

[Massachusetts Section 1115 Demonstration Waiver](#)

Background

Massachusetts has acted as a leader in health care delivery reform. However, coverage rates for residents topping 96%, MassHealth's budget has grown at an unsustainable rate, awakening calls for program restructure and reform. The state submitted a Section 1115 Demonstration Amendment Request to address the raising costs of the Medicaid program in September 2017. (The waiver proposal was also included in Governor Baker's [FY 2019 budget proposal](#).) The waiver is currently pending/waiting CMS approval.

1115 Waiver Elements

The 1115 waiver identifies four amendment requests necessary for the program to achieve enduring sustainability. These are:

1. "Aligning coverage for non-disabled adults with commercial plans;
2. Adopting widely-used commercial tools to obtain lower drug prices and enhanced rebates;
3. Improving care, reducing costs and achieving administrative efficiencies; and
4. Supporting access to health care for veterans and their families."

Changes to Lower Drug Prices

In the waiver, Massachusetts' includes two provisions for permissible coverage restriction requirements of outpatient drugs. The first, would allow the Commonwealth to select preferred and covered drugs through a closed formulary. The second element, would permit MassHealth the procurement of a selective and "more cost effective" specialty pharmacy network.

MassHealth drug spending has experienced a compound annual growth rate of 13% since 2010. The adoption of a closed formulary, would enable MassHealth to negotiate more favorable agreements with manufacturers. The current requirement to cover all drugs in the Medicaid rebate program has obstructed MassHealth's ability to offer volume deals to manufacturers. In recent years, closed formularies have been adopted by the majority of commercial pharmacy benefit managers, allowing the customization of drug offerings based on clinical efficacy and cost considerations. The State will also establish an exceptions process, providing beneficiaries an appeals outlet to address specific clinical needs. The proposal has drawn pushback from health care consumer advocacy groups and PhRMA with concerns that this proposal will limit patient access to necessary prescription drugs.

The Commonwealth additionally requests for the ability to exclude drugs with limited, or inadequate, evidence of clinical efficacy from the formulary. In the waiver, Massachusetts criticizes the FDA's accelerated approval pathway, noting emerging drugs produce have problematic demonstrated clinical benefits resulting from the use of surrogate endpoints. Alternatively, in partnership with the University of Massachusetts Medical School, the State seeks to employ its own "rigorous review" process to determine coverage of new drugs; a method imposed to guarantee patients access to "clinically proven, efficacious drugs."

If these changes are approved, it is likely other states will seek similar waivers to lower drug pricing. (In November 2017, [Arizona signaled](#) that it was interested in doing something similar.) On the other hand, it is also likely that if these changes are approved there will be litigation on the issue.

Additional Waiver Elements

As noted above, the waiver includes additional changes. Massachusetts requests to transition certain Medicaid enrollees with incomes above 100% FPL to plans on the Massachusetts Marketplace. Additionally, non-disabled beneficiaries at or below the poverty level would be moved to a version of the State's Medicaid program that does not cover long-term support and services. The waiver also requests to remove the Medicaid institutions for mental diseases (IMD) exclusion, waive Medicaid requirement to cover non-emergency medical transportation (NEMT) for certain beneficiaries, and allow MassHealth to disregard state funded veteran annuities paid to disabled veterans and to Gold Star parents and spouses as income when determining program eligibility.