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January 27, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9911-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS–9911–P; Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment
Parameters for 2023

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (the Association) in response to the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 proposed rule, which was published in the Federal Register on January 5, 2022.

The Association is a national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

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Health Equity

Since its founding more than 50 years ago, our affiliate, the American Society of Clinical Oncology (ASCO) has been committed to addressing cancer health equity and continually works to improve understanding, advance scientific knowledge, and develop solutions to eliminate disparities in cancer care and outcomes. ASCO strives, through research, education, and promotion of the highest quality equitable patient care, to create a world where cancer is prevented, and every survivor is healthy. In this pursuit, cancer health equity remains a guiding institutional principle that applies to all its activities across the cancer care continuum. ASCO's statement on health equity affirms ASCO's commitment to moving beyond descriptions of differences in cancer outcomes

toward achievement of cancer health equity, with a focus on improving equitable access to care, improving clinical research, addressing structural barriers, and increasing awareness that results in measurable and timely action toward achieving cancer health equity for all.

The Association applauds the efforts the agency has made to address and reduce health disparities through policy updates and changes in this proposed rule. The Association supports the proposed changes discussed below.

The Association strongly supports CMS' proposal to amend 45 CFR 147.104(e) such that its nondiscrimination protections would explicitly prohibit a health insurance issuer and its officials, employees, agents, and representatives from employing marketing practices or benefit designs that would discourage the enrollment of individuals based on sexual orientation and gender identity.

The Association is committed to addressing the needs of sexual and gender minority populations as a diverse group at risk for receiving disparate care and having suboptimal experiences, including discrimination, throughout the cancer care continuum.[1] Sexual and gender minority (SGM), is an umbrella term that encompasses lesbian, gay, bisexual, and transgender populations as well as those whose sexual orientation, gender identity and expressions, or reproductive development varies from traditional, societal, cultural, or physiological norms. This includes individuals with disorders or differences of sex development (DSD), sometimes known as intersex.[2]

SGM populations bear a disproportionate cancer burden. The disparities in cancer outcomes stem from the unique cancer risks, needs, and challenges faced by SGM populations including discrimination and gaps in quality of care.[3,4] SGM populations exhibit low rates of uptake of cancer screening and may therefore present with late-stage disease.[5] Because of fear of discrimination and stigmatization, SGM populations often do not disclose their sexual orientation to their health care providers, and this may create additional barriers to high-quality care.[6]

This proposal restores protections established under the Obama Administration, that were subsequently removed, and are critically important as recent census data has revealed significant economic disparities

[1] Griggs, Jennifer, et al. "American Society of Clinical Oncology position statement: strategies for reducing cancer health disparities among sexual and gender minority populations." *Obstetrical & Gynecological Survey* 72.10 (2017): 598-599.
[2] National Institutes of Health, Sexual and Gender Minority Research Office. https://dpcpsi.nih.gov/sgmro
[3] Graham, R., Berkowitz, B., Blum, R., Bockting, W., Bradford, J., de Vries, B., & Makadon, H. (2011). The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding. *Washington, DC: Institute of Medicine*.
[4] Gibson, A. W., Radix, A. E., Maingi, S., & Patel, S. (2017). Cancer care in lesbian, gay, bisexual, transgender and queer populations. *Future Oncology*, 13(15), 1333-1344.
[5] Griggs, Jennifer, et al. "American Society of Clinical Oncology position statement: strategies for reducing cancer health disparities among sexual and gender minority populations." *Obstetrical & Gynecological Survey* 72.10 (2017): 598-599.
[6] National Institutes of Health. "Strategic plan to advance research on the health and well-being of sexual and gender minorities." (2017).

experienced by SGM Americans. Additionally, data indicate that this community has been harder hit by the pandemic.[7]

The Association supports policies that bolster the rights and protections of SGM patients and enhance the anti-discrimination requirements on health insurers and medical providers. Prohibiting discrimination based on sexual orientation and gender identity has the potential to improve access to equitable cancer care, and adequate insurance coverage to meet the needs of SGM individuals affected by cancer. We ask CMS to preserve the protections afforded to patients and healthcare consumers under the Affordable Care Act and prohibit discrimination based on sexual orientation and gender identity as the ACA intended.

The Association supports CMS' proposal to scale back pre-enrollment Special Election Period (SEP) verification requirements to provide flexibility to state exchanges on the requirement to do pre-enrollment verifications.

In 2017, pre-enrollment SEP verification requirements were established for certain types of SEPs. Like other proposals in this rule, the agency is removing a policy established under the previous Administration and reverting to the original intent of the provision.

People of color have faced longstanding disparities in health coverage that contribute to worse health outcomes. In the United States (U.S.), Black individuals are more likely to lack health insurance than their White counterparts,[8] and having health insurance makes a key difference in whether, when, and where people get medical care and their overall health. Uninsured people are far more likely than those with insurance to postpone health care or forgo it altogether.[9]

The Department of Health and Human Services (HHS) found that pre-enrollment SEP verification disproportionately negatively impacts Black and African American consumers who submit acceptable documentation to verify their SEP eligibility at much lower rates than White consumers. By scaling back pre-enrollment verifications, CMS would eliminate an administrative barrier to enrollment for populations that currently face barriers to accessing health care. Lack of health care coverage is one factor driving health inequity in the U.S., and by finalizing this proposal, CMS has the opportunity to reduce this disparity.

The Association supports CMS' proposal to increase the essential community providers (ECP) threshold from 20 to 35 percent of available ECPs in each plan's service area.

ECPs include providers that serve predominantly low income and medically underserved individuals such as family planning providers, Indian health care providers, Federally Qualified Health Centers, hospitals, and Ryan White providers. ECPs play an integral role in the cancer care continuum as they offer

[7] US Census Bureau. "LGBT Community Harder Hit By Economic Impact of Pandemic." https://www.census.gov/library/stories/2021/08/lgbt-community-harder-hit-by-economic-impact-of-pandemic.html
[8] https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/
[9] https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/

necessary services such as preventive screenings, human papillomavirus (HPV) vaccinations, and Hepatitis C treatment. To reduce cancer disparities and improve health equity among all beneficiaries, networks must be strong enough to support those that rely on these sites for care. Additionally, data shows that physicians who are underrepresented in medicine are more likely to work in underserved areas[10] where these facilities are typically located. Improved workforce diversity in addition to improved access to screening and other preventive cancer services could result from finalization of this policy.

The Association strongly supports CMS' proposal to refine the essential health benefit (EHB) nondiscrimination policy to ensure that benefit designs are based on clinical evidence and do not discriminate based on age, health conditions, and sociodemographic factors.

We strongly agree with CMS that benefit designs must be based on appropriate clinical evidence as discussed in the rule. Benefit designs based on clinical evidence will enhance the quality of care by encouraging consistency in treatment assessment and the care rendered. CMS' examples of presumptively discriminatory benefit designs help clarify EHB nondiscrimination policy, provide a more uniform coverage policy, and may lead to greater protections for individuals seeking medically necessary treatment while boosting access to care. The Association supports policies based on clinical evidence and that ensure all individuals with cancer have equitable access to health insurance coverage.

Inequalities endure within and across multiple cancer diagnoses and population groups. Variations in cancer outcomes continue to be associated with factors such as race/ethnicity, sexual orientation and gender identity, age, geography (e.g., rural v. urban), socioeconomic status, and health literacy, among many others.[11] Refining the essential health benefit nondiscrimination policy has the potential to reduce health disparities and improve health outcomes by ensuring equitable access to health care coverage. We thank CMS for providing examples that illustrate presumptive discriminatory plan designs and encourage the agency to update these examples of potentially discriminatory plan designs routinely and monitor issuer compliance on a regular basis.

Access

The Association supports CMS' proposal to re-interpret the guaranteed availability requirement, which would prevent insurers from requiring payment of past due premiums before accepting the applicant for new coverage.

The guaranteed availability provisions require health insurance issuers offering non-grandfathered coverage in the individual or group market to accept every individual and employer in the state that applies for such coverage unless an exception applies. An issuer may not apply any premium payment made for new coverage in the same or a different plan or product to any outstanding debt owed from

[10] Xierali IM, Nivet MA. The Racial and Ethnic Composition and Distribution of Primary Care Physicians. J Health Care Poor Underserved. 2018;29(1):556-570. doi:10.1353/hpu.2018.0036
[11] NCI: Understanding Cancer Disparities, 2018. https://www.cancer.gov/about-cancer/understanding/disparities

any previous coverage and then refuse to effectuate the new enrollment based on failure to pay premiums. Thus, the guaranteed availability requirement would prohibit issuers from refusing to effectuate new coverage due to failure to pay outstanding premium debt from the previous year.

Finalizing this proposal will remove an unnecessary barrier to individuals and families attempting to enroll into health coverage in the individual market. The Association agrees with CMS that the current policy creates barriers to health coverage that disproportionately affect low-income individuals and is therefore inconsistent with the intent of the guaranteed availability statutory requirements. We agree with CMS that reverting to the previous interpretation of the guaranteed availability rules would ensure coverage to individuals who stand to benefit the most from enrolling in plans in the insurance marketplace and it would promote more equitable access to this coverage.

Even for patients with insurance, out-of-pocket expenses associated with cancer treatment may be substantial and lead to exhaustion of savings and personal bankruptcy. Moreover, these expenses have a disproportionate effect on those with lower incomes. In many circumstances the financial strain of past or ongoing medical treatment may be the cause of the past due premiums. Cancer patients should not be further penalized for the financial struggles they must endure when diagnosed with cancer by not enrolling them in coverage, only worsening their financial situation and health outcomes. Efforts to enroll individuals in health insurance coverage, given the integral link to health care access, can improve cancer health outcomes[12] and must be preserved through finalization of this policy.

The Association strongly encourages CMS to apply appointment wait time standards to oncology specialties--including medical, radiation, surgical, and gynecological oncology—if CMS finalizes the proposal to include appointment wait time standards to assess whether qualified health plans (QHPs) offered through the federally-facilitated exchanges (FFEs) fulfill network adequacy standards.

Cancer patients and survivors are a particularly vulnerable subset of the population. They require timely access to cancer specialists, facilities, and supportive care. Narrowed networks[13,14] are linked to delays in cancer care, delays that adversely affect cancer control and survival.[15] To ensure that cancer patients have immediate access to the necessary anti-cancer therapies, we recommend CMS include oncology in the appointment wait time standards.

Our membership includes oncology practices in every state and across a wide range of settings, including urban, rural, and underserved areas. The Association supports network adequacy standards, including appointment wait times, that promote access based on specific patient needs, availability of

[12] Yabroff KR, Reeder-Hayes K, Zhao J, et al: Health insurance coverage disruptions and cancer care and outcomes: Systematic review of published research. J Natl Cancer Inst 112:671-687, 2020
[13] Wharam JF, Zhang F, Lu CY, et al: Breast cancer diagnosis and treatment after high-deductible insurance enrollment. J Clin Oncol 36:1121-1127, 2018
[14] Wharam JF, Zhang F, Wallace J, et al: Vulnerable and less vulnerable women in high-deductible health plans experienced delayed breast cancer care. Health Aff (Millwood) 38:408-415, 2019
[15] Eriksson L, Bergh J, Humphreys K, et al: Time from breast cancer diagnosis to therapeutic surgery and breast cancer prognosis: A population-based cohort study. Int J Cancer 143:1093-1104, 2018

care and providers, and appropriate utilization of services. We believe inclusion of oncology specialties to the appointment wait time standards will better assure cancer patients and survivors have meaningful access to medically necessary cancer care services in a timely fashion.

The Association supports CMS' proposal to reinstate standardized benefit plans at each metal level where a non-standardized plan is offered and differential display of the standardized plans.

The Association supports CMS's proposal to require FFE and state-based exchange (SBE-FP) issuers to offer standardized options at every product network type, metal level, and throughout every service area that they also offer non-standardized options. Standardized plans and cost sharing parameters should enable consumers to compare plans more easily during the selection process. Many consumers, especially those with limited English proficiency, inadequate internet access, complex medical needs, and low health literacy, do not have the time or ability to analyze plan options. These consumers often focus on premiums, rather than total cost-sharing, which can result in unexpected financial harm, especially for those with a cancer diagnosis. For cancer patients with insurance, out-of-pocket expenses associated with cancer treatment may still be substantial and lead to financial distress.[16] The reinstatement of standardized benefit plans may help cancer patients enrolling in coverage understand and compare their out-of-pocket costs under the standardized plan options in a more straight-forward and less time-consuming manner.

The Association supports resuming differential display of standardized plans on Healthcare.gov and state Exchanges and resuming enforcement of the standardized options differential display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment to ensure consumers correctly identify, and subsequently compare, standardized plans. We agree with CMS that the standardized plan proposal will simplify consumer comparison of plans, and if plans are not appropriately identified on the Exchanges, a consumer will remain just as overwhelmed with choice as CMS describes in the rule. The consumer will not realize the benefits of a standardized plan option if they cannot appropriately compare plans.

Copay Accumulator Policy

Although we appreciate the efforts CMS has made in this proposed rule to improve health equity and bolster enrollee access to health care coverage, we are extremely disappointed that the agency has not reversed the copay accumulator policy that was finalized in the 2021 Notice of Benefit and Payment Parameters final rule. The finalized policy allows issuers to disregard all manufacturer copay assistance when determining whether an enrollee has met their annual deductible and/or out-of-pocket limit, which disproportionately impacts patients with cancer and other chronic illnesses. This policy has a devastating impact on patients and jeopardizes patient access to needed care and life-saving prescription drugs by requiring patients to potentially pay more out of pocket in the long term as it will

[16] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2009-ASCO-Guidance-Statement-The-Cost-of-Cancer-Care.pdf

take more time to meet their deductible. We urge CMS to reverse course and prohibit copay accumulator programs to align with health equity and improved access to coverage policy updates in this rule.

Pharmacy benefit managers (PBMs) and insurers impose a variety of administrative rules to limit or deny coverage for selected treatments. Copay accumulator adjustment programs prevent funds provided by manufacturer copay assistance programs from applying toward a patient's annual out-of-pocket maximum or deductible. Only after the value of the voucher is exhausted can patient out-of-pocket costs begin counting toward an annual deductible and out-of-pocket maximum. As a result, insurers and PBMs are receiving the full amount of the manufacturer copay assistance program's amount. This means that patients will experience increased out of pocket costs and delays in reaching their required deductibles.

Such utilization management tactics negate the intended benefit of patient assistance programs—and remove a safety net for patients who need specialty medications but cannot afford them. This could lead to poorer health outcomes and potentially higher costs to the health care system. Additionally, copay accumulator adjustment programs are often implemented without consumer notice or education, meaning the patient typically discovers one has been added to their plan after they incur an exorbitant cost-share, often in the middle of their plan year.

Appreciating the negative financial impact of copay accumulators for patients, several states have passed laws generally banning their use by insurance companies and PBMS.[17]

The Association strongly opposes the use of copay accumulator adjustment and copay maximizer programs for patients with cancer. We urge CMS to reverse the current policy and eliminate copay accumulator programs. To learn more, please read our position statement.

Solicitation of Comments on Health Equity, Climate Health, and Qualified Health Plans

CMS solicits comments on health equity, climate change and qualified health plans. Health equity and cancer disparities have long been a focus in ASCO's programs and policy work, and we offer our comments below. We look forward to working closely with CMS to ensure equitable access to high quality equitable cancer care and offer our comments on how the agency can improve health equity through data collection.

Should QHP issuers be required to collect demographic and other SDOH data to help issuers gain a better understanding of the populations they serve, and thereby develop more equity-focused QHPs? Which data elements should be considered to advance health equity within QHPs?

[17] Office of Legislative Research, State of Connecticut. https://www.cga.ct.gov/2019/rpt/pdf/2019-R-0311.pdf

ASCO's recently published Cancer Disparities and Health Equity Policy Statement[18] summarizes past efforts and offers numerous recommendations to the broader cancer care community. These recommendations include the promotion of policies and systems to address persistent barriers to equitable care, such as equitable payment reforms, alternative payment models, and financial assistance programs. The policy statement also highlights persistent shortcomings in the clinical cancer research enterprise, as well as structural barriers to equitable care, and proposes solutions to address these obstacles to cancer health equity.

The Association recognizes that patient data are often incomplete, inaccurate, or overly simplified and usually do not consider many social and community factors.[19] Moreover, cancer disparities research is limited by a lack of comprehensive, consistent data on factors that impact disparities in cancer care and patient outcomes, including a patient's social status and demographics, community and lifestyle factors, and genetic factors. Widespread variation in data collection methodologies has also compromised the utility of select data sets for disparities research. In a joint statement regarding the future of cancer disparities research, ASCO joined the American Association for Cancer Research (AACR), the American Cancer Society (ACS), and the National Cancer Institute (NCI) in recommending the that a standard set of race and ethnicity data as well as sociodemographic measures, agreed upon by the cancer health disparity community, be included in clinical registries.[20] Further, it is recommended that to the extent possible, the most granular measures be selected, and in the case of race and ethnicity, questions address ancestry, immigration status and enclave effects. Measures of the built environment should be included, or patient address should be collected and geocoded, to assess neighborhood and structural effects on health, so that physical and other contextual effects can be considered.

The Association supports the collection of demographic elements and use of relevant data for quality improvement. Measures of race, ethnicity, sexual orientation, and gender identity should be self-reported and collected in all clinical settings.[21,22] Including relevant data reporting in all forms, especially the electronic medical record, will allow for patients to accurately record their medical history and individual characteristics that may impact their care.

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[18] Patel, M. I., Lopez, A. M., Blackstock, W., Reeder-Hayes, K., Moushey, E. A., Phillips, J., & Tap, W. (2020). Cancer disparities and health equity: A policy statement from the American Society of Clinical Oncology. Journal of Clinical Oncology, 38(29), 3439-3448.

[19] Polite, Blase N., et al. "Charting the future of cancer health disparities research: a position statement from the American Association for Cancer Research, the American Cancer Society, the American Society of Clinical Oncology, and the National Cancer Institute." Cancer research 77.17 (2017): 4548-4555.

[20] Ibid.

[21] Griggs, Jennifer, et al. "American Society of Clinical Oncology position statement: strategies for reducing cancer health disparities among sexual and gender minority populations." Obstetrical & Gynecological Survey 72.10 (2017): 598-599.

[22] Polite, Blase N., et al. "Charting the future of cancer health disparities research: a position statement from the American Association for Cancer Research, the American Cancer Society, the American Society of Clinical Oncology, and the National Cancer Institute." Cancer research 77.17 (2017): 4548-4555.

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We appreciate the opportunity to comment on this Notice of Benefit and Payment Parameters for 2023. Please contact Gina Hoxie (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

Howard A. Burris III, MD, FACP, FASCO

Chair of the Board

Association for Clinical Oncology