The Transforming Mental and Behavioral Health Landscape:
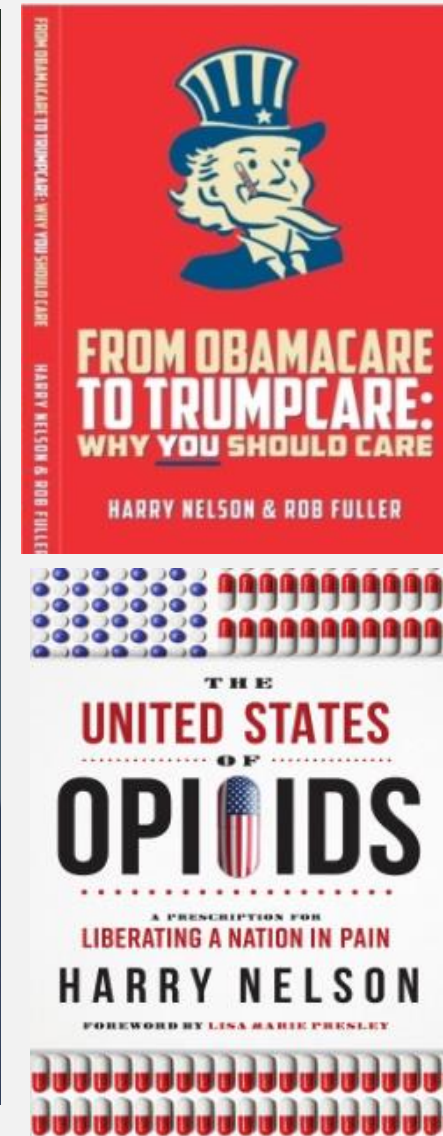## *Regulatory and Clinical Responses*

Overview

I.   Overview of new regulatory developments and evolving enforcement priorities

II. Operational responses on the front line (Screening, Intervention, evolving Models of Care)

III. Implications for healthcare providers and compliance

Presenters:

Harry Nelson
Founder,
Nelson Hardiman LLP

Belinda Waltman
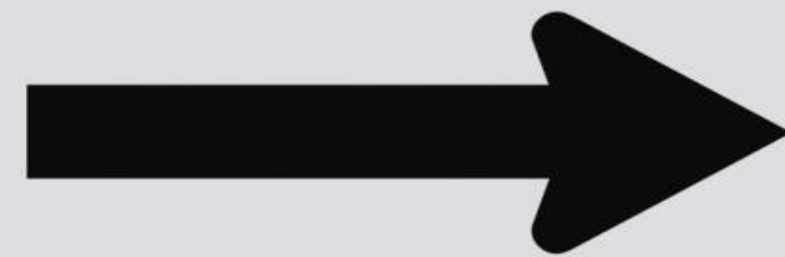Medical Director,
LA County Department of
Health Services

I.
Overview of new regulatory developments and evolving enforcement priorities

I. Overview of new regulatory developments and evolving enforcement priorities

- The Big Picture
- Regulatory Developments
- Models of Care
- Fraud + Abuse
- Licensing etc

THE BIG PICTURE →

1. Overdose rates + rising levels of reported addictive/mental health disorders accelerated inclusion of behavioral health into healthcare

2. Integrating into healthcare paradigms highlights gaps in **models of care**, **fraud and abuse**, **licensing**, and reimbursement, driving change

3. Social/emotional dimensions of behavioral health vs biomedical models

4. Concurrent pressure to reduce cost and improve quality
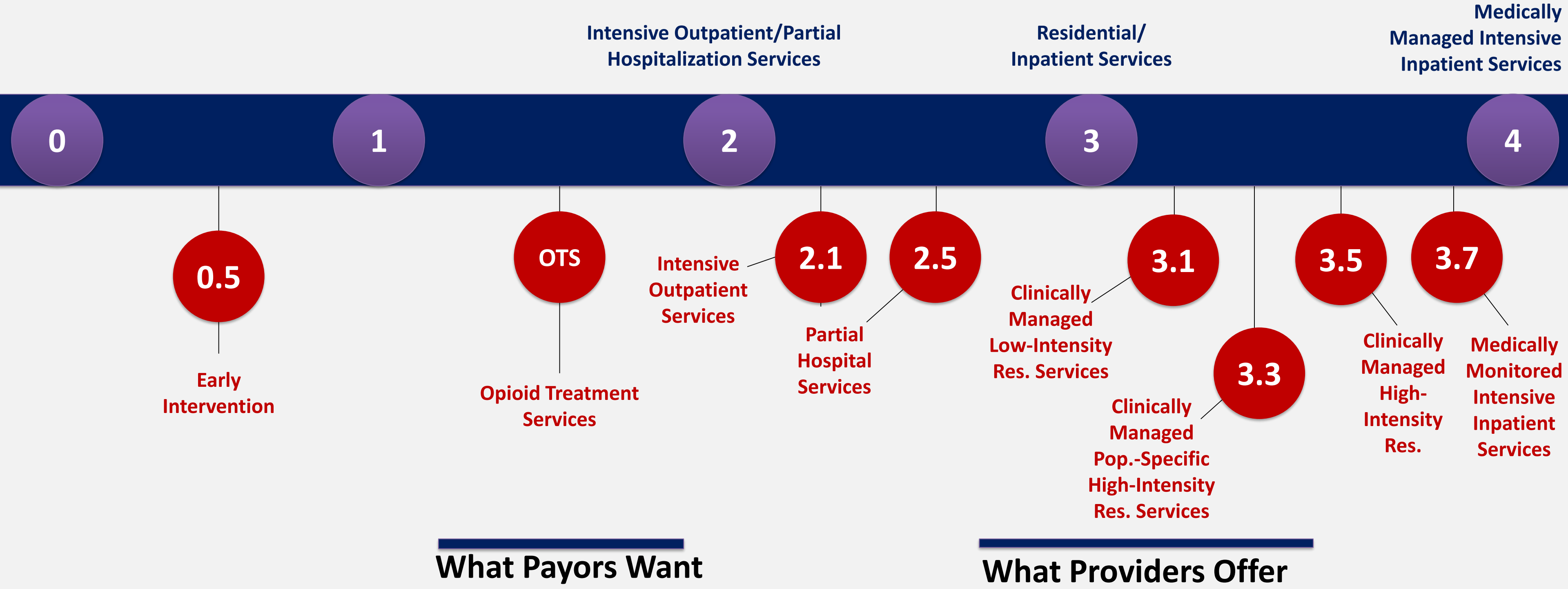
Models of Care

- ASAM Criteria
- MAT Expansion/Discrimination
- IMS

Embedding ASAM Criteria

SB 823 (HSC § 11834.015): DHCS shall adopt ASAM (or equivalent evidence-based) minimum standards of care. . .

Intensive Outpatient/Partial Hospitalization Services

Residential/ Inpatient Services

Medically Managed Intensive Inpatient Services

0   **1**   **2**   **3**   **4**

0.5 — Early Intervention

OTS — Opioid Treatment Services

Intensive Outpatient Services

2.1 — Partial Hospital Services

2.5

3.1 — Clinically Managed Low-Intensity Res. Services

3.3 — Clinically Managed Pop.-Specific High-Intensity Res. Services

3.5 — Clinically Managed High-Intensity Res.

3.7 — Medically Monitored Intensive Inpatient Services

What Payors Want

What Providers Offer

Ending MAT Discrimination

Federal

USDOJ v Selma Med Assocs

Refusal to treat patient on Suboxone violates the ADA

California

SB 992 (H&S §11834.26)

Denying admission to addiction treatment based on MAT Rx violates SB 992

Incidental Medical Services

AB 848/Health and Safety Code § 11834.025/26 (2015) allows MDs in certified residential AOD facilities to:

(1) Obtain medical histories
(2) Monitor health for emergency needs
(3) Test as needed for detox
(4) Oversee self-administered meds
(5) Treat SUDs including detox

DHCS Information Notice (2018) but still waiting on regulations.
Provider-plan conflict on implications for non-IMS facilities.

Fraud and Abuse

- SB 1228
- EKRA
- Patient Financial Responsibility + Travel

New Patient Brokering Laws

EKRA (Eliminating Kickbacks in Recovery Act)

Illegal to knowingly and willfully solicit, receive, offer, or pay anything of value for referral or to induce a referral of a patient to (or in exchange for a patient using) a:
- **recovery home**
- **clinical treatment facility**, or
- **laboratory**

SB1228 (H&S 11831.6)

Discipline/fines for giving or receiving anything of value to induce a referral seeking SUD services from:
- **licensed/certified SUD programs**
- **licensed/certified professionals, owners (10%+), partners, officers, directors**

EKRA Statutory Exceptions

- Payments to bona fide employees and independent contractors (including services that meet the Federal AKS safe harbor for personal services and management contracts)
- disclosed discounts under a healthcare benefit program
- discounts on drugs furnished under the Medicare coverage gap discount program
- coinsurance and copayment waivers and discounts
- FQHC arrangements that meet the Federal AKS exception

Who?

Anyone who gives, gets, or tries to give or get remuneration for referrals to:

- **Labs**
- **Clinical Treatment Facility**: medical setting other than a hospital, providing detox, risk reduction, outpatient, residential treatment, or rehabilitation for SUD
- **Recovery home**: a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from SUD
- **Covers all health plans**

(18 U.S.C. § 220(e))

HR 6 Statutory Exceptions: Certain . . .

- Payments to bona fide employees and independent contractors (including services that meet the Federal AKS safe harbor for personal services and management contracts)
- Disclosed discounts under a healthcare benefit program
- Discounts on drugs furnished under Medicare coverage gap discount program
- Coinsurance and copayment waivers and discounts
- FQHC arrangements that meet the Federal AKS exception
- Expressly does not apply to conduct prohibited under the federal AKS
- Expressly does not preempt state laws on the same subject matter

Focus on Client Inducement
Waiving Deductibles/Co-insurance/Funding Travel

Influencing patient program choice
- **Use of financial hardship, promissory notes, discounts, debt forgiveness must be documented, consistent, reasonable**
- **Funding travel is not permissible**

Licensing/Operations

- AB 3162/SB 992 Constraints
- 42 CFR Part 2
- Crackdown on Overdoses/Suicides
- Pending Legislation: Licensing for Outpatient and Certification for Recovery Residences

Operational Constraints

AB 3162: All treatment services must be provided onsite

SB 992:
- Disclosure of licensed facility/recovery residence financial relationships
- New Requirement for relapse plans, discharge and continuing care planning

42 CFR Part 2: 2018 SAMHSA Final Rule Changes

P-O: Patient consent extended to allow disclosures of SUD information to contractors, sub-contractors, and legal representatives as needed for payment or health care operations:

- Billing, claims management, collections
- Medical necessity/insurance coverage/UR/QA/QI
- Patient safety activities
- Training/assessment of students, practitioners, staff, plan
- Accreditation, certification, licensing, credentialing
- Health benefits, reinsurance, third-party liability coverage;
- Medical review, legal services, and auditing functions; and
- Business planning + management. General administration + compliance

Final Rule Change on Redisclosure

- **Audit and Evaluation**: Lawful Holders (individuals and entities in lawful receipt of protected information), not just programs, may disclose protected information without patient consent for certain audits and evaluations (and to contractors…)

- **Abbreviated notice of the prohibition on redisclosure** (paralleling BAA requirements, effective Feb 2020)

- **Exchange of PII permitted for audits and evaluations of lawful holders**

- **Compliance revisions: 3rd party contracts, patient consent agreements, P&Ps**

New Crackdown on Deaths (Overdoses/Suicides)
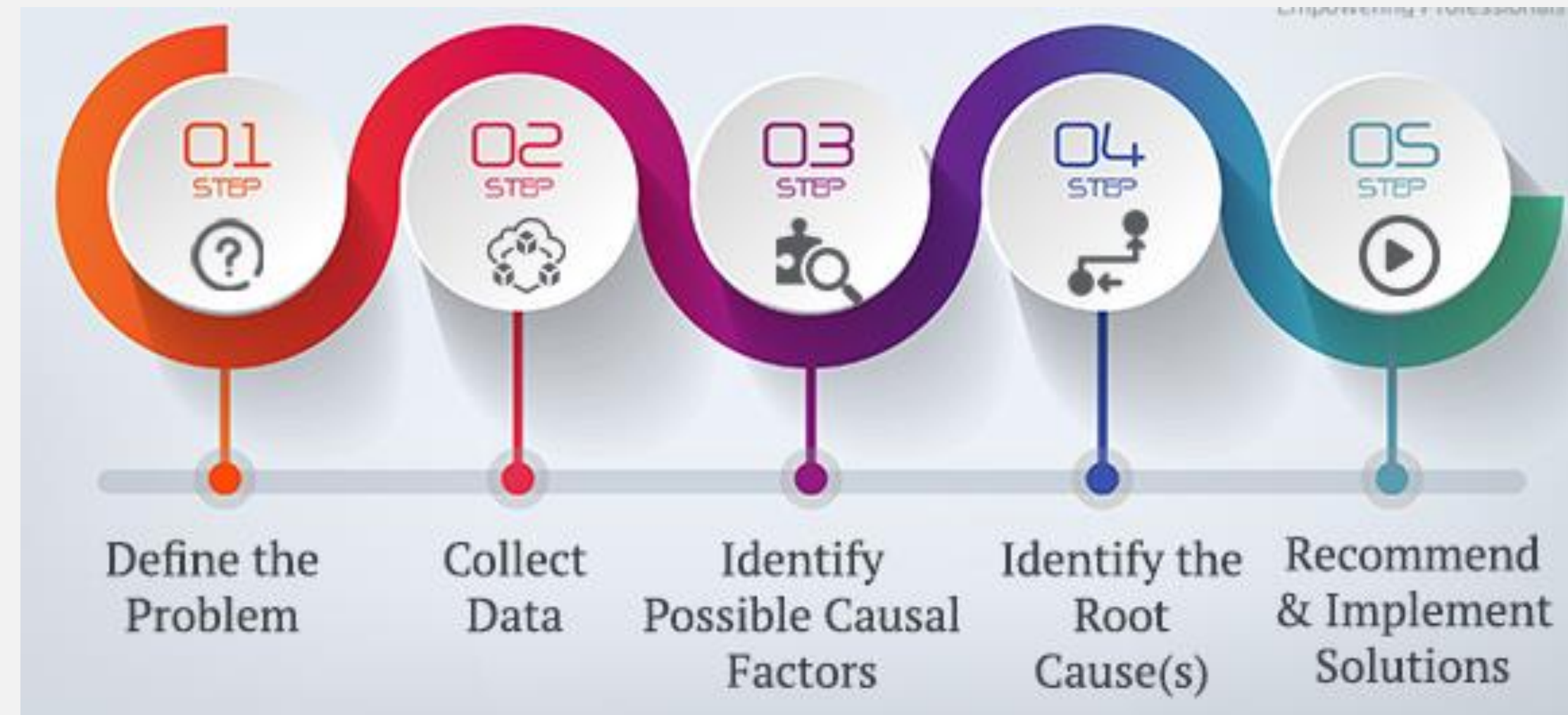
**Regulators looking for prompt root cause analysis and remediation
or else moving to close programs**

Current Legislative Term: Licensing Outpatient

SB 325 would require outpatient AOD treatment programs to be licensed as of 2021 (carve out for Drug Medi-Cal certified programs operating within the Organized Delivery System Waiver)

Voluntary Recovery Residence Certification

SB 1779 would establish voluntary certification process and standards for recovery residences (sober living).

II. Operational Responses on the Front Line

Whole Person Care Los Angeles

Belinda Waltman, MD
Health Care Compliance Association Conference
June 14, 2019

Outline

1. Case
2. Whole Person Care – Los Angeles Overview
3. Regional Care Delivery Model
4. Target Populations and Programs
5. Assessment Tools and Care Planning
6. Care Management Platform and Data Sharing Framework
7. Whole Person Care – Substance Use Disorder program
8. Implementation Successes

Whole Person Care – Los Angeles

Overview

Mission
Build an integrated health system that delivers seamless, coordinated services

Goal: Collaboration
Increase integration and collaboration among county agencies, health plans, providers, and other entities

Whole Person Care
A 5-year (2016-2020) pilot program designed to improve access and quality of care for the most marginalized Medi-Cal beneficiaries

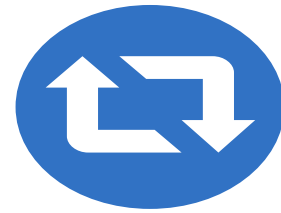**Goal: Coordination**
Increase coordination and appropriate access to care

Goal: Data Integration
Improve data collection and sharing to support case management, monitoring, and program improvement

Whole Person Care – Los Angeles

LA Program Highlights

Integrated Health Delivery
Participant engagement & care coordination enabled by care teams, IT, and data integration

**Regional Care Management Teams**
Regional teams consisting of a social worker and CHW apply a "no wrong door" approach

Community Health Workers (CHWs)
Social service teams driven by CHWs with shared lived experience

Transitional Care Coordination
Accompaniment & linkage to and integration with long term providers during high-risk times

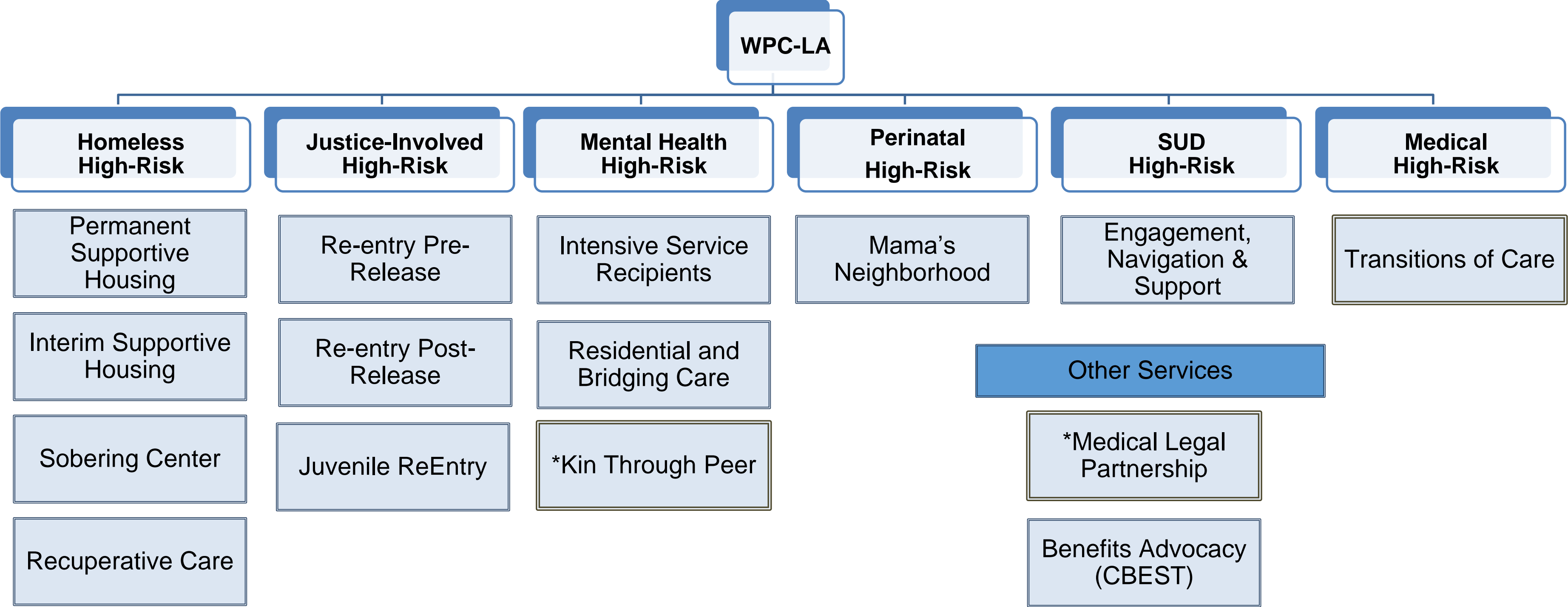**Whole Person Care – Los Angeles**
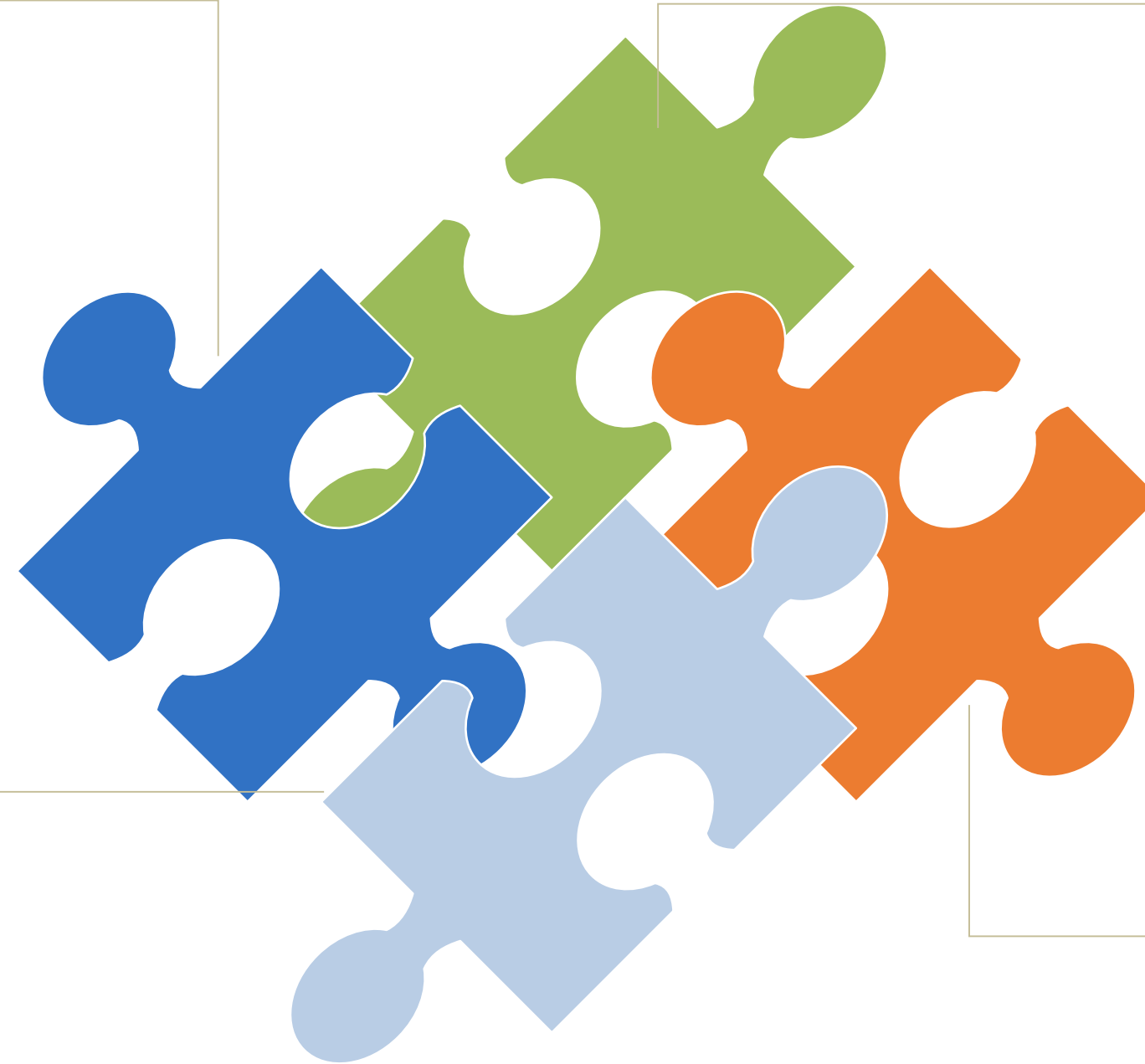
Regional Care Delivery Model

- WPC-LA Care Teams consist of **Supervising Social Worker** and **CHWs** in Regional Coordinating Centers in each service planning area

- Mobile, field-based units

- Leverage and strengthen existing relationships

- Specialize in each neighborhood

LA Target Populations

Life Cycle of the Case

- Receive referrals from different sources

- Engage and enroll participants

- Perform comprehensive needs survey

- Create care plan

- Accompany & help link participants to resources

- Work closely with participant's **longitudinal care team** to ensure coordination of care

- Ensure a seamless handoff to their primary health care team for ongoing care and support

Comprehensive Needs Assessment Examples

Domain	Subdomain	Validated Tool
Social Needs	Food Insecurity	Hunger Vital Sign
	Housing	Accountable Health Communities Health-Related Social Needs Screening Tool and PRAPARE
	Transportation	PRAPARE
Physical Health	Medications	High-risk medication use / polypharmacy screeners
	Activities of Daily Living	Modified Katz
Substance Use		NIDA Quick Screen and Modified Assist
Mental Health		Patient Health Questionaire – 2

WPC Shared Care Plan

- What is a Care Plan
  - A set of client-driven & prioritized activities that the care management team helps the client develop to help a client achieve their goals

- WPC-LA Care Plan has:
  - 4 domains: Social Needs, Physical Health, Mental Health, Substance Use
  - SMART goal
  - Action Steps – that can be assigned to client or Care Team
  - Care Plan case note

Care Management Platform Functionality

- Screening/Intake/Eligibility
- Program Enrollment/Discharge
- Consent Management
- Comprehensive Assessment
- Referral Management
- Waitlist/Call Center
- Care Planning
- Case Notes

- Roster/Care Team Assignment
- Panel Management
- Supervision/Approvals
- Decision Support
- Reporting/Invoicing
- Data Query
- Housing bed slot tracking

Care Management Platform Data Sharing & Consent Management

- Consent-driven, Role-based, field-level security

- Universal Consent across WPC, HfH, CBEST, ODR, part of Jail

- This approach increases data sharing across county & contracted agencies to:
  - Improve care coordination
  - Decrease duplication of effort
    - While being compliant with state and federal regulations around protected/segmented data types

Data Sharing Matrix

Logic behind Consent-driven, Role-based, Regulatory-compliant data sharing

Data Type

Client data sharing preferences from the authorization

	PHI	Mental Health Data	Mental Health Data	Substance use data	Substance Use Data	HIV test results	HIV test results
Client Preferences/Consent		YES	NO	YES	NO	YES	NO
Purpose							
Purpose							
Purpose							
Purpose							
Purpose							

Purpose of accessing data (aligns with role-based workgroups)

Regulations +/- regulatory exceptions that allow/disallow access

Consent status

Whole Person Care – Los Angeles

Health Services
LOS ANGELES COUNTY

Substance Use Disorder – Engagement, Navigation, & Support

- Employs Community Health Workers (CHW) with lived experience in treatment and recovery

- CHWs connect high-risk individuals with appropriate Substance Use Disorder (SUD) Treatment

- Developed in Partnership with Department of Public Health Substance Abuse Prevention and Control (SAPC) program
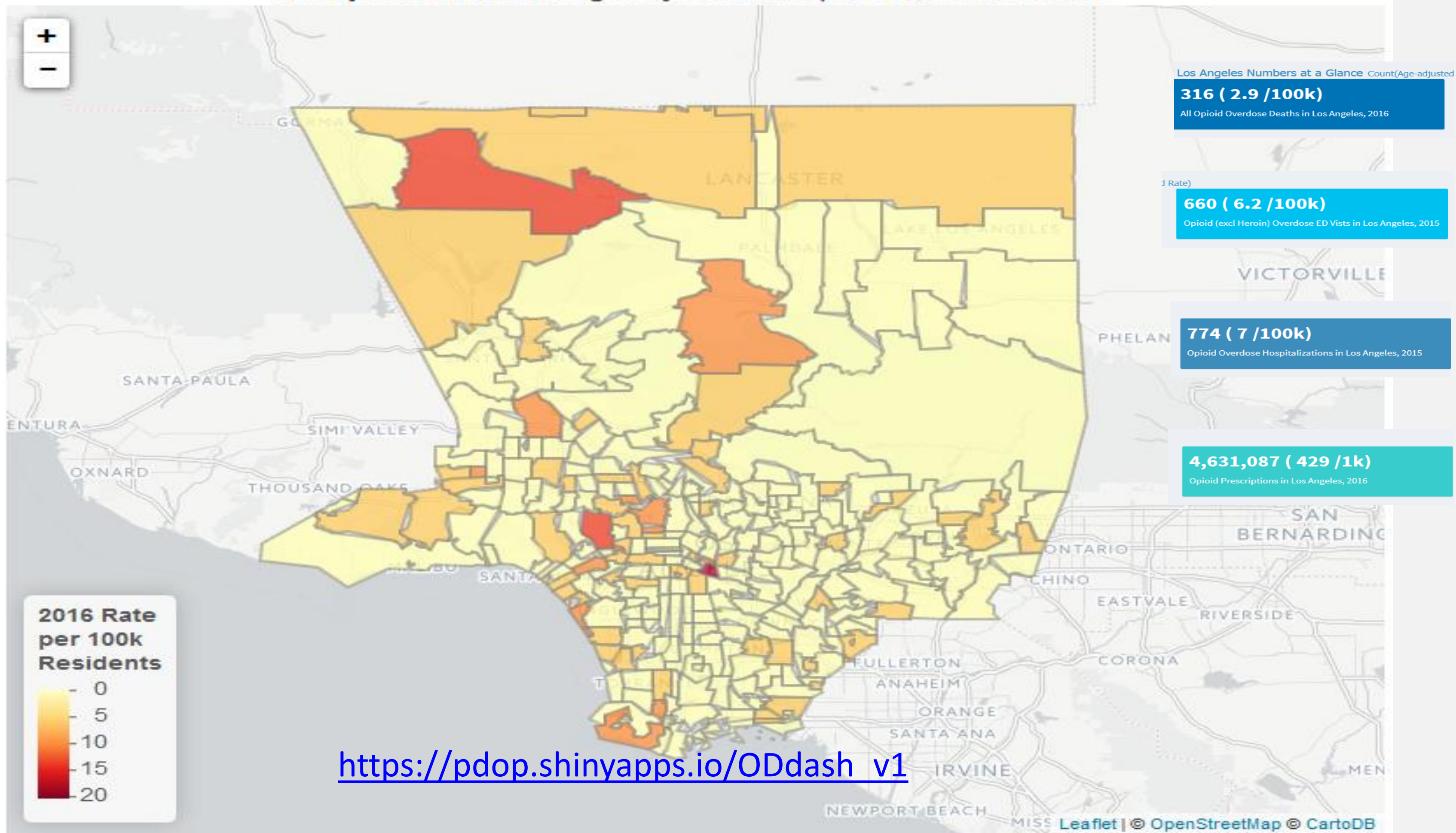
Examples of CHW Support

- SUD Treatment
- Mental Health Treatment
- Primary Care
- Eye & Dental Care
- Employment
- Transportation
- Identification Documents
- Benefits Applications
- Shelter & Housing Applications

Los Angeles Deaths - Total Population - 2016
All Opioid Overdose: Age-Adjusted Rate per 100,000 Residents

Los Angeles Numbers at a Glance Count(Age-adjusted

316 (2.9 /100k)
All Opioid Overdose Deaths in Los Angeles, 2016

Rate)

660 (6.2 /100k)
Opioid (excl Heroin) Overdose ED Vists in Los Angeles, 2015

774 (7 /100k)
Opioid Overdose Hospitalizations in Los Angeles, 2015

4,631,087 (429 /1k)
Opioid Prescriptions in Los Angeles, 2016

2016 Rate per 100k Residents
- 0
- 5
- 10
- 15
- 20

https://pdop.shinyapps.io/ODdash_v1

Leaflet | © OpenStreetMap © CartoDB

Connecting to the SAPC Network

- Substance Abuse Prevention and Control (SAPC) within the Department of Public Health

- Drug Medi-Cal Organized Delivery System (DMC-ODS) waiver

- ASAM triage tool administered on the 24-hr helpline and in different physical locations

- Continuum of care

Health Services

Naloxone Distribution Program

- Distributed to high-risk clients in our jail-based program (upon release) and in the community

- High-risk includes those who might have witnessed an overdose or might have friends/family who use opiates

- Naloxone vending machines after watching a short training video

- Distribution planned for 10,000 intranasal doses

Implementation Successes

Served since January 2017: **31,723**

Care Management Platform with 2500+ users

16 WPC-LA programs operating

Data Sharing Progress and Universal Consent

3rd cohort CHWs hired late **2018**

Pilot Year 3

III. Implications for Healthcare Providers and Compliance

Questions? Grievances?

Harry Nelson
Nelson Hardiman, LLP
310.203.2800
hnelson@nelsonhardiman.com

Belinda Waltman, MD
Whole Person Care, LA County
Department of Health Services
bwaltman@dhs.lacounty.gov