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

Melanie Fontes Rainer Director, Office of Civil Rights U.S. Department of Health and Human Services 200 Independence Avenue, SE Washington, DC 20201

Re: HHS-OS-2022-0012, Nondiscrimination in Health Programs and Activities

Dear Secretary Becerra and Director Fontes Rainer,

On behalf of the Alliance for Aging Research ("Alliance"), we appreciate the opportunity to respond to the Office for Civil Rights' (OCR) notice of proposed rulemaking on Section 1557 of the Affordable Care Act (ACA). The Alliance envisions a culture that respects aging as a greater good and values investments that advance independence, dignity, and equity. We applaud the Administration's efforts to promote equity and inclusion in healthcare and strengthen civil rights protections in the Department of Health and Human Services' (HHS) programs.

Value Assessment

The Alliance believes it is important to understand the relative value of treatments, and as such, we support and take an active role in promoting the development of patient-centered, clinical comparative effectiveness research and value assessment frameworks. The importance of value assessment will take on an even more important role given the passage of the *Inflation Reduction Act of 2022*, which enables the Centers for Medicare and Medicaid Services (CMS) to set prices for a cumulative list of Medicare Part B and Part D drugs that incur the highest total annual expense to

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the program. Work the Alliance commissioned in 2021 from Charles River Associates¹ found that the application of traditional value assessments in other countries such as Australia, Canada, and England fail to consistently consider differences in patient experience of the disease, including those resulting from access disparities, structural racism (which affects transportation, job type, living situation and exposure to environmental factors) and other social determinants of health; and reinforces existing racial bias and certain communities' unequal access to capital. As such, it is vital to ensure that value assessment systems do not contribute to or perpetuate current inequalities and discriminatory constructs in the U.S. healthcare system.

It is important to acknowledge that the development of value assessment techniques that account for biases in traditional models is still, in many ways, in its infancy. While the quantitative nature of traditional value assessments lends an impression of neutrality, the composition of such assessments' underlying formulas is subject to the assumptions and preferences prioritized in their development. Newer models of assessment have been proposed and include elements such as reduction in uncertainty, fear of contagion, insurance value, severity of disease, value of hope, real option value, equity, and scientific spillovers. However, these efforts, and accompanying recommendations for value assessment processes, 3 are not yet included in base case costeffectiveness analyses. For example, the Institute for Clinical and Economic Review (ICER) is a private organization that releases traditional cost-effectiveness analyses (CEA) reports on new medical products months ahead of FDA approval for use by private payers and pharmacy benefit managers (PBMs) in formulary development. To release draft reports enough in advance of annual competitive bidding dates, ICER relies on incomplete clinical data, applies traditional CEA, and mentions other value elements such as equity and other social determinants of health only as "contextual" considerations. The Alliance urges HHS and OCR to recognize that, if equity and other key elements of value are not reflected in value assessment, that is a critical shortcoming of the model in accurately capturing and incorporating value.

The Quality Adjusted Life Year and Other Discriminatory Metrics

We appreciate the language in the proposed rule that notes the impermissible discrimination inherent to the application of certain value assessment frameworks. In particular, coverage and formulary placement decisions that rely upon the Quality Adjusted Life Year (QALY), expected value

¹ "Assessing the value of medicine for diverse patients: Implications of a QALY approach for health disparities," a study for the Alliance for Aging Research, by Kirsten Axelsen and Rajini Jayasuriya, Charles River Associates, November 11, 2021: https://www.crai.com/insights-events/publications/assessing-the-value-of-medicine-for-diverse-patients-implications-of-a-galy-approach-for-health-disparities/.

² Lakdawalla, Darius, et al. Defining Elements of Value in Health Care—A Health Economics Approach: An ISPOR Special Task Force Report [3]. Value in Health. 2018;21(2):131-139.

³ Garrison, Lou, et al. A Health Economics Approach to US Value Assessment Frameworks—Summary and Recommendations of the ISPOR Special Task Force Report [7]. Value in Health. 2018;21(2):161-165.

⁴ Institute for Clinical and Economic Review. "2020-2023 Value Assessment Framework." 31 Jan 2020. https://icer.org/wp-content/uploads/2020/11/ICER_2020_2023_VAF_02032022.pdf

of life years gained (evLYG), disability adjusted life years (DALY), and other averaging metrics have been shown to discriminate against people with disabilities and older adults – the two populations that the Medicare program serves. When the output of these methodologies is used, it has detrimental impacts on patient access, patient-centered care, and shared decision-making. While the Alliance supported many provisions of the *Inflation Reduction Act* (IRA), the Act's direct negotiation provisions do not explicitly restrict the use of QALY and other methodologies that discriminate against older adults and people with disabilities that could severely limit patient access to current and future breakthrough treatments. Since 2019, the Alliance has consistently opposed any prescription drug price-setting proposal—including but not limited to the international reference pricing demonstration and Most Favored Nation initiative—that authorizes the Medicare program to rely upon discriminatory cost-effectiveness standards. We have serious concerns that the IRA provision mandating direct negotiation for high-cost drugs covered by Medicare may permit direct or indirect application of discriminatory cost-effectiveness standards, including contracting with third-party organizations such as ICER that have adopted and endorsed the use of these metrics.

Existing precedent and federal law provide clear guidance barring the use of these methodologies. *The Rehabilitation Act of 1973*, signed into law by President Nixon, ensured people with disabilities would not "be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination" under any program offered by any executive agency, including Medicare. Further, Title II of the *Americans with Disabilities Act* (ADA), enacted in 1990 by President George H.W. Bush, extended this protection to state and local governments' programs and services. Further, in 1992, President George H.W. Bush's Administration established it was an ADA violation for states to employ cost-effectiveness standards in Medicaid out of concern it would discriminate against people with disabilities. In 2010, the ACA included provisions explicitly barring the use of the Quality Adjusted Life Year (QALY) by the Patient-Centered Outcomes Research Institute and in the Medicare program to determine coverage, reimbursement, and incentive programs.

While the IRA utilized most of the ACA's language, including that HHS should not "utilize research that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than other individuals," the language stopped short of including an explicit ban on use of QALYs.⁹

Clear, explicit guidance that prohibits the specific use of discriminatory methodologies, including QALYs, in value assessment is needed. For example, the National Council on Disability (NCD), an independent federal agency, has advised since 2019 against the use of discriminatory price-setting methodologies such as QALY in federally funded programs because their use undermines the

⁵ 29 U.S. Code § 794, 2017.

⁶ 42 U.S. Code § 12131, 1990.

⁷ Sullivan, Louis. "Oregon Health Plan is Unfair to the Disabled." The New York Times. 1 Sept 1992.

⁸ Social Security Act Sec. 1182. [42 U.S.C. 1320e-1]. https://www.ssa.gov/OP_Home/ssact/title11/1182.htm

⁹ Inflation Reduction Act of 2022. https://www.congress.gov/117/bills/hr5376/BILLS-117hr5376enr.pdf

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aforementioned disability and civil rights laws.¹⁰ Earlier this year, the NCD's 2022 health equity framework¹¹ put a finer point on the importance of this and called for a "blanket [legislative] prohibition" on the use of QALYs by "any federal agency" and last November recommended language to unambiguously bar QALYs in the reconciliation bill.¹² A letter last fall signed by more than 130 organizations called on Congress to reject proposals that use the QALY methodology or similar value assessment frameworks,¹³ stating, "As Medicare is the primary source of health insurance for older adults and people with disabilities, utilizing QALYs or similar metrics in pricing would be particularly harmful to the very groups the program is intended to serve."

The end result of the use of the QALY is that therapeutics that treat conditions disproportionately impacting people with disabilities and older adults are systemically viewed as having a lower value. As a result, therapeutics that treat these conditions are more likely to be subject to non-coverage or non-preferred formulary placement in comparison to conditions impacting other population groups. Rather than rely on problematic methodologies as a means to an end, HHS and CMS should invest and collaborate in the development of methods that better acknowledge the complexity of healthcare coverage decisions and elevate the outcomes that matter to patients and their families.

The Alliance is also concerned that HHS may utilize the prices paid by the Department of Veterans Affairs (VA) to help establish the negotiated price for drugs in Medicare. In 2017, the VA entered into a cooperative agreement with ICER as a component of the formulary development process. However, referencing the VA's negotiated prices would inappropriately incorporate and adopt the use of the QALY, which would be antithetical to the language in the ACA that prohibits QALY use for the Medicare program. Further, a 2020 report from the Government Accountability Office noted that the two programs have "very different authorities to bargain and negotiate with drug manufacturers and other market participants." As a result of these differences, the VA formulary is significantly narrower than that of Medicare Part D and Part D plans are better able to tailor their formularies to the beneficiaries they serve. If HHS is concerned about equity within its healthcare programs, it is imperative to ensure that there are no artificial or unnecessary restrictions to patient access to care as a result of reliance upon discriminatory methodologies.

¹⁰ National Council on Disability. "Quality-Adjusted Life Years and the Devaluation of Life with Disability." 6 Nov 2019. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

¹¹ National Council on Disability. "Health Equity Framework for People with Disabilities." Feb 2022. https://ncd.gov/sites/default/files/NCD Health Equity Framework.pdf

¹² National Council on Disability. "NCD Letter to Congress recommending QALY ban in Build Back Better Act." 12 Nov 2021. https://ncd.gov/publications/2021/ncd-letter-galy-ban

¹³ Alliance for Aging Research. "132 Patient, Disability & Provider Organizations Urge Congress to Enact Meaningful Reforms to Improve Prescription Drug Affordability for Older Adults in Medicare Part D." 9 Sep 2021. https://www.agingresearch.org/news/132-patient-disability-provider-organizations-urge-congress-to-enact-meaningful-reforms-to-improve-prescription-drug-affordability-for-older-adults-in-medicare-part-d/

¹⁴ Government Accountability Office. "Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017." Dec 2020. https://www.gao.gov/assets/gao-21-111.pdf

It is imperative that OCR advances and finalizes rulemaking that creates a blanket ban on the use or reference to QALYs and similar value assessment methods that penalize older adults and all consumers on the basis of race, color, national origin, sex, age, or disability as part of utilization management, formulary design, price negotiation, alternative payment models and other incentive-based programs impacting access to care and affordability of care.

Patient-centered methods of value assessment

It is essential that any value assessment that drives care decisions incorporate and respect the care decisions of individual providers and patients. In contrast, ICER's assessments are historically based on a health system or payer's perspective rather than the broader economic impact or consequences of a specific therapy, such as a person's ability to work or a reduction of burden on families and caregivers. However, there are alternatives to ICER that avoid applying discriminatory methodologies as a means to an end.

Several groups are working to define value assessment in ways that do not discriminate and are working to actively identify and quantify endpoints that are meaningful to patients. The Patient-Centered Outcomes Research Institute (PCORI) was established through the ACA and focuses on comparative clinical effectiveness research. PCORI's approach to value assessment calls for consideration of economic impacts as a part of the larger whole of outcomes that matter to patients and caregivers. 15 Other groups are also working to develop consensus-based principles on the most effective methods for value assessment, including specific efforts to address health equity. The Innovation and Value Initiative (IVI) has identified four areas where value assessment has failed to address equity, including lack of incorporation in study objectives, non-representative patient participation, an absence of analysis of impacts across segments or subpopulations, and missing data on patient preferences from communities of color. 16 To address these identified issues, the IVI is now working to develop best practice protocols to inform value assessors and help mitigate these gaps. Given reputable alternatives to the use of QALYs and traditional costeffectiveness analysis, we encourage the HHS and OCR to work closely with CMS to ensure that non-discriminatory methodologies are utilized in the implementation of the Inflation Reduction Act.

Enforcement of provisions related to discrimination against older adults

The proposed rule notes that older adults experience unique age-related discrimination that negatively impacts their health. The Alliance applauds this acknowledgement and supports the language in the proposed rule that would bolster protections for older Americans in healthcare.

¹⁵ Patient Centered Outcomes Research Institute. "About PCORI." https://www.pcori.org/about/about-pcori

¹⁶ Innovation and Value Initiative. "Health Equity Initiative: How Patient Engagement and Innovation of Methods Can Move Us Closer to Achieving Health Equity." 10 Aug 2022. <u>Health-Equity-Initiative-Overview.pdf (thevalueinitiative.org)</u>

Age-related discrimination in healthcare can contribute to the dismissal of important concerns brought forth by patients. A study by Hansen, et al. interviewed Black members of a senior center to identify patterns in their thinking about healthcare. The most common theme that emerged from these interviews was "the added insult of ageism." The study found that ageism cuts across sociocultural and racial divisions, "to become the preeminent defining barrier to health care communication," even among groups that are already discriminated against based on their race and ethnicity. As the proposed rule notes, older adults report being disrespected, rushed, and ignored by their healthcare providers, and this impact is compounded when an older adult also belongs to an underserved community. The Alliance supports OCR's efforts to ensure that protections instituted for older adults must apply to older adults of all communities, backgrounds, and disabilities or cognitive impairments.

Further, older adults should have access to clear, accessible procedures for filing, investigating, and remediating discrimination complaints. As Section 1557 is its own statute enforceable by private right of action in the courts, an older adult who is discriminated against based on age and race, national origin, sex, and/or disability should not be at a disadvantage for seeking recourse due to the Age Act's administrative exhaustion requirements. Therefore, we recommend that HHS include regulatory language in the final rule that clarifies that administrative exhaustion is not required to bring an intersectional claim including age under Section 1557. We urge HHS to identify other ways to address intersectional discrimination in the regulatory provisions of the rule itself, including making an explicit reference to intersectional discrimination in the regulatory text of Sec. 92.101.

COVID-19 and future pandemic preparedness

During the COVID-19 pandemic, ageism was heightened in media narratives on triage decision making that led to harmful stereotyping of the older population. This unacceptable practice came about largely due to a lack of preparedness of our country's health systems to manage the impacts of a pandemic, which led to shortages and an initial deprioritizing of older adults for hospital and ventilator care. At the time, health systems including HHS were developing COVID-19 action plans and toolkits that provided guidance to medical professionals on creating emergency triage plans and rationing care.

While healthcare decisions inherently involve calculations based on risk and potential outcomes, they should never be based on the idea that it's more valuable to save a younger life than an older

¹⁷ Hansen, Bryan, Nancy Hodgson, and Laura Gitlin. "It's a Matter of Trust: Older African Americans Speak About Their Health Care Encounters." 9 Feb 2015. https://pubmed.ncbi.nlm.nih.gov/25669876/

¹⁸ Rueda, Jon. "Ageism in the COVID-19 pandemic: age-based discrimination in triage decisions and beyond." Hist Philos Life Sci. 13 Jul 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8276843/

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life, or a person who is disability-free than a person with a disability. Not only is it unethical, but little research has been done to see whether rationing strategies for COVID-19 would actually save lives.

It is well known and accepted that there will be future pandemics, and a new study finds that most people are likely to experience an extreme pandemic in their lifetime.¹⁹ We cannot be caught off guard again. We encourage OCR to work with other HHS agencies to ensure that preparedness plans for future emergency situations like COVID-19 do not rely on the rationing of care for populations most at risk, or that are often experience discrimination in the healthcare system. In April 2020, the Alliance led a letter to OCR that was signed by 46 other healthcare organizations, laying out the general guidelines we believe are acceptable in situations of care-rationing due to pandemic or similar emergencies. The Alliance letter²⁰ read as follows:

The guidance should be clear on what constitutes unlawful discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs as it relates to the allocation of limited resources due to the COVID-19 pandemic. This should include determinations concerning the denial, removal, or suspension of health care and services based on perceptions concerning "social worth", quality of life, life years remaining, or the intensity of services needed. [...]

To be clear, covered entities should be permitted to prioritize those with a greater urgency of need and delay non-urgent care. They need not allocate scarce resources to individuals with no chance of survival. But no person should face discrimination in seeking life-sustaining care that they will benefit from. The lives of all people are equally valuable, and healthcare decisions that devalue the lives of people based on their race, color, national origin, disability, age, sex, or exercise of conscience and religion, are discriminatory. "

If a situation does again necessitate care rationing, we urge HHS and OCR make clear that any plan for allocating scarce medical resources during any future or present emergency ensures that all patients are equally eligible for treatment based on their current clinical presentation regardless of underlying condition or demographic factors, including age.

¹⁹ Penn, Michael. "Statistics Say Large Pandemics are More Likely than we Thought." Duke Global Health Institute Research News. 23 Aug 2021. https://globalhealth.duke.edu/news/statistics-say-large-pandemics-are-more-likely-we-thought

²⁰ Alliance for Aging Research. "Advocacy Groups Call on HHS Office of Civil Rights to Issue Guidance on Fair Medical Resource Allocation During COVID-19." 14 Apr 2020. https://www.agingresearch.org/wp-content/uploads/2020/04/Group-sign-on-letter-to-OCR-FINAL-4-13-2020.pdf

Telehealth

We support provisions of the proposed rule that clarify the affirmative duty that covered entities may not discriminate in the delivery of telehealth services. Access to virtual care is vitally important to the health, well-being, and effective treatment of those with cognitive or physical disabilities. Telehealth is not a suitable replacement for all in-person services and does not alleviate our societal responsibility to address care deserts. However, telehealth does serve as a care extender and can contribute to comprehensive efforts to address practitioner shortages, as well as time, travel, and convenience barriers to receiving care.

Unfortunately, some adults are hesitant to use telehealth if they do not feel that they have a high level of technological literacy or reliable access to the internet. A recent study²¹ found that compared to pre-pandemic levels, older age and lower income were negatively associated with telehealth use without technology-enabling factors; however, when technology-enabling factors were included, the effects of age and income disappeared entirely. Further, a 2022 AARP study found that interest in telehealth use among older adults in 2022 was similar to 2020 rates, with women, Black people, and those between ages 50 and 64 more likely to use virtual care services.²²

In the 2023 Physician Fee Schedule, CMS proposed dropping Medicare coverage for audio-only telehealth services due to a provision in the Social Security Act which requires telehealth substitutes to be analogous to in-person care by being able to serve as a substitute for a face-to-face visit.²³ While audio-only visits will not serve as analogous care in all situations of telehealth use, it provides a significant increase in access for patients who do not have the broadband services required for or the technological literacy to operate a video call. CMS's current proposal to restrict coverage for audio-only telehealth highlights the need for the incorporation of equity considerations in access and coverage determinations.

Older adults are also significantly more likely to use technologies for remote patient monitoring than the general population. Remote patient monitoring can include sensors, voice activation, GPS, Bluetooth, cellular connectivity via mobile phones, smartphone monitoring apps, and sophisticated computers. There is ample evidence that use of these technologies allows older adults to "age in

²¹ Choi, Namkee, et al. "Telehealth Use Among Older Adults During COVID-19: Associations With Sociodemographic and Health Characteristics, Technology Device Ownership, and Technology Learning." Journal of Applied Gerontology. March 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8847316/

²² American Association of Retired Persons. "Interest in Telehealth Services is Holding Steady." May 2022. https://www.aarp.org/content/dam/aarp/research/surveys statistics/health/2022/telehealth-use-update.doi.10.26419-2Fres.00525.001.pdf

²³ Goodman, Rachel, Nathaniel Lacktman, and Thomas Ferrante. "Medicare Telehealth Services for 2023 – CMS Proposes Substantial Changes." Health Care Law Today Blog, Foley & Lardner LLP. 14 Jul 2022. https://www.foley.com/en/insights/publications/2022/07/medicare-telehealth-services-2023-cms-changes

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place" and remove some need for long-term care facilities.²⁴ Access to remote monitoring has also been shown to promote activation, self-care, and increased quality of life.²⁵ We encourage OCR to promote the use of these and other telehealth services as the office considers their recommendations on telehealth use for older adults.

Further, it is important to note that many Medicare patients currently can access virtual care and telehealth services as a result of regulatory flexibilities that are available through the ongoing COVID-19 public health emergency (PHE). However, the PHE is only allowed to be extended in 90-day increments and may be allowed to lapse in the near future. HHS should work with Congress to extend these services in perpetuity. The equity arguments laid out above also point toward the need to permanently extend telehealth rights.

Clinical Algorithm Decision Making and Artificial Intelligence (AI) Technologies

The indiscriminate use of race-based clinical algorithms has no place in healthcare. The Alliance supports the proposed Section 92.210 that would make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557. Unfortunately, discrimination is hard coded into to certain clinical support tools and algorithms. While they aim to present unbiased, objective recommendations to physicians, they themselves often import biases that are detrimental to patients of color²⁶ and research has found that false beliefs in a biological basis for race negatively impact patient outcomes. These impacts can be felt in algorithms meant to provide insight on the treatment for kidney disease, heart failure, and pregnancy.

This issue extends beyond clinical algorithms. The World Health Organization (WHO) recently released a report that found that AI technologies that are increasingly used in healthcare risk determinations, deepening discrimination against older adults due to their reliance on large, historical datasets which can themselves be faulty or discriminatory. These datasets have been found to significantly underrepresent older adults and lead to worse health outcomes for this population.

https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/Fact%20Versus%20Fict ion%20Clinical%20Decision%20Support%20Tools%20and%20the%20%28Mis%29Use%20of%20Race%20%282%29.pdf

²⁴ Read, Emily, et al. "Passive Remote Monitoring and Aging in Place: A Scoping Review." https://www.cambridge.org/core/journals/canadian-journal-on-aging-la-revue-canadienne-du-vieillissement/article/passive-remote-monitoring-and-aging-in-place-a-scoping-review/8861B7C15F470453DB1AECF38D91E3C7

Evangelista, Lorraine, et al. "Examining the Effects of Remote Monitoring Systems on Activation, Self-care, and Quality of Life in Older Patients with Chronic Heart Failure." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4447139/
 United States House of Representatives: House Committee on Ways & Means. "Fact Versus Fiction: Clinical Decision Support Tools and the (Mis)Use of Race." 14 Oct. 2021.

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Further, all insurance plans that fall under the jurisdiction of Section 1557 should be barred from the use of hierarchical conditioning codes (HCCs), or risk coding, to estimate the future health needs of patients until such methodologies have been reformulated to compensate for systemic barriers to care. Currently, these risk codes underestimate the future health needs of populations with lower access to medical care – often communities of color – as they have lower healthcare utilization rates than their white counterparts. While intended to be a race-blind metric, a 2019 study found that this effect reduced the number of Black patients identified for extra care by half.²⁷

OCR should recommend the reevaluation of the use of race variables and ethnicity in the design, execution, and evaluation of clinical algorithms, AI training tools, and HCCs to ensure that they are not based in biased or untrue assumptions about a particular group. Additionally, HHS should develop and implement health equity quality metrics, promote diverse patient and community involvement in the clinical trials and research of emerging tools, and institute trainings on the history of racism and ageism in medicine, structural racism, anti-racist policy, and patient-centered health care for professionals working for HHS programs to combat harmful implicit bias.

Contact information

The Alliance thanks HHS for their consideration of the needs of all communities to receive competent and inclusive care. We appreciate the opportunity to comment on this issue and the work that the OCR is doing in this field. If you have any questions or would like to follow up on the items discussed in our comments, please contact Adina Lasser, Public Policy Manager, at alasser@agingresearch.org. We look forward to working with you.

Sincerely,

Michael Ward

Muchael Ward

Adina Lasser

Vice President of Public Policy and Government Relations Manager of Public Policy

Adina Lasson

²⁷ Price, Michael. "Hospital 'risk scores' prioritize white patients." Science News. 24 Oct 2019. https://www.science.org/content/article/hospital-risk-scores-prioritize-white-patients