HCAI Department of Health Care Access and Information

2020 West El Camino Avenue, Suite 800 Sacramento, CA 95833 hcai.ca.gov



NOTICE OF PROPOSED RULEMAKING

CALIFORNIA CODE OF REGULATIONS

Title 22, Division 7, Chapter 8.4

Articles 1 – 3, Sections 95300 – 95316

The Department of Health Care Access and Information (HCAI) proposes adding new Chapter 8.4 Hospital Equity Measures Reporting Program (Sections 95300-95316) to the California Code of Regulations, Title 22, Division 7, Chapter 8.4 to implement the Medical Equity Disclosure Act (Act), Health and Safety Code (HSC) Section 127370 et seq. HCAI proposes to adopt the proposed regulations described below after considering all comments, objections, and recommendations regarding the proposed action.

I. PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the written comment period.

II. WRITTEN PUBLIC COMMENT PERIOD AND CONTACT PERSON

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action. All comments must be received by the Department by 5:00 p.m. on August 13, 2024.

Inquiries and written comments regarding the proposed action should be addressed to the primary contact person named below. Comments delivered by email are suggested. Comments may also be emailed, hand delivered, or mailed.

Alma Lopez, Supervisor Office of Information Services Department of Health Care Access and Information Tel: 916-326-3908 Email: <u>hospitalequity@hcai.ca.gov</u>

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Mailing address:	2020 West El Camino Avenue, Suite 1100
-	Sacramento, CA 95833-1880

Inquiries and comments may also be directed to the backup contact person at the same mailing address:

Irene Serwanga, Health Program Specialist I Office of Information Services Department of Health Care Access and Information Tel: 916-326-3820 Email: <u>hospitalequity@hcai.ca.gov</u> Mailing address: 2020 West El Camino Avenue, Suite 1100 Sacramento, CA 95833-1880

III. AUTHORITY AND REFERENCE

Health and Safety Code Section 127375 authorizes the Department to adopt these proposed regulations. HCAI is proposing to adopt regulations to implement the Act in the California Code of Regulations, Title 22, Division 7, Chapter 8.4, Sections 95300 - 95316.

IV. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

a. Summary of Existing Laws and Effect of Proposed Regulations

Legislative goals of the Act are found in HSC Section 127370 including the following statements from subdivisions (a)-(d): "The COVID-19 health emergency has thrown into sharp relief longstanding health inequities along racial, ethnic, and socioeconomic lines. Black, Hispanic, and Indigenous people have been disproportionately affected during the pandemic; for example, the age-adjusted mortality rate among Black people with COVID-19 is more than three times as high as that of Whites. Disparities in access to care and quality of care contribute to racial health disparities. The disparate impact of the pandemic has highlighted the tiered nature of the current health care system, a structure that significantly impacts the quality of care patients receive along racial, ethnic, and socioeconomic lines. Reporting on the racially disproportionate impact of COVID-19 has called attention to the need for further data on racial and ethnic disparities in health care. Data currently reported by California hospitals that could be used to analyze access to and quality of care by age, sex, race, ethnicity, language, disability status, sexual orientation, gender identity, and socioeconomic status is not available to consumers or the general public."

Specifically, the Act establishes a new program that requires hospitals and hospital systems to file an annual equity report with HCAI and to post a link to the reports on the main page of their internet websites. While HCAI currently collects healthcare facility-

level reports for financial and utilization data and patient-level data from hospitals, these new annual reports are required to include data related to patient access, quality, and outcomes by race, age, ethnicity, language, disability status, sexual orientation, gender identity, and expected payor. The equity reports are due annually by September 30 with the first report due September 30, 2025. The reports must also include a plan to prioritize and address disparities for vulnerable populations identified in the data. The Act authorizes HCAI to impose a fine up to \$5,000 on hospitals and hospital systems for failure to adopt, update, or submit a health equity report consistent with the requirements.

The Department is proposing this regulatory action to implement, interpret and make specific Article 3 (HSC, Section 127370-127376) of Chapter 2, Part 2, Division 107 of the HSC. The regulations being proposed in this rulemaking action aim to standardize the Department's requirements for hospital report submissions regarding various aspects, including submission process, measure definition, and stratification requirements, establishing deliverable timelines, specifying deadline extensions and outlining assessment of penalties for non-compliance.

Specifically, the new regulations address the following:

- Under HSC Section 127371, Section 95300 is added to provide definitions to terms used in Article 1 through 3 of the proposed regulations, ensuring that the program regulations that follow meet the clarity requirement and to provide the specificity necessary for compliance with the regulations and implementation of the reporting requirements mandated by Article 2.
- Proposed regulation Section 95301 outlines the stratification categories as required by statute and specifies that all measures shall be stratified as specified to the extent the data is available, as determined by each hospital and hospital system. Reports shall include the numerator, denominator, and rate of each measure broken down by each stratification category outlined below.
 - 1. Race/Ethnicity
 - 2. Age
 - 3. Sex Assigned at Birth
 - 4. Expected Payor
 - 5. Preferred Language
 - 6. Disability Status
 - 7. Sexual Orientation
 - 8. Gender Identity

The Measures Submission Guide provides further detailed stratification groupings and is incorporated into the regulations by reference.

• Section 95302 is added to require each hospital and hospital system to designate a primary and secondary contact persons for the purpose of receiving compliance and informational communications regarding equity reports. Contacts shall register on the Department's website to provide information about the

hospital or hospital system, report any designee changes within 15 days after any change, and authorize users in the online report submission portal.

- Article 2, Section 95303 is added to specify requirements of hospitals to submit their equity report and the data elements required from each facility type, including general acute care hospitals, children's hospitals, acute psychiatric hospitals, and special hospitals. The section outlines the required elements that all hospitals will need to report including the numerator and denominator of each measure broken down by stratification category, to the extent available and consistent with the California Health and Human Services Agency's "Data De-Identification Guidelines (DDG)," dated September 23, 2016.
- Section 95304 is added to outline the required elements that all hospital systems will need to report including the numerator and denominator of each measure broken down by stratification category, to the extent available and consistent with the California Health and Human Services Agency's "Data De-Identification Guidelines (DDG)," dated September 23, 2016, and aggregated by facility type to encompass all hospitals within the hospital system. The hospital systems are required to report on all core quality measures as outlined in Section 95303, and all structural measures except for the CMS Hospital Commitment to Health Equity Structural (HCHE) Measure. The hospital system equity report is not a substitute for an individual hospital equity report.
- Section 95305 specifies the requirements of the equity report Supplemental Document, which is an optional additional filing hospitals can submit to supplement the information reported in the equity report required by Sections 95303 and 95304.
- Section 95306 specifies requirements for the reporting period and report due date.
- Section 95307 is added to provide that a hospital or hospital system may request, and the Department may grant, a single 60-day extension per report period to file an equity report, when to file the extension request, and the Department responding to an extension request via email.
- Section 95308 is added to specify the required method to submit reports filed pursuant to Sections 95303 or 95304 and references the Department's Format and File Specification for Submission of the Equity Report Version 1.0, dated April 15, 2024, which is incorporated into the regulations by reference and further specifies the requirements for uploading comma separated value (.csv) files.
- Article 3, Section 95309 is added to specify fines for late filings of a report as required in Section 95303 or Section 95304 by a due date established pursuant to Section 95306.
- Section 95310 is added to specify how hospitals will be notified when fines have been accrued, and how the fine amount will be calculated pursuant to Section 95309.
- Section 95311 is added to specify the requirements of a hospital or hospital system that has received notice of an accrued fine that may appeal the fine assessment by requesting a hearing.
- Section 95312 is added to provide contact information for the Department's Hearing Officer.

- Section 95313 is added to specify the prehearing provisions for all parties.
- Section 95314 is added to specify the procedures by which the hearing will be conducted to ensure hearings are fair and consistent.
- Section 95315 is added to specify that the Department shall notify the Hearing Officer if a settlement is reached prior to the hearing.
- Section 95316 is added to define and provide notice of the process for adoption or rejection of the proposed hearing decision by the Director of the Department.

b. Objectives and Anticipated Benefits of Proposed Regulations

The proposed regulations are necessary to achieve standardization, transparency, and the ability to easily compare information presented in hospitals' equity reports. The purpose of these regulations is to implement, interpret, and make specific the hospital equity reporting requirements and health equity plan to prioritize and address disparities for vulnerable populations identified in the data, based on the recommendations of the Hospital Equity Measures Advisory Committee. The benefits of the regulations are to achieve the goals of the Act by identifying disparities to detect areas where certain groups or populations face inequality in access, treatment options, and health outcomes.

The proposed regulations aim to standardize reporting requirements of structural and quality measures, which includes the method of submission. Specifying the submission method in these proposed regulations will greatly improve the efficiency of reporting by hospitals and hospital systems and allow for comparability across hospitals. The proposed regulations also aim to include clear stratification categories to enable reliable grouping and analysis of patient populations across hospitals. Finally, the proposed regulations also aim to specify the inclusion of hospital contact information and registration, allowing for efficient communication channels, and establish firm timetables for deliverables, paired with protocols for deadline extensions and fines for non-compliance to ensure timely reporting.

c. <u>Determination of Inconsistency/Incompatibility with Existing State</u> <u>Regulations</u>

HCAI did an evaluation for any related state regulations and has found that these are the only regulations concerning hospital reporting of equity measures. Therefore, the proposed regulations are neither inconsistent nor incompatible with existing state regulations.

d. Documents Incorporated by Reference

The following are documents HCAI intends to incorporate by reference through these proposed regulations:

- The Department's Measures Submission Guide, version 1.0, dated April 15, 2024.
- The California Health and Human Services Agency's "Data De-Identification Guidelines (DDG)," version 1.0, dated September 23, 2016.
- Department's Format and File Specification for Submission of the Hospital Equity Report Version 1.0, dated April 15, 2024.

V. DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

- A. Mandate on local agencies and school districts: None.
- B. Cost or savings to any state agency: None
- C. Cost to any local agency or school district which must be reimbursed in accordance with Government Code Sections 17500-17630: None.
- D. Other nondiscretionary cost or savings imposed on local agencies: None.
- E. Cost or savings in federal funding to the state: None.
- F. Cost impact on a representative person or business: New regulations are required to implement Chapter 2, Article 3. Medical Equity Disclosure Act (Health and Safety Code Section 127370- 127376), hospitals or hospital systems may incur up to \$1,440.77 per year to upload the statutorily required hospital equity reports and provide required information to the online reporting system prescribed by these proposed regulations.
- G. Statewide adverse economic impact directly affecting businesses and individuals: The Department has made an initial determination that the regulations will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.
- H. Significant effect on housing costs: None.
- I. Cost impact on small businesses: This proposed action does not affect small business because no entities regulated under the proposed action are small businesses.

VI. STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ANALYSIS (EIA)

New regulations are required to implement the Act. HCAI has narrowly tailored the proposed regulations to implement the statutory requirements for the hospital equity reporting requirements. The proposed regulations impose only minor additional reporting or other requirements on any businesses, organizations, or individuals.

The proposed regulations specify the standardization of reporting requirements for structural and quality measures, standardizing key definitions and stratification categories, specifying hospital and hospital system contact information and registration, and establishing firm timetables for deliverables. Furthermore, the regulations define the

process for report submission, extension requests, and appeals procedures regarding fines related to non-submission of reports.

Therefore, the Department concludes that:

- (1) This regulatory action will not create jobs within the state;
- (2) This regulatory action will not eliminate jobs within the state;
- (3) This regulatory action will not create new businesses;
- (4) This regulatory action will not eliminate existing businesses;
- (5) This regulatory action will not expand businesses currently doing business within the state;
- (6) This regulatory action will not impact workers' safety;
- (7) This regulatory action will not impact the state's environment.
- (8) As mentioned above, the information collected in these equity reports will help address health care disparities among different population sectors and communities, which would ultimately benefit the health and welfare of California residents.

VII. CONSIDERATION OF ALTERNATIVES

The Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations during the written comment period.

VIII. AVAILABILITY OF EXPRESS TERMS, INITIAL STATEMENT OF REASONS, AND INFORMATION UPON WHICH PROPOSED RULEMAKING IS BASED

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address given for the contact persons. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the text of the proposed regulations, information upon which proposed rulemaking is based, the initial statement of reasons, and an economic impact analysis (contained in the initial statement of reasons).

The text is available on the Department's website at <u>https://hcai.ca.gov/about/laws-regulations/</u>.

IX. AVAILABILITY OF SUBSTANTIAL CHANGES TO ORIGINAL PROPOSAL

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department adopts the regulations as revised.

Please send requests for copies of the modified text to the listed contact person. The modified text will also be available on the website at https://hcai.ca.gov/about/laws-regulations/. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

X. AVAILABILITY OF FINAL STATEMENT OF REASONS

The Final Statement of Reasons, including all of the comments and responses, will be available, after its completion, through the Department's website at https://hcai.ca.gov/about/laws-regulations/. The Final Statement of Reasons will also be available for review from the designated contact person.

XI. AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the proposed regulations can be accessed through the Department's website at https://hcai.ca.gov/about/laws-regulations/.

XII. BUSINESS REPORTING REQUIREMENT

It is necessary for the health, safety, and welfare of the people of this state that the proposed regulation which requires a report apply to businesses.