



American Cancer Society
Cancer Action Network
PO Box 22770
Portland, OR 97269
www.fightcancer.org

January 6, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team
Attn: Michelle Hatfield
500 Summer St. NE, 5th Floor, E65
Salem, OR 97301

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

Dear Ms. Hatfield:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed changes and extension to Oregon's Section 1115 Demonstration. 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. We commend Oregon's commitment to eliminating health disparities, maximizing coverage, and addressing the social determinants of health. However, the proposed implementation of a closed formulary and other limits on access to medications, as well as the continued use of the "prioritized list" of health services and elimination of retroactive eligibility 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. We strongly urge the state to address the concerns that we and other stakeholders have before moving forward with the waiver process.

More than 24,790 Oregon residents are expected to be diagnosed with cancer this year,¹ and there are more than 213,620 cancer survivors in the state² – 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 application:

¹ American Cancer Society. *Cancer Facts & Figures 2021*. Atlanta, GA: American Cancer Society; 2021.

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

Proposals Regarding Formularies

Access to Prescription Drugs is Essential for Cancer Patients

Closed formulary: The proposal requests authority to implement a “commercial-style” closed formulary with at least one drug available per therapeutic class and exclude new drugs from its formulary based on the state’s “own rigorous review process”. ACS CAN opposes the adoption of a closed drug formulary for the Oregon Health Plan. 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. As such, oncology drugs often have different indications, different mechanisms of action, and different side effects – all of which need to be managed to fit the medical needs of an individual. Oncologists take into consideration multiple factors related to expected clinical benefit and risks of oncology therapies and the patient’s clinical profile when making treatment decisions. For example, one fourth of cancer patients have a diagnosis of clinical depression,³ which may be managed with pharmaceutical interventions that may limit cancer treatment options because of drug interactions or side effects. As such, when enrollees are in active cancer treatment, it can be particularly challenging to manage co-morbid conditions.

Allowing for the use of a closed formulary 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. While the waiver application compares this proposal to coverage provided through Medicare Part D, it fails to mention that the Medicare Part D program has recognized 6 protected drug classes that CMS requires Part D plans to include all drugs, including cancer drugs, on their plan formularies. A closed formulary without protections to ensure that individuals with medically complex and chronic illnesses have access to medically appropriate medication is a policy that will harm cancer patients’ access to care.

Restricting access to Accelerated Approval drugs could limit access to most promising treatments

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, we need to make sure that 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.

The FDA’s accelerated approval pathway was created to allow for a faster approval of drugs that are used to treat serious conditions and fill an unmet need. This pathway has been particularly important in oncology care in that it allows cancer patients faster access to new therapies, thus improving the likelihood of a successful therapeutic outcome for cancer patients.

Drugs approved by the FDA under the accelerated approval pathway are approved based on a surrogate

³ American Cancer Society, *Coping with Cancer: Anxiety, Fear, and Depression*. Available at <https://www.cancer.org/treatment/treatments-and-side-effects/emotional-side-effects/anxiety-feardepression.html>.

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.

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.

Impact on tobacco cessation: ACS CAN is also concerned about the implications a closed formulary will have on individuals' access to smoking cessation products. Currently, there are seven Food and Drug Administration (FDA)-approved tobacco cessation medications available to help people quit. Multiple options are necessary because different treatments work for different people. Tobacco users are disproportionately low-income⁴ and have a higher risk for chronic diseases associated with tobacco addiction, including lung cancer.⁵ Limiting access to a panoply of tobacco cessation products will hinder individuals' ability to break their dependence on tobacco.

Oregon's proposal to duplicate FDA process and lack of patient appeals process: The waiver proposes granting the state flexibility to "use its own rigorous review process to determine coverage of new drugs and to prioritize patient access to clinically proven, effective drugs"⁶ We are concerned that this policy would hinder cancer patients' access to innovative cancer therapies. The application states Oregon "will ensure 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" without any details on how member access will be protected given the broad latitude requested to exclude drugs from the formulary. We are particularly concerned that there appears to be no process for an enrollee or provider to appeal or request an exception to the limited formulary.

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 can 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 appears to seek to allow the state to supplant the FDA's federal role in drug safety and effectiveness. This creates an unnecessary administrative burden as the state would attempt to duplicate existing federal responsibilities. The state lacks the resources necessary to duplicate those already conducted by the FDA.

⁴ Cornelius ME, Wang TW, Jamal A, Loretan CG, Neff LJ. Tobacco Product Use Among Adults — United States, 2019. *MMWR Morb Mortal Wkly Rep* 2020;69:1736–1742. DOI: <http://dx.doi.org/10.15585/mmwr.mm6946a4external> icon.

⁵ U.S. Department of Health and Human Services. *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*, 2014. Available at <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/>.

⁶ Waiver application p.31.

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>.

Furthermore, we are concerned that even if the state were to conduct its own determination as to the effectiveness of a new drug, the waiver provides no information regarding what process the state will use to make that determination and how timely such a determination would be made. Requiring a state to undergo a duplicative approval process to the FDA's process will result in delayed access to innovative treatments. In addition, allowing the state to make its own determination regarding the efficacy of a drug takes the clinical care decision away from the physician-patient relationship and places it on the state.

Waiver of Retroactive Eligibility

Medicaid currently allows retroactive coverage if: 1) an individual was unaware of their eligibility for coverage at the time a service was delivered; or 2) during the period prospective enrollees were preparing the required documentation and Medicaid enrollment application. Policies that reduce or eliminate retroactive eligibility could place a substantial financial burden on enrollees and cause significant disruptions in care, particularly for individuals battling cancer. Therefore, we are concerned about the State's request to continue to waive 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.^{8,9} In 2019, three in ten uninsured adults went without care because of cost.¹⁰ Waiving 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.¹¹ 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.¹² 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 urge the state to reinstate retroactive eligibility.

Prioritized List and the Health Evidence Review Commission

Oregon proposes to continue its waiver of certain federal Medicaid rules to determine Medicaid benefits coverage via the Prioritized List, compiled and maintained by the Health Evidence Review Commission. ACS CAN is concerned that limiting covered Medicaid benefits to a specific list in this way

⁸ 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.

⁹ 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/>

¹¹ 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/>.

¹² 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>.

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.

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 age 6. 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, resulting in loss of access to health care coverage, making 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. The loss of coverage can be devastating to cancer patients and their families. We applaud this proposal to prevent such coverage gaps.

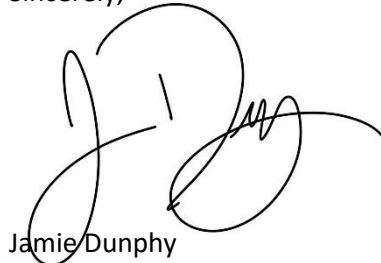
Conclusion

We appreciate the opportunity to provide comments on the proposed changes. The preservation of eligibility and coverage through the Medicaid program remains critically important for many low-income Oregonians who depend on the program for cancer and chronic disease prevention, early detection, diagnostic, and treatment services. We ask the state to reverse plans to adopt a closed formulary and to reinstate retroactive eligibility.

We ask the state to weigh the impact of these proposals on low-income Oregonians' access to lifesaving health care coverage, particularly those individuals with cancer, cancer survivors, and those who will be diagnosed with cancer during their lifetime.

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, and we look forward to working with the Division to ensure that all Oregonians are positioned to win the fight against cancer. If you have any questions, please feel free to contact me at jamie.dunphy@cancer.org or (503) 334-3903.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Dunphy', with a large, stylized loop at the end.

Jamie Dunphy
Oregon Government Relations Director