

# SOMETHING BETTER THAN HOPE

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January 28, 2021

**CIRM**  
CALIFORNIA'S STEM CELL AGENCY

# Proposition 14

- **Approved at November 3, 2020 Election by 8,588,618 California Voters**
- **Authorizes \$5.5 Billion in General Obligation Bond Funding for CIRM Awards and Administration**
- **Makes Substantive and Technical changes to Proposition 71**
- **Imposes New Requirements with respect to Allocation of \$5.5 Billion**
- **Builds on CIRM's Existing Programs and Infrastructure**

# Most Significant Changes

- **Establishes New Programs**
- **Establishes Treatments and Cures Accessibility and Affordability Working Group**
- **Expands Scope of Research**
- **Allocates \$1.5 Billion to Research Involving Diseases/Conditions of Brain/Central Nervous System**
- **Expands Size of Board and Allows for Removal of Members**
- **Makes Governance and Administrative Changes**

# Most Significant Changes (continued)

- **Makes Changes to Review**
- **Requires Review of Accountability Requirements and Adoption of Standards**
- **Allocates Funding for Research, Administration, and Facilities**
- **Includes Key Bond Terms**
- **Earmarks Royalties for Access and Affordability**

# New Programs

- Expands Alpha Stem Cell Clinics Program and Creates Community Care Centers of Excellence Program
  - Requires expansion of Alpha Stem Cell Clinic Program to enhance access to clinical trials and treatments
  - Creates Community Care Centers of Excellence Program to promote access to clinical trials and treatments at geographically diverse centers
- Creates Training and Fellowship Programs
  - Training Awards to CSU and CCC campuses to train undergraduates for technical careers in stem cell research and VROs and to provide fellowships to Master's students for advanced degrees; may include sponsored internships
  - Fellowship Awards to academic/nonprofit research institutions to support graduate, post-doc, and medical students in stem cell research and VROs; may include work in ASCC or CCCE as part of fellowship

# New Programs (continued)

- Re-Establishes Shared Labs Program
  - Awards to academic and nonprofit research institutions for specialized instrumentation, a supply of cell lines, culture materials, and instruction and training in research methods and techniques
  - Requires Shared Lab awardees to provide reasonable access plan for researchers at neighboring institutions
- Allocates Facilities Funding for Community Care Centers of Excellence and Shared Labs
  - Provides funding to build, equip, and operate CCCEs and to build and equip Shared Labs

# Treatments and Cures Accessibility and Affordability Working Group

- Creates Accessibility and Affordability Working Group (AAWG)
  - Composed of the Chair and Vice Chair, five members of the Board, and ten outside experts in coverage, reimbursement, health care delivery, patient access, and health care economics
  - Charges AAWG with developing and recommending policies and programs to the Board to enhance access to, and the affordability of, clinical trials and treatments and cures arising from CIRM-funded research
- Allocates research funding for accessibility and affordability
  - Provides that up to 2% of grant funds may be used for research consulting awards in support of accessibility and affordability
  - Provides for Board to make final decisions on research consulting awards based on recommendations of AAWG

# Scope of Research

- Includes genetic research within scope of CIRM funding
  - Defines “stem cell discovery research” to include genetic research, making it automatically within scope
- Authorizes Board to make awards across the research spectrum, including awards for therapy delivery
- Authorizes Board to designate a research category as a “Vital Research Opportunity” by majority vote
  - Examples of VROs include personalized medicine and aging as a pathology
  - Once designated by Board, VROs are within scope for CIRM funding

# \$1.5 Billion to Diseases and Conditions of Brain and Central Nervous System

- Allocates no less than \$1.5 Billion to Neuro Research
  - Includes research relating to diseases and conditions of the brain and central nervous system
  - Identifies diseases and conditions such as Alzheimer's disease, Parkinson's disease, stroke, dementia, epilepsy, schizophrenia, depression, traumatic brain injury, brain cancer, and autism as targets for funding
- Authorizes Board to make awards across the research spectrum, including research, therapy development, and therapy delivery
- Specifies that the \$1.5 Billion includes the pro rata share of grant oversight and general administrative costs

# Expands Size of Board and Allows for Removal of Members

- Increases number of Board Members from 29 to 35
  - Two new UC appointments: UC Riverside and UCSF Fresno/Clovis Campus
  - Two nurses with clinical trial and/or stem cell or genetic therapy delivery experience
  - Two patient advocates for mental health conditions
- Allows for removal of Board members
  - Appointing authorities may replace members, except Chair and Vice Chair, who have served at least half of their term, by March 16, 2021
  - Appointing authority may remove member based on recommendation of Board by vote of 60% of the members

# Governance and Administrative Changes

- Requires Board to meet at least four times per year
- Imposes cap of 70 employees
  - Allows the hiring of up to 15 additional employees to support access and affordability work
- Authorizes Chair and President to establish Advisory Task Forces
  - Provides for Chair and President to each appoint an equal number of members
  - Charges task forces with providing expert guidance on scientific, policy, ethical, financial, technical and other matters within CIRM's jurisdiction
- Requires Board to develop and implement access and affordability policies and programs based on recommendations of AAWG
- Provides for Patient Advocates to be compensated based on daily consulting rate rather than per diem for all meetings

# Changes to Review

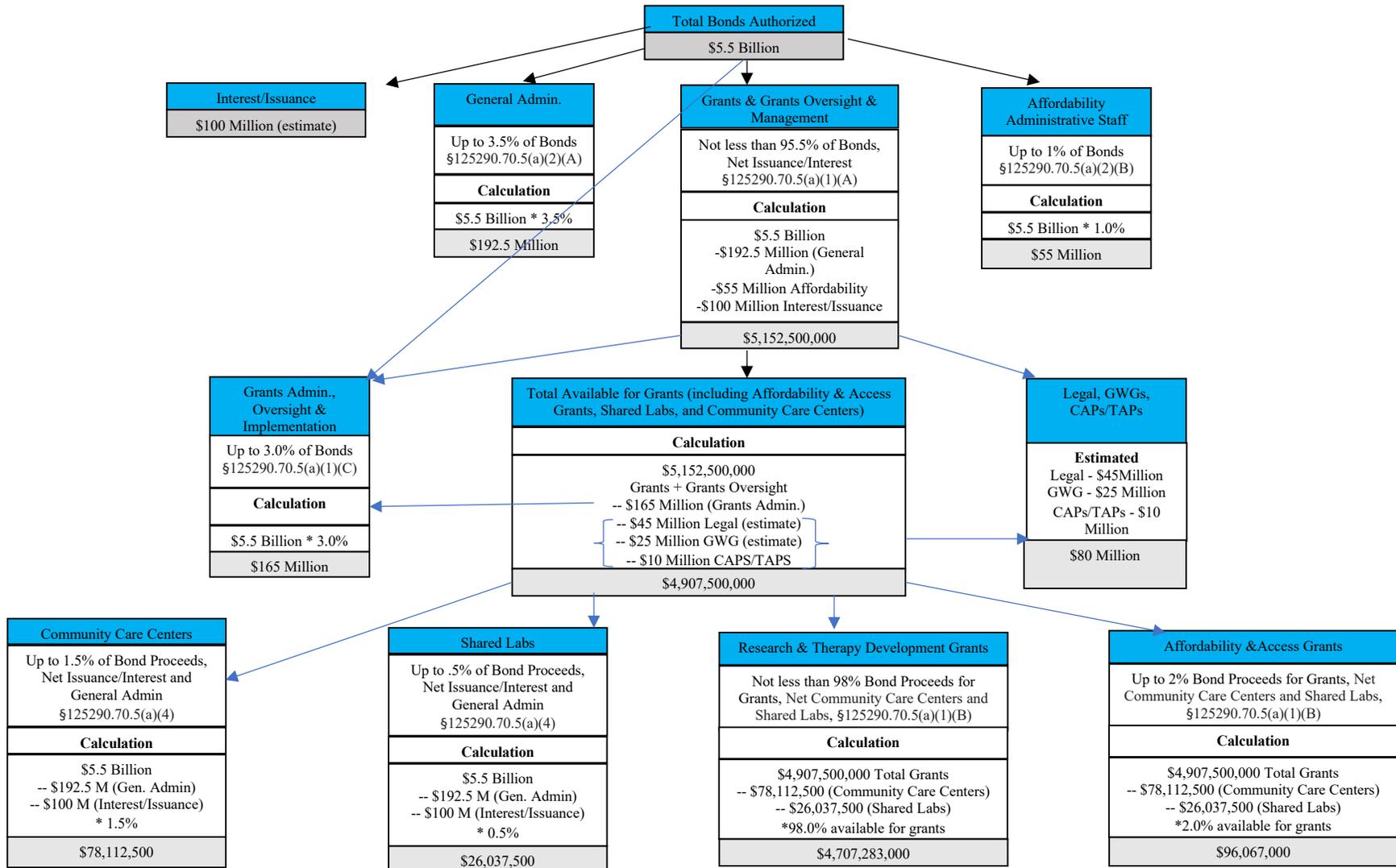
- Allows Board to re-appoint non-ICOC Working Group members who have served two consecutive terms by 2/3 vote
- Allows for the appointment of ad hoc voting group members to obtain necessary expertise
  - Cannot exceed three ad hoc members on any one expert review panel
- Expands expertise of scientific members of GWG to include Vital Research Opportunities
- Requires minority report
  - Requires the submission of a minority report summarizing strengths and weaknesses of application when at least 35% of members score application in funding range
- Provides for appointment of Nurse members of Board to Working Groups, in addition to Patient Advocates

# Review of Accountability Requirements and Adoption of Standards

- Requires Board to review and update conflict of interest standards for the review of applications for funding every four years
  - Consult with National Academy of Sciences and review best practices
- Requires Board to review and update policies governing conflicts, ethical research standards, and standards for independent audits every four years
  - Align with standards adopted by National Academy of Sciences
- Requires Board to adopt standards governing reimbursement of patient expenses
  - Includes medical expenses and travel, meals, and lodging for patients and caregivers
- Requires Board to adopt standards governing genetic research generally based on standards adopted by National Academy of Sciences

# Funding for Research, Administration, and Facilities

- Allocates no less than 95.5% of bond proceeds for grants and grant administration
- Allocates up to 3.5% of bond proceeds for general administration
- Allocates up to 1.5% of bond proceeds for costs of accessibility and affordability team
- Of funds available for grants and grants administration:
  - Allocates no less than \$4,707,283,000 to research grants
  - Allocates up to \$96,067,000 for accessibility and affordability grants
  - Allocates up to \$78,112,500 for CCCE facilities and \$26,037,500 for Shared Labs facilities
  - Allocates up to \$165,000,000 for grants administration



# Key Bond Act Terms

- Requires use of bond proceeds to pay capitalized interest for first five years
  - No payments from General Fund until 2026
- Prohibits issuance of more than \$540 million in bonds annually
  - Requires bond to be sold over a period of no less than 11 years
- Authorizes use of loan proceeds by CIRM
  - Authorizes CIRM to use the proceeds from the repayment of loans to make additional awards and for administrative costs

# Earmarks Royalties for Accessibility and Affordability

- Requires that royalties paid to the State as a result of CIRM-funded research be appropriated for the purpose of offsetting the costs of providing treatments and cures arising from CIRM-funded research
  - Earmarked for California patients who have insufficient means to purchase them
  - Earmarked for reimbursement of patient-qualified costs for participants in CIRM-funded research

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**Thank You!**