

Connecting for Better Health Meeting

March 28, 2024

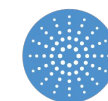


Connecting for Better Health

Advancing data sharing to improve the health of all Californians

Agenda

No.	Item	Minutes
1	Welcome and Introductions	5 minutes
2	Guest Presentation - 42 CFR Part 2 Final Rule	20 minutes
3	State Updates <ul style="list-style-type: none">● California State Legislation Tracking● Data Exchange Framework Updates	15 minutes
4	C4BH Sponsor Opportunity	15 minutes
5	News, Events and Announcements <ul style="list-style-type: none">● Introduce Maya Harrison	5 minutes



About The Coalition

Our Vision: Every Californian and their care teams have the information and insights they need to make care seamless, high quality and affordable.



Policy Priorities

- **DSA Education & Implementation:** Promote awareness of the DSA and support data exchange implementation to realize the promise of AB 133
- **Funding:** Advocate for the state to dedicate continued funding for health and social services data sharing and encourage state agencies to seek federal match when and where appropriate
- **Integration of social services data:** Develop and communicate case studies and policy recommendations that support cross-sector data sharing, consent, and authorization
- **Advance DxF Governance, Enforcement, and Accountability:** Work towards the passage of DxF legislation, monitor state legislation and budgetary actions related to data sharing, and provide critical feedback to CDII and other state agencies to resolve challenges



Guest Speaker

42 CFR Part 2 Rule Changes

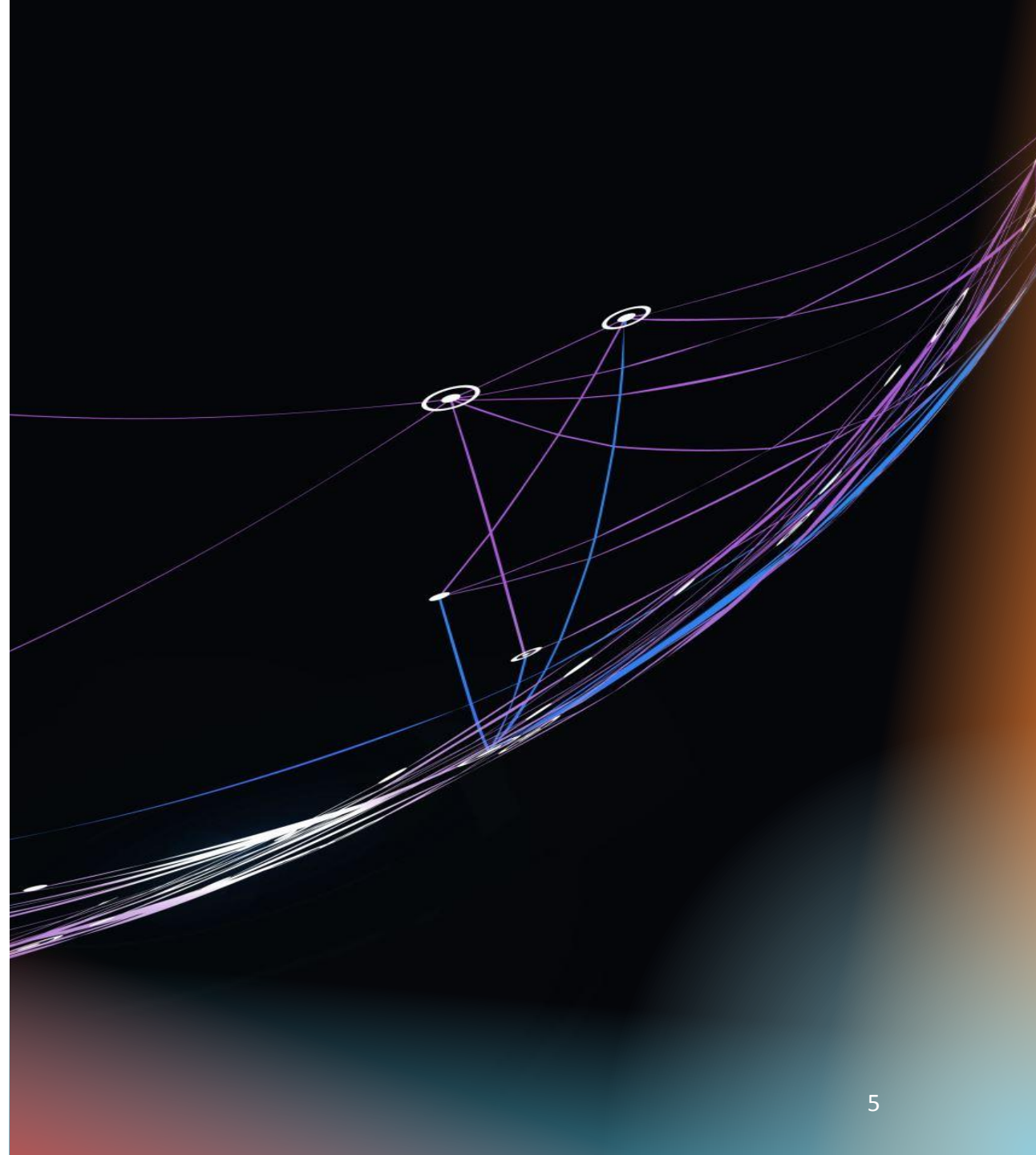
Deven McGraw

Chief Regulatory & Privacy Officer
Citizen



Disclaimer

- Provided for information purposes only – **not legal advice.**
- Does not address intersection of Part 2 with California law
- Consult Part 2 regulatory text for more details (we only have time in this session to hit some high points!)



What is Part 2?

- Statute (42 USC 290dd-2) that protects records of a federally supported substance abuse disorder education, training, treatment, or research program that identify a patient as someone who has or may have a substance use disorder
 - Programs/institutions/offices must be publicly known as places where substance abuse disorder education, training, treatment, or research is provided.
 - Federal support doesn't require federal grant/reimbursement - having a schedule 3 Rx license (DEA) is sufficient for the "federally supported" nexus (42 CFR §2.12(b)(2))
 - Once Part 2-protected data is disclosed from a Part 2 program/institution, the data continues to be protected by Part 2 in the hands of the recipient (even if that recipient is not a federally supported substance abuse disorder program).
- "Part 2" = this statute and regulations issued under this statute.

Why were the regulations amended - and when do they go into effect?

- Congress directed HHS to make changes to the Part 2 regulations consistent with the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020.
 - Required HHS to align certain aspects of Part 2 with HIPAA and HITECH, while maintaining protections against use of SUD (substance use disorder) data against an individual.
- Proposed Part 2 changes were published on December 2, 2022.
- Regulations finalized on February 8, 2024.
- Changes go into effect April 16, 2024 - but entities covered by these rules have until February 16, 2026 to come into compliance; however, they can begin coming into compliance at any time if advantageous to do so.

Major Changes from Current Part 2 Rules (1)

- Allows a single consent for all future uses and disclosures for treatment, payment & health care operations (TPO).
- Allows HIPAA covered entities and business associates that receive records under this consent to redisclose them in accordance with HIPAA (EXCEPT records cannot be used in legal proceedings against the patient without specific consent or a court order, which is more stringent than the HIPAA Privacy Rule).

Major Changes from Current Part 2 Rules (2)

- Permits disclosure without consent to public health authorities as long as the records are de-identified per HIPAA standards.
- Restricts use of records in legal proceedings against patients unless the patient has consented or there is a court order.
- Aligns Part 2 penalties with HIPAA penalties (civil & criminal)
- Applies HIPAA breach notification rule to breaches of Part 2 data.
- Aligns Part 2 patient notice requirements with HIPAA Notice of Privacy Practices provisions

Further modifications from Proposed Rule (1)

- Makes clear that segmenting Part 2 records is not required (except for “SUD Counseling Notes” (see next slide))
- Prohibits combining patient consent for disclosure of records in a legal proceeding against the patient with consent for any other use or disclosure.
- Requires that each disclosure made with patient consent include a copy of the consent or a clear explanation of the scope of that consent.

Further modifications from Proposed Rule (2)

- New right for patients to opt-out of receiving fundraising communications (same as under HIPAA).
- Creates a new definition of SUD Counseling Notes that are SUD clinician notes analyzing the conversation from an SUC counseling session - these are protected like psychotherapy notes are in HIPAA if they are maintained separate from other records.
 - These cannot be used or disclosed based on a broad TPO consent and require specific consent to be further used or disclosed.

Major differences of note (1)

- Under old Part 2 rules (albeit under new interpretation), entities covered by Part 2 could disclose covered SUD data to an HIE with a Qualified Service Organization Agreement (QSOA) without having to first get a patient's consent – however:
 - Any subsequent access to that data - including by a treating provider - required consent.
 - The consent could be broad - “any treating provider member of an HIE”, for example – but then patients upon request could get a list from the QSO (HIE) of any provider who had accessed the patient's SUD data within the past two years.
 - Subsequent nontreatment use and re-disclosures by the recipient provider outside of through the QSO (HIE) would require additional consent except where permitted by Part 2.

Major differences of note (2)

- Under new rules, patients can consent broadly to sharing of data for TPO - no requirement to obtain further consent if that further use and disclosure is by an entity covered by HIPAA and is permitted by HIPAA's rules.

What has not changed?

- Strong protections for SUD data against being disclosed in legal proceedings against the patient without consent or court order.
- Entities may provide stronger protections than Part 2 - but if they do so, they need to include these in the notice to patients (the notice similar to the HIPAA NPP).
- Ability to use or disclose SUD data without consent in an emergency still apply - but need to include this in the notice to patients.

Keep an eye out for....

Additional guidance and FAQs on Part 2 from OCR and/or SAMHSA

OCR plans to finalize changes to the HIPAA NPP to address data also protected by Part 2.

HHS also plans a separate rulemaking on the CARES Act anti-discrimination provisions that prohibit use of patients Part 2 records against them (beyond existing protections against disclosure in legal proceedings).

Helpful resources

- HHS Fact Sheet:

<https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part-2.pdf>

- Be careful about using these resources -

<https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part-2.pdf> and

<https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs> - as both be out of date once the new regulations go into effect.

State Updates



California Legislation Tracking (1/2)

No./Author	Summary	Recent Developments
<u>AB 236</u> (Holden)	Requires health plans and insurers to annually verify and delete inaccurate listings from provider directories to be at least 60% accurate, with administrative penalties for failure to meet benchmarks. Authorizes DMHC and Department of Insurance to develop uniform formats for plans and insurers to request directory information from providers and authorizes the establishment of methodology and processes to ensure accuracy.	Passed Assembly; Awaiting Senate Committee Assignment (1/30)
<u>AB 1011</u> (Weber)	Imposes new restrictions on the sale, disclosure of “social care information” on users of “closed-loop referral systems” including public agencies, non-profits, health care providers, vendors.	Two-year bill in Senate Appropriations
<u>AB 1331</u> (Wood)	Establishes DxF governing board; outlines appointment of members; requires board approval for any amendments to DSA; requires QHIOs to be non-profits; decrease size of board to five members; require certain reports and educational efforts related to consumers and data; among other requirements.	Two-year bill in Senate Appropriations
<u>AB 2089</u> (Holden)	Require cities and counties to include additional collection categories for specified Black or African American groups when collecting demographic data related to ancestry or ethnic origin.	Referred to Judiciary Committee (3/21)
<u>AB 2153</u> (Lowenthal)	Require public agencies to promptly provide written notice prior to release of any personnel, medical, or similar records of a public agency employee.	Referred to Judiciary Committee (2/20); First hearing cancelled at author request



California Legislation Tracking (2/2)

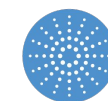
No./Author	Summary	Recent Developments
<u>SB 294</u> (Wiener)	Requires health plans and disability insurers that uphold grievance decisions to automatically submit decisions to the Independent Medical Review System within 24 hours, along with relevant information.	Passed Senate; Held at Desk in Assembly (1/29)
<u>SB 957</u> (Wiener)	Mandates that state health agencies must collect SOGI data to identify and address disparities.	Passed Health Committee; Set for Judiciary Hearing April 2
<u>SB 1016</u> (Gonzalez)	Requires CalFresh to use separate collection categories for Hispanic or Latino groups using OMB standards and require use of separate collection categories for each major Latino group, Mesoamerican Indigenous nation, and Mesoamerican Indigenous language group with reporting requirements.	Passed Human Services (4/1); Set for Health Hearing April 10
<u>AB 2198</u> (Flora)	Exclude dental or vision benefits the APIs that health plans and insurers are required to maintain.	Referred to Health Committee; Set for Hearing April 16
<u>AB 2250</u> (Weber)	Establish SDOH screeners as a covered benefit for Medi-Cal beneficiaries and require health plans and insurers to cover SDOH screenings. Additionally, requires providers to use specified tools or protocols to document patient responses and require health plans and insurers to provide PCPs access to peer support specialists, lay health workers, social workers, or community health workers.	Passed Health (4/2); Sent to Appropriations
<u>AB 1943</u> (Weber)	Require CDII to collect and track data on individual and population health telehealth outcomes.	Passed Health (4/2) on Consent; Sent to Privacy and Consumer Protection Committee w/Consent Recommendation
<u>AB 2058</u> (Weber)	Require disclosures on medical devices to note effectiveness limitations based on patient characteristics, such as age, disability, gender, color, or race.	Set for Health Hearing April 9

California Legislation Tracking - Artificial Intelligence

No./Author	Summary	Recent Developments
SB 721 (Becker)	Creates the California Interagency AI Working Group to deliver a report to the legislature on AI, including a recommended definition of AI use in legislation and study implications.	Passed Senate; Referred to Asm Privacy and Consumer Protection Committee (6/1/23)
SB 892 (Padilla)	Requires the Department of Technology to establish safety, privacy, and nondiscrimination standards relating to AI services and require state contracts to meet these standards.	Referred to Gov Org and Judiciary Committees; Set for Gov Org Hearing April 9
SB 893 (Padilla/Dodd)	Establishes the California Artificial Intelligence Research Hub to facilitate collaboration between government agencies, academic institutions, and private sector partners.	Referred to Gov Org and Judiciary Committees; Amended and Set for Gov Org Hearing April 9
SB 896 (Dodd)	Requires the State to produce a Benefits and Risks of Generative Artificial Intelligence Report, perform a joint risk analysis of potential threats, and notify individuals of AI communications.	Referred to Gov Org and Judiciary Committees; Set for Gov Org Hearing April 9
SB 1047 (Weiner)	Enacts the Safe and Secure Innovation for Frontier Artificial Intelligence Models Act to define “AI models” and require a AI developers to determine whether it can make a positive safety determination before initiating training, among other provisions.	Passed Judiciary (4/2) and sent to Gov Org Committee
SB 1120 (Becker)	Requires health plans and insurers to have licensed physicians supervise AI decision making tools used to review prior authorizations.	Set for Health Committee Hearing April 10
AB 3030 (Calderon)	Requires health entities using generative AI for patient communications to include AI disclaimer and directions to access direct communications. Prohibits licensure, certification, or criminal liability for failure to comply.	Set for Health Committee Hearing April 9
AB 2013 (Irwin)	Requires developers of AI made available to Californians for use to publicly post documentation regarding the data used to train the artificial intelligence system or service.	Set for Privacy and Consumer Protection Committee Hearing April 16
AB 2930 (Bauer-Kahan)	Requires automated decision tool developers and deployers to perform impact assessments annually, make the reports available to the state, notify impacted individuals and accommodate requests, prohibits algorithmic discrimination, and authorizes civil action for violations.	Referred to Privacy and Consumer Protection and Judiciary Committees (3/21); Set for P CP Hearing April 16
AB 3095 (Waldron)	Declares intent of legislature to enact legislation relating to AI.	Introduced (2/16)
AB 3050 (Low)	Establishes watermark standards for AI-generated material and require their usage. Established liability for damages suffered from unauthorized deepfake use of a person’s name, voice, signature, photo, or likeness.	Referred to Privacy and Consumer Protection and Judiciary Committees (3/21); Set for P CP Hearing April 16

Data Exchange Framework Updates

- Administrative Modifications to DxF P&Ps due April 8th:
 - [Participant Directory P&P](#)
 - [Technical Requirements for Exchange P&P](#)
- DxF Technical Advisory Committee Discussions:
 - Discussed DSA/P&P Development and Revision Process, with 180 day minimum before new requirements go into effect
 - Consensus that P&Ps set the “floor” but interested in encouraging a “ceiling” with new standards for others to adopt in future
 - ADTs will be next focus area



DxF Feedback Form

- DxF [feedback form](#) is now live on CDII website. It provides an opportunity to provide feedback on:
 - QHIOs and other DxF Participants
 - DSA Signatory Grants
 - Potential unauthorized access, disclosure, or use of HSSI
 - Types of data exchange (i.e., request, delivery, notification of ADT)
- Participant Directory recommendations from DxF Sandbox team on additional drop down menu options to consider:
 - Sending data out: which content over which transports
 - Receiving data electronically: which content over which transports
- **Additional recommendations for additions to the DxF Participant Directory?**
Email Connecting for Better Health!



C4BH Sponsor Opportunity



C4BH Sponsor Opportunities

With the establishment of C4BH as a non-profit organization, C4BH is seeking coalition sponsors to amplify our impact

Sponsor Opportunities

Platinum

Gold

Silver

Receive exclusive benefits and enhanced access across our programs

Coalition Supporters

Formalize partnership with C4BH

Sponsor-Enabled C4BH Offerings

Advisory Group

To advise on policy stances and analysis, advocacy strategy, and educational activities

Scholarships available to ensure equitable representation

Annual End-of-Year Dinner

DxF Sandbox

Enhanced DxF Education and Technical Assistance



Advisory Group for C4BH Sponsors

Advisory Group

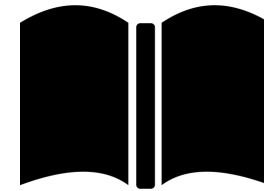
Monthly meetings for C4BH sponsors to advise on:



Coalition Meetings



Advocacy



Education

Scholarships available to ensure equitable representation



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Upcoming C4BH Technical Assistance

	Level of DxF Readiness	C4BH Supports	Outputs
1	Planning	DxF Bootcamp	Develop a DxF Roadmap and Identify Priority Use Cases
2	Assessment	DxF Sandbox Design Studio	Develop Priority Use Case with Trading Partners
3	Ready to Connect!	DxF Sandbox	Test and Validate Use Case to Establish Workflows



2024 Planned Activities



Twice monthly C4BH Coalition Meetings and Round-Up Newsletters



Legislative tracking, letter writing, and submission of public comments



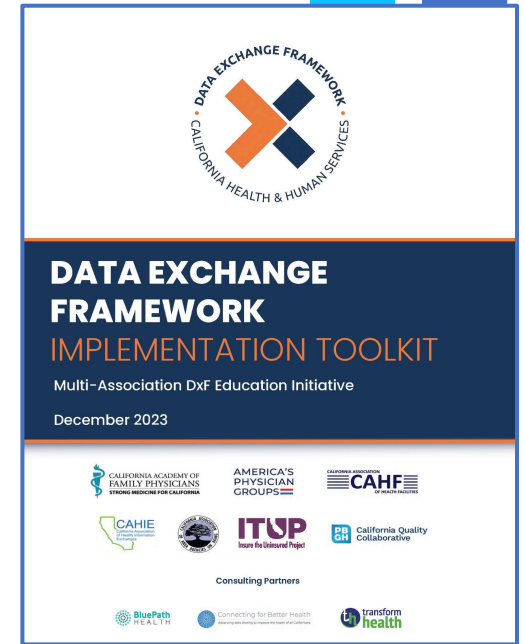
Ongoing policy blogs and fact sheets



Media campaign to advance the conversation around data sharing



DxF education and technical assistance with Toolkit and Bootcamps



New C4BH Activities in 2024



Establish Advisory Group to Guide C4BH Policy and Education Agenda



Launch the DxF Sandbox and Community Design Studio



Host In-Person Events: C4BH Day at the Capitol and End-of-Year Dinner



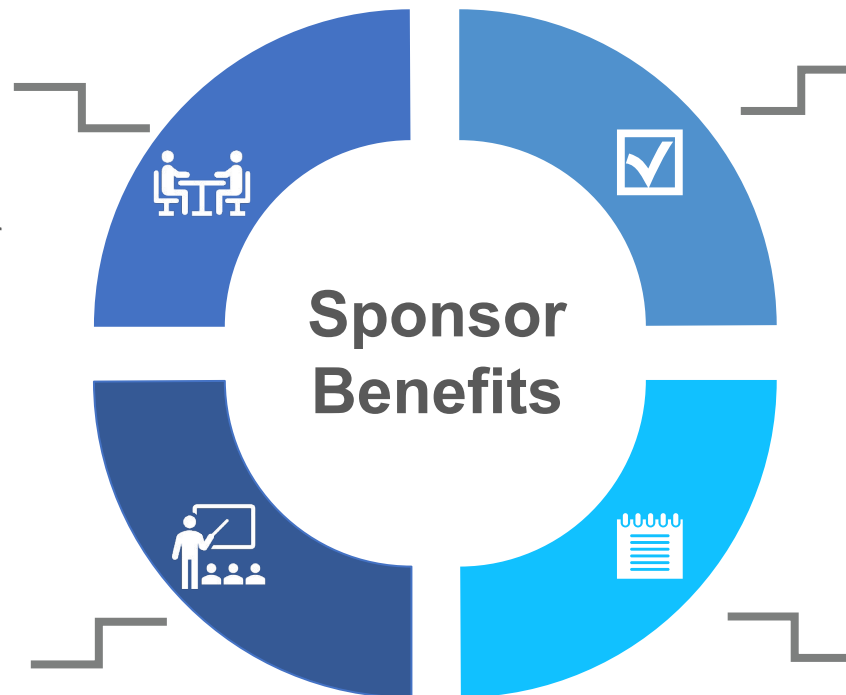
Exclusive Sponsor Benefits

Opportunity

- Advisory Group Representation
- Seats at End-Of-Year Dinner with the Board of Directors and special guests
- Engage in communications initiatives
- Connect with other influential organizations over shared mission

Priority Access

- Office Hours with subject matter experts
- Availability of C4BH staff to answer questions with targeted policy and legislative analysis
- DxF education and technical assistance supports
- Invite C4BH to give guest presentations and table at conferences to educate your partners
- Partner with C4BH to host and organize events, webinars, and in-person gatherings



Impact

- Share perspective to shape C4BH policy stances and advocacy priorities
- Early input on public comments and letters with opt-out naming approach
- Review and share feedback on C4BH fact sheets and other educational materials
- Collective impact to achieve better health in CA through advanced data connectivity

Recognition

- Public alignment with C4BH brand and mission
- Recognition on C4BH website and at End-Of-Year Dinner
- Circulation of relevant content through C4BH social accounts and newsletter

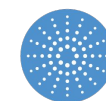


C4BH Annual Sponsor Tiers

Annual Sponsor Tiers <i>See next slide for exclusive sponsor benefits</i>	Platinum \$100,000+	Gold \$50,000	Silver \$25,000	Supporters \$500
End-of-Year Dinner	Table of 8-10 seats with recognition	4 seats with recognition	2 seats with recognition	Priority Invitation
Add Logo to Website and Sign-On Letters with Opt-Out Approach	✓	✓	✓	✓
Access to Office Hours	✓	✓	✓	✓
Advisory Group Representatives	1+	1	1	
Access to DxF Sandbox Community Studio	Priority Access	✓	✓	
Access to DxF Bootcamps	Priority Access	✓		
First Right to Engage in New C4BH Projects	✓			
White-Labeled DxF Implementation Toolkit	✓			



News, Events, And Announcements



What We're Reading – Check Out C4BH's Newsletter!

ONC Shares Priorities for HTI-2 Proposed Rule

Developments for HTI-2 are underway and are anticipated to focus on strategic standards to drive interoperability, implement health IT certification requirements for public health with the CDC, introduce new API certification provisions, and address information blocking deterrents. [Read More](#)

EU Approves First AI Regulations

The EU recently passed the world's first AI Act that intends to govern AI Technology based on its potential risks and impact level. [Read More](#)

EHR Vendors Commit to USCDI+ Cancer

Epic, Oracle, and Meditech are among other EHR vendors that have pledged to implement USCDI+ Cancer to standardize cancer-related data elements that improve interoperability.

[Read More](#)



Upcoming Events

- **April 3, 11AM-12PM PT:** Civitas & Health Begins | Coding and Co-design: Social Care and Health Care Lessons from the Gravity Project Webinar | [Register here](#)
- **April 10, 1:30-4PM PT:** CalHHS CDII | DxF Policies and Procedures Subcommittee Meeting | [Register here](#)
- **April 16:** NorCal State of Reform Health Policy Conference | Sacramento, CA | [Register here](#)
- **April 17, 2-3PM PT:** HIMSS Northern California | Advocacy 101 Webinar | [Register here](#)
- **April 26:** Riverside County Medical Association | First Annual AI Healthcare Conference | Rancho Cucamonga, CA | [Register here](#)
- **May 7-8:** California Medical Association | Annual Health IT Summit | San Francisco, CA | [Register here](#)
- **June 24-26:** 2-1-1 San Diego 2024 CIE Summit | San Diego, CA | [Register here](#)
- **TBD:** DxF Technical Advisory Subcommittee Meeting | [Register here](#)

