

## **Informational Reports**

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# REPORT OF THE BOARD OF TRUSTEES

B of T Report 1-N-21

Subject: Racial Essentialism in Medical Education

Presented by: Bobby Mukkamala, MD, Chair

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## INTRODUCTION

This informational report submitted to the House of Delegates summarizes American Medical Association (AMA) activities in combatting racial essentialism in medical education and is written in response to AMA Policy D-350.981, “Racial Essentialism in Medicine.”

## RACIAL ESSENTIALISM IN MEDICAL EDUCATION

“Racial essentialism” is defined as the belief in a genetic or biological essence that defines all members of a racial category.<sup>1,2</sup> However, this theory is grounded in fallacy, as science has proven that race is a social construct based on a human-invented classification system to define physical differences among people.<sup>3</sup> There is ample evidence that race is a poor proxy for genetic differences and “phenotypic” features commonly referenced in discussions of race fail to correspond to discrete categories or underlying physiology.<sup>4</sup> Additionally, the categorizations of race have led physicians and medical students alike to draw conclusions about the hierarchical organization of humans, which connect an individual to a larger preconceived geographically circumscribed or socially constructed group. This belief contributes to the cultivation of structural racism, which refers to the totality of ways in which societies foster racial discrimination through mutually reinforcing systems of housing, education, employment, earnings, benefits, credit, media, health care, and criminal justice. These patterns and practices in turn reinforce discriminatory beliefs, values, and distribution of resources.<sup>5</sup>

### *Current Manifestations of Racial Essentialism in Medical Education*

Racial essentialism has been preserved in medicine and medical education in multiple ways.

Foundational scientific content and clinical teaching is based upon research that commonly lacks diverse representation among subjects. This can lead to teaching of outdated or ill-informed practices, such as race-based calculation of estimated glomerular filtration rate (eGFR). Renal function estimated glomerular filtration rate (eGFR) calculations have historically been adjusted up for Black/African American race to account for “increased muscle mass,” though no robust scientific evidence exists to support this claim, and patients have been categorized as “Black” and “non-Black.” This practice minimizes the severity of illness in Black patients, has led to the overestimation of kidney function among Black patients, and has translated to devastating consequences such as delayed referrals for treatment, disqualification for transplants, and misguided treatment and counseling. It also creates a blind spot for the treatment of others who may be inaccurately aggregated under one homogeneous “non-Black” label regardless of their genetics or biological ancestry, health profile, or social circumstances. In 2020-2021, following a review of the practice and mirroring the precedent set by Beth Israel Deaconess Medical Center, Mass General Brigham and New York City Health + Hospitals eliminated the use of race as a

1 factor when calculating kidney function and implemented that renal function eGFR calculations  
2 would be solely based on creatinine levels, age, and sex for all patients.<sup>6</sup> Additionally, the National  
3 Kidney Foundation (NKF) and the American Society of Nephrology (ASN) established the NKF-  
4 ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease, a joint task  
5 force to examine the inclusion of race in the estimation of GFR and its implications for the  
6 diagnosis and subsequent management of patients with, or at risk for, kidney diseases. The task  
7 force released an interim report entitled “Reassessing the Inclusion of Race in Diagnosing Kidney  
8 Diseases: An Interim Report from the NKF-ASN Task Force” which detailed the process, initial  
9 assessment of evidence, and values defined regarding the use of race to estimate GFR in June  
10 2021.<sup>7</sup>

11  
12 Lack of diverse representation in educational practices is another challenge. There is a paucity of  
13 educational materials on non-white skin tones and the lack of curriculum devoted to the care of  
14 diverse skin and hair textures of patients demonstrates the lack of inclusion in training materials for  
15 medical students.<sup>8,9</sup> A recent study of race and skin tone depicted in images in textbooks assigned  
16 at top medical schools found that while the textbooks did approximate the racial distribution of the  
17 U.S. population—62.5% white, 20.4% Black, and 17.0% Person of Color—the skin tones in the  
18 illustrations—74.5% light, 21% medium, and 4.5% dark—overrepresent light skin tone and  
19 underrepresent dark skin tone. There is also an absence of skin tone diversity at the chapter and  
20 topic level.<sup>10</sup> The lack of training on diverse skin tones extends into patient care, and patients have  
21 expressed frustration with dermatologists who lack experience and knowledge in the care of  
22 disorders of diverse skin tones and hair textures. Fortunately, dermatology residency programs are  
23 making efforts to incorporate training on treatment of skin of color into their curriculum.<sup>11</sup>  
24 Similarly, simulations and clinical skills frequently lack diverse representation.

25  
26 Perpetuation of stereotypes in the learning environment include naming of implicit bias and social  
27 elements included in clinical case vignettes and examination items. These stereotypes lead to  
28 incomplete framing of social determinants of health and presenting social determinants of health as  
29 a matter of personal choice or unfortunate personal circumstances rather than acknowledging  
30 systemic and structural drivers of those social factors. Stereotyping is a cognitive process in which  
31 individuals use a social category to acquire, process, and recall information about people.  
32 Stereotyping can both lead to and stem from unconscious bias. These processing patterns  
33 unconsciously help individuals organize complex information. The conscious effort to reduce  
34 automatic stereotyping requires considerable cognitive resources and, under heavy cognitive  
35 load—including during clinical training and decision-making—individuals rely more heavily on  
36 stereotyping to process information. Indeed, while structured clinical vignettes have long been  
37 utilized as a resource to illustrate or highlight some aspect of medicine that the clinician can use to  
38 improve one’s knowledge and clinical skills, clinical vignettes are not immune from stereotypes.  
39 Evidence of unconscious bias was found in a study of emergency department physicians’ treatment  
40 of pain using clinical vignettes and found that socially desirable information increased the  
41 prescribing rates by a small but statistically significant percentage.<sup>12</sup> Additionally, a 2019 meta-  
42 analysis of studies conducted from 1990 to 2018 found that Black patients were 40% less likely  
43 and Hispanic patients were 25% less likely to receive medication to ease acute pain compared to  
44 white patients.<sup>13</sup> Equally concerning are patients’ interpersonal experiences of unfair treatment  
45 while seeking care due to their race ethnicity, gender identity, sexual orientation. These  
46 experiences can lead people to delay or forgo care, and to experience adverse health  
47 consequences.<sup>14</sup>

48  
49 Clinical reasoning strategies and algorithms that support clinical decision making frequently lack  
50 diverse representation. Many data repositories collect race and ethnicity data on thousands if not  
51 millions of Americans, and it is not uncommon for multivariate analyses to test whether certain

patient characteristics, such as gender, age, co-morbidities, race and ethnicity contribute significantly to the predictive accuracy of estimates of risks and benefits of the various preventative and therapeutic options. With race now understood as a social, not biological construct, and as proxies for non-biological factors including social determinants of health and structural racism, considerable scholarship has been focused on determining whether race and ethnicity should continue to be included in clinical algorithms and in teaching of clinical reasoning.

## EFFORTS TO ADDRESS RACIAL ESSENTIALISM IN MEDICAL EDUCATION

There have been efforts to examine practices of racial essentialism in medical education at an institutional level. These efforts include review and modernization of outdated material such as slides and clinical case vignettes to mitigate bias, explicit training in health system science, structural competency, structural drivers of social determinants of health and structural racism as well as training in metacognition, implicit bias and common forms of error in clinical reasoning. Institutions are also seeking diverse representation in clinical skills training and simulation (e.g., ophthalmologic examinations). In addition, institutional efforts have strived to actively foster diversity in classroom and clinical learning environments, explicitly consider perspectives missing from any given environment and improve the diversity of the profession by promoting holistic selection into medical school and residency by providing implicit bias training to gatekeepers and supporting pathway programs.

The AMA's Accelerating Change in Medical Education initiative has led to the development and scaling of innovations influencing the full continuum of medical training. The core initiative objectives focus on competency-based approaches to medical education and individualized pathways for students; training in health systems science; and enhancing the learning environment. This initiative has been successful in stimulating change at the consortium schools and propagating those innovations broadly, with outputs involving medical students, faculty, medical schools, affiliated health systems, and the broader educational landscape.

In 2020, this initiative conducted a 4-week series entitled "Combatting structural racism in UME and GME," which featured interactive sessions addressing the structural racism embedded in medical educational programs. Each session was convened for 2 hours and approximately 50 medical educational programs were represented. Structural racism in both undergraduate and graduate medical education was addressed and topics of focus included "The Educational Milieu," "Appraising Programmatic Outcomes," and "Microaggressions."

During the series, member schools of the Accelerating Change in Medical Education Consortium explored the AMA curricular diversity and inclusion self-study process at a high level, with each institution to develop its own plan to follow up. The outline for self-study and action plans can be found at: <https://www.ama-assn.org/system/files/2020-07/curricular-diversity-inclusion-self-study.pdf>. In addition, the series highlighted a session on "Structural racism embedded in educational materials and approaches," which included the naming of implicit bias in training examples, incomplete framing of equity issues, biologic versus sociologic construct of race, and bias in historical clinical protocols taught in basic science and clinical training. During this series, medical schools such as the Warren Alpert Medical School of Brown University and the George Washington University School of Medicine and Health Sciences shared their struggles and strategies for shifting the curriculum from race-based medicine to race-conscious medicine as an alternative to improve health outcomes for all.

Since 2020, the AMA has also conducted the following [webinars](#) on the topic of structural racism in medical education:

- Applying systems thinking to address structural racism in health professions education
- Combating racism in med ed to address health care disparities
- Uprooting structural racism in medical education

The AMA has also hosted *Prioritizing Equity* episodes devoted to this topic, including:

- [Examining race-based medicine](#)
- [Getting to justice in education](#)
- [Moving Upstream](#)
- [The Root Cause & Considerations for Health Care Professionals](#)

These (and other) *Prioritizing Equity* episodes will be featured in the Health Equity Education Center, a new part of the AMA Ed Hub launched by the Center for Health Equity. These videos will be further supported by new educational modules developed in partnership with COVID Black, an organization that helps healthcare systems, academic institutions, non-profit organizations, and companies solve problems around racism and health by developing custom e-learning content based on modern instructional design and visual design principles to create an impactful learning experiences about race, health disparities, health equity, and medicine. The first module serves as an introduction to racism in medicine, with substantial analysis and exploration of the history of racial essentialism and the social construction of race. Modules in development for publication later in 2021 will further examine racism in other aspects of health care, from COVID vaccination inequities to maternal and child health to health communications to public health data.

#### CONCLUSION

The AMA remains committed to pushing for a shift in thinking from race as a biological risk factor to a deeper understanding of racism as a social determinant of health.

## APPENDIX - Relevant AMA Policy

H-65.953, “Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice,”

1. Our AMA recognizes that race is a social construct and is distinct from ethnicity, genetic ancestry, or biology. 2. Our AMA supports ending the practice of using race as a proxy for biology or genetics in medical education, research, and clinical practice. 3. Our AMA encourages undergraduate medical education, graduate medical education, and continuing medical education programs to recognize the harmful effects of presenting race as biology in medical education and that they work to mitigate these effects through curriculum change that: (a) demonstrates how the category “race” can influence health outcomes; (b) that supports race as a social construct and not a biological determinant and (c) presents race within a socio-ecological model of individual, community and society to explain how racism and systemic oppression result in racial health disparities. 4. Our AMA recommends that clinicians and researchers focus on genetics and biology, the experience of racism, and social determinants of health, and not race, when describing risk factors for disease.

D-350.981, Racial Essentialism in Medicine

1. Our AMA recognizes that the false conflation of race with inherent biological or genetic traits leads to inadequate examination of true underlying disease risk factors, which exacerbates existing health inequities. 2. Our AMA encourages characterizing race as a social construct, rather than an inherent biological trait, and recognizes that when race is described as a risk factor, it is more likely to be a proxy for influences including structural racism than a proxy for genetics. 3. Our AMA will collaborate with the AAMC, AACOM, NBME, NBOME, ACGME and other appropriate stakeholders, including minority physician organizations and content experts, to identify and address aspects of medical education and board examinations which may perpetuate teachings, assessments, and practices that reinforce institutional and structural racism. 4. Our AMA will collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors. 5. Our AMA will support research that promotes antiracist strategies to mitigate algorithmic bias in medicine.

H-65.952, Racism as a Public Health Threat

1. Our AMA acknowledges that, although the primary drivers of racial health inequity are systemic and structural racism, racism and unconscious bias within medical research and health care delivery have caused and continue to cause harm to marginalized communities and society as a whole. 2. Our AMA recognizes racism, in its systemic, cultural, interpersonal, and other forms, as a serious threat to public health, to the advancement of health equity, and a barrier to appropriate medical care. 3. Our AMA will identify a set of current, best practices for healthcare institutions, physician practices, and academic medical centers to recognize, address, and mitigate the effects of racism on patients, providers, international medical graduates, and populations. 4. Our AMA encourages the development, implementation, and evaluation of undergraduate, graduate, and continuing medical education programs and curricula that engender greater understanding of: (a) the causes, influences, and effects of systemic, cultural, institutional, and interpersonal racism; and (b) how to prevent and ameliorate the health effects of racism. 5. Our AMA: (a) supports the development of policy to combat racism and its effects; and (b) encourages governmental agencies and nongovernmental organizations to increase funding for research into the epidemiology of risks and damages related to racism and how to prevent or repair them. 6. Our AMA will work to prevent and combat the influences of racism and bias in innovative health technologies.

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## REPORT OF THE BOARD OF TRUSTEES

B of T Report 3-N-21

Subject: Redefining AMA's Position on ACA and Healthcare Reform

Presented by: Bobby Mukkamala, MD, Chair

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At the 2013 Annual Meeting of the House of Delegates (HOD), the HOD adopted Policy D-165.938, "Redefining AMA's Position on ACA and Healthcare Reform," which called on our American Medical Association (AMA) to "develop a policy statement clearly outlining this organization's policies" on several specific issues related to the Affordable Care Act (ACA) as well as repealing the SGR and the Independent Payment Advisory Board (IPAB). The adopted policy went on to call for our AMA to report back at each meeting of the HOD. Board of Trustees Report 6-I-13, "Redefining AMA's Position on ACA and Healthcare Reform," accomplished the original intent of the policy. This report serves as an update on the issues and related developments occurring since the most recent meeting of the HOD.

### IMPROVING THE AFFORDABLE CARE ACT

Our AMA continues to engage policymakers and advocate for meaningful, affordable health care for all Americans to improve the health of our nation. Our AMA remains committed to the goal of universal coverage, which includes protecting coverage for the 20 million Americans who acquired it through the ACA. Our AMA has been working to fix the current system by advancing solutions that make coverage more affordable and expanding the system's reach to Americans who fall within its gaps. Our AMA also remains committed to improving health care access so that patients receive timely, high quality care, preventive services, medications and other necessary treatments.

Our AMA continues to advocate for policies that would allow patients and physicians to be able to choose from a range of public and private coverage options with the goal of providing coverage to all Americans. Specifically, our AMA has been working with Congress, the Administration, and states to advance our plan to cover the uninsured and improve affordability as included in the "2021 and Beyond: AMA's Plan to Cover the Uninsured." The current COVID-19 pandemic has led to many people losing their employer-based health insurance. This has only increased the need for significant improvements to the Affordable Care Act. We also continue to examine the pros and cons of a broad array of approaches to achieve universal coverage as the policy debate evolves.

*Our AMA has been advocating for the following policy provisions:*

#### Cover Uninsured Eligible for ACA's Premium Tax Credits

- Our AMA advocates for increasing the generosity of premium tax credits to improve premium affordability and incentivize tax credit eligible individuals to get covered. Currently, eligible individuals and families with incomes between 100 and 400 percent federal poverty level (FPL) (133 and 400 percent in Medicaid expansion states) are being provided with refundable and advanceable premium tax credits to purchase coverage on health insurance exchanges.
- Our AMA has been advocating for enhanced premium tax credits to young adults. In order to improve insurance take-up rates among young adults and help balance the individual health



insurance market risk pool, young adults ages 19 to 30 who are eligible for advance premium tax credits could be provided with “enhanced” premium tax credits—such as an additional \$50 per month—while maintaining the current premium tax credit structure which is inversely related to income, as well as the current 3:1 age rating ratio.

- Our AMA also is advocating for an expansion of the eligibility for and increasing the size of cost-sharing reductions. Currently, individuals and families with incomes between 100 and 250 percent FPL (between 133 and 250 percent FPL in Medicaid expansion states) also qualify for cost-sharing subsidies if they select a silver plan, which leads to lower deductibles, out-of-pocket maximums, copayments and other cost-sharing amounts. Extending eligibility for cost-sharing reductions beyond 250 percent FPL, and increasing the size of cost-sharing reductions, would lessen the cost-sharing burdens many individuals face, which impact their ability to access and afford the care they need.

#### Cover Uninsured Eligible for Medicaid or Children’s Health Insurance Program

Before the COVID-19 pandemic, in 2018, 6.7 million of the nonelderly uninsured were eligible for Medicaid or Children’s Health Insurance Program (CHIP). Reasons for this population remaining uninsured include lack of awareness of eligibility or assistance in enrollment.

- Our AMA has been advocating for increasing and improving Medicaid/CHIP outreach and enrollment.
- Our AMA has been opposing efforts to establish Medicaid work requirements. The AMA believes that Medicaid work requirements would negatively affect access to care and lead to significant negative consequences for individuals’ health and well-being.

#### Make Coverage More Affordable for People Not Eligible for ACA’s Premium Tax Credits

Before the COVID-19 pandemic, in 2018, 5.7 million of the nonelderly uninsured were ineligible for financial assistance under the ACA, either due to their income, or because they have an offer of “affordable” employer-sponsored health insurance coverage. Without the assistance provided by ACA’s premium tax credits, this population can continue to face unaffordable premiums and remain uninsured.

- Our AMA advocates for eliminating the subsidy “cliff,” thereby expanding eligibility for premium tax credits beyond 400 percent FPL.
- Our AMA has been advocating for the establishment of a permanent federal reinsurance program, and the use of Section 1332 waivers for state reinsurance programs. Reinsurance plays a role in stabilizing premiums by reducing the incentive for insurers to charge higher premiums across the board in anticipation of higher-risk people enrolling in coverage. Section 1332 waivers have also been approved to provide funding for state reinsurance programs.
- Our AMA also is advocating for lowering the threshold that determines whether an employee’s premium contribution is “affordable,” allowing more employees to become eligible for premium tax credits to purchase marketplace coverage.

#### EXPAND MEDICAID TO COVER MORE PEOPLE

Before the COVID-19 pandemic, in 2018, 2.3 million of the nonelderly uninsured found themselves in the coverage gap—not eligible for Medicaid, and not eligible for tax credits because they reside in states that did not expand Medicaid. Without access to Medicaid, these individuals do not have a pathway to affordable coverage.

- Our AMA has been encouraging all states to expand Medicaid eligibility to 133 percent FPL.

#### TEXAS VS. AZAR SUPREME COURT CASE

The Supreme Court agreed on March 2, 2020, to address the constitutionality of the ACA for the third time, granting the petitions for certiorari from Democratic Attorneys General and the House of Representatives. Oral arguments were presented on November 10, 2020, and a decision was expected before June 2021. The AMA filed an amicus brief in support of the Act and the petitioners in this case.

On February 10, 2021, the U.S. Department of Justice under the new Biden Administration submitted a letter to the Supreme Court arguing that the ACA's individual mandate remains valid, and, even if the court determines it is not, the rest of the law can remain intact.

This action reversed the Trump Administration's brief it filed with the Court asking the justices to overturn the ACA in its entirety. The Trump Administration had clarified that the Court could choose to leave some ACA provisions in place if they do not harm the plaintiffs, but as legal experts pointed out, the entire ACA would be struck down if the Court rules that the law is inseparable from the individual mandate—meaning that there would be no provisions left to selectively enforce.

On June 17, 2021, the Supreme Court in a 7-2 decision ruled that neither the states nor the individuals challenging the law have a legal standing to sue. The Court did not touch the larger issue in the case: whether the entirety of the ACA was rendered unconstitutional when Congress eliminated the penalty for failing to obtain health insurance.

#### AMERICAN RESCUE PLAN OF 2021

On March 11, 2021, President Biden signed into law the American Rescue Plan (ARPA) of 2021. This legislation included the following ACA-related provisions that will:

- Provide a temporary (two-year) 5 percent increase in the Medicaid FMAP to states that enact the Affordable Care Act's Medicaid expansion and covers the new enrollment period per requirements of the ACA.
- Invest nearly \$35 billion in premium subsidy increases for those who buy coverage on the ACA marketplace.
- Expand the availability of ACA advanced premium tax credits (APTCs) to individuals whose income is above 400 percent of the federal poverty line (FPL) for 2021 and 2022; and
- Give an option for states to provide 12-month postpartum coverage under State Medicaid and CHIP.

ARPA represents the largest coverage expansion since the Affordable Care Act. Under the ACA, eligible individuals and families with incomes between 100 and 400 percent of the federal poverty level (FPL) (between 133 and 400 percent FPL in Medicaid expansion states) have been provided with refundable and advanceable premium credits that are inversely related to income to purchase coverage on health insurance exchanges. However, consistent with Policy H-165.824, ARPA eliminated ACA's subsidy "cliff" for 2021 and 2022. As a result, individuals and families with incomes above 400 percent FPL (\$51,040 for an individual and \$104,800 for a family of four based on 2020 federal poverty guidelines) are eligible for premium tax credit assistance. Individuals eligible for premium tax credits include individuals who are offered an employer plan that does not

1 have an actuarial value of at least 60 percent or if the employee share of the premium exceeds 9.83  
2 percent of income in 2021.

3  
4 Consistent with Policy H-165.824, ARPA also increased the generosity of premium tax credits for  
5 two years, lowering the cap on the percentage of income individuals are required to pay for  
6 premiums of the benchmark (second-lowest-cost silver) plan. Premiums of the second-lowest-cost  
7 silver plan for individuals with incomes at and above 400 percent FPL are capped at 8.5 percent of  
8 their income. Notably, resulting from the changes, eligible individuals and families with incomes  
9 between 100 and 150 percent of the federal poverty level (133 percent and 150 percent FPL in  
10 Medicaid expansion states) now qualify for zero-premium silver plans, effective until the end of  
11 2022. In addition, individuals receiving unemployment compensation who qualify for exchange  
12 coverage are eligible for a zero-premium silver plan in 2021.

13  
14 In addition, individuals and families with incomes between 100 and 250 percent FPL (between 133  
15 and 250 percent FPL in Medicaid expansion states) also qualify for cost-sharing subsidies if they  
16 select a silver plan, which reduces their deductibles, out-of-pocket maximums, copayments, and  
17 other cost-sharing amounts.

#### 18 19 FY 2022 BUDGET RESOLUTION AND POSSIBLE EXTENSION OF ARPA PROVISIONS

20  
21 The Senate and House of Representatives are working on a proposed FY 2022 Budget Resolution  
22 framework for up to \$3.5 trillion in new federal spending that may allow funding for an extension  
23 of the aforementioned ACA subsidies included within the ARPA well as provisions to close the  
24 Medicaid “coverage gap” in the States that have not chosen to expand.

25  
26 The budget plan is expected to move through what is known as the budget reconciliation process.  
27 Congress must first approve budget instructions for legislation that affects spending, revenue, or  
28 debt. Under Congressional rules, the legislation can then advance on an expedited basis and pass in  
29 the Senate with a simple majority, circumventing the threat of filibuster.

#### 30 31 ACA SPECIAL ENROLLMENT PERIOD

32  
33 President Biden, during his first weeks in office, opened a new ACA special enrollment period,  
34 citing an increased need for coverage during the current economic and health crises. On  
35 March 23, 2021, the Biden administration announced its decision to lengthen the ACA special  
36 enrollment period from May 15 to August 15.

37  
38 The U.S. Department of Health and Human Services (HHS) announced on July 14, 2021, that a  
39 total of 1.5 million Americans have enrolled in coverage through healthcare.gov throughout the  
40 special enrollment period, while another 600,000 signed up using the 15 state-based marketplaces.  
41 HHS subsequently launched the "Summer Sprint to Coverage" campaign as part of robust efforts to  
42 get more Americans to sign up for health coverage in the final 30 days of the special enrollment  
43 period on HealthCare.gov.

#### 44 45 SGR REPEAL

46  
47 The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 repealing and replacing  
48 the SGR was signed into law by President Obama on April 16, 2015.

1 INDEPENDENT PAYMENT ADVISORY BOARD REPEAL

2

3 The Bipartisan Budget Act of 2018 signed into law by President Trump on February 9, 2018,  
4 included provisions repealing IPAB. Currently, there are not any legislative efforts in Congress to  
5 replace the IPAB.

6

7 CONCLUSION

8

9 Our AMA will remain engaged in efforts to improve the health care system through policies  
10 outlined in Policy D-165. 938 and other directives of the House of Delegates.

REPORT 4 OF THE BOARD OF TRUSTEES (N-21)  
2021 AMA Advocacy Efforts

EXECUTIVE SUMMARY

While COVID-19 response efforts remain at the forefront of AMA advocacy in 2021, there has also been continuous activity on many other important issues for physicians and patients at the federal and state levels. This report contains updates on 2021 AMA advocacy efforts on:

- COVID-19 – tackling the public health and practice challenges of the pandemic;
- Scope of practice – protecting patients from unwarranted scope expansions;
- Insurer issues – reducing obstacles based on health insurer practices, specifically:
  - Prior authorization,
  - Surprise billing, and
  - Copay accumulators;
- Medicare payment – seeking to stave off payment cuts and reduce reporting burdens;
- Telemedicine – promoting appropriate telehealth use while protecting patients;
- Maternal mortality – pressing for legislation to address this crisis – particularly for Black mothers;
- Drug overdose and death – advocating for ways to reduce overdoses and death while removing barriers to care;
- Competition in health care – monitoring major mergers for their effect on patients and physicians;
- Access to health care – fighting the Title X “gag clause” and eliminating Medicaid work requirements;
- Anti-racism efforts – supporting hate crime legislation to protect Asian Americans and Pacific Islanders;
- LGBTQ+ health – advocating for the Equality Act and efforts to stop discrimination against transgender individuals;
- Immigration – speaking up for H1-B visa petitioners and “dreamers;”
- Restrictive covenants – created a legislative template for state advocates to use; and
- Medical liability – advancing and defending hard-fought state reforms.

The AMA has made significant progress on many of these challenging issues so far in 2021 and will continue to advocate powerfully for physicians and patients in the second half of the year.

## REPORT OF THE BOARD OF TRUSTEES

B of T Report 4-N-21

Subject: 2021 AMA Advocacy Efforts

Presented by: Bobby Mukkamala, MD, Chair

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### BACKGROUND

Policy G-640.005, “AMA Advocacy Analysis,” calls on the Board of Trustees (the Board) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year’s advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The Board has prepared the following report to provide an update on American Medical Association (AMA) advocacy activities for the year. (Note: The report was prepared in August based on approval deadlines and may be updated if warranted.)

### DISCUSSION OF 2021 ADVOCACY EFFORTS

While COVID-19 response efforts remain at the forefront of AMA advocacy in 2021, there has also been continuous activity on many other important issues for physicians and patients at the federal and state levels. On the COVID-19 front, our AMA is working with policymakers to address the public health aspects of the pandemic while at the same time seeking fixes for the practice issues that COVID-19 has created for physicians. The AMA is also working to quell other practice obstacles, such as payment concerns, harmful insurer practices, unwarranted scope of practice expansions, and hurdles to the appropriate use of technology in providing care. At the same time, the AMA is working on legislative and regulatory efforts to improve public health and reduce health care disparities including pursuing solutions to increased maternal mortality and drug overdose and death. Updates on these key issues follow.

#### *COVID-19 Response*

The COVID-19 pandemic has been an absolute tragedy for many Americans and their families with over 600,000 deaths and over 33 million cases reported nationwide. The global impact is astounding as well with over 4 million deaths. The physical and emotional toll will reverberate world-wide for many years to come, and it has had a significantly disproportionate impact on minoritized and marginalized communities. During this time of pandemic, the AMA has sought ways to reduce the impact of the virus and its variants. From following the science to social distancing to getting tested to wearing masks to getting vaccinated, the AMA has been out front in promoting best practices to the American public. At the same time, the AMA has been promoting policies that assist physicians in fighting the harsh financial realities their practices face due to stay-at-home recommendations, the temporary halts on elective procedures, and general patient hesitance to resuming regular care.

After the Biden administration assumed office, it established a national plan and issued executive orders to address the pandemic that included several AMA priorities: testing; health care worker safety; science as the basis for reopening schools; a COVID-19 Health Equity Task Force; urgent inventory of supplies; use of the Defense Production Act (DPA); enhanced COVID-19 data

collection; strengthening public health infrastructure; requiring masks on domestic forms of transportation; and extending the pause on student loan payments. The Biden administration is also encouraging states to supply more vaccines to primary care physician offices to address immunization inequities and better reach patients who are hesitant to get vaccinated against COVID-19.

Our AMA also advocated to assist physician practices in mitigating the financial impact of the pandemic and made progress on several aspects of this concern, including:

- The Centers for Medicare & Medicaid Services (CMS) announced it will automatically hold physicians harmless from the up to 9% Merit-based Incentive Payment System (MIPS) penalties due to the significant disruptions of the COVID-19 public health emergency on physician practices' performance in 2020 and is accepting hardship exception applications from physicians who need an exemption from MIPS in 2021 due to the ongoing COVID-19 pandemic (for which the maximum performance adjustment will also be +/-9% in 2023).
- CMS also reopened the hardship exception application for group practices, virtual groups, and alternative payment model entities who missed the previous 2020 deadline.
- CMS announced that the 2020 MIPS Cost Performance Category will be reweighted to 0% of the final score even if eligible physicians or groups submitted 2020 data in other MIPS categories in light of the impact of the COVID-19 pandemic.
- Legislation has been introduced to ensure Provider Relief Fund grants do not count as taxable income.
- The American Rescue Plan Act (ARPA) included following provisions:
  - Added an additional \$8.5 billion dollars to the Provider Relief Fund;
  - Directs the utilization of the Defense Production Act to boost domestic production of personal protective equipment (PPE), vaccines, and onshore production of rapid COVID-19 tests;
  - Adds \$15 billion in new funding for Targeted Economic Injury Disaster Loan (EIDL); and
  - Grants funds to provide hard-hit, underserved small businesses with increased flexible monetary relief.
- The Biden administration nearly doubled Medicare payment for administration of the COVID-19 vaccine, including administration of vaccines requiring two doses, to \$40 per administration.

The AMA has also hosted eight webinars with federal officials on key COVID-19 developments which have been viewed by thousands of physicians. The AMA has also partnered with grassroots groups such as Made to Save that focus on ensuring hard-hit populations have access to COVID-19 vaccines and accurate, timely information. For more information on the AMA's COVID-19 advocacy efforts, please see a full [report](#) on the AMA website.

#### *Scope of Practice*

As expected, 2021 was filled with numerous bills related to scope of practice, and the AMA worked to protect patients with 35 state medical associations and other Federation partners to help defeat scope legislation this year, including bills related to Advanced Practice Registered Nurses (APRN) (nurse practitioners, nurse anesthetists, nurse midwives, clinical nurse specialists), naturopaths, optometrists, pharmacists, physician assistants, psychologists, and podiatrists. Due to the tremendous efforts of organized medicine at all levels and physician leaders across the country there have been many wins, but some tough losses as well.

- 1 • APRNs – Key bills that would have significantly expanded APRN scope of practice were  
2 defeated in eight states this year, including Florida, Kansas, Kentucky, Louisiana, Maine,  
3 Mississippi, Tennessee, and Texas. Unfortunately, Delaware, Massachusetts, and Utah also  
4 enacted legislation to allow independent practice of APRNs.
- 5 • Physician Assistants – Physician Assistants introduced the American Academy of physician  
6 assistants (AAPA) Optimal Team Practice Act, their model independent practice legislation, in  
7 multiple states this year. Such bills were defeated in Colorado, Indiana, South Dakota, and  
8 Texas. Other states also had physician assistant legislation, but state medical associations were  
9 able to secure favorable amendments. Unfortunately, a concerning bill was enacted in Utah  
10 (S.B. 27), which replaces physician supervision of physician assistants with collaboration,  
11 requiring such collaboration with a physician only for the first 4,000 hours of practice. Oregon  
12 and Wyoming also enacted legislation replacing physician supervision of physician assistants  
13 with a weakened definition of collaboration. In addition to this legislative activity, AAPA  
14 adopted new policy at their Annual House of Delegates to change the title of physician  
15 assistants to “physician associate.” The AMA stands in strong opposition to this title change.
- 16 • Optometrists – Legislation that would have allowed optometrists to perform eye surgery was  
17 defeated in Alabama and Florida, while favorable amendments were secured in Texas.  
18 Unfortunately, however, legislation expanding optometrist scope of practice passed in  
19 Mississippi and Wyoming.

20  
21 The AMA is working to stop a Department of Veterans Affairs (VA) initiative known as the  
22 Supremacy Project, which would develop national standards for practice for 48 health care  
23 occupations. As the name of the initiative implies, the VA is invoking the Supremacy Clause of the  
24 Constitution to preempt state laws potentially including practice laws for nonphysician health care  
25 professionals. The AMA is concerned this will have negative repercussions for both patient safety  
26 and quality of care available to our nation’s veterans. The AMA also has concerns with the  
27 feasibility of developing a national standard of practice for all physicians.

### 28 *Insurer Practices*

29  
30  
31 The AMA continues to oppose harmful insurer practices through federal, state, and private sector  
32 efforts. Prior authorization requirements remain frustrating for physicians and detrimental to  
33 patients. The AMA conducted and released its annual [physician survey](#) to quantify the impact of  
34 prior authorization on patients and physician practices. According to the results, 94% of physicians  
35 surveyed indicated that prior authorization results in care delays; 79% reported that prior  
36 authorization can lead to care abandonment; and 30% stated that prior authorization has resulted in  
37 an adverse outcome for a patient. In addition, the survey data captured the [lack of progress](#) made on  
38 prior authorization reforms agreed to by insurers over three years ago.

39  
40 At the federal level, the AMA successfully advocated for the reintroduction of the Improving  
41 Seniors’ Timely Access to Care Act, which would require Medicare Advantage plans to abide by  
42 many of the key prior authorization reforms outlined in the 2018 Consensus Statement. The AMA  
43 has also been closely monitoring federal rulemaking on prior authorization and submitted extensive  
44 [comments](#) on a proposed rule issued late last year that would require Medicaid, CHIP, and  
45 federally facilitated health plans to automate medical services prior authorization using technology  
46 embedded in physicians’ EHRs. At the state level, it has been a busy year for prior authorization  
47 legislation as well, with new legislation enacted in Georgia, Texas, and Illinois, and many other  
48 state legislative efforts underway. Many state prior authorization bills are based on the AMA’s  
49 [model legislation](#) on this issue. The AMA continues to build its grassroots advocacy campaign with  
50 its dedicated [FixPriorAuth](#) website and associated social media presence. One of the newer features



1 to the website is an employer-oriented track, which seeks to educate and engage this new and  
 2 important audience.

3  
 4 The AMA is also heavily engaged on the surprise billing issue at the federal and state levels as  
 5 well. The [Consolidated Appropriations Act](#) signed into law on Dec. 27, 2020, included “No  
 6 Surprises Act” provisions that allow for price transparency, more accurate provider directories, and  
 7 patient financial protections against surprise medical bills or unexpected gaps in health insurance  
 8 coverage. The final provisions reflect significant advocacy by the AMA and Federation groups,  
 9 including an independent dispute resolution provision. In 2021, the Department of Health and  
 10 Human Services (HHS), the Department of Labor, and the Department of the Treasury (Tri-  
 11 Agencies), along with the Office of Personnel Management (OPM) released an interim final rule  
 12 with comment period (IFR) entitled the [Requirements Related to Surprise Billing; Part I](#)  
 13 implementing many of the provisions of the NSA. The IFR clarifies the Qualified Payment Amount  
 14 (QPA) by specifying cost sharing calculations for emergency services provided by out-of-network  
 15 emergency facilities and out-of-network providers, and certain non-emergency services furnished  
 16 by out-of-network providers at certain in-network facilities. In addition, the IFR clarifies certain  
 17 notice and consent requirements for health care providers and facilities. The AMA is closely  
 18 reviewing the IFR after submitting [comments](#) to the Tri-Agencies on the implementation and  
 19 calculation of the QPA and the QPA audit process, among other provisions, as well as [comments](#)  
 20 on the Independent Dispute Resolution Process and prepared a [detailed summary](#) to help physicians  
 21 with this topic.

22  
 23 Meanwhile, states continue to evaluate the impact of the new federal law on state regulation of  
 24 surprise medical bills and determine their options. It seems that most comprehensive state laws will  
 25 continue to apply to fully insured plans, and those states can establish opt-ins for self-insured  
 26 ERISA plans. (Georgia enacted such an opt-in earlier this year.) Several states that have not taken  
 27 action or have laws that do not meet the NSA requirements are considering if legislating during the  
 28 NSA implementation is a worthwhile effort or if a wait-and-see approach allows for less confusion  
 29 for patients, physicians, and plans. Most medical societies are advocating for the latter.

30  
 31 The AMA also released the [National Managed Care Legal Database](#) in 2021, which pulls in over  
 32 1,000 patient and physician protections passed at the state and federal levels and seeks to empower  
 33 physicians, patients and their advocates in their dealings with health insurers and to inform  
 34 policymakers, legislators and regulators about key issues—e.g., surprise billing—involving health  
 35 insurers, physicians and patients. The AMA is holding Federation-wide webinars to alert state  
 36 medical and national specialty societies about the Database.

37  
 38 In response to strong advocacy by the AMA, state medical associations, and national medical  
 39 specialty medical societies, UnitedHealthcare (UHC) made positive changes to several problematic  
 40 programs/policies:

- 41  
 42 • Optum Pay™ modified its electronic payment program to offer downloadable remittance  
 43 information, up to 13 months of payment data for UHC claims, and unlimited users for each  
 44 account at no cost through its basic service option. Previously, Optum Pay had required  
 45 enrollment in its premium program, which assessed a 0.5% per payment fee, to continue access  
 46 to these critical revenue cycle functionalities.
- 47 • UHC announced an implementation delay for its emergency department coverage policy, under  
 48 which it could retroactively deny claims deemed nonemergent, through at least the end of the  
 49 COVID-19 national public health emergency. The AMA will continue to advocate for  
 50 complete rescission of this dangerous policy that could discourage patients from appropriately  
 51 seeking emergency care.

- UHC modified its Designated Diagnostic Provider (DDP) program for outpatient laboratory services from a strict coverage/no-coverage model to a tier-based system, under which UHC patients pay lower cost shares for labs performed by DDPs. In response to AMA and Federation concerns, UHC also is launching extensive educational outreach to both physicians and patients about the DDP program.

Finally, the AMA joined the All Copays Count Coalition and signed onto model legislation to prohibit insurers' copay accumulator programs. More than a dozen bills based on Coalition's model have been introduced in the states, with Alaska, Kentucky, and Oklahoma, enacting new laws.

### *Medicare/MIPS*

In addition to the COVID-19 payment relief cited earlier in this report, Congress also enacted legislation that provided relief from the 2% Medicare sequester payment cut through 2021. The AMA led a grassroots effort in support of this legislation that garnered over 5,400 emails to Congress and over 50,000 engagements. Congress also enacted a one year [3.75% increase in Medicare payments](#) to offset the impact of a budget neutrality adjustment required by law to offset the costs in fee schedule policy changes largely related to evaluation and management (E/M) services.

CMS released the proposed rule for the 2022 Medicare physician fee schedule in July 2021. AMA staff continue to analyze the rule and have developed a [summary](#) of the 1,700+ page proposal, it is important to highlight that the 2022 Medicare conversion factor would be reduced by approximately 3.75% from \$34.8931 to \$33.5848. This is largely a result of the expiration of a 3.75% increase to the conversion factor at the end of calendar year 2021, as averted for 2021 by Congressional action. The AMA will strongly advocate that Congress avert this significant cut and extend the 3.75% increase for 2022. The AMA developed a [chart](#) (pages 10-11) to show the proposed rule's specialty impact with and without the 3.75% cut to use in AMA advocacy efforts.

On another front, the AMA and the Physicians Foundation funded novel research about [how much time and money it costs to participate in MIPS](#) and [physicians' perspectives about whether MIPS improves patient care](#). On average, practices spent \$12,800 per physician per year on MIPS and 200 hours per physician per year on MIPS during the 2019 MIPS performance period. Regarding perceptions of MIPS, physician practices are conflicted about whether it improves care but overwhelmingly agree that MIPS is overly burdensome, and that the costs of successful participation generally outweigh any payment incentives received. The findings are based on interviews with small, medium, and large physician practices in primary care, general surgery, and multispecialty groups across the U.S. The AMA will use these concerning findings to bolster advocacy to reduce burden and improve the clinical relevance of MIPS for physicians in every specialty, practice size, and location.

### *Telemedicine*

During the pandemic, telehealth services emerged as a critical tool to provide care to patients while supporting physical distancing efforts and reducing the spread of COVID-19 and other infectious diseases by avoiding unnecessary in-person patient encounters. In response, Congress acted to temporarily expand access to Medicare covered telehealth services to all Medicare beneficiaries by authorizing HHS to waive outdated statutory restrictions on where telehealth services may be provided. Stories poured in from all over the country from physicians and patients alike about the

1 positive effects of expanded telehealth benefits. It has continued to allow physicians to provide  
2 high-quality care using new digital tools.

3  
4 The AMA is now strongly advocating for enactment of legislation introduced in both the House  
5 and Senate that, if passed, would make the expanded access to telehealth services permanent. The  
6 Telehealth Modernization Act of 2021 (H.R. 1332/S. 368) would lift the rural-only restriction and  
7 add any site where a patient is located as a potential originating site and ensure all Medicare  
8 patients may receive covered Medicare telehealth benefits, including at home and via mobile  
9 technologies as appropriate. The CONNECT for Health Act (H.R. 2903/S. 1512) would provide  
10 HHS with permanent authority to waive these restrictions, similar to the authority the agency has  
11 for the duration of the COVID-19 public health emergency (PHE). The success of telehealth  
12 technology adoption during the COVID-19 PHE has made it abundantly clear that Medicare  
13 covered telehealth benefits should be available to all Medicare patients regardless of where they  
14 live or how they access telehealth services.

15  
16 The AMA has also been advocating that CMS maintain Medicare coverage and payment for the  
17 many services that were temporarily added to the Medicare telehealth list during the PHE for two  
18 years after the PHE ends. The COVID-19 PHE was most recently renewed in July 2021 and is  
19 expected to continue through the end of 2021. In the Medicare physician payment schedule  
20 proposed rule, CMS has proposed to continue paying for services placed temporarily on the  
21 telehealth list through the end of 2023, consistent with the AMA's recommendation to provide a  
22 glide path to evaluate whether the services should be permanently added to the telehealth list  
23 following the COVID-19 PHE.

24  
25 Telehealth continues to be a priority for state medical associations and legislators across the  
26 country as states seek opportunities to make permanent policies expanding coverage, payment, and  
27 access to care provided via telehealth. While there has been overwhelming support of telehealth  
28 generally, issues around payment, establishment of patient physician relationships via telehealth,  
29 acceptable modalities, prescribing via telehealth, and licensure continue to be topics of debate. The  
30 AMA worked closely with 18 states reviewing legislative or regulatory language, providing data  
31 and additional resources to help states enact strong telehealth laws aligned with AMA policy.

32  
33 The AMA is also engaged with multiple national organizations developing model state telehealth  
34 legislation. We have provided written comments to the National Conference of Insurance  
35 Legislators (NCOIL) Health Insurance and Long-Term Care Issues Committee, regarding its draft  
36 Telemedicine Authorization and Reimbursement Model Act. In addition, the AMA serves as an  
37 official observer to the Uniform Laws Commission drafting committee on telehealth.

38  
39 Finally, with the increased mobility of physicians and patients and increased utilization of  
40 telehealth, the ability of physicians to provide care to patients across state lines has become  
41 increasingly important as has the ability of physicians to expeditiously gain licensure in multiple  
42 states. The Interstate Medical Licensure Compact (IMLC) continues to gain steam with three more  
43 states (Delaware, Ohio, and Texas) enacting legislation to join the IMLC, bringing the total number  
44 of IMLC members to 35 (33 states plus DC and Guam). Four states still have legislation pending.

#### 45 46 *Maternal Mortality*

47  
48 The AMA is committed to tackling the issues surrounding maternal mortality and morbidity. The  
49 U.S. has the highest maternal mortality rate among developed countries. A 2019 report by the  
50 Centers for Disease Control and Prevention (CDC) found that Black women are 3-4 times more  
51 likely to die from pregnancy-related causes than White women. The AMA understands that there

are a multitude of considerations necessary to address this epidemic, including lack of insurance or inadequate coverage prior to, during, and after pregnancy; closures of maternity units in many rural and urban communities; and a lack of inter-professional teams trained in best practices. There are concrete actions that should be taken to reduce and prevent rising rates of maternal mortality and serious or near-fatal maternal morbidity in the U.S. The AMA urges policymakers to:

- Expand Medicaid and CHIP coverage to 12-months postpartum;
- Increase support for Maternal Mortality Review Committees;
- Implement equitable standardized data collection methods;
- Expand access to medical and mental health care and social services for post-partum women;
- Continue to develop a health care workforce that is diverse in background and experience;
- Address shortcomings in our institutions; and
- Adopt standards to ensure respectful, safe, and quality care before, during, and after delivery.

So far in 2021, HHS approved a [postpartum Medicaid expansion](#) for Georgia, Illinois, and Missouri. Fifteen state legislatures have also enacted legislation to seek federal approval for coverage expansions for postpartum women. The AMA has also successfully sought introduction of the “[Mothers and Offspring Mortality and Morbidity Awareness Act](#),” also known as the MOMMA Act which would extend coverage for postpartum care from the existing 60 days to 12 months under Medicaid and CHIP and would also support training clinicians on implicit bias and health equity issues. The AMA also supports the Connected Maternal Online Monitoring Act which would require CMS to identify barriers to coverage of remote physiologic devices under state Medicaid programs to improve maternal and child health outcomes for pregnant and postpartum women.

### *Drug Overdose and Death*

The AMA remains engaged in fighting the drug overdose and death epidemic. Recent statistics have shown that the epidemic has worsened during the COVID-19 pandemic, but significant progress has been made on the advocacy front on these issues in 2021:

- The Biden administration [adopted policies](#) to address overdose and substance use disorder in ways that will reduce stigma, [more effectively prevent overdose deaths](#), and remove barriers to treatment—and in ways that are consistent with AMA policy recommendations.
- The Biden administration is waiving burdensome administrative requirements so that all physicians will be able to [prescribe buprenorphine](#) for their patients with opioid use disorder.
- Using national principles and working with coalition partners, the AMA supported five state laws directing opioid litigation funds to be earmarked for public health uses.
- As part of a national coalition, the AMA helped support six new state mental health and substance use disorder parity laws that will help enhance oversight and enforcement to protect patients. Our AMA also helped secure a [new rule](#) in Colorado that will be the nation’s first to meaningfully measure substance use disorder network adequacy and provide regulators with actionable information to help hold insurers accountable for inadequate networks.
- Developed a new issue brief focused on [actions employers can take](#) to help improve access to evidence-based care for opioid use disorder and pain, as well as to support harm reduction efforts; worked with the Milken Institute and the DEA to present highlights of the issue brief at multiple regional DEA-sponsored events.
- Held a national webinar with Manatt Health featuring medical, legal and public health experts identifying ways to remove barriers to evidence-based treatment for opioid use disorder in justice-involved settings; a second webinar with Manatt Health focused on evidence-based

initiatives to support harm reduction efforts, including the first overdose prevention site in the nation.

- Highlighting [physician advocacy efforts](#) to help their patients with a substance use disorder or chronic pain and detailed the effects of COVID-19 on physicians and patients with respect to barriers to care for patients with as well as physicians' uptake of new federal telemedicine and other flexibilities.
- AMA Immediate Past President Susan R. Bailey, MD, provided a keynote address on the AMA's advocacy efforts to end the overdose epidemic at the [National Rx Drug Abuse and Heroin Summit](#) and to the American Bar Association.

The AMA also urged advisers to the Centers for Disease Control and Prevention Injury Center to recommend an overhaul of the agency's problematic guideline on opioid prescriptions. Mirroring recommendations of the Opioid Workgroup, the AMA urged the removal of arbitrary thresholds to restore balance and support comprehensive, compassionate care, noting that the opioid epidemic has become more lethal due to illicit rather than prescribed drugs. States and insurers have turned the existing guidelines into laws and unbending regulations that prevent physicians from treating patients as individuals with specific needs, including patients with cancer and sickle cell disease, as well as those in hospice care.

#### *Competition in Health Care*

The AMA is continuing to monitor key health care mergers and acquisitions for their effects on physicians and patients. On July 9, President Biden signed a new [executive order](#) aimed at limiting anticompetitive actions and promoting competition in several sectors, including health care. The "Promoting Competition in the American Economy" executive order includes directives to several federal departments and agencies, including HHS, Food and Drug Administration (FDA), and Federal Trade Commission (FTC), that could potentially impact issues such as prescription drug pricing and access, hospitals, and insurer mergers, use of non-compete clauses in employment contracts, and occupational licensing. Broadly, the order notes its opposition to consolidation in any industry and specifically notes concerns about monopoly and monopsony powers in health care markets. Specifically, the order directs the FTC to curtail the use of non-compete agreements and other clauses that may limit employee mobility and to address the use of "unfair occupational licensing restrictions." The order also includes several directives to HHS, FDA, and CMS to promote competition in the prescription drug space aimed at decreasing prescription drug costs and increasing access to generics and biosimilars. The AMA will review forthcoming agency activity on these issues and provide AMA recommendations as appropriate. Further, the AMA initiated engagement with U.S. Department of Justice, asking for a more thorough investigation, of the proposed merger of United/Optum and Change Healthcare and its potential effects on the U.S. health system.

The AMA also continues to help state medical associations with respect to legislation that improves competition in health care. For example, the AMA worked closely with the Nevada State Medical Association on a piece of legislation that was enacted that, in part, limits the ability of large health care systems to use their market power to injure competition, raise consumer prices, and reduce health care quality.

#### *Access*

Access to health care remains a priority for the AMA in its advocacy work. Positive developments in 2021 include the Biden administration starting the process of [lifting the Title X "gag clause"](#) rule. It is also repealing approvals of state Medicaid work requirements. The [American Rescue](#)

1 [Plan Act \(ARPA\)](#) contained provisions to extend postpartum coverage under Medicaid and CHIP,  
2 increase premium subsidies for ACA marketplace plans, and invest in trust and treaty obligations to  
3 provide essential safety-net programs that serve Native American communities. The American  
4 Families Plan announced by the President on April 28 would make ARPA's Affordable Care Act  
5 (ACA) subsidy enhancements permanent. Finally, a special enrollment period for the ACA was  
6 opened in 2021 to expand access to coverage. Based on this, 2 million Americans have signed up  
7 for coverage.

#### 8 9 *Anti-racism Efforts*

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11 As the AMA continues to focus on anti-racist and social justice policies, it was pleased that the  
12 CDC recognized racism as a "[serious public health threat](#)." The AMA also supported the Asian  
13 American and Pacific Islander federal [hate crime legislation](#), which was signed into law on May 20  
14 after widespread reports of violence against this community. The AMA also successfully opposed  
15 state legislation that would have barred state-funded entities from conducting trainings on diversity  
16 and inclusion. Moving forward, AMA advocacy efforts will incorporate elements of the [AMA's](#)  
17 [strategic plan to embed racial justice and advance health equity](#) as it promotes AMA health equity  
18 policy at the federal and state levels.

#### 19 20 *LGBTQ+ Health*

21  
22 The AMA was very active in supporting LGBTQ+ health in 2021. Efforts include endorsing H.R.  
23 5, the [Equality Act](#), passed by the House, which prohibits discrimination based on sex, sexual  
24 orientation, and gender identity in areas including public accommodations and facilities, education,  
25 federal funding, employment, housing, credit, and the jury system. The Biden administration  
26 withdrew a Trump Administration proposal restricting transgender people in homeless shelters. It  
27 also announced it would [provide protections](#) against discrimination in health care based on gender  
28 identity and sexual orientation, reversing a rule issued by the previous administration that allowed  
29 discrimination against transgender individuals. The AMA strongly opposed the previous policy and  
30 had urged the Biden Administration to reverse it. The AMA was also pleased that the new  
31 administration withdrew the previous administration's proposed rule that would have weakened the  
32 Equal Access Rule which ensures that all individuals—regardless of sexual orientation or gender  
33 identity—have equal access to the Office of Community Planning and Development programs,  
34 shelters, other buildings and facilities, benefits, services, and accommodations. The AMA also  
35 contributed to the defeat of harmful anti-transgender legislation in over a dozen states that would  
36 have criminalized the provision of medically necessary gender-affirming care to minor patients.  
37 The AMA also sent a letter to the National Governors Association urging the nation's governors to  
38 reject legislation that would discriminate against transgender individuals.

#### 39 40 *Gun Violence*

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42 Gun violence is a public health crisis, and the AMA remains committed to finding solutions that  
43 help reduce the impact it has nationwide. Some positive steps occurred in 2021. The Biden  
44 administration issued rules to [require](#) background checks for "ghost guns." The House of  
45 Representatives passed two bills supported by the AMA that would close the so-called "Charleston  
46 Loophole" by extending the time period the FBI has to determine whether a buyer is qualified to  
47 purchase a gun and to expand the existing background check system to cover all firearm sales,  
48 while providing exceptions for law enforcement and family and friend transfers. The AMA also  
49 helped to successfully secure FY 2021 federal appropriations of \$25 million for the National  
50 Institutes of Health and \$25 million for the Centers for Disease Control and Prevention for research  
51 on gun violence.



## *Immigration*

In 2021, the AMA promoted its policy on immigration issues. There were several beneficial developments under the new administration. First, it delayed implementation of a problematic Department of Homeland Security (DHS) final rule regarding cap-subject H-1B visa petitioners. The Biden administration also continued the policy to defer the removal of certain undocumented immigrants who were brought to the United States as children, have obeyed the law, and stayed in school or enlisted in the military (DACA). Also consistent with AMA advocacy, the Biden administration lifted the immigration ban on Muslim countries and rescinded rules that would deem immigrants inadmissible on public charge grounds. The AMA is currently advocating for a broad range of immigration and border security policy changes, including those that would ease visa restrictions for foreign-born physicians seeking to train or practice in the U.S.

## *Restrictive Covenants*

Pursuant to AMA House of Delegates action at the AMA's 2020 Special Meeting, the AMA developed a 60+ page, comprehensive legislative template on restrictive covenants to help the Federation develop legislative proposals that would address concerns that restrictive covenants raise while, at the same time, be cognizant of the interests of physicians who own their own practices and may view the use of reasonable restrictive covenants as a means of protecting their practices' financial viability and their relationships with their patients, and making it easier to bring new physicians into the practice. The AMA also continues to assist individual state medical associations with analyzing and drafting restrictive covenant legislative language.

## *State Medical Liability Efforts*

2021 was a very busy year for state medical liability legislative proposals. These proposals gave qualified immunity from medical liability for physicians, health care professionals, and health care facilities for care that they provided during, or as a result of, the COVID-19 pandemic. Thus far, over half of the states have enacted some form of medical liability immunity legislation. The AMA provided comprehensive resources to state medical associations working on this issue to help them advocate for enactment of liability immunity laws. The AMA also proactively contacted all state medical associations working on this issue to provide support. The AMA helped state medical associations analyze and draft medical liability immunity legislation that became law. Aside from medical liability immunity advocacy, the AMA helped persuade the Illinois Governor to veto legislation that would have imposed prejudgment interest in medical liability cases starting on the day the alleged liability occurred and supported the New Mexico Medical Society in reaching a successful result concerning amendments to its MLR law. The AMA also published the 2021 edition of [MLR NOW!](#).

## *CONCLUSION*

Our AMA has made significant progress on a challenging group of advocacy issues so far in 2021 and will continue to advocate powerfully for physicians and patients in the second half of the year. The situation is somewhat fluid with the Delta variant becoming the dominant COVID-19 strain in the U.S. and hitting unvaccinated pockets of the country very hard. However, the AMA will continue to stress "following the science" in its COVID-19 response. And the AMA will seek to make further progress on the other issues confronting physicians and patients.

REPORT 6 OF THE BOARD OF TRUSTEES (N-21)  
Mitigating the Effects of Racism in Health Care: “Best Practices”  
(Informational)

EXECUTIVE SUMMARY

This report responds to the call for AMA to identify “best practices for healthcare institutions, physician practices, and academic medical centers to recognize, address, and mitigate the effects of racism on patients, providers, international medical graduates, and populations” (H-65.952). It presents preliminary findings from reviews of statements declaring racism a public health threat from state, county, and local governments as well as public health and educational organizations and of anti-racism and/or equity initiatives by health care systems. In addition, it summarizes AMA engagement around issues of anti-racist practice in health care.

The report concludes that strong practice will explicitly acknowledge racism, address racism at the institutional and interpersonal level, and pair commitment with specific, actionable policies and practices to create change. Strong practice cannot be defined globally but must be responsive to the needs and histories of local communities and the institutions that serve them. Strong practice will, at minimum:

- Acknowledge and respond to the unique intersecting local histories of racism within the institution, the community, and their constituent populations.
- Partner with the community to identify local values, needs, and assets and develop concrete plans to meet the full range of needs among the populations served. Secure additional resources as needed to build local capacity.
- Align institutional mission and strategic planning with the needs and values of the local community and populations served.
- Promote and provide resources to support critical self-reflection and transformation on the part of the institution and its staff.
- Collaborate with the community and populations served to design and implement meaningful measures of success and hold the institution accountable for meeting those measures.
- Ensure that at all levels of the institution policies are equity focused, actionable, and aligned with the institution’s community-informed values and mission.



## REPORT OF THE BOARD OF TRUSTEES

B of T Report 6-N-21

Subject: Mitigating the Effects of Racism in Health Care: “Best Practices”

Presented by: Bobby Mukkamala, MD, Chair

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1 At its November 2020 Special Meeting the House of Delegates of the American Medical  
2 Association (AMA) adopted three policies directed toward the ongoing impact of racism in  
3 medicine: [D-350.981](#), “Racial Essentialism in Medicine,” [H-65.952](#), “Racism as a Public Health  
4 Threat,” and [H-65.953](#), “Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in  
5 Medical Education, Research and Clinical Practice.”

6  
7 These policies variously direct AMA to take action to address racism and racial essentialism as  
8 they manifest in medical education, clinical practice, and the development and use of new medical  
9 technologies, notably clinical algorithms. Staff from the Center for Health Equity and AMA’s  
10 Health, Science & Ethics group tasked with co-implementing these directives realized that three  
11 key themes cut across individual policies: identifying best practices to respond to the effects of  
12 racism, addressing algorithmic bias and race-corrected algorithms, and collaborating with key  
13 stakeholders to address how medical education perpetuates mistaken beliefs about race as a  
14 biologic risk factor. Staff concluded that the most effective approach to accomplishing the goals of  
15 these policies would be to engage these cross-cutting themes as organizing rubrics for three  
16 separate reports on best practices, clinical algorithms, and medical education, respectively.

17  
18 The working group concluded that the most effective approach for responding to the HOD’s  
19 directives would be to engage these cross-cutting themes as its organizing rubric in a series of  
20 reports, rather than speak to individual directives policy by policy.

21  
22 The present report responds to the directive to “identify a set of current, best practices for  
23 healthcare institutions, physician practices, and academic medical centers to recognize, address,  
24 and mitigate the effects of racism on patients, providers, international medical graduates, and  
25 populations” ([H-65.952](#)).

26  
27 The broad scope of this directive requires distinguishing best practices first, at the level of  
28 institutionalized or structural racism as well as the level of “personally mediated” racism,<sup>1</sup> and  
29 second, doing so across multiple contexts of practice, from small private offices to large integrated  
30 health systems. As evidenced below, the complexity of the task and the problem(s) to be addressed  
31 argue against defining any single set of “best” practices. Rather, this report seeks to identify  
32 essential features of strong anti-racist practice applicable across multiple levels and settings as they  
33 emerge in anti-racism declarations made by public health departments and local/state governments  
34 and in equity and anti-racism initiatives being undertaken by health care institutions across the  
35 country.

36  
37 To that end, in addition to literature review, as discussed below preliminary reviews were carried  
38 out of (a) declarations regarding racism as a public health crisis posted to the American Public  
39 Health Association’s online database, and (b) publicly available descriptions of programs and  
40 initiatives on the part of health care institutions to address racism and health equity.

## DECLARATIONS ON RACISM AS A PUBLIC HEALTH CRISIS

The American Public Health Association maintains a [database of declarations of racism as a public health crisis](#) or emergency. Submissions to the database are crowd-sourced; thus, it certainly does not include every existing anti-racism declaration. As of May 18, 2021, the database included 208 declarations from city/town governments (102 declarations), county boards (51), state governments (7), public health organizations (44), and educational organizations (4). The working group evaluated a randomly chosen sample of 19 declarations, which surfaced three core themes focused around declaring entities' commitments to acknowledge racism, address racism, and mitigate racism.

### *Acknowledge Racism*

All but one of the nineteen declarations reviewed explicitly named and condemned systemic racism (one used the term "endemic racism"). Declarations gave examples of historical and present-day government sanctioned colonization, genocide, and racism in housing, including redlining and segregation; voting rights; immigration; incarceration; as well as hiring, promotion, compensation, and retention practices. Thirteen acknowledged historical, intergenerational, or contemporary racial trauma; none provided an apology for their role in creating or perpetuating it.

For example, the declaration from Multnomah County, Oregon included the following statement:

Multnomah County recognizes that the entirety of Multnomah County rests on the homelands, villages and ceded territories of the Indigenous Tribal nations. We acknowledge the genocide, forced removal, and systemic erasure of Indigenous peoples that have allowed us to ignore and deny this history and our responsibility to Indigenous people. Further, the state of Oregon was founded on the notion of creating a white utopia, and around the functional and implicit removal, exploitation and/or exclusion of BIPOC individuals and communities. From Black exclusion laws and restrictions that barred Black and Chinese people from voting to a steady stream of discriminatory laws and the practice of redlining in Portland, the legacies of Oregon's founding ideals continue to perpetuate harm, oppression, and marginalization within communities of color today. Racism is codified into our laws and institutions, which were created on a foundation of the ideology of white supremacy; it upholds systems, structures and policies that were created to advantage white people while neither serving nor benefiting people of color.<sup>2</sup>

### *Address Racism*

All but four of the examined declarations included specific anti-racism actions the organization was committing to. Among the actions at the individual, institutional, and community level set out by the 15 organizations that included them are commitments to:

- Providing anti-racism training for all staff, students and volunteers.
- Instituting anti-racism policies and practices in Human Resources; building a workplace culture that promotes racialized repair.
- Developing policies and practices to ensure equity and incorporating anti-racism principles in budgets and contracting; using an equity lens in vendor selection processes.
- Using racial impact assessments in the development of all policy resolutions and ordinances; expanding documented equity decision-making frameworks that are transparent to the public.
- Conducting research, analyzing and collecting data, and monitoring progress to ensure policy approaches are data driven and have built-in accountability measures; improving data systems

1 in order to disaggregate health data by race, ethnicity, gender, transgender, age, sexual  
2 orientation and income and facilitate data-informed decision-making processes to address  
3 health inequities.

- 4 • Sharing power in partnering with community organizations; systematically lifting up the voices  
5 of community members; applying an anti-racism lens to government outreach with all  
6 communities.
- 7 • Seeking upstream solutions to address health inequities at the population level, recognizing that  
8 racism is a social determinant of health outcomes; working to mitigate housing and job  
9 displacement from driving further racial and income segregation by developing strategic  
10 initiatives such as land use and affordable housing finance regulations and housing stability  
11 programs.

### 12 13 *Mitigate the Effects of Racism*

14  
15 The declarations reviewed gave significantly less attention to addressing activities to mitigate the  
16 effects of racism. None committed to a strategy for making reparations. Many did not acknowledge  
17 the need for additional funding or resources to support mitigation. Of those that did, only two  
18 promised specific dollar amounts, while the remainder simply advocated in general for additional  
19 funding.

### 20 21 ANTI-RACISM INITIATIVES AMONG HEALTH CARE INSTITUTIONS

22  
23 Launched in 2016, the Healthcare Anchor Network is a collaboration among now 60 hospitals and  
24 health systems committed to serving as “anchor institutions”<sup>3</sup> in their communities. Network  
25 members recognize that

26  
27 Hospitals and health systems are critical local economic engines and mission-driven  
28 organizations inextricably linked to the long-term well-being of those we serve—because of  
29 this, we as healthcare leaders, are uniquely positioned and incentivized to play a more active  
30 role in supporting our local economies. We have an opportunity and obligation to improve  
31 health and well-being outcomes in the communities we serve and confront economic and social  
32 instability in our nation that remain obstacles to that goal.<sup>4</sup>

33  
34 Collectively, Network members called for action to address racism as a public health crisis,  
35 pledging as institutions to:

- 36  
37 • Re-examine institutional policies with an equity lens and make policy changes that promote  
38 equity and opportunity.
- 39 • Improve access to primary and specialty care.
- 40 • Continue to focus on helping our communities overcome chronic conditions like diabetes, heart  
41 disease, and asthma.
- 42 • Continue to advocate for investments that create innovative solutions to achieve enduring  
43 improvements in access, quality, and health outcomes for our communities.
- 44 • Commit to hiring locally and promoting and retaining leaders of color.
- 45 • Renew and expand the organizations’ commitment to providing anti-racism and unconscious  
46 bias training for our administrators, physicians, nurses, and staff.
- 47 • Advocate for increased funding for social needs, social services and programs that promote  
48 social justice.<sup>5</sup>

49  
50 Members have further “co-created the Anchor Institution Reporting Standard to develop a shared  
51 set of national metrics for anchor strategies.”

1 In 2015 the American Hospital Association's Institute for Diversity and Health Equity (IFDHE)  
2 launched the #123forEquity Campaign to eliminate health care disparities, which to date has  
3 received a total of 1,771 organizational pledges, with 1,711 being hospitals and health systems. The  
4 campaign encourages hospital and health system leaders to:

- 5
- 6 • Increase the collection and use of race, ethnicity, language preference and socio-demographic
- 7 data.
- 8 • Increase cultural competency training.
- 9 • Increase diversity in leadership and governance.
- 10 • Improve and strengthen community partnerships.<sup>6</sup>
- 11

12 The goal of the campaign is to ensure every person in every community receives high-quality,  
13 equitable and safe care.

14

15 The working group delved into the declarations and strategic plans of 11 health systems among  
16 these two initiatives: [Rush University Medical Center](#), [Health Partners](#), [Ohio State University](#)  
17 [Wexner Medical Center](#), [MetroHealth](#), [Ascension](#), [Kaiser Permanente](#), [Mass General Brigham](#),  
18 John Hopkins Medicine, UC Davis Health, Yale New Haven Health, and RWJBarnabas Health.

19

20 Themes among these materials include:

- 21
- 22 • Recognizing the need to understand the historical context of the institution and its community,
- 23 to embed equity in the institution's strategic plan, promote diversity among leadership and staff
- 24 and adopt equitable processes for decision making that do not perpetuate racism and inequity.
- 25 • Commitment to:
  - 26 ○ ensuring equitable policies and practices for recruiting and managing personnel; adopting
  - 27 zero-tolerance policy with respect to racism, harassment and discrimination within the
  - 28 institution; and providing a living wage and equitable benefits; and
  - 29 ○ providing anti-racism and implicit bias training and cultivating a safe environment in
  - 30 which staff are comfortable addressing racism.
- 31 • Promoting quality improvement activities to eliminate variations in care and outcomes.
- 32 • Funding research to address and eliminate racism.
- 33 • Designing data systems that are able to collect, stratify, and report data on race, ethnicity,
- 34 language, sexual orientation, and gender identity.
- 35 • Identifying community health assets and needs and building partnerships to address those
- 36 needs and social determinants of health.
- 37 • Centering the most marginalized/minoritized communities within and outside the institution in
- 38 designing solutions to address community needs.
- 39 • Building coalitions with other health care and community institutions to create resources and
- 40 opportunities and redistribute power to further the interests and well-being of the local
- 41 community.
- 42 • Advocating on behalf of and supporting community members in advocating for themselves.
- 43

44 The Institute for Healthcare Improvement's (IHI) Pursuing Equity initiative also brings together  
45 some twenty institutions committed to addressing the needs of marginalized and minoritized  
46 communities to improve health. (Several institutions are members of both the IHI initiative and the  
47 Healthcare Anchor Network.) The IHI's *Framework to Improve Health Equity* focuses on the need  
48 to make health equity a priority, build infrastructure to support health equity, address the multiple  
49 determinants of health, eliminate racism and other forms of oppression, and partner with the  
50 community to improve health equity.

The IHI identifies five strategies for eliminating racism:<sup>7</sup>

- Understanding the historical context for racism and other forms of oppression nationally, locally, and within the institution itself, including:
  - gaining understanding of the historically marginalized populations in the community where the institution is located; and
  - committing to ongoing learning and transformation regarding race, racism, and inequity.
- Addressing institutional racism and its impact on health equity by:
  - normalizing discussion about racism, oppression, advantage and power,
  - identifying institutional racism as a root cause of inequities;
  - setting organizational priorities to explicitly address racism; and
  - listening to patients, partners, and communities to understand their experiences and partner on solutions.
- Establishing policies and practices to promote workforce diversity and racial equity by:
  - setting specific targets for workforce diversity at all levels; and
  - ensuring that organizational policies and practices promote diversity.
- Implementing business policies and practices that support and promote racial equity by:
  - developing or revising policy through a racial equity lens; and
  - investing in the community.
- Improving clinical processes and outcomes to narrow equity gaps and improve equity for all:
  - building data systems that can identify and track equity gaps in clinical outcomes;
  - using quality improvement to narrow equity gaps and improve care for all; and
  - breaking down silos between departments to motivate clinical teams to work together to reduce equity gaps.

#### ADDRESSING “PERSONALLY MEDIATED RACISM”

Although addressing prejudice and discrimination in the behavior of individuals can never be a sufficient response to racism in health care, it is nonetheless essential for promoting strong anti-racist practice. Differential assumptions about individuals’ abilities or intentions based on race and differential action toward individuals based on race both reflect and help to perpetuate structural inequities.

Prejudice or discrimination by health care personnel toward patients, family members, or fellow health care workers runs counter to the norms of the healing professions and undermines efforts on the part of the institution to mitigate the effects of racism. This has led to calls for providing training to all staff in implicit bias and “cultural competence,” or more properly, cultural humility and structural competence. are needed? are appropriate?

Prejudice on the part of patients or families toward health care personnel also presents a challenge for health care institutions, which have a responsibility to support and protect the dignity and well-being of personnel. Strong practice includes ensuring a safe and respectful working environment by setting clear expectations for the behavior of all parties during health care encounters and ensuring that those expectations are upheld.

Analogous to institutions’ responsibility to collect data on inequities in access to care and outcomes, institutions should collect and analyze data on incidents of prejudiced or discriminatory behavior by health care personnel and patients or families to better understand how such incidents arise and inform efforts to improve the institution’s response. Moreover, institutions have a responsibility to reflect critically on how they treat their staff, how they permit staff to treat one

another and members of the community, and how they permit members of the community to interact with health care personnel and align policies and practices to foster compassion and respect for all stakeholders.<sup>8</sup>

## AMA ENGAGEMENT

The AMA Center for Health Equity is designing and launching large-scale national initiatives to advance a more equitable and healthy society in which physicians use their individual, institutional, and collective power to advance health equity and public health (upstream approaches). These initiatives are focused on three key levels of action: cross-sector engagement, health care institutions, and health care professionals.

*Cross-Sector Engagement.* Coordinate across sectors—including public health, social care, health care, and beyond—to promote people- and community-centered, collective action addressing social and structural drivers of health, and dismantling intersecting systems of oppression. The Center’s *IHI-AMA Equity Campaign*, a two-and-a-half-year initiative, will engage individuals, health systems, payers, biotech/pharma, and professional societies to transform the health care ecosystem to promote optimal health for historically marginalized populations. The *AMA-ACGME Racial Justice and Equity Grand Rounds* will launch a national lectureship and practice lab focused on amplifying high-impact strategies and practices in racial justice and equity across sectors to promote people- and community-centered collective action to address the social and structural drivers of health, and to dismantle intersecting systems of oppression.

*Health Care Institutions.* Eliminate harmful variation in health care delivery, access, and outcomes, by embedding equity in the DNA of hospital operations, including quality, safety, data, and education; and promoting a place-based, equity-focused anchor mission strategy that centers community and marginalized voices. The *AMA-BWH Q&S For Impact in Racial Justice an Equity Peer Network* is designed to equip all participating U.S. health care delivery systems with the knowledge and tools to address root causes of inequities by systematically incorporating equity into the operational DNA of healthcare delivery—by leveraging equity-informed high-performance quality and safety practices and technologies that will address structural and social drivers of health and advance equity for patients, staff, and local communities.

*Health Care Professionals.* Develop a pipeline of health care leaders equipped with anti-racist, structural justice praxis capable of redesigning health care for social health.

## LESSONS LEARNED

Defining a single set of “best” practices to respond to the challenge of racism in health care is an illusory goal. Best practices can be effective tools for responding to problems that are (relatively) circumscribed in nature and scope, affect a limited set of readily definable stakeholders, and are amenable to reasonably straightforward solutions. Racism and its effects on patients, physicians and other health care personnel, and the institutions and communities within which they live and work, is of a different order. Racism is deeply rooted historically and pervasive across U.S. society, manifest in entangled policies, practices, institutions, and habits of mind among multiple stakeholders who bring diverging values and goals to the table and for whom different “solutions” can carry significantly different implications.

The responses to systemic racism discussed above don’t delineate a set of “best practices.” Rather, they suggest features that will be common to strong solutions across the board, however different those solutions may be in their details. These initiatives indicate that at minimum, effective efforts

1 to mitigate the impact of racism will explicitly name the problem for what it is, will engage both  
2 institutional and interpersonal racism, and will pair commitment with specific policies and concrete  
3 practices to create change.  
4

5 Strong solutions will acknowledge and respond to the unique intersecting local histories of racism  
6 within the institution, the community, and their constituent populations. They will partner with the  
7 community to identify local values, needs, and assets and develop concrete, actionable plans to  
8 meet the full range of needs among the populations served. They will secure additional resources as  
9 needed to build local capacity. And they will adapt as the needs of the community change over  
10 time.  
11

12 As essential partners in initiatives to mitigate racism, health care institutions will align institutional  
13 mission and strategic planning with the needs and values of the local community and populations  
14 served. They will promote and provide resources to support critical self-reflection and  
15 transformation on the part of the institution and its staff. Institutions will collaborate with the  
16 community and local populations served to design and implement meaningful measures of success  
17 and hold the institution accountable for meeting those measures. And they will ensure that at all  
18 levels of the institution policies are equity focused, actionable, and aligned with the institution's  
19 community-informed values and mission.

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## REPORT OF THE BOARD OF TRUSTEES

B of T Report 7-N-21

Subject: Improving Clinical Algorithms: Moving Beyond Race and Ethnicity

Presented by: Bobby Mukkamala, MD, Chair

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At its November 2020 Special Meeting the House of Delegates of the American Medical Association (AMA) adopted three policies directed toward the ongoing impact of racism in medicine: [D-350.981](#), “Racial Essentialism in Medicine,” [H-65.952](#), “Racism as a Public Health Threat,” and [H-65.953](#), “Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice.”

These policies variously direct AMA to take action to address racism and racial essentialism as they manifest in medical education, clinical practice, and the development and use of new medical technologies, notably clinical algorithms. Staff from the AMA’s Center for Health Equity and Health, Science & Ethics group tasked with co-implementing these directives realized that three key themes cut across individual policies: identifying best practices to respond to the effects of racism, addressing algorithmic bias and race-corrected algorithms, and collaborating with key stakeholders to address how medical education perpetuates mistaken beliefs about race as a biologic risk factor. Staff concluded that the most effective approach to accomplishing the goals of these policies would be to engage these crosscutting themes as organizing rubrics for three separate reports on best practices, clinical algorithms, and medical education, respectively.

The present report responds to directives to “promote antiracist strategies to mitigate algorithmic bias in medicine” [[H-65.952\(6\)](#)] and “innovative health technologies” [[H-65.953\(5\)](#)] and, importantly, to “collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors” [[D-350.981\(4\)](#)].

### BACKGROUND

With the advent of longitudinal clinical registries, electronic health record systems, and other large repositories of clinical data, many specialty societies, health systems, health plans, researchers, patient-facing organizations, government entities, and others have used the data to develop or support development of algorithms to inform the clinical care of individual patients and populations. As constructs based on real-world data and using mathematical and statistical methods such as multivariate analysis, these algorithms have been widely adopted, in part based on their implied or explicit promise to objectively synthesize and interpret data and offer clinical decision support that circumvents the potential biases of human decision makers.<sup>1</sup> Yet as is increasingly clear, much more remains to be done if clinical algorithms are to come closer to achieving that promise.

Clinical algorithms are only as good as the data on which they are trained and operate and can be subject to bias arising from several directions and due to many causes: limitations in the geographic origins and ancestral representativeness of data collection; missing data; small sample sizes; the implicit biases and inaccurate or inexperienced judgments of clinicians; or differential care

delivered in different clinical settings to different populations of patients.<sup>1</sup> As a result, technical solutions to mitigate bias before, during, or after an algorithm processes data may not be sufficient to ensure that an algorithm benefits patients as intended.<sup>2,3,4</sup>

Collection of data to identify and describe individuals is ubiquitous, and often required, in clinical health care settings and research. In addition to name, address, and date of birth, health care organizations, clinicians, and researchers often collect information on gender, co-morbidities, race, ethnicity, and other characteristics that they believe contribute or may contribute significantly to the predictive accuracy of estimates of the risks and benefits of the various preventive, diagnostic and therapeutic options considered and discussed, recommended or advised against, and offered or not offered in clinical care settings. With race and ethnicity now understood as social, not biological constructs, and as proxies for nonbiological factors such as social determinants of health and structural racism, considerable scholarship has been focused on what “race” and “ethnicity” mean as descriptive or explanatory categories in clinical care and research, and what role, if any, data on race and ethnicity should play in clinical algorithms.<sup>5</sup>

## CONGRESSIONAL INTEREST

AMA is not alone in recognizing and responding to the imperative to come to terms with racism endemic in American society, which manifests in stark health inequities among members of marginalized and minoritized communities compared to white patients. Understanding and redressing how clinical algorithms create, perpetuate, or exacerbate those inequities is essential. A growing body of literature reveals the way in which race corrections, intended to enhance the accuracy of predictive models, can in fact systematically disadvantage patients of color and contribute to differential outcomes.<sup>6</sup>

In September 2020, Congressman Richard E. Neal, chairman of the Committee on Ways and Means of the U.S. House of Representatives, directed a request to a number of medical professional societies and other entities, asking them to describe how they are addressing the challenges that can be associated with use of clinical algorithms that incorporate race and ethnicity data, among other factors.<sup>7</sup> The organizations’ responses indicate that there is considerable variation within the professional community with respect to what ways and how far along different organizations are in their journey to address these issues.

Although respondents differed in the scope of their efforts to address the challenges associated with the use of race and ethnicity data in clinical algorithms, several shared concerns emerged:

- The need for guidelines on the *appropriate* use of race/ethnicity in research and clinical care.
- The need to identify and pay for, race-neutral well-validated biomarkers, if available, to improve estimates of risk of particular outcomes (e.g., use of cystatin to estimate a race-neutral creatinine clearance).
- The need for transparency on the part of algorithm developers, in particular:
  - information about the population(s) studied and the extent to which algorithms have been tested in different populations,
  - the extent to which algorithmic estimates predict outcomes and differences in outcomes that are important to people, and
  - the confidence intervals, or degree of uncertainty, associated with algorithmic estimates of outcomes of an intervention or no intervention, and
  - How algorithmic estimates change with inclusion or exclusion of race and ethnicity.
- The need to encourage and pay for collection and reporting of granular population data to identify and address inequities.

- 1 • The need to develop guidelines and opportunities for medical education about:
  - 2 ○ race and racism,
  - 3 ○ implicit bias, and
  - 4 ○ AI technologies.
- 5 • The need to establish and apply antiracist practices and policies throughout the total lifecycle
- 6 of a clinical algorithm from conceptualization to implementation in practice.
- 7 • The need for federal support of research to advance the science of algorithm development, and
- 8 identify and advance solutions that recognize racism, rather than race, as the driver of racial
- 9 health inequities.
- 10 • The need for clear accountability and metrics of equitable access to care.

## 11 AMA ENGAGEMENT

12  
13  
14 The need for collaboration emerged as a dominant theme among respondents to the Committee on  
15 Ways and Means, one that AMA, with its power to convene, is well-positioned to address. As part  
16 of its larger mission to improve health equity nationwide, AMA is exploring opportunities to  
17 engage stakeholders across multiple domains.

18  
19 Initiatives under development by the AMA Center for Health Equity provide an overarching  
20 framework for AMA engagement. Notably, collaboration with the Institute for Healthcare  
21 Improvement (IHI) will address issues at the level of health care institutions and health systems.  
22 The AMA-IHI Equity Campaign is designed to help institutions build equity and racial justice into  
23 their operations in all domains, from quality, safety, data, and education to place-based equity-  
24 focused anchor mission strategies that center community and marginalized voices.

25  
26 Going forward, clinical algorithms must address the fact that in health datasets, race and ethnicity  
27 are proxies, not for ancestry or genetics, but for nonbiological causal factors such as social  
28 determinants of health and the effects of systemic racism. This has led to calls, such as those that  
29 surfaced in responses to the Committee on Ways and Means, to replace race/ethnicity with more  
30 appropriate data elements in EHRs, registries, and research datasets.

31  
32 Further, race/ethnicity data currently available are problematic in that they are in some instances  
33 self-reported by patients and in others ascribed to patients by researchers and clinicians, with the  
34 latter approach more subject to error than the former. Furthermore, the options offered to reporters  
35 have varied as societal perspectives on race and ethnicity have changed over time. Some early data  
36 systems and evidence reports have limited choices or analyses to White and non-White, where  
37 systems today may offer 90 or more options, including giving individuals the opportunity to self-  
38 identify as multi-racial and to decline to report.<sup>8</sup> Arriving at a meaningful consensus on how race  
39 and ethnicity should be defined and reported in clinical care and research is fundamental.

40  
41 AMA's [Integrated Health Model Initiative](#) (IHMI) is in a position to address these data issues, in  
42 particular, to introduce and advocate for appropriate data elements to replace race/ethnicity where  
43 they have served as proxies for biological risk factors. IHMI is a founding member of [The Gravity](#)  
44 [Project](#), a consensus-building community that "seeks to identify coded data elements and  
45 associated value sets to represent social determinants of health data documented in EHRs" for  
46 screening, diagnosis, planning, and intervention.

47  
48 Input from the medical specialty societies and other organizations that have expertise and direct  
49 experience in developing and using clinical algorithms will be key to understanding the range of  
50 algorithms currently in use and to identifying if and where bias and racism exist in these tools as a

first step to ensuring that they do not adversely affect health and access to care among marginalized and minoritized communities.

Following the publication of “Hidden in Plain Sight: Reconsidering the Use of Race Correction in Clinical Algorithms” in the *New England Journal of Medicine* more than a year ago,<sup>2</sup> the AMA communicated with the American College of Cardiology and the leadership of its National Cardiovascular Data Registry and the American College of Obstetricians and Gynecologists, as well as the Society of Thoracic Surgery (STS) and leadership of the STS Database and, subsequently, other stakeholder organizations, to gauge interest in convening a work group to address issues surfaced in the article.

AMA looks to engage specialty societies within the Federation, as well as clinical registry stewards and subject matter experts within and outside AMA, more broadly in 2022 to map more completely existing clinical algorithms and stakeholders’ understandings of the challenges and opportunities they pose. We intend to provide a collaborative space in which stakeholders can share expertise and insights, regardless of their current or previous level of engagement with clinical algorithms, toward identifying key principles for antiracist design and implementation of clinical algorithms.

To be clear, it is not the intent of the AMA to eliminate the collection of race and ethnicity data. AMA recognizes that there is value in that data as it strives to overcome U.S. medicine’s history of bias based on race and ethnicity. Absent such collection, it may be impossible to know if progress is being made and to what approaches such progress can be attributed. The AMA intends to convene organizations that are committed to making such progress and to sharing their expertise and experience and best practices, to make recommendations in support of equitable health outcomes.

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## OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS\*

CEJA Opinion 1-N-21

Subject: Amendment to Opinion 9.3.2, “Physician Responsibilities to Impaired Colleagues”

Presented by: Alexander M. Rosenau, DO, Chair

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### INTRODUCTION

At the June 2021 Special Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 3, “Amendment to Opinion 9.3.2, ‘Physician Responsibilities to Impaired Colleagues.’” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

#### E-9.3.2 – Physician Responsibilities to Colleagues with Illness, Disability or Impairment

Providing safe, high-quality care is fundamental to physicians’ fiduciary obligation to promote patient welfare. Yet a variety of physical and mental health conditions—including physical disability, medical illness, and substance use—can undermine physicians’ ability to fulfill that obligation. These conditions in turn can put patients at risk, compromise physicians’ relationships with patients, as well as colleagues, and undermine public trust in the profession.

While some conditions may render it impossible for a physician to provide care safely, with appropriate accommodations or treatment many can responsibly continue to practice, or resume practice once those needs have been met. In carrying out their responsibilities to colleagues, patients, and the public, physicians should strive to employ a process that distinguishes conditions that are permanently incompatible with the safe practice of medicine from those that are not and respond accordingly.

As individuals, physicians should:

- (a) Maintain their own physical and mental health, strive for self-awareness, and promote recognition of and resources to address conditions that may cause impairment.
- (b) Seek assistance as needed when continuing to practice is unsafe for patients, in keeping with ethics guidance on physician health and competence.

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\* Opinions of the Council on Ethical and Judicial Affairs will be placed on the Consent Calendar for informational reports, but may be withdrawn from the Consent Calendar on motion of any member of the House of Delegates and referred to a Reference Committee. The members of the House may discuss an Opinion fully in Reference Committee and on the floor of the House. After concluding its discussion, the House shall file the Opinion. The House may adopt a resolution requesting the Council on Ethical and Judicial Affairs to reconsider or withdraw the Opinion.

1 (c) Intervene with respect and compassion when a colleague is not able to practice safely.  
2 Such intervention should strive to ensure that the colleague is no longer endangering  
3 patients and that the individual receive appropriate evaluation and care to treat any  
4 impairing conditions.

5  
6 (d) Protect the interests of patients by promoting appropriate interventions when a colleague  
7 continues to provide unsafe care despite efforts to dissuade them from practice.

8  
9 (e) Seek assistance when intervening, in keeping with institutional policies, regulatory  
10 requirements, or applicable law.

11  
12 Collectively, physicians should nurture a respectful, supportive professional culture by:

13  
14 (f) Encouraging the development of practice environments that promote collegial mutual  
15 support in the interest of patient safety.

16  
17 (g) Encouraging development of inclusive training standards that enable individuals with  
18 disabilities to enter the profession and have safe, successful careers.

19  
20 (h) Eliminating stigma within the profession regarding illness and disability.

21  
22 (i) Advocating for supportive services and accommodations to enable physicians who require  
23 assistance to provide safe, effective care.

24  
25 (j) Advocating for respectful and supportive, evidence-based peer review policies and  
26 practices that will ensure patient safety and practice competency. (II)

# REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-N-21

Subject: Drug Shortages: 2021 Update

Presented by: Alexander Ding, MD, MS, MBA, Chair

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## INTRODUCTION

American Medical Association (AMA) Policy H-100.956, “National Drug Shortages,” directs the Council on Science and Public Health (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

## METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2018 to August 2021, using the text term “drug shortages.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine (NASEM), U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), Duke Margolis Center for Health Policy, and by direct contact with key FDA, ASHP, and University of Utah Drug Information Service (UUDIS) staff who monitor drug shortages and related issues daily.

## BACKGROUND

CSAPH has issued eleven reports on drug shortages.<sup>1-11</sup> The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15, “National Drug Shortages: Update.”<sup>4</sup> The remainder of this informational report will provide an update on drug shortages since the 2020 report was developed, specifically commenting on issues associated with the drug supply chain that lead to drug shortages.

## CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing public health concern in the United States and the AMA continues to monitor the situation and take action when appropriate. Overall, new drug shortages are decreasing; however, a large number of shortages are still ongoing and pose continued problems for patient care. Additionally, new shortages may occur as manufacturing capacity in the pharmaceutical industry is prioritized during the continuing COVID-19 public health emergency, specifically for the production of COVID-19 vaccines and treatments.

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by ASHP in cooperation with the UUDIS (see Box 1 for links to these resources).<sup>12,13</sup>

## *ASHP and UUDIS*

According to the most recent data compiled by ASHP and UUDIS, provided in Appendix 1 of this report, there were 129 new shortages reported in 2020 and 38 new shortages reported as of June 30, 2021; this is compared to the 166 new shortages reported for 2019. The number of active drug shortages has decreased to 236 in the second quarter of 2021 from 271 in quarter one of this year. In 2019, 39 percent of shortages were in injectable drugs; this increased to 50 percent in 2020 and is currently at 47 percent for 2021. The top five classes of drugs implicated in active drug shortages include CNS medications (43); cardiovascular medications (31); antimicrobials (26); chemotherapy agents (19); and hormonal agents (19).<sup>14</sup>

The reasons for drug shortages vary and unknown/unreported reasons account for 57 percent of drug shortages in 2020, down from 82 percent in 2019 (See Appendix for ASHP/UUDIS data).<sup>14</sup> In the past year, significantly more suppliers did provide a reason for shortages. Additionally, “business decision” is included as a reason in 2020, with 14 percent of manufacturers reporting this as the reason for a shortage.

The ASHP Shortage Resource Center provides a list of shortages, guidance on managing critical shortages, as well as shortage metrics (Box 1).<sup>12</sup>

## *FDA*

The FDA continues to utilize a mobile app to provide up-to-date access to information about drugs in shortage as well as notifications about new and resolved drug shortages. This mobile app also gives physicians the ability to report a drug shortage. The FDA Drug Shortages webpage includes a current shortages list, a link to the mobile app, and additional information (Box 1).<sup>13</sup>

The eighth annual report on drug shortages from the FDA to Congress published in early 2021 summarizes the major actions the FDA took in calendar year 2020 related to drug shortages.<sup>15</sup> During the COVID-19 pandemic in 2020, FDA continued to closely monitor the medical product supply chain and, as expected, the supply chain was impacted by the pandemic, leading to supply disruptions or shortages of drug products in the United States. Appendix 2 includes a breakdown of the FDA’s calendar year 2020 metrics, including the number of expedited reviews (471) and expedited inspections (19).<sup>15</sup>

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law on March 27, 2020, to aid response efforts to the COVID-19 pandemic and to ease the economic impact of COVID-19.<sup>16</sup> In addition, the CARES Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include authorities intended to enhance FDA’s ability to identify, prevent, and mitigate possible drug shortages by, among other things, enhancing FDA’s view into drug supply chains.<sup>17</sup> Specific authorities to enhance FDA’s ability to identify, prevent, and mitigate drug shortages took effect on September 23, 2020 and include the following:<sup>18</sup>

- Amendments to expand the requirement for manufacturers of certain drugs to provide information on permanent discontinuances and interruptions in manufacturing that may lead to a meaningful disruption in supply to FDA.
- Amendments to require FDA to prioritize and expedite, as appropriate, the review of certain applications and inspections that could help mitigate or prevent a shortage of a drug covered by section 506C(a).
- The addition of a section of the code of federal regulations requiring manufacturers of drugs described in section 506C(a) of the FD&C Act or of any active pharmaceutical ingredient (API) or any associated medical device used for preparation or administration



- included in the drug to develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates the risks to the supply of the drug, as applicable, for each establishment in which the drug or API of the drug is manufactured.
- Amendments to require drug manufacturers registered under section 510 of the FD&C Act to annually report on the amount of each drug that they have “manufactured, prepared, propagated, compounded, or processed” for commercial distribution.

## DRUG SHORTAGES AND COVID-19

The FDA reports that it has been closely monitoring the supply chain with the expectation that the COVID-19 pandemic would likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products in the United States. The COVID-19 pandemic has also increased the risks of shortages due to sudden increases in demand for drugs used in hospitalized patients, particularly the most critically ill. To respond to this risk, Drug Shortage Staff within the FDA’s Center for Drug Evaluation and Research (CDER) has asked manufacturers to evaluate their entire supply chain, including key starting materials, APIs, finished dose forms, packaging components, and any other components that may be impacted in any area of the supply chain due to the COVID-19 outbreak.

FDA reports proactively reaching out to manufacturers as part of an approach to identify potential disruptions or shortages and notes that the Agency will use all available tools to react swiftly and mitigate the impact to U.S. patients and health care professionals when a potential disruption or shortage is identified.

### *Actemra/RoActemra (tocilizumab)*

Recently, Roche reported that the demand for Actemra/RoActemra (tocilizumab), a drug widely used to treat hospitalized patients with severe or critical COVID-19 around the world, has increased to unprecedented levels globally.<sup>19</sup> Actemra/RoActemra is not approved for the treatment of COVID-19 in any country but was recently granted an Emergency Use Authorization in the United States for hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).<sup>20</sup> Additionally, tocilizumab has also now been included in the World Health Organization (WHO) Therapeutics and COVID-19 Living Guideline, based on the body of evidence that has been generated throughout the last 18 months. A statement from Roche acknowledges the increase in demand and the global shortage of the drug and also details the company’s efforts to minimize the impact of global supply constraints.<sup>19</sup> ASHP has developed an information sheet regarding the tocilizumab shortage.<sup>21</sup>

## DRUG SUPPLY CHAIN AND DRUG SHORTAGES

Over the last several years, natural disasters, quality problems, manufacturer consolidation, and other issues have disrupted pharmaceutical manufacturing and have left the U.S. healthcare system on the brink of a significant public health crisis multiple times. The COVID-19 public health emergency further underscored the vulnerability of our nation’s healthcare supply chain and stress-tested supply chains, highlighting the fragilities and deficiencies.

Considerable attention has been focused on supply chain resilience in the past several months. This year, the FDA has published several guidance documents related to supply chain security,<sup>22</sup> the White House released a report and fact sheet on policies to support the creation of resilient supply

1 chains,<sup>23,24</sup> and The Duke-Margolis Center for Health Policy and the COVID Collaborative  
2 released a new white paper on challenges and potential solutions for resilient drug supply chains  
3 that complements the White House reports.<sup>25</sup> All of these publications address aspects of AMA  
4 policy regarding drug shortage, including calls for increased transparency, global cooperation,  
5 resiliency and redundancy in manufacturing capability, and the creation of a quality rating system.

## 6 7 CURRENT AMA DRUG SHORTAGE ACTIVITIES

8  
9 AMA staff continue to remain engaged in drug shortage activities. Staff are involved in a multi-  
10 stakeholder effort to remain current on policies, drug shortage and supply chain issues, and to  
11 develop group recommendations on the topics. The effort includes the AMA, the ASHP, the  
12 American Hospital Association (AHA), the United States Pharmacopeia (USP), the American  
13 Society of Anesthesiologists (ASA), and the American Society of Clinical Oncology (ASCO).  
14 Earlier this year, the group sent a letter to the Secretary of Health and Human Services and leaders  
15 in the office of the Assistant Secretary for Preparedness and Response (ASPR) offering to assist the  
16 administration in its efforts to improve our nation's healthcare supply chains and specifically  
17 noting that:

18  
19 For a number of years, we have worked collaboratively to address drug shortages. Recently,  
20 our organizations have begun developing consensus recommendations on a number of other  
21 supply chain issues, including Strategic National Stockpile (SNS) enhancement, visibility into  
22 supply chains, quality and manufacturing improvement (e.g., reducing contamination in  
23 finished pharmaceuticals), and medical supply and medical device supply chain reinforcement.  
24 We would welcome the opportunity to meet with you to share these recommendations, which  
25 are drawn from our members' expertise and their real-world experience with utilizing complex,  
26 and sometimes fragile, medical supply chains. We greatly appreciate the work ASPR and FDA  
27 are already undertaking on EO 14017, and we look forward to continuing to work closely with  
28 you.

## 29 30 SUMMARY

31  
32 The rate of new medical product shortages is decreasing, but the current COVID-19 public health  
33 emergency requires continued diligence in monitoring any shortage or supply chain issues due to  
34 manufacturing capacity prioritization for COVID-19 vaccines and treatments.

35  
36 The AMA's drug shortage policy is timely and already addresses a variety of issues that are under  
37 consideration by the White House, FDA, and other stakeholders including the improvement of  
38 quality assurance systems; expedited facility inspections and manufacturing  
39 changes/improvements; necessary resiliency and redundancy in manufacturing capability;  
40 evaluation of root causes of drug shortages; transparent analysis of economic drivers and  
41 reasonable and sustainable payment rates for prescription drugs; greater transparency of the  
42 manufacturing process; and including drug manufacturing sites as part of the nation's critical  
43 infrastructure plan. Therefore, the Council feels that an update to AMA policy is not warranted at  
44 this time.

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- [iGBVyPjaqLAy9GDCWfBvrcsgX8L8qWnKPLxIoh5xvWbRDA&utm\\_content=150263261&utm\\_source=hs\\_email](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-treatment-covid-19). Published August 16, 2021. Accessed August 17, 2021.
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**Box 1. Resources available to assist in mitigation of drug shortages.**

1. [ASHP Resource Center](#)
2. ASHP [list](#) of current shortages
3. [FDA Drug Shortages Page](#) (includes current shortages list, mobile app, and additional information)

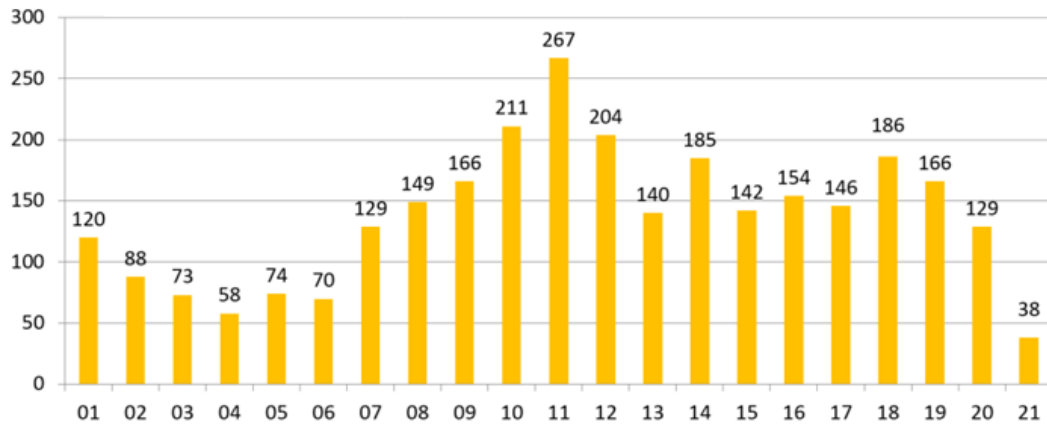
## APPENDIX 1

### ASHP/University of Utah Drug Information Service Drug Shortage Data

**Figure 1.**

#### National Drug Shortages: New Shortages by Year

January 2001 to June 30, 2021



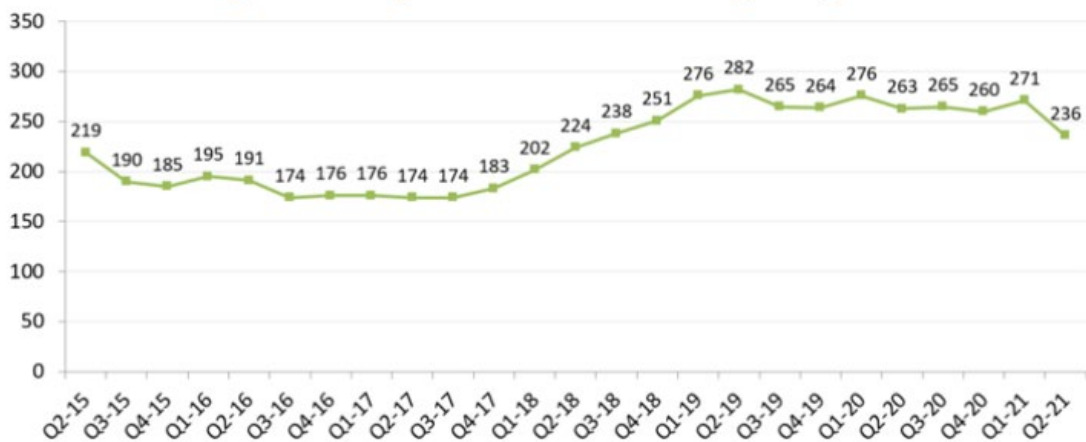
**Note:** Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

Contact: [Erin.Fox@hsc.utah.edu](mailto:Erin.Fox@hsc.utah.edu), [@foxerinr](https://twitter.com/foxerinr) for more information.

**Figure 2.**

#### National Drug Shortages: Active Shortages by Quarter



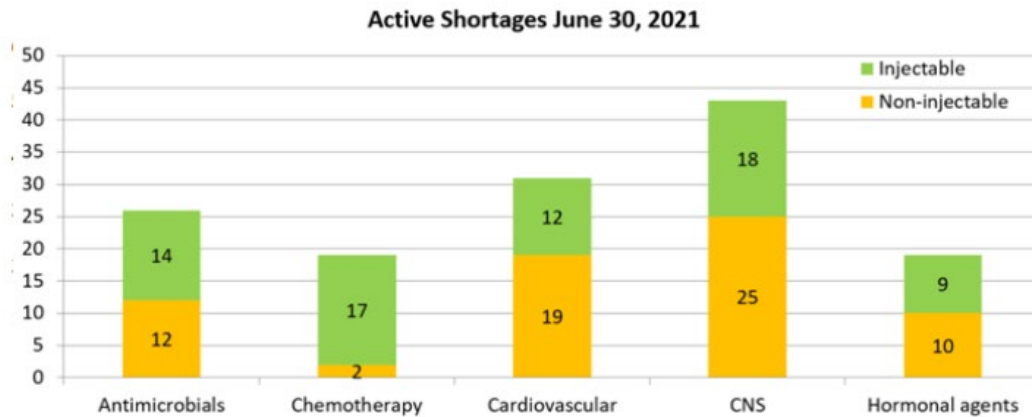
**Note:** Each point represents the number of active shortages at the end of each quarter.

University of Utah Drug Information Service

Contact: [Erin.Fox@hsc.utah.edu](mailto:Erin.Fox@hsc.utah.edu), [@foxerinr](https://twitter.com/foxerinr) for more information.

Figure 3.

### National Drug Shortages: Active Shortages Top 5 Drug Classes



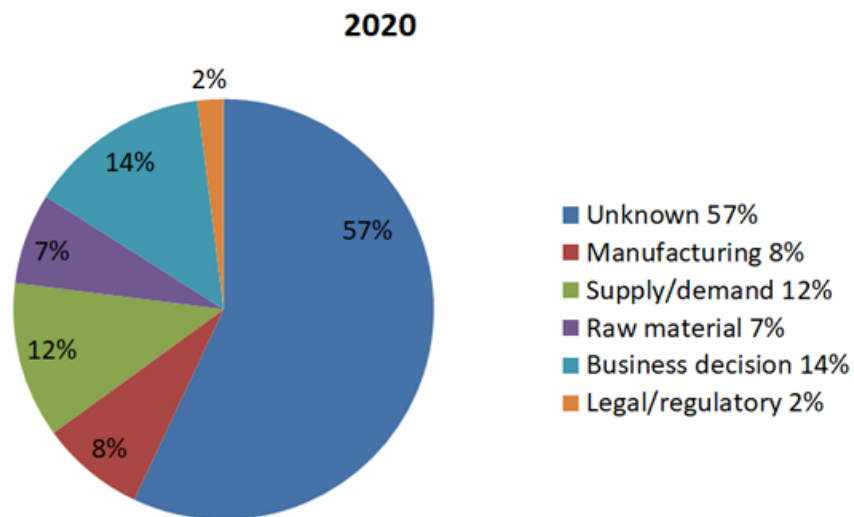
University of Utah Drug Information Service

Contact: [Erin.Fox@hsc.utah.edu](mailto:Erin.Fox@hsc.utah.edu), [@foxeinr](https://twitter.com/foxeinr) for more information.

Figure 4.

### National Drug Shortages

Reasons for Shortages as Determined by UUDIS During Investigation — 2020



University of Utah Drug Information Service

Contact: [Erin.Fox@hsc.utah.edu](mailto:Erin.Fox@hsc.utah.edu), [@foxeinr](https://twitter.com/foxeinr) for more information.

## APPENDIX 2

## FDA Drug Shortage Data

**Breakdown of CDER's and CBER's Shortage Numbers, CY 2020**

	<b>CDER</b>	<b>CBER</b>
New Shortages	43	0
Prevented Shortages	179	20
Ongoing Shortages	78	8
Notifications	473	39
No. of Manufacturers Notifying	93	29
<b>ACTIONS TAKEN TO MITIGATE SHORTAGES</b>		
Regulatory Flexibility and Discretion	110	1
Expedited Reviews	471	18*
Expedited Inspections	19	0

\* This number includes expedited reviews for nine biologics license application (BLA)/BLA supplements and nine lot-release submissions for CBER-regulated products.