



July 6, 2021

VIA ELECTRONIC FILING TO: <http://www.regulations.gov>

Shalanda Young  
Acting Director  
The Office of Management and Budget  
725 17th Street, NW  
Washington, DC 20503

**Re: Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government**

Dear Ms. Young:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on your Request for Information (RFI), “Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government,” which was published in the *Federal Register* on May 5, 2021.

Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity and inclusion are essential to the discovery of new medicines and that people of all ethnic and racial backgrounds should have equitable access to treatment.

Our comments follow below and are focused on Area 1: Equity Assessments and Strategies, Area 2: Barrier and Burden Reduction, and Area 5: Stakeholder and Community Engagement.

Thank you for the opportunity to comment on this important matter. Please feel free to contact Courtney Christian, MPA for any questions about this comment letter.

**Contact Information**

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Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity and inclusion are essential to the discovery of new medicines and that people of all ethnic and racial backgrounds should have equitable access to treatment.<sup>2</sup> We support policies that will help achieve these goals, including improving clinical trial diversity; building a diverse workforce; investing in data infrastructure to assess disparities; filling gaps in health data to improve disparities measurement; promoting best practices to improve equity in health care screening, diagnosis, and treatment; and supporting incentives for health systems to align data and best practices. Researchers have found that there are some diseases and conditions which affect racial and ethnic communities at a higher rate than the average population, such as Alzheimer’s disease, certain cancers, chronic lung conditions, type 2 diabetes, heart conditions, HIV infection, liver disease, obesity, sickle cell disease and stroke.<sup>3</sup> Today, there are 829 medicines in development by biopharmaceutical research companies to address these diseases, all of which are in in-human clinical trials or awaiting review by the FDA.<sup>4</sup>

We commend the Office of Management and Budget (OMB) for issuing this RFI, which seeks information on many of these policies and look forward to working with OMB and other Federal agencies to achieve these goals. PhRMA is committed to closing gaps in medication access to improve the health and well-being of all Americans. We are concerned by the numerous studies demonstrating that certain racially/ethnically diverse populations have lower medication

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<sup>1</sup> 86 Fed. Reg. 24029 (May 5, 2021).

<sup>2</sup> PhRMA, “Building a Better Health Care System: PhRMA’s Patient-Centered Agenda” (available at: <https://phrma.org/report/Building-a-Better-Health-Care-System-PhRMAs-Patient-Centered-Agenda>).

<sup>3</sup> PhRMA’s Medicines in Development. 2021 Report: Health Equity. <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/MID-Reports/MID-Health-Equity-2021-Report.pdf>

<sup>4</sup> Number of medicines obtained through public government and industry sources, and the Springer “AdisInsight” database; current as of June 8, 2021

utilization and/or adherence than their white counterparts.<sup>5,6,7</sup> Evidence has shown that the downstream consequences of such medication nonadherence include increased health care costs,<sup>8</sup> poor health outcomes,<sup>9,10</sup> and increased risk of mortality.<sup>11</sup> In an effort to drive meaningful dialogue and potential solutions to these and other systemic challenges, PhRMA released a patient-centered agenda, “Building a Better Health Care System,” which demonstrates the biopharmaceutical industry’s commitment to working with all stakeholders to deliver a stronger, more resilient, affordable and equitable health care system for all.<sup>12</sup>

We support the Administration's interest in advancing health equity, particularly in Federal health care programs.<sup>13</sup> The COVID-19 pandemic has disproportionately impacted diverse and underserved communities due to factors such as inequitable access to health care, a shortage of racially/ethnically diverse health care workers, the racial wealth gap, increased rates of living in crowded housing, and systemic racism.<sup>14</sup> The pandemic’s disproportionate impact on Black and Brown communities clearly demonstrates that we can wait no longer to fix inequities in our health care system, and we look forward to supporting the Federal government in these important efforts.

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<sup>5</sup> Mehta KM, Yin M, Resendez C, Yaffe K. Ethnic differences in acetylcholinesterase inhibitor use for Alzheimer disease. *Neurology*. 2005 Jul 12;65(1):159-62. doi: 10.1212/01.wnl.0000167545.38161.48. PMID: 16009909; PMCID: PMC2830864.

<sup>6</sup> Lauffenburger JC, Robinson JG, Oramasionwu C, Fang G. Racial/ethnic and gender gaps in the use of and adherence to evidence-based preventive therapies among elderly Medicare part D beneficiaries after acute myocardial infarction. *Circulation*. 2014; 129:754–763.

<sup>7</sup> Schmittiel JA, Steiner JF, Adams AS, et al. Diabetes care and outcomes for American Indians and Alaska natives in commercial integrated delivery systems: a SURveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM) Study. *BMJ Open Diabetes Res Care*. 2014;2(1):e000043. Published 2014 Nov 17. doi:10.1136/bmjdr-2014-000043

<sup>8</sup> Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care*. 2005 Jun;43(6):521-30. doi: 10.1097/01.mlr.0000163641.86870.af. PMID: 15908846.

<sup>9</sup> Bansilal S, Castellano JM, Garrido E, Wei HG, Freeman A, Spettell C, Garcia-Alonso F, Lizano I, Arnold RJ, Rajda J, Steinberg G, Fuster V. Assessing the Impact of Medication Adherence on Long-Term Cardiovascular Outcomes. *J Am Coll Cardiol*. 2016 Aug 23;68(8):789-801. doi: 10.1016/j.jacc.2016.06.005. PMID: 27539170.

<sup>10</sup> Choudhry NK, Glynn RJ, Avorn J, Lee JL, Brennan TA, Reisman L, Toscano M, Levin R, Matlin OS, Antman EM, Shrank WH. Untangling the relationship between medication adherence and post-myocardial infarction outcomes: medication adherence and clinical outcomes. *Am Heart J*. 2014 Jan;167(1):51-58.e5. doi: 10.1016/j.ahj.2013.09.014. Epub 2013 Oct 17. PMID: 24332142.

<sup>11</sup> Khunti K, Seidu S, Kunutsor S, Davies M. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. *Diabetes Care*. 2017 Nov;40(11):1588-1596. doi: 10.2337/dc16-1925. Epub 2017 Aug 11. PMID: 28801474.

<sup>12</sup> PhRMA, “Building a Better Health Care System: PhRMA's Patient-Centered Agenda” (available at: <https://phrma.org/report/Building-a-Better-Health-Care-System-PhRMAs-Patient-Centered-Agenda>).

<sup>13</sup> Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Executive Order 13958. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

<sup>14</sup> Health Equity Considerations and Racial and Ethnic Minority Groups. Centers for Disease and Control. Updated April 9, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>

Our comments follow below and are focused on Area 1: Equity Assessments and Strategies, Area 2: Barrier and Burden Reduction, and Area 5: Stakeholder and Community Engagement.

### **Area 1: Equity Assessments and Strategies**

The OMB seeks input on approaches and methods for holistic program- and policy-specific assessments of equity and public sector entities, including the development of strategies and use of data to assess whether policies, budgets, regulations, grants, or programs are effective in advancing equity. PhRMA believes it is imperative that Federal health care agencies assess whether their future policies and regulations will reflect and achieve the Administration's stated goals of advancing equity.

#### **(1a) Methods and Practices to build evidence to reflect underserved individuals and communities**

***Build Robust Data Infrastructure.*** Failure to gather information on race and ethnicity that can improve health outcomes has allowed health disparities to persist. A robust, interoperable data infrastructure that includes consistent measures of health outcomes associated with race, ethnicity, language, and social determinants of health is imperative to assess and make progress toward equality and reducing disparities in care.<sup>15,16</sup> The current lack of disaggregated data related to race and ethnicity in Federal health care programs and beyond limits visibility into how communities are faring, and compromises efforts to measure and address health disparities. While standards exist for the collection and reporting of race, ethnicity, language, sex, and disability data in all publicly funded national administrative files and health surveys, these standards do not apply to many other reporting entities at the Federal, state, and local levels, including administrative, billing, and medical records that are key health data collection sources.<sup>17</sup> Additionally, current Federal standards are not sufficiently granular to reflect diversity, and therefore health disparities, for smaller underrepresented communities within broad categories of race and ethnicity.<sup>18</sup> PhRMA suggests that Federal regulators consider testing, piloting, and facilitating activities to generate standardized, granular data on ethnically

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<sup>15</sup> COVID-19 shows why united action is needed for more robust international health architecture. World Health Organization. 30 March 2021. <https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>

<sup>16</sup> Statement by HHS Secretary Xavier Becerra on the President's FY 2022 Discretionary Funding Request. CMS.gov. 9 Apr 2021. <https://www.hhs.gov/about/news/2021/04/09/statement-hhs-secretary-xavier-becerra-presidents-fy-2022-discretionary.html>

<sup>17</sup> Office of Management and Budget (1997). Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. <https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf>

<sup>18</sup> *Ibid.*

diverse populations in Federal health care programs, so that data representing diversity across a broad range of cultures, backgrounds and lived experiences can be synthesized.<sup>19,20</sup>

Enhancing health disparity data may also require consideration of incentives to encourage data collection and the infrastructure investment needed to facilitate interoperability. There is an opportunity for Federal programs and related entities, such as health care practices and systems, to promote data sharing to measure the uptake of underserved communities in Federal programs/activities and the impact of Federal programs and activities on closing health disparities. Electronic data sharing among plans could reduce burdens on providers and patients. For example, doctors spend about four hours per week on administrative tasks such as addressing drug formulary issues, prior authorization requests, and clarifying claims information.<sup>21</sup> Currently, fewer than 15 percent of administrative health care transactions are fully electronic, including eligibility verification, checking on claim status, prior authorization, and clinical information submitted with claims.<sup>22</sup>

We also recommend looking for opportunities to leverage existing data to better inform health care use and outcomes across important subpopulations, particularly as it relates to health disparities. These data could be conveyed in dashboard-style outputs. For example, the Centers for Medicare & Medicaid Services (CMS) publicly reports select information on the Medicare and Medicaid populations using deidentified administrative claims data. CMS' Medicare Enrollment Dashboard includes information regarding the number of Medicare beneficiaries with hospital/medical coverage and prescription drug coverage.<sup>23</sup> There also are dashboards on drug spending in Medicare Part D<sup>24</sup>, Medicare Part B<sup>25</sup> and Medicaid<sup>26</sup> that could be enhanced to

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<sup>19</sup> The Initiative on Asian Americans and Pacific Islanders. The White House. Available at:

<https://obamawhitehouse.archives.gov/administration/eop/aapi/data/data>

<sup>20</sup> U.S. Department of Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language and Disability Status. Department of Health and Human Services. October 31, 2011. Available at: <https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status#IV>

<sup>21</sup> Blanchfield et al. (2010). Saving Billions of Dollars- And Physicians' Time-By Streamlining Billing Practices. *Health Affairs*, 29(6), 1248-1254. Retrieved from <https://www.healthaffairs.org/doi/10.1377/hlthaff.2009.0075>

<sup>22</sup> CAQH, 2018 CAQH Index: A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings, 2019. <https://www.caqh.org/sites/default/files/explorations/index/report/2018-index-report.pdf>

<sup>23</sup> Centers for Medicare & Medicaid Services: Medicare Enrollment Dashboard. Available at:

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/Dashboard>

<sup>24</sup> Centers for Medicare & Medicaid Services: Medicare Part D Drug Spending Dashboard and Data. Available at :

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD>

<sup>25</sup> Centers for Medicare & Medicaid Services: Medicare Part B Drug Spending Dashboard. Available at:

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB>

<sup>26</sup> Centers for Medicare & Medicaid Services: Medicaid Drug Spending Dashboard. Available at:

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Medicaid>

display disparities in outcomes. The Office of Minority Health also reports data on racial and geographic health disparities for select diseases and outcomes.<sup>27</sup> CMS' Office of Minority Health also has designed an interactive tool – the Mapping Medicare Disparities Tool – to identify areas of disparities between subgroups of Medicare beneficiaries, such as racial and ethnic groups, in health outcomes, utilization, and spending.<sup>28</sup> These tools could serve as a model for functional and comprehensive “disparity dashboards” that could be developed across agencies, with consistent definitions and outputs that reflect a broader range of diseases, outcomes, and treatment uses, particularly for medicines.

We recommend that Federal programs also continue to develop safeguards to protect personally identifiable information. The collection of data should serve to improve health care programs for underserved communities, not provide a means for discrimination or harming individuals.<sup>29</sup> We recommend that OMB and Federal agencies engage experts to test and implement safeguarding of data elements, ensuring that personally identifiable information remains protected throughout the process. Lastly, Federal programs should consider collecting and evaluating qualitative and quantitative data from underserved communities and standardized metrics to assess the impact of current and future Federal programs on health equity.

***Partner with Community Stakeholders to Develop Culturally Sensitive Data Collection Strategies.*** Direct engagement with community stakeholders (e.g., community-based organizations and community leaders) can help Federal agencies reach and collect data on underserved communities in a culturally sensitive manner. Agencies administering Federal health care programs should strongly consider working alongside community leaders and organizations that serve predominately underserved groups and have a history of engaging the underserved, such as Federally qualified health centers (FQHCs), historically black colleges and universities (HBCUs), Tribal groups, and other entities to implement culturally sensitive engagement strategies to collect data and evidence.

Community-based organizations like FQHCs and HBCUs can assist with the accurate identification and reporting of race and ethnicity data. Studies consistently show that inconsistencies in reporting of race and ethnicity are prevalent. In one study, the authors note that inaccurate data collection on race and ethnicity can lead to a misunderstanding of the burdens of diseases and result in under-appropriation of funds to fight health disparities. The authors note

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<sup>27</sup> Available at: [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV\\_Dashboard](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_Dashboard)

<sup>28</sup> Centers for Medicare & Medicaid Services Office of Minority Health: Mapping Medicare Disparities. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities>

<sup>29</sup> Redden J. The Harm That Data Do, *Scientific American* (Nov. 1, 2018), available at: <https://www.scientificamerican.com/article/the-harm-that-data-do/>

that the way in which information on race and ethnicity is collected may need to be re-evaluated in order to ensure that the data is accurately captured.<sup>30</sup>

Over the course of this effort, the Federal government should consider piloting and testing approaches to assess hurdles facing engagement and data collection on a regular basis. We note that studies have found that reimbursing community health centers (CHC) for tasks including activities related to social determinants of health (SDOH) helped increase their success in screening for SDOH.<sup>31</sup> Consistent with these findings, we recommend that Federal agencies consider providing financial and/or non-financial incentives for time spent on providing feedback and/or collecting data to advance the government's efforts to engage underserved communities.

### **(1b) Methods and practices for agencies to build capacity and provide training and support for teams conducting this work**

***Build and Invest in Diverse Teams and STEM Education.*** Continued scientific and technological innovations are critical to fostering continued economic growth, global competitiveness, and most importantly, helping patients live longer, healthier, and more productive lives. The innovative biopharmaceutical industry is committed to building on new scientific discoveries and technological advances, relying on a work force with education and skills in science, technology, engineering and math (STEM). Around the world, an increasing number of countries have recognized that a robust diverse and inclusive STEM-skilled work force is needed to fuel continued economic growth. STEM workers have been shown to be key drivers of innovation and, thus, contributors to significant economic productivity. Research shows that organizations that promote an inclusive and diverse environment boost creativity and increase innovation.<sup>32</sup> Studies have shown that diversifying the workforce offers organizations tangible and profitable benefits, including increased performance.<sup>33</sup> The advantages of increased creativity, innovation, and diverse perspectives are essential in advancing equity efforts in the health care and technology sectors. Efforts to improve equity across diverse communities will be most successful if the teams are themselves diverse and representative of the communities they seek to engage. To that end, we recommend that agencies continue to support a diverse STEM

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<sup>30</sup> Magaña Lopez M, Bevans M, Wehrlen L, *et al.* Discrepancies in Race and Ethnicity Documentation: A Potential Barrier in Identifying Racial and Ethnic Disparities. *Journal of Racial and Ethnic Health Disparities.* (2017). Available at: <https://doi.org/10.1007/s40615-016-0283-3>

<sup>31</sup> Gruss Inga, Bunce A, David, J, *et al.* Initiating and Implementing Social Determinants of Health Data Collection in Community Health Centers. *Population Health Management.* Feb. 2, 2021. Available at: <https://doi.org/10.1089/pop.2019.0205>

<sup>32</sup> Diversity and Inclusion: Are there really any tangible benefits to diversity and inclusion? Isn't this just corporate jargon? OPM.gov. Available at: <https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/faqs/>

<sup>33</sup> Hunt V, Prince S, Dixon-Fyle S, Yee L. McKinsey & Company, "Delivering through Diversity," January 2018.

pipeline<sup>34</sup> for diversification of the Federal workforce,<sup>35</sup> to provide pathways for diverse students and experienced employees to join the Federal ranks at all levels.

Building deeper ties with STEM programs that encourage diverse gender and ethnic enrollment will help foster community trust and provide a forum to help agencies understand the needs of under-represented populations in STEM. Fostering partnerships with STEM programs will also increase the knowledge needed to improve recruitment efforts and professional growth opportunities for a diverse, qualified workforce. We encourage Federal agencies to continue recruitment through the Pathways Programs at economically disadvantaged HBCUs and other ethnically diverse institutions that offer a STEM program. Historically, the Internship Program (formerly the Student Career Experience Program (SCEP) and Student Temporary Employment Program (STEP)) proved beneficial in increasing diversity at agencies, including the National Aeronautics and Space Administration (NASA) and the United States Patent and Trademark Office (USPTO), and we encourage the Administration to consider how such efforts can serve as a model for STEM programs across Federal agencies.

***Promote Diversity, Inclusion, and Equity Training.*** Additionally, we recommend that agencies continue to support and potentially expand diversity, inclusion, and equity training focused on evidence-based practices.<sup>36</sup> This training is pivotal to building inclusive and diverse teams in the Federal government and preparing current employees of all backgrounds to engage with the communities they serve. Many companies in the biopharmaceutical industry have incorporated these trainings as part of a holistic strategy to strengthen a culture of diversity and inclusion—these activities could be a model for Federal agencies. A 2020 survey of PhRMA members shows that member companies have increased opportunities for historically underrepresented populations and cultivated an environment of inclusion through a variety of activities, including diversity and inclusion (D&I) trainings focused on unconscious bias.<sup>37</sup> Training on diversity, equity, and inclusion will allow Federal employees to learn culturally sensitive communication strategies and promote inclusive workplace environments. We recommend that the Federal government conduct assessments of diversity and inclusion on a regular basis to promote continual development in these areas. We would welcome sharing our activities in this area for use as a potential model for Federal agencies.

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<sup>34</sup> Federal and External STEM Education Resources. Office of Economic Impact and Diversity.

<https://www.energy.gov/diversity/federal-and-external-stem-education-resources>

<sup>35</sup> Executive Order 13583- Establishing a Coordinated Government-wide Initiative to Promote Diversity and Inclusion in the Federal Workforce. 18 August 2011. White House. <https://obamawhitehouse.archives.gov/the-press-office/2011/08/18/executive-order-13583-establishing-coordinated-government-wide-initiative>

<sup>36</sup> See citation, Executive Order 13958

<sup>37</sup> The Biopharmaceutical Industry: Improving Diversity and Inclusion in the Workforce. PhRMA report. 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DI-ReportFinal.pdf>

Consistent with the June 2021 Executive Order on Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce,<sup>38</sup> we support the development and issuance of a Government-wide Diversity, Equity, Inclusion, and Accessibility Strategic Plan to define standards of success for diversity, equity, inclusion, and accessibility efforts based on leading policies and practices in the public and private sectors and to establish an updated system for agencies to report regularly on progress on key DEI priorities across federal agencies.

### **(1c) Methods and practices to incorporate community engagement and feedback from underserved individuals into equity assessments**

***Pilot and Test Engagement Strategies.*** We recommend that Federal agencies consider piloting and testing different engagement strategies to gain feedback on how to best incorporate the experiences of underserved communities in equity assessments. Community-based participatory research provides a model for agencies to engage members of underserved communities as partners in research.<sup>39</sup> The Detroit Urban Research Center (Detroit URC) is one such model. It is a well-established community-based participatory research partnership between local Detroit organizations and the University of Michigan that aims to promote health equity, having established more than 10 affiliated partnerships and 30 community-based participatory research projects over the past 25 years.<sup>40</sup> These partnerships include the Healthy Environments Partnership, which is working to address issues that contribute to racial and socioeconomic disparities in cardiovascular disease, and the Participatory Action for Access to Clinical Trials (PAACT), which aims to improve the representation of the African American and other minority communities in cancer clinical trials. The Detroit URC is a model for community engagement that can be looked to as a best practice for Federal agencies.

Community-based participatory research has been funded by several government programs, including the National Institute on Minority Health and Health Disparities (NIMHD),<sup>41</sup> the Agency for Healthcare Research and Quality (AHRQ),<sup>42</sup> and the Patient-Centered Outcomes Research Institute (PCORI).<sup>43</sup> In seeking to incorporate the diversity of lived experiences,

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<sup>38</sup> Executive Order on Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce. 25 June 2021. White House. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/06/25/executive-order-on-diversity-equity-inclusion-and-accessibility-in-the-federal-workforce/>

<sup>39</sup> Holkup PA, Tripp-Reimer T, Salois EM, Weinert C. (2004). Community-based participatory research: an approach to intervention research with a Native American community. *ANS. Advances in nursing science*, 27(3), 162–175. <https://doi.org/10.1097/00012272-200407000-00002>

<sup>40</sup> [https://www.detroiturc.org/sites/default/files/2020-09/detroit-urc\\_timeline.pdf](https://www.detroiturc.org/sites/default/files/2020-09/detroit-urc_timeline.pdf)

<sup>41</sup> Community-Based Participatory Research Program (CBPR). NIMHD. <https://www.nimhd.nih.gov/programs/extramural/community-based-participatory.html>.

<sup>42</sup> AHRQ Activities Using Community-Based Participatory Research to Address Health Care Disparities. Content last reviewed April 2020. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/research/findings/factsheets/minority/cbprbrief/index.html>

<sup>43</sup> Community-Based Participatory Research (CBPR) for African-American Patients with Serious Mental Illness. Patient-Centered Outcomes Research Institute (PCORI). Updated 12 Nov 2019. <https://www.pcori.org/research-results/2014/community-based-participatory-research-cbpr-african-american-patients-serious>

Federal programs should consider seeking input from individuals with experiences of overlapping identities and characteristics, such as gender, race/ethnicity, geography, culture, and background.

## **Area 2: Barrier and Burden Reduction**

### **(2a) Methods and practices to address burdens and barriers in Federal programs in assessments of program delivery**

*Evaluate burdens in equity assessments of program delivery.* There have been multiple cited approaches to improve access to covered services under Federal health care programs, such as advancing health literacy and increasing support for community-based organizations to reach underserved areas.<sup>44,45</sup> In addition, financial barriers such as transportation costs and time lost from work are often more significant for lower-income workers and can contribute to disparities in health and health outcomes. A 2017 analysis demonstrated that Hispanic, Black, and Asian American/Pacific Islander workers are more likely to be paid poverty-level wages as compared to white workers and that the share of Hispanic workers with poverty-level wages is twice as high as white workers (19.2% vs. 8.6%).<sup>46</sup> These realities must be considered when evaluating potential solutions to reduce barriers, promote access, and relieve health care burdens.

An overarching concern is that individuals who could benefit significantly may not be enrolling in Federal programs because of a lack of health literacy or limited resources to identify and register for such programs (e.g., lack of internet access, transportation, or paid time off). Equity assessments should consider whether opt-in requirements for Federal programs, such as the Medicare Part D low-income subsidy (LIS), disproportionately limit access to these programs for individuals in minority communities. It has long been the case that LIS take-up has lagged well behind LIS eligibility. For example, in 2011, only 35 percent of beneficiaries who were eligible for the LIS and who were not auto-enrolled applied for and received the LIS.<sup>47</sup> Federal agencies should review these data and consider alternatives to opt-in requirements. Moreover, additional data and analyses could assist in determining the extent to which non-enrollment in programs like the Part D LIS disproportionately impacts diverse communities and therefore may benefit from culturally nuanced solutions.

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<sup>44</sup> U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2010). National Action Plan to Improve Health Literacy. Washington, DC: Author.

<sup>45</sup> HHS Announces \$250 Million from American Rescue Plan to Develop and Support a Community-Based Workforce to Increase COVID-19 Vaccinations in Underserved Communities. HHS. 4 May 2021. <https://www.hhs.gov/about/news/2021/05/04/hhs-announces-250-million-from-american-rescue-plan-to-develop-and-support-underserved-communities.html>

<sup>46</sup> Cooper D. Workers of color are far more likely to be paid poverty-level wages than white workers. Economic Policy Institute. 21 June 2018. <https://www.epi.org/blog/workers-of-color-are-far-more-likely-to-be-paid-poverty-level-wages-than-white-workers/>

<sup>47</sup> Shoemaker JS, Davidoff A, Stuart B, *et al.* Eligibility and Take-up of the Medicare Part D Low-Income Subsidy. Inquiry Journal. Fall 2012. Available at: [https://journals.sagepub.com/doi/pdf/10.5034/inquiryjrnl\\_49.03.04](https://journals.sagepub.com/doi/pdf/10.5034/inquiryjrnl_49.03.04)

Regardless of LIS enrollment, racially and ethnically diverse Part D patients may face barriers to participating in Part D initiatives that could improve their health outcomes. For example, research has shown that certain non-white racial and ethnic subgroups have a lesser chance of meeting Medicare Part D's medication therapy management (MTM) program requirements than white enrollees, and that the MTM eligibility criteria may need to be modified to address these disparities.<sup>48,49,50</sup>

Many private sector organizations have launched initiatives to prioritize addressing inequities in access including social determinants of health. Best practices from these initiatives could prove useful to Federal agencies working to eradicate health disparities and inequity in Federal health care programs. Moreover, to measure burden across communities, we recommend collecting information on barriers to access with standardized outcomes/metrics flexible enough to be delivered in a culturally sensitive and population-specific manner. In addition, agencies may wish to consider standard and continuous evaluation of the evaluation metrics, so that the measures remain relevant.

### **(2b) Methods and principles for agencies to remove duplicative burden for individuals seeking services from multiple agencies**

***Seek continuous feedback.*** Agencies should consider collecting information from individuals at the point of service through short questionnaires designed to measure satisfaction on the administrative processes required to seek and/or attain services from agencies.

Questionnaires can be designed to promote collection of satisfaction data on duplicative administrative burden. This information can be systematically reviewed, along with information from complaints and grievances, and incorporated in routine quality processes. In the case of health care, providers may be another important source of information on duplicative burdens that patients face when accessing Federal benefit programs. Providers can play an increasing role in identifying patients' social risk factors, such as food insecurity, exposure to violence, unemployment, or housing issues, and helping patients receive assistance. Many providers have incorporated screening tools into their practices and embedded social workers to provide patients with resources, and there is a growing body of literature documenting the effectiveness of these

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<sup>48</sup> Wang J, Brown L, Hong SH. Racial and Ethnic Disparities in Meeting Part D MTM Eligibility Criteria Among the Non-Medicare Population. *Journal of the American Pharmacists Association*. September 2012. Available at: [https://www.japha.org/article/S1544-3191\(15\)30545-8/fulltext](https://www.japha.org/article/S1544-3191(15)30545-8/fulltext)

<sup>49</sup> Qiao Y, Spivey C, Wang J. Higher Predictive Value Positive for MMA Than ACA MTM Eligibility Criteria Among Racial and Ethnic Minorities: An Observational Study. *The Journal of Health Care Organization, Provision and Financing*. September 3, 2018. Available at: <https://doi.org/10.1177/0046958018795749>

<sup>50</sup> Wang J, Mullins CD, Brown, L; *et. al.* Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services. *Health Services Research*. Aug. 2010. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2910569/>

screening tools.<sup>51</sup> Through learning about patients' social needs and recording data on social determinants of health, providers can lend insight and play a unique role in closing gaps between benefit programs where patients are not enrolled due to administrative challenges.

A growing practice among providers is screening for food insecurity, particularly among the Medicaid population, many of whom experience food insecurity. However, Supplemental Nutrition Assistance Program (SNAP) benefit eligibility determinations rely on a complex set of income calculations and are not always well coordinated with Medicaid eligibility.<sup>52</sup> A pilot project that was conducted by Kaiser Permanente of Colorado to screen patients for food insecurity and connect them with resources found that providing patients with written resources and handouts was much less likely to result in patients ultimately registering for assistance programs, as compared with active on-site referral and outreach on the part of the provider teams.<sup>53</sup> We encourage Federal agencies to identify how to better collect social risk data from providers and leverage this information to identify and begin to solve gaps and barriers.

## **Area 5: Stakeholder and Community Engagement**

### **(5a) Methods and principles to proactively engage with underserved individuals and communities that will be most affected by programs, policies, rules, processes, or operations**

***Engage community-based organizations and leaders.*** OMB should consider encouraging additional engagement by Federal agencies with community-based organizations and leaders consistently in the development and evaluation of programs, policies, rules, processes, and operations relevant to addressing health inequities. Community-based stakeholders understand the specific needs of communities, which is crucial for successfully designing and implementing outreach efforts to engage the underserved. The Federal government also might consider offering incentives to community-based organizations currently serving as partners to increase recruitment and engagement of underserved communities. Recreational centers, faith-based and religious centers, and other local organizations can recommend and implement consistent approaches that are relevant and culturally sensitive to community members. For engagement related to health care policies, OMB also should consider engaging with relevant disease-specific provider and/or patient groups.

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<sup>51</sup> Andermann A. Screening for social determinants of health in clinical care: moving from the margins to the mainstream. *Public Health Rev.* 2018;39:19. Published 2018 Jun 22. doi:10.1186/s40985-018-0094-7 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6014006/>

<sup>52</sup> Hall et al. Food Insecurity and Health: Addressing Food Needs for Medicaid Enrollees as Part of COVID-19 Response Efforts Kaiser Family Foundation. (August 2020). <https://www.kff.org/report-section/food-insecurity-and-health-addressing-food-needs-for-medicaid-enrollees-as-part-of-covid-19-response-efforts-issue-brief/>

<sup>53</sup> Stenmark SH, Steiner JF, Marpadga S, Debor M, Underhill K, Seligman H. Lessons Learned from Implementation of the Food Insecurity Screening and Referral Program at Kaiser Permanente Colorado. *Perm J.* 2018;22:18-093. doi:10.7812/TPP/18-093

***Distribute culturally competent promotion materials.*** We recommend that the OMB consider supporting the development and distribution of culturally competent engagement materials. We applaud CMS for developing targeted and culturally competent Medicare Part D outreach materials and encourage the continuation of this practice.<sup>54</sup> In addition, we commend Federal health agencies, such as the Department of Health and Human Services (HHS), for providing resources for individuals with limited English proficiency to access information on HHS programs.<sup>55</sup> Continuing to provide information on programs in clear and accessible language is key to proactively and successfully engaging underserved communities.

***Implementing strategies to learn from communities on engagement practices.*** To meaningfully engage with underserved communities, we recommend that OMB consider practical approaches to seek community feedback. For example, surveys may be deployed with the aim of increasing understanding of the timing, frequency, and modalities of methods to improve engagement on Federal programs.

### **(5b) Methods and practices that can be put in place to make Washington DC and policymakers more accessible to underserved populations**

***Deploy inclusive approaches to increase engagement.*** OMB should consider deploying inclusive approaches to increase engagement with underserved communities. We note the importance of addressing technology barriers, as about four out of ten adults with lower incomes lack access to home broadband services.<sup>56,57</sup> In addition to income barriers, geographic disparities remain, with Americans in rural areas remaining less likely to have home broadband than Americans in urban and suburban areas.<sup>58</sup> In addition, technological access barriers are further compounded if the patient has a psychiatric diagnosis.<sup>59</sup> OMB and other Federal agencies can consider reaching communities through organizations with long-standing engagement with underserved populations.

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<sup>54</sup> Medicare for American Indians and Alaskan Natives. CMS.gov. Accessed 24 June 2021.

[https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Outreach-and-Education/pdf/medicare-prescription-drug-plans-for-aians\\_909416-N.pdf](https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Outreach-and-Education/pdf/medicare-prescription-drug-plans-for-aians_909416-N.pdf)

<sup>55</sup> Limited English Proficiency. HHS.gov. <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html>

<sup>56</sup> Vogels E. Digital divide persists even as Americans with lower incomes make gains in tech adoption. Pew Research Center. June 22, 2021. Available at: <https://www.pewresearch.org/fact-tank/2021/06/22/digital-divide-persists-even-as-americans-with-lower-incomes-make-gains-in-tech-adoption/>

<sup>57</sup> Reddick C, Enriquez R, Harris R, Sharma B. Determinants of broadband access and affordability: An analysis of a community survey on the digital divide. U.S. National Library of Medicine. Sept. 9, 2020. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7480260/>

<sup>58</sup> Perin A. Digital gap between rural and nonrural America persists. Pew Research Center. May 31, 2019. Available at: <https://www.pewresearch.org/fact-tank/2019/05/31/digital-gap-between-rural-and-nonrural-america-persists/>

<sup>59</sup> Ojha R, Syed S. “Challenges Faced by Mental Health Providers and Patients during the Coronavirus 2019 Pandemic Due to Technological Barriers.” *Internet Interventions*, vol. 21. June 3, 2020. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7267786/>

Thank you for the opportunity to comment on this important matter.

Sincerely,

A handwritten signature in black ink that reads "Courtney Christian". The signature is written in a cursive style with a large initial 'C'.

Courtney Christian, MPA  
Senior Director, Policy and Research

A handwritten signature in black ink that reads "Jacquelyn McRae". The signature is written in a cursive style with a large initial 'J'.

Jacquelyn McRae, PharmD, MS  
Director, Policy and Research