Patient Support Program

Update for Access & Affordability Working Group
November 4, 2025

CIRM
CALIFORNIA INSTITUTE FOR
REGENERATIVE MEDICINE

Goals for Today

1. To provide an update on the status of the CIRM Patient Support Program (PSP), what we've learned to date, and to answer any questions about the program

2. To gather AAWG feedback in preparation for a CIRM board (ICOC) presentation in December

Patient Support Program Update

① Background

② Timeline

③ Program Pilot and Improvement Areas

④ Next Steps

Proposition 14 - Patient Assistance Fund (PAF)

Revenues received by CIRM shall be deposited into the General Fund "Licensing and Revenue Fund" to be spent on "offsetting the costs of providing treatments and cures arising from Institute-funded research to **California** *patients who have insufficient means to purchase such treatment or cure, including* <u>the reimbursement of patient-qualified costs for research participants</u>.*" - Proposition 14 125290.30(j)(1)*

Strategic Allocation Framework (SAF)

Goal 5 - **Ensure** that every BLA ready program has a strategy for access and affordability

Strengthen Clinical Infrastructure Connectivity
➢ Build interconnectivity & performance metrics between CIRM Clinical Infrastructure (Alpha Clinics, CCCEs, PSP) to ensure enhanced **referral, enrollment, & retention** of California patients in clinical trials

Program Funding - Grant vs. PAF

Funds to directly cover patient costs

- Dedicated to allowable expenses for eligible CA residents in CIRM funded trials
- Fund may be supplemented by future CIRM royalty streams

Patient Assistance Fund (PAF)
15.6M

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Patient Assistance Fund (PAF)
15.6M

Patient Support Program (PSP)
2.5M

CIRM INFR7 Award

- Grant for program design planning, and operational expenses
- Supported by CIRM AA budget
- Issued to ensure that the PAF is utilized to directly address patient financial and logistical barriers

Patient Support Program (PSP) Award

- The PSP awardee was required to perform **4 primary operational activities**:

  1. **Patient intake and navigation** through development of a call center

  2. Assessing **patient financial eligibility** for access to PSP support

  3. **Distributing payments for eligible expenses** for transportation, travel, lodging, and nutrition

  4. Coordinating with CIRM and trial sites to **maintain accounting and assurance of non-duplication of permitted costs**

PSP Support Services Offered

Nutrition

Meals or other nutritional assistance (up to $100/day)

Travel

Travel coordination (e.g. flight booking up to $500 per flight)

Lodging
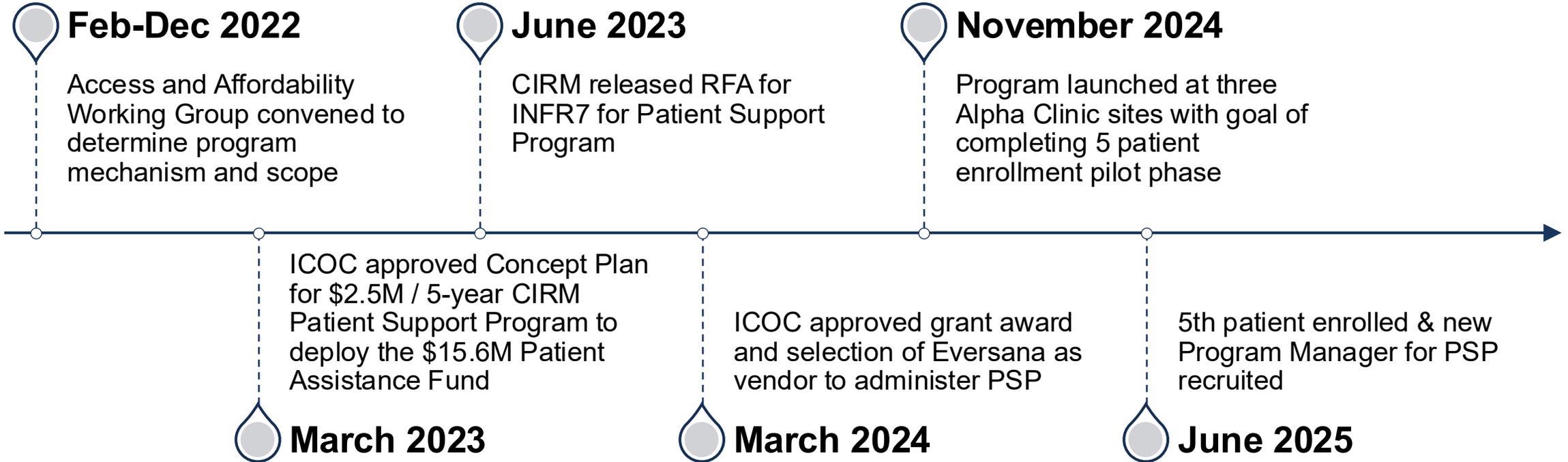
Lodging throughout clinical visits ($275 per night)

Transportation

Including gas, ride share and parking ($50 limit)

Program exceptions for additional funds are reviewed on a case-by-case basis, consistent with State travel policy

PSP Development Timeline

Feb-Dec 2022

Access and Affordability Working Group convened to determine program mechanism and scope

June 2023

CIRM released RFA for INFR7 for Patient Support Program

November 2024

Program launched at three Alpha Clinic sites with goal of completing 5 patient enrollment pilot phase

ICOC approved Concept Plan for $2.5M / 5-year CIRM Patient Support Program to deploy the $15.6M Patient Assistance Fund

ICOC approved grant award and selection of Eversana as vendor to administer PSP

5th patient enrolled & new Program Manager for PSP recruited

March 2023

March 2024

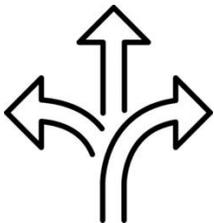**June 2025**

PSP Initial Pilot

Program well received by participating clinical trial sites, Alpha Clinics, and patients

Smooth enrollment process through text and email allows for efficient communication with patients

Use of pre-paid debit card increases accessibility and reduces administrative burden on patients

Program infrastructure adaptable to emerging needs (e.g. ground transportation, additional service offerings)
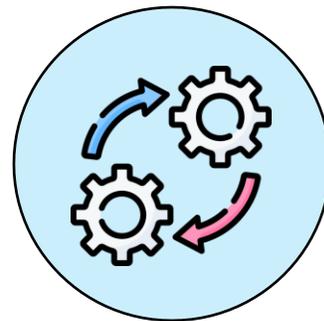
PSP Pilot Improvement Areas

Reporting

Modifying reports to be **more robust** for comprehensive expense category reporting

Compliance

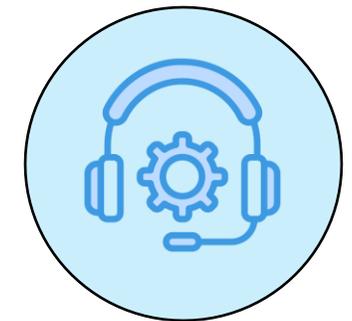**Refining allowable merchant codes** and transaction tracking

CLIN2 Outreach

Increasing awareness with CLIN2 study teams and Alpha Clinics

Policy & Legal

Engaging CIRM Legal and Finance to inform program **eligibility and compliance** questions

Navigation

Implementing **enhanced clinical navigation** support

PSP Pilot Extension
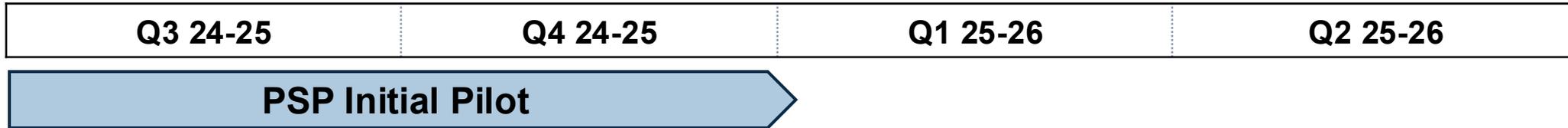
Q3 24-25	Q4 24-25	Q1 25-26	Q2 25-26

PSP Initial Pilot

- Operational framework, call center scripting, platform and business rules developed

- Debit card vendor (Klyre) and travel vendor (Concur) contracted

- Program launched at 3 Alpha Clinics 12/24

- Fiscal agreement finalized 1/25

- Program expanded to all Alpha Clinics and CLIN2 award sites 5/25

- Program expanded to support screening 6/25

- Fifth patient enrolled 6/25

PSP Pilot Extension

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Limitations of Pilot

- **Low** overall **patient volume**
- **Only 3** clinical trial **sites**
- **Not enough data** on costs and utilization
- **Not enough variety** of data on patient usage to identify edge cases to **strengthen business rules**

PSP Pilot Extension

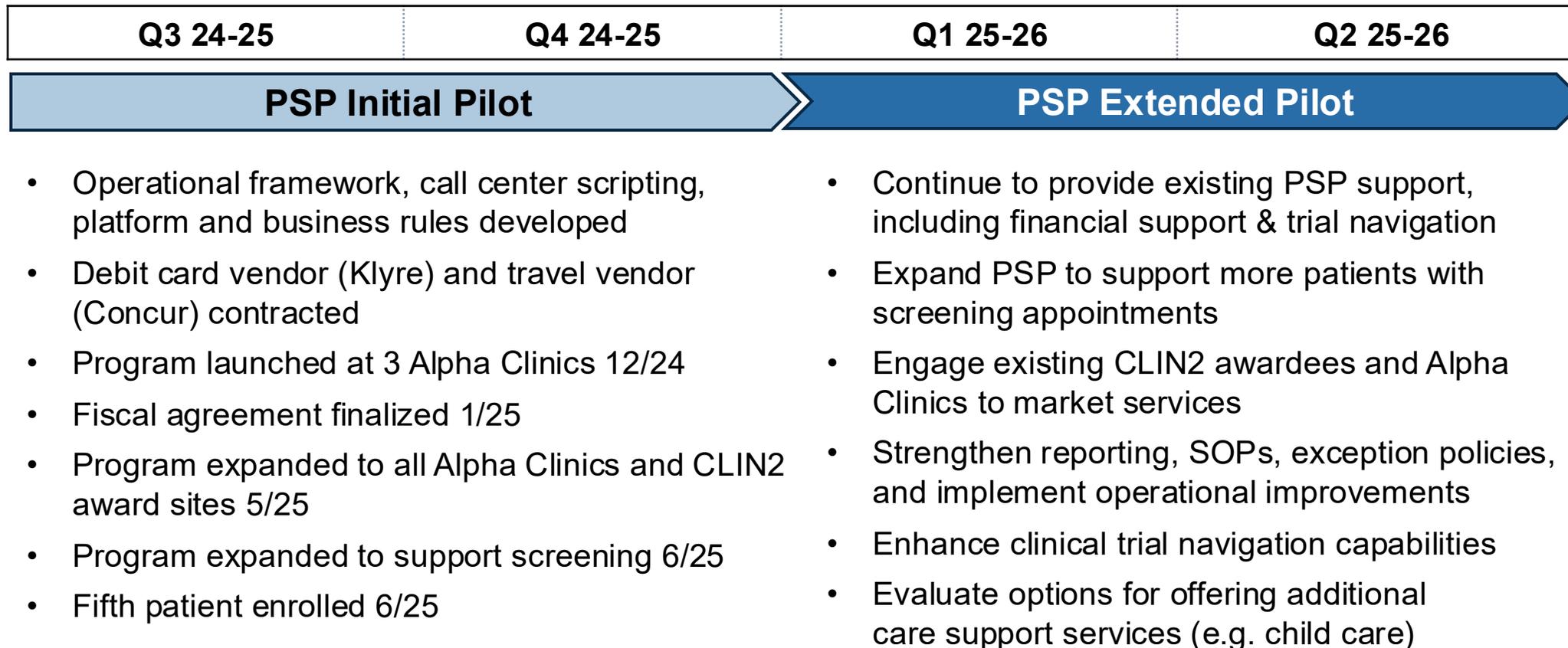| Q3 24-25	Q4 24-25	Q1 25-26	Q2 25-26

PSP Initial Pilot ➤ **PSP Extended Pilot** ➤

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- Continue to provide existing PSP support, including financial support & trial navigation
- Expand PSP to support more patients with screening appointments
- Engage existing CLIN2 awardees and Alpha Clinics to market services
- Strengthen reporting, SOPs, exception policies, and implement operational improvements
- Enhance clinical trial navigation capabilities
- Evaluate options for offering additional care support services (e.g. child care)

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PSP Pilot Extension

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PSP Initial Pilot → **PSP Extended Pilot**

Rationale for Expansion

- **Increase** overall **enrollment**
- Gather **more data on costs and utilization**
- **Strengthen program integrity, business rules, and reporting**
- **Identify more edge cases** that may inform business rules development

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PSP Award Implementation Schedule

Award Start: 8/1/2024
Award End: 7/31/2029

**Phase 2
Discovery
1/1/26 – 6/30/26**

- Move into full program implementation as more CLIN2s come online

**Phase 3
Expansion
7/1/26 – 12/31/26**

- Solidify full program implementation

**Year 3
Steady State
1/1/27-12/31/27**

- Steady state program implementation

**Year 4
Steady State
1/1/28-12/31/28**

- Steady state program implementation

**Year 5
Assessment
1/1/29-7/31/29**

- Wind-down of award
- Ramp up next phase of program (if applicable)

Questions?