# Pharmacy Innovations: Pharmacy and Collaborative Care Agreements (CPA)

## *2019 CTC-RI Annual Conference: Advancing Integrated Primary Care: Innovations at Work*

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# Learning Objectives

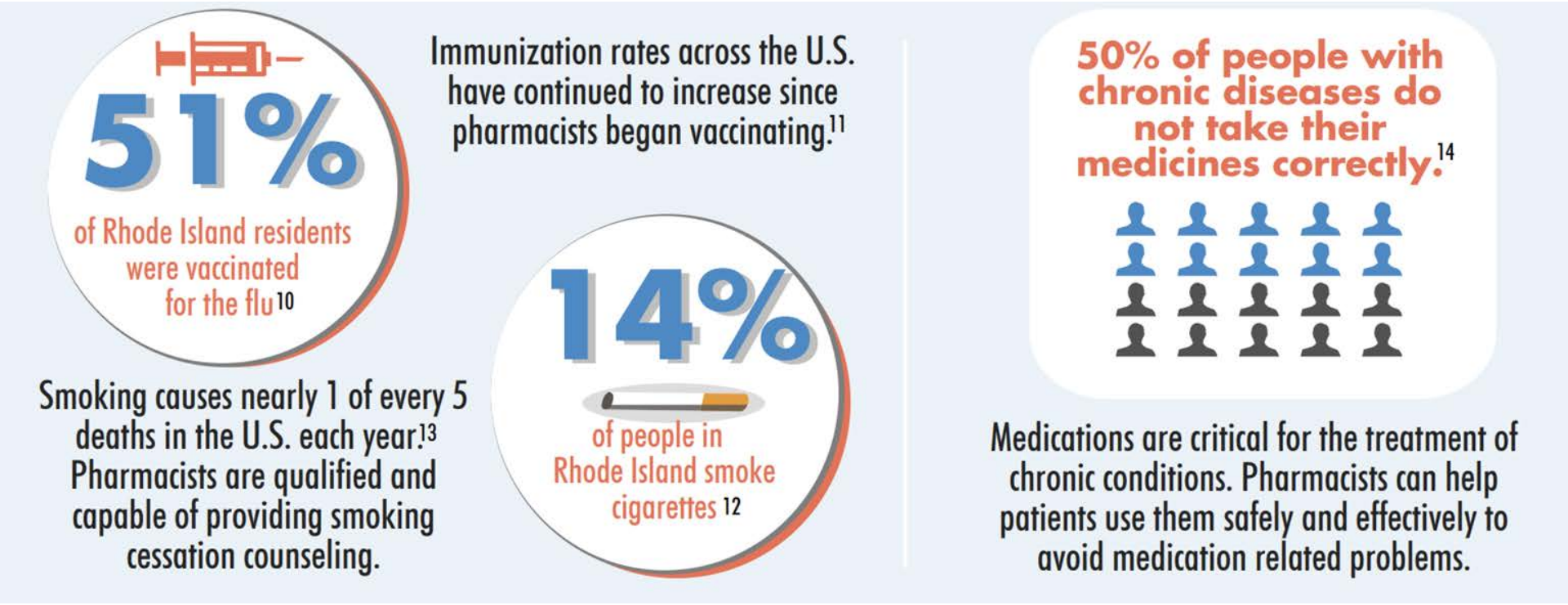
- Discuss novel uses of collaborative practice agreements (CPA) that increase access to public health and medication management interventions
- Identify training, regulatory and financial environments required for sustainable implementation
- Compare and contrast patient experiences, outcomes, and encountered barriers overcome as described by two participating CPA pharmacists

# Rhode Island: Need to Expand the Role of Pharmacists?

Rhode Island has 14 designated HPSAs and only 67% of the primary care needs in those areas are currently being met.


Source: National Association of State Pharmacy Associations
https://naspa.us/wp-content/uploads/2018/08/Rhode-Island_2018.pdf

# Rhode Island: Need to Expand the Role of Pharmacists?




Source: National Association of State Pharmacy Associations
https://naspa.us/wp-content/uploads/2018/08/Rhode-Island_2018.pdf

# Collaborative Practice Agreements

Establish a formal relationship

Delegate patient care functions

Contain negotiated conditions

# Novel Uses of CPA for Public Health

**Existing in Rhode Island**

- Overdose prevention –
  - **Naloxone (Narcan)**
- Lyme disease prophylaxis
  - **single-dose doxycycline**
- Medications for opioid use disorder (MOUD) maintenance
  - **buprenorphine and oral naltrexone**
- Treatments for nicotine cessation
  - **NRT/varenicline/buproprion**

**Future / Exists Elsewhere**

- MOUD *induction* and administration
- HIV Pre-exposure prophylaxis (PreP)
- HIV Post-exposure prophylaxis (PEP)
- Curative medications for hepatitis C
- Women's reproductive health
- Latent tuberculosis testing
- Influenza treatment/prophylaxis antivirals
- 100 pack syringes for bloodborne virus transmission prevention
- Bioterrorism treatment/prophylaxis

# Naloxone

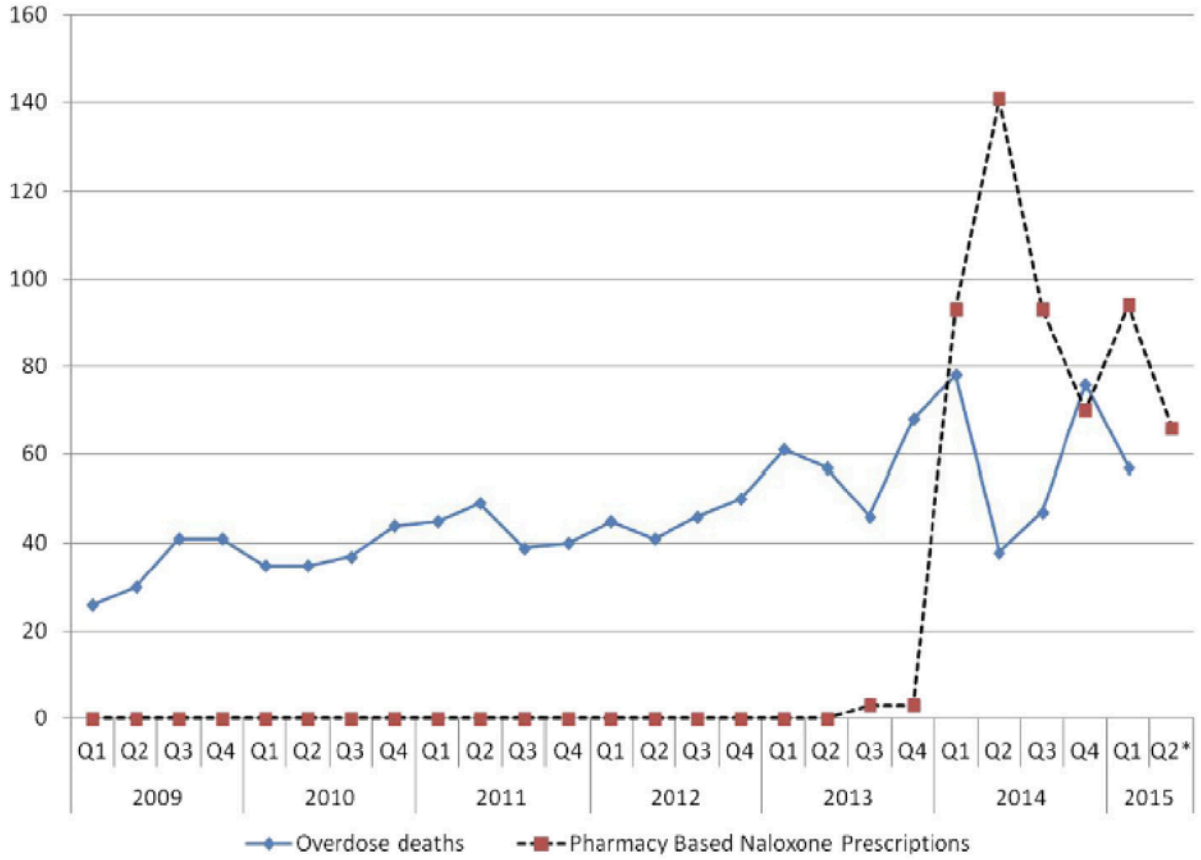



**Figure 2** Overdose deaths and pharmacy-based naloxone prescriptions dispensed in Rhode Island, 2009 to 2015, by quarter. SOURCE: Rhode Island Department of Health, 2015

Green TC, Dauria EF, Bratberg J, Davis CS, Walley AY. Orienting patients to greater opioid safety: models of community pharmacy-based naloxone. *Harm Reduct J*. 2015;12:25. doi:10.1186/s12954-015-0058-x

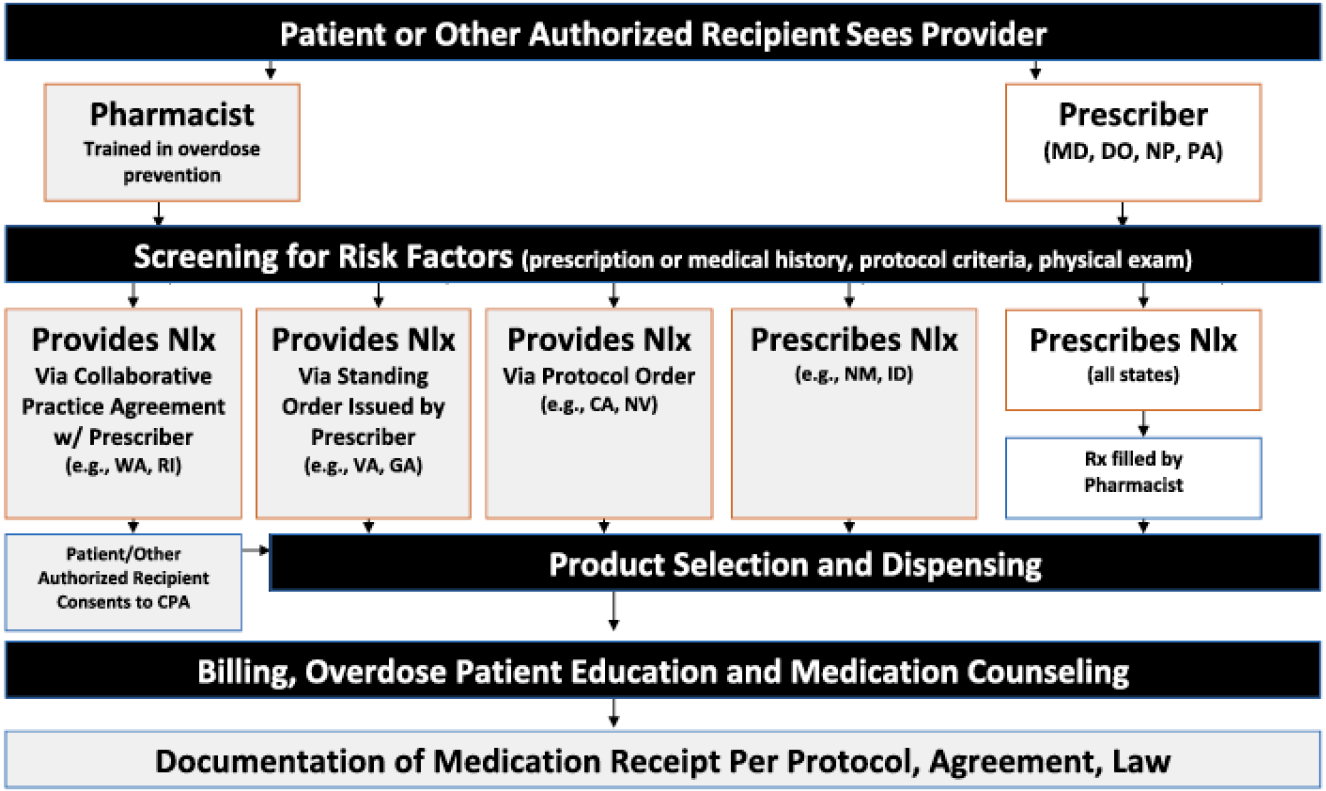



**Figure 1** Pharmacy Naloxone Access Models. Process flow as experienced by patient and pharmacist. *Nlx* Naloxone, *Rx* prescription, *MD* medical doctor, *DO* doctor of osteopathic medicine, *NP* nurse practitioner, *PA* physician assistant, *CPA* collaborative practice agreement, State abbreviations: *WA* Washington, *RI* Rhode Island, *VA* Virginia, *GA* Georgia, *CA* California, *NV* Nevada, *NM* New Mexico, *ID* Idaho

Green TC, Dauria EF, Bratberg J, Davis CS, Walley AY. Orienting patients to greater opioid safety: models of community pharmacy-based naloxone. *Harm Reduct J*. 2015;12:25. doi:10.1186/s12954-015-0058-x

# Lyme

# Pharmacist-Initiated Lyme Prophylaxis

**The Rhode Island Foundation** One Union Station, Providence, RI 02903 phone 401 274-4564 fax 401 751-7983

- Grant from the RI Foundation $6,594.00
  - Medical Research Grant
- IRB approval and adherence to study protocol and budget allocations
- Collaborative practice agreement
- Patients enrolled May through October 2012
  - Ocean Pharmacy, Charlestown RI

# Informed Consent or Release of Protected Health Information (PHI)

- Assess health literacy
- Process may take several minutes, Q & A format
- Ensure patient is comfortable with study and freely willing/able to participate, agrees to survey

# Potential Significance of Research

- Timely access to effective therapy for patients
  - No appointment
  - Open during hours when primary care offices may be closed, such as nights, weekends and holidays
  - Reduction in erythema migrans with doxycycline 200mg prophylaxis 87% in study of 482 subjects
  - Meta-analysis suggests between 11 and 49 patients need to be treated to prevent one case of Lyme disease (NNT decreases with engorgement)

# Study Results – Year One

- To date eight patients have enrolled under the study protocol (n = 8)
- Seven patients (88%) met the criteria for doxycycline prophylaxis and were dispensed therapy
- Two patients (25%) reported side effects from doxycycline, including:
  - Fatigue, Dizziness, Flushing, Nausea
- Potential reasons for low study enrollment
  - Many patients never find tick
  - New service, first offering
  - Small advertising budget
  - One location

# Results (cont.)

- Two patients (25%) reported seeking medical attention within 30 days of study enrollment
  - One patient tested for Lyme, results negative, no antibiotics given
  - One patient received a full course of amoxicillin therapy (10 days) for inner ear pain/fullness

- All eight patients (100%) were contacted 30 - 60 days following the initial visit and agreed to complete the patient satisfaction survey
  - Responses averaged for each of the 9 satisfaction survey questions
  - Average response range 8.5 to 9.75

# Medications for Opioid Use Disorder (MOUD)

# Pharmacists are uniquely positioned to support public health initiatives on opioid overdose and MAT

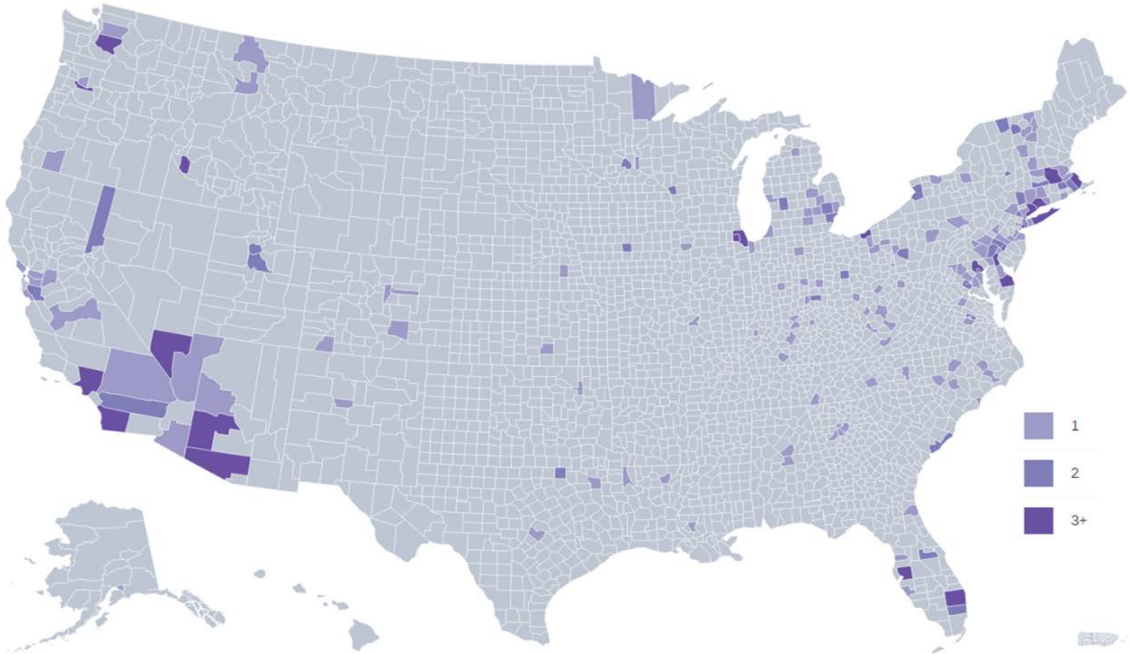
- 80% of the 2.4 million people living with an opioid use disorder (OUD) in the US do not have access to lifesaving medications for addiction treatment
- When patients with OUD do receive MAT, their risk of death from an unintentional opioid overdose declines at least 50%.
- Pharmacists are the most accessible health professional, and can provide MAT in rural areas where people have the least access to MAT providers


Wu, L., Zhe, H. & Swartz, M.S. (2016). Treatment Utilization among persons with opioid use disorder in the United States. *Drug Alcohol Depend,* 169, 117-127, doi: 10.1016/j.drugalcdep.2016.10.015

National Institute on Drug Abuse, Effective Treatments for Opioid Addiction. Last updated: November 2016, available at: https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction

National Association of Chain Drug Stores (March 2011). Pharmacies: Improving Health, Reducing Costs, available at: https://www.nacds.org/pdfs/pr/2011/PrinciplesOfHealthcare.pdf, last accessed: February 21, 2018.

# Pharmacotherapy Treatment Gaps




Effective pharmacotherapy offered in only:

- 23% of publicly funded treatment programs
- 5% of specialty treatment programs

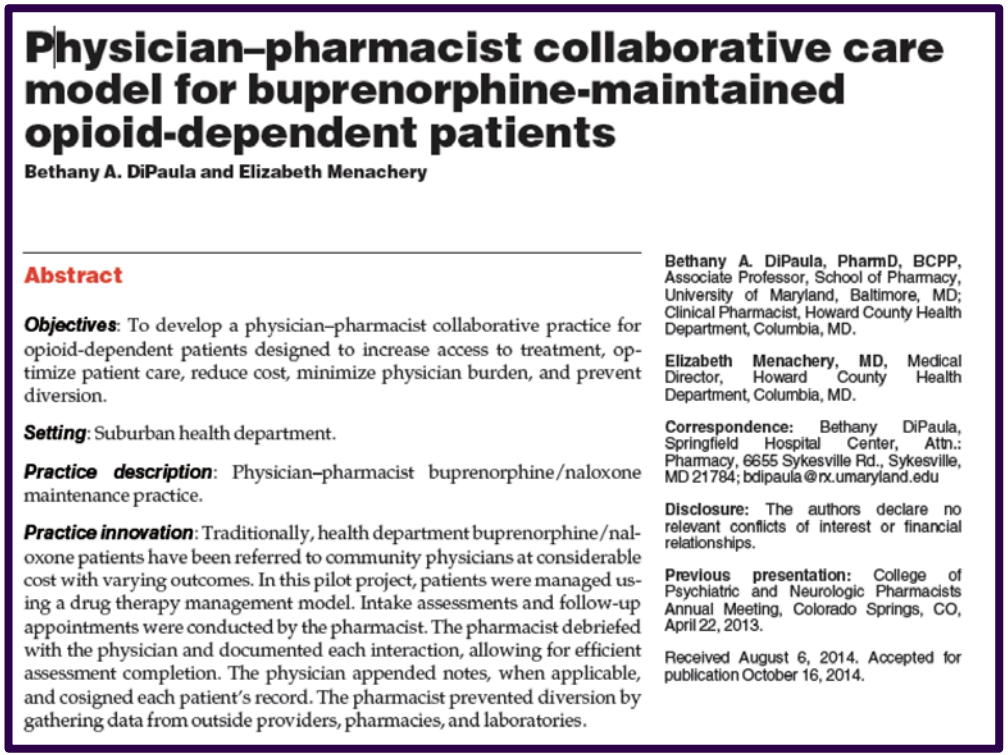
1.4 million people in treatment capacity gap:

- 53% of U.S. counties lack prescribers for buprenorphine
- 30 million people lack access to OUD treatment

Knudsen HK, Abraham AJ, Roman PM. Adoption and Implementation of Medications in Addiction Treatment Programs: Journal of Addiction Medicine 2011;5(1):21–7. American Society of Addiction Medicine. http://www.asam.org/quality-practice/practice-resources/nurse-practitioners-and-physician-assistants-prescribing-buprenorphine (Accessed on 28 August 2017).
Jones CM, et al. *Am J Pub Health*. 2015;105(8) e55-63. van BoekelLC, , et al. *Drug Alcohol Depend*. 2013;131(1-2): 23-35. Feder KA, et al. *J Adolesc Health* 2017;60(6): 747-750.

# Environmental scan results

- Three working examples of CPAs for MAT in the US, primarily focused on provision of buprenorphine, rarely naltrexone, and never methadone
- CPAs tended to be implemented in highly structured institutional environments, were integrated into medical teams or co-located with medical services; billing for cognitive services was a significant barrier
- There were physical space considerations of the CPA pharmacies (i.e., private room)



**Physician–pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients**

**Bethany A. DiPaula and Elizabeth Menachery**

**Abstract**

***Objectives***: To develop a physician–pharmacist collaborative practice for opioid-dependent patients designed to increase access to treatment, optimize patient care, reduce cost, minimize physician burden, and prevent diversion.

***Setting***: Suburban health department.

***Practice description***: Physician–pharmacist buprenorphine/naloxone maintenance practice.

***Practice innovation***: Traditionally, health department buprenorphine/naloxone patients have been referred to community physicians at considerable cost with varying outcomes. In this pilot project, patients were managed using a drug therapy management model. Intake assessments and follow-up appointments were conducted by the pharmacist. The pharmacist debriefed with the physician and documented each interaction, allowing for efficient assessment completion. The physician appended notes, when applicable, and cosigned each patient's record. The pharmacist prevented diversion by gathering data from outside providers, pharmacies, and laboratories.

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**Elizabeth Menachery, MD,** Medical Director, Howard County Health Department, Columbia, MD.

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**Disclosure:** The authors declare no relevant conflicts of interest or financial relationships.

**Previous presentation:** College of Psychiatric and Neurologic Pharmacists Annual Meeting, Colorado Springs, CO, April 22, 2013.

Received August 6, 2014. Accepted for publication October 16, 2014.

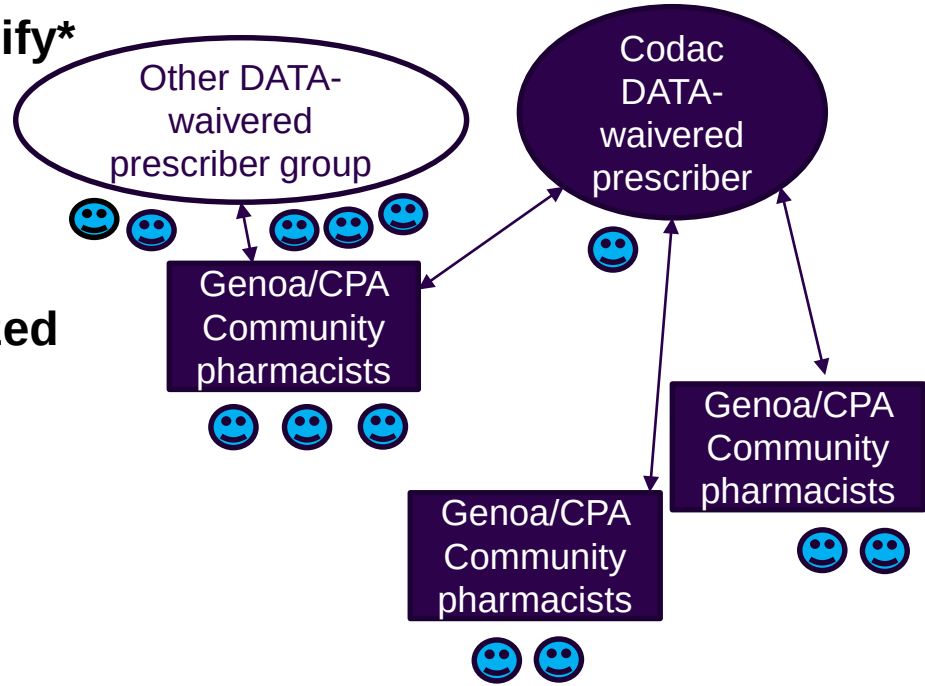
**DiPaula BA, Menachery E. Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients. J Am Pharm Assoc (2003) 2015;55(2):187–92.**

# Collaborative Practice Agreement (CPA) establishes the protocol that allows participating, trained pharmacists to:

**Continue ~ Discontinue ~ Taper ~ Modify***

- - buprenorphine (Subutex)
- - buprenorphine/naloxone (Suboxone)
- - naltrexone (Revia)

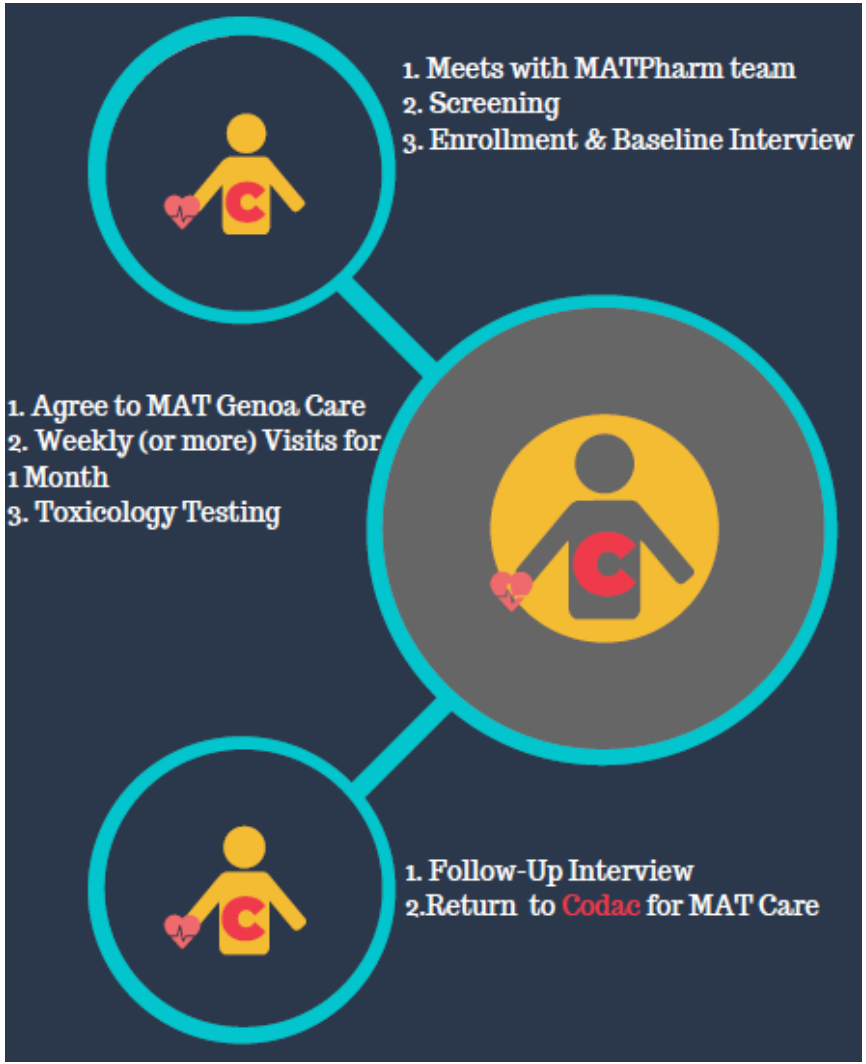
***In patients already inducted and stabilized on therapy**




**CPA-MAT authorized August 26, 2018,**
**Pilot commenced September 8, 2018**

# Pilot Study

- ▪2 Genoa locations:  Providence, Warwick
- ▪11 patients recruited and enrolled from Codac
- ▪5 women, 6 men
- ▪Ages 23-60
- ▪40% non white race, 20% Hispanic/Latinx ethnicity
- 70 pharmacy visits
- ▪1 patient reincarcerated, returned to pharmacy post-release
- ▪1 patient entered residential treatment, accommodated daily dosing at pharmacy



# Patient experiences

”…I felt comfortable to bring my babies to Genoa for my visits.”

“I never felt embarrassed going there…”

"the hours were perfect for me.”

"It was even better than i thought it would be. it was quick, easy. clean, people were so nice. not out of my way at all. very easy thing to do"

"It's very convenient. People are happy and look like they like to be there. It was a nice environment"

"It was the same thing; no surprises; on schedule, easy to do; that’s exactly what I wanted. I was excited to go to the pharmacy"

# Next Steps and Future Considerations

**NIDA funded Randomized Control Trial**

Sites/Collaborators

- 6 Genoa Pharmacy locations in Rhode Island
- CPA with multiple Centers of Excellence in MAT, Codac, OBOT providers

Patients

- N=250
- Usual care vs. Pharmacy care
- Baseline, 1 month / 3 month follow up

- **Initiation/induction** of MAT in the pharmacy
- May need to expand the pharmacist scope of practice for administration of medicines
- Amending methadone dispensing regulations could further expand pharmacy MAT for all three FDA-approved medications

# Pharmacists Role in Tobacco Cessation Therapy

- According to the CDC, in 2010, 68.8% of adult smokers reported a desire to quit smoking.[1]
- 91% of Americans live within 5 miles of a community pharmacy[2]

- Pharmacists are readily accessible, can typically be seen without an appointment, and are open extended hours (many 24 hours/day) and on weekends.
  - Decision to quit may be spontaneous, pharmacist has to turn people away to get Rx from another healthcare provider (may not return).

1. CDC. Morbidity and Mortality Weekly Report: Quitting Smoking Among Adults – 2001-2010. Available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a2.htm?s_cid=%20mm6044a2.htm_w. Accessed 2/18/19.
2. National Association of Chain Drug Stores. Face-to-face with community pharmacies. Available at http://www.nacds.org/pdfs/about/rximpact-leavebehind.pdf. Accessed 2/18/19.

# Tobacco Cessation Protocol

- Pharmacist is authorized to decide if nicotine replacement
  - Should be used
  - Duration of use
  - The specific form of nicotine replacement (e.g. patch, gum, inhaler, nasal spray, and lozenge)
  - If bupropion is recommended -> authorized only after discussion with provider.
  - For written prescriptions, the names of both the referring physician and the clinical pharmacist will be used
  - Tobacco cessation medications, when deemed appropriate, may be discontinued
- If a patient is under the age of 18, pregnant or nursing, no medications will be used unless authorized by the physician, but counseling for behavioral modification will be provided.

# Proactive Supports for Enhanced Tobacco Cessation Prescribing in Rhode Island - S0306/H5558 (2019)

- High risk patients or those with a contraindication to first line therapies referred to primary care provider
- Communication with primary care provider required when medication is prescribed within 5 business days
- Must complete Board-approved continuing education in tobacco cessation
- Prescribing limited to patients 18 years of age and older who are willing to participate in initial evaluation and follow-up
- Must follow evidence based guidelines for product selection and provision of behavioral modification counseling referral to Department of Health resources

# Training Requirements

Certification from the Board of Pharmaceutical Specialties relevant to CPA

ASHP or other accredited residency program in the area of practice covered by CPA

PharmD (or B.S. in pharmacy) with 3 years of experience relevant to CPA and has completed an ACPE, CME, or other continuing education provider  certificate program in areas relevant to CPA

# Annual CPE

M. Any pharmacist participating in a collaborative pharmacy practice agreement shall earn at least five (5) additional contact hours or 0.5 continuing education units of board-approved continuing education that addresses areas of practice generally related to collaborative practice agreements each year and shall maintain documentation of these hours at the practice site to be made available for inspection by the Boards of Medical Licensure and Discipline and Pharmacy

https://rules.sos.ri.gov/regulations/part/216-40-15-1

# Specific Training Requirements

**Existing in Rhode Island**

- Overdose prevention – **Naloxone**

**Training Requirements**

- 1 hour training / 1 hour annually
  (4 annual credits waived)

(URI, prescribetoprevent.org)

- Lyme disease prophylaxis – **single-dose doxycycline**

- 2 hour interactive lecture Lyme disease background
  - Epidemiology
  - Clinical features
  - Laboratory diagnosis
  - Treatment
  - Prevention
  - Prophylaxis project/RPh role
  - Case studies

# Specific Training Requirements

**Existing in Rhode Island**

- Medications for opioid use disorder **– buprenorphine, oral naltrexone**

**Training Requirements**

- ASAM Treatment of Opioid Use Disorder Course
- 4-hour online / 4 hour in-person (8 hour online for additional pharmacists)

- Urine/oral swab testing/interpretation
- Motivational interviewing
- Harm reduction
- Clinical documentation
- Stigma reduction / communication

# Rhode Island: Need to Expand the Role of Pharmacists?

**82% of Rhode Island hospitals were penalized for high readmission rates.**[19]

Patients are **2X** more likely to stay out of the hospital when pharmacists provide clinical services after discharge.[20]

**Rhode Island spent $1.04 billion on Medicaid in 2016.**[22]

Pharmacists in Ohio delivered a 4.4:1 ROI when providing medication therapy management services to Medicaid patients. Rhode Island pharmacists could do this too![21]

**$4.40** saved per $1 spent on pharmacists' services

Source: National Association of State Pharmacy Associations
https://naspa.us/wp-content/uploads/2018/08/Rhode-Island_2018.pdf

# CPA in Primary Care

**Patient population**:

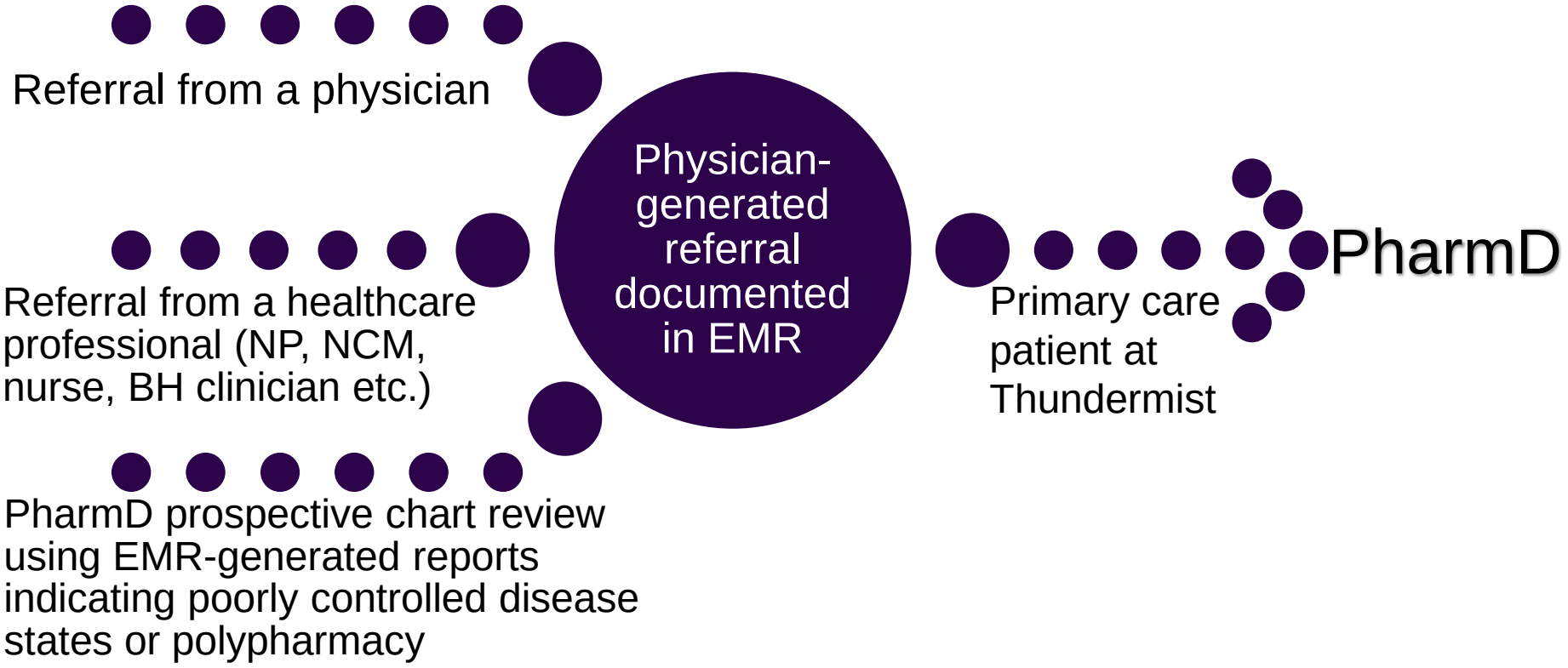
Existing primary care patients with uncontrolled chronic diseases, multiple chronic conditions requiring complex medication regimens, patients with newly diagnosed chronic disease states or newly prescribed medications, and/or patients with poor medication adherence

**Purpose:**

To expand upon care provided by PCP, allowing for longer, more intensive, and/or more frequent follow-up with patients in order to improve control of chronic disease states and health outcomes

- Optimizes medication regimens based on evidence based medicine and expertise in pharmacotherapy
- Provides additional patient education to improve adherence and remove barriers

# CPA in Primary Care: Patient Recruitment



# Interventions

- Therapeutic modification:

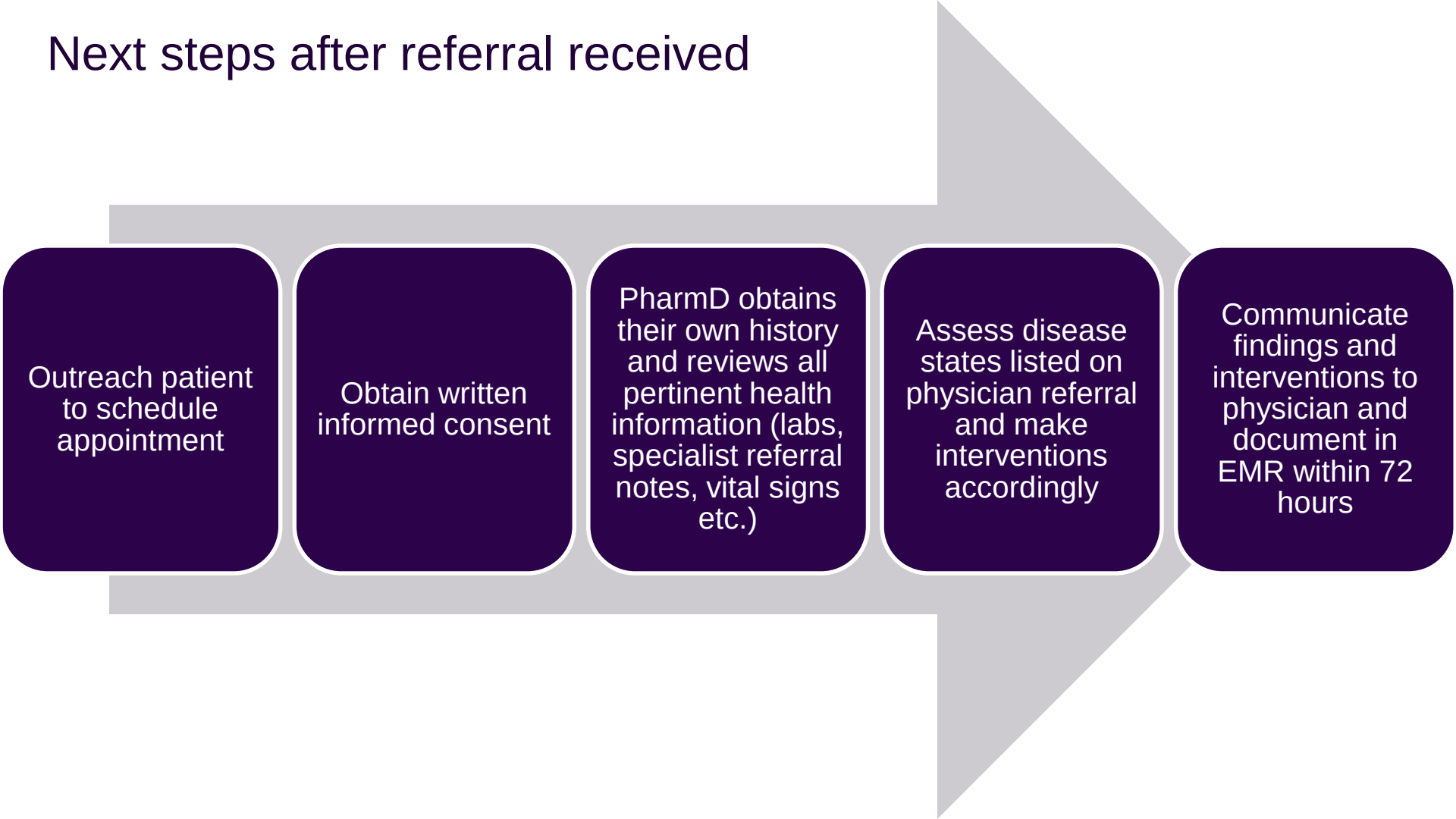
  -Initiate, modify continue and/or discontinue medications
  - Diabetes mellitus
  - Asthma
  - COPD
  - Hypertension
  - Hyperlipidemia
  - Tobacco abuse
  - Disease states requiring anticoagulation
  - Disease prevention (i.e. immunizations

- Consultations:
  - Congestive heart failure
  - Hypothyroidism and hyperthyroidism
  - HIV
  - Hepatitis C
  - Osteoarthritis
  - Substance use disorder
  - Chronic pain
  - Depression
  - Anxiety
  - Weight loss

# Pharmacist activities under CPA

- Performing patient assessments
- Collecting and reviewing patient histories
- Obtaining and checking vital signs
- Ordering and evaluating drug therapy-related laboratory tests
- Preparing and performing point-of-care laboratory testing including HbA1c, INR, urine toxicology, and cholesterol screening.
- Administering medications orally, subcutaneously, intramuscularly, or topically
- Monitoring, continuing, discontinuing, modifying, and initiating drug regimens
- Providing patient education related to drug regimens and disease states

# Next steps after referral received



Management by specialists

RI law limited to physicians

Arduous implementation process

- Lack of clear guidance

Patient perception

- No-show rates

Documentation Requirements - (written consent, referral etc.)

Reimbursement

# Barriers

Ability to link to quality/outcomes data

Scope of practice is subjective (review boards)

Unclear wording of collaborative practice law

# Regulatory and Financial Barriers/Solutions

- Regulatory Barriers
  - No PA/NP can sign (most states allow)
  - 5 credits CE per protocol in addition to 15 credits/year
  - Boards of Pharmacy / Medicine must approve
  - Informed consent
  - Liability insurance
- Financial Barriers
  - No pharmacist reimbursement without medication
  - “Incident-to” billing only in ambulatory care

- Regulatory Solutions
  - Standing Orders (no informed consent) or protocols (immunization)
  - Allow all prescribers to sign
  - Make pharmacists providers
  - Permit pharmacists to bill equally as providers for insurance plans
  - Reduce CE / permit collaborator to determine
  - Create faster Board-approval pathways
  - Test provider-pharmacist reimbursement model of health department/medical supervisor signer

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