

Department of Legislative Services
 Maryland General Assembly
 2019 Session

FISCAL AND POLICY NOTE
 Third Reader - Revised

Senate Bill 598
 Finance

(Senator Nathan-Pulliam)

Health and Government Operations

Maryland Medical Assistance Program - Coverage - Hepatitis C Drugs

This bill requires Medicaid, subject to the limitations of the State budget, to provide medically appropriate drugs that are approved by the U.S. Food and Drug Administration (FDA) for the treatment of hepatitis C, regardless of the fibrosis score, and that are determined to be medically necessary.

Fiscal Summary

State Effect: Medicaid expenditures increase by \$4.0 million (68% federal funds, 32% general funds) in FY 2020, as discussed below. Federal fund revenues increase accordingly. The FY 2020 Medicaid budget restricts \$1.3 million in general funds for this purpose. Future years reflect annualization, an increase in the prevalence of hepatitis C, and a reduction in individuals seeking treatment due to the high cure rate. **This bill increases the cost of an entitlement program beginning in FY 2020.**

(\$ in millions)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
FF Revenue	\$2.7	\$3.2	\$2.9	\$2.6	\$2.4
GF Expenditure	\$1.3	\$1.6	\$1.4	\$1.3	\$1.2
FF Expenditure	\$2.7	\$3.2	\$2.9	\$2.6	\$2.4
Net Effect	(\$1.3)	(\$1.6)	(\$1.4)	(\$1.3)	(\$1.2)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law/Background: Maryland Medicaid has established certain criteria for individuals to be eligible for new hepatitis C therapies, including having a diagnosis with chronic hepatitis C; having liver fibrosis corresponding to a Metavir score (a measure of liver damage or fibrosis) of F2 or greater; prior hepatitis C treatment history and outcomes; having a treatment plan; having a medication adherence evaluation; and if, of childbearing age or having a partner of childbearing age, utilizing two forms of contraception during and within six months of treatment. However, the fiscal 2020 budget includes \$29.3 million to expand access to hepatitis C treatment for individuals with a Metavir score of F1 or more.

The Maryland Department of Health submitted a report to the budget committees in January 2019 that outlines a hepatitis C strategic plan with four goals: (1) preventing new hepatitis C infections through increased community awareness and ensuring access to prevention services; (2) expanding hepatitis C testing especially among high-risk populations through the promotion of routine testing at key service-delivery points with more complete testing after a positive screening; (3) improving access to treatment and adherence services through improved linkages to services, increasing screening and treatment capacity in rural and urban settings, and addressing the high cost of drugs; and (4) enhancing hepatitis C surveillance, monitoring, and evaluation through timely submission of reports to appropriate surveillance entities, expanded reporting, and monitoring of health services and outcomes.

The report also noted several challenges, including a lack of awareness about risk factors for hepatitis C and the consequences of infection and the need for treatment, limited access to testing, incomplete data reporting that limits surveillance, an increase in individuals with substance use disorders, lack of social supports for those with confirmed infections, stigma around the disease, and the cost of treatment.

In calendar 2016, there were 22,352 Medicaid participants with a hepatitis C diagnosis code. Assuming only those with an F2 score or above could access treatment (estimated at 54% or 12,070 individuals), only 1,041 individuals received the new drug therapies, a treatment rate of just 8.6%. The total cost to treat those individuals was \$138.9 million before drug rebates, or about \$73.9 million after rebates.

Most other states have adopted medical criteria like Maryland to determine which Medicaid recipients receive the new therapies, including limiting therapies to those with certain Metavir scores. As of January 2019, 6 states used a Metavir criteria less inclusive than Maryland's, 5 states and the District of Columbia used the same criteria, 1 had a lesser restriction, and 37 had no restrictions (including 1 state that was expected to finalize no restrictions in February 2019).

According to the U.S. Centers for Disease Control and Prevention, hepatitis C is a liver infection caused by the hepatitis C virus (HCV). For some people, hepatitis C is a short-term illness, but for 70% to 85% of people who become infected with hepatitis C, it becomes a long-term, chronic infection. The majority of infected persons might not be aware of their infection because they are not clinically ill. The treatment for HCV has evolved substantially since the introduction of highly effective HCV protease inhibitor therapies in 2011. Since that time, new drugs with different mechanisms of action have become and continue to become available. Currently available therapies can achieve sustained virologic response, defined as the absence of detectable virus, 12 weeks after completion of treatment, indicative of a cure of HCV infection. Over 90% of HCV-infected persons can be cured of HCV infection with 8 to 12 weeks of oral therapy.

State Fiscal Effect: Medicaid expenditures increase by an estimated \$4.0 million (68% federal funds, 32% general funds) in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. Federal fund revenues increase accordingly. This reflects the cost to expand coverage for new hepatitis C drug therapies that are determined to be medically necessary, regardless of fibrosis (or Metavir) score. The information and assumptions used in calculating this estimate are stated below.

- As the fiscal 2020 budget includes funding to expand hepatitis C treatment to individuals with a Metavir score of F1 or more, this estimate reflects the cost to expand coverage to enrollees, regardless of fibrosis score (those with a Metavir score of F0).
- There are approximately 2,542 individuals enrolled in Medicaid with a Metavir score of F0.
- An estimated 12% of Medicaid enrollees with HCV will seek treatment (305).
- Of the 305 individuals who seek treatment, 290 (95%) will be cured.
- The per person cost of treatment is \$17,500.
- Federal matching funds are provided at a rate of 68%.
- Medicaid receives drug rebates for approximately 25% of the cost of the drug, which offsets total costs.

Future years reflect an increase in the prevalence of HCV in the Medicaid population of 2% annually and a decrease in the number of individuals seeking treatment due to the high cure rate.

The fiscal 2020 Medicaid budget restricts \$1.3 million in general funds otherwise intended for provider reimbursements to be used only to expand access to drug treatments for hepatitis C by removing any restriction related to having liver fibrosis corresponding to a Metavir score.

Additional Information

Prior Introductions: SB 943 of 2018, a bill with similar provisions, received a hearing in the Senate Finance Committee, but no further action was taken.

Cross File: HB 962 (Delegate Wilkins, *et al.*) - Health and Government Operations.

Information Source(s): U.S. Centers for Disease Control and Prevention; Maryland Department of Health; Department of Legislative Services

Fiscal Note History: First Reader - March 5, 2019
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