DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-01-16 Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

State Demonstrations Group

June 20, 2016

Mari Cantwell Chief Deputy Director Department of Health Care Services Director's Office, MS 0000 P.O. Box 997413 Sacramento, CA 95899-7413

Dear Ms. Cantwell:

This letter is to inform you that the Centers for Medicare & Medicaid Services (CMS) has approved the attached evaluation design for the Drug Medi-Cal Organized Delivery System component of California's section 1115(a) demonstration, entitled "California Medi-Cal 2020 Demonstration" (11-W-00193/9), as submitted by the state and as modified through our discussions. A copy of the approved evaluation design is enclosed.

We look forward to continuing to work with you and your staff on the California Medi-Cal 2020 Demonstration. If you have any questions, please contact your project officers, Ms. Mehreen Hossain, at either 410-786-0938 or by email at Mehreen.Hossain@cms.hhs.gov, and Ms. Heather Ross, at either 410-786-3666 or by email at Heather.Ross@cms.hhs.gov.

We appreciate your cooperation throughout the review process.

Sincerely,

/s/

Angela D. Garner Director Division of System Reform Demonstrations

Enclosure

cc: Henrietta Sam-Louie, Acting ARA Region IX

California Drug Medi-Cal Organized Delivery System:

Proposed Evaluation for California's Section 1115 Demonstration Waiver

October 12, 2015

June 14, 2016 REVISION



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California's Drug Medi-Cal Organized Delivery System

1. Demonstration Background

Substance Use Disorders (SUD)s substantially impact both individual and public health, and are major drivers of health care costs among publicly insured populations. Individuals with untreated SUDs utilize an excess of costly inpatient and emergency services. Improving access to a full array of evidence-based SUD treatment has the potential to improve the health of Medicaid beneficiaries while significantly reducing their overall medical costs.

In California, SUD services for Medi-Cal beneficiaries have historically covered only five modes of treatment: outpatient drug-free services, narcotic replacement therapy (methadone), naltrexone services, day care rehabilitation (intensive outpatient care) for pregnant women, and perinatal residential services for pregnant and postpartum women. In addition, there was a limited fee-for-service DMC benefit for interventions provided by licensed physicians and for inpatient withdrawal management services. They did not include many essential services, such as widely available residential treatment, that can assist individuals with SUDs in achieving and sustaining recovery. Other challenges included lack of access to evidence-based medications, poor coordination with mental health and physical health services, and limited flexibility to select providers and hold them accountable.

The DMC-ODS demonstration has the potential to address the aforementioned limitations on California's DMC-funded services. It will provide access to treatment modalities and services previously not covered by DMC benefits, making available a full continuum of evidence-based SUD treatment and thus increasing the likelihood that beneficiaries will be able to achieve and sustain long-term recovery. See Table 1 below (source: STCs).

In addition, the DMC-ODS demonstration will facilitate increased coordination and integration of SUD services with physical health and mental health care, potentially leading to improved clinical and fiscal outcomes. Furthermore, by enhancing counties' ability to selectively contract with providers and expanding the provider types included in the SUD workforce, the DMC-ODS demonstration can address limitations that have hampered the delivery of effective SUD services to Medi-Cal beneficiaries (see Table 2). Consequently, it is anticipated that the implementation of the DMC-ODS demonstration will lead to improvements in four key areas: (1) access to care, (2) quality of care, (3) cost, and (4) the integration and coordination of SUD care, both within the SUD system and with medical and mental health services.

Table 1: State Plan and DMC-ODS Services Available to DMS-ODS Participants (with Expenditure Authority and Units of Service)					
DMC-ODS Service	Current State Plan	Allowable 1905(a) services – not covered in State Plan*	Costs Not Otherwise Matchable (CNOM)	Units Of Service	
Early Intervention (Note: SBIRT services are paid for and provided by the managed care plans or by fee-for- service primary care providers.)	x (preventive service; physician services)			Annual screen, up to 4 brief interventions	
Outpatient Drug Free	x (rehab services)			Counseling: 50 min session	
Intensive Outpatient	x (rehab services)			per day	
Partial Hospitalization		X		Diagnosis- related Group (DRG)/Certified Public Expenditures (CPE)	
Withdrawal management General Acute Care Hospital (VID, INVID) (non-IMD)	x inpatient services			DRG/CPE	
CDRH/Free Standing Psych (IMD)			Х	DRG/CPE	
Residential (perinatal, non- IMD)	x (rehab services)			Per day/bed rate	
(all pop., non-IMD)		X		Per day/bed rate	
(IMD)			<u>X</u>	Per day/bed rate	
NTP	x (rehab services)			Per day dosing; 10 minute increments	
Additional MAT (drug products)	x (pharmacy)			Drug cost	
(physician services)	x (physician services; rehab)			Per visit	

Recovery	X	Counseling: 50	
Services		min session	

TABLE 2 CHANGES TO SERVICE DELIVERY AND SYSTEM ORGANIZATION UNDER THE DMC-ODS DEMONSTRATION				
Change	Description			
Assessment and Placement	The DMC-ODS will facilitate the utilization of the American Society of Addiction Medicine (ASAM) assessment tool to determine the most appropriate level of care, so that clients can enter the service system at an appropriate level and step up or step down depending on their response to treatment.			
Care Coordination and Residency	Counties will coordinate care for individuals residing within the county.			
Selective Provider Contracting	Counties will have more authority to select quality providers. Safeguards include providing that counties cannot discriminate against providers, that beneficiaries will have choice within a service area, and that a county cannot limit access.			
Provider Appeals Process	The DMC-ODS will create a provider contract appeal process where providers can appeal to the county and the state. State appeals will focus solely on ensuring network adequacy.			
Clear State and County Roles	Counties will be responsible for oversight and monitoring of providers as specified in their county contract.			
Coordination	Supporting coordination and integration across systems, such as with the provision that counties enter into Memoranda of Understanding (MOUs) with managed care health plans for referrals and coordination, providing that county substance use programs collaborate with criminal justice partners.			
Authorization and	Providing that counties authorize services, with preauthorization for			
Utilization Management	residential treatment required, and ensuring utilization management.			
Workforce	Expanding service providers to include Licensed Practitioners of the Healing Arts for the assessment of beneficiaries, and other functions within their scope of practice.			
Program Improvement	Promoting a consumer-focus, using evidence-based practices including medication assisted treatment services and increasing system capacity for youth services.			

2. Demonstration Requirements

County participation in the DMC-ODS demonstration project will be voluntary. In participating counties, the DMC-ODS will bring about the following changes in the delivery, structure, content, and organization of Medicaid-funded SUD services:

1. Service Eligibility

There will be no age restrictions on DMC-ODS services. For adults over 21, medical necessity for DMC-ODS services will be determined using definitions from the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM) and the ASAM Criteria. For youth under 21, medical necessity will be determined by an assessment for risk of developing SUD. Counties or county-contracted providers will determine eligibility for DMC-ODS benefits, and eligibility for ongoing receipt of DMC-ODS services will be determined at least every six months through a reauthorization process.

2. Benefits

DMC-ODS beneficiaries will have access to all of the following services:

- Outpatient Services: Recovery and motivational enhancement therapies and strategies, given for less than nine hours per week for adults and less than six hours per week for adolescents. These services will be provided in facilities certified as Outpatient Facilities by the California Department of Health Care Services (DHCS).
- <u>Intensive Outpatient Services</u>: These services will be given for nine or more hours per week for adults, and six or more hours per week for adolescents, and will be provided in facilities certified as Intensive Outpatient Facilities by DHCS.
- Residential Services: Initially, at least one level of residential services, as defined in the ASAM Criteria. Counties will be required to provide all three levels of residential services as defined in the ASAM Criteria within three years of opting in to the waiver.
- <u>Withdrawal Management Services</u>: At least one level of Withdrawal Management Services, as defined in the ASAM Criteria.
- Opioid Treatment: Daily or several times a week, medication (methadone, buprenorphine, naloxone, disulfiram) and counseling will be available to help individuals with severe opioid use disorders maintain stability. These services will be delivered by DHCS-licensed Narcotic/Opioid Treatment Providers.
- <u>Recovery Services</u>: Services that emphasize beneficiaries' role in managing their health, and teach them to use effective self-management support strategies.
- <u>Case Management Services</u>: Assistance for beneficiaries who need help accessing needed medical, educational, social, prevocational, vocational, rehabilitative, and other community services; coordination of SUD care with other services; assistance in interactions with the criminal justice system.

In addition, counties participating in the DMC-ODS will have the option to provide:

- <u>Partial Hospitalization Services</u>: 20 or more hours of treatment per week of services for individuals who do not require full-time care.
- <u>Additional Residential Services</u>: More than one level of residential services (three levels of residential service become required after three years).

- <u>Additional Withdrawal Management Services</u>: More than one level of withdrawal management services.
- <u>Additional MAT</u>: SUD medications (buprenorphine, naloxone, disulfiram, injectable naltrexone) in all DMC settings and clinically necessary adjunctive services for beneficiaries with opioid and/or alcohol use disorders.

3. Provider Specifications

Professional staff delivering DMC-ODS services will need to be licensed, registered, certified, or recognized under the California State scope of practice statutes. In DMC-ODS counties, the SUD workforce will be expanded to include Licensed Practitioners of the Healing Arts, such as physicians, nurse practitioners, physician assistants, registered nurses, registered pharmacists, licensed clinical psychologists, licensed clinical social workers, licensed clinical professional counselors, and licensed marriage and family therapists.

All professional and nonprofessional staff will be required to have appropriate experience and necessary training before they begin delivering services. In addition, Counties will require contracted providers to be capable of providing culturally competent services, MAT, and at least two EBPs.

4. County Responsibilities

Counties that participate in the DMC-ODS will have the following responsibilities:

- <u>Implementation Plan</u>: Counties will create and submit a DMC-ODS implementation plan to the State.
- Selective Provider Contracting: Counties will choose which providers will participate in the DMC-ODS benefit, and will be required to ensure that all beneficiaries have access to services and a choice of providers that are geographically accessible to them. Counties will be responsible for maintaining and monitoring a network of providers that is appropriate for the anticipated number of DMC-ODS clients, the expected utilization of SUD services, and the expected number and types of providers needed to meet beneficiaries' SUD service needs. Counties will need to have written policies and procedures for selecting, retaining, credentialing, and re-credentialing providers, and contract requirements will need to stipulate that providers must provide services that are safe, effective, patient-centered, timely, efficient, and equitable.
- <u>Residential Service Authorization</u>: To assure appropriate utilization of residential services, counties will be responsible for authorizing their utilization. Counties will need to provide prior authorization for residential services within 24 hours of the prior authorization request being submitted by the provider.
- <u>Beneficiary Access Number</u>: Counties will have a toll-free number for prospective beneficiaries to call to access DMC-ODS services. Counties will be required to make oral interpretation services available to beneficiaries as needed.
- <u>Coordination with Managed Care Plans</u>: To facilitate clinical integration, counties will enter into a memorandum of understanding (MOU) with any Medi-Cal managed care plan that enrolls beneficiaries served by the DMC-ODS in their county. MOUs will, at a

minimum, include bidirectional referral protocols between plans, the availability of clinical consultation, management of beneficiaries' care, procedures for the exchange of medical information, and a process to ensure that beneficiaries receive medically necessary services uninterrupted in the event of disputes between counties and Medi-Cal managed care plans.

- Quality Improvement Plan: Counties that participate in the DMC-ODS demonstration will be required to have a Quality Improvement plan that monitors service delivery, service capacity, and the types and geographic distribution of SUD services. A Quality Improvement committee will review the quality of SUD services provided to beneficiaries, recommend policies, ensure and follow-up Quality Improvement processes, and evaluate the results of Quality Improvement Activities.
- <u>Utilization Management</u>: Counties will assure that beneficiaries have appropriate access
 to different levels of SUD care, as needed. They will also assure that medical necessity
 has been established for each beneficiary, that they are placed in the appropriate level of
 care, and that the services given are appropriate for beneficiaries' diagnosis and level of
 care.
- <u>Financing</u>: Counties will propose county-specific rates to be approved by the State. If the State denies proposed rates, counties will have an opportunity to adjust rates and resubmit to the State.

5. State Oversight, Monitoring, and Reporting

State responsibilities will be as follows:

- The State will maintain a plan for oversight and monitoring of DMC-ODS providers and counties in order to assure compliance and facilitate corrective action when necessary. In particular, the State will ensure that DMC-ODS services facilitate timely access to care, and it will monitor provider activities in order to identify and address suspicious or fraudulent activity.
- The State will monitor and report DMC-ODS enrollment information, operational issues, and policy developments.
- The State will conduct Triennial reviews of the status of quality improvement and county monitoring activities.

Proposed Evaluation

1. Evaluation Purpose

The Drug Medi-Cal Organized Delivery System (DMC-ODS) is a program under California's Section 1115 demonstration waiver, originally approved by the Centers for Medicare and Medicaid Services (CMS) on August 13, 2015.

Through the DMC-ODS, the State will restructure Medi-Cal SUD services (Drug Medi-Cal, DMC) in participating counties to operate as a DMC Organized Delivery System (DMC-ODS) that: (1) provides a continuum of SUD care modeled after the American Society of Addiction Medicine's Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions (ASAM Criteria); (2) increases local control and accountability; (3) creates mechanisms for greater administrative oversight; (4) establishes utilization controls to improve care and promote efficient use of resources; (5) facilitates the utilization of evidence-based practices (EBPs) in SUD treatment; and (6) increases the coordination of SUD treatment with other systems of care (e.g. physical health and mental health). The principal aims of the DMC-ODS will be to improve access to SUD services, improve the quality of SUD care, control costs, and facilitate greater service coordination and integration, both among SUD providers and between SUD providers and other parts of the health care system.

The DMC-ODS will be consistent with the Center for Medicare and Medicaid Services (CMS) guidance issued in the July 27, 2015 State Medicaid Directors letter on new service delivery opportunities for individuals with SUD. California's DMC-ODS demonstration is the first to be approved under CMS' recent guidance, and meets many of the standards set forth in the July 2015 letter, including: an evidence-based benefit design covering a full continuum of SUD care, requirements for providers to meet industry standards of care, a strategy to coordinate and integrate services across systems of care, reporting of specific quality measures, program integrity safeguards and a benefit management strategy, and other programmatic expectations. Counties that participate in the DMC-ODS demonstration will be able to selectively contract with providers in a managed care environment in order to deliver a full array of services consistent with the ASAM Criteria, including recovery supports and services.

The University of California, Los Angeles, Integrated Substance Abuse Programs (UCLA ISAP) will conduct an evaluation to measure and monitor outcomes of the DMC-ODS demonstration project. The evaluation will focus on four areas: (1) access to care, (2) quality of care, (3) cost, and (4) the integration and coordination of SUD care, both within the SUD system and with medical and mental health services. UCLA will utilize data gathered from a number of existing state data sources as well as new data collected specifically for the evaluation.

¹ SMD Letter #15-003, Re: New Service Delivery Opportunities for Individuals with a Substance Use Disorder. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf

2. Evaluation Strategy

A. Goals and Objectives

The primary goals of the DMC-ODS waiver demonstration are enhanced access to SUD treatment, quality of care, and coordination of care while maintaining cost neutrality for the Medicaid program. The evaluation will examine each of these goals using a variety of measures, which will be discussed further in the Methods section.

An aim of the evaluation is to be as comprehensive and useful as possible within practical constraints by following several principles:

- Analyze existing state administrative datasets where possible.
- Align measures with existing or expected future data requirements.
- Where necessary, collect new data while minimizing the burden on stakeholders.
- Provide results to stakeholders quickly to inform ongoing implementation efforts.

Both quantitative and qualitative measures will be used to mitigate the weaknesses of each. Quantitative methods will be used to analyze trends and the degree of changes over time, while qualitative methods will be used to help interpret quantitative data within the broader context of stakeholder perceptions.

B. Hypotheses

Evaluation hypotheses can be organized into the following four categories, or domains:

- 1. Beneficiary <u>access</u> to treatment will increase in counties that opt in to the waiver compared to access in the same counties prior to waiver implementation and access in comparison counties that have not opted in.
- 2. Quality of care will improve in counties that have opted in to the waiver compared to quality in the same counties prior to waiver implementation, and quality in comparison counties that have not opted in.
- 3. Health care <u>costs</u> will be more appropriate pre/post waiver implementation among comparable patients; e.g., SUD treatment costs will be offset by reduced inpatient and emergency department use.
- 4. SUD treatment <u>coordination</u> with primary care, mental health, and recovery support services will improve.

C. Design

1. Model discussion and approach

In principle, a randomized controlled trial would be the best approach to determine the causal effect of the DMC-ODS waiver. Unfortunately, this would require random assignment of

counties or providers to determine whether they participate in the waiver rather than allowing them to participate based on their own readiness and willingness to do so. Such random assignment in this case would be not be feasible and may even be considered unethical due to the randomly assigned denial of certain services that would be necessary; therefore, such an evaluation design has been eliminated as a possibility.

When considering alternative designs, a significant consideration is the important role of counties in waiver implementation, the uncertainty in the number of counties that will opt in, and the timing of each county's participation. A recent survey by UCLA suggests that the majority of California's 58 counties may opt in. On this survey, only two counties responded that they do not plan to opt in, but many are uncertain. However, it is unclear when the counties will opt in during the five-year waiver period. The state will open participation in the waiver to counties in regional phases, but counties will not be required to begin immediately when their phase opens. Therefore, it is likely that implementation will not be tightly tied to phases, and instead may occur as depicted in Figure 1. As shown, a phase 2 county could actually begin participating before a phase 1 county. Due to this likely overlap between phases, the start dates used in data collection or analyses will be based on each county's individual implementation start date, as defined by final approval of its implementation plan, rather than by the county's phase.

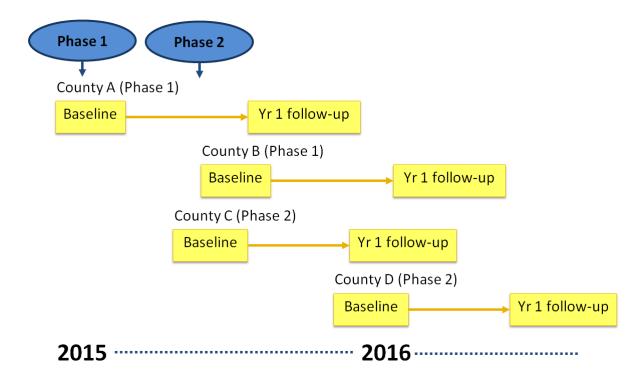


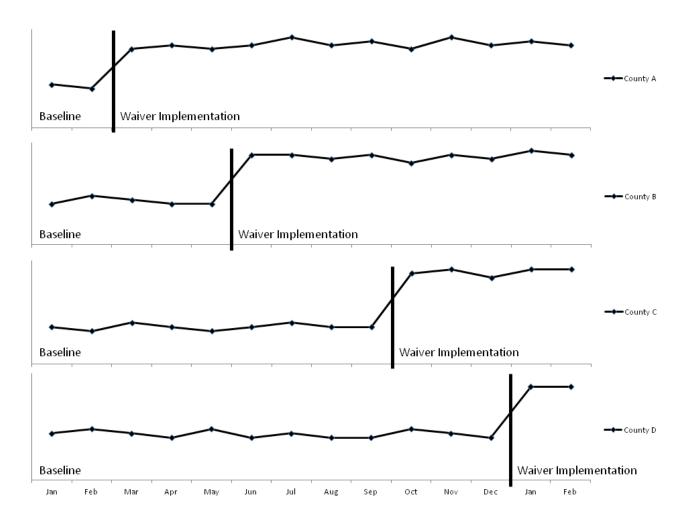
Figure 1- Hypothetical scenario: overlapping phases and start dates.

The likely staggered nature of implementation presents both challenges and potential advantages for evaluation purposes. If the entire state were to begin implementation at the same time, a regression discontinuity analysis similar to the one proposed for the Arkansas

1115 waiver evaluation (Arkansas Center for Health Improvement, 2014) would be one reasonable evaluation approach. In California's case, however, there is an opportunity to take advantage of the expected county-by-county implementation using a different approach.

The proposed evaluation will use a relatively new type of design known as a stepped wedge or multiple baseline design (for clarity, this latter term will be used). This method is similar to an interrupted time series design except that, under a multiple baseline design, groups receive the intervention (in this case, waiver implementation) at multiple points staggered over time, matching the expected scenario in California. Figure 2 illustrates this design using an example of four counties. The hypothetical outcome could, for example, be a measure of treatment access or quality.

Figure 2- Example of a multiple baseline design measuring a hypothetical outcome in four counties.



Examining implementation of the intervention across time in different counties will enable the evaluation to monitor the possible influence of extraneous variables (e.g. statewide policies, changes in the state's economy, etc.) on outcome measures with sufficient data. Similar

changes in outcomes following waiver implementation in each county, coupled with the absence of changes in other counties that had not yet opted in at that point in time, suggests that the change observed resulted from the waiver.

While an ideal implementation of this design would include random assignment of the timing of county participation (Hawkins et al., 2007; Sanson-Fisher, 2015), as discussed above, this is not feasible. However, the multiple baseline design can still be used to study the "natural experiment" created by the waiver. Recent examples of such applications of the multiple baseline design include Fell et al. (2014) and Fedeli et al. (2015).

2. Logic Model

The primary goals of the DMC-ODS demonstration are improved access to care, improved quality of care, and better coordination/integration of care, while maintaining cost neutrality for the Medicaid program. These ultimate impacts are reflected in the evaluation logic model (see Appendix A).

Implementation of the waiver will lead to multiple system changes, including selective provider contracting, treatment authorization, and a beneficiary access line; the development of a continuum of care with recovery support services; use of EBPs; requirements for MOUs supporting the facilitation of MAT and physician consultation and coordination of SUD treatment with physical and mental health service; and quality improvement planning.

To determine whether these changes have been effective in supporting an organized system of care, UCLA will examine the availability of services along the full continuum of SUD care, patient placement in treatment according to ASAM Criteria assessment, care transitions and discharges within the SUD continuum of care, coordination and referrals to mental health and medical services, use of EBPs and MAT in SUD treatment, and any health care cost offsets resulting from appropriate use of SUD services. Further description of these measures are described in the following Methods section.

3. Methods

The proposed methods can be divided into four broad domains: Access, Quality, Cost, and Coordination of Care. The measures we are proposing for each of these domains is described below. The data sources cited in this section are described in further detail in the Data Sources section that follows.

A. Access Measures

<u>Hypothesis</u>: Access to treatment will increase in counties that opt in to the waiver compared to access in the same counties prior to waiver implementation and access in comparison counties that have not opted in.

Access will be determined in the aggregate at the county level, or a regional level if multiple small counties choose to use the regional option available to them. Access will be evaluated using the following measures:

Availability and use of full required continuum of care –Data will be used to determine whether all required levels of care are being used in county systems.,For periods prior to implementation CalOMS-Tx will be used as an approximation. CalOMS-Tx provides data on withdrawal management (outpatient, residential hospital, residential non-hospital), outpatient, intensive outpatient/day care rehabilitative, and residential treatment. During waiver implementation, Drug Medi-Cal data will be used to obtain a more exact measure of ASAM levels of care. DHCS is currently adding HCPCS codes and modifiers to identify these ASAM levels of care.

- a) Use of MAT DMC and Medi-Cal claims will be analyzed to examine changes in MAT.²
- b) Number of Admissions (DMC Claims, CalOMS-Tx) DMC claims and CalOMS-Tx data will both be examined to determine changes in the number of admissions by level of care, to determine whether the number of patients accessing care is increasing, decreasing, or remaining the same.
- c) Penetration rates UCLA will examine trends in statewide penetration rates before and after waiver implementation based on CalOMS-Tx data on the number of people entering treatment divided by estimates of the prevalence of dependence from SAMHSA's National Survey on Drug Use and Health (NSDUH). SAMHSA does not report data at the county level, however, and substate data from SAMHSA that would be necessary for county-level analysis is currently unavailable. UCLA therefore proposes to evaluate the waiver with an approach analogous to the "intention to treat" approach commonly used in research. This approach would evaluate the statewide effect of making the waiver available, rather than examining only counties in which it has been implemented. Using this approach, the more counties opt in, the more likely the penetration rates will change. Counties that do not opt in

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² In the STCs, there are two measures that have been combined here due to their overlap. The original measures were Number of Admissions and Numbers and trends by type of service.

will not receive any of the benefits of the waiver and will therefore likely have unchanged penetration rates, just as patients who drop out in treatment studies receive no treatment effect. Based on SAMHSA data currently available, UCLA will be able to estimate penetration rates by alcohol and separately by other illicit drugs.

- d) Adequacy of network UCLA will approach network adequacy using multiple measures:
 - Availability of first appointments: UCLA will call withdrawal management, residential, outpatient, and narcotic treatment program (NTP) treatment providers in counties that do not have a central access point to determine whether treatment is available and how long wait times for admission, if any, are estimated to be. In centralized counties, UCLA will call the centralized number and ask when the first available admission would be. We will also ask when the first available assessment appointment is, if applicable. This will be done in each county at least annually. Amount of time spent on hold will also be recorded.
 - Average distance to provider UCLA will use patient address information from the Medi-Cal Eligibility Data System (MEDS) and provider address information from DHCS's Prime database to estimate whether a subset of patients live within a 15-mile radius from the treatment provider where they received services.
 - i. UCLA will acquire ASAM data from all opt-in counties via DHCS. This data will minimally include the level of care indicated, the level of care the patient was placed in, the reason for the discrepancy, if any, and dates of the assessment. These will be compared to the dates of admission from CalOMS-Tx. Using this data, UCLA will be able to calculate the time from ASAM assessment to admission and the percentage of admissions that match the ASAM level indicated by the assessment. To the extent that there are mismatches, UCLA will determine what percentage of these are due to unavailability of the indicated level of care.
 - Residential, withdrawal management, and NTP capacity UCLA will analyze data from DHCS's Drug and Alcohol Treatment Access Report (DATAR) or state licensing data to determine whether the waiver was associated with changes in residential, withdrawal management, and NTP capacity (number of beds/slots).
 - Outpatient capacity While DATAR data is available for outpatient treatment, there is concern that it may not always reflect the true capacity of outpatient or intensive outpatient programs. Capacity is inherently flexible in these levels of care, since programs can generally add or reduce treatment groups, the number of counselors at the site, or change operating hours to expand or contract capacity at any time. UCLA will therefore use CalOMS-Tx or Medi-Cal billing data to determine the maximum patient census on any given day in these programs over the course of a year to provide an approximate picture of maximum utilization as a proxy for capacity. If other capacity data becomes available during the evaluation, these alternative sources will be used instead if they are determined to be more accurate.
- e) Existence of a 24/7 functioning beneficiary access phone number UCLA will survey all counties (whether they have opted in or not) to determine whether they have a number and whether it provides services in languages other than English. The number will be called to confirm it is functioning.

- f) Availability of services in languages other than English Providers will be surveyed about the languages they provide services in, and patients will be surveyed about whether staff is sensitive to their cultural/ethnic background (e.g., race, religion, language).
- g) Availability of provider directory to patients UCLA will ask county administrators to provide this to the evaluation team.
- h) Patient perceptions of access to care
 - Cross-sectional patient surveys will be administered at multiple time points. Items adapted from the MHSIP or similar survey may be used to measure consumer perceptions of access to care (e.g., location is convenient, services are available when I need them, I am able to see a counselor when I want to). (See data sources below.)
- i) **Initiation/engagement** DHCS will report the Medicaid Adult and Children's Quality Measures for individuals with SUD Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (NQF #0004). Initiation is defined as the percentage of patients who initiate treatment within 14 days of the diagnosis. Engagement is defined as the percentage of patients who initiated treatment and who had two or more additional services within 30 days of the initiation visit.

B. Quality Measures

<u>Hypothesis</u>: Quality of care will improve in counties that have opted in to the waiver compared to quality in the same counties prior to waiver implementation, and quality in comparison counties that have not opted in.

Quality will be evaluated using the following measures:

- a) Use of ASAM criteria-based tool for patient placement and assessment County administrator and treatment provider surveys will include questions inquiring about the status of the ASAM criteria for placing patients in the appropriate level of care and assessment.
- b) Appropriate placement UCLA will acquire ASAM data from all of the opt-in counties (via DHCS) to examine placement using multiple measures.
 - Percent of individuals receiving ASAM criteria-based assessment prior to an admission in level of care. UCLA will acquire ASAM data from all opt-in counties. This data will minimally include the level of care indicated, the level of care the patient was placed in, and dates of the assessment. These will be compared to the dates of admission from CalOMS-Tx data. Using this data, UCLA will be able to calculate the percentage of patients for which the ASAM assessment has been used as the basis to determine the level of care prior to treatment admission.
 - Comparison of ASAM indicated level of care and actual placement and reasons documented for the difference if they do not match - ASAM and CalOMS-Tx data will be analyzed to calculate the percentage of matches between ASAM indicated

level of care and actual placement. Among the cases where there are mismatches, UCLA will calculate the percentage of assessments that have documented reasons for the mismatch. Reasons for mismatches will be analyzed to identify patterns that may indicate quality of care issues (e.g., timeliness of placement, effective ASAM assessment, patient-centered focus). Changes will be tracked before and after waiver implementation, annually over the course of the evaluation, and by modality (residential, NTP, withdrawal management, outpatient) to examine whether the match between the ASAM indicated level of care and actual placement is improving over time and whether the reasons for the mismatches change over time.

- Use of continuing ASAM assessments, appropriate movement UCLA will analyze ASAM assessment data (including dates of assessments, indicated levels of care, and actual placements) to track whether and how frequently ongoing ASAM assessments are being conducted for patients in treatment and the time between assessment and placement in a different level of care, if indicated. UCLA will also track movement to different levels of care (e.g., residential to outpatient) to examine whether and how effectively and efficiently patients are moving along the continuum of care.
- c) Appropriate treatment consistent with level of care after placement, residential:
 - ASAM Audits County ASAM data will be compared to DHCS ASAM audits, which will determine the level of care being provided by residential treatment programs. This will enable the evaluation team to determine how well the ASAMindicated level of treatment (e.g. 3.1, 3.3) matched with the actual treatment level received.
 - Percentage of referrals with successful treatment engagement (based on length of stay) among patients for whom treatment was indicated according to an ASAM assessment. The Washington Circle defines treatment engagement as having two additional SUD treatments within 30 days after initiating treatment. At a minimum UCLA will use CalOMS-Tx data to examine admission and discharge dates to track treatment engagement/retention in treatment³ and length of stay (at least 30 days). Alternatively, if feasible, DMC claims data will be used to count the number of encounters during the 30-day period to provide a more precise measure.
- d) Successful care transitions The Washington Circle defines continuity of care as receiving additional services within a 14-day period after discharge from either withdrawal management or residential treatment. UCLA will analyze CalOMS-Tx or DMC claims data to measure whether patients are moving along the continuum based on the ASAM scores within a timely manner. In addition, questions asking about care coordination practices will be included in the Treatment Provider surveys and care coordination experiences will be included in patient surveys. To the extent possible, Medi-Cal pharmacy data will also be used to determine whether and when SUD medications were filled (billed) following discharge.

e) Successful discharge

• UCLA will track the number of patients who left before completion of treatment with unsatisfactory progress in CalOMS-Tx, which are is the closest measure

³ In the STCs, this was originally listed under Access.

available for discharges against medical advice. Changes will be tracked before and after waiver implementation, and over the course of the evaluation in order to determine changes over time. Discharges will also be compared to counties that have not opted in.

f) Use and monitoring of evidence based practices

• Where possible, the evaluation will collect data from county EBP monitoring and assess the adequacy of such monitoring. The nature of the efforts counties will use to monitor this is unknown at the time of this evaluation plan but will be included in the county implementation plans for opt-in counties. UCLA will develop a plan for assessing county efforts based on the approved implementation plans.

g) Patient perceptions of quality of care

- Cross-sectional patient surveys will be administered at multiple time points. Selected items from the MHSIP or other surveys will be used to measure consumer perceptions of the quality of care (e.g., staff is sensitive to my cultural/ethnic background, staff helps me get the information I need to manage my illness, I, not staff, decide my treatment goals.)
- h) Establishment of quality improvement committees and plans
- i) County administrator surveys (see data sources below) will inquire about counties' quality improvement practices, committees, and plans. Both county administrator and treatment provider surveys will include questions asking about the collection of patient satisfaction/perceptions of care.

j) Outcome Measures

- CalOMS-Tx, Patient surveys
 - i. Alcohol or other drug (AOD) use UCLA will use CalOMS-Tx data to calculate the number of days the patient's primary drug was used in the last 30 days prior to admission and prior to discharge.
 - ii. Social support/social connectedness UCLA will use CalOMS-Tx data to calculate the average number of days in the last 30 days the patient participated in any social support recovery activities (e.g., 12-step meetings, interactions with family member and/or friend supportive of recovery). UCLA will track changes between admission and discharge, and aggregate trends over the course of the waiver.
 - iii. Living arrangements/housing situation UCLA will use CalOMS-Tx data to calculate the percentage of patients with the following living arrangement: currently homeless, dependent living, independent living.
 - iv. Employment CalOMS-Tx data will be used to calculate the percentage of patients reporting their current employment status as the following: employed full time (35 hours or more), employed part time (less than 35 hours), unemployed/looking for work, unemployed/not in the labor force/not seeking, not in the labor force/not seeking.

- v. To the extent that patient outcome questions may be included in the patient perceptions of care survey (see data sources), UCLA analyze changes over time on those measures.
- k) Grievance reports The number of grievances received by the state will be tracked by type (e.g., access, benefits/coverage, quality of care/services) and modality.
- 1) Effectiveness of all levels of care
 - Readmissions to withdrawal management, residential and intensive outpatient treatment will be tracked using CalOMS-Tx and/or DMC claims data. We will analyze readmissions both at 30 days (common in medical care) and 90 days, consistent with a measure discussed by ASAM. In describing their measure, ASAM made the point that in SUD withdrawal management and treatment, waiting lists are common, which justifies allowing a longer period for the person to be readmitted.
 - The following questions will be addressed using CalOMS-Tx outcomes (e.g. emergency room use in the last 30 days), and Medi-Cal claims to determine which health services have been billed.
 - i. Are there differences that are associated with the use of different treatment modalities in health outcomes?
 - ii. Are there differences that are associated with the different residential lengths of stay in health outcomes?

C. Cost Measures

<u>Hypothesis</u>: Health costs will be more appropriate pre/post waiver implementation among comparable patients.

Cost offsets will be evaluated based on Drug Medi-Cal and Medi-Cal data. Where data is available under fee for service, we will have the actual dollar amounts in a paid amount field. Under managed care, encounters and charges will appear, the latter of which aren't necessarily equal to what was paid. To estimate costs in these cases, UCLA plans to conduct "shadow pricing" by using FFS rates to aggregate rates into a diagnosis related group, then assume the cost of the office visit in managed Medi-Cal is the same. UCLA will collaborate closely with DHCS on these efforts. The following measures will be examined:

- a) Change in health care costs for individuals who receive residential care (pre/post and vs. comparable patients placed in other modalities)
- b) Change in ED utilization and costs
- c) Change in inpatient utilization and costs
- d) Change in SUD treatment utilization and costs
- e) Differences in health care costs that are associated with the use of different treatment modalities in costs

- f) Differences in health care costs that are associated with the different residential lengths of stay in costs
- g) Differences in health care costs among patients who receive SUD medications versus patients who do not receive SUD medications, analyzed to the extent possible by location and type of medication.

Overall cost neutrality will be analyzed separately from this evaluation as part of the larger Medi-Cal 2020 waiver evaluation.

D. Coordination Measures

<u>Hypothesis</u>: There will be improved SUD treatment coordination for beneficiaries both within the SUD continuum of services as well as with primary care, mental health, and recovery support services.

Two levels of assessment are required to evaluate the integration and coordination of care component:

- 1. Activities within the SUD continuum of services
- 2. Activities across the healthcare service systems (i.e., SUD with MH and SUD with PC)

To date, there have been limited validated measures in the field on the measurement of integration of services and coordination of care, and even less so specifically focused on SUD integration and/or at the SUD system of care level. UCLA conducted a literature search on published articles, reports, and other resources from leading integrated health care organizations and initiatives (e.g., SAMHSA-HRSA CIHS, AHRQ, NQF, CCI, CalMHSA, etc). Surveys will be informed by these resources (UCLA is also a leading organization in this area). For example, the following will be collected from county administrators: (1) collaboration and communication protocols or activities between departments/divisions; (2) the existence of formal agreements and partnerships across department/divisions; (3) policies or guidelines to their providers to establish formal procedures to partner with MH or PC providers outside of the SUD system; (4) policies or guidelines provided to their providers to establish formal procedures with other SUD providers offering different modalities; and (5) methods in place to track referrals and movement within the SUD continuum of care.

UCLA will measure coordination of care and integration of services within the SUD continuum of services and across the broader health care service systems (MH and PC) by evaluating the following measures:

- a) Using document reviews where possible, coupled with administrator surveys, UCLA will assess the existence of required MOUs with:
 - Comprehensive substance use, physical, and mental health screening, including ASAM Level 0.5 Screening, Brief Intervention, and Referral to Treatment (SBIRT) services;

- Beneficiary engagement and participation in an integrated care program as needed;
- Shared development of care plans by the beneficiary, caregivers and all providers;
- Collaborative treatment planning with managed care;
- Delineation of case management responsibilities;
- A process for resolving disputes between the county and the Medi-Cal managed care plan that includes a means for beneficiaries to receive medically necessary services while the dispute is being resolved;
- Availability of clinical consultation, including consultation on medications;
- Care coordination and effective communication among providers including procedures for exchanges of medical information;
- Navigation support for patients and caregivers; and
- Facilitation and tracking of referrals between systems including bidirectional referral protocols.

In addition, the evaluation team will conduct additional surveys and/or interviews to determine whether and how these required MOU items are actually being implemented. This will include administrator, provider, health plan, and patient surveys (see data sources section below).

- b) Assessment of coordination goals: The following will be assessed using stakeholder surveys and interviews (e.g., health plan, administrator, provider, patient).
 - Comprehensive substance use, physical, and mental health screening. This will be assessed using health plan surveys and SUD program surveys;
 - Beneficiary engagement and participation in an integrated care program as needed. This will be assessed using SUD treatment provider surveys and patient surveys.
 - Shared development of care plans by the beneficiary, caregivers and all providers. This will be assessed using SUD treatment provider surveys and patient surveys.
 - Care coordination and effective communication among providers. This will be assessed using county administrator and SUD treatment provider surveys.
 - Navigation support for patients and caregivers. This will be assessed using county administrator and SUD treatment provider surveys.
 - Facilitation and tracking of referrals between systems. This will be assessed using county administrator surveys and treatment program surveys.
- c) Referrals to and from primary care and mental health quantified using information from CalOMS-Tx on whether patients were referred from other health care providers, coupled with surveys and interviews with SUD administrators, providers, and health plan stakeholders.
- d) Referrals to and from recovery services paid for by the DMC-ODS Although claims may help to quantify these recovery services, there are no existing datasets that track referrals to

and from these services. Therefore, UCLA will use stakeholder surveys and/or interviews to understand current and emerging practices.

- e) SUD identification in the health care system. To the extent possible, Medi-Cal diagnosis codes will be used to examine trends in SUD identification in the health system.
- f) Follow-up after discharge from the Emergency Department for Alcohol or other drug use. To the extent possible Medi-Cal diagnosis codes and Drug Medi-Cal claims data will be used to measure the extent to which patients with SUD begin SUD treatment.

4. Data Sources

The data sources below will be used to create the measures described above.

See Appendix B for the list of data sources (below) organized by domain, and Appendix C for a timeline for data collection.

1. Administrative data sources⁴

• CalOMS-Tx – CalOMS Treatment (CalOMS-Tx) is California's existing data collection and reporting system for all patients in publicly-funded substance use disorder (SUD) treatment services (data will be linked to Drug Medi-Cal claims to identify patients whose treatment is funded by this source specifically). Treatment providers collect information from patients at admission and discharge, and send this data to DHCS each month. This treatment data includes patient information on alcohol/drug use, employment and education, legal/criminal justice, medical/physical health, mental health, and social/family life. CalOMS-Tx meets national requirements for the Treatment Episode Dataset (TEDS) maintained by the Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration (SAMHSA) and includes National Outcome Measures (NOMS). More information on CalOMS-Tx can be found at:

http://www.dhcs.ca.gov/provgovpart/Pages/CalOMS-Treatment.aspx

To the extent possible CalOMS-Tx and Drug Medi-Cal claims data will be examined together to check for inconsistencies and conduct data cleaning as necessary.

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⁴ These data sets have many of the same shortcomings as other administrative data sets, particularly related to inconsistent reporting and missing data (see for example Evans, et al, 2010 for a discussion of CalOMS-Tx). However, while these factors inject noise and potential biases due to underreporting into the data, as long as these factors are largely consistent over time and across large numbers of counties, the important comparisons in this design can still be carried out. For example, outcome data (e.g. drug use in the last 30 days) is sometimes missing at discharge, particularly among patients in outpatient treatment who do not complete their treatment. This means the absolute percentage of patients using drugs at discharge may be understated if one takes CalOMS-Tx data at face value. However, when comparing data from the same county (or statewide) over time, as long as the same bias is present at both time points (which can be checked, and adjusted for if necessary), the relative difference between the two time points can still be measured (i.e., if drug use at discharge is rising or falling, even if the absolute level may be unclear). Consistent with this, CalOMS-Tx data has been used in a large number of peer-reviewed publications.

- DATAR Drug and Alcohol Treatment Access Report (DATAR) is the DHCS statewide system to collect data on SUD treatment capacity and waiting lists. DATAR is useful for measuring treatment capacity where capacity is easily measured by beds or slots. For more information on DATAR, see http://www.dhcs.ca.gov/provgovpart/Pages/DATAR.aspx. Where possible, DATAR will also be compared to program licensing data to check for discrepancies. If discrepancies are found, UCLA will discuss this with DHCS to determine the best course of action.
- Medi-Cal Eligibility Data System (MEDS) The MEDS contains data on all Medi-Cal beneficiaries statewide, including demographic information and residential addresses.
- Medi-Cal/DMC Claims Data The evaluation will use California's data for Medicaid claims in addition to the MEDS, which provides identifying information on Medi-Cal eligible beneficiaries that can allow linkage to other datasets (e.g., CalOMS-Tx).
- **NSDUH** SAMHSA's National Survey on Drug Use and Health (NSDUH). This national survey provides limited conservative state-level estimates of alcohol and illicit drug use prevalence.
- **Prime** DHCS's Prime system contains information on all SUD provider facilities, including mailing addresses and DMC certification and decertification dates, among other provider-level information.

In addition to the above datasets, UCLA will evaluate others, e.g. data from the California Office of Statewide Health Planning and Development (OSHPD) or any other datasets that may become available during the evaluation to determine whether they would add substantially to the planned analyses. If so, these datasets will be incorporated into the evaluation to the extent possible.

2. New data collection activities (specific for the evaluation)

Where secondary analysis of existing datasets will not adequately address the hypotheses, UCLA will supplement this data with additional primary data collection:

ASAM Criteria Data

Counties that have opted in to the waiver will collect ASAM criteria data as part of their medical necessity determination under DMC ODS. Data from all assessments will be sent to DHCS, which will then share it with UCLA for evaluation purposes. The total sample size will depend on the number of counties opting in and the number of clients seeking treatment in those counties, but is exected to be substantial. At a minimum this data will include the date of the assessment, the type of treatment indicated, the type of treatment the patient was actually referred to, the reason for the difference (if any), and sufficient identifying information to enable data matching to other data sources (e.g., to CalOMS-Tx, to determine

whether and where the patient actually entered treatment). ASAM data will be used to address access and quality of care measures as described in the previous section, as well as to satisfy state reporting requirements as described in the STCs. ASAM criteria data is not expected to be available before waiver implementation or in counties that are not participating in the waiver, so it will be a used for descriptive purposes and to track trends during the course of the demonstration.

Stakeholder Surveys

The stakeholder surveys will address multiple needs. For example, the treatment provider surveys will include questions on access to care, quality of care, and coordination of services within and outside of the SUD system of care (e.g. with primary care). These questions will supplement the administrative data analyses we will be conducting on these same issues.

UCLA County Administrator Survey - UCLA will collect information from county administrators in both opt-in and non-opt-in counties through this web-based survey, with items pertaining to three of the four evaluation domains: access to care; quality of care; and coordination of care within the SUD continuum of care and with the physical health and mental health systems. UCLA will also inquire about implementation challenges and training/technical assistance needs to help inform State level implementation activities. This information will supplement information submitted by administrators in their County Implementation Plans.

UCLA Treatment Provider Survey - UCLA will conduct web-based surveys of a selected sample of providers at the service delivery unit (SDU) level. An SDU refers to a treatment modality (e.g., inpatient, outpatient, methadone maintenance) at a specific site. UCLA has adopted this terminology in order to avoid ambiguity associated with the term "treatment program," which may indicate different levels depending on provider type.

The SDU-level survey will contain questions relating to services provided at the SDU and will be directed toward the clinical director of the SDU. Data pertinent to answering the research questions in the Access (e.g., treatment capacity), Quality (e.g., ASAM criteria, electronic health records) and Coordination of Care (e.g., partnerships with other treatment and recovery support providers, levels of integration with physical and mental health scare systems) domains of the evaluation will be collected.

UCLA Managed Care Plan Survey - UCLA will conduct short web-based surveys of Medi-Cal managed care plan representatives to assess perspectives and practices relevant to coordination of care with SUD treatment systems, including: prevalence of early intervention practices (e.g., screening, brief intervention, referral to specialty SUD services); perceptions about the extent to which substance use conditions among their members contributes to the costs of medical care; coordination activities with SUD treatment providers; and use of data to track the medical costs of members with SUD diagnoses and the impact of substance use treatment on medical costs.

UCLA Patient Survey - Discussions are ongoing with DHCS and other stakeholders regarding use of an adapted (simplified) version of the Mental Health Statistics Improvement Program (MHSIP) survey⁵ or other similar survey to collect data on consumer experiences with and perceptions of care. Specific items or components from validated surveys widely used with consumers receiving behavioral health services, including SUD (e.g., Modular Survey, Treatment Effectiveness Assessment, Experience of Care and Health Outcomes [ECHO]), will be reviewed and incorporated into the survey to collect data needed to answer the evaluation's research questions while balancing this against practical considerations, in recognition that this survey could lay the groundwork for ongoing surveys of this nature in SUD programs in California.

As county behavioral health departments receiving MHBG funds are already familiar with and experienced in administering the MHSIP survey, with some counties incorporating the results into their quality improvement efforts (e.g., external quality reviews, performance improvement projects) for specialty mental health services, the current adult MHSIP form (to be used for ages 18 and over) is a candidate for adaptation to address SUD services for purposes. The survey would be shortened but also include an additional construct: perception of coordination and integration of care. UCLA is aware of at least two counties in California that are using the MHSIP survey with consumers receiving services in both SUD and MH publicly funded treatment programs. In addition, several other counties are including adaptations of the MHSIP survey in their SUD patient surveys. Further, a search of the Internet shows that at least two states (Connecticut and Nebraska) are using the MHSIP survey for consumers in both their SUD and MH treatment systems. However, because the MHSIP survey was developed for and is widely used with consumers receiving services in publicly funded mental health systems, to our knowledge, data on the reliability and validity of the instrument for consumers receiving services in SUD treatment facilities have not been established (e.g., published). UCLA will conduct a stakeholder engagement process to determine how to collect this data and provide results using procedures that are most useful and least burdensome to stakeholders, while still addressing evaluation needs.

The California Institute for Behavioral Health Solutions (CIBHS) is the current contractor responsible for coordinating the collection of MHSIP data twice a year, as part of the California DHCS' Performance Outcomes and Quality Improvement program, for purposes of annually reporting National Outcomes Measures for mental health services required by SAMHSA for states receiving MHBG funds. There are four types of forms available: adult, older adult, youth services survey, and youth services survey for families. Each of these

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⁵ The MHSIP was developed through a collaborative effort of consumers, the Mental Health Statistics Improvement Program (MHSIP) community, and the Center for Mental Health Services. It has been nationally standardized and is in wide use by 55 states and territories, including California. Survey results can be compared across states over time. States that receive Mental Health Block Grant (MHBG) funds from SAMHSA routinely collect adult consumer survey data using the MHSIP to fulfill federal requirements for reporting indicators of outcomes. Various versions of the MHSIP survey that are available in the public domain ask consumers to report on their experiences with behavioral health care and cover the following domains: general satisfaction; perception of access; perception of quality and appropriateness; perception of participation in treatment planning; perception of outcomes of services; perception of functioning; and perception of social connectedness.

forms is available in seven languages (English, Spanish, Chinese, Russian, Vietnamese, Tagalog, and Hmong).

CIBHS has agreed to serve as consultants to UCLA to modify the form and protocol for the SUD treatment system. (See Appendix D for the current adult MHSIP form.) Data from the survey will be used for the current evaluation to measure consumer perceptions of access, quality of care, and coordination/integration of care. As part of the evaluation, MHSIP data will be collected once during the first year of the evaluation, with at least one follow-up survey toward the end of the waiver. UCLA will select providers to participate from a representative subsample of Treatment Provider Survey respondents (see above).

Stakeholder Survey Sampling Strategies - County administrator surveys will be targeted toward the full population of 57 administrators (although there are 58 counties, Yuba and Sutter counties are administratively combined for SUD purposes, leaving a total of 57).

Treatment provider surveys will be administered to a representative sample of providers stratified by size, region, and level of care. Surveys will be conducted at the service delivery unit (SDU) level, i.e. one treatment level at one location. Baseline surveys will be administered upon implementation plan approval (these surveys require sampling and therefore the baseline sampling will occur after implementation plan approval (and approval of this evaluation plan) in order to allow us to determine which counties are opt-in vs opt-out (or early opt in vs later opt in, as the case may be). We believe implementation will not occur immediately, so it will still be possible to take a "baseline" measure shortly after implementation plan approval.

For patient surveys, if the MHSIP survey is used, sampling may be generally consistent with current mental health practices, which involve surveying the population of patients present in participating programs during a designated time frame. The data collection methods will be discussed during the stakeholder engagement process on this topic, and procedures may be adjusted accordingly. For evaluation purposes, a subset of the sample of treatment provider survey respondents will be used.

Qualitative Stakeholder Interviews

The evaluation team will conduct key informant interviews and/or focus groups (group interviews) with stakeholders (e.g., county administrators, managed care plan representatives) concurrently with the survey data collection and administrative data analysis at baseline and at multiple time points throughout the waiver demonstration. Although UCLA does not plan to conduct systematic statewide interviews with consumer stakeholders due to resource constraints, if the consumer and/or treatment provider perspective is needed to help evaluators interpret the consumer and/or treatment provider survey results, several focus groups will be held for this purpose.

Interviews and/or focus groups will be conducted with stakeholder groups (e.g., county administrators, managed care plan representatives) following the initial round of survey administration and at several time points after implementation of the waiver (e.g., several months after county implementation plans are approved and again during the waiver period). The purpose of the individual and group interviews is to collect in-depth and emerging data on a range of stakeholders' experiences with and perceptions of the waiver implementation,

including factors facilitating and impeding the implementation, and recommendations for improving the implementation, particularly in terms of access to care, quality of care, and coordination/integration of care. The information-rich data will be used to complement the quantitative data collected for purposes of corroboration/triangulation as well as to provide more in-depth information that affords a deeper understanding of stakeholders' perspectives and experiences. This information will help with the interpretation of the quantitative data, reveal lessons learned from the stakeholder perspectives to inform the State's and counties' implementation efforts, identify emerging areas for further examination, and ultimately contribute toward answering the research questions. Selected samples of county administrators (e.g., the first five counties that obtain implementation plan approval in each of the Phases), managed care plan representatives, and other key stakeholders will initially be interviewed early on during the implementation of counties' approved implementation plans. This qualitative work will help inform other counties' and the State's planning and implementation efforts (e.g., implementation barriers, strategies to overcome barriers, promising practices, lessons learned, training and technical assistance needs, unintended/unanticipated consequences of the waiver).

Experienced qualitative interviewers will use semi-structured interview guides, which will include probing questions tailored to the stakeholder group (e.g., questions for each county administrator based on that county's survey responses and approved implementation plan). Interviews will be conducted in person or by phone and will last approximately 60 minutes, and focus groups 60-90 minutes. Individual and group interviews will be audio recorded and transcribed. Interviews will be conducted at several time points during the evaluation. The initial interview protocols will be modified prior to subsequent interviews to address new issues that may emerge during the course of the waiver evaluation.

3. Document Review

UCLA will review county implementation plans and county MOUs with managed care plans, and may review other documents such as grievance reports, in order to inform evaluation activities. UCLA will obtain these documents from DHCS and intends to use the information collected to gain background on county practices and specific plans for implementation, inform sampling procedures, and help develop stakeholder surveys and guides for qualitative interviews. These activities will complement but not duplicate DHCS's planned review process, which is intended to ensure that baseline requirements from the STCs are met in order for counties to begin implementation.

5. Analysis Plan

A. Statistical Data Analysis

Multivariate regression models using indicator variables for county opt-in status (counties have or have not yet opted in) along with other possible confounding factors will be used to control for differences based on characteristics (e.g. potentially Medi-Cal enrollment, race, age, geographic region). It is also possible to test for interactions between these confounding variables and opt-in status. When looking at binary outcomes, it is possible to account for the differences using logistic regression. For example, there might be overall differences in gender in an outcome, yet the difference may be more pronounced on the opt-in counties than those who have not or have not yet opted in. Interaction terms between the opt-in status and gender, in this case, could detect that difference.

When longitudinal quantitative data is available annually (e.g. administrative data, survey data), generalized linear models (mixed effects models) will be used to model changes over time. This is similar to the multivariate regression model above. Mixed effects regression models can account for the correlation seen between years within the same county. For instance, if one county is better at transitioning those coming out of withdrawal management to another level of care, then that will influence the next year's measurement within that county. Generalized linear models can also handle the clustering or hierarchical nature of treatment providers within counties. When looking at provider level data from surveys, it is necessary to account for differences that are at a county level, such as some counties having a centralized placement system or having specific transition policies in places while other counties may not have these. An analogous set of analyses can be conducted using a logistic mixed model to account for binary outcomes over time.

Where data (e.g., administrative data) is sufficient, a multiple baseline approach (also known as a *discontinuity mixed model* or *piecewise mixed model*) may be applied to account for different implementation periods and comparisons among the two county types (e.g., looking at data pre-implementation, partial implementation when some counties have implemented the waiver and some are yet to do so, and post-implementation, using a separate mixed effects model for each piece of the data).

An interrupted time series analysis (intervention model) is another way to account for the pre-implementation and post-implementation differences. This uses a specialized autoregressive integrated moving-average (ARIMA). ARIMA models take into account previous values to predict the next one in the series. ARIMA models can only be applied whenever the data has a sufficient number of data points equally spaced across time. Therefore, this model may not be applicable to some measures. For instance, when looking at utilization of residential programs in Phase I counties, monthly numbers can be calculated from CalOMS. The ARIMA model will enable accounting for seasonal changes over multiple years, the correlated nature of the repeated measure, and help determine if there has been overall growth over the duration of the waiver. If more appropriate, the piecewise model discussed above will be used instead.

In some cases, data may be insufficient for the analyses described above, e.g. due to an insufficient number of time points, low number of participating counties during early analyses, or severe violations of underlying statistical requirements, e.g. normality. In these cases repeated measures methods will be used to compare baseline to any specific later observation or composite of later observations. If necessary, methods that are robust to violations of normality or equality of variance can be employed.

Power analysis

Since statistical significance is a way of evaluating the likelihood that differences found in a sample would be found in the full population, in the case of the main administrative data analyses statistical power will not come into play because we are analyzing the data from essentially the full population. The same is true of surveys of county administrators and managed care organizations, since we will be surveying the entire populations. For surveys of treatment providers, however, it will become a consideration, since we will be conducting surveys on a sample of providers.

Although the number may be adjusted up or down based on resource availability, our current proposed sample size of 300 provider surveys will be able to detect a small effect size (d) of 0.16 in estimating the pre-and-post change of a continuous outcome. In testing a change of an outcome status between baseline and the year 1 follow-up (i.e., McNemar test for ratio of discordant: $p_{12}/p_{21}=1$), the detectable ratio (p_{12}/p_{21}) will be 2.24, 1.84, 1.72 and 1.61 when proportion of discordant pairs in the studied sample is 20%, 30%, 40% and 50%, respectively.

Additionally, the proposed sample will provide adequate statistical power in two-group comparisons (i.e., opted-in vs. opted-out counties). The sample size will be allowed for detecting an effect size (d) of 0.32 given a balanced sample in the two groups (i.e., opted-in vs. opted-out counties). Even in comparison of two groups with an unbalanced sample, a moderate effect size of 0.34 and 0.43 is still detectable given a sample of 100 vs. 150 and a sample of 50 vs. 250, respectively. The detectable difference in measures associated with rates (%) with a balanced sample in the two groups will range from 12% to 16% when the rate in the study population is 50%-10%. With an unbalanced sample of 50 vs. 250, the detectable difference in rates will be 17-21% when the rate in the study population is 50%-10%.

In multiple regression analysis, which defines opted-in vs. opted-out as the main independent covariate and baseline measures as other controlling covariates, the sample will detect R² of 0.06 with 15 covariates. Using logistic regression to assess predictors of a binary outcome, the sample will allow for the detection of odds ratios of 1.54-1.81 for a predictor controlling for other predictors, assuming moderate correlations of 0.1-0.5 among controlling predictors with the outcome and about 20% successful outcome rate.

All analyses above were computed with a two-sided alpha of .05 and power of .80.

B. Qualitative Analysis

The qualitative data collected from the different stakeholder groups (e.g., county administrators, managed care plan representatives, treatment providers) will be analyzed separately as well as across the different groups, by phase of implementation, and over time (e.g., early vs. later in the implementation of the waiver) to identify themes and patterns. As the interviews and/or focus groups with county administrators and managed care plan medical directors will be conducted after they have completed the baseline surveys (prior to submission of counties' implementation plans) and after counties have obtained approval of their implementation plans, the rich detailed information will give a deeper understanding of stakeholders' experiences, which will be used to supplement and expand on the survey data to answer the research questions.

In addition, the evaluation team will systematically review results from both the qualitative (e.g., semi-structured interviews, focus groups, responses to open-ended survey questions, documents) and quantitative (e.g., survey, administrative) data sets, consider how they contribute to answering the research questions in the relevant domains, and examine whether and where the results from the data sets converge, complement one another, and expand on one another (Palinkas et al., 2011).

Data analyses and interpretation will begin as soon as qualitative data collection and document review start, and will continue in a systematic and iterative process according to established and accepted procedures for qualitative research (Cresswell, 2003; Glaser & Strauss, 1967; Patton 1990). This process involves the repeated reading of the transcripts and notes, developing code lists, and coding the data to identify, compare and contrast emerging patterns and themes using the constant comparative method (Glasser & Strauss, 1967).

Preliminary code lists will be guided by three of the evaluation domains of focus - access, quality, and coordination of care. Examples of preliminary codes include: major environmental changes, barriers/challenges to implementation, training/technical assistance needs, promising practices, unintended/unanticipated consequences of the waiver, client flow, lessons learned, capacity, MAT, recovery services, ASAM criteria, staffing, data collection and monitoring, care coordination with mental health, care coordination with physical health. In addition, inductive codes that emerge from the data collected will be added, and adjustments and refinements will be made to the initial code lists using an iterative process as the data are collected to develop primary and secondary codes. ATLAS.ti, a computerized qualitative data management and analysis software program, will be used to organize the data and conduct these analyses. Portions of coded transcripts will be randomly and independently coded by two researchers to ensure that the codes are being applied consistently and have acceptable levels of agreement indicating good reliability. The evaluation team will meet regularly to share insights and observations from the interviews and/or focus groups throughout the evaluation and discuss emerging themes. Multiple researchers will review the analytic findings, qualitative data will be triangulated with survey and other quantitative data, and preliminary findings will be shared with the Evaluation Advisory Board and other stakeholder groups (e.g., CBHDA, consumer focus groups, treatment providers), and their input solicited to help interpret the findings.

6. Evaluation Implementation

A. Independent Evaluation

The evaluation will meet all standards of leading academic institutions and academic journal peer review, as appropriate for each aspect of the evaluation, including standards for the evaluation design, conduct, interpretation, and reporting of findings. Among the characteristics of rigor that will be met for the interim and final evaluations are use of best available data and controls for and reporting of the limitations of data and their effects on results and the generalizability of results. Treatment and control or comparison groups will be used, and appropriate methods will be used to account and control for confounding variables. The evaluation design and interpretation of findings will include triangulation of various analyses, wherein conclusions are informed by all results with a full explanation of the analytic limitations and differences.

B. Additional Data

CMS is exploring availability of additional state data from a comparable state to be used for comparison. If these data become available, the evaluation team will work with CMS to include these data in the evaluation.

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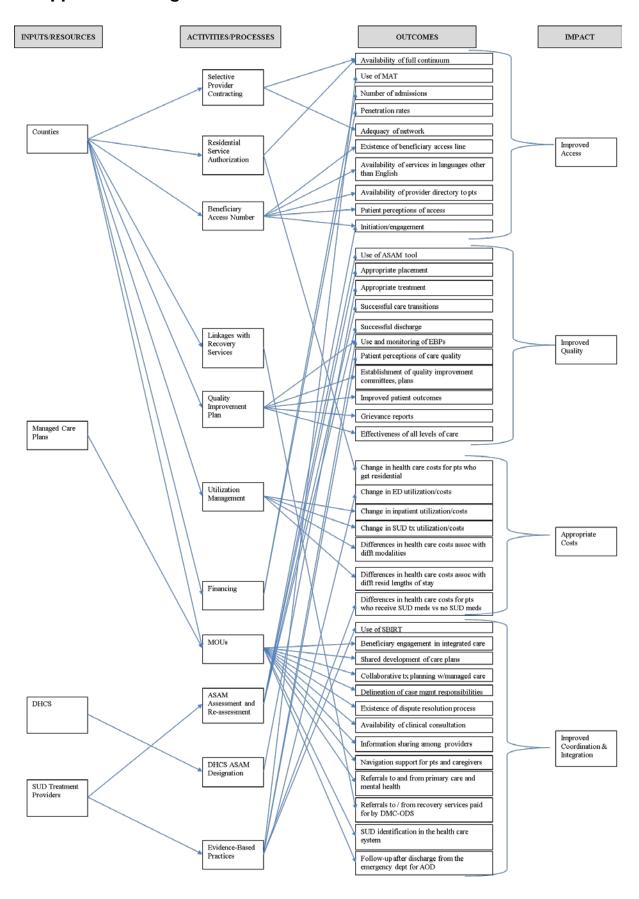
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Appendices

Appendix A: Logic Model



Appendix B: Data Sources by domain

ACCESS	QUALITY	COORDINATION /INTEGRATION	COST
	Administrative I	Data Sources	
Availability and use of required continuum of care Use of medication assisted treatment Number of admissions Statewide penetration rates Maximum utilization (see also DMC Claims)	CalOMS-Tx Successful care transitions Successful discharge vs. discharges against medical advice Patient AOD use Patient social support Patient living arrangements Patient employment	CalOMS-Tx ● Referrals to and from primary care and mental health (also using DMC billing data)	
Drug Medi-Cal Claims Use of medication assisted treatment (also see CalOMS-Tx) Number of admissions (also see CalOMS-Tx) Maximum utilization (also see CalOMS-Tx)		Prug Medi-Cal Claims ■ Referrals to and from recovery services paid for by the DMC-ODS	■ SUD treatment utilization and costs
 DATAR Capacity in state- licensed residential treatment, withdrawal management, and NTP 			
	OSHPD Chemical Dependency Recovery Hospitals and		

Medi-Cal Claims • # admissions, # patients receiving MAT, telehealth billing, use of other services (ER, hospital inpatient days,	freestanding psych (in conjunction with Medi-Cal claims, or surveys as necessary) Medi-Cal Claims • ER and psychiatric emergency visits; hospital inpatient days		Medi-Cal Claims • Health care utilization and costs
MH) NSDUH Prevalence of dependence			
 MEDS Average distance to provider (using patient address information) 			
Prime • Average distance to provider (see MEDS)			
	New Data C	Collection	
Stakeholder Surveys and/or Interviews	Stakeholder Surveys and/or Interviews	Stakeholder Surveys and/or Interviews	
	Patient Surveys	Patient Surveys • Patient perceptions of coordinated care	

Level of care indicated and actual placed level of care	ASAM Data • Appropriate placement		
	 DHCS Audits Appropriate treatment consistent with level of care after placement 		
Existence of a 24/7 functioning beneficiary access number Existence of a 24/7 functioning beneficiary access number in languages other than English Availability of services in language other than English Availability of provider directory to patients	● Grievance reports	Existence of required MOUs	
Participant Observation			

Appendix C: DMC-ODS Waiver Evaluation Activities Timeline

Planned Activities by County Stage of Waiver Implementation

(Analysis dependent on implementation stage)

	Pre- Implementation Plan Approval	Upon Implement ation Plan Approval (0-12 months)	Annual Follow-ups
Administrative Data:			
CalOMS-Tx	X	X	X
DATAR	X	X	X
OSHPD	X	X	X
MEDS	X	X	X
Medi-Cal/Drug Medi-Cal Claims	X	X	X
NSDUH	X	X	X
Prime	X	X	X
New Data Collection:			
ASAM Criteria Data		X	X
UCLA Treatment Provider Survey		X	X^1
UCLA Patient Survey		X	X
Stakeholder Interviews		X	X

X = Activity to occur at least one time during stage

 X^1 = Treatment Provider Surveys will be conducted every <u>two years</u> after the initial round.

Planned Activities by Waiver Demonstration Year

(Analysis NOT dependent on implementation stage)

	Year 1	Year 2	Year 3	Year 4	Year 5
New Data Collection:					
UCLA County Administrator Survey	X	X	X	X	X
UCLA Managed Care Plan Survey	X	X	X	X	X
County/DHCS Audit	X	X	X	X	X

X = Activity to occur at least one time during year period

Appendix D: Sample Adult MHSIP Form



ADULT SURVEY Spring 2015

ENGLISH
Without QOL



Please help our agency make services better by answering some questions. Your answers are confidential and will not influence current or future services you receive. For each survey item below, please fill in the circle that corresponds to your choice. Please fill in the circle completely.

EXAMPLE: Correct Incorrect

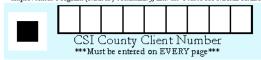
MHSIP Consumer Survey*:

Please answer the following questions based on the LAST 6 MONTHS <u>OR</u> if you have not received services for 6 months, just give answers based on the services you have received so far. Indicate if you **Strongly Agree**, **Agree**, are **Neutral**, **Disagree**, or **Strongly Disagree** with each of the statements below. If the question is about something you have not experienced, fill in the circle for **Not Applicable** to indicate that this item does not apply to you.

		Strongly Agree	Agree	I am Neutral	Disagree	Strongly Disagree	Not Applicable
1.	I like the services that I received here.	Ŏ	0	0	0	0	0
2.	If I had other choices, I would still get services from this agency.	0	0	0	0	0	0
3.	I would recommend this agency to a friend or family member.	0	0	0	0	0	0
4.	The location of services was convenient (parking, public transportation, distance, etc.).	0	0	0	0	0	0
5.	Staff were willing to see me as often as I felt it was necessary.	0	0	0	0	0	0
6.	Staff returned my calls within 24 hours.	0	0	0	0	0	0
7.	Services were available at times that were good for me.	0	0	0	0	0	0
8.	I was able to get all the services I thought I needed.	0	0	0	0	0	0
9.	I was able to see a psychiatrist when I wanted to.	0	0	0	0	0	0
10.	Staff here believe that I can grow, change and recover.	0	0	0	0	0	0
11.	I felt comfortable asking questions about my treatment and medication.	0	0	0	0	0	0
12.	I felt free to complain.	0	0	0	0	0	0
13.	I was given information about my rights.	0	0	0	0	0	0
14.	Staff encouraged me to take responsibility for how I live my life.	0	0	0	0	0	0
15.	Staff told me what side effects to watch out for.	0	0	0	0	0	0
16.	Staff respected my wishes about who is, and who is not to be given information about my treatment.	0	0	0	0	0	0
17.	I, not staff, decided my treatment goals.	0	0	0	0	0	0
18.	Staff were sensitive to my cultural background (race, religion, language, etc.).	0	0	0	0	0	0
19.	Staff helped me obtain the information I needed so that I could take charge of managing my illness.	0	0	0	0	0	0
20.	I was encouraged to use consumer-run programs	0	0	0	0	0	0
$\mathbf{A}\mathbf{s}$	(support groups, drop-in centers, crisis phone line, etc.). a direct result of the services I received:	Strongly Agree	Agree	I am Neutral	Disagree	Strongly Disagree	Not Applicable
	. I deal more effectively with daily problems.	Ô	0	0	0	o	0
	2. I am better able to control my life.	0	0	0	0	0	0

*The MHSIP Consumer Survey was developed through a collaborative effort of consumers, the Mental Health Statistics Improvement Program (MHSIP) community, and the Center for Mental Health Services.

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DHCS 1740 EN (05/13)





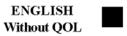
ENGLISH Without QOL Not I am Strongly Strongly Disagree As a direct result of the services I received: Agree Applicable Agree Neutral Disagree 23. I am better able to deal with crisis. O 24. I am getting along better with my family. 25. I do better in social situations. 26. I do better in school and /or work. 27. My housing situation has improved. 28. My symptoms are not bothering me as much. 29. I do things that are more meaningful to me. 30. I am better able to take care of my needs. 31. I am better able to handle things when they go wrong. 32. I am better able to do things that I want to do. For Questions #33-36, please answer for relationships with Strongly I am Not Strongly persons other than your mental health provider(s). Disagree Agree Applicable Neutral Agree Disagree As a direct result of the services I received: 33. I am happy with the friendships I have. 34. I have people with whom I can do enjoyable things. O 35. I feel I belong in my community. 36. In a crisis, I would have the support I need from O family or friends.

CONTINUED ON NEXT PAGE...









Please answer the following questions to let us know how you are doing.

Please answer Questions #2 - 4, below, if you have been receiving services for ONE YEAR OR LESS. If you have been receiving services for "MORE THAN ONE YEAR," please SKIP to Questions #3. 2. Were you arrested since you began to receive mental health services? O Yes O No 3. Were you arrested during the 12 months prior to that? O Yes O No 4. Since you began to receive mental health services, have your encounters with the police O been reduced (for example, I have not been arrested, hassled by police, taken by police to a shelter or crisis program) O increased O not applicable (I had no police encounters this year or last year) Please answer Questions #5 - 7 only if you have been receiving mental health services for "MORE THAN ONE YEAR." 5. Were you arrested during the last 12 months? O Yes O No 6. Were you arrested during the last 12 months Prior to that? O Yes O No 7. Over the last year, have your encounters with the police O been reduced (for example, I have not been arrested, hassled by police, taken by police to a shelter or crisis program) O stayed the same O increased O not applicable (I had no police encounters this year or last year) Please answer the following questions to let us know a little about you. 8. What is your gender? O Female O Male O Other 9. Are you of Mexican / Hispanic / Latino origin? O Yes O No O Unknown 10. What is your race? (Please mark all that apply.) O American Indian / Alaskan Native O Native Hawaiian / Other Pacific Islander O Unknown O Asian O White / Caucasian O White / Caucasian O Other	 Approximately, how long have you reco O This is my first visit here. O I have had more than one visit but I have received services for less than one mont 	O 1 - 2 Months O 3 - 5 Months	More than 1 year
3. Were you arrested during the 12 months prior to that? O Yes O No 4. Since you began to receive mental health services, have your encounters with the police O been reduced (for example, I have not been arrested, hassled by police, taken by police to a shelter or crisis program) O stayed the same O increased O not applicable (I had no police encounters this year or last year) SKIP to Question #8, below Please answer Questions #5 - 7 only if you have been receiving mental health services for "MORE THAN ONE YEAR." 5. Were you arrested during the last 12 months? O Yes O No 6. Were you arrested during the 12 months prior to that? O Yes O No 7. Over the last year, have your encounters with the police O been reduced (for example, I have not been arrested, hassled by police, taken by police to a shelter or crisis program) O stayed the same O increased O not applicable (I had no police encounters this year or last year) Please answer the following questions to let us know a little about you. 8. What is your gender? O Fernale O Male O Other 9. Are you of Mexican / Hispanic / Latino origin? O Yes O No O Unknown 10. What is your race? (Please mark all that apply.) O American Indian / Alaskan Native O Native Hawaiian / Other Pacific Islander O Unknown O Asian O White / Caucasian O Black / African American			
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Please answer Questions #5 - 7 only if you have been receiving mental health services for "MORE THAN ONE YEAR." 5. Were you arrested during the last 12 months? O Yes O No 6. Were you arrested during the 12 months prior to that? O Yes O No 7. Over the last year, have your encounters with the police O been reduced (for example, I have not been arrested, hassled by police, taken by police to a shelter or crisis program) O stayed the same O increased O not applicable (I had no police encounters this year or last year) Please answer the following questions to let us know a little about you. 8. What is your gender? O Female O Male O Other 9. Are you of Mexican / Hispanic / Latino origin? O Yes O No O Unknown 10. What is your race? (Please mark all that apply.) O American Indian / Alaskan Native O Native Hawaiian / Other Pacific Islander O Unknown O Asian O White / Caucasian O Black / African American O Other			
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10. What is your race? (Please mark all that apply.) O American Indian / Alaskan Native O Native Hawaiian / Other Pacific Islander O Unknown O Asian O White / Caucasian O Black / African American O Other	8. What is your gender? O Female	O Male O Other	
O American Indian / Alaskan Native O Native Hawaiian / Other Pacific Islander O Unknown O Asian O White / Caucasian O Black / African American O Other	9. Are you of Mexican / Hispanic / L	atino origin? O Yes O No	O Unknown
	O American Indian / Alaskan Native O Asian	O Native Hawaiian / Other Pacific O White / Caucasian	: Islander O Unknown CONTINUED ON NEXT PAGE

CSI County Client Number
Must be entered on EVERY page



	Without QOL
11. What is your date of birth? (Write it in the boxes A Date of Birth (mm-dd-yyyy)	AND fill in the circles that correspond. See Example.) EXAMPLE: Date of birth on April 30, 1967: Date of Birth (mm-dd-yyyy) 1. Write in your date of birth 2. Fill in the corresponding circles 2. Fill on the corresponding circles
12. Were the services you received provided in the lan	guage you prefer? O Yes O No
Was written information (e.g., brochures describing health education materials) available to you in the	ng available services, your rights as a consumer, and mental e language you prefer? O Yes O No
 14. What was the primary reason you became involve O I decided to come in on my own. O Someone else recommended that I come in. O I came in against my will. 	ed with this program? (Mark one):
 15. Please identify who helped you complete any part O I did not need any help. O A mental health advocate / volunteer helped me. O Another mental health consumer helped me. O A member of my family helped me. 	of this survey (Mark all that apply): O A professional interviewer helped me. O My clinician / case manager helped me. O A staff member other than my clinician or case manager helped me. O Someone else helped me. Who?:
negative feedback. Also, if there are areas which v been, please write them here. Thank you for your	of this form, if needed. We are interested in both positive and were not covered by this questionnaire which you feel should have time and cooperation in completing this questionnaire.
, ,,	time to answer these questions!
FOR OFFI	CE USE ONLY:
REQUIRED Information: County Code:	Optional County Questions: County Question #1 (mark only ONE bubble):
Date of Survey Administration:	O 01 O 02 O 03 O 04 O 05 O 06 O 07 O 08 O 09 O 10 O 11 O 12 O 13 O 14 O 15 O 16 O 17 O 18 O 19 O 20 County Question #2 (mark only ONE bubble):
Reason (if applicable): O Ref O Imp O Lan O Oth	O 01 O 02 O 03 O 04 O 05 O 06 O 07 O 08 O 09 O 10 O 11 O 12 O 13 O 14 O 15 O 16 O 17 O 18 O 19 O 20 County Question #3 (mark only ONE bubble):
Make sure the same CSI County Client Number is written on all pages of this survey.	O 01 O 02 O 03 O 04 O 05 O 06 O 07 O 08 O 09 O 10 O 11 O 12 O 13 O 14 O 15 O 16 O 17 O 18 O 19 O 20
CSI County Client Number ****Must be entered on EVERY page**** Page	County Reporting Unit: