January 8, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-9895-P– Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025
88 Fed. Reg. 82510 (November 24, 2023)

Dear Secretary Becerra and Administrator Brooks-LaSure:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters (NBPP) for 2025. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

More than 1.9 million Americans will be diagnosed with cancer this year and more than 18 million Americans living today have a history of cancer.[1] For these individuals finding the right doctor is one of the most important factors in their treatment and has a direct bearing on the overall affordability of their care. In general, we support many of the proposals contained in the 2025 NBPP proposed rule and offer comments on the following:

- *Increase State Flexibility in the Use of Income and Resource Disregards for Non-MAGI Populations*
- *Election to Operate an Exchange after 2014*
- *Additional Required Benefits*
- *Initial and Annual Open Enrollment Periods*
- *Special Enrollment Periods*
- *Establishment of Exchange Network Adequacy Standards*
- *Prescription Drug Benefits*

III. Provisions of Proposed HHS Notice of Benefit and Payment Parameters for 2024

B. 42 CFR Parts 435 and 600

1. Increase State Flexibility in the Use of Income and Resource Disregards for Non-MAGI Populations (42 CFR 435.601)

Currently states' flexibility is significantly limited to use income disregards to expand Medicaid eligibility for certain populations. CMS proposes to change its policy for non-MAGI populations and allow states to target income and/or resource disregards at discrete subpopulations in the same eligibility group, provided the subpopulation is reasonable and does not violate other federal statutes. This would increase state flexibility

[1] American Cancer Society. *Cancer Facts & Figures 2023.* Atlanta: American Cancer Society; 2023.

and provide states more options to extend Medicaid eligibility to specific populations based on the state's circumstances. CMS believes that more broadly eliminating the comparability rule in the use of income and/or resource disregards would enable states to achieve targeted expansions of coverage that best meet their needs.

ACS CAN strongly supports this change, which would allow states to expand Medicaid eligibility to certain targeted sub-populations. It is critical that all individuals have access to affordable, comprehensive health insurance, and Medicaid and CHIP play a key role in providing this access to many individuals with limited incomes and under other circumstances. Extensive evidence shows that expanding access to Medicaid increases early-stage diagnosis rates among cancer patients.[2] Several studies have also showed that expanding access to Medicaid resulted in patients having timelier access to treatment,[3,4,5] and improvements in cancer mortality rates.[6,7,8] One recent study showed that expanding access to Medicaid was associated with increases in overall cancer survival, and the increase was prominent among non-Hispanic Blacks and in rural areas – highlighting the role expanding Medicaid access has in increasing health equity.[9]

If finalized, we encourage CMS to monitor the use of this new flexibility in states – particularly monitoring whether states use this change to discontinue the use of income disregards in a broader population now that they are able to target the policy to a smaller sub-population. If this flexibility is used to reduce Medicaid eligibility in many cases, CMS should re-examine the policy.

D. 45 CFR Part 155 – Exchange Establishment Standards and Other Related Standards

2. Election to Operate an Exchange after 2014 (§ 155.106)

CMS is proposing to require states to provide details of their State Exchange implementation plans and makes

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[2] Kaiser Family Foundation. Building on the Evidence Base: Studies on the Effects of Medicaid Expansion, February 2020 to March 2021. Published May 6, 2021. Accessed October 20, 2022. https://www.kff.org/medicaid/report/building-on-the-evidence-base-studies-on-the-effects-of-medicaid-expansion-february-2020-to-march-2021/.

[3] Adam B. Weiner et al., "Insurance Coverage, Stage at Diagnosis, and Time to Treatment Following Dependent Coverage and Medicaid Expansion for Men With Testicular Cancer," PLOS ONE 15 no. 9 (September 2020), https://doi.org/10.1371/journal.pone.0238813.

[4] Benjamin B. Albright et al., "Impact of Medicaid Expansion on Women with Gynecologic Cancer: a Difference-in-Difference Analysis," American Journal of Obstetrics and Gynecology 224 no. 2 (February 2021): 1-17, https://doi.org/10.1016/j.ajog.2020.08.007.

[5] Johanna Catherine Maclean, Michael T. Halpern, Steven C. Hill, and Michael F. Pesko, "The Effect of Medicaid Expansion on Prescriptions for Breast Cancer Hormonal Therapy Medications," Health Services Research, 55 no. 3 (April 2020): 399-410, https://doi.org/10.1111/1475-6773.13289.

[6] Ji X, Shi K, Castellino SM, et al. Association between the Affordable Care Act Medicaid expansion and survival in young adults newly diagnosed with cancer. JCO. 2022;40(16_suppl):1502-1502. doi:10.1200/JCO.2022.40.16_suppl.1502.

[7] David Barrington et. al., "Where You Live Matters: A National Cancer Database Study of Medicaid Expansion and Endometrial Cancer Outcomes," Gynecologic Oncology 158 no. 2 (August 2020): 407-414, https://doi.org/10.1016/j.ygyno.2020.05.018.

[8] Miranda B. Lam, Jessica Phelan, John Orav, Ashish K. Jha, and Nancy L. Keating, "Medicaid Expansion and Mortality Among Patients With Breast, Lung, and Colorectal Cancer," Jama Network Open 3 no. 11 (November 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2772535.

[9] Han X, Zhao J, Yabroff KR, Johnson CJ, Jemal A. Association Between Medicaid Expansion Under the Affordable Care Act and Survival Among Newly Diagnosed Cancer Patients. J Natl Cancer Inst. 2022 Aug 8;114(8):1176-1185. doi: 10.1093/jnci/djac077. PMID: 35583373; PMCID: PMC9360456.

clear that CMS would have the authority to request additional information it deems necessary to determine a state's readiness to operate a State Exchange. In addition, CMS is also proposing to strengthen the state engagement requirements for states transitioning to a State Exchange, requiring states to hold at least one public forum to inform interested parties of the intent to offer a State Exchange and periodic meetings with interested parties to inform them of their progress toward establishing the State Exchange.

ACS CAN supports these requirements. We agree with CMS that absent such notice it can be hard for consumer or advocate groups to know if a State has applied to establish a State Exchange and that having a more transparent process can help build trust and help support a State's enrollment goals.

3. Additional Required Benefits (§ 155.170)

Currently, if a state enacts a mandated benefit after December 31, 2011, and that benefit meets certain requirements, the state is required to make payment to the individual enrollee or the issuer on behalf of the enrollee (e.g., the state mandate defrayal policy). CMS now proposes that beginning with plan year 2025, benefits covered in a state's Essential Health Benefits (EHB) benchmark plan would be considered EHB (not "in addition to EHB") and therefore would not be subject to the state mandate defrayal policy. CMS notes that if the state later removes the mandated benefit from its EHB-benchmark plan, the state may have to defray the cost of the benefit given that it would no longer be an EHB. CMS also notes that beginning in plan year 2025 a state that is currently defraying the cost of a state-mandated benefit would be able to cease defraying the costs of the benefit if it is included in the EHB-benchmark (but states would not be able to recoup the costs of those benefits that have already been defrayed).

ACS CAN advocates in many states for mandates for certain evidence-based benefits related to cancer prevention, early detection, and treatment. We have found the current mandate cost defrayal policy discourages certain states from passing life-saving cancer-related mandates because of the cost or complications in implementing this defrayal. Therefore, ACS CAN strongly supports this proposal to change the policy so states will not need to defray costs for many mandated benefits if the state includes the benefit in their EHB benchmark.

One important example of the benefits of this policy change is in biomarker testing. Increasingly the use of precision medicine has been a vital component to improving cancer outcomes. Research has resulted in the availability of targeted therapies that are designed to work in patients with very specific biomarkers.[10] To use these targeted therapies, a cancer patient must have been tested for biomarkers. Unfortunately, medical advancements such as biomarker testing are not uniformly covered by health insurance plans, which can impede patients' access to these vital tests. The current state mandate defrayal policy hinders patients' access to new and innovative items and services, can create a chilling effect on state legislation to improve access to new innovations, and is antithetical to CMS' intended goal of providing states flexibility to design their own EHB benchmark standards.

However, as CMS finalizes this policy, we urge further clarification regarding whether the proposed policy applies to EHB categories broadly or whether the new policy would apply to specific items, services, or benefits within an EHB category. Take, for example, a state whose EHB-benchmark plan specifically covers diagnostic tests. After the beginning of plan year 2025 the state enacts legislation to mandate coverage of biomarker testing. The proposed rule is not clear whether the enactment of the biomarker legislation would trigger the defrayal policy. It is possible that in this example, the defrayal policy is not triggered because the state

[10] The term "biomarkers" refers to the biological molecules found in blood, tissues, or other bodily fluids that provide insight into the physiological process, medical conditions, or diseases.

legislation is not creating a new benefit, per se, but rather providing clarification on what constitutes a diagnostic test. However, the proposed rule is not clear in this regard and further clarification is critical to ensure states are consistent in their interpretation to meet the intended outcome of the proposed update in the rule.

16. Initial and Annual Open Enrollment Periods (§ 155.410)

HHS proposes, for benefit years beginning on or after January 1, 2025, that State Exchanges would be required to adopt an open enrollment period that begins in November of the calendar year preceding the benefit year and ends no earlier than January 15 of the applicable benefit year.

ACS CAN supports this standardization of open enrollment periods across state-based exchanges and federal exchanges, as well as with Medicare and many employers. We agree that this alignment will reduce consumer confusion, provide additional time for enrollment, and could increase Exchange enrollment. The American Cancer Society's National Cancer Information Center fields calls regularly from cancer patients who are looking for options to enroll in or switch their health insurance coverage, and these callers have many more viable options when they call during open enrollment. Everyone will benefit from a standardized open enrollment season that gives individuals ample time to enroll.

17. Special Enrollment Periods (§ 155.420(b))

a. <u>Effective Dates of Coverage</u>

HHS proposes to align the effective dates of coverage after selecting a plan during certain special enrollment periods (SEPs) across all Exchanges, including State Exchanges. Beginning January 1, 2025 an individual who selects and enrolls in a QHP during an SEP would receive coverage beginning the first day of the month beginning after the individual selects the QHP. This would be regardless of what day during the month the individual makes the selection.

ACS CAN supports this standardization of effective dates of coverage, as it will lessen confusion for enrollees and navigators who help enrollees. It will also allow new coverage to start as quickly as possible for new enrollees, which lessens the chances of the enrollee experiencing a gap in coverage.

b. <u>Monthly SEP for APTC-Eligible Qualified Individuals with Household Income at or Below 150 Percent of the FPL</u>

Currently, at the option of an Exchange, there is a monthly SEP for APTC-eligible qualified individuals with a projected household income at or below 150 percent of the FPL (the 150 percent FPL SEP). This SEP is currently linked directly to the temporary enhanced subsidies established in the American Rescue Plan and extended through 2025 by the Inflation Reduction Act. HHS proposes to make this SEP, at the option of the Exchange, permanent by removing the requirement that it only be available while enhanced subsidies are in place.

ACS CAN strongly supports the extension of the enhanced marketplace subsidies and will advocate to make them permanent through statute. We hope HHS will do all it can to accomplish this goal as well, but recognize that this is an action that ultimately requires congressional action. We support this proposal to keep this SEP active if the enhanced subsidies are not renewed. Individuals with limited incomes are more likely to be uninsured, and people facing cancer and survivors with limited incomes experience higher health care costs and significantly more financial hardship compared to individuals who have not been

diagnosed with cancer.[11] Because of their limited incomes, these individuals are also less able to afford any health insurance options they have off-marketplace and may fall prey to non-comprehensive junk insurance products. We support this policy to give this population access to comprehensive marketplace plans year-round through this SEP, even if the enhanced subsidies expire.

19. Establishment of Exchange Network Adequacy Standards (§ 155.1050)

CMS is proposing to improve network adequacy standards for State-based Exchanges (SBEs) and State-based Exchanges on the Federal Platform (SBE-FPs). CMS is requiring SBEs and SPE-FPs to establish quantitative time and distance QHP network adequacy standards that are at least as stringent as those required by QHPs in the FFEs. CMS is also requiring SBEs and SBE-FPs to conduct network adequacy reviews before certifying any plan as a QHP. SBEs and SBE-FPs would also be mandated to require all issuers seeking QHP certification to submit information about whether the network providers offer telehealth services.

ACS CAN supports these proposals to improve the adequacy of a plan's network. For a cancer patient – whether newly diagnosed, in active treatment, or cancer survivors – adequate access to needed providers is one of the most important components in fighting their disease. We support CMS' requirement that SBEs and SBE-FPs are required to conduct their own quantitative network adequacy reviews and are no longer permitted to accept an issuer's attestation as the only means for plan compliance with network adequacy requirements. Requiring the SBE or SBE-FP to conduct its own network adequacy determination is important to ensure that a plan's network is adequate to meet the needs of its enrollees – particularly those enrollees like cancer patients who have specialized health care needs – before the plan is marketed so that shortfalls can be addressed prior to the plan's availability.

ACS CAN supports telehealth as an option for consumers, particularly for underserved populations. While the use of telehealth services has increased, particularly after the COVID-19 pandemic, telehealth cannot replace all in-person visits. Telehealth should supplement, but not replace, traditional in-person care. Thus, while we support the collection of data with respect to providers who utilize telehealth services (to be used, for example, for provider directory information), we would not support the availability of telehealth services to be counted towards a health plan's network adequacy determination.

E. Part 156 – Health Insurance Issuer Standards Under the Affordable Care Act Including Standards Related to Exchanges

4. Prescription Drug Benefits (§ 156.122)

a. <u>Classifying the Prescription Drug EHB</u>

CMS is considering a future requirement to replace the United States Pharmacopeia (USP) Medicare Model Guidelines (MMS) with the USP Drug Classification system (DC) as a classification system for prescription drugs required to be covered as EHB.

ACS CAN supports the change to the USP DC as the standard to define the EHB prescription drug category because this system is not only updated on an annual basis but also contains new and expanded categories and classes of drugs.

[11] American Cancer Society Cancer Action Network. The Costs of Cancer for People with Limited Incomes. October 19, 2022. https://www.fightcancer.org/sites/default/files/coc_limited_incomes_final2.pdf.

We also urge CMS to consider expanding the EHB requirement beyond current policy of (1) one drug in every United States Pharmacopeia (USP) category and class or (2) the same number of prescription drugs in each category and class as the EHB benchmark plan. We are concerned the current standard is insufficient to meet the needs of individuals with serious illnesses, like cancer, that often require access to innovative new therapies. There is no single oncology drug that is medically appropriate to treat all cancers. Cancer is not just one disease, but more than 200 diseases. Cancerous tumors respond differently to prescription drugs depending on the type of cancer, stage of diagnosis, and other factors. As such, oncology drugs often have different indications, mechanisms of action and side effects – all of which need to be managed to fit the medical needs of an individual. We urge CMS to revise the prescription drug EHB benchmark standard and require plans to cover at least two drugs per USP category and class, in line with Medicare Part D requirements.

b. Coverage of Prescription Drugs as EHB

CMS proposes to clarify that prescription drugs in excess of those covered by a state's EHB-benchmark plan are considered EHB, and thus would be subject to requirements such as the annual limitation on out-of-pocket costs and the restriction on annual and lifetime dollar limits. This requirement would not apply where the coverage of the drug is a result of a state mandate and is in addition to EHB.

ACS CAN supports CMS' clarification. We are aware that plans are designating some prescription drugs (usually specialty drugs) as non-essential in order to prevent patient out-of-pocket payments from counting towards the maximum out-of-pocket limit. We believe that such action is contrary to the intent of the EHB requirements and appreciate CMS' clarification that such practices are prohibited.

CONCLUSION

Thank you for the opportunity to comment on the Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for plan year 2025. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network