Update on Massachusetts' Waiver Request to use a Drug Formulary for Medicaid

On June 27, 2018, the Centers for Medicaid and Medicare Services (CMS) denied Massachusetts' request to implement a closed drug formulary in its Medicaid program. In a previous post, the Source described the request and explained why it has the potential to save the state millions of dollars every year. In denying the request, CMS said that it would consider the waiver if Massachusetts no longer used the federal Medicaid Drug Rebate Program in which manufacturers give the state rebates when the state purchases a drug to ensure that Medicaid receives the "best price."[1] States may negotiate below this federal "best price" when purchasing drugs for their state.

In its letter denying the use of the formulary, CMS noted that if Massachusetts chose to forgo all manufacturer rebates available under the federal Medicaid Drug Rebate Program and negotiate directly with manufacturers, "[t]he state could then be provided flexibility to exclude specific drugs from coverage cost-effectiveness..."[2] Under this program, Massachusetts would have to ensure that costs to the federal government would be less under the waiver than without the waiver. CMS' suggestion of an alternative way to implement a closed formulary in a state Medicaid program likely reflects questions about whether CMS has the legal authority to waive the drug coverage mandate without also waiving the rebate mandate. Earlier news reports suggest that U.S. Health and Human Services Secretary Alex Azar believes allowing a waiver to permit a closed formulary would allow drug manufacturers to successfully sue the United States. Legal scholars, however, question whether

such a lawsuit would be successful.

After the Trump Administration released a <u>blueprint</u> and <u>detailed</u> <u>steps</u> to increase price competition for pharmaceuticals, the decision by CMS appears to be a setback. If the federal government is serious about increasing pharmaceutical competition, they need to allow states to test different methods of bringing down prices, including using closed formularies, to force drug manufacturers to demonstrate the value of their products to patients.

^{[1] &}quot;Best price" is defined in 42 U.S.C. § 1396r-8(c)(1)(C) to be the "lowest price available from the manufacturer ... to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States", with a few specific exclusions including the Veterans Affairs and the Indian Health Service.

^[2]https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-ca.pdf