

SOMETHING BETTER THAN HOPE

James Harrison

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

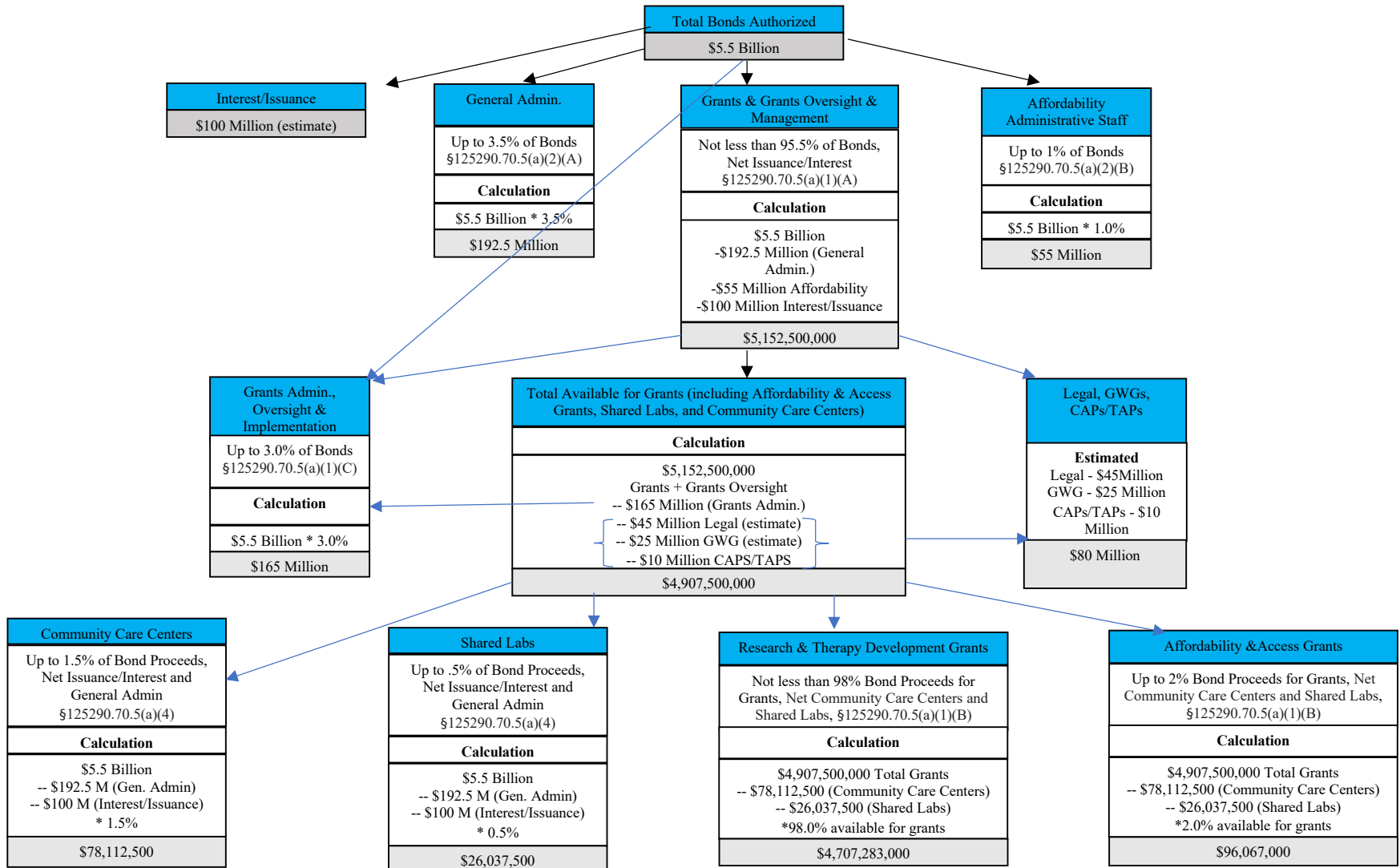
- Allows Board to re-appoint non-ICOC Working Group members who have served two consecutive terms by 2/3 vote
- Allows for the appointment of ad hoc voting group members to obtain necessary expertise
 - Cannot exceed three ad hoc members on any one expert review panel
- Expands expertise of scientific 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

**SOMETHING
BETTER
THAN HOPE**

Thank You!