State of California

Office of the Attorney General

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ATTORNEY GENERAL

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Submitted via Federal eRulemaking Portal

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

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U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW, Floor 7
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Re: "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" (88 FR 23746)

Dear Secretary Becerra and Dr. Tripathi:

Thank you for the opportunity to provide comments on the Notice of Proposed Rulemaking issued by the U.S. Department of Health and Human Services (HHS) and the Office of the National Coordinator for Health Information Technology (ONC) entitled "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing," 88 FR 23746 (April 18, 2023) (the "Proposed Rule"). The Proposed Rule seeks to update regulations implementing the Electronic Health Record (EHR) Reporting Program provision of Title IV of the 21st Century Cures Act (Pub. L. 114–255, Dec. 13, 2016) (Cures Act) by establishing new requirements for health information technology (health IT) developers. On behalf of the California Department of Justice (DOJ) and State of California, I urge the federal government to move expeditiously to finalize the Proposed Rule because we view it as an essential step toward protecting healthcare consumers from the serious, unintended consequences of health IT.

Algorithmic decision-making tools present unique opportunities to improve productivity, efficiency, and cost reduction across the healthcare industry, but they equally lack accountability, transparency and explainability.[1] As discussed in more detail below, California welcomes the changes made in the Proposed Rule, which recognize the need for regulation of algorithmic tools in the healthcare industry. Given the complex technical requirements outlined in the Proposed Rule, California's comments are limited to the provisions that require more transparency in the use of decision-making tools, from algorithm-based programs to Artificial Intelligence (AI) outlined in Section III.C.5 of the Proposed Rule. Of practical importance to Californians, patients everywhere, and to the California Department of Justice, which enforces state laws that protect healthcare consumers, the proposed revision to the Certification Program criteria for clinical decision support programs with the inclusion of "Predictive Decision Support Interventions," reflect the emerging software functionalities that already aid clinical decision-making across the healthcare sector. We share HHS's interest in ensuring that the use of algorithmic tools promote equitable access to healthcare for all and welcome oversight that includes clear regulatory frameworks and transparent guidelines for these emerging and complex technologies.

The Proposed Rule Takes Aim at the Growing Need for Transparency in the Use of Decision-Making Tools Across the Healthcare Industry to Offset Inherent Risks

The Cures Act, signed into law on December 13, 2016, is a major healthcare bill with the aim of accelerating medical product development and bringing innovations and advances to patients who need them faster and more efficiently.[2] The Cures Act has several provisions that have a significant impact on healthcare technology, including the development and use of electronic health information (EHI),[3] the sharing of health data, and the development of information blocking provisions.[4] The Proposed Rule outlines detailed technical provisions

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[1]As ONC has described, *explainability* or *interpretability* refers to the ability for developers to explain in plain language how their data models are intended to be used. *See* Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. 23,746; 23,793 (Apr. 18, 2023) (to be codified at 45 C.F.R. pts. 170, 171).

[2] *See, e.g.*, 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

[3] ONC defines "EHI" as the electronic protected health information (ePHI) in a designated record set (as defined in the Health Insurance Portability and Accountability Act (HIPAA) regulations) regardless of whether the records are used or maintained by or for a covered entity. *See Understanding Electronic Health Information (EHI)*, HealthIT.gov (Nov. 2, 2022), https://www.healthit.gov/topic/information-blocking/understanding-electronic-health-information-ehi (last visited May 24, 2023).

[4] *See* 21st Century Cures Act. The Cures Act defines information blocking as "a practice that – interfere[s] with, prevent[s], or materially discourage[s] access, exchange, or use of electronic health information." Information blocking, 42 U.S.C.A. § 300jj-52(a)(1).

designed to give patients and their healthcare providers secure access to health information through improved transparency.[5]

Cures Act regulations require ONC to adopt specific certification criteria for the use of Clinical Decision Support (CDS) algorithmic programs.[6] CDS programs encompass a variety of clinical data analytical tools including alerts, guidelines, and diagnostic support systems. However, the criteria were last revised in 2015 and the health IT that supports CDS has evolved rapidly. In addition, ONC's current definition of CDS only covers a relatively narrow slice of the vast range of technology that informs decision-making in healthcare today.

The responsible use of data and technology by the healthcare industry has the potential to improve patient outcomes and increase efficiency. However, the use of predictive algorithmic models also presents risks that could lead to adverse outcomes, including bias, unfair discrimination, or other unconscionable impacts. Today, the adoption of algorithm-based programs and AI in healthcare is widespread within hospitals, drug companies, insurers, and many other entities within the healthcare sector. Reports indicate nine in ten hospitals now have an artificial intelligence strategy in place, and 75 percent of healthcare executives believe AI initiatives are more critical now because of the pandemic.[7] Now more than ever, predictive models and other forms of artificial intelligence are used to inform decision-making in clinical, administrative, population health management, payment, and operations contexts across the healthcare industry.[8]

In response to this increased use, Section III.C.5 of the Proposed Rule seeks to broaden the existing CDS definition in § 170.315(a)(9) to cover contemporary and emerging software functionalities that aid user decision-making in health care, including artificial intelligence and machine learning. The Proposed Rule would add a new term, "Predictive Decision Support Interventions,"[9] defined as "[t]echnology intended to support decision-making based on

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[5] *See* Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. at 23,746.

[6] 45 C.F.R. § 170.315(a)(9).

[7] Jessica Kent, *90% of Hospitals Have Artificial Intelligence Strategies in Place*, HealthITAnalytics (Mar. 11, 2021), https://healthitanalytics.com/news/90-of-hospitals-have-artificial-intelligence-strategies-in-place (last visited May 31, 2023).

[8] For example, clinicians report use of AI to diagnose breast cancer, read X-rays and predict which patients need more care. *See* Ryan Levi & Dan Gorenstein, *AI in Medicine Needs to be Carefully Deployed to Counter Bias – And Not Entrench It*, NPR (June 6, 2023), https://www.npr.org/sections/health-shots/2023/06/06/1180314219/artificial-intelligence-racial-bias-health-care (last visited June 7, 2023).

[9] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. at 23,746; *Health Data, Technology, and Interoperability: Decision Support Intervention*, Office of the National Coordinator for Health

algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."[10] The Proposed Rule also recommends specific new certification criteria for these "Predictive Decision Support Interventions,"[11] and significant data transparency requirements.[12] More transparent access to data would enable users (such as medical practitioners, healthcare providers, researchers, and other stakeholders) to know when an algorithmic program uses specific data elements relevant to health equity, including social determinants of health,[13] race, ethnicity, language, gender identity and sexual orientation.[14]

When patients and regulators do not know how decisions are made by artificial intelligence, patients are unable to participate in a healthcare system they know is free from bias. The Proposed Rule reinforces the principle that transparency is the building block for accountability and serves our mutual goals of delivering fair and equitable access to healthcare services. California supports the transparency elements of the Proposed Rule to shed light into the validity of these decision-making tools and allow regulators to review a fuller picture of the data used to build predictive models. The Proposed Rule would allow law enforcement officials to more easily evaluate whether and how the use of these models comports with consumer protection laws, such as California's non-discrimination laws, including but not limited to, Government Code section 11135, Health & Safety Code section 1317, Civil Code section 51 *et seq.*, and Business & Professions Code section 17200 *et seq.*

Artificial Intelligence, Algorithms, and Predictive Models: A New Frontier with Risks and Opportunities

California welcomes HHS's transparency and certification requirements—the Proposed Rule is an important first step to address the troubling pitfalls of automated decision-making. The use of these modeling tools have become more complex and pervasive throughout the healthcare sector.[15] Healthcare data tools harness volumes of macro- and micro-data to influence

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Information Technology (ONC) (May 3, 2023), https://www.healthit.gov/sites/default/files/facas/2023-05-03_Decision_Support_Interventions_%28DSI%29_and_Predictive_Models_Group_2_Full.pdf (last visited May 24, 2023).

[10] *Id.*

[11] *See* Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. at 23,746.

[12] *Id.*

[13] The CDC defines "social determinants of health" as the nonmedical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. *See Social Determinants of Health at CDC*, Centers for Disease Control and Prevention (Dec. 8, 2022), https://www.cdc.gov/about/sdoh/index.html (last visited June 7, 2023).

[14] *Health Data, Technology, and Interoperability: Decision Support Intervention*, *supra* note 1.

[15] *See, e.g.,* Stephen F. DeAngelis, *Artificial Intelligence: How Algorithms Make Systems Smart*, Wired Magazine (Sept. 2014), https://www.wired.com//insights/2014/09/artificial-intelligence-

decisions affecting people in need of healthcare, from predicting who will develop medical conditions like heart disease or diabetes, to flagging potentially deadly reactions to infections, to deciding who will be offered charity care.[16] However, these predictive modeling tools need to be trained on large, diverse datasets to be generalizable across a variety of populations and to ensure that they are not biased in a way that affects their accuracy and reliability.[17]

1. Discriminatory Algorithmic Decision-Making

We share the concerns HHS identifies in the Proposed Rule in relation to complex predictive models that incorporate "difficult-to-observe validity or fairness issues that may lead to harm."[18] Research reveals some concerning examples in which the reality of algorithmic decision-making falls short of our expectations of fair and equitable delivery of healthcare services. In particular, algorithmic decision-making runs the risk of replicating and even amplifying human biases, particularly those affecting historically disadvantaged (and legally protected) groups.[19] Algorithmic discrimination occurs when these automated systems contribute to unjustified different treatment or disfavor people based on their race, color, ethnicity, sex (including pregnancy, childbirth, and related medical conditions, gender identity, intersex status, and sexual orientation), religion, age, national origin, disability, veteran status, genetic

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algorithms-2/ (last visited May 24, 2023); *see also,* Education Ecosystem (LEDU), *Clearing the Confusion: AI vs Machine Learning vs Deep Learning Differences*, Towards Data Science (Sept. 14, 2018), https://towardsdatascience.com/clearing-the-confusion-ai-vs-machine-learning-vs-deep-learning-differences-fce69b21d5eb (last visited May 24, 2023).

[16] Nicole Wetsman, *Here's How an Algorithm Guides a Medical Decision*, Duke University Office for Translation and Commercialization (Mar. 23, 2022), https://otc.duke.edu/news/heres-how-an-algorithm-guides-a-medical-decision/ (last visited May 24, 2023); *see also*, Michael Kearns, *Data Intimacy, Machine Learning and Consumer Privacy*, University of Pennsylvania Law School (May 2018), https://www.law.upenn.edu/live/files/7952-kearns-final.pdf (last visited May 24, 2023).

[17] *How FDA Regulates Artificial Intelligence in Medical Products*, The Pew Charitable Trusts (Aug. 5, 2021), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products (last visited May 24, 2023).

[18] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. at 23,778 (citing Darshali A. Vyas, et al., *Hidden in Plain Sight—Reconsidering the Use of Race Correction in Clinical Algorithms*, 383 New Eng. J. Med. 874 (2020)).

[19] *See, e.g.*, *Big Data: A Report on Algorithmic Systems, Opportunity, and Civil Rights*, Executive Office of the President (May 2016), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2016_0504_data_discrimination.pdf (last visited May 24, 2023); *see also*, Ruha Benjamin, *Race After Technology: Abolitionist Tools for the New Jim Code*, Polity (2019), https://www.ruhabenjamin.com/race-after-technology (last visited May 24, 2023).

information, or any other classification protected by law.[20] Depending on the specific circumstances, algorithmic discrimination may violate federal and/or state civil rights laws.

To better describe the concept of algorithmic discrimination, we point to three examples of disparities resulting from algorithmic modeling. A groundbreaking study published by *Science* in 2019 revealed that a healthcare prediction algorithm used by hospitals and insurance companies throughout the country to identify patients in need of "high-risk care management" was far less likely to nominate Black patients.[21] The tool recommended White patients for high-risk care management programs, which provide intensive—and often expensive—services to people with complex health needs.[22] The tool used higher healthcare costs as a proxy for medical need. Because Black patients are less likely to have access to care, even if they are insured, their healthcare costs tend to be lower. As a result, the algorithm systematically underestimated the health needs of Black patients and excluded them from high-risk care programs.[23]

In another incident, researchers discovered that gender imbalances in data sets used to train algorithms to review chest X-Rays for diagnosis of thoracic diseases severely affected the performance of computer-aided diagnoses.[24] This case demonstrates that bias in algorithms can emanate from unrepresentative or incomplete training data or the reliance on information that reflects historical inequalities.[25] If left unchecked, biased algorithms can lead to decisions that

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[20] *Algorithmic Discrimination Protections*, The White House Office of Science and Technology Policy, https://www.whitehouse.gov/ostp/ai-bill-of-rights/algorithmic-discrimination-protections-2/ (last visited May 24, 2023).

[21] *See* Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations,* Science, Oct. 25, 2011, at 447-53; *See also* Casey Ross, *Epic Overhauls Popular Sepsis Algorithm Criticized for Faulty Alarms*, STAT (Oct. 3, 2022), https://www.statnews.com/2022/10/03/epic-sepsis-algorithm-revamp-training/ (last visited May 24, 2023); Andrew Wong et al., *External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients*, 181 JAMA Internal Med. 1065 (2021).

[22] *Id*.; Carla K. Johnson, *Racial Bias in Health Care Software Aids Whites Over Blacks*, THE SEATTLE TIMES (Oct. 25, 2019) https://www.seattletimes.com/seattle-news/health/racial-bias-in-health-care-software-aids-whites-over-blacks/ (last visited May 30, 2023).

[23] Obermeyer, *supra* note 21 (according to the author, the healthcare costs of unhealthier black patients were on par with the costs of healthier white people, which meant they received lower risk scores, even when their needs were greater.)

[24] Agostina J. Larrazabal, et al., *Gender Imbalance in Medical Imaging Datasets Produces Biased Classifiers for Computer-Aided Diagnosis*, 117 Proc. Natl. Acad. Sci. 12592–12594 (2020), https://www.pnas.org/doi/10.1073/pnas.1919012117 (last accessed May 24, 2023).

[25] A.R. Lange, et al., *Understanding Bias in Algorithmic Design*, Medium (Sept. 6, 2017), https://medium.com/impact-engineered/understanding-bias-in-algorithmic-design-db9847103b6e (last visited May 24, 2023).

can have a collective, disparate impact on certain groups of people even without the programmer's intention to discriminate.[26]

In California, we have seen algorithms integrated directly into existing electronic health record programs produce disappointing results. The University of California San Francisco reported bias in an algorithm used to identify potential appointment no-shows to facilitate double booking for that appointment.[27] In practice, the model resulted in low-resourced and marginalized populations being double-booked more often than others.[28] This seemingly innocuous program produced an output that reflected underlying structural inequalities and calls attention to bias in the labeling of data. These examples highlight how algorithmic tools that can create feedback loops that worsen discrimination.

2. AI Tools in Healthcare Can Exacerbate Social Inequities

We agree with HHS's assessment that the use of predictive models, such as AI, invariably present model risk (the potential that use of a model negatively influences an entity) that can lead to patient harm, bias, widening health disparities, discrimination, inefficient resource allocation decisions, or ill-informed clinical decision-making.[29] Sophisticated AI-powered tools like the viral chatbot, ChatGPT, are swiftly gaining steam in the healthcare industry and highlight the need for more oversight. So-called "generative AI" allows users including healthcare providers to produce new answers in response to prompts, based on accumulated data.[30] Despite the widespread enthusiasm for AI tools, experts have flagged flaws in these systems, including inaccuracies, the perpetuation of bias, and lack of accountability.[31] These tools could pose risks if they are not deployed appropriately and monitored carefully.

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[26] Adam Hadhazy, *Biased Bots: Artificial-Intelligence Systems Echo Human Prejudices*, Princeton University (Apr. 18, 2017), https://www.princeton.edu/news/2017/04/18/biased-bots-artificial-intelligence-systems-echo-human-prejudices (last visited May 24, 2023).

[27] Brandie M. Nonnecke, et al., *University of California Presidential Working Group on AI, Responsible Use of Artificial Intelligence: Recommendations to Guide the University of California's Artificial Intelligence Strategy*, Univ. of California (Oct. 2021), https://www.ucop.edu/ethics-compliance-audit-services/compliance/uc-ai-working-group-final-report.pdf (last visited June 13, 2023); Scott Mace, et al., *Root of Some Health Disparities May Be Buried in Technology*, HealthLeaders (March 31, 2021), https://www.healthleadersmedia.com/technology/root-some-health-disparities-may-be-buried-technology (last visited June 14, 2023).

[28] *Id*.

[29] *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* at 23,785-86.

[30] Casey Ross, et al., *What does generative AI mean for health care? We asked the experts*, STAT+ (May 23, 2023), https://www.statnews.com/2023/05/23/chatgpt-generative-ai-research-medicine-health/ (last visited May 25, 2023).

[31] Rebecca Pifer, *Hurtling into the future: The potential and thorny ethics of generative AI in healthcare*, HealthcareDive (Apr. 21, 2023), https://www.healthcaredive.com/news/generative-AI-healthcare-gpt-potential/648104/ (last visited May 25, 2023); *see also* Julia Angwin, et al., *Machine Bias,*

We welcome HHS's inclusion of complex predictive models leveraging machine learning in the Proposed Rule, including the addition of generative AI and other adaptive models in the term "predictive decision support intervention."[32] This recognition serves as a necessary step to combat bias and promote equity amid the growing number and increased use of AI tools.

3. The Propensity for Bias is Just One of the Challenges of these Decision-Making Tools

We also have serious concerns related to patient privacy and the lack of oversight mandating the disclosure of algorithmic tools in patient care. Patients rarely have any say — or even any insight — into how these predictive tools have influenced the course of their care or healthcare coverage. These tools could be part of the reason a patient does not receive a certain treatment, or the reason a patient is recommended for an unnecessary procedure.[33] Even when tools are trained and validated on diverse patient populations, the lack of transparency means that healthcare providers and patients might not have all the information they need to make informed decisions about whether the use of these products is appropriate in a particular context and for particular purposes.[34] Even purported neutral data can create negative feedback loops. More oversight is necessary to evaluate not just the data, but also its use, interpretation, and the impact on patient care.

We applaud HHS's efforts to recognize the challenges of complex predictive models and the general need for public disclosure of source data to determine their reliability.[35] We encourage HHS to consider additional measures to oversee another major challenge of these tools: explainability of the data output. That is, how easy it is to explain to the end user how a program produced a certain result—and the lack of transparency around how an algorithmic-

ProPublica (May 23, 2016), https://www.propublica.org/article/machine-bias-risk-assessments-in-criminal-sentencing (last visited May 28, 2023).

[32] *Id.* at 23,776-77.

[33] Rebecca Robbins & Erin Brodwin, *An Invisible Hand: Patients Aren't Being Told About the AI Systems Advising Their Care*, STAT+ (July 15, 2020), https://www.statnews.com/2020/07/15/artificial-intelligence-patient-consent-hospitals/ (last visited May 30, 2023).

[34] Sigal Samuel, *AI Can Now Outperform Doctors at Detecting Breast Cancer. Here's Why It Won't Replace Them,* Vox (Jan. 3, 2020), https://www.vox.com/future-perfect/2020/1/3/21046574/ai-google-breast-cancer-mammogram-deepmind (last visited May 30, 2023); W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 Michigan Law Review 42 (2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2938391; Casey Ross, *Could AI Tools for Breast Cancer Worsen Disparities? Patchy Public Data in FDA Filings Fuel Concern,* STAT+ (Feb. 11, 2021), https://www.statnews.com/2021/02/11/breast-cancer-disparities-artificial-intelligence-fda (last visited May 30, 2023).

[35] *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* at 23,793 (describing black box models); at 23,804 (describing proprietary concerns); at 23,788 (describing source attributes).

based program is developed.[36] Complex predictive models known as "Black-box" models, or algorithms derived from large datasets using intricate techniques, reflect underlying patterns that may be too convoluted for a person, including the initial programmer, to understand, and create serious challenges for transparency.[37] Health IT developers often choose to keep algorithms confidential, which further compounds these challenges. Developers do not always publicly report detailed information on the datasets they use to develop or validate algorithms, limiting the ability of healthcare providers to evaluate how well these tools will perform for their patients.[38]

We encourage HHS to adopt broad policies that ensure public access to both models and their data sources. Doing so will enable users, patients, regulators and law enforcement entities to review and drill down into source attributes to assess model risk and their compliance with state and federal law.

California's Leadership Investigating Algorithmic Bias Informs Our Concerns

As the primary enforcer of consumer laws in California, I have made the protection of Californian's access to quality, affordable and equitable healthcare a chief priority. In this regard, the DOJ has a unique vantage point into the scope of issues presented by predictive modeling tools in the healthcare industry. On August 31, 2022, my office initiated a first-of-its-kind inquiry focused on health equity, examining how healthcare providers address racial and ethnic disparities in their utilization of commercially available decision-making technologies.[39]

While this inquiry is still in the early phases, our initial analysis reinforces the risks associated with the use of algorithmic tools and the barriers to their effective and fair deployment. In California, these types of decision-making tools are now regularly used by hospitals to make judgments about patients across many contexts, ranging from medical

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[36] Pew Charitable Trusts, Issue Brief, *How FDA Regulates Artificial Intelligence in Medical Products* (Aug. 5, 2021), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products (last visited May 24, 2023).

[37] *Id.*

[38] For example, a report examining companies' public summaries about their FDA-approved AI tools found that, of the 10 products approved for breast imaging, only one included a breakdown of the racial demographics in the dataset used to validate the algorithm. Breast cancer is significantly more likely to be fatal in Black women, who may be diagnosed at later stages of the disease and who experience greater barriers to care. Some or all of the AI devices in question may have been trained and validated on diverse patient populations, but the lack of public disclosure means that healthcare providers and patients might not have all the information they need to make informed decisions about the use of these products. *See* Ross, *supra* note 34.

[39] *See, e.g.,* State of California Department of Justice, Press Release, *Attorney General Bonta Launches Inquiry into Racial and Ethnic Bias in Healthcare Algorithms* (Aug. 31, 2022), https://oag.ca.gov/news/press-releases/attorney-general-bonta-launches-inquiry-racial-and-ethnic-bias-healthcare.

treatments to managing revenue. Yet, many hospitals report three problematic issues. First, hospitals use analytical tools procured from third-party vendors and report that they rely on the vendor's assessment that the tools they use are ethical and unbiased. Second, hospitals generally lack insight into vendors' data modeling and report that important information is often shrouded behind proprietary walls. Third, while some hospitals report de-identifying data and/or removing race as a data coefficient, these same hospitals do not report any internal assessment as to whether altering data sets have an impact perpetuating bias. As multiple real-world examples have revealed, analytical decision-making tools can be disturbingly inaccurate, even when race is removed from data sets.[40]

One thing is clear; hospitals are struggling to ensure that tools they procure from vendors can be used in a manner that is truly ethical and robust, in part because no established federal standards for evaluating all such tools currently exists. While analytical decision-making tools have the potential to increase patient safety, they also raise concerns and challenges with regard to safety, effectiveness, transparency, data sharing, property rights, and privacy in addition to algorithmic bias and discrimination. We encourage HHS to adopt a regulatory framework that accounts for both the development of these models and their application by providers, such as hospitals, in order to evaluate their impact on patients.

1. The Proposed Rule Does Not Relieve Users of Their Legal Obligations

We strongly encourage HHS to impress upon users of decision-making tools that transparency and certification of health IT do not relieve the continuing obligations of medical practitioners, healthcare providers, and other stakeholders, to ensure that their use of certified technology complies with all applicable laws. Users of analytical tools must avoid the conscious and unconscious bias or discrimination that can and often does result from the use of algorithmic tools in developing patient care. Doing so includes a responsibility by the user to evaluate the models continual use. Health industry professionals must be aware and accountable when the use of purportedly neutral individual characteristics as a proxy for prohibited characteristics results in racial bias, unfair discrimination, or disparate impact. Considering the complexity of these data analysis tools, health systems may need to recruit or train staff members with the technical skills to evaluate these models, understand their limitations, and implement them effectively.

Automated processes should be safe, effective, and deployed without reinforcing unjust racial patterns of health and disease. We encourage HHS to remind end users of their ongoing legal obligations, irrespective of the transparency recommendations and certification requirements of the Proposed Rule.

2. The Proposed Rule Presents an Opportunity for Oversight

We urge HHS to make clear that the Proposed Rule establishes a floor, not a ceiling, for the protection of healthcare patients, particularly for those who experience intersectional

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[40] Obermeyer, *supra* note 21.

discrimination such as people of color and those with disabilities. The field of algorithmic tools is fast-moving and interacts in complicated ways. The Proposed Rule's transparency requirements will allow regulators and law enforcement entities, including state agencies like the California Department of Justice, to ask for more systemic information, such as details about how algorithms and AI are used across the healthcare industry and look more proactively to ways in which we can protect equitable healthcare access for the public.

The Proposed Rule presents an opportunity for HHS to establish additional regulatory parameters. We encourage HHS to consider requirements for regular algorithmic impact assessments that analyze data sets, biases, how users interact with the systems, and the overall design and monitoring of system outputs. While the Proposed Rule does not expressly require high-quality datasets feeding the algorithmic tools to reduce risks and discriminatory outcomes, HHS should consider expressly incorporating data-set best practices and data standards. Finally, in this or in future rulemaking, HHS may wish to consider elaborating on the ways in which these tools could be more transparent. For example, the Proposed Rule does not expressly require detailed documentation providing all information necessary on an algorithmic system and its purpose in order for regulators to assess its compliance. The Proposed Rule also does not require patients to be notified of the use of algorithmic assessments in their healthcare—we believe the public has a right to know whether treatment recommendations are based on an algorithmic assessment. Furthermore, detailed open data sets would empower regulators and others overseeing their use to evaluate transparency and privacy issues pertaining to data. While opponents may suggest that oversight may hinder competition—the consequences of inaction can very well result in life-or-death treatments for patients. Accordingly, we urge HHS to consider more ways to provide additional oversight, industry guidance and opportunities to inform the public of the use of decision-making tools in their care.

We appreciate HHS's recognition of the role that states and other regulatory agencies play in the oversight of the healthcare industry. States have a compelling interest in protecting the health and welfare of their residents. Consistent with that interest, states have traditionally overseen and regulated healthcare to ensure access and to protect their residents. The Proposed Rule does not supplant existing federal or state civil rights or consumer protection laws, nor does it preempt additional state regulation in this area (to the extent consistent with federal standards).[41] California has an interest in ensuring a high level of robust oversight, as well as ensuring that systems are secure and accurate and has already taken steps to protect its residents.[42] State and federal agencies should work collaboratively to ensure use of algorithms

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[41] *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* at 23905 ("Nothing in this proposed rule imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications.").

[42] *See, e.g.*, California Civil Rights Council, *Proposed Modifications to Employment Regulations Regarding Automated-Decision Systems* (Ver. July 28, 2022), https://calcivilrights.ca.gov/wp-content/uploads/sites/32/2022/07/Attachment-G-Proposed-Modifications-to-Employment-Regulations-Regarding-Automated-Decision-Systems.pdf ; *see also*, State of California Department of Insurance,

and AI use across the healthcare industry is trustworthy and secure. Doing so will increase our understanding of these tools and the associated advantages, risks, and limitations. The Proposed Rule serves as foundational guidance to establish common definitions and allow law enforcement agencies like the California Depart of Justice to look more directly at the use of these models to better protect the public's equitable access to healthcare.

CONCLUSION

We applaud HHS for the proposed certification guidelines for decision-making models and the requirements for increased transparency of the data behind these models. The Proposed Rule provides the opportunity for transparent, thoughtful decision-making by requiring users, including medical practitioners, healthcare providers, and other stakeholders of AI and algorithmic tools to evaluate, disclose, and mitigate the impacts on patients. For the reasons stated in this letter, we urge the federal government to finalize the Proposed Rule expeditiously.

Sincerely,

ROB BONTA
California Attorney General

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