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U.S.

## Federal Officials Warn States on Hepatitis C Drug Restrictions

Officials say state Medicaid programs may be violating law by denying expensive medicines

By **JOSEPH WALKER**

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In a sign of growing government interest in rising prescription-drug costs, federal officials on Thursday said state Medicaid programs may be violating federal law by denying patients expensive hepatitis C medications.

They also asked drug makers to provide information on their pricing arrangements with health insurers, which officials said could help ease the financial burden on state budgets.

The Centers for Medicare and Medicaid Services said in a notice to state Medicaid directors that some states may be “imposing conditions for coverage that may unreasonably restrict access” to hepatitis C drugs. Such restrictions may be “contrary to the statutory requirements” of a federal law requiring Medicaid programs to pay for all medically necessary treatments, defined as any use approved by the Food and Drug Administration or by certain medical guidelines known as compendia, the notice said.

CMS’s notice, which was posted online Thursday, said that some states have restricted use of hepatitis C drugs to Medicaid patients with severe liver disease and those who can prove they have abstained from drug and alcohol abuse. Patient advocates and doctors have long complained that such conditions aren’t included in the drugs’ FDA-approved prescribing labels.

CMS’s notice to states was announced in a blog post by Andy Slavitt, acting administrator of CMS. Mr. Slavitt said that the high cost of hepatitis C drugs had “strained personal as well as public budgets, particularly state health-care budgets.” Referring to what he called “heated” public debate on rising drug costs, he said that “it can appear as if some of those who produce the pharmaceuticals and those whose lives often depend on them have unaligned interests.”

Mr. Slavitt wrote letters to the chief executives of several hepatitis C drug makers to request information about the companies’ “value-based” pricing arrangements with commercial and government health insurers. Mr. Slavitt said in the letters, which were also posted online, that he was requesting the information to better understand such arrangements, which he said could impact the discounts state Medicaid programs are entitled to receive for drugs.

Value-based pricing is an industry term for when the price paid by insurers and pharmacy-benefit managers depends in part on how effective a drug is with a given patient. Mr. Slavitt said states should be given the opportunity to participate in such pricing arrangements.

The letter also asks the CEOs if they have “other ideas to assist states in the affordability of these new, unbudgeted pharmaceuticals?”

The letters were sent to Gilead Sciences Inc., AbbVie Inc., Johnson & Johnson, and

Merck & Co.

AbbVie said it intends to respond to CMS's request. Gilead declined to comment. J&J and Merck didn't respond to requests for comment.

Medicaid, which provides health insurance to low-income people, is entitled under federal law to receive rebates of at least 23.1% of the "best price" at which a drug maker sells brand-name drugs. A manufacturer's "best price" is defined as the lowest price a company gave to a buyer after discounts and rebates.

Aaron Albright, a CMS spokesman, said in an email that the agency had received questions about how value-based pricing "fits into the best price rules, so we are trying to gather information to understand what's happening."

Patient advocates praised CMS's guidance to states, which they said would help increase the availability of treatments for patients. Robert Greenwald, director of Harvard University's Center for Health Law and Policy Innovation, said in an email that his group "applauds CMS for clearly articulating that restricting access to HCV treatments solely on the basis of cost and using medically unjustifiable criteria is unacceptable."

Many states have complained that the high cost of new medications has strained their budgets. In 2014, Texas refused to pay for Gilead's hepatitis C drug Sovaldi, which state officials attributed to the drug's \$84,000 list price per treatment course, The Wall Street Journal reported earlier this year.

Through the first half of this year, state Medicaid programs spent a combined \$1.33 billion before rebates on Gilead's hepatitis C drugs Harvoni and Sovaldi, according to preliminary data posted on CMS's website.

In its notice to states, CMS also said it was concerned that health insurers known as managed-care organizations, which are paid by states to provide health insurance to some Medicaid beneficiaries, have "more restrictive" policies on hepatitis C drugs than traditional plans administered by states.

States should "examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment" of new hepatitis C drugs, CMS said in the notice. CMS also said it would monitor states' policies on hepatitis C drugs "to ensure compliance with the requirements" of the law.

CMS also said that, "given the costs" of the drugs, it shared states' budget concerns, but that states should take advantage of increased competition among drug manufacturers to negotiate larger rebates or other pricing arrangements to reduce their costs.

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