

Department of Legislative Services
Maryland General Assembly
2021 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1107 (Delegate Hill)
Health and Government Operations

Maryland Medical Assistance Program - Supplemental Rebate Program -
Subscription Model for Hepatitis C Therapies

This bill requires the Maryland Department of Health (MDH), by December 1, 2021, to apply to the federal Centers for Medicare and Medicaid Services (CMS) for a State plan amendment (SPA) that (1) authorizes the State to enter into value-based arrangements with drug manufacturers through supplemental rebate agreements and (2) authorizes a subscription model for hepatitis C virus (HCV) therapies regardless of disease severity or fibrosis level, as determined by Metavir score (a measure of liver damage or fibrosis) or an alternative nationally recognized assessment tool. To the extent practicable, MDH, in coordination with the Department of Public Safety and Correctional Services (DPSCS) and any other relevant State agency, must develop a subscription model for HCV therapies that covers all eligible individuals served by a State program while preserving the ability to maximize the use of federal funds. **The bill takes effect June 1, 2021.**

Fiscal Summary

State Effect: MDH can apply for an SPA using existing budgeted resources. MDH advises that a subscription model contract likely increases Medicaid expenditures (61% federal funds, 39% general funds) for HCV therapies by an indeterminate but potentially significant amount over the life of the contract, as discussed below. Federal matching funds increase accordingly. **Sufficient information was not available in time to include further analysis of the fiscal impact of this legislation on other State agencies.**

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law: Maryland Medicaid covers HCV treatment, including direct-acting antiviral therapies first approved in 2013. However, due to the high cost of the drugs, MDH initially restricted access to Medicaid participants with a Metavir score of F2 or greater (on a scale of F0 to F4), unless the individual had a viral condition known to result in more rapid disease progression and/or liver decompensation. MDH expanded treatment to those with Metavir scores of F1 or greater beginning July 1, 2019. In January 2020, MDH removed fibrosis restrictions for accessing HCV therapies. These treatment expansions align with Maryland's [Hepatitis C Strategic Plan](#), which was released in January 2019.

DPSCS offers HCV screening for inmates upon patient request or where clinically indicated. Offenders identified at intake of being on HCV treatment in the community are referred to the medical provider to ensure continuity of treatment. In fiscal 2019, DPSCS screened 2,170 inmates for HCV based on risk factors or clinical findings. Of those screened, 660 (30.4%) inmates tested positive for HCV, and 536 received HCV treatment. The cost of HCV treatment for DPSCS is \$21,195 per inmate.

State Fiscal Effect: MDH advises that, under a subscription model for HCV therapies, a state Medicaid program contracts with a drug manufacturer to purchase unlimited access to a given treatment in exchange for a flat annual fee. Contracts typically are negotiated for multiple years and presume the state will meet a certain threshold of treatment each year. To the extent the state's actual use exceeds the threshold, the state saves money and additional individuals can be treated at no additional cost. However, in the event actual use is lower than the threshold amount, the state must still pay the flat rate. Furthermore, to the extent that the cost of HCV prescription drugs that the state would have paid absent the subscription model decreases over time, the amount of savings is reduced.

According to MDH, the cost of HCV treatment has decreased substantially in recent years due to the introduction of new drugs to the market and generic equivalents. For example, in calendar 2016, the cost for a full course of treatment averaged \$87,174; in calendar 2020, this cost had declined to \$25,469. MDH estimates the cost will continue to decrease by an estimated 5.39% annually to approximately \$19,303 by calendar 2026. Medicaid treats approximately 3,200 enrollees for HCV annually.

Based on the assumptions that a subscription model contract would be for a five-year period with a negotiated price slightly below the current cost per treatment, MDH estimates that Medicaid expenditures (61% federal funds, 39% general funds) likely *increase* under a subscription model contract over the course of the contract compared to projected costs under current law. While the cost may be reduced initially, over the course of the contract, expenditures are estimated to increase relative to what they would have been absent the contract due to estimated annual declines in the price of HCV drug therapies in the

competitive market. Medicaid estimates that, over a five-year contract, expenditures for HCV therapies could increase by a total of \$41.1 million based on pricing.

In addition, to the extent MDH does not meet treatment thresholds in the contract, MDH pays for more treatments than are utilized. MDH advises that Washington State has experienced this challenge with its contract, particularly in light of the COVID-19 pandemic. To the extent Medicaid fails to meet utilization targets, Medicaid expenditures increase further.

This analysis does not reflect any impact resulting from the bill's provision that requires MDH, in coordination with DPSCS and any other relevant State agency, to develop a subscription model for HCV therapies that covers all eligible individuals served by a State program while preserving the ability to maximize the use of federal funds. Sufficient information was not available in time to include an analysis of this provision.

Additional Comments: In 2019, Louisiana became the first state to enter into a subscription model for unlimited access to HCV medication for a period of five years. During that period, Louisiana will treat as many Medicaid patients and incarcerated individuals as it can under one set contract price rather than paying for individual prescription costs. CMS approved Louisiana's SPA, which authorizes the state to negotiate supplemental rebate agreements using a subscription model. Washington entered into two contracts for HCV medication in 2019: (1) a traditional drug rebate arrangement for those in state-operated facilities (incarcerated individuals) and public and school employees; and (2) a modified subscription model for Medicaid. CMS approved Washington's value-based purchasing SPA for a subscription model. Washington's contract includes quantity thresholds that the state must meet in order to achieve price discounts.

Additional Information

Prior Introductions: None.

Designated Cross File: None.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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