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October 11, 2017

Eric D. Hargan
Acting Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: MassHealth Section 1115 Demonstration Amendment Request

Dear Acting Secretary Hargan,

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on Massachusetts' proposal to amend the MassHealth demonstration waiver. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

Over 37,000 Massachusetts residents are expected to be diagnosed with cancer this year[1] – many of whom are receiving health care coverage through the MassHealth program. It is imperative that low-income Massachusetts residents continue to have access to comprehensive health care coverage under the MassHealth program.

We value the transparent process the Centers for Medicare and Medicaid Services (CMS) utilizes to seek input and comments on 1115 demonstration waiver proposals. An open and transparent process provides organizations like ACS CAN an opportunity to share our views on how waiver proposals will affect people with chronic conditions, like cancer.

ACS CAN supports Massachusetts' goal to provide near-universal coverage to low-income Massachusetts residents through the MassHealth program. We are, however, concerned with several of the proposed amendments to the waiver, most notably the proposal to potentially limit access to new and innovative drug therapies by imposing a closed formulary with only a single drug per therapeutic class and shifting non-disabled adults whose income is between 101 to 138 percent of the federal poverty level (FPL) from MassHealth to the Health Connector. Each of these proposed amendments could severely curtail critical access to care for cancer patients and survivors. Further, as written, the proposal does not meet the criteria for application of an 1115 demonstration waiver. Therefore, we strongly urge CMS to reject the waiver in its current form.

[1] American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta, GA: American Cancer Society; 2017.

If CMS moves forward with the waiver, we urge you to consider the following recommendations to improve the waiver application – particularly for cancer patients and survivors.

Closed Prescription Drug Formulary and Specialty Pharmacy Network

The Massachusetts Executive Office of Health and Human Services (EOHHS) seeks a waiver to impose a closed formulary with at least a single drug per therapeutic class. ACS CAN is extremely concerned that the proposed policy could hinder cancer patients' access to medically necessary prescription drugs. Cancer patients need access to the most innovative treatments to help improve their odds of surviving their cancer diagnosis.

We oppose EOHHS' request to adopt a closed drug formulary for MassHealth. There is no single oncology drug that is medically appropriate to treat all cancers. Cancer tumors respond differently depending on the type of cancer, stage of diagnosis, and other factors, as evidenced by the National Comprehensive Cancer Network Guidelines. Oncology drugs often have different indications, different mechanisms of action, and different side effects, and therefore could be targeted to different sub-populations within a tumor type. Oncologists take into consideration multiple factors related to the expected clinical benefit and risks of oncology therapies and the patient's clinical profile when making treatment decisions. Making oncology medicines subject to a closed formulary would restrict the ability of the doctor to make the best medical decision for the care of the patient, which is of great concern, given the life-threatening nature of cancer.

We note that the waiver cites the Medicare Part D program as justification for permitting a closed formulary. However, we suggest that this comparison falls short. The Medicare Part D program covers outpatient prescription drugs and it is not clear from the proposal whether the waiver seeks to impose a closed formulary for all prescription drugs (e.g., physician-administered prescription drugs) or would only apply to outpatient prescription drugs.

In addition, while the Medicare Part D program allows plan sponsors to create a formulary with at least two drugs per therapeutic class, it also requires sponsors to cover all or substantially all drugs in six classes and categories of prescription drugs including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antitretrovirals, and immunosuppressants (the so-call "protected classes"). In fact, the Medicare Part D manual clearly states that "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[2] It does not appear that similar protections are contemplated under the MassHealth waiver.

ACS CAN is also concerned about the implications a closed formulary will have on smoking cessation products. There are seven FDA-approved cessation medications currently available to help people quit, and different treatments work for different people. Tobacco users are disproportionately low-income[3]

[2] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.

[3] Centers for Disease Control and Prevention: Current Cigarette Smoking Among Adults—United States, 2005–2015. *Morbidity and Mortality Weekly Report* 2016;65(44):1205–11.

and at higher risk for chronic diseases associated with tobacco addiction, including lung cancer.[4] Therefore, preserving access to health care services and medications for these individuals is particularly important. Tobacco dependence often requires multiple interventions and attempts to quit.[5] One of the best ways to save lives and reduce health care spending is through prevention, including reducing tobacco use. The most effective way to realize this savings is to ensure that all seven FDA-approved drugs are offered to Medicaid enrollees.

Finally, we note that the waiver states that MassHealth will continue to maintain an exceptions process to cover drugs not on the formulary if medically necessary. However, the proposal fails to articulate the safeguards needed to ensure that enrollees have access to the prescription drugs they need – including access to an expedited appeals process when warranted. Cancer patients undergoing an active course of treatment for a life-threatening health condition need uninterrupted access to the prescription drugs they need. Disruptions in cancer treatment care or adjuvant therapy, such as hormone therapy, can result in negative health outcomes. Additionally, switching patients' medications mid-treatment could provide undue anxiety and uncertainty for patients and potentially impact their treatment outcome. Therefore, we urge CMS to deny Massachusetts' request to impose a closed formulary with only a single drug per therapeutic class, as it would severely impact cancer patients that rely on receiving innovative treatments to help fight their cancer diagnosis.

Evidence of Clinical Efficacy
We are concerned with the EOHHS' assertion that use of FDA-accelerated approval results in less efficacious medicines. Evidence has actually shown the contrary, that drugs accessing expedited review pathways contribute more life-years than those that are reviewed under normal approval pathways.[6] FDA is the world standard for drug approval, and we are extremely concerned that EOHHS might attempt to create its own reviewing body to recreate FDA's review process rather than recognizing FDA approval decisions.

Some cancer patients are appropriately prescribed off-label use drugs to treat their disease, a practice that is especially common with rarer cancers like pediatric cancer.[7,8,9] Allowing EOHHS to determine what drugs are or are not effective on a closed formulary effectively takes the clinical care decisions away from the doctor and patient and gives it to the state. Therefore, we urge CMS to deny the state's request to exclude drugs with limited clinical efficacy from its primary formulary.

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[4] 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/.
[5] U.S. Department of Health and Human Services. Public Health Service. *Treating Tobacco Use and Dependence: 2008 Update*. Available at https://www.ncbi.nlm.nih.gov/books/NBK63952/.
[6] Chambers JD, Thorat T, et al., Drugs Cleared Through The FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process. Health Affairs. 2017; 36(8): 1408-1415.
[7] Krzyzanowka MK. Off-label use of cancer drugs: A benchmark is established. *J Clin Oncol.* 2013; 31(9):1125-7.
[8] Bonifazi M, Rossi M, Moja L, et al. Bevacizumab in clinical practice: Prescribing appropriateness relative to national indications and safety. *Oncologist.* 2012; 17: 117-24.
[9] Conti RM, Bernstein AC, Villaflor VM, et al. Prevalence of off-label use and spending in 2010 among patent-protected chemotherapies in a population-based cohort of medical oncologists. *J Clin Oncol.* 2013; 31: 1134-39.

Shifting Non-Disabled Adults to Health Connector

ACS CAN is deeply concerned with Massachusetts' proposal to reduce eligibility and transfer coverage for MassHealth enrollees whose incomes fall between 101 to 138 percent of the FPL to Health Connector – a subsidized commercial plan. We appreciate that the EOHHS excludes those in the breast and cervical cancer treatment program and those determined by MassHealth to be medically frail; however, we are concerned this particular change could cause an estimated 100,000 parents or caretakers and 40,000 childless adults to lose affordable coverage, pushing them into a program with fewer benefits and greater cost sharing.

Individuals who are shifted from the MassHealth program to the Health Connector program could experience higher out-of-pocket costs and may be more likely to forgo needed care. Imposing copayments on low-income populations has been shown to decrease the likelihood that they will seek health care services, including preventive screenings.[10,11,12] Cancers that are found at an early stage through screening are less expensive to treat and lead to greater survival.[13] Uninsured and underinsured individuals already have lower screening rates resulting in a greater risk of being diagnosed at a later, more advanced stage of disease.[14] Proposals that place greater financial burden on the lowest income residents create barriers to care and could negatively impact MassHealth enrollees – particularly those individuals who are high service utilizers with complex medical conditions. We urge the Department to consider our recommendations to ensure that low-income Massachusetts residents continue to have access to quality, affordable, and comprehensive health insurance.

Moving cancer patients and survivors out of the more robust MassHealth and into Health Connector's qualified health plans (QHP) could result in reduced benefits and a significant increase in out-of-pocket cost sharing – even with cost-sharing reduction subsidies – making coverage less comprehensive and unaffordable. Individuals enrolled in Health Connector are responsible for copays as high as $50 (for emergency room services and inpatient hospital services)[15] with annual out-of-pocket expenses capped at $1,250 for an individual and $2,500 for a family. While we appreciate EOHHS' proposal to offer some lower-income individuals $0 premium plan options, absent a similar reduction in out-of-pocket costs, we are concerned that the proposal would still leave individuals exposed to significant cost-sharing, beyond what is permitted under the federal requirements.

The level of the out-of-pocket maximum would be particularly burdensome for a high-utilizer of health care services, such as an individual in active cancer treatment or a recent survivor. Cancer patients in

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[10] Solanki G, Schauffler HH, Miller LS. The direct and indirect effects of cost-sharing on the use of preventive services. *Health Services Research.* 2000; 34: 1331-50.

[11] Wharam JF, Graves AJ, Landon BE, Zhang F, Soumerai SB, Ross-Degnan D. Two-year trends in colorectal cancer screening after switch to a high-deductible health plan. *Med Care.* 2011; 49: 865-71.

[12] Trivedi AN, Rakowsi W, Ayanian JA. Effect of cost sharing on screening mammography in Medicare health plans. *N Eng J Med.* 2008; 358: 375-83.

[13] American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2016-2017*. Atlanta: American Cancer Society; 2017.

[14] Ibid.

[15] Powerpoint presentation by Marylou Sudders, Secretary Executive Office of Health & Human Services. FY18 MassHealth and commercial market reform package. Presented July 25, 017.

active treatment require many services shortly after diagnosis and thus incur a significant portion of cost sharing over a relatively short period of time. It can be challenging for an individual – particularly an individual with limited means – to be able to afford their cost-sharing requirements. Likewise, a recent survivor may require frequent follow-up visits to prevent cancer recurrence. Having to pay the full cost up front would likely result in many cancer patients and survivors delaying their treatment and could result in them forgoing their treatment altogether.

We strongly urge CMS to reject Massachusetts's request to enroll individuals whose income falls between 101 and 138 percent of the FPL to subsidized commercial plans through the Health Connector. At the very least, if the Department decides to allow Massachusetts to move forward with this provision, we ask that CMS require the EOHHS amend their definition of medically frail to include individuals in active cancer treatment and recent cancer survivors so that they have access to health care coverage under MassHealth until they are no longer deemed "medically frail."

Consolidating Coverage for Non-Disabled Adults ≤100 Percent FPL

We ask that CMS request further clarification from EOHHS regarding the consolidation of coverage for non-disabled adults with incomes up to 100 percent of the FPL from MassHealth Standard into MassHealth CarePlus before making any decisions on this proposal. It is unclear from the waiver whether individuals transferred to CarePlus would be required to pay cost sharing higher than what they currently pay under MassHealth Standard. Additionally, it is unclear what, if any, actions would be taken if an enrollee is unable to pay a cost sharing requirement.

Studies have shown that imposing premiums or cost sharing on low-income individuals, particularly those below 100 percent of FPL, is likely to deter enrollment in the Medicaid program.[16,17,18] Proposals that place greater financial burden on the lowest income residents, especially those under 100 percent of the FPL, create barriers to care and could negatively impact MassHealth enrollees – particularly those individuals who are high service utilizers with complex medical conditions.

We urge CMS to reject this proposal if EOHHS clarifies that they would require premiums or cost sharing on individuals with incomes up to 100 percent of the FPL. This will ensure Massachusetts residents below 100 percent FPL will not be denied access to services for an inability to pay.

Transitioning Coverage & Continuity of Care

Cancer patients undergoing an active course of treatment for a life-threatening health condition need uninterrupted access to the providers and facilities from whom they receive treatment. Disruptions in primary cancer treatment care, as well as longer-term adjuvant therapy, such as hormone therapy, can result in negative health outcomes.

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[16] Hendryx M, Onizuka R, Wilson V, Ahern M. Effects of a Cost-Sharing Policy on Disenrollment from a State Health Insurance Program. *Soc Work Public Health*. 2012; 27(7): 671-86.

[17] Wright BJ, Carlson MJ, Allen H, Holmgren AL, Rustvold DL. Raising Premiums and Other Costs for Oregon Health Plan Enrollees Drove Many to Drop Out. *Health Affairs*. 2010; 29(12):2311-16.

[18] Office of the Assistant Secretary for Planning and Evaluation. Financial Condition and Health Care Burdens of People in Deep Poverty. Published July 16, 2015. Accessed April 21, 2016. http://aspe.hhs.gov/basic-report/financial-condition-and-health-care-burdens-people-deep-poverty.

We note that the MassHealth 1115 waiver amendment fails to provide specific provisions to ensure that individuals transitioning from MassHealth to Health Connector or MassHealth CarePlus coverage, beginning January 1, 2019, can continue to see their health care provider if medically necessary. Failure to consider the care delivery and/or treatment regimen of patients, especially those individuals managing a complex, chronic condition like cancer, could have devastating effects on patients, their families, and providers.

If CMS were to move forward with these provisions, we ask the Department to require EOHHS to provide additional continuity of care provisions that would minimize disruptions in coverage and care for individuals in active treatment for life-threatening illnesses, such as cancer. Additionally, the state should be required to establish a clearly defined process through which MassHealth enrollees being transitioned to Connector or CarePlus or their physician can inform EOHHS that they are in active treatment; allowing them to maintain their cancer care treatment regimen and continue to see their providers through the same health care systems through the end of their treatment.

Non-Emergency Medical Transportation Waiver Request
We are also concerned that Health Connector and MassHealth CarePlus enrollees transitioned under these proposals would not receive some of the wrap-around services typically required by Medicaid health plans, such as non-emergency medical transportation (NEMT).

As discussed in our August 23rd letter to CMS regarding Massachusetts's initial request to waive NEMT services, ACS CAN is opposed to EOHHS waiving NEMT for Connector and MassHealth CarePlus enrollees, particularly those childless, non-disabled adult enrollees below 100 percent of the FPL. Waiving NEMT creates barriers to CarePlus and Connector members accessing primary care and preventive services, such as cancer screenings and diagnostic testing services. Early detection of cancer through preventive services generally results in less expensive treatments and better health outcomes.[19] For example, colorectal and cervical cancer screenings can prevent cancer by detecting and removing pre-cancerous lesions. Community health centers and beneficiary advocates indicate that a lack of access to transportation through the Medicaid program results in patients missing appointments. Therefore, we strongly urge CMS to deny EOHHS' request to waive NEMT to MassHealth CarePlus and Connector enrollees.

Implementing Narrower Networks in MassHealth's Primary Care Clinician (PCC) Plan
We are pleased that the draft 1115 waiver seeks to promote the use of primary care services. A significant proportion of cancers are preventable through lifestyle changes and screening.[20] However, the waiver fails to provide sufficient information to determine the extent to which enrollees transitioning from the Primary Care Clinician (PCC) plan to an Accountable Care Organization (ACO) or Managed Care Organization (MCO) will have access to specialized medical services and subspecialists. ACS CAN urges the Department to require EOHHS provide clarification on how it intends to guarantee that health plan networks include an adequate number of specialists to ensure that enrollees have

[19] American Cancer Society. Cancer Prevention & Early Detection Facts & Figures 2015-2016. 2016 Update. Atlanta: American Cancer Society; 2016.
[20] American Cancer Society. Cancer Facts & Figures: 2016. Atlanta: American Cancer Society, 2016.

access to the specialists necessary to treat their medical condition, especially oncologists, cancer surgeons, and radiologists, before considering this provision.

Cancer patients undergoing an active course of treatment for a life-threatening health condition need uninterrupted access to the providers and facilities from whom they receive treatment. Disruptions in cancer treatment care can result in negative health outcomes. Therefore, if the narrower network proposal for the PCC plan is accepted, we urge CMS to require EOHHS establish a clearly defined process through which a MassHealth enrollee can maintain their cancer care treatment regimen and continue to see their providers through the same PCC plan delivery system through the end of their treatment. Failure to consider the care delivery and/or treatment regimens of patients, especially those individuals managing a complex, chronic condition like cancer, could have devastating effects on patients, their families, and providers.

Modifying the Premium Assistance Program and Wrap-Around Services for Non-Disabled Adults

ACS CAN is concerned with the proposal to waive wrap-around benefits and cost-sharing protections as required by the Medicaid statute if a premium assistance enrollee receives services from a provider that is not enrolled as a MassHealth provider. Compared with MassHealth, commercial coverage – through employer sponsored insurance (ESI) or student health insurance (SHI) – often provides less generous benefits and imposes higher out-of-pocket costs.

The proposal fails to consider the unique health care needs of individuals and their families and could prevent low-income residents – who frequently have greater health care needs relative to other populations – from accessing lifesaving treatments. What is comprehensive for one individual may not be comprehensive for another. For example, not all ESIs or SHIs require coverage of all critical cancer treatments and/or all prescription drugs. By waiving wrap around benefits, even if only for providers not enrolled as a MassHealth provider, the state could inadvertently prevent a cancer patient from receiving a lifesaving treatment or a survivor from receiving the maintenance therapies required to prevent recurrence of their disease.

The request to waive the Medicaid cost sharing wrap-around coverage is particularly concerning for individuals with chronic and/or high-cost health care needs, such as cancer patients and survivors. Research from Milliman suggests that out-of-pocket costs for patients on ESI average between $1,000 to $5,000 per year, depending on the insurance coverage, cancer type, year of diagnosis, and time of year diagnosed,[21] compared to the much lower cost sharing requirements under Medicaid. For an adult at 175 percent of FPL who makes approximately $21,000 per year (or $1,759 per month),[22] out-of-pocket expenses at those costs could be unaffordable, as they may be required to pay those costs within the first month or so of their diagnosis.

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[21] Dieguez G, Ferro C, Pyenson BS. *A multi-year look at the cost burden of cancer care*. Milliman Research Report. Published April 11, 2017. Accessed August 2017. http://www.milliman.com/uploadedFiles/insight/2017/cost-burden-cancer-care.pdf.

[22] Office of the Assistant Secretary for Planning and Evaluation. U.S. federal poverty guidelines used to determine financial eligibility for certain federal programs. Published January 31, 2017. Accessed August 2017. https://aspe.hhs.gov/poverty-guidelines.

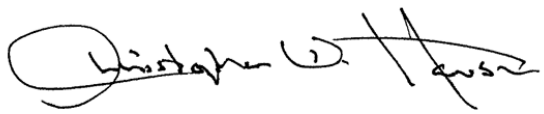
We urge CMS to deny Massachusetts' request to waive wrap-around cost sharing coverage for the MassHealth Premium Assistance population when they use a provider not enrolled in MassHealth. If the provision is approved, we ask the Department to require the state to provide an appeals process through which individuals with unique medical needs can formally request approval to access specialized services and/or care from providers that do not participate in MassHealth, without being subject to additional cost-sharing or a lengthy appeals process. Some individuals with rare conditions – like some cancers – need access to specific specialized services and/or providers, who may not be included in a plan's network. It is critical that patients and their physicians are able to utilize the appeals and grievances process when warranted to prevent denial of services or additional cost sharing.

Conclusion

We appreciate the opportunity to provide comments on the MassHealth amendment request. The preservation of eligibility, coverage, and access to MassHealth remains critically important for many low-income Massachusetts residents who depend on the program for cancer prevention, early detection, diagnostic, and treatment services that help improve outcomes and save lives. We ask CMS to weigh the impact these policy proposals may have on access to lifesaving health care coverage, particularly for 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 Administration to ensure that all Americans are positioned to win the fight against cancer. If you have any questions, please feel free to contact me or have your staff contact Michelle DelFavero of our policy team at Michelle.DelFavero@cancer.org or 202-585-3266.

Sincerely,



Christopher W. Hansen
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