April 11, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Oregon Health Plan 1115 Demonstration Application for Renewal and Amendment

Dear Secretary Becerra:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on Oregon's application for renewal of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver for the 2022-2027 demonstration period. 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 critical to the fight for a world without cancer.

ACS CAN supports the Oregon Health Plan's goals of providing quality healthcare to members and ensuring access to care – particularly its proposals to establish some form of continuous eligibility for all enrollees. We commend Oregon's commitment to eliminating health disparities, maximizing coverage, and addressing the social determinants of health. However, the proposed limits on access to medications, as well as the continued use of the "prioritized list" of health services could limit – rather than ensure – access to care for some of the most vulnerable Oregon residents, including those with cancer, cancer survivors, and those who will be diagnosed with the disease. While we recommend that CMS approve Oregon's waiver renewal, we strongly urge the agency to reject the requested authorities related to excluding drug coverage and the use of the "prioritized list" of health services.

More than 25,130 Oregon residents are expected to be diagnosed with cancer this year,[1] and there are more than 213,620 cancer survivors in the state[2] – many of whom rely on the Medicaid program. ACS CAN wants to ensure that enrollees have adequate access and coverage under the Medicaid program, and that specific requirements do not create barriers to care for cancer patients, survivors, and those who will be diagnosed with cancer.

Following are our specific comments on Oregon's 1115 waiver renewal application:

[1] American Cancer Society. *Cancer Facts & Figures 2022*. Atlanta, GA: American Cancer Society; 2022.
[2] American Cancer Society. *Cancer Treatment & Survivorship Facts & Figures 2019-2021*. Atlanta, GA: American Cancer Society; 2019.

Continuous Eligibility
ACS CAN strongly supports Oregon's proposal to provide continuous coverage to children through age 6, and 2-year continuous coverage for all enrollees over the age of 6, including the expansion population. ACS CAN wants to ensure that cancer patients and survivors in Oregon will have coverage under the Medicaid program, and that program requirements do not create barriers to care for low-income cancer patients, survivors, and those who will be diagnosed with cancer. This large, proposed expansion of the use of continuous eligibility will reduce barriers and requirements for enrollees, allowing more patients to access essential health care, including cancer prevention and treatment.

Without continuous eligibility, individuals can lose coverage due to small – often temporary – fluctuations in income. They can also lose coverage when they are still eligible for it because they missed a letter in the mail requiring them to submit new paperwork to prove their eligibility. Losing access to health care coverage makes it difficult or impossible for those with cancer to continue treatment. For cancer patients who are mid-treatment, a loss of health care coverage could seriously jeopardize their chance of survival. Since loss of coverage can be devastating to cancer patients and their families, we applaud this proposal to prevent such coverage gaps, and we urge CMS to approve this expansion of continuous eligibility and are hopeful that Oregon will serve as an example to other states to implement a similar policy, particularly as all states prepare for the eventual end of the Public Health Emergency.

Proposals Regarding Access to Drugs
ACS CAN applauds Oregon for removing its harmful proposal to implement a "commercial-style" closed formulary with at least one drug available per therapeutic class. There is no single oncology drug that is medically appropriate to treat all cancers. Cancer is not just one disease, but hundreds of diseases. Cancer tumors respond differently depending on the type of cancer, stage of diagnosis, and other factors. Using a closed formulary in a state Medicaid program would severely restrict a physician's ability to prescribe the medically appropriate treatment for an individual without going through a lengthy appeals process. Denying enrollees access to medically appropriate therapies can result in negative health outcomes, which can increase Medicaid costs in the form of higher physician and/or hospital services to address the negative health outcomes. Removing this proposal from the renewal application ensures that more individuals with medically complex and chronic illnesses have access to medically appropriate medication.

However, in its application to CMS for renewal, Oregon continues to request the authority to exclude certain drugs from coverage that have been approved through the accelerated approval pathway. The application states that the targeted drugs are ones "that have not been converted to full Food and Drug Administration (FDA) approval and for which the state has determined the drugs have limited or inadequate evidence of clinical efficacy."[3] The waiver application does not define what constitutes a drug with limited or inadequate efficacy. ACS CAN urges CMS to reject this requested authority in the waiver for several reasons:

- If implemented, the policy will likely limit access to the newest life-saving drugs for cancer patients.

[3] Oregon Health Plan 1115 Demonstration Waiver – Application for Renewal 2022-2027. February 18, 2022. https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/or/or-health-pln-extnsion-appl-2022-2027.pdf. See pg. 42.

- The requested authority and implied processes are duplicative of the FDA's, and inappropriate for a state Medicaid agency.
- The proposal does not include details on the patient protections the agency claims will be in place to maintain patient access to medically necessary drugs.

Drug therapies play an integral role in cancer treatment. Advances in research have improved our understanding of cancer at the molecular level, leading to the development of more precise detection and diagnostic tools and corresponding therapies that are able to more specifically attack cancer. Cancer patients and survivors rely on drug therapies to treat their disease and prevent recurrence. As more innovative therapies become available, it is imperative that ALL patients who are likely to benefit from these advances have access to them so that we can achieve the national goal of eliminating death and suffering from cancer and not inadvertently contribute to widening cancer disparities due to restrictive coverage policies.

The FDA's accelerated approval pathway was created to allow for a faster approval of drugs that are used to treat serious conditions and to fill an unmet treatment need. Drugs approved by the FDA under the accelerated approval pathway are approved based on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict a drug's clinical benefit, such as increased survival or quality of life. Because it can often take years to measure primary outcomes like survival; surrogate, or intermediate endpoints can serve as a proxy for clinical benefit. Common surrogate endpoints used in cancer include reduced tumor size or decreasing biomarker levels. Additionally, drugs approved under the accelerated pathway must provide a meaningful advantage over available therapies.

This pathway has been particularly important in oncology care in that it allows cancer patients faster access to new therapies (in oncology a median of 3.4 years earlier than trials using traditional endpoints[4]), thus improving the likelihood of a successful therapeutic outcome for cancer patients. The majority of accelerated approvals are within oncology, and the majority of new oncology drugs approved in any recent year has been via the accelerated approval pathway, meaning this proposal would disproportionately impact cancer patients.

The use of surrogate outcomes is grounded in science, and approval through the accelerated pathway should not be viewed as substandard. As is the case with any drug, regardless of approval pathway, the more it is used, the more that is learned about its impact on patient outcomes. In the case of accelerated approval drugs, the FDA has the chance to revisit the approval based on additional data. If policymakers wish to change the process or rules around accelerated approval drugs, federal legislation is the appropriate venue to do so – particularly if the goal genuinely is to encourage manufacturers to meet their clinical trial timelines. Note that Congress currently has pending legislation that would

[4] Beaver JA, Howie LJ, Pelosof L, et al. A 25-Year Experience of US Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review. JAMA Oncol. 2018;4(6):849–856. doi:10.1001/jamaoncol.2017.5618. Accessed online 10/1/2020.

institute changes in the accelerated approval program,[5] and recently the House Committee on Energy & Commerce held a hearing on this topic.[6]

The FDA is the world standard for drug approval. The agency employs physicians, statisticians, chemists, pharmacologists, and other scientists to ensure that drugs that are approved clinically demonstrate safety and effectiveness.[7] The agency also invests significant resources in research, development, and technology to aid in this evaluation and review process. The waiver seeks to allow the state to supplant the FDA's federal role in drug safety and effectiveness. CMS should not approve a waiver provision that duplicates existing responsibilities already conducted by the FDA and that would have a significant detrimental impact on cancer patients in Oregon.

Lastly, there is a troubling lack of details in the application on a provision that is so far-reaching, impacts many critically ill patients, and imparts novel authority to the Medicaid agency. In the application Oregon submitted to CMS, the agency provides only two paragraphs that allude to the details of how this new authority will be implemented:

> *Oregon proposes to limit the coverage of drugs that have been approved through the accelerated pathway under narrow circumstances. Under this proposal, Oregon would utilize the timelines set out in the FDA approval letter and review confirmation of benefit data in peer reviewed literature or clinicaltrials.gov. Applying the FDA-developed guidance and timetables ensures a universal standard, with clinically [sic] feasibility and drug sponsor agreement… As part of our efforts, we will ensure continued pharmacy protections for members, so that Oregon's closer management of pharmacy costs does not negatively impact member access to the spectrum of safe and effective drugs to treat various conditions.*[8]

It is very unclear from this language how Oregon intends to implement their requested authority. Would the Medicaid program initially cover a new approved drug, but then remove it from coverage if the clinical trials are not completed on the original timeline? What will be the trigger for removing a drug from coverage? Will it automatically be removed once a deadline is missed? Are there acceptable reasons for the timeline to be delayed, and who decides what reasons are acceptable? Will the decision to remove a drug be made by a committee (and if so, who will be on this committee, and what interests do they have?)? What provisions will be in place for patients who are currently taking the drug slated for removal? Will patients and the general public have the opportunity to participate in these removal decisions? If a doctor determines a patient needs a drug that has been removed from coverage under

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[5] H.R.6963 - Accelerated Approval Integrity Act of 2022, Text - H.R.6963 - 117th Congress (2021-2022): Accelerated Approval Integrity Act of 2022 and H.R.6996 - Accelerating Access for Patients Act of 2022 Text - H.R.6996 - 117th Congress (2021-2022): Accelerating Access for Patients Act of 2022

[6] Subcommittee on Health of the Committee on Energy and Commerce. The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight. March 17, 2022. https://energycommerce.house.gov/committee-activity/hearings/hearing-on-the-future-of-medicine-legislation-to-encourage-innovation

[7] Food and Drug Administration. *Drug Development and Approval Process*. Updated June 13, 2018. Accessed December 2019. https://www.fda.gov/drugs/development-approval-process-drugs.

[8] Oregon Health Plan 1115 Demonstration Waiver – Application for Renewal 2022-2027. February 18, 2022. https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/or/or-health-pln-extnsion-appl-2022-2027.pdf. See pg. 42.

this authority, will the doctor or patient have the opportunity to appeal to gain coverage? If so, are there defined timelines for this appeals process, and are they rapid enough for a cancer patient to gain coverage of a drug that is urgently needed to fight their cancer?

With all of these questions unanswered, and major concerns about how this policy could limit cancer patient access to the latest life-saving cancer drugs, ACS CAN strongly urges CMS to reject this element in the Oregon waiver application.

Removal of Request to Waive Retroactive Eligibility
Previous versions of this demonstration and waiver application included a waiver of the Medicaid retroactive coverage requirements. In this application to CMS, Oregon has elected to remove this request, meaning the state will provide retroactive eligibility to Medicaid enrollees under normal Medicaid policy parameters.

We commend Oregon for removing this from their waiver application and proposing to re-instate retroactive eligibility. Many uninsured or underinsured individuals who are newly diagnosed with a chronic condition already do not receive recommended services and follow-up care because of cost.[9,10] In 2019, three in ten uninsured adults went without care because of cost.[11] Continuing to waive retroactive eligibility could mean even more people are unable to afford care and forgo necessary care due to cost.

Safety net hospitals and providers also rely on retroactive eligibility for reimbursement of provided services, allowing these facilities to keep the doors open. For example, the Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals to stabilize and treat individuals in their emergency room, regardless of their insurance status or ability to pay.[12] Retroactive eligibility allows hospitals to be reimbursed if the individual treated is eligible for Medicaid coverage. Likewise, Federally Qualified Health Centers (FQHCs) offer services to all persons, regardless of that person's ability to pay or insurance status.[13] Community health centers also play a large role in ensuring low-income individuals receive cancer screenings, helping to save the state of Oregon from the high costs of later stage cancer diagnosis and treatment. For these reasons, we commend the state for no longer seeking to remove retroactive eligibility.

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[9] Hadley J. Insurance coverage, medical care use, and short-term health changes following an unintentional injury or the onset of a chronic condition. *JAMA*. 2007; 297(10): 1073-84.
[10] Foutz J, Damico A, Squires E, Garfield R. The uninsured: A primer – Key facts about health insurance and the uninsured under the Affordable Care Act. *The Henry J Kaiser Family Foundation*. Published January 25, 2019. Accessed November 2019. https://www.kff.org/report-section/the-uninsured-a-primer-key-facts-about-health-insurance-and-the-uninsured-under-the-affordable-care-act-how-does-lack-of-insurance-affect-access-to-health-care/.
[3.] Tolbert J, Nov 06 ADP, 2020. Key Facts about the Uninsured Population. KFF. Published November 6, 2020. Accessed August 17, 2021. https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/
[12] Centers for Medicare & Medicaid Services. Emergency medical treatment & labor act (EMTALA). Updated March 2012. Accessed October 2019. https://www.cms.gov/regulations-and-guidance/legislation/emtala/.
[13] National Association of Community Health Centers. America's Health Centers' Snapshot. Published August 2021. Accessed August 2021. https://www.nachc.org/wp-content/uploads/2020/10/2021-Snapshot.pdf.

Prioritized List and the Health Evidence Review Commission
While Oregon has removed its request to waive Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirements for children, it continues to request a waiver of certain federal Medicaid rules to determine Medicaid benefits coverage via the Prioritized List, compiled and maintained by the Health Evidence Review Commission. If a patient needs a service that is not covered via this list, they must initiate a 'medical necessity appeal.' ACS CAN is concerned that limiting covered Medicaid benefits to a specific list in this way may limit access for necessary cancer treatments that do not make it onto this list, or that are not placed high enough on the list. This is particularly a concern for patients with rare cancers, or comorbidities or other special circumstances that sometimes warrant less common treatments. The state itself acknowledges that, "these [medical necessity appeals] processes can be lengthy and burdensome to providers and families."[14] Recently, the Office of Management and Budget recognized the disproportionate impact of such administrative burdens on families of color and recommended reducing these barriers as a key step in achieving equity.[15] We recommend CMS reject this piece of the waiver application.

Conclusion
Maintaining access to quality, affordable, accessible, and comprehensive health care coverage and services is a matter of life and survivorship for thousands of low-income cancer patients and survivors. While we encourage CMS to approve Oregon's waiver renewal request, we urge the agency to reject the state's proposals that limit patient access to needed treatments. We look forward to working with you to ensure that coverage through the Oregon Health Plan meets the health care needs of eligible individuals and families and reduces the burden of cancer for lower income Oregonians. If you have any questions, please feel free to contact my staff at 202-839-3531 or Jennifer.Hoque@cancer.org.

Sincerely,

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

[14] Oregon Health Plan 1115 Demonstration Waiver – Application for Renewal 2022-2027. February 18, 2022. https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/or/or-health-pln-extnsion-appl-2022-2027.pdf. See pg. 53.
[15] Executive Office of the President of the United States. Office of Management and Budget. Study to Identify Methods to Assess Equity: Report to the President. July 2021. https://www.whitehouse.gov/wp-content/uploads/2021/08/OMB-Report-on-E013985-Implementation_508-Compliant-Secure-v1.1.pdf#page=21