverage standards for employer-sponsored plans were established in 2000, when a federal ruling from the Employment Equal Opportunity Commission found it unlawful under the Civil Rights Act for plans to deny coverage for contraceptives if they covered other preventive prescription drugs and services.[13] By 2010, 28 states required insurers that cover prescription drugs to provide coverage for the full range of FDA-approved contraceptives.[14]

Private Insurance and the ACA

In 2010, the Affordable Care Act (ACA) took state laws further by requiring most private plans (including self-funded, small and large group, and individual plans) to cover a wide range of recommended preventive services, without cost to policyholders. In 2011, Health Resources and Services Administration (HRSA), following recommendations issued by the Institute of Medicine, added that all FDA-approved contraceptive methods and patient counseling for women with reproductive capacity, as prescribed by a health care provider, be included as a preventive service.[15]

The policy requires that most private health insurance plans cover at least one form of each of the 18 FDA-approved contraceptive methods for women as prescribed without cost sharing.[16] This means that plans must cover at least one of each of the three different types of oral contraceptives – the combined pill, the progestin-only pill and the continuous use pill – though it is up to an insurer's discretion using reasonable medical management practices whether to cover a brand name or generic contraceptive if both are available.[17] Insurers are required to cover other contraceptives if medically necessary, and must provide a process for policyholders to request coverage of a contraceptive that is not already covered without cost sharing by the plan.

Additionally, 14 states (CA, CT, DE, IL, ME, MD, MA, NV, NH, NM, NY, OR, VT, and WA) and DC have passed laws that build on the federal requirement for no cost sharing for FDA-approved contraceptive

methods for women **(Table 2)**. Some of these states have gone beyond the ACA requirements, mandating coverage of vasectomies and/or over-the-counter contraceptives.

Table 2: Policies Expanding Contraceptive Coverage and Availability

State	Expansion of pharmacists' prescribing authority (oral contraceptives)[1]	Insurers must cover FDA-approved contraception without cost sharing[2]	Insurers must cover 12-month supply[3]	Insurers must apply same cost-sharing rules to over-the-counter and prescription contraception
California	X	X	X	
Colorado	X		X[4]	
Connecticut		X	X	
Delaware		X	X	
District of Columbia	X	X	X	
Hawaii	X		X[4]	
Idaho	X			
Illinois		X	X	X
Maine		X	X	
Maryland	X	X	X[5]	X
Massachusetts		X	X	
Nevada		X	X	
New Hampshire		X	X	
New Mexico	X	X[5]		X
New York		X	X	
Oregon	X	X	X	X
Rhode Island			X[4]	
Tennessee	X			
Vermont		X	X	
Virginia			X[4]	
Washington	X	X	X	X
TOTALS	10	15	18	5

[1] Some states require pharmacists to have a collaborative partnership with a physician or advanced practice clinician. States that have given pharmacists only expanded dispensing authority are not included here. NH, OH, UT, and WV permit pharmacists to *dispense* certain self-administered hormonal contraceptives under a standing prescription drug order or consult agreement with a licensed physician, but not to *prescribe* them.

[2] **Insurers may apply cost sharing for drugs or devices that are therapeutically equivalent to another contraceptive drug or device that is already covered under the same policy. Some states require that all contraceptive drugs, devices, and other products be covered, while others require that at least one be covered. Also, some states require the method be prescribed. Many states permit exemptions for employers with religious and/or moral objections to contraception.**

[3] **Effective in 2020, NM will require insurers to cover a 6-month supply of contraceptives.**

[4] **State law does not prohibit cost sharing.**

[5] **Effective in 2020.**

Since the implementation of the ACA's contraceptive coverage provision, fewer women are paying out of pocket for contraceptives.[18] According to a 2019 Kaiser Family Foundation unpublished analysis of the Truven Health Analytics MarketScan Commercial Claims and Encounters Database, among women with health insurance from a large employer who use OCP, the share experiencing out-of-pocket spending on OCP declined from 94% in 2012 to 11% in 2017.[19]

Controversial since its inception, the provision has sparked litigation and new regulations in response to lawsuits that have reached the Supreme Court. Although the Obama administration allowed certain religious employers with an objection to contraception to request an exemption from the requirement, the Trump administration recently expanded eligibility to almost all employers that have a religious or moral objection. Female employees, dependents, and students of these exempt employers would no longer be entitled to coverage for the full range of FDA-approved contraceptives at no cost.[20] These regulations were set to go into effect January 14, 2019, but the Federal District Court for Eastern Pennsylvania issued a national stay in January 2019, blocking the implementation of the regulations while the litigation brought by states proceeds through the courts.[21]

Public Programs

Federal law has long required state Medicaid programs to cover family planning services and supplies without cost sharing and provides states with an enhanced federal match for providing these services. States that expanded Medicaid under the ACA must follow the ACA requirements for private plans and are required to cover all 18 FDA-approved contraceptive methods for women. There is no similar requirement for populations that were traditionally eligible for full-scope Medicaid or through a Medicaid family planning expansion program, and there is variation between states on the specific services that are covered.[22]

Since the passage of the ACA, some states have strengthened their contraceptive coverage requirements. For example, in 2014, California passed the Contraceptive Coverage Equity Act of 2014 which extends the ACA's coverage policy beyond private plan beneficiaries to all Medicaid managed care enrollees, regardless of whether they qualify as a result of the ACA expansion or through traditional pathways. MA, NV, and VT have since enacted similar laws.

Coverage for oral contraceptives is also required in the Indian Health Service, the federal program that provides care on or near Indian reservations as well as in the Tricare program for active military personnel and their dependents.

Medicare, the federal program for seniors 65 and older as well as younger adults with permanent disabilities, does not require coverage for oral contraceptives. In 2016, an estimated 1.35 million women under age 50 were enrolled in Medicare. [23] Medicare beneficiaries that have enrolled in private Medicare Advantage plans or who have opted in to the Medicare Part D prescription drug benefit *may* have coverage for oral contraceptives, but the scope of coverage varies between plans. There were an estimated 956,000 women of reproductive age that were dually eligible for Medicaid and Medicare. [24]

Expanding Access to Contraception

In 2011, one third of women at risk for unintended pregnancy who tried to obtain a prescription for contraception reported having trouble doing so.[25] Furthermore, it is estimated that more than 19 million women of reproductive age live in an area considered to be a 'contraceptive desert', meaning there is limited access to a publicly-funded provider who offers contraception.[26] Research also points to the effects of state policies on the shrinking number of family planning providers that offer the full scope of contraceptive methods in some communities.[27]

In recent years, there has been public debate and emerging state policy action to mitigate some of these access barriers by expanding the availability of daily oral contraceptive pills through different mechanisms. Approaches that are being considered include: making OCP available over-the-counter without a prescription; expanding the ability of pharmacists to furnish OCP without the need for a clinical visit; extending the supply amount that is dispensed at one time; and using mail-based online services or smartphone applications.

Over the Counter (OTC)

Research suggests that OTC access would increase the use of contraception and facilitate continuity of use.[28] It could also allow women to save time spent on travel, at doctor's office, and off work. Leading medical groups including the American Medical Association, American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists have endorsed the principle of making some oral contraceptives available OTC and the issue has garnered broad public support. In a national survey, 74% of women reported that they supported OTC access of OCP.[29]

The switch from prescription-only to OTC availability requires FDA review and approval. This action is typically triggered by the manufacturer's petition for an FDA review, can take upwards of three or four years, and a separate review is required for each product. In order for the FDA to approve the conversion to OTC status a drug must meet certain criteria:[30] users can easily diagnose need for the drug and monitor use without clinician screening; the drug must have low toxicity and low potential for abuse or

interactions with other drugs; the drug cannot have significant toxicity if overdosed; and the drug must not have properties that make it impractical for OTC use.

Research shows that OTC oral contraception generally meets these requirements,[31] and women can effectively use checklists to identify contraindications.[32] One study found 96% of cases demonstrated agreement between women's assessment of contraindications using the checklist and a clinician's independent evaluation.[33] Currently, Plan B emergency contraception and its generic equivalents, which contain a higher dose of progestin only (found in OCP), is available OTC.[34] In December 2016, HRA Pharma and Ibis Reproductive Health announced that they were in partnership to submit an application to make a progestin-only pill available for OTC use in the U.S. The progestin-only pills have fewer and rarer contraindications than combined pills, making them a better candidate for FDA approval for OTC use.

The ACA currently requires no-cost coverage for contraceptives, but only when the method is prescribed. Legislation at the federal or state level, or administrative changes to the ACA's preventive services policy would be needed to define coverage to include non-prescribed contraceptives. At the state level, Maryland became the first state to enact such a law, effective January 2018, requiring insurers to cover OTC contraceptives without a prescription with the same cost-sharing rules that apply to prescription contraceptives. IL, NM, OR, and WA have passed similar laws since then.

Pharmacy Access

Another avenue that is gaining support in some states allows pharmacists to furnish or dispense OCP without first requiring an in-person medical visit to a physician. As of February 2019, nine states (CA, CO, HI, ID, MD, NM, OR, TN, and WA) and DC allow pharmacists to prescribe OCP to women (**Table 2**). All of these states allow pharmacists to prescribe at least oral contraceptives, but states vary in other details, such as prescriptive authority (e.g., collaborative practice agreements and statewide protocols),[35] minimum age requirements, other types of contraceptives that pharmacists can prescribe, the length of the supply, and whether the patient needs a prior prescription from a physician.

Some states, including NH, OH, UT, and WV, permit pharmacists to *dispense* certain self-administered hormonal contraceptives under a standing prescription drug order or consult agreement with a licensed physician, but not to *prescribe* them.

Although pharmacy access can remove some barriers to obtaining contraceptives, some challenges still remain for women seeking a contraception prescription from a pharmacist. For example, pharmacies typically charge consultation fees, which some reports suggest can be as high as $50 in certain areas.[36] Although insurers are generally required to cover contraceptives without cost sharing, they are not obligated to cover this fee. Also, pharmacies can choose not to participate or may not have any trained pharmacists.[37]

From the pharmacy perspective, pharmacists must elect to complete additional education requirements, which vary by state, and often include several hours of continuing education from an accredited training program.[38] Additionally, states may not have a reimbursement mechanism in place to pay pharmacists for providing this service. For example, while OR and HI require plans to reimburse the dispensing entities, CA's law does not require reimbursement for payers other than Medicaid. In the absence of reimbursement, many pharmacies instead rely on the consultation fees mentioned above.

12-Month Supply

Another approach to facilitate access to oral contraceptives involves increasing the dispensing period of contraceptives to 12 months per prescription. Currently, dispensing patterns vary by insurer, with many plans limiting supply of pills to one-to-three month periods.[39] In fact, 70% of women receive a supply of 3 months or less, while only 15% receive a supply for more than 6 months.[40] Providing women with a longer lasting supply of pill packs may lead to more consistent contraceptive use.[41] Women who receive a one-year supply have been found to be 30% less likely to have an unintended pregnancy compared to women receiving a one to three month supply.[42]

In 2015, Oregon heralded the movement of extended supply and passed a law requiring insurers to provide coverage for a three-month supply of contraceptives when first prescribed, followed by a 12-month supply of contraceptives.[43] Laws requiring coverage for 12 months of oral contraceptives have since been enacted in 15 additional states plus DC: CA, CO, CT, DE, HI, IL, ME, MA, NV, NH, NY, RI, VT, VA, and WA; MD's law will take effect in 2020 **(Table 2)**. Beginning in 2020, NM will require coverage for a 6 month supply. While most of these states have enacted policies that require no-cost contraceptive coverage similar to the ACA's contraceptive coverage provision, CO, HI, RI, and VA have not yet done so. This means that although insurers must cover a 12-month supply in these four states, state law does not prohibit cost sharing; however, most plans must abide by the federal requirement and not charge any cost sharing for prescribed, FDA-approved contraceptive methods.

Online Services and Smartphone Applications

A new intermediary telemedicine market has emerged between health care providers and the patient that may decrease barriers to obtaining the pill, particularly for women living in contraceptive deserts. A growing number of online services and smartphone applications offer options for patients to speak with providers by video or chat, get prescriptions, and order birth control pills through mail delivery. These services work by collaborating with physicians, pharmacies, and sometimes health insurers to prescribe and ship OCP to the patient's home or a local pharmacy.

Costs for these services vary between companies.[44] Most charge a fee for the prescription and/or consultation, which is typically not covered by insurance and ranges in price from free up to $99. Planned Parenthood Direct and PRJKT RUBY do not charge a consultation/prescription fee. Some companies, like Nurx, accept insurance, including Medicaid, to pay for the pills, while others to do not. Without insurance, pills range in price from $15 to $20 per pack.

Most companies ship the OCP free of charge to the patient's home, while some require pick up from a local pharmacy. Prescriptions are often valid for 12 months and patients are sent either a one- or three-month supply of pills. Video/audio consultations are required by certain services, including PlushCare, HeyDoctor, and Maven, before receiving the prescription. Services that do not require a consultation do require patients to complete a health assessment or questionnaire to determine eligibility and the appropriate pill.

People in every U.S. state have access to at least one of these services, but the minimum age to use the service varies by company and state law, although many require the person to be at least 18 years old. One service, only available to people in California, Pandia Health, offers service to any age, per state law.

***

Oral contraceptives are the most commonly used form of prescription contraception in the U.S. Most women with private insurance or Medicaid can receive no-cost coverage for OCPs. There has been interest and action to make OCP available over-the-counter nationally, but this has not yet been approved by the FDA, although a progestin-only pill is under FDA review for OTC provision. Several states have enacted policies to broaden OCP access, particularly through pharmacies and insurance coverage for longer lasting supplies, and many more states are considering them. The use of telemedicine to expand OCP access continues to evolve, with many women now able to obtain OCP using smartphone and web-based services.

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Community Pharmacists and Medication Therapy Management

Medication therapy management (MTM) is a distinct service or group of services provided by health care providers, including pharmacists, to ensure the best therapeutic outcomes for patients. MTM includes five core elements: medication therapy review, a personal medication record, a medication-related action plan, intervention or referral, and documentation and follow-up. Within the context of cardiovascular disease (CVD) prevention, MTM can include a broad range of services, often centering on (1) identifying uncontrolled hypertension (2) educating patients on CVD and medication therapies, and (3) advising patients on health behaviors and lifestyle modifications for better health outcomes. MTM is especially effective for patients with multiple chronic conditions, complex medication therapies, high prescription costs, and multiple prescribers. MTM can be performed by pharmacists with or without a collaborative practice agreement (CPA), and it is a strategy that can be considered to straddle both Domains 3 (health care system interventions) and 4 (community-clinical links).

Summary

MTM is care provided by pharmacists with the goal of ensuring the most effective use of drug therapy. It is a cost-effective strategy for increasing patient knowledge and medication adherence and lowering blood pressure.

Stories From the Field:
Ohio Department of Health.

Evidence of Effectiveness

Effect	Implementation Guidance	Research Design
Internal Validity	Independent Replication	External & Ecological Validity

Legend: Well supported/ Supported | Promising/ Emerging | Unsupported/ Harmful

Evidence of Impact

Health Impact	Health Disparity Impact	Economic Impact

Legend: Supported | Moderate | Insufficient

Evidence of Effectiveness

Strong evidence exists that the use of MTM by pharmacists is effective. Although the exact combination of MTM activities tends to vary between settings, studies examining MTM have generally found it to be effective and to have strong internal and external validity. MTM trials have been replicated in many different contexts with positive results. Implementation guidance on MTM is available from several sources, including the guidance provided under Medicare Part D.

Evidence of Impact

Health Impact

In 2015, the Agency for Healthcare Research and Quality (AHRQ) found the evidence behind MTM to be insufficient because of inconsistency in the operationalization of MTM across studies, but concluded that MTM can improve medication adherence.[1] MTM has been shown to be effective for lowering systolic and diastolic blood pressure; lowering LDL cholesterol and other health indicators (e.g., glycosylated A1C, HBA1c); increasing patient knowledge; improving patient quality of life and medication adherence; and improving the safe and effective use of medications, including reducing therapeutic duplication, decreasing total medications prescribed, and increasing adherence for therapeutic care.[2–8]

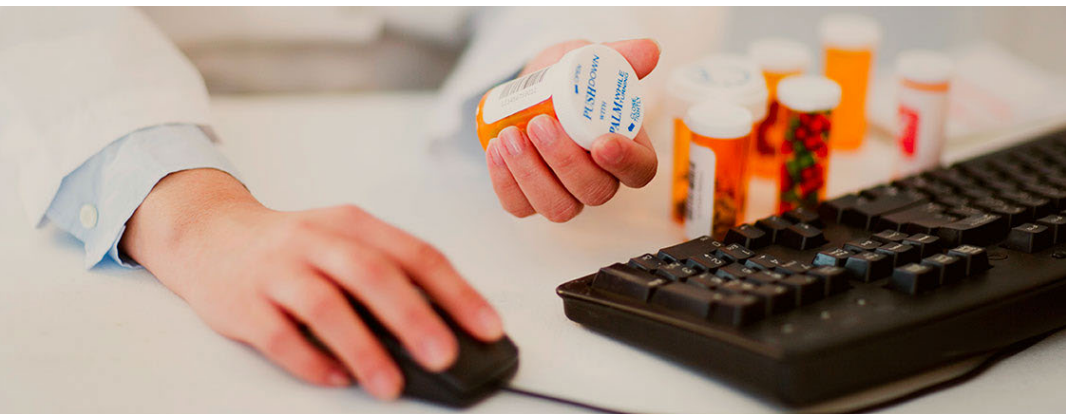
Health Disparity Impact

Expanding the pharmacist's role through MTM is likely to increase access to health care for populations facing the most barriers to care. However, few studies have examined the ability of MTM to reduce health disparities in CVD outcomes. Although some evidence exists that MTM can achieve positive outcomes among minority and low-income populations, the extent of this evidence is limited and inconsistent.[4,5] More research is needed to directly examine the effect of MTM on different populations.

Economic Impact

Studies have indicated that MTM can produce health care cost savings and a positive ROI for health care systems.[9–11] A study that examined the effect of providing MTM in a large health system for over 10 years found that the cost to providing MTM services was $76 per patient encounter, and the return on investment (ROI) that resulted from health care cost savings was $1.29 per $1 spent on MTM services over this period.[10]

Another study that evaluated the use of MTM by a self-insured employer reported an intervention cost of $145.61 per patient and a ROI to the payer of $1.67 per $1 of MTM costs over a 6-month period.[11] Despite early findings of potential economic benefits, recent meta-analyses and systematic reviews have identified a need for better cost-effectiveness data on expanded pharmacist care.[7,8]



Strong evidence exists that the use of MTM by pharmacists is effective.

Stories from the Field
Medication Therapy Management

MTM at Ohio Department of Health

In 2014, the Ohio Department of Health (ODH) teamed up with three Federally Qualified Health Centers (FQHC) sites to assess the effect of MTM counseling sessions on patients with hypertension. This effort involved collaboration among the Ohio State University College of Pharmacy, Ohio Pharmacists Association, Ohio Association of Community Health Centers, and the Health Services Advisory Group. These partners helped plan and develop the assessment. Pharmacists administered MTM to 5,000 patients with hypertension who were receiving care at one of the three FQHC sites. After 6 months, assessments found that hypertension control had increased to 68.6% among these patients. There were key components related to the project's achievement, which included maintaining relevant partnerships, implementing the pilot in one type of pharmacy setting, allowing FQHC sites to develop their own protocols for patient enrollment, using effective dissemination processes, and selecting data points that align with current pharmacy practices. Challenges included finding champions for the MTM model.

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Four Considerations for Implementation

1 Settings

MTM has been implemented in several settings, including federally qualified health centers, patient-centered medical homes, managed care health systems, community pharmacies, hospital pharmacies, and primary care clinics.

2 Policy and Law-Related Considerations

MTM is currently supported under the Centers for Medicare & Medicaid Services (CMS), as a service available to selected Medicare beneficiaries. As a part of Medicare Part D regulations, enrollees with multiple chronic diseases who are taking multiple Part D drugs are eligible for MTM programs.[12] Outside of the CMS guidelines, reimbursement for time and services is a key issue for pharmacists performing MTM. Regional variations in training and scope of practice can limit pharmacists when they attempt to provide MTM services. For MTM to work most effectively, pharmacists and prescribers can develop CPAs with shared blood pressure management protocols. Other policy considerations that need attention are determining the inclusion criteria for patients to receive MTM and encouraging payers to make the service available and offer reimbursement for pharmacists.

3 Implementation Guidance

Implementation guidance has been developed by various organizations, including:

- Centers for Medicare & Medicaid Services.[12]
- American Pharmacists Association's MTM Central,[13] which includes implementation guidance, an MTM resource library, and information about the added value of MTM.

4 Resources

Several federal agencies are working on initiatives that focus on greater involvement of pharmacists in cardiovascular prevention and MTM. They include the following:

- Centers for Medicare & Medicaid Services.[12]
- AHRQ, which provides the National Guideline Clearinghouse[14] and a list of resources related to innovations in MTM.[15]
- CDC's 6|18 Initiative.[16]
- CDC's Million Hearts Initiative.[17]

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Pharmacy: Collaborative Practice Agreements to Enable Collaborative Drug Therapy Management

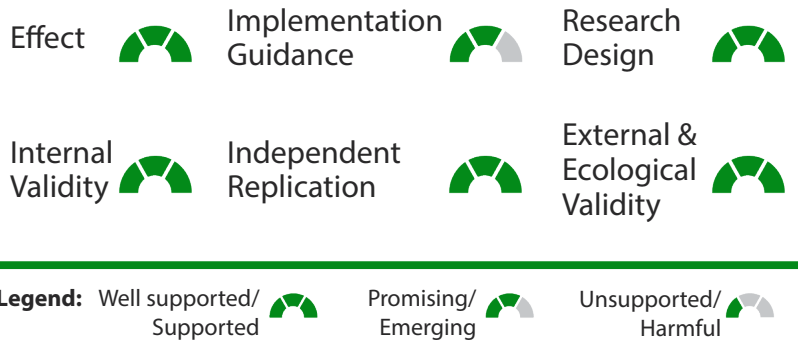
Collaborative drug therapy management (CDTM), also known as coordinated drug therapy management, involves developing a collaborative practice agreement (CPA) between one or more health care providers and pharmacists. A CPA allows qualified pharmacists working within the context of a defined protocol to assume professional responsibility for performing patient assessments, counseling, and referrals; ordering laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens.[1] The use of CDTM through a CPA is a strategy that can be considered to straddle both Domains 3 (health care system interventions) and 4 (community-clinical links).

Summary

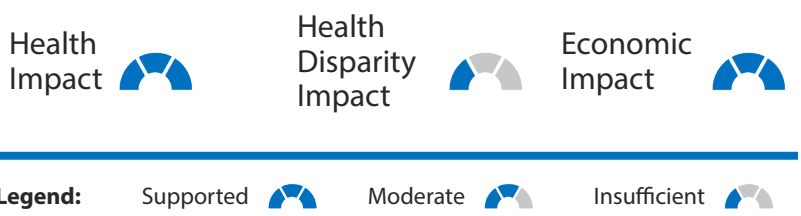
CDTM enabled by a CPA is a formal partnership between qualified pharmacists and prescribers to expand a pharmacist's scope of practice. CDTM is a cost-effective strategy for lowering blood pressure, blood sugar, and LDL cholesterol levels; improving treatment quality; and increasing medication adherence.

Stories From the Field:
El Rio Community Center (Pima County, Arizona).

Evidence of Effectiveness



Evidence of Impact



Evidence of Effectiveness

Strong evidence exists that CDTM enabled by a CPA is effective. Solid evidence exists that this strategy achieves desired outcomes, with studies demonstrating internal and external validity. This strategy has also been independently replicated, and systematic reviews assessing the use of CDTM have confirmed reliability of impact. Implementation guidance on CPAs to enable CDTM was found to be lacking in comprehensiveness.

Evidence of Impact

Health Impact

CDTM, enabled by CPAs between pharmacists and other health care providers, has been shown effective in improving clinical and behavioral health indicators, including lowering blood pressure, HbA1c, and LDL cholesterol levels; improving treatment quality through pharmacist compliance with clinical guidelines; and increasing patient knowledge and adherence to medication regimens.[2]

Health Disparity Impact

The goals of reaching populations at risk and reducing health disparities have been taken into account in the development and implementation of CPAs, particularly by pharmacy organizations (e.g., the American Pharmacists Association), state medical and pharmacy boards, and state pharmacy organizations. However, no studies have directly examined the impact of CPAs between pharmacists and providers serving low-income populations. Because pharmacists often work directly with the public in community settings, they are often considered the public's most accessible health care providers. CPAs can authorize pharmacists to make changes to a patient's medication or dosage, which can reduce the number of visits a patient has to make and lower costs, while also making it easier for patients to adhere to their medications.

Economic Impact

Research suggests that clinical pharmacy services like CDTM can be cost-saving to the health care system, primarily through avoided hospitalizations and emergency room (ER) visits.[3] For example, in 2006, Missouri's Pharmacy-Assisted CDTM program resulted in a 12% decrease in any-cause hospitalizations, a 25% reduction in ER visits, and a decrease in drug-related problems among beneficiaries after 1 year. This program was also found to have a 2.5 to 1 ROI to the state, with an estimated savings of $518.10 per patient per month.[3]

Strong evidence exists that CDTM enabled by a CPA is effective.

Stories from the Field
Collaborative Practice Agreements

CPAs at El Rio Community Center

El Rio Community Health Center serves over 75,000 people in Pima County, Arizona. In 2011, 20% of El Rio's adult patients (8,954 of 44,952) had diagnosed hypertension, but only 67% of those diagnosed had the condition under control. Pharmacists at El Rio were encouraged to establish CPAs with the center's medical providers. These agreements enable pharmacists to work directly with patients to help them manage their hypertension and other chronic conditions, such as diabetes and hyperlipidemia. Within the scope of the CPA, pharmacists have the discretion to change patient medications. After CDTM was implemented, El Rio reported improved clinical outcomes (e.g., lower cholesterol and blood pressure levels), increased use of recommended screenings, and reduced ER visits. The El Rio case study highlights several important considerations for CDTM implementation. These considerations include instilling mission-driven values through training and orientation, accepting pharmacy student interns, and using broad strategies and networks to improve patient care and increase potential partnerships that may extend the use of CPAs.

For more information:
Phone: 520-670-3909
Website: www.elrio.org

Four Considerations for Implementation

1 Settings

Enabling CDTM through CPAs has been found to be effective in several clinical and community settings, including federally qualified health centers (FQHC), patient-centered medical homes, managed care health systems, community pharmacies, hospital pharmacies, and primary care clinics.

2 Policy and Law-Related Considerations

CPAs are typically authorized through state scope-of-practice laws that may or may not allow for their use within pharmacist scope-of-practice laws. Challenges associated with billing for services exist, even at the federal level.[12,13] When a CPA is developed, the pharmacist and the prescriber work together to develop the terms of the CPA. They may use recommendations and model language available from various organizations.[5,6,14]

3 Implementation Guidance

CDC has recently developed a CPA tool kit that provides implementation guidance:

- Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team.[4]

Guidance from the state level comes from the following sources:

- National Association of State Pharmacy Associations.[5]
- American Pharmacy Association.[6]

4 Resources

Several guides and examples are available to educate and guide health care providers, decision makers, insurers, and pharmacists about how pharmacists and other health care providers can better serve patients through CPAs and CDTM. Examples include the following:

- Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists.[7]
- A Resource for Nurses, Physician Assistants, and Other Providers.[8]
- A Resource for Government and Private Payers.[9]
- A Program Guide for Public Health: Partnering with Pharmacists.[10]
- Agency for Healthcare Research and Quality, Pharmacy Quality Alliance.[11]

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PSNet
PATIENT SAFETY NETWORK

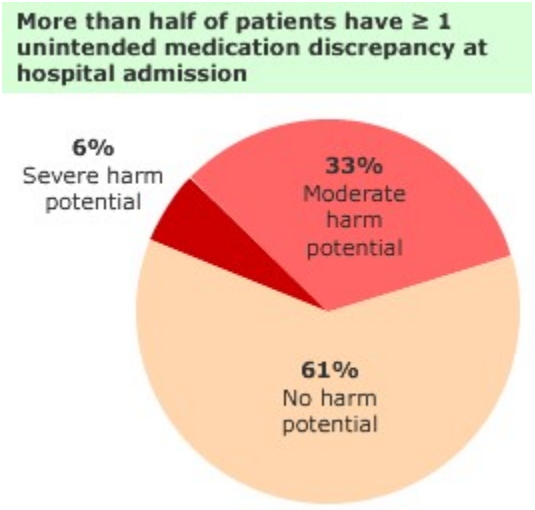
Patient Safety Primer Last Updated: January 2019

Medication Reconciliation

Background

Patients often receive new medications or have changes made to their existing medications at times of transitions in care—upon hospital admission, transfer from one unit to another during hospitalization, or discharge from the hospital to home or another facility. Although most of these changes are intentional, unintended changes occur frequently for a variety of reasons. For example, hospital-based clinicians might not be able to easily access patients' complete pre-admission medication lists, or may be unaware of recent medication changes. As a result, the new medication regimen prescribed at the time of discharge may inadvertently omit needed medications, unnecessarily duplicate existing therapies, or contain incorrect dosages. These discrepancies place patients at risk for adverse drug events (ADEs), which have been shown to be one of the most common types of adverse events after hospital discharge. Medication reconciliation refers to the process of avoiding such inadvertent inconsistencies across transitions in care by reviewing the patient's complete medication regimen at the time of admission,

transfer, and discharge and comparing it with the regimen being considered for the new setting of care.



Source: Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. Arch Intern Med. 2005;165:424-429. [go to PubMed]

Accomplishing Medication Reconciliation

The evidence supporting patient benefits from reconciling medications is relatively scanty. Most medication reconciliation interventions have focused on attempting to prevent medication errors at hospital admission or discharge, but the most effective and generalizable strategies remain unclear. A 2016 systematic review found evidence that pharmacist-led processes could prevent medication discrepancies and potential ADEs at hospital admission, in-hospital transitions of care (such as transfer into or out of the intensive care unit), and at hospital discharge. A 2013 systematic review published as part of the AHRQ *Making Health Care Safer II* report also found that pharmacist engagement in medication reconciliation prevented discrepancies and potential ADEs after discharge. However, both the actual clinical effect of

medication discrepancies after discharge appears to be small, and therefore, medication reconciliation alone does not reduce readmissions or other adverse events after discharge.

Information technology solutions are being widely studied, but their effect on preventing medication discrepancies and improving clinical outcomes is similarly unclear. A 2016 systematic review found that electronic tools often lacked the functionality to accurately reconcile medications, perhaps explaining why medication discrepancies persist even in organizations with fully integrated electronic medical records. Several studies have also investigated the role of enhanced patient engagement in medication reconciliation in the outpatient setting and after hospital discharge. These efforts are promising but also lack evidence regarding the impact on medication error rates.

Medication reconciliation has therefore become an example of a safety intervention that has been effective in research settings but has been difficult to implement successfully in general practice. A 2016 commentary identified the major reasons for difficulty achieving safety improvements via medication reconciliation. They include the resource intensive nature of interventions such as clinical pharmacists, which disincentivizes organizations from investing in medication reconciliation; the alterations to clinical workflow that result from interventions, which creates inefficiencies and confusion regarding the best possible medication history; and conflict between medication reconciliation and other system quality improvement priorities, such as patient flow improvement. The commentary provides recommendations for

organizations, clinicians, and researchers on how to better implement and evaluate medication reconciliation interventions.

Current Context

Medication reconciliation was named as 2005 National Patient Safety Goal #8 by the Joint Commission. The Joint Commission's announcement called on organizations to "accurately and completely reconcile medications across the continuum of care." In 2006, accredited organizations were required to "implement a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient" and to communicate "a complete list of the patient's medications to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization."

The Joint Commission suspended scoring of medication reconciliation during on-site accreditation surveys between 2009 and 2011. This policy change was made in recognition of the lack of proven strategies for accomplishing medication reconciliation. As of July 2011, medication reconciliation has been incorporated into National Patient Safety Goal #3, "Improving the safety of using medications." This National Patient Safety Goal requires that organizations "maintain and communicate accurate medication information" and "compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies."

Editor's Picks

JOURNAL ARTICLE › STUDY

Incidence of clinically relevant medication errors in the era of electronically prepopulated medication reconciliation forms: a retrospective chart review.

Stockton KR, Wickham ME, Lai S, et al. CMAJ Open. 2017;5:E345-E353.

CASE

A Pill Organizing Plight

JOURNAL ARTICLE › COMMENTARY

The problem with medication reconciliation.

Pevnick JM, Shane R, Schnipper JL. BMJ Qual Saf. 2016;25:726-730.

TOOLS/TOOLKIT › TOOLKIT

MARQUIS Medication Reconciliation Resource Center.

Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS). Philadelpha, PA: Society for Hospital Medicine.

JOURNAL ARTICLE › STUDY

Engaging patients in medication reconciliation via a patient portal following hospital discharge.

Heyworth L, Paquin AM, Clark J, et al. J Am Med Inform Assoc. 2014;21:e157-e162.

JOURNAL ARTICLE › REVIEW

Medication reconciliation during transitions of care as a patient safety strategy: a systematic review.

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TOOLS/TOOLKIT › TOOLKIT

Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation.

Gleason KM, Brake H, Agramonte V, Perfetti C. Rockville, MD: Agency for Healthcare Research and Quality; Revised August 2012. AHRQ Publication No. 11(12)-0059.

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Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial.

Kripalani S, Roumie CL, Dalal AK, et al; PILL-CVD (Pharmacist Intervention for Low Literacy in Cardiovascular Disease) Study Group. Ann Intern Med. 2012;157:1-10.

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CASE

Reconciling Records

CASE

Medication Reconciliation Pitfalls

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Schnipper JL, Hamann C, Ndumele CD, et al. Arch Intern Med. 2009;169:771-780.

CASE

Medication Reconciliation Victory After an Avoidable Error

CASE

Hospital Admission Due to High-Dose Methotrexate Drug Interaction

WEB RESOURCE › MULTI-USE WEBSITE

National Patient Safety Goals.

Oakbrook Terrace, IL: The Joint Commission; 2018.

PERSPECTIVE

Integrating Multiple Medication Decision Support Systems: How Will We Make It All Work?

CASE

Medication Reconciliation: Whose Job Is It?

JOURNAL ARTICLE › STUDY

Role of pharmacist counseling in preventing adverse drug events after hospitalization.

Schnipper JL, Kirwin JL, Cotugno MC, et al. Arch Intern Med. 2006;166:565-571.

CASE

Reconciling Doses

JOURNAL ARTICLE › STUDY

Unintended medication discrepancies at the time of hospital admission.

Cornish PL, Knowles SR, Marchesano R, et al. Arch Intern Med. 2005;165:424-429.