SB 943

Department of Legislative Services

Maryland General Assembly
2018 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 943 (Senator Nathan-Pulliam)
Finance

Maryland Medical Assistance Program and Health Insurance - Coverage - Hepatitis C Drugs

This bill requires Medicaid as well as insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers) to provide specified coverage of any medically appropriate drug that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of hepatitis C. The bill applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2019.

Fiscal Summary

State Effect: Minimal increase in special fund revenues for the Maryland Insurance Administration (MIA) in FY 2019 only. Review of filings can likely be handled with existing resources. Medicaid expenditures (62% federal funds, 38% general funds) increase *significantly* beginning in FY 2019, as discussed below. Federal fund revenues increase correspondingly. Expenditures for the State Employee and Retiree Health and Welfare Benefits Program increase by an indeterminate but likely minimal amount beginning in FY 2019.

Local Effect: Health insurance premiums likely increase for any local governments with fully insured medical plans. Revenues are not affected.

Small Business Effect: None.

Analysis

Bill Summary: Medicaid must provide, subject to the limitations of the State budget, any medically appropriate drug that is approved by FDA for the treatment of hepatitis C and that is determined to be necessary by the treating physician of the Medicaid recipient.

A carrier that provides hospital, medical, or surgical benefits must provide coverage for any medically appropriate drug that is approved by FDA for the treatment of hepatitis C and that the insured's or enrollee's treating physician or other appropriately licensed health care provider certifies is necessary for the treatment of hepatitis C. A carrier may not deny the insured or enrollee coverage based on the insured's or enrollee's level or severity of liver damage or reduce or eliminate coverage in health insurance policies or contracts due to the requirements of the bill.

Current Law: Under Maryland law, there are 49 mandated health insurance benefits that certain carriers must provide to their enrollees. The federal Patient Protection and Affordable Care Act (ACA) requires nongrandfathered health plans to cover 10 essential health benefits (EHBs), which include items and services in the following categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including dental and vision care.

Under § 31-116 of the Maryland Insurance Article, EHBs must be included in the State benchmark plan and, *not withstanding any other benefits mandated by State law*, must be the benefits required in (1) all individual health benefit plans and health benefit plans offered to small employers (except for grandfathered health plans) offered outside the Maryland Health Benefit Exchange (MHBE) and (2) all qualified health plans offered in MHBE.

Background: 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.

Medicaid has established certain criteria for individuals to be eligible for the new HCV 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, must be utilizing two forms of contraception during and within six months of treatment.

The Maryland Department of Health (MDH) advises that most other state Medicaid programs have adopted similar criteria to determine which recipients receive the new therapies. These include limiting therapies to those with certain Metavir scores (23 states use a Metavir criteria that is less inclusive than Maryland's), requiring some period of abstinence from abuse of alcohol or drugs, and requiring a specialist to prescribe the therapy. However, a small number of states have no restrictions (in some cases a result of legal action).

In a letter to MDH dated December 1, 2017, the American Civil Liberties Union of Maryland announced its intention to take legal action if Medicaid did not commit, by January 2, 2018, to remove restrictions on access to the new hepatitis C therapies. MDH's response indicated that it was developing a broad-based plan to address hepatitis C in Maryland that would be complete by June 2018.

In a January 24, 2018 report to the budget committees, MDH recommended no changes to its current coverage policy, noting concerns about the potential budgetary impact, with a general fund cost of as much as $27 million to $59 million annually for the most extensive access to treatment. The uncertainty in the potential costs reflected concerns on price volatility, an increase in the prevalence of hepatitis C in the Medicaid population, and limited information about the Metavir scores of the infected population. The report also noted that there are potential savings from decreased transmission, improved quality of life, and the potential to avoid subsequent treatment with more expensive medications; however, benefits (and cost savings) may not accrue for many years.

State Fiscal Effect:

Medicaid

Maryland Medicaid currently covers HCV treatment for enrollees with liver damage rated at an F2 or greater on the Metavir scale. Under the bill, coverage must be extended to individuals with liver damage rated at F0 and F1. Medicaid estimates that as many as 10,873 individuals could qualify for coverage under the bill. Thus, Medicaid expenditures increase *significantly* beginning in fiscal 2019 to provide coverage of any medically

appropriate drug that is approved by FDA for the treatment of hepatitis C that is determined to be necessary by the treating physician of the Medicaid recipient.

For illustrative purposes only, based on a conservative uptake in treatment of 11.64%, 1,266 additional individuals receive treatment for HCV. The average cost of a full course of treatment ranges from $26,400 to $133,000. If approximately one-third of individuals are treated at a cost of $26,400, and the remaining two-thirds are treated at a cost of $133,000, the total cost to Medicaid is $123.8 million, or $68.3 million after pharmaceutical rebates. If the full eligible population seeks treatment under the bill, Medicaid costs increase by as much as $586.7 million, net of pharmaceutical rebates.

State Employee and Retiree Health and Welfare Benefits Program

Self-insured employer plans are exempt from State health insurance mandates and requirements under the federal Employee Retirement Income Security Act. The Department of Budget and Management (DBM), therefore, advises that the State Employee and Retiree Health and Welfare Benefits Program (program) is generally not subject to these mandates because all but one of its medical plans are self-insured; Kaiser is fully insured and subject to mandates.

Although not required to follow health insurance mandates, the program generally does. Thus, this estimate is based on the assumption that the program will follow the bill's requirements. FDA-approved medications for the treatment of hepatitis C are already covered under the program. Three drugs are included on the program's 2018 preferred drug list (Harvoni, Epclusa, and Vosevi). By requiring coverage for any medically appropriate, FDA-approved drug for the treatment of hepatitis C, DBM advises the bill essentially prohibits prior authorization for nonpreferred drugs and may result in coverage of more costly drugs. Thus, program expenditure increase by an indeterminate but likely minimal amount under the bill.

Additional Comments: According to MIA, the bill establishes a new mandated benefit for the large group market only. Under the ACA, each state must pay, for every health plan purchased through MHBE, the additional premium associated with any state-mandated benefit beyond EHBs. As such, if the Insurance Commissioner elects to include the mandate in the State benchmark plan, the State would be required to defray the cost of the benefits to the extent it applies to the individual and small group market ACA plans.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): U.S. Centers for Disease Control and Prevention; Department of Budget and Management; Maryland Department of Health; Maryland Health Benefit Exchange; Maryland Insurance Administration; Department of Legislative Services

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