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NOTICE OF PUBLIC MEETING

HEALTH CARE PAYMENTS DATA PROGRAM (HPD)

DATA RELEASE COMMITTEE (DRC)

Date:

November 7, 2023
Draft Meeting Minutes

Members Attending: Nuriel Moghavem, Clinical Instructor of Neurology Miranda Dietz, Project Director, California Simulation of Insurance Markets (CalSIM); Jan Hanley, Director of Research Programming; Terry Hill, Physician Consultant, Researcher, Writer; Koh Kerdsri, Vice President, Risk Adjustment, Compliance, and IT; Barbara Koenig, Professor Emerita of Bioethics; Daniel Ruiz, Vice President, Operations Quality; Paul Bouganim, Executive Director, Finance Operations; Genia Fick, Vice President, Quality; and Janet Coffman, Professor, Institute for Health Policy Studies.

Members not in attendance: Cora Han, Chief Health Data Officer; Paul Bouganim, Executive Director, Finance Operations.

HCAI Presenters: Chris Krawczyk, Chief Analytics Officer; Tara Zimonjic, Chief Planning Officer.

Public Attendance: 77

Agenda Item I: Welcome and Meeting Minutes
Nuriel Moghavem, DRC Chair

Nuriel Moghavem, DRC Chair, welcomed the committee and members of the public. The committee members conducted a roll. The chair reviewed the meeting ground rules and introduced the reading of the HPD program goals and statement from the committee.

The committee reviewed and approved the meeting minutes from the September 5, 2023, DRC Meeting. The motion was made by Terry Hill and seconded by Miranda Dietz.

The following members voted to approve the minutes: Miranda Dietz, Jan Hanley, Terry Hill, Koh Kerdsi, Barbara Koenig, Daniel Ruiz, and Nuriel Moghavem.

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Janet Coffman and Genia Fick abstained from voting.

The motion to approve the minutes was carried by a vote of seven in favor and two abstentions.

Questions and comments from the committee:

There were no questions from the committee.

Public comment:

There was no public comment.

Agenda Item II: Appointment of HPD DRC Vice Chair
Michael Valle, Chief Information Officer, and Deputy Director, HCAI
Miranda Dietz, DRC Vice Chair

Michael Valle expressed gratitude to Miranda Dietz for accepting the role of vice chair for the HPD DRC. He outlined that Miranda would work closely with Nuriel Moghavem to ensure the committee's smooth operation, with specific roles detailed in the board manual discussed later in the meeting. Miranda expressed her happiness to be part of the committee, and readiness to contribute and collaborate with Nuriel and the entire HCAI team. Nuriel expressed appreciation for Miranda taking on the role, noting that they had already started meeting to prepare for regular sessions, and anticipated improved efficiency and collaboration with her involvement in the committee.

Questions and comments from the committee:

There were no questions from the committee.

Public Comment:

There was no public comment.

Agenda Item II: HPD Program Updates and September Meeting Recap
Nuriel Moghavem, DRC Chair
Chris Krawczyk, Chief Analytics Officer, HCAI

The DRC Chair provided a recap of the previous meeting in September, highlighting discussions on HPD data quality, completeness, race, ethnicity data, and Sexual Orientation and Gender Identity (SOGI) data. The meeting also touched upon data linkage possibilities and decisions regarding applications for lower-quality data sets.

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Recognition was given to the staff for including written public comments in meeting materials, fostering public engagement and trust.

Program updates were introduced, including a legislative update on Bagley-Keene requirements, potential changes in meeting locations, and updates on the timeline for data release. Chris Krawczyk shared operational components and preparations for data release, emphasizing legal considerations, the data use agreement, application processes, pricing, and a demonstration of the Data Enclave. The timeline was adjusted, with an expected completion of regulations in Q1 or early Q2 of 2024. The committee discussed future meeting schedules and agendas, ensuring transparency and efficient operations.

Questions and comments from the committee:

The committee members discussed various aspects related to the timeline for data release. They sought clarification on the timeline, expressing concerns about potential delays in reviewing applications. HCAI explained that they are planning a simulation with the committee in January 2024, with an actual review likely in late Q1 or early Q2, depending on the completion of regulations and initial requests.

The committee inquired about the process of revising regulations. HCAI explained that revisions are being made, and they anticipate a second 45-day public comment period, planning to release the updated regulations by the end of the month or early December.

The committee sought clarification on their authority in shaping regulations, with HCAI emphasizing that the regulations must align with the authority granted by the statute. The committee also inquired about the level of interest from potential data users and the security measures in place, with HCAI providing responses explaining the stakeholder engagement approach and privacy considerations.

The committee expressed agreement on emphasizing the importance of utilizing Q1 for raising awareness about the data release among potential users. The chair sought the committee's input on meeting preferences for the upcoming months, and in response, the committee expressed a preference for shorter meetings during non-review periods should there be no applications to review.

The committee discussed the option of canceling meetings, having shorter meetings, or incorporating educational content. The committee expressed interest in learning more about the technical features of the HCAI Secure Data Enclave.

Public Comment:

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The public expressed appreciation for the committee's thoughtfulness in avoiding overregulation and also under regulation. They mentioned that they hadn't had the opportunity to read through the regulations but inquired about their format and whether they followed a specific template, mentioning familiarity with Center for Medicare and Medicaid Services (CMS) and Ambulatory Payment Classification (APC) applications. The commenter also indicated excitement among their colleagues at Stanford University regarding the data and hoped to be among the first to access it.

The committee acknowledged the question and mentioned that the staff could follow up with a more detailed response via email. HCAI responded, directing the commenter to the website where the current regulations are available and mentioning that the California Attorney General's regulations for their CURES database was a primary reference. They invited the commenter to contact the HPD team for any additional information.

Agenda Item IV: HPD DRC Scope and Considerations for Decision Making
James Yi, Attorney, HCAI
Chris Krawczyk, Chief Analytics Officer, HCAI

James Yi provided an overview of the legal basis for DRC decision-making, discussing how the committee wishes to approach the evaluation of applications. He highlighted that the DRC, as a decision-making authority, has veto power over sensitive data requests. The DRC's role, as outlined in statute, is to provide an independent check to HCAI and incorporate outside perspectives to address potential blind spots. The legal considerations for the DRC are broad and open-ended, including assessing whether data use aligns with HPD program goals. James emphasized that the current regulations do not specify detailed criteria for DRC reviews, offering flexibility for initial applications. Tara Zimonjic clarified that the information on additional DRC considerations table was not included in the board manual, and that HCAI is seeking feedback from the committee on its potential inclusion.

<u>Questions and comments from the committee:</u>

The committee expressed concern about certain substantive issues in the table related to data release and information products. They highlighted the importance of discussing critical issues, such as the biggest risks and impact of misuse of the data. The committee proposed discussing these concerns either in the current conversation or during the board manual discussion. HCAI suggested incorporating the feedback into the board manual regardless. HCAI clarified the legal basis for DRC decisions and

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emphasized the need for flexibility. Committee members provided feedback on the table's specificity and suggested considerations for inclusion, such as making the criteria more open-ended. The discussion also touched on the importance of a reasonable turnaround time for reviewing research results from the HCAI Secure Data Enclave.

Terry Hill shared insights from his experience in reviewing the manual, emphasizing the interpretive role of committee members based on their experience. The committee expressed support for the broadness and flexibility of the table, with some suggesting some modifications.

Public comment:

There was a public comment expressing appreciation for the committee's discussion and emphasizing the importance of providing latitude for a wide range of questions to inform policy discussions. The commenter suggested avoiding stringent regulations that might impede the exploration of the database's potential in addressing critical policy issues.

Another public comment was provided echoing the previous commenter's sentiments and advised against locking in regulations that might be challenging to change in the future. They encouraged the committee to facilitate initial data use without imposing barriers, allowing for quick and meaningful exploration of the database's capabilities. The commenter also emphasized the need to closely monitor and differentiate between public policy goals and commercialization efforts. Overall, both commenters highlighted the significance of flexibility, quick initiation of data use, and a focus on public policy objectives.

Agenda Item V: Overall HPD Data Release Process
Jasmine Neeley, Research Data Analyst II, HCAI
James Yi, Attorney, HCAI
Terrence Nolan, Healthcare Data Request Unit Supervisor, HCAI
Wade Iuele, HPD Consultant, HCAI

Chris Krawczyk expressed gratitude for the presenters and the HCAI team, acknowledging the complexity of their work across different components. He highlighted ongoing user acceptance testing for systems like the data request environment and HCAI Secure Data Enclave. Chris commended the team's extensive efforts, referencing research into various state approaches and collaboration with state partners. Jasmine Neeley presented details on the data request workflow, request form, and request

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portal. She outlined the standard HCAI review process for existing data programs, involving analysts, supervisors, privacy officers, and final approvers, as well as the new role of a science advisor for specialized reviews. Jasmine also discussed the request form, emphasizing data security, alignment with HPD goals, and a dynamic form structure based on request types. Screenshots demonstrated applicant perspectives, including project goals, data access tables, and project security sections, with plans to present the complete form in a future meeting.

Jasmine Neeley provided an overview of the HCAI data request portal, emphasizing the upcoming small group and individualized training sessions. She showcased screenshots of the portal's dashboard, explaining how committee members would access and manage their assigned requests. Jasmine detailed the task system, where individuals are informed of their roles in a request, and how closing tasks affect the application's progress. Moving to the request view, she highlighted key information, attachments, and variables. The communication process with applicants was shown through the work notes and additional comments in the notes tab.

James Yi discussed the data use agreement process, emphasizing its statutory requirement. Terrance Nolan explained the pricing schedule, with considerations for access through the HCAI Secure Data Enclave and through direct transmission and categories for potential price reductions. Wade Iuele provided insights into the HCAI Secure Data Enclave system's structure, security measures, and scalability and shared screenshots from the user acceptance testing phase.

Questions and comments from the committee:

The committee expressed confusion about a specific slide related to the indicator for Medi-Cal variables in the data request forms. HCAI explained that the question aims to identify requests for Medi-Cal data, triggering additional DHCS questions and review. The committee recommended changing the term "variables" to "Medi-Cal population data" for improved clarity.

The committee raised questions about the history of data applicants, especially regarding breaches, convictions, and civil actions. They inquired about the definition of a data applicant and how to handle situations where an individual joined an organization with a history of data breaches. HCAI attorney James Yi clarified that the application seeks history information for both the data applicant and the authorized representative, and adjustments can be made for changes in personnel.

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The committee raised concerns about the complexity of questions related to data security experience and suggested refining the distinction between individual investigators and institutions. They also questioned whether requests could be for quality improvement rather than research, highlighting potential challenges in defining clear definitions for what is, and is not, research. The committee further inquired about an appeals process for denied requests.

The meeting continued with the committee discussing the limitations on Medicare data access and suggesting the need to document the restrictions for transparency. The conversation touched on exploring creative solutions through discussions with CMS and potentially seeking support from the committee. The committee raised questions about standard limited data sets, research identifiable data, and the importance of providing access to provider information. HCAI clarified that the standard limited “plus” product with identifiable provider information would initially be available only through the HCAI Secure Data Enclave.

The committee expressed appreciation for the detailed discussion and emphasized the importance of institutions and streamlined processes. The committee acknowledged the complexity of defining research and expressed willingness to grapple with these issues.

The focus shifted to the pricing structure and price reductions. The committee raised questions regarding the definitions of student requesters and academic fellows and emphasized the need for clarity. The committee also requested clarity for scenarios where various entities may be partnering together on a project, such as a non-profit consumer group and an academic institution. HCAI explained that decisions would be made on a case-by-case basis, considering factors such as stipends, grants, and financial hardship. Scenarios where various entities would be collaborating would also be handled case by case, with an emphasis on transparency.

The committee emphasized the importance of transparency in decision-making and suggested clear criteria for eligibility and reduction amounts. The committee echoed the need for predictability in the process, expressing concerns about the potential impact of unclear pricing on the demand for and use of the data. The committee expressed concerns about the affordability of the pricing structure, suggesting there may be challenges for researchers at the current rates. They also inquired about how to solicit input from the public and the HPD Advisory Committee on pricing.

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HCAI highlighted that 2024 would be a learning period, refining processes and gaining a better understanding of regular demand.

The committee raised questions about cost allocation for projects and storage within the HCAI Secure Data Enclave, seeking clarification on additional storage costs. HCAI addressed questions about storage, explaining that projects come with default storage and compute capacity, with the option to purchase additional storage. The committee also inquired about the review process for source code, prompting HCAI to explain that standalone code, without associated data, would not require extensive review, but temporary files with potential data references might.

The committee sought clarification on the signatories of Data Use Agreements (DUAs), expressing concerns about the burden on individuals to sign DUAs individually, rather than as an institution. HCAI clarified that individuals accessing data must sign separate DUAs, as required by statute.

Public Comment:

A public comment was provided expressing concern about the HCAI Secure Data Enclave's pricing structure. The public suggested 'a rework of pricing tiers to better accommodate those with more restrictive budgets. They also highlighted concerns about the first come, first serve nature of reductions, and emphasized the need for predictability for data users to incorporate the cost of data into their future budgets.

Another public comment was received echoing previous concerns about the high cost of data access, emphasizing the challenges researchers face due to stagnant funding lines, particularly with National Institutes of Health grants. The commenter expressed concern that such a high cost for data access could hinder research progress. They suggested that the data is a public good, emphasizing that taxpayers have already contributed to the care, data collection, and research costs. The commenter advocated for making the data available at the lowest cost possible to maximize its public value. They acknowledged that the fees collected may not significantly contribute to the necessary funding for the HPD Program in the first year but emphasized the importance of working to bring down costs to levels that are affordable for research and conducive to producing impactful work.

Agenda Item V. DRC Manual Review
Tara Zimonjic, Chief Planning Officer, HCAI

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Tara Zimonjic and Nuriel Moghavem lead the discussion on the DRC Board Manual. Tara emphasized that the purpose of the meeting was to gather feedback from committee members to refine the manual further before a formal vote in the January Data Release Committee meeting. She mentioned that the manual covers administrative aspects of being a board member and specific logistics related to the committee's operations.

Questions and comments from the committee:

The committee provided feedback on Section I, suggesting clarifications on how the document can be amended over time, including a provision for regular reviews every two years. The committee also shared their thoughts on language consistency and the need to coordinate with national initiatives.

The discussion then moved to Section II, where the committee suggested adding a line about serving as a forum for public comment and user feedback. Formatting issues were addressed.

The meeting progressed to Section III, covering the Application Review Process. HCAI explained the HCAI internal review process and the committee's role as an independent check. The timeline for primary reviewers, voting options (recommend, conditional, tabled), and the distinction between conditional and tabled approvals were discussed. The committee members provided feedback on specific points, including the need for clear communication between HCAI and committee members, the importance of recognizing the burden on committee members, and the timeline for primary reviewers. The committee discussed Section III feedback regarding the role of the primary reviewer in preparing materials for the meeting. The committee raised a question about who prepares the application excerpt, and HCAI clarified that HCAI will provide it. The committee expressed concerns about public access to application materials, citing potential issues with Bagley Keene public meeting requirements. HCAI clarified that only primary reviewers have access to the full applications due to transparency requirements. HCAI attorney James Yi explained the complexity of sharing documents under Bagley Keene, especially concerning the detailed information required about cybersecurity controls. The meeting also touched upon Section III considerations for application review. The committee suggested adding considerations for balancing risks, including security, competitive, and commercial risks. Additionally, concerns about responding to subpoenas or legal requests were raised. The committee sought clarification on the process for adopting DRC recommendations, especially if no majority

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is reached. The distinction between conditional approval and tabling was discussed, with tabling requiring the item to return to the DRC.

Moving on to Section IV, the committee inquired about the sources of the quoted content in the Conflicts of Interest section and suggested adding citations.

Public comment:

There was no public comment.

Agenda Item VII. Next Meeting Topics
Nuriel Moghavem, DRC Chair

Nuriel Moghavem provided a preview of the January DRC meeting agenda, including:

- Review of previous DRC discussions
- Application Review Simulation

The next meeting will be held on January 17 from 1:00 p.m. to 4:00 p.m. and will be an in-person meeting.

Questions and comments from the committee:

There were no comments from the committee.

Agenda Item VIII: Public Comment for Items Not on the Agenda
Nuriel Moghavem, DRC Chair

There was no public comment.

The meeting was adjourned at 1:05 p.m.