

October 20, 2017

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

Re: Massachusetts Section 1115 Demonstration Amendment Request

Dear Acting Secretary Hargan:

The National Coalition for Cancer Survivorship represents survivors of all forms of cancer. We advance public policy initiatives aimed at improving access to quality cancer care for all. We believe that quality care begins with a shared decision-making process and should include access to information about treatment options and side effects of treatment.

We are writing to express our deep reservations about the proposal from the Commonwealth of Massachusetts to amend its Section 1115 waiver. We appreciate the very significant challenge that the Commonwealth confronts in maintaining near universal insurance coverage and at the same time controlling the costs associated with this accomplishment. However, we are concerned that the waiver amendment may put some patients at risk and deny them access to the best possible treatment option.

Many cancer patients have been assured access to care through MassHealth, the state's Medicaid program. We are concerned that the waiver amendment request will not ensure that those who are enrolled in MassHealth will have access to appropriate cancer treatment without unreasonable delay.

The waiver amendment application from the Commonwealth includes a proposal to adopt a "commercial-style closed formulary with at least one drug available per therapeutic class" for MassHealth. The Commonwealth has not explained why the tools available to it, including a preferred drug list, prior authorization requirements, and rebates, are not adequate for management of drug utilization. Without addressing the adequacy of these tools, the Commonwealth moves to a formulary plan that may adversely affect cancer patients.

Cancer care is often combination therapy incorporating drugs from different drug classes or multiple drugs in a class. In addition, cancer treatment is increasingly targeted according to the patient's individual profile, often established through molecular testing. An individual patient may receive a clinical benefit from one drug in a class and not another, and a closed formulary may not be responsive to these individual needs. For some cancer patients, the management of the side effects of cancer treatment poses serious medication challenges. We are concerned that the closed formulary proposed by the Commonwealth for MassHealth patients will make it more difficult – if not impossible – for cancer patients to receive the drugs necessary for appropriate treatment therapies for those enrolled in MassHealth.

We note that the waiver application references an exceptions process for obtaining drugs off-formulary. Without more details, we cannot conclude that this process is adequate or that it will be accomplished in timely fashion to ensure patient access to recommended therapy.



NATIONAL COALITION
FOR CANCER SURVIVORSHIP

The power of survivorship. The promise of quality care.

NCCS does not agree with the manner in which the waiver application describes the process for accelerated approval of drugs that is utilized by the Food and Drug Administration (FDA). The Commonwealth maintains that there is limited or inadequate evidence of clinical efficacy of drugs that are approved according to the FDA accelerated approval process.

The accelerated approval process is intended to be used in situations where there is an unmet medical need for a serious condition or disease. As FDA states, this approval process is used to sure that therapies for serious illness are available as soon as it can be concluded that their benefits justify their risks. Many cancer drugs have been approved by FDA according to the accelerated approval pathway, and many cancer patients have benefited from them. For many of these patients, there are inadequate treatment options and the accelerated approval drug does in fact address an “unmet” clinical treatment need.

We do believe that the entire accelerated approval pathway should be completed, which means that post-approval trials should be completed to establish the clinical benefit of drugs approved through this pathway.

We do not agree with the assertions in the Commonwealth application about the shortcomings of accelerated approval. Even if we did, we would not be willing to accept a review and approval process that the Commonwealth would substitute for FDA review.

Even if we conceded that the standards of the accelerated approval process are lacking, we would not find the review process generally referenced by the Commonwealth to be an appropriate substitute for FDA review. The waiver application does not explain how review would occur, except to reference the engagement of experts at the University of Massachusetts. The application leaves open questions about the standard for drug review that would be undertaken by the Commonwealth, the data that would be reviewed (proprietary data from sponsors, other clinical trials data, real world evidence), or the actual process for review. For example, will there be a conflicts of interest policy for reviewers? Standards for public comment during the review process? Over a period of years, cancer patient advocates have pressed for revisions of the FDA review process to ensure greater transparency and public process, with the understanding that the review process involves proprietary data from sponsors and that there will be some limits on the public nature of the process. In contrast, these questions are left unanswered in the Commonwealth waiver application.

We applaud the Commonwealth for making quality cancer care available to many through MassHealth. We are concerned that the changes to MassHealth proposed in waiver amendment would pose obstacles to quality care for some cancer patients. We urge the Centers for Medicare & Medicaid Services (CMS) to reject the waiver application submitted by the Commonwealth of Massachusetts because it may compromise access to quality care for people with cancer and others with serious illnesses.

Sincerely,

A handwritten signature in black ink, appearing to read "Shelley Fuld Nasso".

Shelley Fuld Nasso, MPP
Chief Executive Officer