

HHS Office for Civil Rights in Action



July 20, 2020

BULLETIN: Civil Rights Protections Prohibiting Race, Color and National Origin Discrimination During COVID-19

Application of Title VI of the Civil Rights Act of 1964

As part of the national response to the COVID-19 public health emergency,¹ the U.S. Department of Health and Human Services (HHS) has provided substantial Federal financial assistance to state and local agencies, hospitals, and other healthcare providers on the front lines of the COVID-19 response.²

The Office for Civil Rights (OCR) continues to issue guidance³ to ensure that the recipients of this Federal financial assistance understand that they must comply with applicable Federal civil rights laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs. This Bulletin focuses on recipients' compliance with the prohibitions against race, color, and national origin discrimination contained in Title VI of the Civil Rights Act of 1964 (Title VI).

Title VI states that “[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.”⁴ Title VI prohibits both intentional discrimination⁵ and methods of administration that have a disproportionate and adverse impact on the basis of race, color, or national origin.⁶ Title VI’s implementing regulation explains that a recipient may not:

... utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.⁷

While OCR is responsible for enforcing Title VI, our HHS partners are taking steps to identify the populations most vulnerable to COVID-19 and to improve prevention, testing, and treatment in

those populations.⁸ For example, the Centers for Disease Control and Prevention (CDC) have reported that “current data suggest a disproportionate burden of illness and death among racial and ethnic minority groups,”⁹ including African American, Hispanic, and Native American populations. Additionally, several states, including Arizona,¹⁰ Illinois,¹¹ Michigan,¹² New Mexico,¹³ New York,¹⁴ and South Carolina,¹⁵ have identified racial and ethnic disparities in COVID-19 cases and deaths.

In response, CDC has appointed a COVID-19 Chief Health Equity Officer¹⁶ and augmented nationwide data collection to track COVID-19 cases, hospitalizations,¹⁷ and deaths, by race and ethnicity.¹⁸ Moreover, the National Institutes of Health (NIH), including the National Institute on Minority Health and Health Disparities (NIMHD), have issued funding opportunities for urgent research to understand the social, behavioral, and economic health impacts of COVID-19 on health disparity and other vulnerable populations.¹⁹ In addition, the NIH Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP) Initiative will support implementation science projects to provide access to diagnostic testing in underserved communities.²⁰

On the ground, the HHS Office of Minority Health has entered into a cooperative agreement to build the “National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities Initiative.” The Morehouse School of Medicine, as the principal awardee, will lead the Initiative to coordinate a strategic network of state, territorial, tribal, community, and faith-based organizations to disseminate culturally and linguistically diverse COVID-19 information nationwide; support linkages to testing, vaccination, healthcare and social services in communities hardest hit by the pandemic; and deliver COVID-19 response, recovery, and resilience strategies to minority, rural, and socially vulnerable communities.²¹ The Health Resources and Services Administration (HRSA) also has made awards to over 4,500 rural health clinics²² and 1,385 community health centers in all 50 states, the District of Columbia, and eight U.S. territories to expand COVID-19 testing.²³ This is in addition to existing Community-Based Testing Sites,²⁴ including testing sites in pharmacies and retail chains.²⁵ Similarly, the Indian Health Service (IHS) has provided additional allocations to IHS, Tribal, and Urban Indian Health programs to expand testing capacity and related surveillance activities.²⁶

“HHS is committed to helping populations hardest hit by COVID-19, including African-American, Native American, and Hispanic communities,” said Roger Severino, OCR Director. “This guidance reminds providers that unlawful racial discrimination in healthcare will not be tolerated, especially during a pandemic.”

To help ensure Title VI compliance during the COVID-19 public health emergency, recipients of Federal financial assistance, including state and local agencies, hospitals, and other health care providers, should:

- Adopt policies to prevent and address harassment or other unlawful discrimination on the basis of race, color, or national origin.²⁷

- Ensure – when site selection is determined by a recipient of HHS funds – that Community-Based Testing Sites and Alternate Care Sites,²⁸ are accessible to racial and ethnic minority populations.²⁹ For example, to support this end, recipients may consider making walk-in testing sites available in urban areas where racial and ethnic minority populations may not have access to vehicle transportation, or providing home visitation testing in rural areas where transportation is a challenge for racial and ethnic minorities.
- Confirm that existing policies and procedures with respect to COVID-19 related services (including testing) do not exclude or otherwise deny persons on the basis of race, color, or national origin.³⁰
- Ensure that individuals from racial and ethnic minority groups are not subjected to excessive wait times, rejected for hospital admissions, or denied access to intensive care units compared to similarly situated non-minority individuals.³¹
- Provide ambulance service, non-emergency medical transportation, and home health services – if part of the program or services offered by the recipient – to all neighborhoods within the recipient’s service area, without regard to race, color, or national origin.³²
- Appoint or select individuals to participate as members of a planning or advisory body, which is an integral part of the recipient’s program, without exclusions on the basis of race, color, or national origin.³³
- Assign staff, including physicians, nurses, and volunteer caregivers, without regard to race, color, or national origin. Recipients should not honor a patient’s request for a same-race physician, nurse, or volunteer caregiver.³⁴
- Assign beds and rooms, without regard to race, color, or national origin. For multi-bed rooms, recipients should not grant a patient’s request to exclude a roommate of a particular race; and for single-bed rooms, recipients should assign patients in a non-discriminatory manner.³⁵
- Make available to patients, beneficiaries, and customers information on how the recipient does not discriminate on the basis of race, color, or national origin in accordance with applicable laws and regulations.³⁶

During these challenging times, recipients of Federal financial assistance, including state and local agencies, hospitals, and other health care providers, should continue to take steps to serve the whole community, while providing culturally appropriate messaging to individuals with limited English proficiency; racial and ethnic minority populations; community-based organizations; social service providers; and diverse faith communities. As part of the Federal response to this public health emergency, OCR will continue to work in close coordination with our HHS partners and recipients to remove discriminatory barriers which impede equal access to quality health care, recognizing the high priority of COVID-19 testing and treatment.

Additional Resources

To learn more about non-discrimination on the basis of race, color, national origin, sex, age, and disability; conscience and religious freedom; and health information privacy laws, and to file a complaint with OCR, please visit: <https://www.hhs.gov/ocr/index.html>.

To read OCR's March 28, 2020 *BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)*, please visit: <https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>.

To read OCR's May 15, 2020 *BULLETIN: Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19*, please visit: <https://www.hhs.gov/sites/default/files/lep-bulletin-5-15-2020-english.pdf>.

For a directory of HRSA testing sites (located in health centers), by state, please visit: www.bphc.hrsa.gov/emergency-response/expanding-capacity-coronavirus-testing-FY2020-awards.

For a directory of HHS Public-Private Partnership testing sites (located in pharmacies and retail chains), by state, please visit: <https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html>.

For more resources on COVID-19, civil rights, and health information privacy, please visit: <https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html> and <https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html>.

For general information regarding COVID-19, please visit: <https://www.coronavirus.gov>.

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DISCLAIMER:

Effective February 4, 2020, the HHS Secretary's "Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19" may apply with respect to some private claims arising from the use or administration of a covered countermeasure and may provide immunity from certain liability under civil rights laws.³⁷

This guidance document is not a final agency action and may be rescinded or modified in the Department's discretion. Noncompliance with any voluntary standards or suggested practices contained in guidance documents not required by law will not, in itself, result in any enforcement action.

¹ The Secretary declared a Public Health Emergency, January 31, 2020, under Section 319 of the Public Health Service Act (42 U.S.C. § 247d) in response to COVID-19. See U.S. Dep’t of Health and Hum. Servs., *Secretary Declares Public Health Emergency for United States for 2019 Novel Coronavirus* (Jan. 31, 2020), <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html>. This declaration was renewed on April 20, 2020. See U.S. Dep’t of Health and Hum. Servs., *Renewal of Determination That A Public Health Emergency Exists* (Apr. 21, 2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx>.

This guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA). See 5 U.S.C. § 553 (b) (A). The Office for Civil Rights finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date. See 5 U.S.C. § 553 (b) (B) & (d) (3).

² See, e.g., U.S. Dep’t of Health and Hum. Servs., *HHS Announces Enhanced Provider Portal, Relief Fund Payments for Safety Net Hospitals, Medicaid & CHIP Providers* (June 9, 2020), <https://www.hhs.gov/about/news/2020/06/09/hhs-announces-enhanced-provider-portal-relief-fund-payments-for-safety-net-hospitals-medicare-chip-providers.html>.

³ See U.S. Dep’t of Health and Human Servs., Office for Civil Rights, *BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)* (Mar. 28, 2020), <https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>; and U.S. Dep’t of Health and Human Servs., Office for Civil Rights, *BULLETIN: Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19* (May 15, 2020), <https://www.hhs.gov/sites/default/files/lep-bulletin-5-15-2020-english.pdf>.

⁴ 42 U.S.C. § 2000d. Section 1557 of the Patient Protection and Affordable Care Act (ACA) also prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity that receives Federal financial assistance from HHS, or under any program or activity that is administered by an executive agency under Title I of the ACA or by an entity established under Title I. See Patient Protection and Affordable Care Act of 2010, § 1557, 42 U.S.C. § 18116, and its implementing regulation, U.S. Dep’t of Health and Human Servs., *Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority*, 85 Fed. Reg. 37160 (June 19, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-06-19/pdf/2020-11758.pdf>. Section 1557 references Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d-2000d7; Title IX of the Education Amendments of 1972, 20 U.S.C. §§ 1681-1688; the Age Discrimination Act of 1975, 42 U.S.C. §§ 6101-6107; and Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794. Section 1557 further provides that “[t]he enforcement mechanisms provided for and available” under these laws “shall apply for purposes of violations” of Section 1557. 42 U.S.C. § 18116(a).

⁵ See 45 C.F.R. § 80.3(a)-(b)(2005).

⁶ See 45 C.F.R. § 80.3(b)(2).

⁷ See *id.*

⁸ U.S. Dep’t of Health and Hum. Servs., *HHS Initiatives to Address the Disparate Impact of COVID-19 on African Americans and Other Racial and Ethnic Minorities* (June 8, 2020), www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf.

To prevent and treat COVID-19 in racial and ethnic minority communities, “[b]roader initiatives that address both economic opportunity and healthcare disparities are critical . . . , including the creation of Opportunity Zones, the White House Council on Eliminating Barriers to Affordable Housing, and HHS’s targeted efforts on chronic underlying health conditions such as diabetes, hypertension, maternal morbidity, and tobacco use, all of which are more prevalent among some minorities.” See *id.*

⁹ Centers for Disease Control and Prevention, *COVID-19 in Race and Ethnic Minority Groups* (June 25, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>.

Each week, CDC provides provisional death counts for coronavirus disease (COVID-19), by race and ethnicity. On July 15, 2020, CDC reported that African Americans make up a 16.9% weighted distribution of the U.S. population, but 22.9% of the COVID-19 deaths; American Indians and Alaska Natives make up a 0.3% weighted distribution of the U.S. population, but 0.7% of the COVID-19 deaths; and Hispanics or Latinos make up a 28.2% weighted distribution of the U.S. population, but 17.2% of the COVID-19 deaths. See Centers for Disease Control and Prevention, *Weekly Updates by Select Demographic and Geographic Characteristics - Provisional Death Counts for Coronavirus Disease (COVID-19)*, at Table 2a (July 15, 2020), www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#Race_Hispanic. CDC explains that:

[T]he majority of COVID-19 deaths have occurred in New York City and other more urban areas where the racial distribution is different than the racial distribution of the United States. The weighted populations reflect the population distribution of the areas experiencing the greatest number of COVID-19 deaths which tend to have a smaller percent of their populations that are non-Hispanic white and . . . larger percentages that are non-Hispanic black, non-Hispanic Asian, or Hispanic. As a consequence, the disproportionate impact of COVID-19 mortality among some groups is smaller after ensuring that the population estimates and percentages of COVID-19 deaths are more comparable on the basis of geography. See *id.*

¹⁰ Native Americans make up 4.5% of Arizona’s population, but 6% of the COVID-19 cases and 14% of the deaths. Compare U.S. Census Bureau, *American Community Survey* (2018), <https://www.census.gov/acs/www/data/data-tables-and-tools/data-profiles> (hereinafter U.S. Census Bureau), with Arizona Dep’t of Health Servs., *COVID-19 Data Dashboard* (July 17, 2020), <https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php>.

¹¹ African Americans make up 14.2% of Illinois’ population, but 16.8% of the COVID-19 cases and 27.6% of the deaths. Hispanics/Latinos make up 17% of Illinois’ population, but 31.5% of the COVID-19 cases and 20.7% of the deaths. Compare U.S. Census Bureau, with Illinois Dep’t of Public Health, *COVID-19 Statistics* (July 16, 2020), <https://www.dph.illinois.gov/covid19/covid19-statistics>.

¹² African Americans make up 13.8% of Michigan’s population, but 29.2% of the COVID-19 cases and 39.5% of the deaths. Compare U.S. Census Bureau, with Michigan Dep’t of Health & Hum. Servs., *COVID-19 Cases by Race* (July 17, 2020), www.michigan.gov/coronavirus/0,9753,7-406-98163_98173---,00.html.

¹³ American Indians make up 9.6% of New Mexico’s population, but 42.4% of the COVID-19 cases. Compare U.S. Census Bureau with New Mexico Dep’t of Health, *COVID-19 Public Dashboard* (July 16, 2020), <https://cvprovider.nmhealth.org/public-dashboard.html>.

¹⁴ For New York State, excluding New York City, African Americans make up 9% of the population, but 17% of the COVID-19 deaths; and Hispanics/Latinos make up 12% of the population, but 14% of the COVID-19 deaths. For New York City, African Americans make up 22% of the population, but 28% of the COVID-19 deaths; and Hispanics/Latinos make up 29% of the population, but 34% of the COVID-19 deaths. See New York St. Dep’t of Health, *COVID-19 Fatalities* (July 17, 2020), <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-Fatalities?%3Aembed=yes&%3Atoolbar=no&%3Atabs=n>.

¹⁵ African Americans make up 27% of South Carolina’s population, but 33% of the COVID-19 cases and 42% of the deaths. Hispanics/Latinos make up 5.6% of South Carolina’s population, but 11% of the COVID-19 cases and 4% of the deaths. Compare U.S. Census Bureau, with South Carolina Dep’t of Health & Envtl., *Demographic Data (COVID-19)*, (July 14, 2020), <https://www.scdhec.gov/infectious-diseases/viruses/coronavirus-disease-2019-covid-19/sc-demographic-data-covid-19>.

¹⁶ Centers for Disease Control and Prevention, *Health Equity Matters Newsletter: CDC’s New COVID-19 Chief Health Equity Officer* (June 16, 2020), <https://www.cdc.gov/minorityhealth/newsletter/2020/summer/announcements.html>.

¹⁷ CDC reports racial and ethnic health disparities in COVID-19 hospitalization rates: “Non-Hispanic American Indian or Alaska Native persons have an age-adjusted hospitalization rate approximately 5.6 times that of non-Hispanic White persons and non-Hispanic Black persons and Hispanic or Latino persons have a rate approximately 4.6 times that of non-Hispanic White persons.” Centers for Disease Control and Prevention, *COVIDView: A Weekly Surveillance Summary of U.S. COVID-19 Activity* (July 17, 2020) (analyzing data from a surveillance system which covers 10% of the U.S. population and reports lab-confirmed COVID-19 hospitalization rates occurring in 250 acute care hospitals, located in 99 counties, across 14 states), www.cdc.gov/coronavirus/2019-ncov/covid-data/pdf/covidview-07-17-2020.pdf.

¹⁸ See Centers for Disease Control and Prevention, *COVID-19 in Race and Ethnic Minority Groups* (June 25, 2020), www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html. See also U.S. Dep’t of Health and Hum. Servs., *HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing* (June 4, 2020) (issuing guidance on reporting COVID-19 demographic data, as required by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. Law No. 116-136, § 18115(a)(2020)), <https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html>.

¹⁹ See National Institutes of Health, *Community Interventions to Address the Consequences of the COVID-19 Pandemic among Health Disparity and Vulnerable Populations (R01- Clinical Trial Optional)* (June 17, 2020), <https://grants.nih.gov/grants/guide/pa-files/PAR-20-237.html>.

²⁰ See National Institutes of Health, *Rapid Acceleration of Diagnostics (RADx) – RADx Underserved Populations (RADx-UP)* (July 6, 2020), <https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-up>.

²¹ See U.S. Dep’t of Health and Hum. Servs., *HHS Announces Partnership with Morehouse School of Medicine to Fight COVID-19 in Racial and Ethnic Minority and Vulnerable Communities - \$40 Million Initiative Will Help Communities Hardest Hit by the Pandemic* (June 23, 2020), <https://www.hhs.gov/about/news/2020/06/23/hhs-announces-partnership-morehouse-school-medicine-fight-covid-19-racial-ethnic-minority.html>.

²² See U.S. Dep’t of Health and Hum. Servs., *HHS Provides \$225 Million for COVID-19 Testing in Rural Communities* (May 20, 2020), <https://www.hhs.gov/about/news/2020/05/20/hhs-provides-225-million-for-covid19-testing-in-rural-communities.html>. See also Health Resources & Servs. Admin., *Allocation to Rural Health Clinics for COVID-19 Testing* (May 7, 2020), <https://www.hrsa.gov/rural-health/coronavirus/rural-health-clinics-covid-19-testing-fy20-awards>.

²³ See U.S. Dep’t of Health and Hum. Servs., *HHS Awards More than Half Billion Dollars Across the Nation to Expand COVID-19 Testing* (May 7, 2020), <https://www.hhs.gov/about/news/2020/05/07/hhs-awards-more-than-half-billion-across-the-nation-to-expand-covid19-testing.html>.

²⁴ Community-Based Testing Sites (CBTS) were developed by HHS, the U.S. Public Health Service Commissioned Corps, and the Federal Emergency Management Agency. See Federal Emergency Mgmt. Agency, *Option To Transition Federal Community-Based Testing Sites To State Management* (Apr. 9, 2020), www.fema.gov/news-release/2020/04/09/option-transition-federal-community-based-testing-sites-state-management.

²⁵ See U.S. Dep’t of Health and Hum. Servs., *Community-Based Testing Sites for COVID-19: Public-Private Partnership* (July 6, 2020) (identifying testing sites located in pharmacies and retail chains), <https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html>.

²⁶ Letter from the Assistant Surgeon Gen. and U.S. Pub. Health Serv. Director to Tribal Leaders and Urban Indian Org. Leaders (May 19, 2020), https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/2020_Letters/DULL_DUIOLL_05192020.pdf.

²⁷ See 45 C.F.R § 80.3.

²⁸ An Alternate Care Site can provide three levels of care: (1) Non-Acute Care (“General, low-level care for mildly to moderately symptomatic COVID-19 patients.”); (2) Hospital Care (“Mid-level care for moderately symptomatic COVID-19 patients.”); and (3) Acute Care (“Higher acuity care for COVID-19 patients.”). See Centers for Disease Control and Prevention, *Alternate Care Sites* (Apr. 24, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/alternative-care-sites.html>.

²⁹ 45 C.F.R. § 80.3(b)(3) (“In determining the site or location of a facilit[y], an applicant or recipient may not make selections with the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the ground of race, color, or national origin; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the Act or this regulation.”).

³⁰ In a letter to the Secretary of HHS, the American Hospital Association (AHA), the American Medical Association (AMA), and the American Nurses Association (ANA), stated “[m]any people of color are uninsured or lack access to primary care ” and therefore have limited access to referrals for testing. See Letter from the AHA, the AMA and the ANA, to the Secretary (Apr. 16, 2020), www.aha.org/lettercomment/2020-04-16-hospitals-physicians-nurses-urge-hhs-address-covid-19-disparities.

³¹ See 45 C.F.R. § 80.3(a)-(b).

³² See *id.*

³³ See 45 C.F.R. § 80.3(b)(1)(vii).

³⁴ See 45 C.F.R. § 80.3 (b)(1)(iii). Cf. *Chaney v. Plainfield Healthcare Center*, 612 F.3d 908, 910 (7th Cir. 2010) (holding that long term care facility which acceded to a Caucasian patient’s racial bias and prohibited African American certified nursing assistant from caring for the Caucasian patient created a hostile work environment and violated Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e – 2 (a) (1)). This provision of the Title VI implementing regulation should not serve as an impediment to bilingual staff members being called upon to provide interpreter services to patients with limited English proficiency, even when the available pool of bilingual staff members is correlated to a particular national origin group.

³⁵ See 45 C.F.R. § 80.3(b)(1)(iii). See also *Cypress v. Newport News Gen. & Nonsectarian Hosp. Ass’n*, 375 F.2d 648, 657 (4th Cir. 1967) (“Our holding is simply that race cannot be a factor in the admission, assignment, classification, or treatment of patients in an institution like this, which is state-supported and receives federal funds. Room assignments may be made with due regard to sex, age, type of illness, or other relevant factors, but racial distinctions are impermissible, since the law forbids the treatment of individuals differently or separately because of their race, color, or national origin.”).

³⁶ See 45 C.F.R. § 80.6(d).

³⁷ See U.S. Dep’t of Health and Hum. Servs., Office of the Secretary, *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19*, 85 F.R. 15198–15203 (Mar. 17, 2020), www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf. See also Office of the Gen. Counsel, *Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020, Declaration Under the Act April 17, 2020, as Modified on May 19, 2020* (May 19, 2020), <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf>.