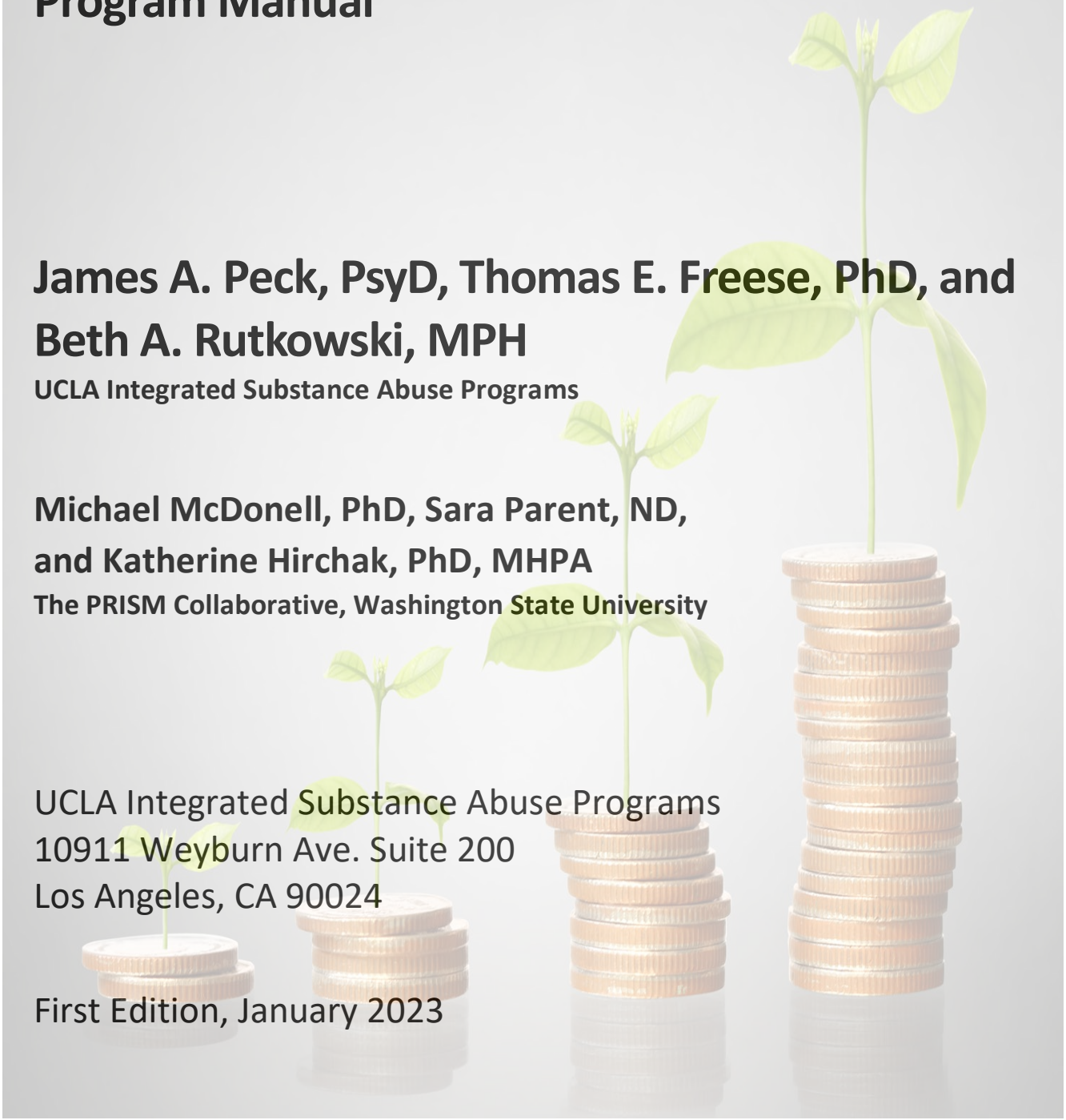
Recovery Incentives Program: California's Contingency Management Benefit Program Manual



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Appendices:

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Common Terms and Abbreviations

Member (Medi-Cal member)*

California Department of Health Care Services (DHCS)

Client*

Cognitive Behavioral Therapy (CBT)

Community Reinforcement Approach (CRA)

Contingency Management (CM)

Contingency Management Coordinator (CM Coordinator; the primary CM team member)

Contingency Management Supervisor (CM Supervisor)

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

Incentive Manager (IM)

Methamphetamine (Meth)

Motivational Incentives

Motivational Interviewing (MI)

Recovery Incentives

Serious Mental Illness (SMI)

Substance Use Disorder (SUD)

Stimulant Use Disorder (StimUD)

Urinalysis (UA)

Urine Drug Test (UDT)

**Throughout this Manual, the terms member and client are used somewhat interchangeably. When discussing contingency management in general, we use the term client. When discussing the specific protocol and procedures associated with the Recovery Incentives Program, we use the term member.*

Chapter 1. Overview of Contingency Management

Contingency management (CM) is one of the most powerful ways to help people stop using stimulant drugs and is associated with increased abstinence for up to one year after treatment.[1,2] CM is a behavioral intervention for SUD where tangible reinforcers (e.g., gift cards, prizes) are provided when an individual meets a goal for reduction of or abstinence from one or more target substances. CM has also been applied to other treatment-related behaviors such as attendance. In the Recovery Incentives Program, CM will be used to reinforce negative urine tests for stimulant drugs (i.e., cocaine, amphetamine, and methamphetamine). In this Program Manual, we provide information on how to implement a specific research-based CM intervention that is associated with reduced stimulant drug use.

Positive Reinforcement in Contingency Management

CM is based on the learning theory of operant conditioning. In operant conditioning, a behavior increases or decreases when something in the environment (a stimulus) is either added or taken away. Three methods of changing behavior exist in operant conditioning: (1) positive reinforcement, (2) negative reinforcement, and (3) punishment. CM relies on the use of **positive reinforcement** to reinforce drug abstinence.

Psychologists have studied positive reinforcement for nearly 70 years and understand the important ways in which it influences individual behavior. Positive reinforcement occurs when a behavior (e.g., a child completes their homework) is followed by a desirable result (e.g., the parent lets them watch TV) and because of that result that behavior increases (e.g., the child completes their homework more often in the future). While all forms of operant conditioning change behavior, we know that positive reinforcement is the best way to change behavior because it does not have the negative side effects (e.g., shame, discomfort) that come with other types of operant learning such as punishment.

Positive reinforcement occurs all the time in our daily lives, from a compliment you receive from your boss for completing a project on time, to a smile from a stranger when you hold the door for them. The key aspects of positive reinforcement are that a behavior increases because someone learns that the behavior is followed by a desirable result. Positive reinforcement may happen without us being consciously aware of it, though there are substantial changes taking place in the brain in response to these activities.

Long-term use of alcohol and drugs causes damage to several areas of the human brain. One area of the brain that is highly susceptible to the effects of psychoactive substances is the reward pathways that release dopamine whenever we experience something pleasurable. Another affected area is the prefrontal cortex, where conscious thinking, reasoning, and decision-making occur. Because of this damage, it becomes much more difficult for a person using drugs to make healthy choices. CM helps rewire the neural pathways so that the person begins to make healthier choices (like not using drugs) in the future.

In CM, positive reinforcement is used to help people choose abstinence over continued substance use. A tangible reward like a gift card is given when a person submits evidence that they have not used one or more drugs. This is particularly exciting because many people living with a substance use disorder are not used to being recognized and encouraged for choosing to reduce or stop their drug use. It is also refreshing for the clinician to emphasize the benefits of negative drug test results rather than negative consequences of positive drug test results.

Questions People Ask about CM

Here are some common questions people ask about CM when they are first introduced to the intervention.

"You pay people to stop using drugs?"

Many people ask this question when first introduced to the concept of CM. While many people stop using drugs on their own, it is far more difficult to achieve abstinence without effective treatment interventions, such as CM. It is important to recognize that stimulant drugs can hijack the natural reward pathways in the brain. CM helps bring the reward pathways back into balance by offering people non-drug rewards in exchange for achieving specific goals for substance use-related behaviors. This is especially important when people are just starting treatment or are new to recovery. In the Recovery Incentives Program, small incentives will be provided to help encourage people to choose abstinence over continued stimulant use. This effect is amplified by the feelings of reward from personal changes that they begin to make in their lives. [1,3–5]

"Wait, what happens if someone slips or lapses and uses drugs, do they still get rewards?"

While CM does not use punishment, it does emphasize accountability. So, a person who submits a urine sample that is positive for stimulant drugs will not receive a reward during that visit. However, they will be eligible to receive a reward the next time they submit a stimulant-free urine sample. In CM, people are encouraged to keep trying and they are offered many opportunities to succeed.

"Can CM be added onto existing treatment?"

Definitely! CM was created to be an adjunct to traditional intensive outpatient and outpatient SUD treatment and to treat co-occurring stimulant drug use in people receiving methadone in a narcotic/opioid treatment program (NTP/OTP).[7] The Recovery Incentives Program is being offered in outpatient, non-residential treatment. Because CM visits typically occur at least twice a week, CM is ideal to add to outpatient treatment models that require multiple visits per week.

"Can CM be delivered without other treatments?"

While it is ideal that CM be added to ongoing outpatient treatment, research has found that it is associated with large reductions in substance use in people who are not involved in other SUD treatment.[8–11] In fact, many individuals report that while they are not interested in "treatment," they are interested in CM. Therefore, CM is an important tool for engaging people in care. Once engaged in CM, individuals may become interested in other available SUD treatments and ancillary services. We can also encourage individuals who are struggling to achieve abstinence to participate in other available services.

Chapter 2. Key Elements of CM

Several key elements of CM are necessary to consider when implementing an effective CM program.

The behavior selected for reinforcement (e.g., stimulant drug abstinence) should be:

- **Objective, observable, and easily measurable** by the staff member/CM Coordinator.
    - The most commonly available objective, observable measurement for stimulant abstinence is a negative urine drug test (UDT).
    - Self-report of stimulant abstinence is ***not*** an appropriate marker for monitoring behavior because it is not objective, observable, or measurable by both the clinician and client.
- **Clear and unambiguous** for the client and CM staff.
    - It should be communicated at the beginning of the CM program that the results of the UDT will be how stimulant abstinence is demonstrated, so that there is no opportunity for disagreement or confusion.
    - The Recovery Incentives Program will utilize point-of-care UDTs to assess for recent cocaine, amphetamine, or methamphetamine use. A list of UDT products that meet minimum standards for reliability and contain built-in validity assessments have been approved for this Program (see Chapter 4). Only tests from this list may be used for this Program unless otherwise approved by DHCS.
    - While other substances, such as opioids, may be identified in the UDT, this does not impact the member's receipt of an incentive; however, it should prompt a conversation about overdose prevention and general safety when using drugs.
- **Achievable** for the client.
    - The goal should be attainable early in the program. Because stimulant use can be detected by point-of-care urine drug tests for approximately 2 to 3 days after use, most individuals can stop using long enough to earn their first CM reward (i.e., they only need to have been abstinent from stimulants for a few days to earn their first incentive).

Monitoring of the behavior should be:

- **Frequent**.
    - CM works best when rewards are delivered regularly (at least once a week). Less often than that is too infrequent to counteract the immediate reinforcing effects of drug use.
    - The Recovery Incentives Program will require UDTs twice per week for the first 12 weeks and once per week for weeks 13-24.

- **Feasible**.
    - CM must be administered consistently over time. Longer treatment periods are associated with better outcomes. The standard active intervention period for CM is 12 weeks. In the Recovery incentives Program, you will be administering an escalating CM schedule (this will be explained in Chapter 4) for 12 weeks, followed by a stabilization period of an additional 12 weeks (for 24 total weeks).
    - Fitting CM into your clinic workflow will require advance preparation. CM will be administered in each site by the CM Coordinator, a Back-up CM Coordinator, and/or a CM Supervisor. Prior to launching CM services, it will be important to determine specific protocols for your agency regarding where UDTs will be collected and interpreted, where CM rewards will be discussed and delivered, when CM visits will be scheduled, and how clients will be linked with other needed services. These are important factors to consider as they affect the overall flow through the clinic for both members and CM staff. You will be provided guidance on this during the 2-part Implementation Training and as part of the Readiness Assessment process. Ongoing technical assistance is also available, should you need additional assistance.

CM Rewards (reinforcers) should be:

- **Contingent**.
    - Rewards are only provided when the agreed-upon behavior occurs. For stimulant abstinence, this means a UDT that is negative for stimulant drugs (i.e., cocaine, amphetamine, and methamphetamine).
- **Tangible**.
    - Rewards should be tangible. In this Program, rewards will be delivered in the form of gift cards. While other approaches like community reinforcement approach (CRA) do emphasize social rewards, in CM, rewards should be given for the demonstration of a specific behavior.
- **Desirable**.
    - Rewards should be desirable and something that clients want, while still promoting recovery and health. Rewards must also be large enough in magnitude that they are desirable to individuals. For instance, $0.50 might not be a large enough reward to change behavior, whereas studies have shown that people will choose an incentive of $2.00 over cocaine use.
- **Immediate**.
    - Delivered as soon as possible after the behavior has been achieved and verified.
- **Escalating**.
    - Rewards should increase over time when the behavior is consistently achieved.
- **Closely Tracked**.
    - It is critical to monitor the CM incentives your agency uses for two reasons: (1) to assure high fidelity to the CM program and positive client outcomes; and (2) to

assure that your program is compliant with federal regulations (more information on federal regulations will be presented in Chapter 6 and in Appendix F).

With CM for stimulant use, the **objective**, **observable**, and **measurable** behavior is stimulant drug abstinence as measured by a point-of-care UDT. We know that the point-of-care UDTs will be able to detect most use if administered weekly. We use UDTs because they provide a measure of abstinence that is **clear and unambiguous**. Clients only need to achieve a few days of abstinence to submit a negative UDT and receive a CM reward, an **achievable goal** for most clients. The detection period of these tests means that we must conduct UDTs at least twice a week to accurately assess abstinence in the first 12 weeks of treatment, which also provides **frequent opportunities** for clients to receive rewards.

Point-of-care UDTs are utilized in CM because it is important that reinforcers are provided **immediately** after the behavior is demonstrated. This allows the client to receive their reward right after they submit a stimulant-negative UDT. This kind of immediate gratification is essential to supporting people who are new to stimulant abstinence, since they are used to the instant "reward" they feel when they use drugs.

The **escalating nature** of the reward system is very important for maintaining stimulant abstinence and we will discuss that more in Chapter 4. The most important thing to remember when implementing CM is to make your system as **feasible** for you and your clients as possible, while still maintaining the other key characteristics of CM that make it effective (i.e., observable, tangible, desirable, immediate, and escalating). Feasibility was carefully considered in the design of the Recovery Incentives Program and regular input was gathered from key stakeholders across the Drug Medi-Cal Organized Delivery System (DMC-ODS) Treatment System.

The Recovery Incentives Program protocol will be implemented in a standard fashion across all participating sites. Your treatment **setting** will also have to consider all the Program requirements to determine how to best incorporate these into existing clinic policies and procedures and workflows. You will be using a web-based Incentive Manager (IM), and you will enter information into the IM Portal during each member's visit. The IM will calculate, track, and deliver the rewards. It is important to **closely track** the CM rewards for each member you serve to assure that you are conducting CM according to best-practice standards and consistently across members. Fidelity is an important component of implementing any behavioral intervention; however, in CM, it is also critically important to assure that you are safeguarding the Program against fraud and abuse. Applicable laws and regulations are discussed in Chapter 6 and in Appendix F.

Incentives. When implementing CM, thought should be given to what types of rewards are made available. If the rewards are not appealing enough, the CM intervention may be less effective. For this Program, the protocol stipulates the use of gift cards delivered using an IM Portal. Training and consultation will be provided on the use of the IM Portal during the training and Readiness Assessment period. Ongoing technical assistance is also available should you need additional help.

Some clinicians worry that gift cards could be exchanged for drugs, or they could be used to buy alcohol. It is important to remember that if a client uses their gift card to purchase and use

stimulants, they will test positive for that drug at their next CM visit and they will not receive a reward at that visit. Therefore, they will learn that this strategy really does not work for them if they want to continue earning incentives. In addition, individuals in the Program will be asked to sign a consent form acknowledging that they will not make prohibited purchases.
Importantly, the gift cards used in the Recovery Incentives Program will be restricted to prohibit the purchase of alcohol, tobacco, cannabis, lottery tickets, and in the case of Walmart, firearms and ammunition. While some CM projects have used other tangible prizes as rewards in CM, we will not be using "prizes" in the Recovery Incentives Program and will only be providing rewards using gift cards.

How CM Builds Success: Escalation, Reset, and Recovery

Below we describe three important aspects of CM that help people stay motivated to achieve abstinence. Understanding and correctly calculating the appropriate incentive amounts is one of the most challenging aspects of CM to explain and may be the most challenging aspect of CM to implement. While CM staff need to understand these concepts, the IM will automatically perform the calculations when a UDT result is entered.

Three concepts, ***escalation***, ***reset,*** and ***recovery***, are essential to an effective CM intervention and are what makes CM different from other types of reward-based interventions. These concepts are based on many years of research, where investigators figured out exactly how to design a positive reinforcement intervention that maximized abstinence.[8–12] Below we describe these concepts in general. However, more detailed information on escalation, reset, and recovery in the Recovery Incentives Program will be provided in Chapter 4.

Escalation. In CM, we want people to be invested in their goals and we want them to learn that the longer they stay stimulant-free, the more they can gain. To facilitate this learning, CM uses an **escalating schedule of reinforcement**.[13] In other words, the amount of reward increases the longer a person remains abstinent from stimulants.

For example, a client starts CM and receives a $10 gift card for their first stimulant-free UDT. In CM, we increase the reward (e.g., by an extra $1.50) for every week of abstinence a client achieves. That means that at their first two visits they would earn $10/visit for their negative UDT, but by their second week they would earn $11.50/visit if they submit another negative UDT. This is because the two-consecutive negative UDTs represent one week of stimulant abstinence, which earns them an even higher escalation reward amount. If they submit two more stimulant-negative UDTs, their reward will increase again, for a total of $13/visit, and so on. So, by the end of 12 weeks of abstinence, a client could receive up to $26.50/visit for their final two stimulant-free drug tests. The longer the client is abstinent, the bigger their rewards get with every week of continuous abstinence. This is further illustrated in Chapter 5 (page 37).

Reset. Punishments are not used in CM, though we do emphasize accountability. In the Recovery Incentives Program, when a member has a drug test that indicates they used stimulants, the member does not receive a reward that visit. The other consequence is that the IM portal will temporarily "**reset**" the reward level. This means that members who earned the escalated amount for one or more weeks of continuous stimulant abstinence will temporarily lose the

escalation. For example, when they submit their first stimulant-negative urine test after a stimulant-positive test they will reset to the original week 1 level of rewards (e.g., $10). This can be a big consequence for someone who has worked their way up to a large escalation amount. It is important to explain the concept of the reset to members, especially as they build success, and their rewards escalate in value. When they are aware that they can lose their escalated amount, this can help members stay motivated to maintain their abstinence.

Slips, Lapses, and Resets are Common in Recovery. This can be disheartening, so when a reset occurs, the CM Coordinator should remain positive and encouraging. Remember, members are typically attempting to change longstanding behaviors. Change is challenging for everyone. Make sure to praise their efforts (e.g., attending their CM appointment) and remind them of upcoming appointments and opportunities for additional rewards. You can also remind them of the opportunity for 'recovery' of their escalated reward amounts, which we describe below.

Resets and Missed Appointments. In CM, a missed appointment is a missed opportunity to submit a UDT, which results in no reward and triggers a reset. While we encourage you to be flexible (e.g., allow the member to come in later in the day if they miss a morning appointment, or allow them to reschedule for a contiguous day), we do want to emphasize accountability and we can only reward behaviors when we can objectively measure them. It is important to explain the consequences of a missed test to members.

Excused Absences. In some instances, a member may have a legitimate reason not to attend an appointment. If the member notifies the clinic or CM Coordinator ahead of time with a valid reason for missing an appointment, the CM Coordinator should attempt to reschedule the visit for an earlier or later time that same day or on a contiguous day, so that the visit is not missed. If the visit cannot be rescheduled, it is counted as an 'excused absence' instead of an 'unexcused absence'. Excused absences include a planned surgery or other medical procedure, illness, death in the family, or a court date, etc. The member must provide documentation of the reason for the absence at the next scheduled visit (e.g., note or receipt from a medical clinic, funeral announcement, or court document). Failure to provide documentation for an excused absence will result in that absence being coded as an unexcused/missed appointment and an incentive reset will occur. A member may have up to two consecutive excused absences; if the excused absence extends to three or more visits, it will trigger an incentive reset.

Recovery. 'Recovery' refers to the return to previously achieved reward levels when a member returns to sustained abstinence (as defined by two consecutive stimulant-negative UDTs). This is possibly the most challenging aspect for the CM Coordinator to track, though the IM will take the guess work out of things since it automatically calculates the correct reward amount at each CM visit. The idea of the recovery is that we do not want a single episode of using (one stimulant-positive test) to turn into continued drug use. Therefore, if a member has achieved an escalated reward amount, let's say of $16 per stimulant-negative UDT and then they submit a UDT that indicates use (or they have an unexcused absence) and the reset occurs, we want to give them motivation to return to abstinence as soon as possible. So, if the member submits a stimulant-negative UDT after a reset, they receive the $10 incentive for that UDT. If the next UDT is also negative for stimulants, they return to the place in the escalation schedule where they would have been had the positive UDT or unexcused absence not occurred. For instance, if they had the

positive UDT or unexcused absence at the second visit of week 5, when they would have earned $16 for a stimulant-negative UDT, the next stimulant-negative UDT would result in a $10 incentive, and if the next UDT after that is also negative, they would earn $17.50 (recovery of the $16 escalation, plus the next escalation). They will then continue the incentive schedule from that reward amount. This will be demonstrated in more detail in Chapter 4. The 'recovery' helps people get back on track after a stimulant-using episode and gives them a reason to return to abstinence after use. We will put it all together later and show you how escalation, reset, and recovery work through an example client's CM program.

Chapter 3. Evidence that CM Works

Now that we have told you about CM in general, it's time to share with you the evidence that CM is an effective intervention for treating stimulant use disorder (StimUD).

Research Evidence. Multiple studies conducted over the past 30+ years demonstrate that CM is the most effective intervention for StimUD, including methamphetamine, amphetamine, and cocaine use disorders.[1,3–5,7] It also works well for treating nicotine use disorder and opioid use disorder.[7,17] Given the lack of medication-assisted treatment options for stimulant drugs, such as methamphetamine and cocaine (there are currently no FDA-approved medications for StimUD), CM is an important clinical tool in the treatment of StimUD.

More evidence supports the effectiveness of CM for StimUD than any other treatment.[1,3,4,9,18] Multiple meta-analyses have been published on CM. A meta-analysis is a comprehensive review of research studies where all the studies done on a topic are combined and analyzed together.

Several meta-analyses collectively support the efficacy of CM as an intervention for stimulant use and other substance use disorders.[1,7,16,19–21] One meta-analysis found that compared to all other cognitive and behavioral interventions for substance use disorders, CM was the most powerful way to assist clients to stop using drugs.[1]

Research also finds that the effect of CM is lasting. In fact, one study found that the effects on abstinence rates of a treatment episode of CM at a 12-month follow-up assessment are comparable to the effects on abstinence rates of a treatment episode of cognitive behavioral therapy at a 12-month follow-up assessment.[2,22] We also know that those individuals who stay in CM longer are more likely to continue to be abstinent after the CM intervention is completed.[22]

CM also has important secondary positive benefits and impacts on health. It has been found that when one drug is targeted in CM (e.g., a stimulant such as methamphetamine) individuals not only stop using that drug, they stop using other substances, as well (e.g., alcohol).[8–10,23] In another study, researchers found that people with co-occurring StimUD and serious mental illness (SMI) who received CM had fewer psychiatric symptoms and inpatient psychiatric hospitalizations than those who did not receive CM.[9]

In addition, multiple cost-effectiveness studies demonstrate that the cost savings of CM associated with reduced substance use and improved mental health outweigh the costs of rewards, UDTs, and staff time needed to implement the intervention.[14, 24] Therefore, CM reduces substance use and saves money too.

CM is also an effective intervention for diverse cultural groups. The CM team at Washington State University (WSU) partnered with five American Indian and Alaska Native communities to study whether CM was associated with reduced alcohol and drug use. They found that CM was associated with lower alcohol, stimulant drug, and cannabis use.[10,11] Participants and clinicians also reported that the adapted CM intervention was consistent with their community values. WSU has developed a separate CM manual and training materials for American Indian and Alaska Native communities who are interested in this culturally-adapted CM model.

Clinician and Client Evidence. After implementing CM for a while, clinicians have seen the positive impact it has on their clients, their practice, and on their overall clinic or agency. In surveys, clients appreciate the more positive environment of their CM program and providers viewed CM more positively because their clients' treatment attendance increased.[25–27] Clients affirmed that incentives enhanced their motivation to remain abstinent and the CM program provided accountability to do so.

While clients report that they like receiving prizes or gift cards, more often they emphasize that they really liked their CM providers and how CM helped them change their lives. Specifically, they report how positive their CM providers are, that CM holds them accountable in a positive way, and that CM providers are respectful. One of the WSU CM studies was called the HONOR project, in part because as CM providers we are honoring people when they choose to be abstinent.[11]

Clinicians also like CM, with 77% of clinicians saying they would use it if given the opportunity to do so.[27] Many clinicians share concerns when the idea of CM is first introduced to them. These concerns relate to "paying" people to stop using drugs and the belief that people should be intrinsically motivated to change. Another concern is that CM only rewards abstinence, so it seems inconsistent with harm reduction approaches that meet people where they are currently. CM was initially developed to help people who were receiving methadone to reduce or stop using stimulant drugs, like cocaine. So, CM was originally developed in the context of medication-assisted treatment to reduce the harms associated with substance use. Overall, when it comes to clinicians' initial concerns about CM, it is very common that as soon as clinicians start seeing the successes their clients have in CM, their opinions change.

Currently, the biggest barrier to implementation of CM is financial. More specifically, there has not been an easy way to pay for CM rewards, despite the average cost per client ($300-$500) being relatively low. Increasingly, federal, state, and local governments, as well as treatment agencies and insurers are seeing the benefits of CM, particularly for StimUD. Some are now providing funding for CM incentives. The Recovery Incentives Program is funded as a Medi-Cal benefit. California is the first state in the nation to cover CM as a Medicaid benefit under CalAIM (California Advancing and Innovating Medi-Cal).

Chapter 4. A CM Model for Stimulant Drugs

So far, we have reviewed CM, what it is, what makes it work, and how it is based on research evidence. Now it is time to talk about how to implement the Recovery Incentives Program protocol in your site. Below we describe an evidence-based CM model to reward stimulant drug abstinence. That means it is based on models used in CM studies that are associated with clinically significant reductions in drug use.

CM for Stimulants Overview

- **Identify Behavior for Reinforcement –** Stimulant abstinence as measured by point-of-care UDTs for amphetamine, methamphetamine, and cocaine.
- **Frequency of Monitoring and Reinforcement –** Twice-weekly on non-consecutive days, such as Mon/Thurs or Tues/Fri for the first 12 weeks and once weekly in weeks 13-24.
- **CM Intervention –** 12-weeks of CM starting at $10 for each stimulant-abstinent sample, escalating by $1.50 for each week of consecutive abstinence (assessed twice-weekly). This will be followed by a 12-week stabilizing period in which UDTs will be collected once per week and stimulant-free samples will be rewarded with either a $10 or $15 gift card, with a final possible gift card worth $21 in week 24.

Stimulant Urine Drug Testing in CM

A list of DHCS-approved UDT products is included below.

UDTs as a Tool for Success. In CM, we use UDTs in a very different way than they are traditionally used in typical SUD treatment. In CM, we celebrate UDT results that demonstrate abstinence, and we value an individual's efforts to remain engaged in treatment even after recent drug use (i.e., UDT positive for stimulants). UDTs are a tool for facilitating rewards, not a tool for "catching" clients who have used drugs. In fact, you will notice that we never use the terms "clean" or "dirty" when we refer to UDT results. These terms are stigmatizing and judgmental, so we do not use them in CM. Instead, we use the terms recommended by the test manufacturers: positive (indicates use) and negative or stimulant-free (indicates no recent use).

It may take some time for clients and treatment programs to get accustomed to this new way of using UDTs. In CM, UDTs are still used to keep people accountable, but the focus is on a positive accountability that facilitates trust, self-efficacy, and pride. In fact, many CM clients report that they really value urine testing because it helps them remember that they are accountable to themselves and their CM provider when they have urges to use.

To facilitate this new approach to urine testing we do not require directly observed tests, though we do use tools like integrated thermometers to reduce the chances that someone will be tempted to carry in someone else's urine or to dilute their own urine sample using water or other liquids or to contaminate the sample using bleach or other chemicals. Temperature strips ensure that the sample temperature is near normal body temperature, creatinine levels detect dilution,

and pH levels detect contamination. All of these safeguards are included in the UDTs approved for the Recovery Incentives Program. It is important to include validity measures such as requiring the member to wash their hands before handling the testing supplies (to prevent members from putting bleach under their fingernails and urinating on them, which would contaminate the urine sample), applying bluing agent in the toilet the member will use, and turning off the hot water in the restroom that will be used for the UDTs. And if you do suspect an inaccurate test, it is important to have a conversation with the member, informing them that they will only earn rewards for valid samples.

Remember, many members are trying to unlearn a history where a positive UDT resulted in negative outcomes, like judgment from the treatment provider, shame, jail time, loss of custody, or being "fired" from a treatment program. So, having a nonjudgmental conversation often solves the problem of inaccurate or invalid tests. The bottom line is that if you emphasize the positive and nonjudgmental approach to urine testing that balances accountability and trust, and remind members that the results are confidential, and that the only negative consequence for this visit is not earning an incentive, they will be less likely to tamper with their urine samples.

What if the Results Seem Wrong? CM studies have conducted tens of thousands of UDTs over the last 30+ years. And if you are an SUD treatment provider, you probably have a lot of experience with UDTs, as well. Like us, you probably have at times obtained a UDT result from a client that just doesn't seem to make sense. It might be a negative test from a person you knew was arrested for possession over the weekend or a test that indicates use from someone who has been in recovery for months.

UDTs are not perfect and understanding the detection periods of each test is important to using them appropriately. At the same time, we know that UDTs are more accurate than self-report, when they are used frequently enough to detect use. They also take self-report off the table, so clients are not tempted to provide inaccurate information about their use. In CM, rewards are based on the UDT result and it is important that clients are informed of this right from the start.

In the tens of thousands of UDTs that have been conducted, it is almost always the case that after the dust settles, it is the person's self-report that was inaccurate, not the UDT (when the test is used properly). Additionally, there are prescription and over-the-counter medications containing amphetamine, pseudoephedrine, or their metabolites that can cause a false positive test. Members will be provided with a list of medications that may cause a false positive test (see the Recovery Incentives Sample Consent Form in Appendix A) and informed that they should not use these during their participation in the Recovery Incentives Program. Rewards will be based solely on the results of the UDTs, and all positive tests will be treated the same, even if they result from the use of one of these medications.

Note: when there is a voiced dispute from a member who insists that there must be a problem with the test being performed, you may offer to retest the member to either confirm the original test or to overturn it. This should be done with a new point-of-care UDT. The member should be informed that the results of the second test will be binding. A second test should be used **very sparingly** and primarily as a way to preserve the clinical relationship with a member who is very upset. Clinical judgment must be used, so we encourage you to consult the CM Supervisor if this situation occurs. Also remember that reimbursement rates are based on a single test per visit, so

additional tests would be an expense incurred by the site. We also encourage you to seek out consultation from an expert on the UCLA Training and Implementation Team if you are confused by a test result. You can request individualized expert consultation at: https://uclaisap.org/recoveryincentives/warm-line.html.

Frequency of UDTs. In the first 12 weeks of the Program, we will be monitoring stimulant drug use twice per week, on two non-consecutive days. This fits well within the standard intensive outpatient treatment setting, where clients attend group two to five times a week. Testing on a Monday and Thursday OR Tuesday and Friday schedule is ideal in order to allow stimulant metabolites to clear.

The Recovery Incentives Program may only be implemented in DMC-ODS outpatient, intensive outpatient, partial hospitalization, and NTP/OTP treatment clinics/programs. CM implemented in these settings will consist of twice-weekly visits for the first 12 weeks of the program and once weekly visits for the second 12 weeks of the program (i.e., weeks 13-24).

Stimulant-Specific UDTs. Point-of-care UDTs are available for stimulants, including amphetamines, methamphetamine, and cocaine. A selection of UDT kits have been approved for use in the Recovery Incentives Program. Each cup includes tests for amphetamines, methamphetamine, cocaine, cannabis, oxycodone, and opiates. They also test for benzodiazepines, MDMA, PCP, and several other substances depending on the specific test kit. The purpose of testing for oxycodone and opiates is to assess relative risk of exposure to fentanyl or other synthetic opioids; this is based on the concept that a person who uses in a polysubstance pattern has a greater potential to accidentally ingest fentanyl than a person who uses a single substance due to the likelihood of additional drug sources. Please note that reimbursement for covered CM services in the Recovery Incentives Program does not include urine testing for fentanyl, nor does it include reimbursement for fentanyl test strips. However, DMC-ODS providers are not prohibited by DHCS from independently testing for fentanyl as part of urine drug testing. Please refer to the Frequently Asked Questions document for additional information regarding harm reduction safety strategies and reimbursable

The tests for opiates and oxycodone, even if positive, shall not impact the member's ability to receive an incentive; however, counseling should be provided, and an assessment should be completed for the clinical need for induction of an evidence-based medical treatment for opioid use disorder. If the CM Coordinator is an LPHA or certified/registered SUD counselor, they can complete the assessment. If the CM Coordinator is not an LPHA or certified/registered SUD counselor (i.e., a Peer Support Specialist), the CM Coordinator shall refer the member to an LPHA or SUD counselor for the assessment. In addition, the CM Coordinator shall discuss the risks associated with fentanyl, harm reduction safety strategies including the use of fentanyl test strips, and ensure the member has access to naloxone and knows how it is used. If the member is positive for any of the substances tested in the UDT cup, this shall not impact their ability to receive incentives related to their stimulant test results. However, inquiring if the use of other substances is impacting their stimulant use and assessing for the need for referral to other behavioral treatments to address these substances may be warranted, particularly if the member is having difficulty attaining consecutive stimulant-negative UDTs.

The cocaine UDT detects only the use of cocaine; it will not detect amphetamine or methamphetamine use. The Recovery Incentives Program requires UDTs that test for all three substances. The amphetamine test is designed to detect prescription drugs, like methylphenidate (Ritalin®, Concerta®) or other amphetamines (i.e., Adderall®). It is likely that a person who uses methamphetamine will return a positive test for amphetamines too. The methamphetamine UDT will identify methamphetamine and not other amphetamines. As mentioned above, it is possible that a member could test positive for amphetamine or methamphetamine if they take a cold medicine that contains amphetamines, pseudoephedrine, or similar compounds. All positive tests will be handled the same (i.e., no reward) even if they result from use of medications. Therefore, it is very important to discuss this with members as they enroll in the Recovery Incentives Program.

The amphetamine, methamphetamine, and cocaine tests approved for use in the Program have the following metabolite detection thresholds:

	Metabolite	Threshold	Min Detection	Max Detection
Amphetamine	d-Amphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine	D(+)-Methamphetamine	500 ng/mL	2-7 hours	2-4 days
Cocaine	Benzoylecgonine	150 ng/mL	1-4 hours	2-4 days

*Minimum and maximum detection periods as listed in package insert for CLIAwaived, Inc. Instant Drug Test Cup (https://cliawaived.com/cliawaived-inc-idtc-12-panel-cup-with-adulterants.html).

Remember the detection periods described above are provided for overall guidance. However, detection periods of UDTs for any given person will vary depending on the amount of drug used and individual-level factors. Also, the detection period for methamphetamine and cocaine urine tests is up to four (4) days. Therefore, if you are conducting CM visits twice a week, it may take up to two (2) UDTs before a member tests negative for these drugs after they stop using. Reminding the member of this can help maintain motivation as they are working toward their first stimulant-negative UDT. If you ever have questions about a potential "false" positive or negative test you can always request consultation.

It is also important to remember that point-of-care UDTs have an expiration date. Therefore, it is important that you do not order more tests than you can use over a given period and that you ask for the expiration date of the tests you purchase before you place your order if your volume of urine drug testing is relatively low.

CLIA-Waived Certification. In order to participate in the Recovery Incentives Program and receive Medi-Cal reimbursement for CM services, DMC-ODS providers must attain a Clinical Laboratory Improvement Amendments (CLIA) "waived test" certification and be registered with the California Department of Public Health (CDPH) (or be accredited by an approved accreditation body). Laboratory Field Services, which is part of the California Department of Public Health, has an online application

process through which providers can apply for both the CLIA Waiver and State Lab Registration. Sites should choose certificate type "Registration" and be prepared to upload three forms: the CMS 116, LAB 182, and LAB 183. Sites that already have a CLIA Waiver and State Lab Registration in place can use these certificates for the Recovery Incentives Program, even if their original application was for another test. It may take up to six months for CDPH to process applications once they are correctly submitted. It is therefore essential that sites submit applications as soon as possible, if needed. The user manual for submitting CLIA waiver applications can be found here: https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ELLFS_NewSingle.aspx.

Each UDT must be performed in accordance with the manufacturer's instructions for the test (see Appendix B), and the identified Site Lab Director must ensure that waived testing personnel meet facility-defined minimum requirements and have records of training and competency assessment.

Importance of Point-of-Care Tests. Several commercially available UDT cups make onsite, immediate testing feasible without the need for specialized laboratory equipment or training. Table 1 provides a list of approved cups that meet minimal standards for validity testing, cutoff values, and coverage of necessary substances (amphetamines, methamphetamine, and cocaine).

If you are currently using a different UDT device that you think meets the recommended standards, you can request a review of the product for potential addition to the recommended product list. If you would like for your existing UDT product to be evaluated for use in the Recovery Incentives Program, please email the following information to: recoveryincentives@dhcs.ca.gov:

- Package insert
- Cut-off values for amphetamine, cocaine, methamphetamine, opiates, and oxycodone
- Cross-reactivity list for amphetamine, cocaine, methamphetamine, opiates, and oxycodone (if applicable)
- Information on specimen validity measures (whether the cup includes these):
    - Temperature strip
    - pH
    - Creatinine
- Certification: CLIA-waived and/or FDA approved

The DHCS toxicology consultant will review each request submitted by a provider for an alternative UDT and DHCS will either approve or deny the request for an alternative UDT based on her recommendation. The site will not receive reimbursement for CM unless the test has been approved by DHCS.

UDT kits will be purchased directly by each participating site or through their County according to their usual procurement process. Check with your County Recovery Incentives Program staff to determine how to obtain the UDT kits.

Table 1. DHCS-approved UDT Kits

Company Name	Product Name	Cost Estimate	Company Website/ Product Page	Contact Information
CLIAWaived, Inc.	12-panel IDTC Cup II with adulterants	$4.99/cup; $124.75/box of 25	https://cliawaived.com/cliawaived-inc-idtc-12-panel-cup-with-adulterants.html	858-481-5031 info@cliawaived.com
CLIAWaived, Inc.	14-panel IDTC Cup II	$4.50/cup; $112.50/box of 25	https://cliawaived.com/cliawaived-inc-14-panel-idtc-ii.html	858-481-5031 info@cliawaived.com
Lochness Medical*	Multi-Drug One Step Cup II	$5.40/cup	https://www.lochnessmedical.com/Product/Cups/16970	888-506-2658 info@lochnessmedical.com
Premier Biotech	Premier Biotech 12-panel Drug Test	$2.50-$3.00/cup; $68.75/box of 25	https://premierbiotech.com/innovation/rapid-testing/urine-testing/premier-bio-cup/	855-374-6759 customerservice@simplymedical.com

*The Lochness Medical UDT product requires a customized order to ensure that all cut-offs are in line with the minimum requirements of the Program. This necessitates a 10-16 week production time and minimum order of 1,200 kits.

**For the most up to date list of approved UDT products, please visit the Recovery Incentives Program website at: https://uclaisap.org/recoveryincentives

Tracking UDT Results and Rewards. Tracking and monitoring of members will be done electronically through the Incentive Manager (IM) Portal (see Chapter 5). Carefully tracking and documenting UDT results and incentives earned and disbursed is essential to making sure your site is compliant with specific rules pertaining to providing CM as a Medi-Cal benefit (see Chapter 6, Federal Law and Incentive Payments). Entering data into the IM Portal accurately will help ensure that the Recovery Incentives Program is compliant with state and federal laws, regulations, and DHCS program requirements.

Specific Program Elements of the Recovery Incentives Program: California's Contingency Management Benefit

Below is a step-by-step process for implementing the Recovery Incentives Program.

Reinforce Behavior. Stimulant abstinence as objectively measured by point-of-care urine drug testing. The point-of-care UDTs measure cocaine, methamphetamine, and amphetamine. They will also assess for opiates and oxycodone. A test that is positive for opiates or oxycodone but negative for stimulants will still earn an incentive, because stimulant use is the focus of the Program. Because of the presence of synthetic opioids in much of the stimulant drug supply in

California, the following steps shall be taken for a member who tests positive for opiates and/or oxycodone.

Recovery Incentives Program sites shall:

- Establish and implement a protocol to prescribe naloxone to all members with an opioid, sedative and/or stimulant use disorder as outlined below.
- Establish and implement a naloxone distribution protocol for members who do not obtain prescription naloxone.
- Provide education to each member regarding:
    - The risks associated with fentanyl and other synthetic opioids and their presence in the street-level drug supply.
    - Harm reduction safety strategies, such as the use of fentanyl test strips and harm reduction agencies that distribute test strips for home use, based on information from the California Department of Public Health (see https://www.cdph.ca.gov/Programs/CCDPHP/sapb/Pages/Fentanyl.aspx).
    - Specific education regarding the use of naloxone to reverse an opioid overdose.

Whenever a member needs an additional naloxone dose, due to the naloxone expiring, or due to use in the community, CM Teams shall either replace the naloxone or remind a member to obtain a new dose through a pharmacy or local organization. DMC-ODS providers are able to dispense naloxone onsite to members by leveraging the Medi-Cal pharmacy benefit. As a best practice overdose prevention measure, sites can prescribe naloxone to all DMC-ODS members who are participating in the Recovery Incentives Program and arrange for staff to routinely fill these naloxone prescriptions at a pharmacy on behalf of the members. The community pharmacy should bill these naloxone prescriptions to the Medi-Cal pharmacy benefit. Pharmacists can also directly dispense naloxone and bill to Medi-Cal. The CM Team could then bring the dispensed naloxone back to the provider site for furnishing directly to members. This method would enable Recovery Incentive sites to better facilitate onsite access to naloxone reimbursed through the Medi-Cal pharmacy benefit.

Monitoring and Reward Schedule. Twice-weekly during the initial 12 weeks, either 1) Mondays and Thursdays or 2) Tuesday and Friday, if possible. If this is not possible, for instance in the event of an excused absence being rescheduled to a different day, then twice-weekly on non-consecutive days as long as there are at least 48 hours between UDTs.

Duration of Intervention. 12-weeks of CM treatment, which serves as the escalation/reset/recovery period, plus 12 weeks of a stabilizing period. During the initial 12 weeks of CM treatment, participating members will visit the treatment program twice per week for CM services as stated above, and during the stabilizing period in weeks 13-24, participating members will visit the treatment program once per week for CM services.

Many CM interventions conducted as part of research studies have ended after 12 weeks and have not included a stabilizing period after the active intervention period. In the Recovery Incentives Program, weeks 13-24 will serve to help members stabilize and maintain the progress they made in weeks 1-12. This period is also important in terms of treatment retention. For members who have taken advantage of other clinical interventions offered by sites implementing

the CM benefit, such as group or individual counseling, the continuing incentives that can be earned during the stabilizing period will be a tool to encourage members to remain fully engaged in those interventions.

Reinforcement Amount, Escalation, Reset, and Recovery. The gift card values for each qualifying urine sample will be at least $10. For each week the client achieves abstinence (i.e., two consecutive stimulant-abstinent UDTs), the gift card value increases by $1.50. Therefore, the maximum a person could earn if they attend every CM visit and are abstinent for the entire 12 weeks is $438. During weeks 13-18, clients will test once per week and will earn $15 for each negative test. Weekly testing will continue in weeks 19-23 with each negative test earning $10. In week 24, a negative test would receive $21. Thus, a person can earn a maximum of $161 for weeks 12-24, for a total of $599 across the entire 24-week period if they attend every visit and submit a stimulant-negative UDT every time.

Although the total reward per participant may be as high as $599, it is unlikely that everyone will achieve this level of success in CM. Due to missed appointments and periodic stimulant use, the average cost of incentives in your implementation of the Recovery Incentives Program will probably be approximately half of the maximum amount possible ($599), or approximately $300 per member.

A **reset** will occur when a member submits a positive UDT or has an unexcused absence. The next time they do submit a stimulant-negative UDT, their reward level will "reset" to the initial incentive value (e.g., $10).

A **recovery** will occur after two consecutive stimulant-negative urine tests. At that time, the member will "recover" their previously earned incentive level plus the next escalation of $1.50. See Table 2 below for an example of how this process works.

Gift Cards. The IM Portal will manage incentives and will dispense gift cards as the CM rewards, because they are both desirable and feasible. The current list of available gift cards appears in Chapter 5, Figure 6.

UDT and Incentive Tracking

The IM will automatically calculate the appropriate incentive amount based on the UDT results with adjustments for the escalating value, reset, and recovery features described above. At each visit, the CM Coordinator will enter the results of the UDT into the IM Portal, and the IM Portal will indicate the appropriate incentive amount, per the protocol. A positive test for stimulants will result in the participating member receiving no incentive, along with encouraging coaching from the CM Coordinator. A negative test for stimulants will result in an incentive amount as indicated by the IM Portal, considering escalations and resets.

After the incentive amount is determined, the IM Portal will either disburse the incentive for that visit in the form of a gift card, or "bank" the incentive amount for future use by the member. It will also track all incentives awarded to all participating members. Additional data in the IM Portal will include the CM Team member who conducted the visit (e.g., CM Coordinator, Back-up CM Coordinator, or CM Supervisor), the format of the incentive provided to the member (i.e., text, email, or hard copy), the date the incentive was distributed, and the amount of the incentive.

Participating members will receive incentives in the form of gift cards to which the IM will make deposits upon entry of stimulant-negative UDT results. Restrictions will be placed on the incentives so they cannot be used to purchase cannabis, tobacco, alcohol, lottery tickets, or firearms.

Table 2 depicts an example of a CM gift card tracking table demonstrating reset and recovery with a stimulant-positive UDT, a missed appointment (unexcused absence), and an excused absence. For the purposes of easy tracking and clear communication, we use the following terms: positive (urine test was positive for at least one stimulant drug), negative (urine test was negative for all stimulants), missed (unexcused absence), and excused (approved absence). An example table of incentives when all of a member's UDTs are stimulant-negative appears on page 37 in Chapter 5. Remember that although you need to understand how incentives are calculated in order to explain to members, the IM will calculate the incentive for you.

Table 2. Missed Sample and Positive UDT (Demonstrating Reset and Recovery)

Starting Incentive = $10, incentives escalate by $1.50 for each week of continuous abstinence

Week #	Visit #	UDT Result	Incentive Earned ($)	Week #	Visit #	UD Result	Incentive Earned ($)
1	1	Negative	10.00	7	13	**Missed**	**0**
1	2	Negative	10.00	7	14	**Positive**	**0**
2	3	Negative	11.50	8	15	Negative	**10.00**
2	4	Negative	11.50	8	16	Negative	19.00
3	5	Negative	13.00	9	17	Negative	19.00
3	6	Negative	13.00	9	18	Negative	20.50
4	7	Negative	14.50	10	19	Negative	20.50
4	8	**Positive**	0.00	10	20	Negative	22.00
5	9	Negative	**10.00**	11	21	**Excused**	**0.00**
5	10	Negative	16.00	11	22	Negative	22.00
6	11	Negative	16.00	12	23	Negative	23.50
6	12	Negative	17.50	12	24	Negative	23.50
				Total			**$323.00**

- **At visit 8**, the member submitted a stimulant-**positive** UDT. They **did not receive an incentive** that day.
- **At visit 9**, the member submitted a negative UDT, and their gift card amount was **reset** to the base amount, $10.
- **At visit 10**, the member again submitted a negative UDT, which represents another consecutive negative UDT. So, they **recovered** the previous escalation they had earned ($14.50) from visits 1-7. They also earned an additional escalation for another week of abstinence (visits 9 and 10), for a total of $16 earned that day.
- A similar cycle of reset and recovery is triggered on **visits 13-14** after the member **missed a visit** and **submitted a positive UDT**.

- At **visit 15**, their gift card amount **reset** to $10, when they returned and submitted a stimulant negative UDT.
- At **visit 16**, they demonstrated another consecutive stimulant-negative UDT, so they again **recovered** their previously earned escalations much like they did above, this time totaling $19.
- At **visit 21**, they missed their CM session due to advance notice of an excused absence. A **reset** and **recovery** is not triggered because it was an excused absence.
- At **visit 22**, their gift card amount continued at $23, again because visit 21 was an excused absence.

Program Readmission. A member will be considered a readmission if they leave the Recovery Incentives Program for more than 30 days. At readmission, the member must have a new ASAM multidimensional assessment that indicates they can appropriately be treated in an outpatient treatment setting (i.e., ASAM levels 1.0–2.5) and confirm that the member meets the medical necessity criteria for CM. Based on the assessment, the site may offer other treatments *as alternatives to the CM program* if there is strong clinical evidence that CM is unlikely to produce the intended results. However, if the determination from the new assessment is that CM is an appropriate course of treatment for that member, the member may receive CM and the incentive structure would restart at Week 1. The maximum amount of incentives that can be received is $599 per member per calendar year. A member who is readmitted to the Recovery Incentives Program will earn incentives according to the schedule described above until they earn $599 for all program participation during that calendar year. They would then be discontinued from the Recovery Incentives Program and encouraged to continue with other program services. In January of the next calendar year, the member could be reassessed and, if they meet all criteria, readmitted to the program, again with a maximum earning potential of $599 for that calendar year.

If a member leaves the CM program (for any reason) and returns to the program within 30 days, they will return to the schedule of UDTs and incentives as if there was no break in service.

Establishing Member Eligibility for CM Services

The Recovery Incentives Program is only available to Medi-Cal members who meet the following conditions:

- Are enrolled in Medi-Cal and meet criteria for a comprehensive, individualized course of SUD treatment. Medi-Cal enrollment must be confirmed prior to initiating services through the Recovery Incentives Program.
- Reside in a participating DMC-ODS county that elects and is approved by DHCS to participate in the Recovery Incentives Program.
- Receive services in a non-residential level of care operated by a DMC-ODS provider participating in the Recovery Incentives Program and offering CM in accordance with DHCS policies and procedures.

CM services delivered under the Recovery Incentives Program are only covered when medically necessary and appropriate as determined by an initial SUD assessment consistent with DMC-ODS Intergovernmental Agreement (IA) showing (1) moderate or severe StimUD as defined by the clinical criteria in the Diagnostic and Statistical Manual (DSM, current edition); (2) clinical determination that outpatient treatment is appropriate per the American Society of Addiction Medicine (ASAM) criteria; and (3) that the CM benefit is medically necessary and appropriate based on the fidelity of treatment to the evidence-based practice. The presence of additional substance use disorders and/or diagnoses does not disqualify an individual from receiving CM services.

Members may access CM when transitioning from residential care or carceral settings to outpatient treatment settings, including services initiated on the day of admission to the outpatient program and discharge or release from residential care or a carceral setting. Providing CM services on the date of admission to the outpatient program and the date of discharge from a DMC-ODS residential level of care is an acceptable circumstance justifying multiple service billing for both a residential treatment service and a CM service at a non-residential level of care. Members transitioning to outpatient treatment from a controlled environment such as residential treatment or a carceral setting who have not used a stimulant in more than three months (i.e., no longer have a *current* StimUD) are still eligible for the Recovery Incentives Program as long as all other eligibility requirements are met.

CM should never be used in place of medications for addiction treatment (MAT). CM may be offered in addition to MAT for people with co-occurring stimulant and alcohol or opioid use disorders.

Eligible Medi-Cal members shall be referred to, and admitted into, treatment through a participating site's routine client admission process. Consistent with other DMC-ODS programs, there is no minimum age limit for an individual to receive CM services if they meet all eligibility criteria. In addition, pregnant and parenting people with StimUD are eligible to receive CM services. Medi-Cal members who are receiving care in residential treatment (e.g., ASAM levels 3.1–4.0) or institutional settings are ineligible for CM services until the day of discharge, when they are transitioned into outpatient care.

Members Under the Age of 21. Covered services provided under the Recovery Incentives Program shall include all medically necessary SUD services for individuals under 21 years of age as required pursuant to Section 1396d(r) of Title 42 of the United States Code. Federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) statutes and regulations require States to furnish all Medicaid-coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions, regardless of whether those services are covered in California's Medicaid State Plan. Consistent with federal guidance, services need not be curative or completely restorative to ameliorate a mental health condition, including substance misuse and SUDs. Services that sustain, support, improve, or make more tolerable substance misuse or a SUD are considered to ameliorate the condition and are thus covered as EPSDT services.

CM Visit Flow

Greet. Establish a positive relationship. Always keep the interaction pleasant and non-confrontational. The positive nature of CM allows for an opportunity to strengthen the therapeutic alliance. Your positive attention is also reinforcing to most members.

Assessment. Assessment consists of activities to evaluate or monitor the status of a member's behavioral health and determine the appropriate level of care and course of treatment for that member. Consistent with DMC-ODS policies described in BHIN 21-075, members must have an ASAM multidimensional assessment completed within 30 days following the first visit with a Licensed Professional of the Healing Arts (LPHA) or registered/certified counselor for members 21 and older that indicates they can appropriately be treated in an outpatient treatment setting (i.e., ASAM levels 1.0–2.5) or within 60 days if under 21 years old or experiencing homelessness. The initial clinical assessment shall confirm: (1) the individual has a diagnosis of a moderate or severe StimUD from the Substance-Related and Addictive Disorders chapter of the current edition of the DSM; (2) outpatient treatment is appropriate per the ASAM criteria; and (3) that treatment for a Stimulant Use Disorder is medically necessary.

Intake Visit. During a member's first visit, the CM Coordinator will complete several steps to initiate the service, specifically:

- Conduct eligibility check as described above – The CM Coordinator or other designated CM Team member (e.g., Back-up CM Coordinator, CM Supervisor) at the site will confirm the member's current Medi-Cal eligibility, as well as their eligibility for the program before initiating the CM service. The eligibility check should be done via the Automated Eligibility Verification System (AEVS) for Medi-Cal.
- The member should also be asked whether they are currently enrolled in a residential SUD treatment program. Members may not be enrolled in the Recovery Incentives Program if they are attending residential treatment.
- Before beginning CM treatment, a member must complete a thorough orientation and consent to the conditions of the Recovery Incentives Program. The orientation will address the following:
    - The days/times that a member must visit the facility in order to be eligible for incentives (during weeks 1-12, twice-weekly visits; during weeks 13-24, once-weekly visits).
    - The method of incentive delivery, as well as how and where incentives can be redeemed, including the prohibition of using incentives to purchase alcohol, cannabis, tobacco, firearms, lottery tickets, or for any form of gambling.
    - The availability of incentives and ongoing program participation when a member lapses or relapses and seeks readmission and the process for a member to seek readmission.
    - The site's UDT procedures and an explanation and review of medications/substances that may result in false-positive UDTs.
    - The rules governing when an incentive will be provided, including:

        - An explanation that the incentives are contingent on the absence of evidence of stimulant (e.g., cocaine, amphetamine, methamphetamine) use on a UDT.
        - An explanation that opioid testing will be done for the purpose of safety, due to association with overdose deaths, but will not impact the delivery of an incentive.
        - An explanation that all positive tests will be treated the same even if they result from use of one of the medications/substances known to provide false positive UDT results.
    - The amount of the initial incentive and how the value increases with consecutive stimulant-free UDTs and how the value will be reset to the initial $10 value in the case of a positive test or unexcused absence, and that increases will be recovered upon the submission of two consecutive stimulant-negative UDTs.
    - Program participation consent – The CM Coordinator will review with the member, and obtain their signature on, a consent form authorizing services and the secure sharing of data with DHCS and the program evaluation team, including all DHCS-required consent elements. See sample consent form available in Appendix A.
    - Explain the CM process and reinforce the expectations set forth above.
    - Enroll the member into the Incentive Manager (IM) Portal – The CM Coordinator will complete a member profile to enroll them into the web-based IM Portal that will keep track of UDT results and incentive gift cards distributed.

Ongoing CM Visits. Engage the member and initiate the visit – The CM Coordinator will greet the member, review their progress in the program (e.g., weeks completed out of 24), log into the IM Portal and locate the member's record/profile.

- Conduct eligibility check – The CM Coordinator or other staff within a provider agency offering CM will check member Medi-Cal eligibility monthly or more frequently if required by agency policy.
- At the same time as the monthly Medi-Cal eligibility check, the member should be asked whether they have enrolled in a residential SUD treatment program in the past month. If the member has been enrolled in a residential level of care, they must be immediately disenrolled from the Recovery Incentives Program. They may be readmitted to the Recovery Incentives Program when they are discharged from the residential treatment program, as detailed above.
- Administer UDT – The CM Coordinator will administer the UDT, including processing the results of the UDT in real time.
- Log results in IM Portal – The CM Coordinator will log the results of the UDT for stimulants (i.e., positive or negative).

- Discuss results – The CM Coordinator will discuss the UDT results with the member and offer other services if/as appropriate, which could include brief encouragement, motivational interviewing, and/or education based on the CM Coordinator's scope of practice and training. The CM Coordinator will encourage the member to meet with their counselor or LPHA. If opiate and/or oxycodone UDT results are positive, the CM Coordinator will document these results in the clinical chart, reinforce the risk of overdose, ensure the member has naloxone, and offer other treatment services as appropriate, including referral for MAT if the member has a co-occurring alcohol or opioid use disorder.
- Disburse incentives consistent with the "Incentive Delivery" section in Chapter 5.
    - If the UDT result entered is negative for stimulants, the IM will disburse the incentive generated by the IM consistent with the "Incentive Delivery" section in Chapter 5.
    - If the UDT result entered is positive for stimulants, the IM will not disburse an incentive.
- Plan for next appointment – The CM Coordinator will remind the member of their next scheduled appointment (date and time). The CM Coordinator should offer to answer any questions before adjourning the visit.
- Documentation – The CM Coordinator shall document the visit in the member's medical record (or chart). The CM Coordinator shall also document StimUD on the problem list (or treatment plan for Narcotic Treatment Providers, NTPs) within a member's medical record. Consistent with best clinical documentation practices, the CM Coordinator shall describe all interventions utilized with the member as part of their progress notes for each service to include CM in addition to any other outpatient services, such as motivational interviewing, cognitive behavioral therapy, or Community Reinforcement Approach. CM should not be offered to a member as a stand-alone treatment, but rather as one component of an individualized treatment plan. However, if a member chooses to participate only in selected services (e.g., they only participate in CM and not in other aspects of treatment), they shall not be penalized, chastised, criticized, or discharged from the program for declining to participate in any treatment or recovery service or for failure to participate in all recommended treatment services. Members needing or utilizing CM must be served and cannot be denied CM or be required to participate in other aspects of a SUD treatment program as a condition of entering or remaining in the Recovery Incentives Program.
    - If the member does not attend a scheduled visit, the CM Coordinator should document the absence and any extenuating circumstances in the member's medical record and in the IM Portal.
- Billing – The CM Coordinator shall complete claims documentation to bill the DMC-ODS county for the service, using as many units of the 15-minute code H0050 as appropriate, given the length of the visit, and using one of two required ICD-10 diagnoses (in addition to any other relevant codes for the visit; for example, the primary diagnostic code may be

for stimulant use disorder, with the appropriate code below used as a secondary diagnosis):

  - R82.998: Positive urine test for stimulants
  - Z71.51: Negative urine test for stimulants
- Thank the member for coming to the clinic/program that day. Validate success as well as frustration, but always model a positive and hopeful attitude.

Chapter 5. Incentive Manager

Overview of Incentive Manager Portal

- CM Coordinator enters UDT results.
- System automatically assesses member-specific circumstances.
- System automatically applies correct incentive amount.
- Incentive amount is “dispatched”, meaning CM Coordinator can select delivery method and incentive vendor in consultation with the member.
- Incentive transaction is logged.

Adding a New Member (see Figure 1)

- Open “dashboard pane”.
- Click “+” button to the left of “member” on the top of the data table.
- Input required patient information, including client identification number (CIN) and DOB.
- Input optional information for email and/or cell number (these fields support incentive delivery).
- The CM Coordinator’s name should appear on the pane automatically.
- Confirm that your agency verified the member’s Medi-Cal eligibility in the AEVS and eligibility for CM.
- After clicking “Submit,” the CM Coordinator may see an error stating that the member already exists in the system. This is a safeguard against members trying to enroll in multiple programs simultaneously. It may also occur because the member is seeking to transfer to your site from another program.
- Instances may occur when a member needs to transfer to another site and/or county temporarily or permanently. In the case of temporary travel, the CM Coordinator at the member’s current site should engage in the following procedures.

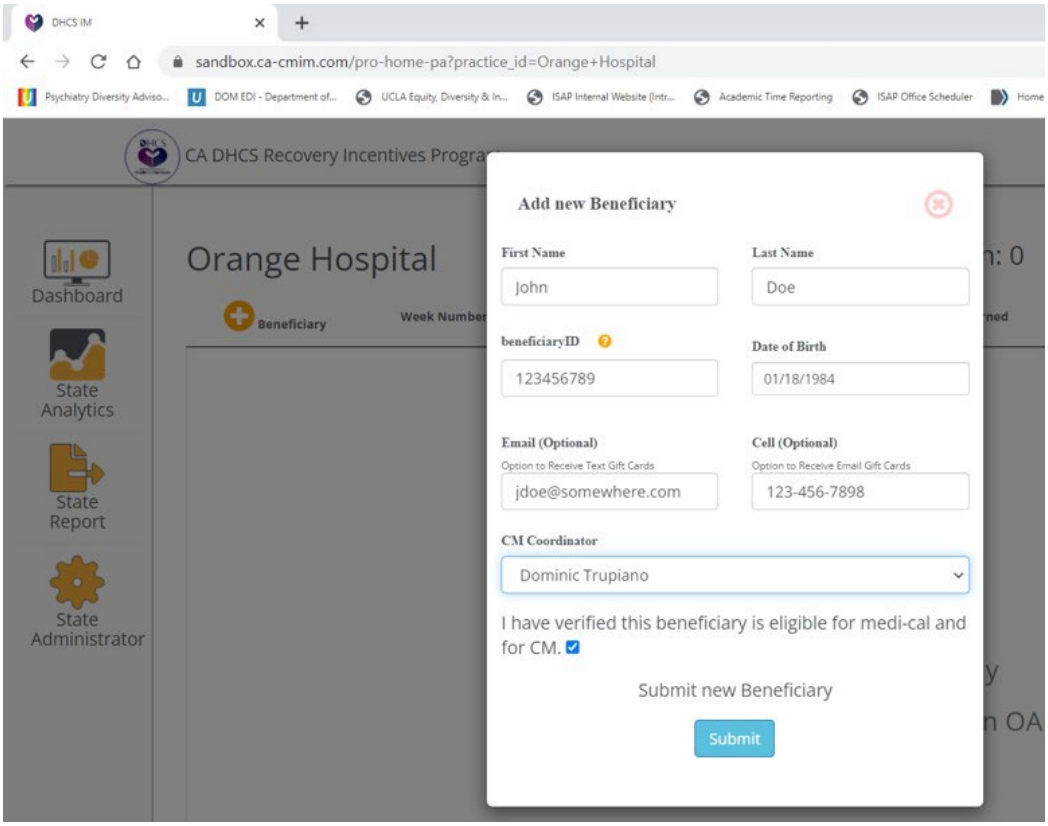
Courtesy Services for Temporary Travel

In situations where a member receiving CM services from their DMC-ODS County of Responsibility temporarily travels to another DMC-ODS county that also participates in the Recovery Incentives Program, and the member is unable to attend scheduled CM service appointments during their travel, the DMC-ODS County of Responsibility **shall** reimburse CM services that an out-of-county DMC-ODS provider participating in the Recovery Incentives Program delivers to the member.

Prior to the member traveling out of county, the CM Coordinator from their DMC-ODS County of Responsibility (Home CM Coordinator) shall identify and contact a participating Recovery Incentives Program provider located within the travel location’s DMC-ODS County (Travel

Recovery Incentives Program provider) to notify them of the member's travel plans and schedule an appointment for the member based on their current UDT schedule. The Home CM coordinator shall also contact the incentive manager call center and provide them with the same information, so the call center can change the member service location within the incentive manager program during the member's temporary travel. Prior to the member returning to their County of Responsibility, the CM Coordinator from the travel location's DMC-ODS County (Travel CM Coordinator) shall contact the County of Responsibility Recovery Incentives Program provider to notify them of the member's pending return and schedule an appointment for the member based on their current UDT schedule. The Travel CM coordinator shall also contact the incentive manager call center and provide the information so the call center can change the member service location within the incentive manager program, prior to the member returning to their County of Responsibility.

Figure 1. Adding a new member

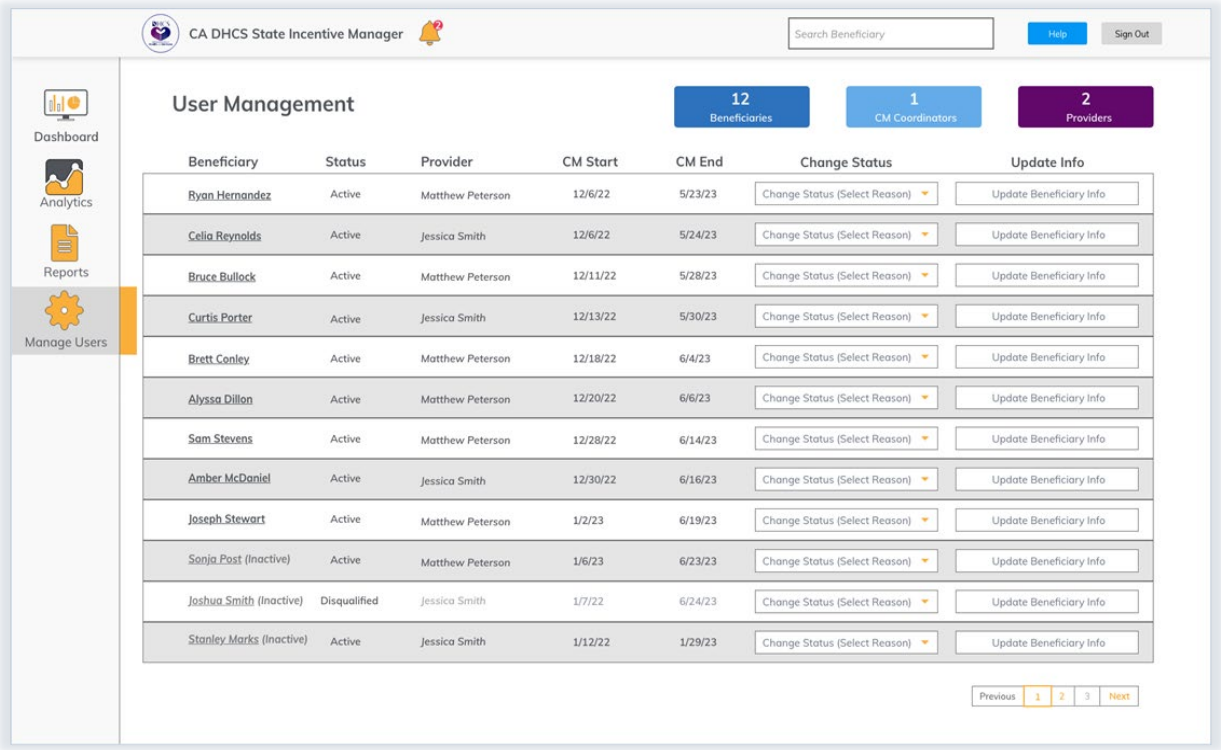


Entering Member Changes (see Figure 2)

DHCS or County Users may update member information.

- Click “Manage Users” on left pane.
- Find the relevant member.
- In the data table, click “Update Member Info.”
- At any point, a DHCS or County User can utilize the call center to assist with these changes.

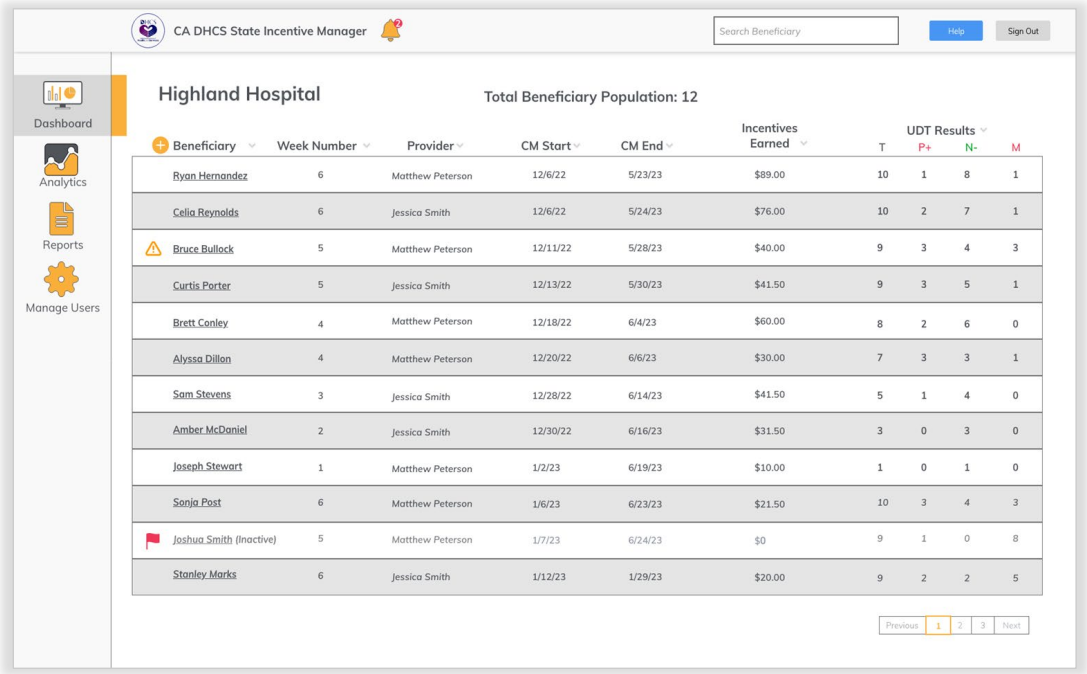
Figure 2. Member Changes



Selecting a Member to Enter UDT Results (see Figure 3)

- Open the “dashboard pane.”
- Find the member either by sorting or searching.
- Click on the member’s name (it will be underlined).
- This action will open that specific member’s chart.

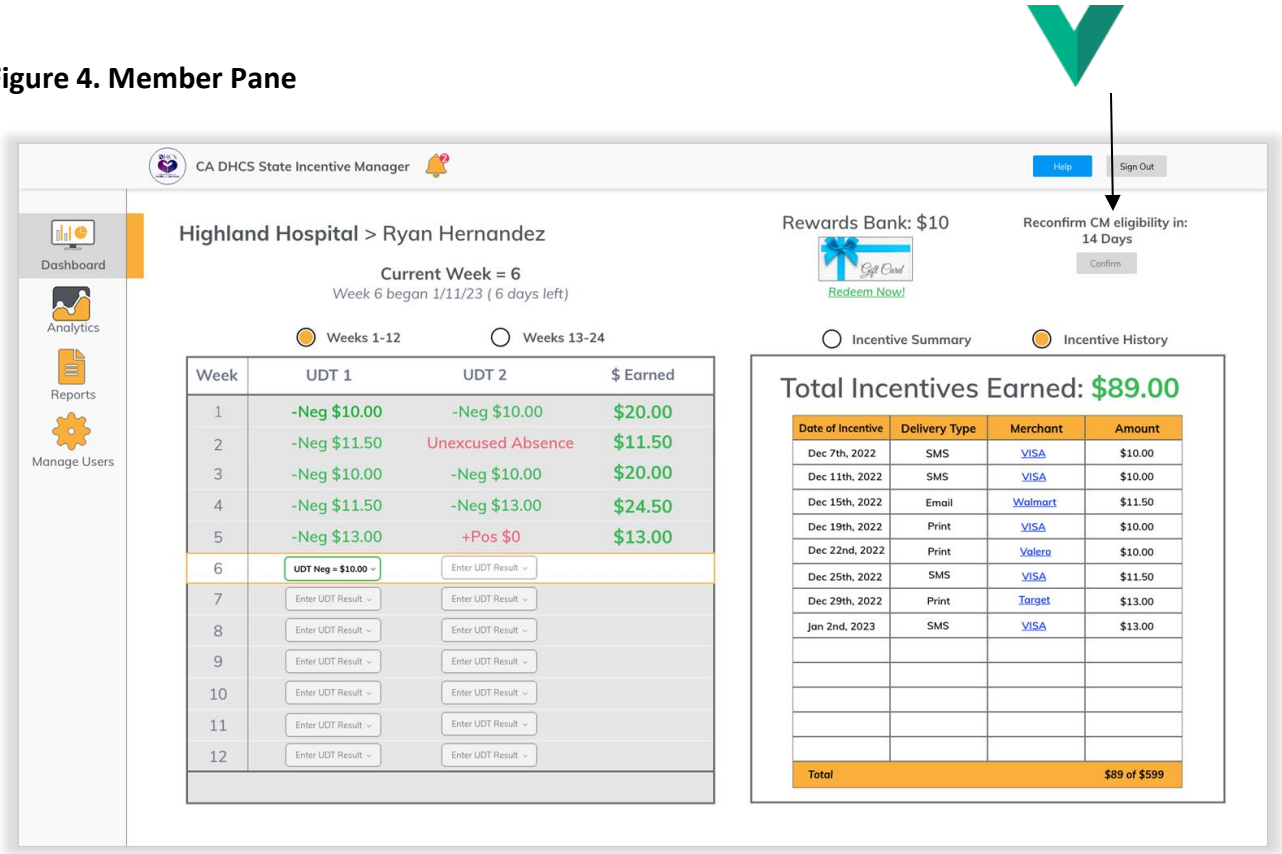
Figure 3. Selecting a Member



Member Pane (see Figure 4)

- This page contains member-specific information (from left to right).
- UDT results by visit.
- Incentives earned by week and visit.
- Next incentive amount available if UDT is negative for stimulants.
- Rewards bank.
- Reconfirmation of program eligibility (to be completed monthly; see arrow).
- Summary of incentives earned.
- Incentive history (date, delivery type, merchant, and amount).

Figure 4. Member Pane

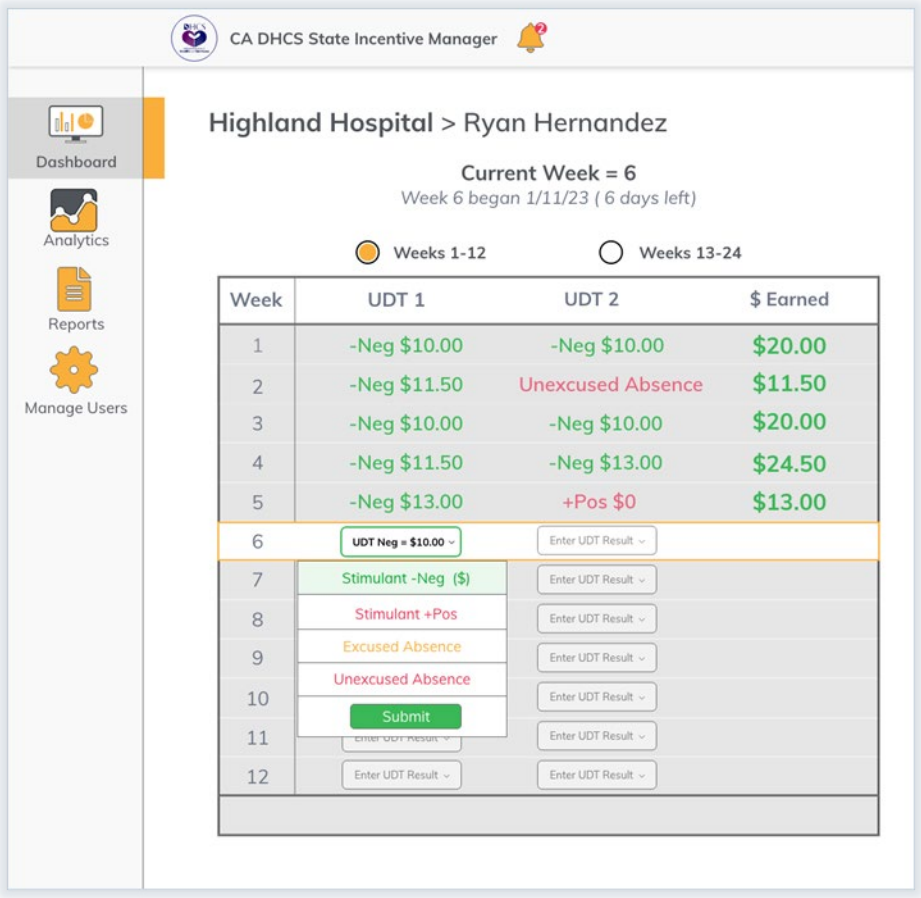


Entering UDT Results or Absence (see Figure 5)

Once you are on the member pane:

- Identify the next available session.
    - This will be the “Enter UDT result” button that is not grayed out.
    - Other session buttons will not work when clicked on as they are locked.
- Click the “Enter UDT result” button.
- From the dropdown list, select the relevant option:
    - If the UDT was negative for stimulants, select “Stimulant-Neg ($).”
    - If the UDT was positive for stimulants, select “Stimulant +Pos”.
    - If the member has an excused absence, select “excused absence” and add a note.
    - If the member’s absence is unexcused, select “unexcused absence.”
- When you select the appropriate option, the “submit” button will turn green.
- To submit the result, you must click the “submit” button.
- The system will automatically calculate the correct incentive amount.
- *Note: If all options are greyed out, look in the upper right and indicate that Medi-Cal eligibility has been confirmed in last 30 days.*
- *Note: UDT results can only be entered at least 48 hours after the previous input.*

Figure 5. Entering UDT Results or Absence



Managing Incentive Rewards

How are rewards calculated?

- Rewards will be earned after a stimulant-negative UDT is entered into the system.
- Rewards are calculated by the system using a well-defined schedule, which is:
    - **For weeks 1-12 (2 visits per week)**, the reward amount starts at $10 and increases by $1.50 for each two consecutive stimulant-negative UDTs. Rewards "reset" (as described above) to $10 upon the next stimulant-negative UDT following a positive UDT or unexcused absence. Upon the next consecutive stimulant-negative UDT, the reward amount "recovers" to the place in the schedule where the member would have been if there had been no stimulant-positive UDT or unexcused absence.
    - **For weeks 13-24 (1 visit per week)**, the reward amounts do not change. Each stimulant-negative UDT in weeks 13-18 receives a $15 reward and each stimulant-negative UDT in weeks 19-23 receives a $10 reward. A stimulant-negative UDT in week 24 receives $21.

How are rewards delivered?

- Rewards are offered as vendor-specific gift cards.
- Rewards can be redeemed immediately or “banked” to aggregate earnings to larger amounts
- Rewards can be delivered via text, email, or printed out in the clinic; the CM Coordinator should inform members when enrolling them into the incentive manager that they are asking for the member’s mobile number and email address to deliver rewards in the manner they choose.
- If shared via text or email, the reward can be added to an Apple or Google wallet.
- Gift cards are only available for vendors who prohibit purchases of alcohol, tobacco, firearms, lottery tickets, and cannabis.

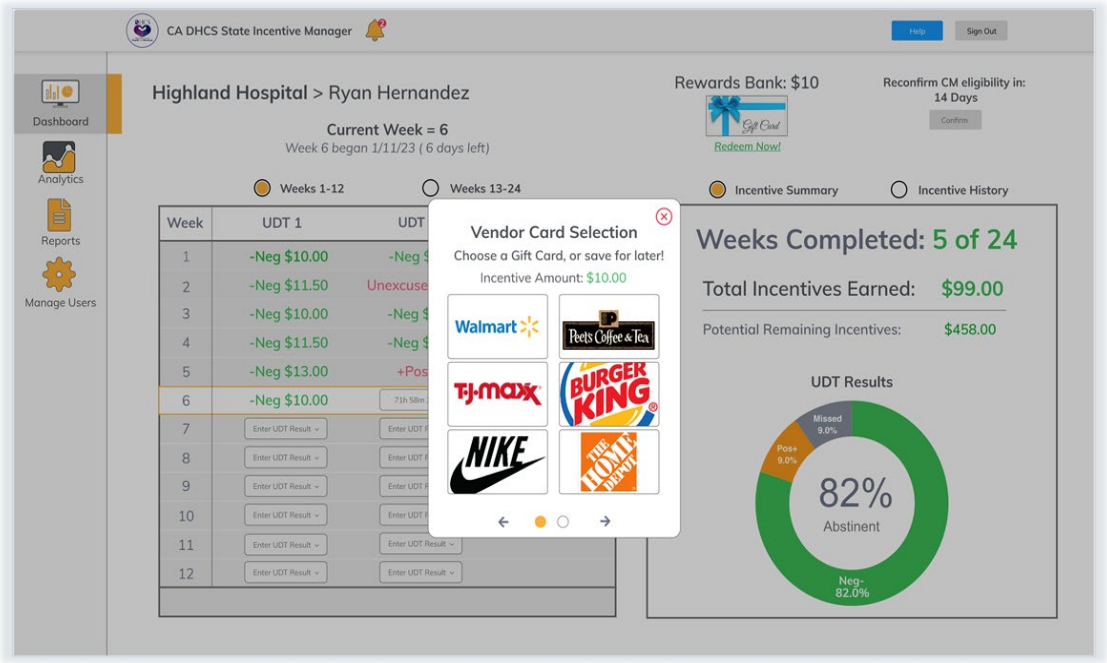
Sample Reward Schedule with all Stimulant-Negative UDTs

Week	Reward for Stimulant-Free Test
Week 1	$10 + $10 = $20
Week 2	$11.50 + $11.50 = $23
Week 3	$13 + $13 = $26
Week 4	$14.50 + $14.50 = $29
Week 5	$16 + $16 = $32
Week 6	$17.50 + $17.50 = $35
Week 7	$19 + $19 = $38
Week 8	$20.50 + $20.50 = $41
Week 9	$22 + $22 = $44
Week 10	$23.50 + $23.50 = $47
Week 11	$25 + $25 = $50
Week 12	$26.50 + $26.50 = $53
Weeks 13-18	$15 per week/test
Weeks 19-23	$10 per week/test
Week 24	$21 per week/test
Total	**$599**

Reward Type Selection (see Figure 6)

- Once a negative UDT is input, the system will offer the reward type selection.
- The CM Coordinator will work with the member to select the preferred vendor.
- There are two options:
    - Gift card for a specific vendor.
    - Adding funds to a virtual “bank.”
- Click the preferred option and proceed to “delivery type” selection.

Figure 6. Reward Type Selection

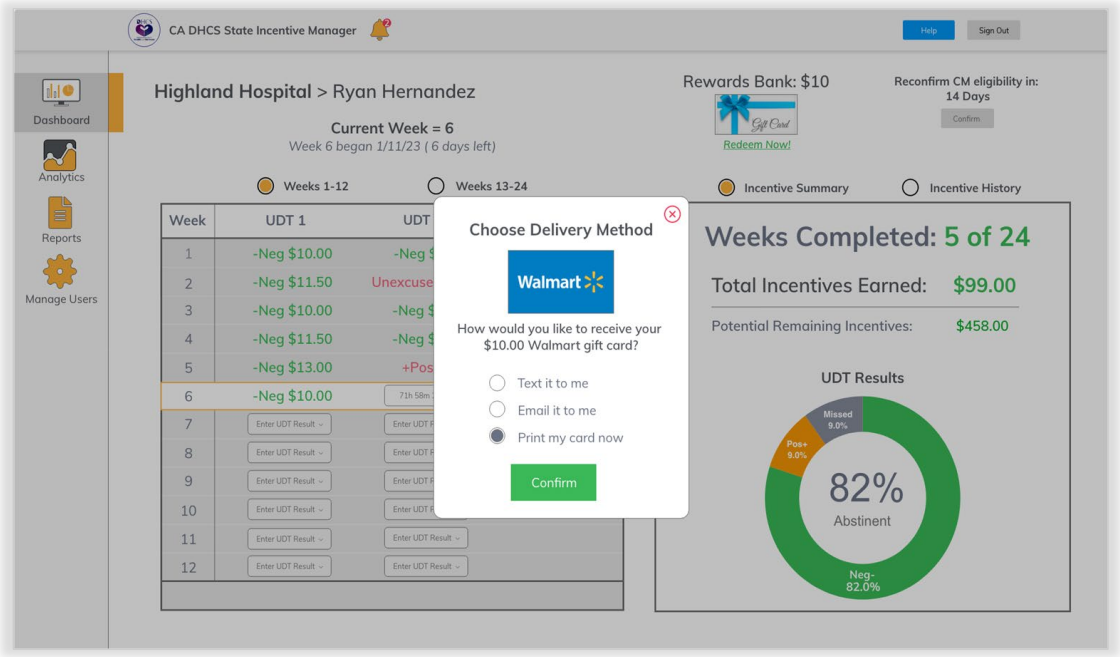


A full list of gift card vendors is available in the IM Portal.

Reward Delivery Type Selection (see Figure 7)

- Once a reward type is selected, the system will offer the delivery type option.
- For vendor-specific gift cards, the member can select text, email, or printed hard copy.
- *Note: For "banking" of rewards, this screen will not appear.*
- For texts, members will be required to input their phone number.
- For emails, members will be required to input their email address.
- For printed gift cards, once they are generated and printed, they *cannot* be reprinted, so the member must keep track of them.
- Text and email gift cards can be added to Apple or Google wallets.

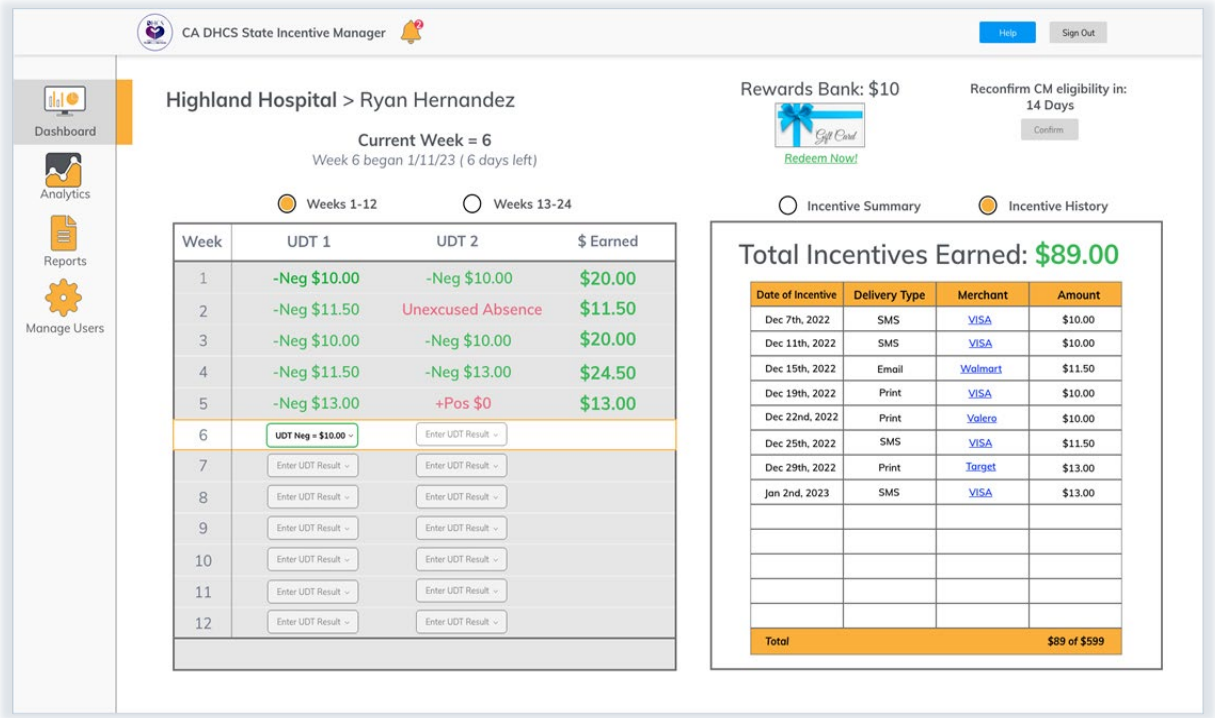
Figure 7. Reward Delivery Type Selection



Rewards Bank (see Figure 8)

- Once a reward amount has been generated, if the member chooses not to redeem it for an eGift card, unused dollars will be stored in the Rewards Bank.
- The Rewards Bank will allow the member to “save up” for higher denominations of eGift cards to redeem in the future.
- *Note: since the member will not be receiving an immediate reward, the CM Coordinator should demonstrate interest and enthusiasm; for instance, by asking the member what they are saving up for and praising them for it.*

Figure 8. Rewards Bank

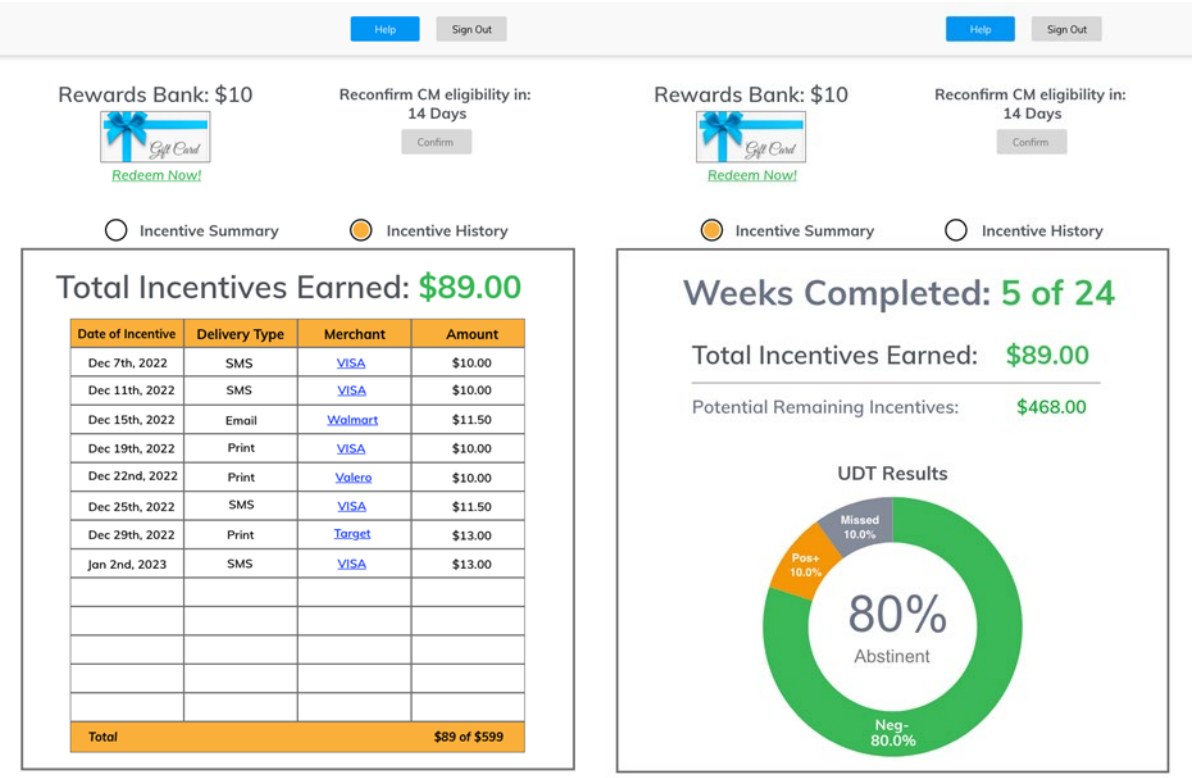


Rewards History (see Figure 9)

Rewards history for a specific member can be seen in two ways:

- As a comprehensive list of every reward earned:
  - Date
  - Delivery type
  - Vendor
  - Amount
- As a summary of results earned in total:
  - Total earnings
  - Potential remaining rewards
  - Percentage of sessions with a negative UDT

Figure 9. Rewards History



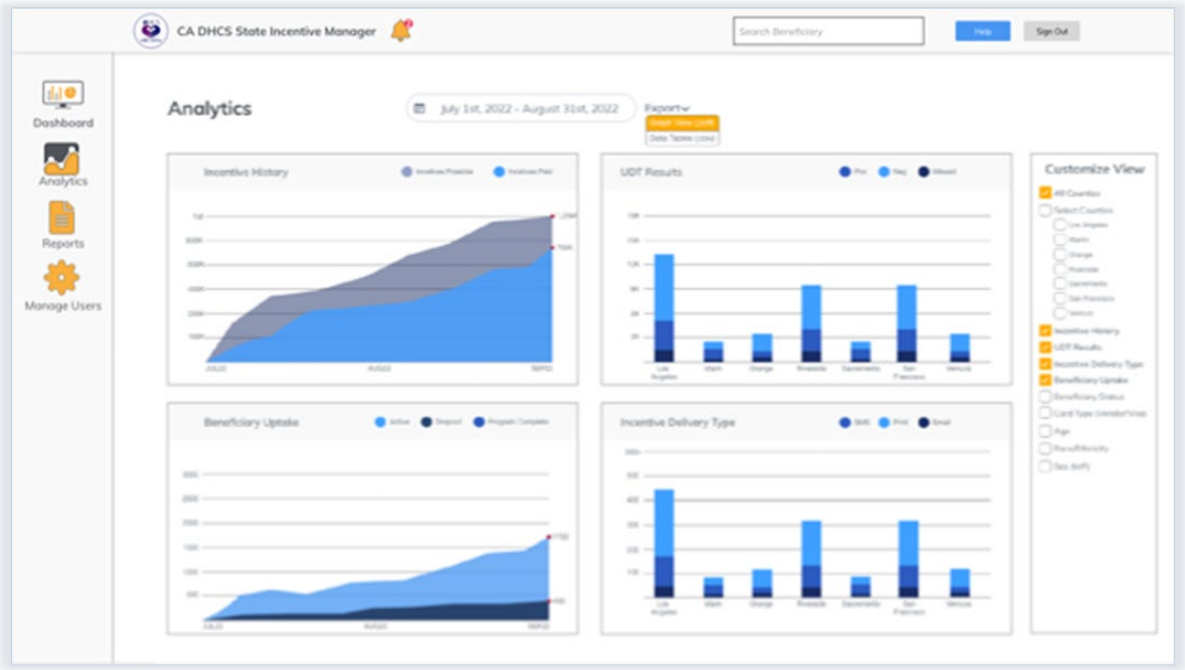
- The CM Coordinator should remind members that rewards cannot be used for purchasing alcohol, tobacco, gambling, cannabis, or firearms.
- Vendor-specific gift cards are either for vendors who do not offer these items or have inherent restrictions on purchasing prohibited items.
- The CM Coordinator should also remind members that rewards cannot be given out again once they have been delivered, so they should make sure to keep track of them.

CM Coordinator Analytics (see Figure 10)

CM staff can run analyses and reports. Available reports will vary depending on their level of permissions. To run a report, click on the “analytics” button on the left side of the portal pane.

- The analytics pane is highly customizable by the user using the “customize view” pane on the right side.
- Data can be downloaded as charts (i.e., a pdf) or raw data (i.e., csv or json).
- Data can be selected based on a specific date range.

Figure 10. Analytics Pane

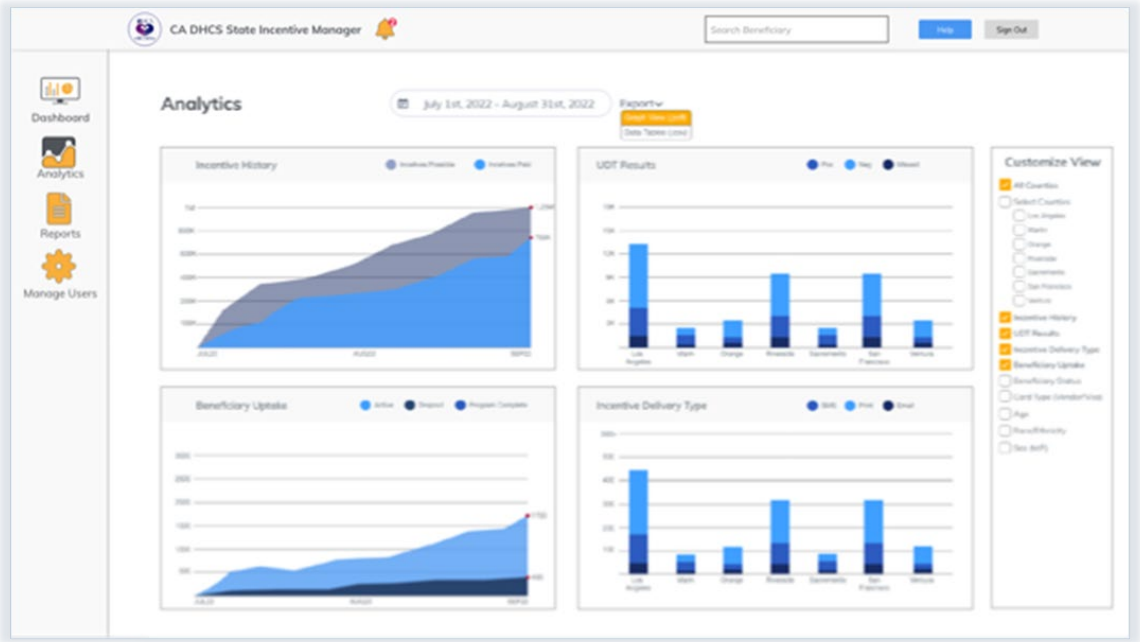


Analytics Customization (see Figure 11)

Analytics panes can be customized based on several factors.

- Selections by county will filter the data available in the charts on the left.
- Other selections will add new charts to the left side (shown in Figure 11 as reward history, UDT results, member uptake, and reward delivery type).

Figure 11. Analytics Customization



Analytics Report Pane (see Figure 12)

Reports will be compiled automatically by the system.

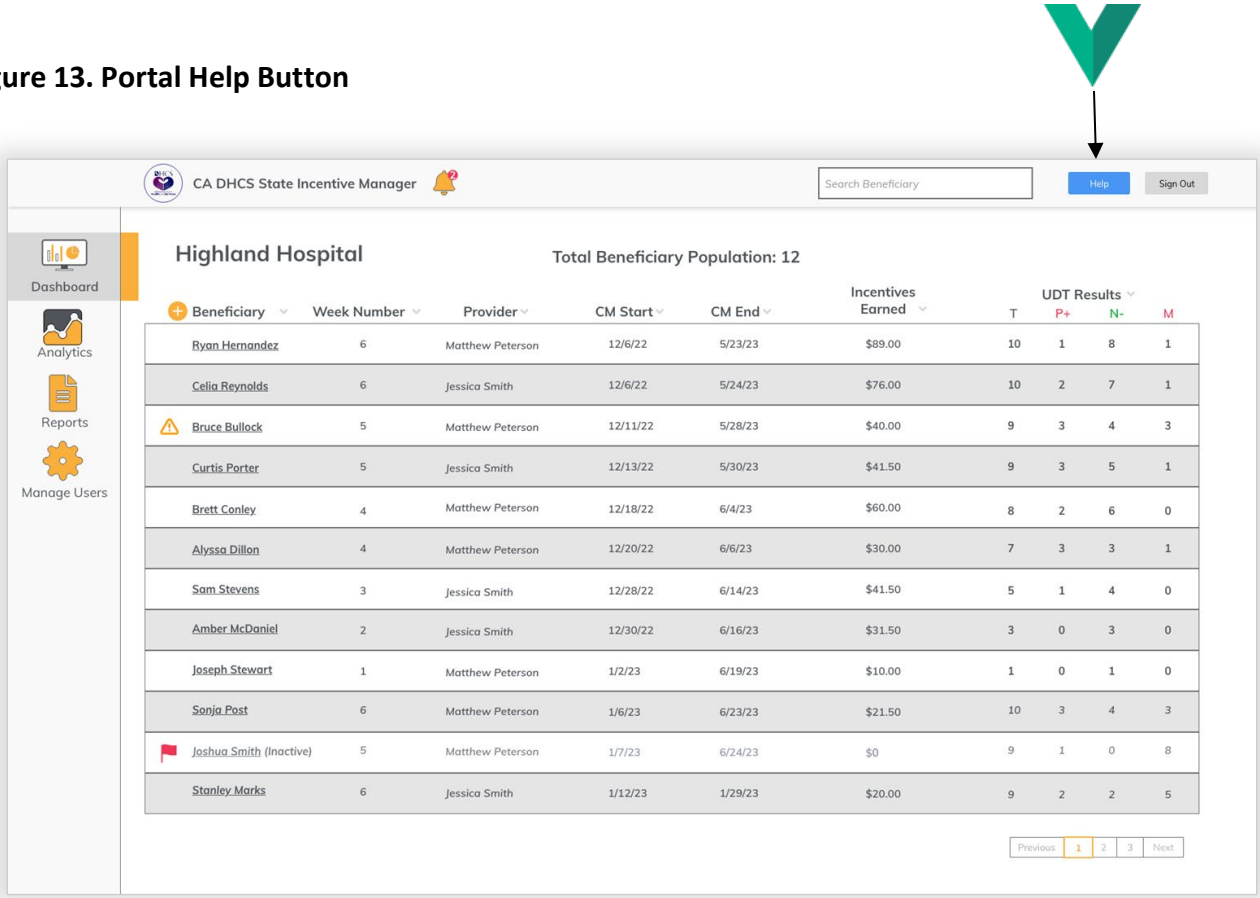
- Reports are available monthly.
- Reports are available at all levels for your role, i.e., CM Coordinator, CM Supervisor, County administrator, etc. and can be selected via a dropdown menu.
- Reports can be selected for specific sites or counties.
- To select a report, click the icon.
- The reports do not contain any member-level information (i.e., PHI).
- Reports may be downloaded, printed, or emailed.
- Once a specific report is selected, the report preview will pop-up.

Figure 12. Analytics Report Pane

Portal Help Center (see Figure 13)

The help button is on every pane of the portal, on the upper right-hand side.

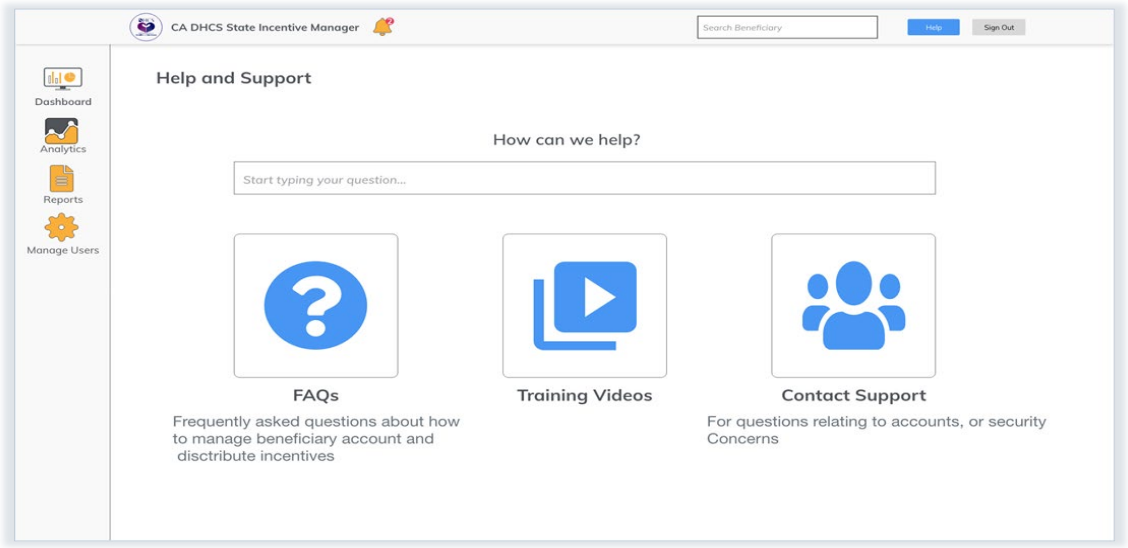
Figure 13. Portal Help Button



Three types of support are available in the IM Portal (see Figure 14):

1. Frequently asked questions documents.
2. Training videos.
3. Call center available by phone.

Figure 14. Portal Help Center



Chapter 6. Other Implementation Issues

Identifying Eligible Members

When beginning a new CM program, it is best to focus on addressing one target behavior, and therefore not everyone at your treatment site will be eligible. When implementing the Recovery Incentives Program, it is important to follow established criteria to identify eligible members. These criteria can be found in the BHIN 23-040 (see Appendix D) and should be shared with your site's intake staff and/or any treatment providers who may be able to make referrals.

The Recovery Incentives Program developed a series of outreach and communication resources, building on current efforts, for treatment providers to educate and inform Medi-Cal members about CM and its availability for individuals living with StimUD. The Recovery Incentives Program Provider Outreach and Communications Toolkit (see Appendix C) includes sample messaging for providers to use to conduct outreach with members who may be eligible for CM. The guidelines are reflective of the diverse racial/ethnic backgrounds of members who may be eligible for the CM program. A flyer and business cards (of various sizes) are available, as well, in Appendix C.

Program Roles, Supervision, Fidelity, and Evaluation

Once you have set up your CM program using the instructions provided in this Manual, DHCS policy documents (BHIN 23-040, Appendix D), and other materials generated by UCLA, you can take the following steps to select and train staff, implement the Program, and set up systems for ongoing supervision and monitoring.

Two reasons exist for closely monitoring your CM program. The first one is, just like all other evidence-based treatments, fidelity to the treatment model is essential to making sure your efforts result in good outcomes. CM is not likely to work if you do not implement the model in a way that is consistent with how it was tested in research studies. Second, you must make sure your Program consistently meets requirements for delivery and documentation of CM services. Unlike other evidence-based interventions, if you don't implement CM correctly, you could be accused of Medicaid fraud.

While we are not lawyers, we have worked closely with leading CM experts, the federal government, and DHCS to develop a CM model that is consistent with current requirements. We strongly encourage you to monitor your CM program, so it is consistent with the requirements. Additionally, the County, DHCS, and UCLA will be assisting with monitoring of service documentation and delivery and will notify any site where problems are noted so that that they can be quickly addressed and resolved.

Choosing Staff. Contingency management protocols must be delivered consistently to be successful, so it is helpful to identify specific staff members to deliver CM. The great thing about CM is that you do not need to be a clinical treatment provider to deliver CM. CM can be delivered by therapists, counselors, physicians, nurses, peer support specialists, case managers, or medical assistants, as long as the staff have been trained in CM and certified to serve as a CM Coordinator, Back-Up CM Coordinator, or CM Supervisor. For the Recovery Incentives Program, each

participating site will be required to select from existing staff or hire a part-time or full-time staff member to serve in the role of the CM Coordinator.

The person(s) implementing CM must be recovery-oriented and believe in the positive, non-judgmental approach to treatment. If the CM Coordinator does not have training in motivational interviewing, further training will be made available by UCLA.

It is important that you make sure that the entire treatment team knows how an individual is doing in CM. If they are doing great, then the whole team should know so they can all celebrate the member's success. If, however, the member is not doing well, it is important that the clinical team knows so that they can offer additional support to them. The member should be made aware that their progress in the CM program will be shared with other providers within the site, so CM is integrated into a "team" approach to their overall clinical care. Your site should include language to that effect in your consent documents.

The CM Coordinator will be the point person for the CM program when questions arise. There is a list of Frequently Asked Question on the DHCS CM Website. UCLA has also set up a website for consultation and questions. Other staff involved with CM protocols should have their roles clearly defined as well.

- The only staff members who can administer CM are the CM Coordinator, the Back-up CM Coordinator, and the CM Supervisor. The CM Coordinator may be a Licensed Practitioner of the Healing Arts (LPHA), a certified or registered SUD counselor, certified peer support specialist, or other trained staff under the supervision of an LPHA.
- The optimal caseload for one full-time CM Coordinator is no more than 30 members at any given time and approximately 60 to 100 members over the course of a year.

Ongoing Supervision. It is required that the designated CM Supervisor perform fidelity checks for any staff involved in providing CM. This involves scheduling regular check-ins to assure that your CM program is being delivered consistently and rigorously over time. This routine can help to detect when a procedural shift or misunderstanding has occurred. A fidelity monitoring tool will be administered by the UCLA Training and Implementation Team.

Research has shown that fidelity to CM procedures is directly tied to CM implementation success and provider satisfaction.[12] Supervision can take the form of recorded or observed CM visits or scheduled paper or in-person assessments where the staff can demonstrate some aspects of CM delivery to their supervisor. CM Supervisors can also use the analytics features of the IM Portal to generate reports to ensure procedures are being implemented correctly and consistently. Clinic meetings should occur regularly with the CM Team to address any administrative and clinical issues that arise.

Steps for Training New Staff

1. All CM staff must complete the self-paced CM Overview Training (2 hours) and the 2-part live virtual CM Implementation Training (6 hours total delivered in two 3-hour sessions) and successfully complete a 2-part Readiness Assessment process prior to initiating CM services. Live virtual trainings will be scheduled regularly to ensure that we can accommodate new staff quickly. Training dates and times are available here. See

Appendix E for a visual flow chart of the CM Team Requirements for completing all required trainings.

2. Use this Program Manual and other training materials to orient the CM Team to administer CM for stimulant use disorders.
3. Develop and disseminate site-specific policies and procedures on how this CM protocol will be implemented at your site. This could include preparing or accessing CM protocol checklists, forms, and electronic tools, policies regarding restroom setup and UDT procedures, how space will be utilized, EHR-specific documentation/billing requirements, etc. Site-specific policies and procedures must conform to the requirements set forth in BHIN 23-040 and this Manual.
4. Next, the CM Team can practice CM with role-playing exercises and reviewing their site protocol for various scenarios to ensure they understand the CM principles and protocols. Examples of role-playing activities include practicing how to describe the CM protocol to new members or practicing the delivery of CM.
5. Have trained personnel (i.e., CM Supervisor) sit in on initial CM visits conducted by new CM Coordinators.
6. Regularly review CM documentation conducted by new CM Coordinators.

Tips for Handling Contested Stimulant-Positive UDT Results

- Remain non-confrontational (do not be accusatory or defensive) about the results, though stay firm that awarding the reinforcer is contingent on the result of the objective marker *("The gift cards can only be given out when a stimulant-negative urine test is submitted."*) Remind the member that this was agreed upon at the start of their participation in the Recovery Incentives Program so there would not be any confusion.
- If the member is insistent that they have remained abstinent since the last test, a second point-of-care UDT can be administered to determine if the first test result was a false positive. The member should be informed that the result of the second test will be the determining factor in whether they receive an incentive that day. This course of action should be used very sparingly and preferably in consultation with the CM Supervisor. If a member is VERY upset and there is concern about them leaving the program over this result, the second test can be offered. It is also important to remember that billable rates include only one UDT per visit, so the second test would not be reimbursed to your agency.
- Remind the member that some over-the-counter cold and flu medications may contain ingredients that will result in a stimulant-positive drug screen. Some amphetamine-based hallucinogens (e.g., MDMA) may also result in an amphetamine-positive drug screen. Review the list of medications to avoid (see last page of Sample Consent Form in Appendix A) with them to see if they have begun using one recently.
- Remind the member that it may take a few days for the drug metabolite to clear their system. It may take two regularly scheduled UDTs after use before a stimulant-negative test occurs.

- As a reminder, members who are taking a prescribed amphetamine (such as Adderall® – amphetamine-dextroamphetamine salts) will not be eligible for participation in the Recovery Incentives Program as there is no way to distinguish between these medications and non-prescribed use of amphetamines. Members who are taking these medications should be offered other treatment services.

Handling Excused Absences

Members will be informed in the Recovery Incentives Program consent form that if they cannot attend a scheduled appointment, they will need to tell the CM Coordinator ahead of time to reschedule or receive an excused absence. An excused absence must be requested and approved by the CM Coordinator prior to the scheduled visit. Absences cannot be approved as excused after the scheduled visit. Reasons for excused absences include having a doctor's appointment that cannot be rescheduled, illness, a court date, or a death in the family. The member must provide documentation of the reason for the absence at the next scheduled visit (i.e., receipt from healthcare clinic, funeral announcement, or court document).

- **Retention is the Goal.** Clearly establish attendance expectations at the beginning and find ways to work with each member on a case-by-case basis. Be flexible if possible and reschedule the appointment. Where possible, members should be rescheduled for the same day. Alternatively, a member can be scheduled on a contiguous day. If they reschedule in this way, they will still receive rewards according to the schedule.
    - For example: If a member tends to get called into work last minute, see if they can commit to providing a urine sample on their way into work or during a lunch break. They can always receive their incentive on a different day when they have more time.
- If the member has an excused absence as defined above, their incentive schedule will continue at their next appointment with no reset. They will not receive an incentive for the missed appointment(s), nor would their timeline be extended to 'make up' the missed appointment, but their gift card value will not be reset.
- Likewise, a staff or member holiday is a valid excused absence. The member should be rescheduled for the day before or after the holiday if possible, or they may be able to provide only one sample during a holiday week, without penalty.
- All absences will be entered into the IM Portal as either excused or missed (unexcused) so that incentives can be calculated accurately and there is no confusion later. Absences must be entered into the IM Portal on the day of the appointment since it will not be possible to enter two results on the same day later in the week (or on the following week, in the case of an absence on a Thursday or Friday). The IM Portal will automatically account for the excused or unexcused absence.
- In the event of one or more missed visits (unexcused absences), the CM Coordinator should attempt to contact the member to facilitate their return to the clinic on their next scheduled visit.

Readiness Assessment

After completion of Part 2 of the Recovery Incentives Program: California's Contingency Management Benefit Implementation Training, sites will first complete an online Readiness Assessment Self-Study Survey via Qualtrics and then participate in an interactive 1-hour Readiness Assessment Interview with UCLA staff via Zoom. To be eligible to initiate the Readiness Assessment process, at least one CM Coordinator and one CM Supervisor per site must first complete all required trainings (2-hour CM Overview on-demand course and 2-part Implementation Training).

The purpose of the Readiness Assessment is to ensure that sites are fully prepared to offer CM services in accordance with DHCS standards and the rules and regulations of the Recovery Incentives Program. Both components of the Readiness Assessment (Qualtrics Survey and Zoom Interview) are required to be completed in full prior to being permitted to administer CM services. The Readiness Assessment process includes:

- Interactive demonstration of procedures and site-specific implementation goals.
- Entering practice cases into the Incentive Manager Portal to demonstrate proficiency with these tools.
- Responding to pre-set clinical scenarios, including, though not limited to, how to handle unexcused absences, disputes over test results and positive results for drugs other than stimulants.

See Appendix E for a visual flow chart of the CM Team Requirements for completing the Readiness Assessment process.

Evaluation

The evaluation approach is organized around the RE-AIM framework, as follows.

1. **Reach:** This will be measured as the percentage of members in treatment for stimulant use disorder who participate in the Recovery Incentives Program. UCLA will also evaluate whether there are disparities in reaching different member populations.
2. **Effectiveness:** Effectiveness will be based on the results of UDTs. Data will be collected from the IM Portal. UCLA will track the impact of CM on treatment retention and treatment attendance.
3. **Adoption:** Adoption will be measured by evaluating how many treatment sites implement the Recovery Incentives Program. This will be evaluated using DMC-ODS claims data.
4. **Implementation**: Implementation will be evaluated by the degree to which the Recovery Incentives Program is implemented with fidelity to the treatment protocol. Perceptions of challenges and areas for potential improvement will also be collected from treatment program staff and Recovery Incentives Program participants.
5. **Maintenance**: Maintenance will be measured by evaluating the degree to which sites implementing the Recovery Incentives Program continue providing the benefit

throughout the evaluation period, based on data collected from the web-based IM Portal and Medi-Cal claims data. In addition, surveys and qualitative interviews with CM Coordinators and Supervisors will be conducted and focus on factors that could promote or impede the continued delivery of the contingency management benefit.

Additional evaluation expectations for sites:

- Recovery Incentives Program sites will be asked to give an online survey link or QR code to members to participate in a short (5-minute) survey or provide them with a way to participate onsite (e.g., tablet or computer). Ideally this will occur at intake or early in treatment, and members will be encouraged (but not coerced) to participate. Members will be compensated by gift card (disbursed by UCLA, not the IM Portal) and become eligible for additional follow-up surveys (also compensated). Some members participating in a survey may also be invited by UCLA to participate in interviews. Although plans may be revised, we currently anticipate that each site will be required to meet a specified number of members, at which time the site will be contacted and distribution of the survey link can be paused.
- Sites may be contacted by e-mail to participate in surveys and interviews themselves. This will be an opportunity to provide ideas on how to improve the Recovery Incentives Program and describe barriers, successes, and lessons learned that may help others in the field. The CM Coordinator may be asked to distribute an additional survey to counselors at the site.

Planning for both the member and site surveys is currently underway, and additional details and instructions will be forthcoming, but both will be essential to the evaluation of the Recovery Incentives Program, and your participation is greatly appreciated.

Federal Law and Incentive Payments

In general, federal law restricts providers' abilities to offer financial incentives as part of patient therapy or patient recruitment. The Anti-Kickback Statute (AKS) is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).[1] The Civil Monetary Penalties Law (CMPL) authorizes the Secretary of Health and Human Services to impose civil money penalties, an assessment, and program exclusion for various forms of fraud and abuse involving the Medicare and Medicaid programs.[2]

Over the years, the U.S. Department of Health & Human Services Office of Inspector General (OIG) has cautioned providers about various problematic activities that may create legal risk

[1] https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/
[2] Ibid.

under the AKS or the CMPL, including paying people to receive care that was not medically necessary.

However, the federal government has explicitly stated that the AKS and the CMPL do not apply to motivational incentives that are delivered as part of the Medicaid-covered CM benefit, and in compliance with the DHCS-approved CM protocol. For the purpose of the Medi-Cal contingency management benefit authorized under the CalAIM 1115 demonstration:

> *These motivational incentives are considered a Medicaid-covered item or service and are used to reinforce objectively verified recovery behaviors using a clinically appropriate contingency management protocol consistent with evidence-based research. Consequently, neither the Federal anti-kickback statute (42 U.S.C. § 1320a-7b(b), "AKS") nor the civil monetary penalty provision prohibiting inducements to members (42 U.S.C. 1320a-7a(a)(5), "Member Inducements CMP") would be implicated.*[3]

For more information on OIG rules for Non-Medicaid-funded Contingency Management Programs, see Appendix F.

Non-Federal Share of CM Costs

DHCS will initially finance the non-federal share of CM services with state funds that are available for a limited period of time as a result of the DHCS Home and Community-Based Spending Plan, which includes CM services. DHCS must spend these funds by March 31, 2024.

If counties elect to continue participation in this optional benefit after the end of the DHCS Home and Community-Based Spending Plan, they shall be responsible for the non-federal share of CM services. Because of payment lag, counties shall submit claims and applicable certifications for CM services by February 15, 2024, in order for DHCS to cover the non-federal share of these services. In effect this means that counties shall be responsible for the non-federal share of CM services for any claims submitted after February 15, 2024. DHCS will extend the pilot period through at least the duration of the CalAIM 1115 demonstration period (ending December 31, 2026), allowing approved DMC-ODS counties to continue services beyond the original pilot end date of March 2024.

Please refer to the DMC-ODS Billing Manual for general guidance about billing.

[3] https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Approval-Letter-and-STCs.pdf

Chapter 7. Communicating with Members about the Recovery Incentives Program

Member Outreach

DHCS recognizes that effective outreach and marketing strategies will increase the likelihood that eligible members will learn about the Recovery Incentives program. DHCS' goal in offering CM is to ensure that eligible Medi-Cal members have access to evidence-based treatment for StimUD. Appropriate outreach may increase the likelihood that members will initiate and adhere to a treatment program for StimUD. One of the primary goals of the Recovery Incentives Program is to retain members with StimUD in treatment.

Treatment program communications about CM (and any other health care service) should be accurate, non-misleading, and non-coercive. When communicating about the CM benefit with current members, potential members, or the general public, treatment programs should avoid any statements that are inaccurate, misleading, or coercive.

See below for a list of DOs and DON'Ts, which apply to general CM outreach materials as well as conversations with current or potential CM members.

DO	DON'T
✓ Clarify that the CM benefit is available to individuals who meet certain eligibility criteria, such as having a qualifying StimUD, enrolling in Medi-Cal, and residing in a participating county	✘ Use language that could mislead ineligible people into believing that they will qualify for CM incentives
✓ Explain that CM is intended to support treatment goals over time, such as substance non-use and treatment adherence	✘ Suggest that a member will receive an incentive just for showing up
✓ Accurately describe the nature and potential value of the motivational incentives (e.g., "up to $599," "gift cards to retail and grocery stores").	✘ Overstate the potential value of the incentives (e.g., "almost $1,000!"), or state that incentives will be made in cash
✓ Ensure members understand that the CM benefit is optional	✘ Suggest that a member *must* enroll in CM to receive other health care services
✓ Let potential members know that CM incentives are conditioned on undergoing a medical assessment and taking regular drug tests, in accordance with DHCS' CM protocol	✘ Suggest that CM incentives are conditioned on members receiving services beyond those required under DHCS' CM protocol

DO	DON'T
✓ Emphasize that CM is a new and exciting option under DMC-ODS to support people with StimUD	✘ Suggest that the CM benefit is unique to a particular provider, or that one provider's CM benefit is better than another's
✓ Emphasize that use of motivational incentives is based on research	✘ Suggest that it is the only proven approach to StimUD treatment

Participating sites have the flexibility to craft their own outreach messages as long as all communications are accurate and are not misleading or coercive. As part of the 2-part Implementation Training, CM Teams will receive a Provider Outreach Toolkit (see Appendix C) that includes sample messages to communicate about the Recovery Incentives Program with eligible members.

Additional Resources

DHCS Recovery Incentives Program Website:
https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx

UCLA Recovery Incentives Program Website and Warmline:
https://uclaisap.org/recoveryincentives/

Chapter 8. References/Further Reading

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Appendix A

Sample Beneficiary Consent Form

Appendix A

Recovery Incentives Program: California's Contingency Management Benefit
Sample Member Consent Form/Agreement

NOTE: This template is provided as a guide to counties and treatment provider sites participating in the Recovery Incentives Program. Counties are encouraged to adapt this content to fit within the parameters of existing member consent forms/agreements, including county/agency-specific branding, logos, and letterheads, and larger font size and spacing to meet accessibility standards.

I understand that the goal of the Recovery Incentives Program is to help me reduce my stimulant use and to continue to receive services even if I have use episodes or miss appointments along the way. To accomplish this, I agree with the following statements related to my participation:

1. To participate in the Recovery Incentives Program, I must be admitted to an outpatient, intensive outpatient, partial hospitalization, or narcotic treatment program (also known as opioid treatment program).
2. I confirm that I am not currently enrolled in a residential treatment program.
3. During my enrollment in the Recovery Incentives Program, I will notify the program site if I am admitted into a residential treatment program.
4. I understand that I am ineligible to participate in the Recovery Incentives Program while I am enrolled in a residential treatment program. However, I may be eligible to resume participation in the Recovery Incentives Program on the same date that I am discharged from a residential treatment program.
5. I can start the Recovery Incentives Program at any time. During the first 12 weeks, I will be expected to come to the clinic two (2) times per week and submit a urine sample for a urine drug test (UDT). For the following 12 weeks, I will be expected to come to the clinic one (1) time per week and submit a urine sample for a UDT.
6. I may come to the clinic more often to participate in services, and these visits will not involve submitting a urine sample for a UDT as part of the Recovery Incentives Program.
7. Participation in the Recovery Incentives Program is voluntary, and I can discontinue at any time. Leaving the Recovery Incentives Program will not impact my eligibility to participate in any other medically necessary clinical services.
8. I will receive an incentive payment each time I submit a Recovery Incentives Program scheduled UDT that is stimulant-negative (i.e., free of amphetamine, methamphetamine, and cocaine). The incentive payment will take the form of an electronic or paper gift card.
9. I will receive the incentive payment immediately when I give a stimulant-negative UDT.
10. In the initial 12 weeks, for the first stimulant-negative UDT, the incentive payment will be worth $10. If I give two (2) stimulant-negative UDTs in a row, the incentive payment will increase to $11.50. The value of the incentive payment will keep increasing by $1.50 for every two times I give stimulant-negative UDTs. The highest amount an incentive payment can reach for an individual test is $26.50.

11. During the second 12 weeks of the Program, weekly stimulant-negative UDTs will be worth $15 in weeks 13-18, $10 in weeks 19-23, and $21 in week 24.
12. If all tests are stimulant-negative over 24 weeks, I will earn $599. If for any reason I need to restart the program, the maximum that I can earn is $599 per calendar year including current and any previous participation in the Recovery Incentives Program.
13. I will not receive an incentive payment if I submit a UDT that is stimulant-positive (i.e., presence of amphetamine, methamphetamine, and/or cocaine). The results of the urine drug test are final, and I agree to accept the outcome and decision of Recovery Incentives Program staff even if I disagree with it.
14. During the first 12 weeks, if I submit a stimulant-positive UDT, the incentive payment will return to $10 the next time I provide a stimulant-negative UDT. Once I give a second stimulant-negative UDT, I will get back all the increases I earned previously and will continue to earn increases each time I test negative for stimulants two (2) times in a row.
15. During the second half of the Program (weeks 13-24), if I submit a stimulant-positive UDT, I will not receive an incentive for that visit. On my next stimulant-negative UDT I will receive an incentive in the amount that is scheduled for that week ($15 in weeks 13-18, $10 in weeks 19-23, and $21 in week 24).
16. While participating in the Recovery Incentives Program, I will not use over-the-counter medications, prescription medications, or health supplements known to cause a stimulant-positive UDT. I have reviewed the list of items that could interfere with test results. I understand that use of these items may affect my UDT results. I agree I will discuss making any changes to my prescribed medications with my medical provider prior to making any changes in my medications.
17. I will not receive an incentive payment when my urine sample tests positive for stimulants even if the stimulant-positive UDT is from one of the medications from the list of items known to cause a stimulant-positive UDT result.
18. For unavoidable absences (e.g., a doctor appointment, illness, funeral, etc.), I will reschedule my UDT visit on a contiguous day if at all possible. If I cannot reschedule, I can request an excused absence by notifying the clinic ***before*** the missed session. I will provide documentation of the reason for the absence at the next scheduled visit (e.g., receipt from the doctor, funeral announcement, travel ticket, employer work schedule, document from judicial authority). I understand that if the clinic approves the absence, it will be recorded as excused, I will not receive an incentive for that visit, and at my next visit the incentive payment will continue at the same level as if the absence had not occurred, for up to two consecutive excused absences. If the excused absence extends to three or more visits, my incentive amount will reset to the original $10.
19. I understand that excused absences must be requested and approved prior to the scheduled visit. Visits cannot be approved as excused after the date of a scheduled visit and would be recorded as missed.
20. If I do not submit a urine sample or have an unexcused absence from the clinic, it will be recorded as a stimulant-positive UDT result. It will not negatively affect any other treatment services I am receiving or eligible to receive.

21. I agree that I will give my own urine for all urine drug tests; I will not tamper with the urine sample; and I commit to following the rules and procedures of the Recovery Incentives Program.
22. I agree to use the incentive payments earned only for my own personal use. I will not sell or trade any incentive payments. I agree that I will not use incentive payments to purchase alcohol, tobacco, cannabis, or lottery tickets.
23. I will not enroll in the Recovery Incentives Program with more than one (1) treatment provider at a time. I understand that if I am registered with more than one (1) Recovery Incentives Program provider, the providers must meet to determine which provider will assume responsibility to continue my treatment.
24. During my enrollment in the Recovery Incentives Program, I will not participate in contingency management services for treatment of Stimulant Use Disorder(s) outside of the Program.
25. The clinic will collect information about me throughout my participation in the Recovery Incentives Program for evaluation and incentive tracking purposes.
26. The Recovery Incentives Program staff will record my attendance, UDT results, and any incentive payments distributed in an electronic database.
27. My personal and medical information will be protected according to required state and federal privacy and confidentiality regulations (HIPAA and 42 CFR Part 2) and will only be shared when medically necessary or with the provider organization, the County, State, UCLA-affiliated staff and Incentive Manager-affiliated staff for program payment, monitoring, oversight, auditing, and/or evaluation purposes.
28. I will be able to submit any feedback about the Recovery Incentives Program by emailing recoveryincentives@dhcs.ca.gov.
29. I agree to complete evaluation surveys and forms related to my participation in the Recovery Incentives Program to help program staff understand how this program helped me and others.

_____	_____	_____
Member Name (Print)	Member Signature	Date

The Recovery Incentives Program: California's Contingency Management Benefit
Sample Member Consent Form/Agreement

Medicines that Can Cause You to Test Positive for Stimulants

- **Prescription and over-the-counter medicines for cough and cold, with decongestants**
  - Pseudoephedrine (Sudafed, SudoGest, Zephrex-D, Claritin-D, Allegra-D, others)
  - Levmetamfetamine (Vicks Vapoinhaler)
- **Prescription medicines for Attention Deficit Hyperactivity Disorder (ADHD):** if you take any of these, your urine drug tests will always be positive for stimulants and you will be ineligible to earn incentives in the Recovery Incentives Program.
  - Methylphenidate (Ritalin, Concerta, Dayrana, Quillivant, Mthylin, Aptensio XR, Cotempla XR, Metadate CD)
  - Dexmethylphenidate (Focalin XR)
  - Serdexmethylphenidate/dexmethylphenidate (Azstarys)
  - Amphetamine salts (Adderallm Mydayis)
  - Dextroamphetamine (Dexedrine, Spansule, Zenzdi, ProCentra)
  - Lisdexamfetamine (Vyvanse)
- **Prescription medicines for mental health conditions**
  - Chlorpromazine (Thorazine and Largacti)
  - Trazodone (Desyrel, Desyrel Dividose, Oleptro)
  - Bupropion (Wellbutrin, Forfivo XL, Aplenzin, and Zyban)
- **Prescription and over-the-counter medicines for weight loss/diet aids**
  - Phentermine (Adipex-P, Lomaira)
  - Benzphetamine (Didrex, Regimex)
  - Phenulpropanolamine (PPA, Dexatrim, Accutrim)
  - Ephedra (Ma-huang)
- **Prescription medicine for hypertension**
  - Labetalol
- **Prescription medicine for Parkinson's Disease**
  - Selegiline (Eldepryl, Zelapar, Emsam)
- **Prescription medicine for diabetes**
  - Metformin (Glucophage, Riomet, Glumetza)
- **Prescription and over-the-counter medicines for asthma and allergies**
  - Eldepryl, Zelapar, Emsam (Marax)
  - Ephedrine (Primatene)
  - Promethazine (Phenergan Promacot)
- **Prescription medicines used for bacterial infections**
  - Ofloxacin (Floxin, Ocuflox)
- **Other substances**
  - Methylenedioxymethamphetamine (MDMA, Ecstasy, Molly, Mandy Pingers)
  - Dimethylamylamine (DMAA, Forthane, Geranamine, Geranium Extract)
- **Other considerations**
  - It is possible that other medicines not on this list may cause a urine drug test to be positive for stimulants. If you are concerned about any prescription, over-the-counter medicine, herbal supplement, or other substance that you are taking, please consult with your medical provider or Recovery Incentives Program staff.

Appendix B

Instructions for Administering Approved UDT Kits

NOTE:

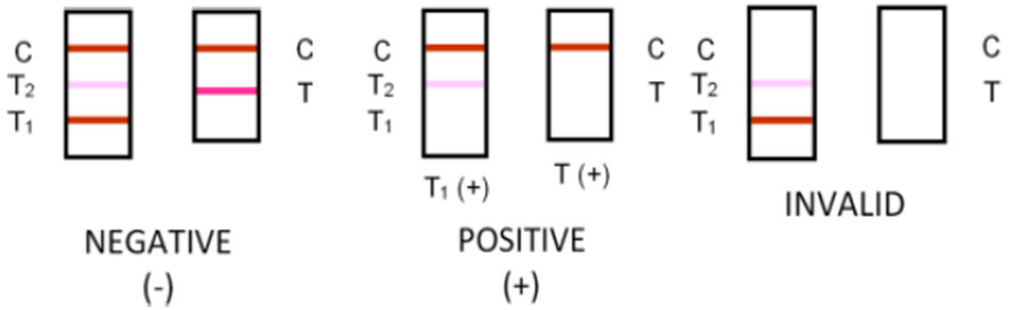
Enclosed files include:

- Tip Sheet for Interpreting UDT Results
- CLIAwaived UDT Instructions (applies to both CLIA-waived UDT kits)
- Premier BioTech Instruction Manual
- Lochness Medical Instructions

Tip Sheet For Interpreting UDT Results

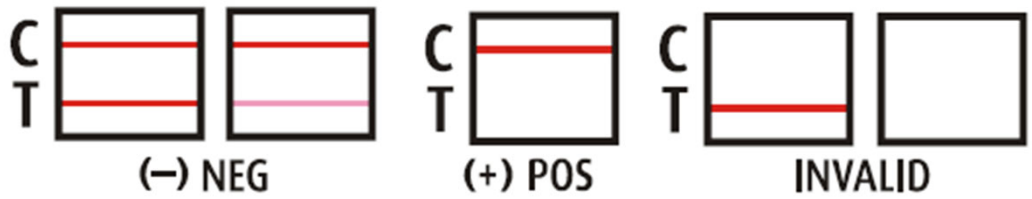
1) CLIAWaived, Inc. 12 Panel IDTC Cups II with Adulterants

2) CLIAWaived, Inc. 14 Panel IDTC II



3) Premier Biotech Bio-Cup 12-Drug Panel Drug Test

4) Lochness Medical Multi-Drug One Step Cup II



"C" = Control "T_1" = Test 1 "T_2" = Test 2

CLIAwaived™ Inc.
Instant Drug Test Cup Training

Product
Performance / Interpretation

The *CLIAwaived Inc.* Instant Drug Test Cup (IDTC)

- ***CLIAwaived Inc.* IDTC Cup**
  - Instant on-site drug screening test device for the detection of drugs in urine samples.
  - Collect anywhere, anytime.
  - Results within minutes.

- **The *CLIAwaived Inc.* IDTC Cup tests for the following drugs:**
  - **AMP:** Amphetamines
  - **COC:** Cocaine
  - **PCP:** Phencyclidine
  - **MTD:** Methadone
  - **BAR:** Barbiturates
  - **OXY:** Oxycodone
  - **BUP :** Buprenorphine
  - **MET:** Methamphetamine
  - **OPI:** Opiates
  - **THC:** Marijuana
  - **EDDP:** Metabolite of Methadone
  - **BZO:** Benzodiazepines
  - **TCA:** Tricyclic Antidepressants
  - **MDMA:** Methylenedioxymethamphetamine (Ecstasy)

  - **Additionally, IDTC can screen for adulteration or verify specimen validity**

    CRE: Creatinine ● **OX:** Oxidants/PCC ● **PH:**PH ● **N:** Nitrite ● **G:** Glutaraldehyde ● **S :** Specific Gravity

- **Gather all necessary testing supplies**
  - *CLIAwaived Inc.* IDTC Test Cup
  - *CLIAwaived Inc.* IDTC specimen lid
  - Specimen Adulteration validity color chart (if applicable)

The Process: Performing the Drug Screen

- **Have Donor Select Test Kit**
  - Allow donor to select sealed *CLIAwaived Inc.* IDTC from test kit box.
  - Donor should hand sealed test kit to collector to record lot number and test expiration date.
  - Ensure Expiration date (EXP) is within range.
- **Return Collection Device to Donor**
  - Instruct donor on proper specimen collection.
  - Have donor open foil pouch and remove kit.
  - Have donor provide urine sample in specimen cup.

Urine Specimen Cup

Temperature Strip Label (On Back of Cup)

Also Included:
- Package Insert
- Security Seal (If Applicable)
- Adulterant Color Chart (If Applicable)

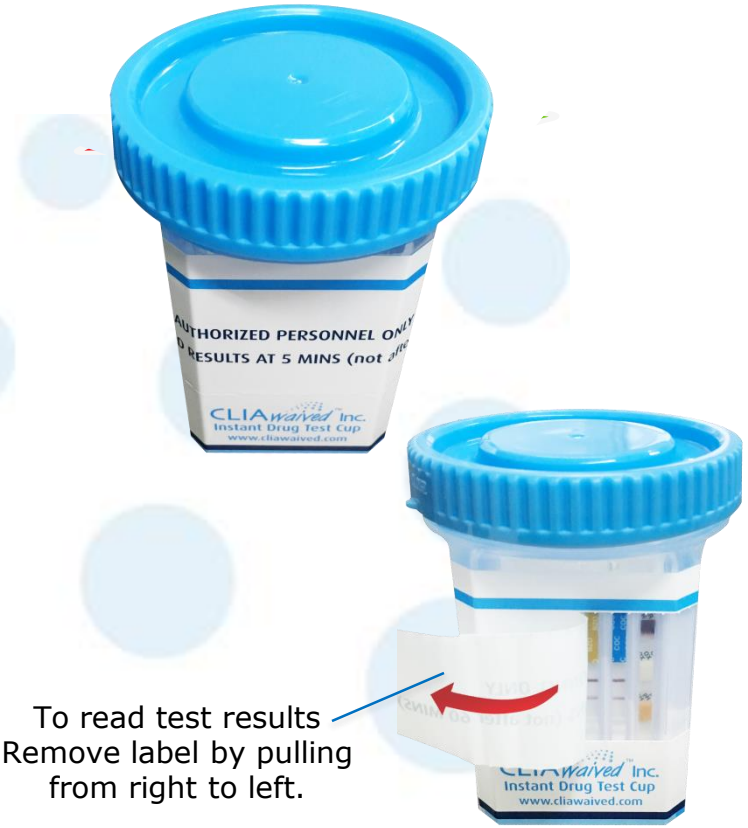
The Process: Performing the Drug Screen (cont'd)

Temperature Verification

- A temperature strip is present on the back of the collection cup serves as an initial specimen validity check.
- The temperature should be checked within **4 minutes** of the donor providing the specimen.
- A freshly voided specimen will be in the range of **90° - 100° F**.

The Process: Performing the Drug Screen (cont'd)

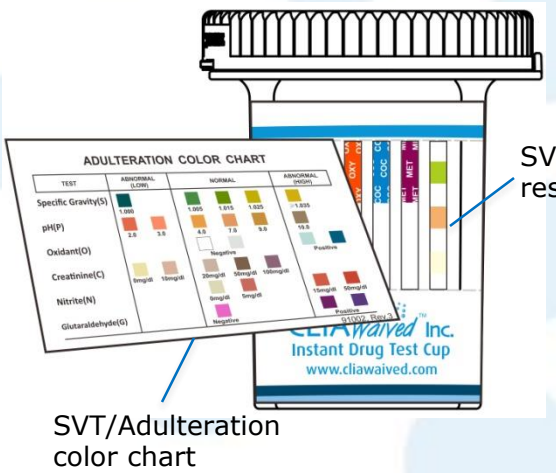
- Have collector screw the *CLIAwaived Inc.* IDTC lid onto the collection cup. To properly seal the lid, first place the lid on the cup and gently turn until lid stopper catches built-in cup stopper. Then, firmly turn the lid clockwise until the lid locks in place.
- Pull label from right to left to remove and expose test results. Read results of drugs of abuse tests in 5 minutes. **DO NOT** interpret the test results after 60 minutes.



Adulteration / Specimen Validity Test Interpretation

- Collector should interpret **validity strip** from front of the *CLIAwaived Inc*. IDTC.
- Read validity/adulteration strips between 3-5 minutes.
- Interpretation of the SVT:
  - Compare the development of the results on the *CLIAwaived Inc.* IDTC test with the **specimen validity color chart**.
  - If **any** of the results are in the **<u>abnormal range</u>**, the specimen should be recollected with a new cup or sent to the laboratory for **additional testing.**

When applicable, read SVT/adulteration results by visually comparing color of reagent pads to corresponding blocks on the Color Chart at the time indicated.



Refer to color chart included in test box.

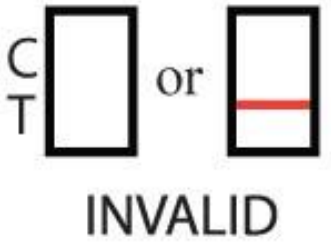
CLIAwaived Inc. IDTC Test Results: Interpretation

- Interpret the drug test results at **five (5) minutes**.
- Drug test results are stable for **sixty (60) minutes.**
- Each drug test strip in the device includes an internal procedural control (C) to verify sufficient specimen volume, adequate membrane wicking, and correct procedural technique.
- **Control lines** should form next to the “C” or control area on all strips.
- Drug test interpretation:
  - The **presence of a line** (or any indication of a colored line) indicates a **Negative** result.
  - The **absence of a line** indicates an abnormal or **Presumptive Positive** result.

CLIAwaived Inc. IDTC Test Results: Invalid

- Each test strip within the device includes an internal procedural control (C) that ensures proper device function.
- Control lines should form on all drug test strips, to verify sufficient specimen volume, adequate membrane wicking, and correct procedural technique.
- The **absence** of a control line in one or multiple test strips indicates that the test is **Invalid** (even if one or more drug lines are absent).
- ***DO NOT*** record test results. This test must be administered again.

Note: We don't recommend giving drug screen results to the donor

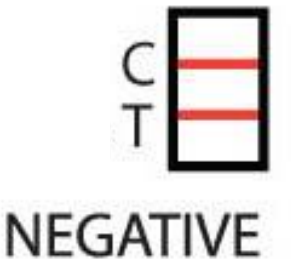


No line next to C = Invalid Result

CLIAwaived Inc. IDTC Test Results: Negative

- The appearance of a line next to each and every **T (Test Line)** corresponding to a specific drug *and* ***ALL*** control areas.
- Record **Negative** test results and discard test device.
- **Any indication of a colored line** regardless of color intensity would be correctly interpreted as a **Negative** test result.

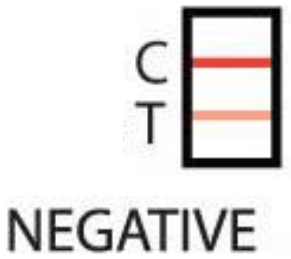
Note: We don't recommend giving drug screen results to the donor



All Lines Present = Negative Test Result

CLIAwaived Inc. IDTC Test Results: Negative

- The appearance of a line next to each and every **T (Test Line)** corresponding to a specific drug *and* ***ALL*** control areas.
- This shows an example of a ***light line***. This should still be interpreted as a **Negative.**
- Record **Negative** test results and discard test device.
- **Any indication of a colored line** regardless of color intensity should be correctly interpreted as a **Negative** test result.

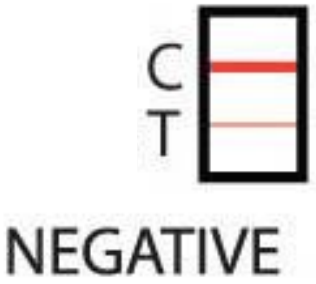


All Lines Present = Negative Test Result

Note: We don't recommend giving drug screen results to the donor

CLIAwaived Inc. IDTC Test Results: Negative

- The appearance of a line next to each and every **T (Test Line)** corresponding to a specific drug *and* ***ALL*** control areas.
- This shows an example of a **pencil thin line**. This should still be interpreted as a **Negative**.
- Record **Negative** test results and discard test device.
- **Any indication of a colored line** regardless of color intensity should be correctly interpreted as a **Negative** test result.

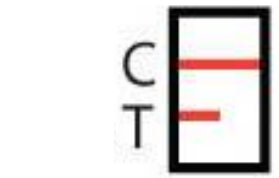


All Lines Present = Negative Test Result

Note: We don't recommend giving drug screen results to the donor

CLIAwaived Inc. IDTC Test Results: Negative

- The appearance of a line next to each and every **T (Test Line)** corresponding to a specific drug *and* ***ALL*** control areas.
- This shows an example of a **broken line**. This should still be interpreted as a **Negative.**
- Record **Negative** test results and discard test device.
- **Any indication of a colored line** regardless of color intensity should be correctly interpreted as a **Negative** test result.



NEGATIVE

All Lines Present = Negative Test Result

Note: We don't recommend giving drug screen results to the donor

CLIAwaived Inc. IDTC Test Results: Presumptive Positive

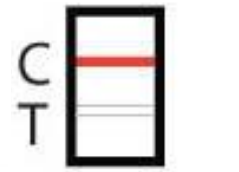
- The **absence** of a line next to one or more **T (Test Lines)** corresponding to a specific drug *and* the presence of a line in ***ALL*** control areas.
- Record **Presumptive Positive** test results.
  Note: We suggest all Presumptive Positive test results be confirmed by an alternative method.
- Example shows **Presumptive Positive** test result.

No line next to drug name = Presumptive Positive test result

Note: We don't recommend giving drug screen results to the donor

CLIAwaived Inc. IDTC Test Results: Presumptive Positive

- This shows an example of a "**ghost" line** with valid control (C) lines. This should still be interpreted as a **Presumptive Positive**.
- Although there appears to be a change in the test area, the **absence of color** makes it different from a Negative.
- Record **Presumptive Positive** test results.
  Note: We suggest all Presumptive Positive test results be confirmed by an alternative method.



No line next to drug name = Presumptive Positive test result

Note: We don't recommend giving drug screen results to the donor

Thank You

For more information, please visit us on the web:
www.cliawaived.com

Or call (858) 481-5031 *(phone)*
(888) 882-7739 *(toll-free)*
info@cliawaived.com *(e-mail)*

Premier Bio-Cup & Bio-Dip

For *in vitro* diagnostic use

Package Insert for OTC and Professional Use

The Premier Bio-Cup and Bio-Dip offer a variety of solutions for fast and reliable drug testing in the privacy of your own home. This product can detect up to 15 commonly abused drugs in human urine:

Abbreviation	Drug	Cutoff (ng/mL)
AMP	Amphetamine	500
BAR	Barbiturates	300
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
COC	Cocaine	150
EDDP	Methadone Metabolite	300
MET	Methamphetamine	500
MDMA	Ecstasy	500
MTD	Methadone	300
OPI 300	Morphine	300
OPI 2000	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50
PPX*	Propoxyphene	300

* PPX available for professional use only

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas Chromatography / Mass Spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

INSTRUCTIONS FOR OTC USE:

BEFORE TESTING

Read the instructions completely.
Check the expiration date on the box and pouch labels. Do not use the test if it is expired. Have a watch, clock or timer ready.

The following items are needed only if you choose to ship samples for confidential confirmation lab testing:

- Pre-addressed shipping box
- Plastic transportation bag
- Identification label

PERFORMING THE TEST

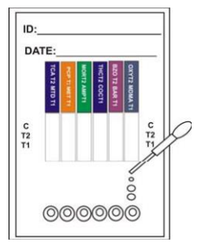
Step 1: Take Out the Test Device

Take the test device from the sealed foil pouch. The test comes in three (3) types: cassette, dip card and cup.

Step 2: Apply Urine to the Test Device

Cassette:

1. Remove the cassette from the sealed pouch. Write the donor name or ID in the provided space.
2. With the provided dropper, **add 3 drops of urine specimen** to each sample well



Bio-Dip:

1. Remove the dip card from the sealed pouch. Write the donor name or ID in the provided space, then remove the cap.
2. With the arrows pointing toward the urine specimen, **immerse the sample tips vertically** in the urine specimen for **at least 20 seconds**. Put the cap back on the dip card. Place the dip card on a flat surface.

Bio-Cup:

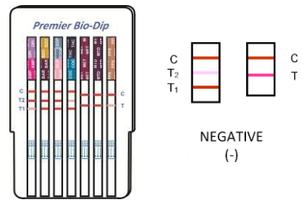
1. Remove the cup from the sealed pouch. Write the donor name or ID in the space provided.
2. **Collect urine** in the cup.

Step 3: Read Result

Read results after 5 minutes. Do not wait longer than 60 minutes.

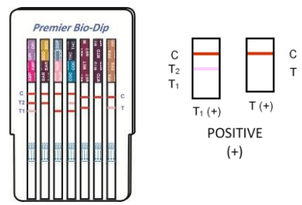
A red or pink line must appear next to the letter "C" (control) on all of the test strips. The appearance of a red or pink line next to the letter "C" on each test strip indicates that the test has worked properly. If you see control lines on all the test strips, you can read your test results.

Negative Result:
A red or pink line next to the "T1" or "T2" (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the "T1" or "T2" for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



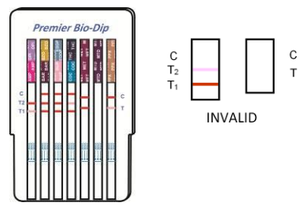
Preliminary Positive Result:
If NO red or pink line appears next to the "T1" or "T2" under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.

The illustration on the right shows preliminary positive results for AMP and THC, but negative for all other drugs.



Invalid Result:
A colored line should always appear next to the letter "C" on every test strip. If no control line appears on any of test strips, the result is invalid.

The illustration on the right shows no line next to the letter "C" on the first strip (AMP, OPI) and sixth strip (MTD). The test results for those two test strips are invalid.



QUESTIONS AND ANSWERS

Premier Bio-Cup & Bio-Dip is user friendly, if you have question about the test or result, please call the Premier Helpline: (888) 686-9909, a 24/7 recorded information service is available for your use. In addition, the Premier Biotech team is available to answer your question weekdays from 7am to 7pm EST.

What do my test results mean?

Q. **The drug line is lighter than control line. Does it mean the drug is present in the urine?**
A. No. The drug line may be darker or lighter than the control line. The line intensities of different drugs will vary for many reasons. No matter how faint the drug line appears on the test strip, it is considered a negative result. No further testing is required.

Q. **What does a Preliminary Positive Result mean?**
A. The sample may contain one or more of the drugs being tested for. It is possible to get a "preliminary positive" when someone has not taken the drug. We recommend you send the urine to our laboratory for additional confirmation testing. Additional fees may apply.

- Medicinals such as diet pills, inhalers, cough syrup, and pain pills may cause a preliminary positive result.
- The tests may yield preliminary positive results with prescription drugs such as tricyclic antidepressants, barbiturates, benzodiazepine, methadone, buprenorphine (including Subutex, Suboxone, Temgesic, Buprenex, Norspan, and Butrans), and opiates (including morphine, hydrocodone, Oxycodone, and codeine) are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine. To find more information on false positive results caused by prescription drugs, see www.askdocweb.com/falsepositives.html.

Q. **What does a Negative Result mean?**
A. If you get a negative result, the sample did not contain the drug being tested for. No further testing is required. However, it is possible to get a negative result even if a person has taken drugs. Some reasons why this might happen are:

- The urine sample was collected at the wrong time. It was collected before the drug got into the urine or after it was no longer in the urine.
- The person took a drug other than the one tested for in this test; e.g. they might have taken LSD, when this test is for drugs other than LSD.

Q. **What does an Invalid Result mean?**
A. If any of the strips do not show a control, the result is invalid. We recommend that you re-test or contact customer service at (888) 686-9909.

Laboratory Confirmation Testing:

Q. **How can a Preliminary Positive Result be confirmed?**
A. The urine specimen needs to be sent to our laboratory for confirmation testing. See the shipping instructions in **"Shipping the Urine Sample to the Lab for Confirmation Testing"** section below.

Other Questions:

Q. **When is the best time to take the test?**
A. The drug test can be used at any time of day. Approximate detection times using each drug are listed in the following table:

Drug	Cutoff	Minimum	Maximum
Amphetamine (AMP)	500 ng/mL	2-7 hours	2-4 days
Cocaine (COC)	150 ng/mL	1-4 hours	2-4 days
Methamphetamine (MET)	500 ng/mL	2-7 hours	2-4 days
Opiates (OPI)	2,000 ng/mL	2 hours	2-3 days
Marijuana (THC)	50 ng/mL	2 hours	Up to 40 days
Tricyclic Antidepressants (TCA)	1,000 ng/mL	8-12 hours	2-7 days
Phencyclidine (PCP)	25 ng/mL	4-6 hours	7-14 days
Barbiturates (BAR)	300 ng/mL	2-4 hours	1-3 weeks
Benzodiazepines (BZO)	300 ng/mL	2-7 hours	1-4 days
Oxycodone (OXY)	100 ng/mL	1-3 hours	1-2 days
Methadone (MTD)	300 ng/mL	3-8 hours	1-3 days
Ecstasy (MDMA)	500 ng/mL	2-7 hours	2-4 days
EDDP	300 ng/mL	3-8 hours	1-3 days
Buprenorphine (BUP)	10 ng/mL	4-24 hours	3-6 days

The Substance Abuse and Mental Health Services Agency (SAMHSA) has set cutoff levels when testing for marijuana, cocaine, amphetamine, opiates, PCP, Ecstasy and methamphetamine. Screening tests may not detect amounts of drugs in a urine sample that are below the cutoff level. Even if some drug is present in a urine sample, the sample would be considered negative if the drug level is below the cutoff level.

Q. **How much urine do I need?**

A. The Premier Bio-Cup and Bio-Dip require just 30 mL of urine. Fill the collection cup to the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

Q. **Do I have to wait the full 5 minutes before reading the test?**

A. Yes, we recommend that you wait the full 5 minutes before reading the result.

Q. **Are there any factors that could affect the drug testing result?**

A. Yes, certain factors may affect the drug testing result.

1. Certain over the counter medicines and prescription medicines may cause a preliminary positive result.
2. Urine can be adulterated (i.e. contaminated or tampered) by using bleach, cleaning supplies and other liquids. This may dilute the urine and the test may not be accurate.
3. Drinking large amount of liquids may dilute the urine so that the drug (if present) cannot be detected.
4. Failure to use the Premier Bio-Cup or Bio-Dip as directed may result in an inaccurate screening result.
5. The following compounds are detected positive in urine by the Premier Bio-Cup or Bio-Dip. Concentrations are given in ng/mL; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)		
BUP			
Buprenorphine	10 (100%)	Norbuprenorphine	10 (100%)
Buprenorphine glucuronide	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)	Nitrazepam	250 (120%)
Clobazam	200 (150%)	Norchlordiazepoxide	500 (60%)
Clorazepate	750 (40%)	Nordazepam	390 (76.9%)
Desalkylflurazepam	1,200 (25%)	Nordiazepoxide	400(75%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
α-Hydroxyalprazolam	1,900 (15.8%)		
COC			
Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
OPI 300			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
MTD			
Methadone	300 (100%)		
OPI 2000			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
PPX			
Propoxyphene	300 (100%)	Norpropoxyphene	300 (100%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor-Δ^9-THC-9-COOH	50 (100%)	(-)-Δ^8-THC	20,000 (0.3%)
(+/-)-11-Hydroxy-Δ^9-THC	5,000 (1%)	(-)-Δ^9-THC	20,000 (0.3%)

SHIPPING URINE SAMPLES FOR CONFIRMATION TESTING (OTC ONLY)

About confirmation testing:

Negative samples do not need further testing. You should only send preliminary positive samples to a laboratory for confirmation.

Check the provided shipping package:

The following items are provided (OTC only):

- Mailer: Pre-addressed Mailing Box with Transportation Label
- Zip-lock Plastic Transportation Bag
- Identification Label

Package urine samples for shipping:

- Attach the top portion of the identification label to the urine collection cup.
- Attach the lower portion of the identification label to the instruction sheet where labeled “place identification label here.” For security reasons, you will need this number to retrieve your lab test results.
- Place the urine collection cup in the zip-lock plastic transportation bag, seal and place into the pre-addressed mailing box and close. On the pre-addressed mailing box label, fill in the sample collection date.
- On the mailing box label, check off the drug(s) that gave a preliminary positive result. IT IS IMPORTANT THAT YOU INDICATE WHICH DRUG WAS POSITIVE SO THAT A LAB CONFIRMATION TEST CAN BE PERFORMED FOR THAT DRUG. WITHOUT THIS LABEL, YOUR SAMPLE CANNOT BE TESTED.
- Mail the preliminary positive urine sample as soon as possible. Urine samples cannot be accurately tested if more than 7 days old.
- The mailing box is not pre-paid. To ensure prompt delivery, be sure to pay the appropriate shipping charges.

INSTRUCTIONS FOR PROFESSIONAL USE:

For test procedure and result interpretation, see “Performing The Test” in the Instructions For OTC Use section, above.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators.

Quality control testing should be performed with each new lot, with each new shipment, and every thirty days to check storage conditions. External controls can be purchased from the following vendor: Biochemical Diagnostics, 1-631-595-9200, www.biochemicaldiagnostics.com.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the Premier Bio-Cup and Bio-Dip was evaluated in comparison to GC/MS and LC/MS. 40 drug-free urine samples collected from presumed non-user volunteers were tested with the Premier Bio-Cup and Bio-Dip. Of these 40 negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 40 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA). A summary of the accuracy and discordant results on Cassette, Dip Card and Cup formats are shown in the following tables:

Summary of Accuracy Results on the Premier Cassette

Drug Test/ Cutoff (ng/mL)	Result	Range of GC/MS or LC/MS Data: Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/ 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/ 500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/ 1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the Premier Cassette

Drug Test/ Cutoff (ng/mL)	Premier DOA Test Cassette Result	Result w/ GC/MS or LC/MS: Drug Concentration (ng/mL)	Result w/ GC/MS or LC/MS: Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoylecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine
OPI/300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
PPX/300	Positive	242	Norpropoxyphene
	Positive	285	Norpropoxyphene
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor-Δ^9-THC-9-COOH

Summary of Accuracy Results on the Premier Bio-Dip

Drug Test/ Cutoff (ng/mL)	Result	Range of GC/MS or LC/MS Data: Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/ 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/ 500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/ 1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the Premier Bio-Dip

Drug Test/ Cutoff (ng/mL)	Premier DOA Test Dip Card Result	Result w/ GC/MS or LC/MS: Drug Concentration (ng/mL)	Result w/ GC/MS or LC/MS: Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoylecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine
OPI/300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
PPX/300	Positive	242	Norpropoxyphene
	Positive	285	Norpropoxyphene
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor-Δ^9-THC-9-COOH

Summary of Accuracy Results on the Premier Bio-Cup

Drug Test/ Cutoff (ng/mL)	Result	Range of GC/MS or LC/MS Data						
		Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/ 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/ 500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/ 1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the Premier Bio-Cup

Drug Test/ Cutoff (ng/mL)	Premier DOA Test Cup Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/mL)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoylecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine
OPI300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
PPX/300	Positive	242	Norpropoxyphene
	Positive	285	Norpropoxyphene
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor-Δ^9-THC-9-COOH

ANALYTICAL SENSITIVITY/PRECISION

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days. Each level of solution was tested in 10 replicates randomly by each operator at each POL site. Results showed over 99% agreement at +/-50% cutoff levels with the Premier Bio-Cup and Bio-Dip.

B. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the Premier Bio-Cup and Bio-Dip. Concentrations are given in ng/mL; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP 500			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)		
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)	Nitrazepam	250 (120%)
Clobazam	200 (150%)	Norchlordiazepoxide	500 (60%)
Clorazepate	750 (40%)	Nordazepam	390 (76.9%)
Desalkylflurazepam	1,200 (25%)	Nordiazepoxide	400(75%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
α-Hydroxyalprazolam	1,900 (15.8%)		
COC 150			
Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET 500			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
MTD			
Methadone	300 (100%)		
OPI 300			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
OPI 2000			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
PPX			
Propoxyphene	300 (100%)	Norpropoxyphene	300 (100%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor-Δ^9-THC-9-COOH	50 (100%)	(-)-Δ^8-THC	20,000 (0.3%)
(+/-)-11-Hydroxy-Δ^9-THC	5,000 (1%)	(-)-Δ^9-THC	20,000 (0.3%)

C. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the Premier DOA Test. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the Premier Cassette, Bio-Cup, and Bio-Dip. An unaltered sample was used as control. No interference was found for the following compounds at a concentration of 100 µg/mL when tested with the Premier Cassette, Bio-Cup, and Bio-Dip:

Acetaminophen	Diphenhydramine	Nicotine
Acetone	Dopamine	(+/-)-Norephedrine
Albumin	(+/-)-Isoproterenol	Oxalic acid
Ampicillin	1R,2S(+)-Ephedrine	Penicillin-G
Ascorbic acid	Erythromycin	Pheniramine
Aspartame	Ethanol	Phenothiazine
Aspirin	Furosemide	L-Phenylephrine
Atropine	Glucose	B-Phenylethylamine
Benzocaine	Guaiacol glyceryl ether	Procaine
Bilirubin	Hemoglobin	Quinidine
Caffeine	Ibuprofen	Ranitidine
Chloroquine	(+/-)-Isoproterenol	Riboflavin
(+)-Chlorpheniramine	Ketamine	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	
4-Dimethylaminoantipyrine	Niacinamide	

SPECIMEN VALIDITY TEST (SVT)

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results.

The Premier DOA Test Specimen Validity Test (SVT) is based on the color response of chemical indicators in the presence of adulterants. pH (P), specific gravity (S), oxidant/PCC (O), creatinine (C), nitrite (N) and glutaraldehyde (G) are tested to determine the integrity of urine samples.

pH: The pH determination of urine samples is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. Values outside of this range may indicate the sample has been altered.

Specific Gravity: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. The normal range for specific gravity is from 1.003 to 1.030. Values outside this range generally indicate specimen dilution or adulteration

Oxidants/PCC (Pyridinium Chlorochromate): Bleach, hydrogen peroxide, pyridinium chlorochromate or other oxidizing agents react with an oxidant indicator to form a color complex. A blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents. Normal human urine should not contain oxidants.

Creatinine: Creatinine reacts with an indicator in an alkaline medium to form a purplish-brown color complex. The normal range of creatinine is from 20 to 300 mg/dL. Values outside this range generally indicate a manipulated test.

Nitrite: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/dL is considered adulterated.

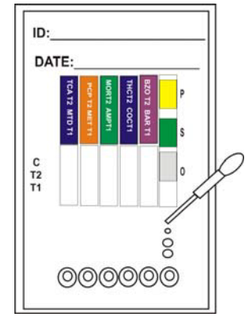
Glutaraldehyde: Adulterants such as "Clear Choice" contain glutaraldehyde which may disrupt the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in human urine.

PROCEDURE FOR DRUG TEST WITH SPECIMEN VALIDITY TEST (SVT)

Preparation:

1. Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

Cassette:

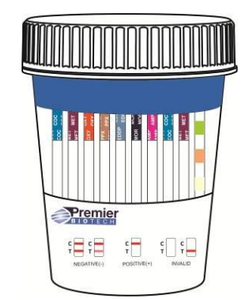


1. Remove the cassette from the sealed pouch and write the donor name or ID on the device in the provided space.
2. Add 3 drops of specimen with the provided dropper to each sample well.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read Specimen Validity Test (SVT) results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.

Bio-Dip:

1. Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
2. With the arrows pointing toward the urine specimen, immerse the sample tips vertically in the urine specimen for at least 20 seconds. Replace the cap back onto the dip card and place the dip card on a flat surface.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read Specimen Validity Test (SVT) results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.

Bio-Cup:



1. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
2. Collect urine in the cup.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read Specimen Validity Test (SVT) results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.

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36001-PB2 Revision 2

LOCHNESS MEDICAL

REF DX.X-1V

Multi-Drug One Step Cup

(Urine)

The Rapid Response™ One Step Cup is an easy-to-use, one-step solution for drugs screening that can simultaneously detect multiple drugs in urine samples. This format is a great alternative to the industry's complicated testing processes and is available with and without adulterant tests.

- All in one step with no direct contact with the sample
- Longer detection window than saliva tests
- Results in 5 minutes
- Wide range of drug test combinations available

Kit Content

- Individually packaged test cups with integrated drug test panels
- Caps
- Adulteration Color Chart (when applicable)
- Product Insert

Product Information

- Product Code: DX.X-1V
- Sample: Urine
- Format: Cup
- Time-to-Result: 5 minutes
- Storage Condition: 36-86°F/2-30°C
- Test Principle: Lateral Flow Assay

Ordering Information

Product Code	Product Name	Contents
DX.X-1V	Multi-Drug One Step Cup	100 Tests / Kit

To learn more contact your local Sales Representative, call us at +1 888-506-2658, or email us at info@lochnessmedical.com

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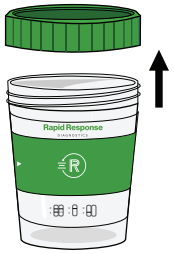
LOCHNESS MEDICAL

REF DX.X-1V

Multi-Drug One Step Cup

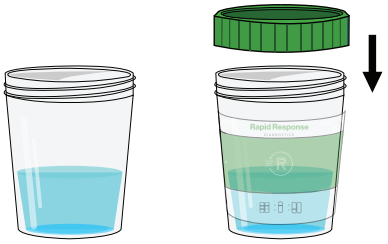
Testing Procedure

1



Unscrew the cap from the cup.

2

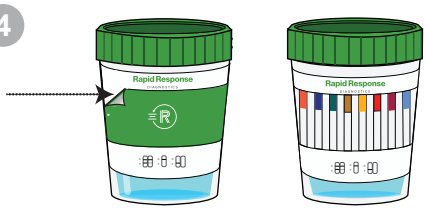


Collect the sample in the cup, then screw the cap onto the cup.

3

Immediately start the timer for 5 minutes

4

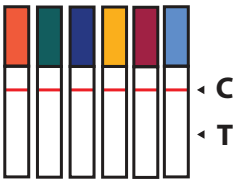


After 5 minutes, peel the sticker off and read the results.

These instructions are for illustrative purposes only. Please read the Instructions for Use supplied with the test before use.

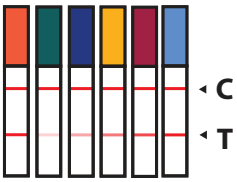
Result Interpretation

Positive/Non-Negative



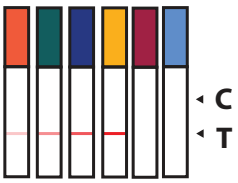
Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

Negative



Two colored bands appear on the membrane. One band appears in the control (C) and another appears in the test region (T).

Invalid



No line appears in the control (C). The result is invalid.

Ordering Information

Product Code	Product Name	Contents
DX.X-1V	Multi-Drug One Step Cup	100 Tests / Kit

To learn more contact your local **Sales Representative**, call us at **+1 888-506-2658**, or email us at **info@lochnessmedical.com**

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Email: info@lochnessmedical.com
www.lochnessmedical.com

LOCHNESS MEDICAL

REF DX.X-1V

Multi-Drug One Step Cup

Popular Multi-Drug One Step Cup Products

PRODUCT CODE	PRODUCT NAME	PRODUCT PARAMETERS
D5.75-1V	5-Panel Urine Drug Screen	COC300, MET1000, AMP1000, OPI2000, OXY100
D5.1-1V	5-Panel Urine Drug Screen	COC300, AMP1000, MET1000, THC50, OPI2000
D10.3-1V	10-Panel Urine Drug Screen	COC300, AMP1000, MET1000, THC50, OPI2000, PCP25, BAR300, BZO300, MTD300, MDMA500
D10.32-1V	10-Panel Urine Drug Screen	COC300, MET1000, AMP1000, OPI2000, OXY100, MTD300, PCP25, BAR300, BZO300, MDMA500
D10.14-1V	10-Panel Urine Drug Screen	COC150, AMP500, MET500, THC50, MTD300, MOP2000, OXY100, PCP25, BAR300, BZO300
D12.5-1V	12-Panel Urine Drug Screen	AMP1000, BAR300, BUP10, BZO300, COC300, MDMA500, MTD300, MET1000, OPI2000, OXY100, THC50, PCP25
D12.11-1VA	12-Panel Urine Drug Screen	MOP300, OXY100, BZO300, OPI2000, MET1000, AMP1000, COC300, THC50, MDMA500, BUP10, BAR300, MTD300 + Cre/pH/Oxi
D12.26-1VA	12-Panel Urine Drug Screen	AMP1000, BUP10, BZO300, COC300, EDDP100, ETG500, FYL10, MDMA500, MET1000, MOP300, OXY100, THC50, + Cre/SG/pH

Available Drug Parameters

- 6-MAM (Heroin)
- Amphetamines
- Barbiturates
- Buprenorphine
- Benzodiazepines
- Cocaine
- Ecstasy (MDMA)
- ETG (Alcohol)
- Fentanyl
- Ketamine
- Marijuana
- Methadone/EDDP
- Methamphetamine
- Morphine / Opiates
- Oxycodone
- Phencyclidine
- Propoxyphene
- Tricyclic Antidepressants
- Tramadol
- And more

Available Adulterant Tests

- Creatinine
- Glutaraldehyde
- Nitrites
- Oxidants
- pH
- Specific Gravity

Ordering Information

Product Code	Product Name	Contents
DX.X-1V	Multi-Drug One Step Cup	100 Tests / Kit

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LOCHNESS MEDICAL

Rapid Response™

One Step DOA Cup MOR 2000 (Urine)

For in vitro diagnostic use only. Product Insert

INTENDED USE

The Rapid Response™ One Step DOA Cup MOR 2000 (Urine) are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone,Secobarbital,Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level (ng/mL)
Amphetamine(AMP)	1000
Barbiturates (BAR)	300
Buprenorphine(BUP)	10
Benzodiazepines(BZO)	300
Cocaine(COC)	300
Methadone metabolite(EDDP)	300
Ecstasy(MDMA)	500
Methamphetamine(MET)	1000
Morphine(MOR)	2000
Methadone(MTD)	300
Oxycodone(OXY)	100
Phencyclidine(PCP)	25
Propoxyphene (PPX)	300
Notriptyline (TCA)	1000
Marijuana(THC)	50

Configuration of the Rapid Response™ Single/Multi DOA Panel MOR 2000 (Urine) and the Rapid Response™ One Step DOA Cup MOR 2000 (Urine) can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

SUMMARY

The Rapid Response™ One Step DOA Cup MOR 2000 (Urine) is a drug-screening test that will give you a result for the presence of abuse in human urine. During testing, a urine sample moves upward on the test strip. A drug-positive urine sample will not produce a colored line in the specified test line area of the strip. A drug-negative urine sample will produce a colored line in the test line area. A colored line will always show in the control line area.

MATERIALS PROVIDED

Materials Provided

- Test Cup
- Product Insert

Materials Required But Not Provided

- Timer

PRECAUTIONS

- Do not use after the expiration date.
- The device should remain in the sealed pouch until use.
- Do not re-use the test.

STORAGE

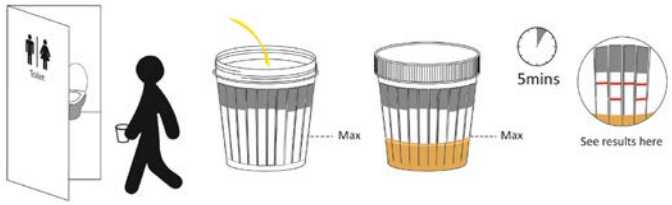
- Store between 39.2°F and 86°F.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat.

SAMPLE COLLECTION AND PREPARATION

Collect urine specimen in the provided test cup. Urine collected at any time of the day may be used.

DIRECTIONS FOR USE

1. Remove the Cup from the sealed pouch and use it within the first hour after opening.
2. Collect urine specimen in the provided cup.
3. Screw the cap onto the cup and immediately start the timer.



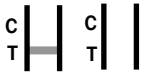
Reading Result:

4. The result should be read at 5 minutes.

INTERPRETATION OF RESULTS

PRELIMINARY POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



INVALID: NO line appears in the C – Control region, then the result is Invalid.

UNDERSTANDING THE TEST RESULTS

A positive result does not mean a person took illegal drugs. A negative result does not mean a person did not take illegal drugs. There are many factors that affect the test. Certain drug tests are more accurate than others.

IMPORTANT: The results from the test are preliminary. The sample must be tested by a lab to confirm the result. Refer to the Confirmation Testing part of this insert.

1. What Is A False Positive Test?

   A false positive test result means the drug is not present but shows as detected by the device. The most common causes for a false positive test are cross reactants. Certain food and medicines, diet plan drugs and nutritional supplements may cause a false positive result with this product.

2. What Is A False Negative Test?

   A false negative test means the drug is present but is not detected by the device. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

LIMITATIONS

- This test is for human urine only. Do NOT use this device to test any other fluids.
- Bleach or baking powder, in urine samples may produce incorrect results. If contamination is suspected, repeat the test with another urine sample.
- The test does not distinguish between drugs of abuse and certain medications.

FREQUENTLY ASKED QUESTIONS

1. What does the Rapid Response™ One Step DOA Cup MOR 2000 (Urine) do?These tests indicate if one or more prescription or illegal drugs are present in urine. The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for additional testing.
2. What is "cut-off level"?
   The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.
3. What are drugs of abuse?
   Drugs of abuse are illegal or prescription medicines that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.
4. Common Street Names for the Drugs to be detected?

Drug	Common Street Names
Amphetamine (AMP)	Speed, Jelly Beans or Super Jellies , Hearts,
Secobarbital(BAR)	Uppers, Pick me ups or Wake me up ups, Get ups, Boot ups, Sparkles Amytal, Downers, Nembutal, Pheno Reds, Red Birds, Red devils, Seconal, Yellowjackets
Oxazepam (BZO)	Benzos, Downers, Nerve Pills, Tranks
Cocaine (COC)	Blow, C, candy, coke, do a line, free happy dust, Mama coca, mojo, monst pimp, shot, smoking gun, snow, suga stuff, and white powder.
Methamphetamine (MET)	Speed, Ice, Chalk, Meth, Crystal, Cra Glass
Methylenedioxymethamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Speed
Buprenorphine(BUP)	Bupe, Subbies, Temmies
Morphine (MOR)	Aunt Hazel, big H, black pearl, brow capital H, charley, china white, dop horse, H, hard stuff, hero, heroina, li mud, perfect high, smack, stuff and tar.
Methadone (MTD)	Amidone, Dolophine, Methadose
Phencyclidine (PCP)	Angel dust, belladonna, black wha cliffhanger, crystal joint, Detroit pink, tranquilizer, hog, magic, Peter Pan, soma, TAC, trank, white horizon and z
Notriptyline (TCA)	Pamelor
Marijuana (THC)	420, Aunt Mary, baby, bobby, boon chronic, ditch, ganja, grass, greens, ha Mary Jane, nigra, Pot, reefer, rip, root stack, torch, weed and zambi.
Oxycodone (OXY)	OC, Ocycotton, OX, and Kicker
Propoxyphene (PPX)	Darvon

5. How accurate is the test?
   The tests are sensitive to drugs and accurate. These tests, however, accurate as lab tests. In some cases, certain foods and drugs may c positives as well as false negatives for those who use drug-testing kits.
6. If the test results are negative, can the conclusion be that the urine drugs?
   This means that if the sample was collected properly and the test was according to the directions, either the urine sample is free of the drugs or the drug levels were below the detection limit of this test.
7. Does a preliminary positive screen test mean that you have found of abu
   This means that the test has reacted with something in the sample and must be sent to the lab for a more accurate test.
8. What should I do, if the lab test confirms a positive result?
   If you have received a confirmed positive result, please consult with ou proper course of action. We will help you identify counselors who can h is important that you remain calm and do not react in a negative situation. If you do not believe the test result, please consult with your They will have your background medical history and be able to provid detailed information on both the test and the meaning of the result.
9. How long can drugs be detected in the body with a urine drug test?

Drug	Minimum detection time	Ma det t
Amphetamine (AMP)	2-7 hours	1-2
Secobarbital(BAR)	2-4 hours	1-4
Oxazepam (BZO)	2-7 hours	1-2
Cocaine (COC)	1-4 hours	2-4
Methamphetamine (MET)	2-7 hours	2-4
Methylenedioxymethamphetamine (MDMA)	2-7 hours	2-4
Buprenorphine(BUP)	4 hours	1-3
Morphine (MOP)	2 hours	2-3
Methadone (MTD)	3-8 hours	1-3
Phencyclidine (PCP)	4-6 hours	7-1

Notriptyline (TCA)	8-12hours	2-7 days
Marijuana (THC)	2 hours	Up to 5+ days
Oxycodone(OXY)	4 hours	1-3 days
Propoxyphene (PPX)	2~4 hours	1-4 days
Methadone metabolite (EDDP)	2 hours	2 to 6 days

CONFIRMATION TESTING

- Write Identification Number on the label.
- Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap.
- Please fill out name, return address, and cell phone number on Mailing Box.
- Place labeled vial in shipping bag and seal the bag.
- Place the sealed Shipping bag in the Mailing Box.
- Mail the box using any US Postal Service.
- Contact the lab if you do not get the result in 5 days.

MORE INFORMATION AND RESOURCES

You can contact your health care provider, or any of the following organizations listed below for additional information and/or counseling regarding substance abuse prevention and treatment:

- American Council for Drug Education (ACDE)
  1-800-DRUGHELP / www.ade.org
- Center for Substance Abuse Treatment (CSAT)
  1-877-SAMHSA-7 / www.samhsa.gov
- The National Council on Alcoholism and Drug Dependence (NCADD)
  1-800-NCA-CALL / www.ncadd.org
- Pride Youth Program formerly Parent's Resource Institute for Drug Education , Inc. (PRIDE)
  1-800-668-9277 / www.prideyouthprogram.org
- The Treatment Center
  1-877-409-9043 / www.thetreatmentcenter.org

PERFORMANCE CHARACTERISTICS

A lay user study was performed at three intended user sites. There were 310 lay persons for the drug test. They had different educational and professional backgrounds. Their age range was from 21 to >50. Urine samples were prepared at the various concentrations. These concentrations were prepared by adding drug(s) into drug-free pooled urine samples. The concentrations of the samples were confirmed. Lay user results were compared to results obtained by GC/MS. It demonstrated that lay users understood the device's instructions and could use the device accurately.

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2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's the Pharmacological Basis of Therapeutics. 6th Ed. New York: Macmillan; 1980

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	2	Do not reuse

BTNX, Inc.
722 Rosebank Rd,
Pickering, ON, L1W 4B2, Canada
Customer Service Phone: 1-888-339-9964
9AM – 5PM. EST (M-F)

BTNX INC.

Appendix C

Provider Outreach and Communications Toolkit, Flyer, and Business Cards

Recovery Incentives Program

Provider Outreach & Communications Toolkit

January 9, 2024

DHCS

Contents

Toolkit Introduction

To expand access to evidence-based treatment for stimulant use disorder, DHCS is piloting Medi-Cal coverage of contingency management services in participating counties through the Recovery Incentives Program. Contingency management is an evidence-based practice that recognizes and reinforces individual positive behavior change consistent with meeting treatment goals, including medication adherence, as well as substance and stimulant nonuse.

The purpose of this Toolkit is to provide organizations offering the Recovery Incentives Program with messaging and resources to spread awareness about the new program among Medi-Cal members living with stimulant use disorder. This Toolkit includes sample messages and templates that can be used in various forms of outreach, including print and digital media. DHCS encourages organizations to integrate this messaging into existing communications channels. Outreach efforts may include, but are not limited to:

- Updating website text and scheduling email newsletters for Medi-Cal members (see "Sample Messages")
- Printing and distributing fliers to provider sites to increase referrals
- Preparing and sharing social media posts

DHCS recommends providers begin outreach to Medi-Cal members one month in advance of the launch of the Recovery Incentives Program. Find additional information about the Recovery Incentives Program on the DHCS Website.

Sample Messages

Sample Messages: Overview & Objectives

Overview

This section includes sample messages related to the efficacy and availability of the Recovery Incentives Program. DHCS encourages participating organizations to use the sample messages included in this Toolkit to ensure consistency in messaging throughout the State.

Target Audience

The messages included in this section are intended primarily, but not exclusively, for Medi-Cal members diagnosed with stimulant use disorder.

Objectives

The messages included in this Toolkit are intended to provide information about:

- Evidence of the effectiveness of contingency management services in treating stimulant use disorder;
- Role of incentives in driving positive behavior change over time; and
- Eligibility criteria for the Recovery Incentives Program.

Sample Messages: Website Text

Do you or someone you know use cocaine, methamphetamine, or other stimulants? An effective new treatment can help you or someone you know stop using and recover from stimulant use disorder. It's called the Recovery Incentives Program.

Beginning [Date], the Recovery Incentives Program is available to individuals who are enrolled in Medi-Cal and diagnosed with stimulant use disorder. The Recovery Incentives Program works by giving participants up to $599 in gift cards for not using cocaine, meth and other stimulants. The program measures changes in stimulant use with negative drug tests.

Please visit [Provider Name] or contact [Contact Information] to learn more about the Recovery Incentives Program.

Sample Messages: Email Newsletter

Subject: Recovery Incentives Program Now Available at [Provider Name].

Do you or someone you know use cocaine, methamphetamine, or other stimulants? An effective new treatment can help you or someone you know stop using and recover from stimulant use disorder. It's called the Recovery Incentives Program.

Beginning [Date], the Recovery Incentives Program is available to individuals who are enrolled in Medi-Cal and diagnosed with stimulant use disorder. The Recovery Incentives Program works by giving participants up to $599 in gift cards for not using cocaine, meth and other stimulants. The program measures changes in stimulant use with negative drug tests.

Please visit [Provider Name] or contact [Contact Information] to learn more about the Recovery Incentives Program.

Sample Messages: Social Media Posts

Sample Post 1

Beginning [date], individuals enrolled in Medi-Cal member can join the Recovery Incentives Program and may receive up to $599 for not using meth, cocaine, and other stimulants. Learn more at: [Website Link]

Sample Post 2

Do you or someone you know use cocaine, methamphetamine, or other stimulants? An effective new treatment can help. It's called the Recovery Incentives Program. Learn more at: [Website Link].

Sample Post 3

[Provider Name] is participating in the Recovery Incentives Program. Medi-Cal members may receive up to $599 to support recovery from stimulant use disorder. Learn more at: [Website Link].

Outreach Materials

Outreach Materials: Overview

Overview

This section includes materials developed by DHCS to support outreach to Medi-Cal members living with stimulant use disorder. Participating organizations should use these outreach materials to share information about the efficacy and availability of the Recovery Incentives Program with Medi-Cal members in their communities.

Materials

The outreach materials in this Toolkit include:

- Recovery Incentives Program Flyer
- Recovery Incentives Program Wallet Card
- Frequently Asked Questions

Outreach Materials: Flyer

Recovery Incentives Program

DO YOU OR SOMEONE YOU KNOW
USE COCAINE, METHAMPHETAMINE, OR OTHER STIMULANTS?

An effective new treatment can help you or someone you know stop using and recover from stimulant use disorder.

It's called the **Recovery Incentives Program.**

- ☑ If you are enrolled in Medi-Cal, **you may get up to $599 in gift cards** for not using meth, cocaine, and other stimulants.
- ☑ The program measures changes in stimulant use with negative drug tests.

WHY USE THIS PROGRAM?

Giving someone money or a gift card can trigger the same feeling of reward in their brain as cocaine or meth. This can help them replace their stimulant use with the rewards.

Research shows many benefits to treating stimulant use with programs like this, including:

☑ Reduce stimulant use ☑ Reduce stimulant cravings ☑ Increased number of days in treatment

Site/name: Phone #:

Recovery Incentives Program

HOW DOES THE RECOVERY INCENTIVES PROGRAM WORK?

The Recovery Incentives Program provides Medi-Cal members with small gift cards totaling up to $599 for not using meth, cocaine, and other stimulants, as measured by negative drug tests. Participants are rewarded for changing their behavior and receive support on their path to recovery.

HOW LONG IS THE PROGRAM?

- » The outpatient treatment lasts 24 weeks.
- » You must attend an in-office visit 2 times a week for 12 weeks.
- » You then must attend an in-office visit 1 time a week for 12 more weeks.

HOW DO YOU QUALIFY FOR THE PROGRAM?

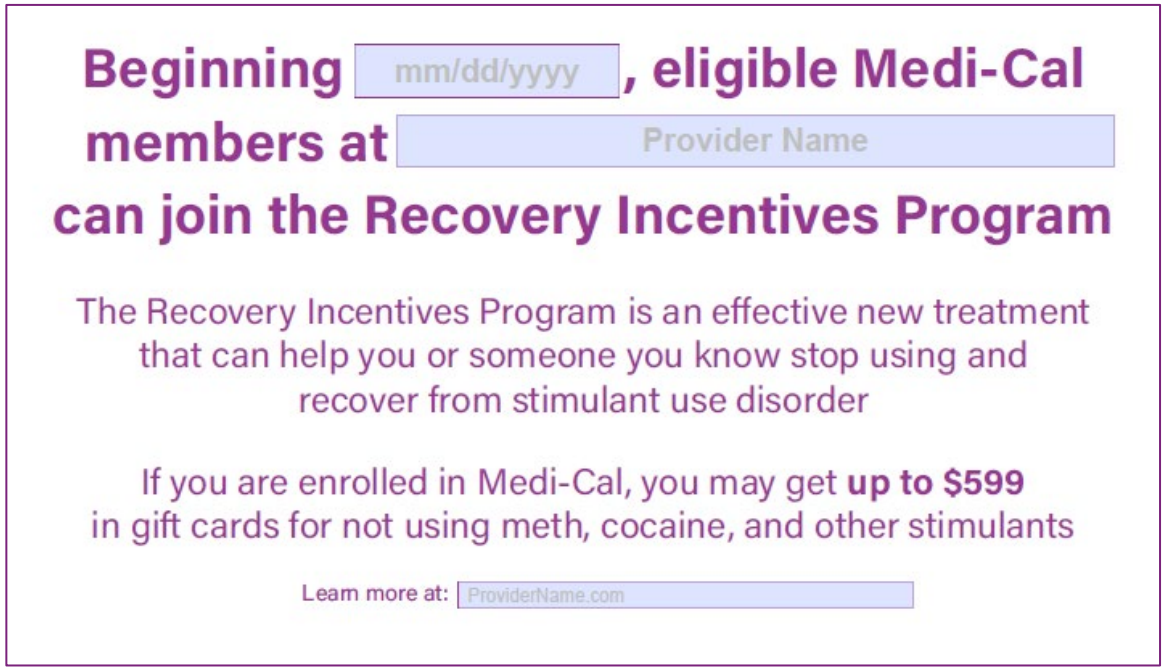
- » If you are enrolled in Medi-Cal and have a diagnosis of medium or severe stimulant use disorder, you can use this program.
- » To learn more about program requirements and which counties and provider organizations take part, go to https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx

CAN YOU GET MEDICATION ASSISTED TREATMENT (MAT) OR OTHER TREATMENTS WHILE IN THE PROGRAM?

- » If you have Medi-Cal and qualify for the program, you can keep getting other substance use disorder treatments, including MAT.
- » This program is not meant to replace MAT for opioid use or alcohol use disorders.

Recovery Incentives Program

Outreach Materials: Wallet Card



Outreach Materials: Frequently Asked Questions

What is the Recovery Incentives Program?

The Recovery Incentives Program is an evidence-based treatment for stimulant use disorder. The Recovery Incentives Program provides Medi-Cal members with small gift cards totaling up to $599 for not using meth, cocaine, and other stimulants, as measured by negative drug tests. Program participants are rewarded for changing their behavior and receive support on their path to recovery.

How does the program work?

Unlike with opioids, there is no approved medication to treat meth, cocaine, or other stimulants. Substance use offers a powerful, immediate reward. The Recovery Incentives Program confronts this challenge by offering financial incentives for not using stimulants. Giving someone money or a gift card can trigger the same feeling of reward in their brain as cocaine or meth. This can help them replace their stimulant use with the rewards.

How do you qualify for this program?

If you are enrolled in Medi-Cal and have a diagnosis of medium or severe stimulant use disorder, you can use this program. To learn more about program requirements and which counties and provider organizations take part, go to https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx.

Outreach Materials: Frequently Asked Questions

How long is the Recovery Incentives Program treatment?

The Recovery Incentives Program outpatient treatment lasts 24 weeks. Eligible Medi-Cal members must attend an in-office visit 2 times a week for 12 weeks, and then must attend an in-office visit 1 time a week for 12 more weeks.

Can you get Medication Assisted Treatment (MAT) or other treatments while in the program?

If you have Medi-Cal and qualify for the program, you can keep getting other substance use disorder treatments, including MAT. This program is not meant to replace MAT for opioid use or alcohol use disorders.

What happens if I test positive for stimulants during the Recovery Incentives Program?

Members will not be kicked out of the Recovery Incentives Program if they test positive for stimulants during an in-office visit. For each visit a member has a positive test, they will not receive an incentive. The member will have an opportunity to test negative for stimulants and re-earn the incentive in a follow-up visit.

Recovery Incentives Program

DO YOU OR SOMEONE YOU KNOW USE COCAINE, METHAMPHETAMINE, OR OTHER STIMULANTS?

An effective new treatment can help you or someone you know stop using and recover from stimulant use disorder.

It's called the **Recovery Incentives Program.**

- ☑ If you are enrolled in Medi-Cal, **you may get up to $599 in gift cards** for not using meth, cocaine, and other stimulants.
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☑ Reduce stimulant use ☑ Reduce stimulant cravings ☑ Increased number of days in treatment

Site/name: Phone #:

Site/name: Phone #:

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CAN YOU GET MEDICATION ASSISTED TREATMENT (MAT) OR OTHER TREATMENTS WHILE IN THE PROGRAM?

- If you have Medi-Cal and qualify for the program, you can keep getting other substance use disorder treatments, including MAT.
- This program is not meant to replace MAT for opioid use or alcohol use disorders.

Recovery Incentives Program | Recovery Incentives Program | Recovery Incentives Program | Recovery Incentives Program | Recovery Incentives Program | Recovery Incentives Program | Recovery Incentives Program | Recovery Incentives Program

Programa de incentivos para la recuperación

¿USTED O ALGUIEN QUE USTED CONOCE CONSUME COCAÍNA, METANFETAMINAS U OTROS ESTIMULANTES?

Un tratamiento nuevo y eficaz que puede ayudarle a usted o a alguna persona que usted conozca para dejar de consumir y recuperarse del trastorno por consumo de estimulantes. Se llama **programa de incentivos para la recuperación.**

- Si está inscrito en Medi-Cal, **usted puede recibir hasta $599 en tarjetas de regalo** por no consumir metanfetamina, cocaína, y otros estimulantes.
- El programa mide los cambios en el uso de estimulantes con pruebas de drogas negativas.

¿POR QUÉ UTILIZAR ESTE PROGRAMA?

Darle dinero o una tarjeta de regalo a alguien le causa el mismo sentimiento de recompensa en su cerebro que la cocaína o la metanfetamina. Esto puede ayudarles a reemplazar su consumo de estimulantes por otras recompensas.

Las investigaciones muestran muchos beneficios de tratar el uso de estimulantes con programas como éste, incluyendo:

- Reducción en el uso de estimulantes
- Reducción de los antojos por estimulantes
- Aumento en el número de días en tratamiento

Site/name: Phone #:

Site/name: Phone #:

Site/name: Phone #:

Site/name: Phone #:

Site/name: Phone #:

Site/name: Phone #:

Site/name: Phone #:

Site/name: Phone #:

Programa de incentivos para la recuperación

¿CÓMO FUNCIONA EL PROGRAMA DE INCENTIVOS PARA LA RECUPERACIÓN?

El programa de incentivos para la recuperación ofrece a los miembros de Medi-Cal pequeñas tarjetas de regalo de hasta $599 por no consumir metanfetamina, cocaína y otros estimulantes, medidos con pruebas de drogas negativas. Los participantes reciben recompensas por cambiar su comportamiento y reciben apoyo en su camino a la recuperación.

¿CUÁNTO DURA EL PROGRAMA?

- El tratamiento como paciente externo dura 24 semanas.
- Usted deberá asistir a una cita al consultorio 2 veces a la semana durante 12 semanas.
- Después usted deberá asistir a una cita al consultorio 1 vez a la semana durante 12 semanas más.

¿CÓMO CALIFICA USTED PARA EL PROGRAMA?

- Si está inscrito en Medi-Cal y tiene un diagnóstico de trastorno por consumo de estimulantes media o grave, usted puede utilizar este programa.
- Para obtener más información sobre los requisitos del programa y cuáles condados y organizaciones de proveedores participan, ir a https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx

¿PUEDE UNO RECIBIR TRATAMIENTO ASISTIDO POR MEDICAMENTOS (MAT, POR SUS SIGLAS EN INGLÉS) U OTROS TRATAMIENTOS MIENTRAS ESTÉ EN EL PROGRAMA?

- Si tiene Medi-Cal y califica para el programa, usted puede seguir recibiendo otros tratamientos para enfermedades por abuso en el consumo de sustancias, incluyendo MAT.
- Este programa no pretende reemplazar a MAT para enfermedades por consumo de opioides o por consumo de alcohol.

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Recovery Incentives Program Now Available

Provider Name: Provider Name

Phone Number: (123) 456-7890

Physical Address: 123 Main Street, Ste. 100, Anytown, US 54321

Email: YourEmail@providername.com

Website: ProviderName.com

Beginning mm/dd/yyyy, eligible Medi-Cal members at Provider Name can join the Recovery Incentives Program

The Recovery Incentives Program is an effective new treatment that can help you or someone you know stop using and recover from stimulant use disorder

If you are enrolled in Medi-Cal, you may get **up to $599** in gift cards for not using meth, cocaine, and other stimulants

Learn more at: ProviderName.com

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Appendix D

Behavioral Health Information Notice No: 23-040

NOTE:

Behavioral Health Information Notice No. 23-040 was released on August 18, 2023, and supersedes BHIN 22-056 (released on October 14, 2022). To ensure that you are reading the most up-to-date version of the BHIN, visit https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx, and scroll down to the Resources and Documents – Policy Documents section of the website.

Appendix E

CM Team Requirements Flow Chart

RECOVERY INCENTIVES: CALIFORNIA'S CONTINGENCY MANAGEMENT BENEFIT - CM TEAM REQUIREMENTS

Individuals serving as CM Coordinator, Back-up CM Coordinator, and CM Supervisor must complete all steps prior to initiating services at their site. More information about the Recovery Incentives Program, including Implementation training slides and handouts, training dates/times, contact information, and warmline assistance can be found here: https://uclaisap.org/recoveryincentives/index.html

Step 1

Completion of Recovery Incentives: California's Contingency Management Program – Contingency Management Overview Training, a 2-hour self-paced overview course. This can be found here.

Step 2

Attend Part 1 and Part 2 of the Implementation Trainings. Registration for Part 2 will be confirmed following attendance at a Part 1 session. Dates and times for sessions can be found here. Completion of the post-test with an 16/20 (80%) or higher is required for all participants.

Step 3

Complete the Readiness Assessment Self-Study in Qualtrics. Only one Self-Study is needed per physical site. Following the completion of Part 1 and Part 2 of the Implementation Trainings by at least 1 CM Coordinator and 1 CM Supervisor, the link for the self-study will be sent to the site.

Step 4

Entry of 3 practice cases in the IM Portal Sandbox by all CM team members. The login for the IM Portal can be found at the end of the Readiness Assessment self-study. All CM Team members, including those who join later, must successfully enter 3 practice cases into the IM Portal prior to delivering CM services

Step 5

Complete the interactive Zoom Portion of the Readiness Assessment with a UCLA Team Member. This will be scheduled within a week of the submission of the Qualtrics self-study, including entry of the 3 practice cases into the IM Portal.

Step 6

Following the successful completion of the Readiness Assessment, personalized logins for the IM Portal will be sent. Sites will not be able to launch services until sites have at least 1 CM Coordinator, 1 Back-up CM Coordinator, and 1 CM Supervisor complete this process.

Appendix F

OIG Rules Applying to Non-Medicaid-Funded Contingency Management Programs

Appendix F

OIG rules applying to non-Medicaid funded Contingency Management programs

In general, federal law restricts providers' abilities to offer financial incentives as part of patient therapy or patient recruitment. The Anti-Kickback Statute (AKS) is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).[1] The Civil Monetary Penalties Law (CMPL) authorizes the Secretary of Health and Human Services to impose civil money penalties, an assessment, and program exclusion for various forms of fraud and abuse involving the Medicare and Medicaid programs.[2]

Over the years, the U.S. Department of Health & Human Services Office of Inspector General (OIG) has cautioned providers about various problematic activities that may create legal risk under the AKS or the CMP, including paying people to receive care that was not medically necessary.

However, the federal government has explicitly stated that the AKS and the CMP do not apply to motivational incentives that are delivered as part of the Medicaid-covered CM benefit, and in compliance with the DHCS-approved CM protocol. For the purpose of the Medi-Cal contingency management benefit authorized under the CalAIM 1115 demonstration:

> *These motivational incentives are considered a Medicaid-covered item or service and are used to reinforce objectively verified recovery behaviors using a clinically appropriate contingency management protocol consistent with evidence-based research. Consequently, neither the Federal anti-kickback statute (42 U.S.C. § 1320a-7b(b), "AKS") nor the civil monetary penalty provision prohibiting inducements to beneficiaries (42 U.S.C. 1320a-7a(a)(5), "Beneficiary Inducements CMP") would be implicated.*[3]

Providers may offer and promote this benefit as they would any other benefit under DMC-ODS, subject to the CM protocols established by DHCS, outlined in BHIN #23-040. This protection does **not** apply to any patient incentives beyond those authorized in DHCS' contingency management protocol. Standard AKS and CMP principles will apply if a provider offers other types of patient incentives outside the CM benefit. For example, depending on the circumstances, it may create legal risk if a provider were to:

[1] https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/
[2] Ibid.
[3] https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Approval-Letter-and-STCs.pdf

- Offer motivational incentives to patients who do not qualify for the DMC-ODS CM benefit.
- Market the CM benefit in a manner that is inaccurate, misleading, or coercive (see below for best practices).
- Offer financial incentives to Medi-Cal patients over and above the motivational incentives available under the CM benefit.
- Offer the CM benefit in a manner inconsistent with DHCS' contingency management policies and protocols.
- Pay for marketing or patient recruitment services on a commission basis, or in a manner that otherwise takes into account the volume or value of business generated.
- Offer financial incentives to other health care providers in exchange for telling patients about, or referring patients for, CM and related SUD services.

State Requirements

To ensure contingency management services meet federal requirements, providers participating in the CA Recovery Incentives Program must abide by all policies and protocols established by DHCS.

CM services are only available to Medi-Cal members who are enrolled in a comprehensive treatment program that offers Recovery Incentives and meet other eligibility requirements. All Medi-Cal members participating in CM must be assessed and determined to have a moderate or severe StimUD as defined by the clinical criteria in the Diagnostic and Statistical Manual (current edition i.e., DSM-5-TR). The assessing clinician must determine that in addition to the diagnosis, outpatient, intensive outpatient, or partial hospitalization treatment is appropriate per the American Society of Addiction Medicine (ASAM) criteria, and the CM benefit is medically necessary based on existing medical necessity criteria. Each treatment program must also maintain fidelity to the evidence-based CM practice. SUD treatment providers will collaborate with eligible members to develop and document an individualized treatment plan that includes CM as one component of that plan. Each CM visit will be documented consistent with existing DHCS policy.

Additional details related to state documentation requirements and other CM protocols are available in BHIN #23-040.