



Consider the Unintended Consequences on Patient Care

The Centers for Medicare & Medicaid Services should hit pause on a proposal.

October 15, 2020 By Adrienne Simmons

The Trump administration has presented proposals aimed at improving prescription drug access and affordability for Americans. In 2018, the administration laid out a Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, and the president recently released proposals designed to reduce costs in the Medicare and Medicaid programs.

Yet the process for creating these policies has been flawed, and several proposed changes may have an unintended negative impact on patients. It's exactly the reason why the Centers for Medicare & Medicaid Services (CMS) should delay a [Medicaid proposal](#) that could have implications for patients with hepatitis C and other conditions.

Under existing law, drug manufacturers must pay a higher Medicaid rebate for "line extensions" of drugs. Manufacturers self-report drugs as line extensions when they make enhancements to existing treatments. The line extension policy was intended to prevent manufacturers from making small changes to oral solid dosage forms — such as an extended release formulation — in an attempt to extend the drug's patent.

However, CMS recently proposed a rule that would broaden the line extension definition and retrospectively require drug manufacturers to pay a Medicaid rebate for a wider range of treatments, including many more effective, more convenient and better tolerated drugs for hepatitis C, HIV and other severe chronic diseases.

The proposed definition would include any product that has at least one ingredient in common with the original drug, even if it is a different dosage form. This would include combination drugs, which have been a key to success in curing hepatitis C and preventing HIV. If implemented, this expanded definition of "line extension" could disincentivize manufacturers from developing combination antivirals, which reduce pill burden and are known to improve a patient's ability to take a medication as prescribed.

Take hepatitis C for example. Because of medical advancements, hepatitis C is now an easily curable condition. Today, patients diagnosed with hepatitis C may be cured with a once daily pill regimen in eight to 12 weeks. But continued research and development is necessary to inform

future formulation changes that could allow patients to take their treatment over an even shorter timeframe. For example, future formulations could help eliminate hepatitis C in harder to reach populations, such as people who inject drugs and people experiencing homelessness.

If finalized, this rule would call into question the likelihood of whether manufacturers will continue pursuing the development of long-acting antivirals, such as a monthly dose or a single dose cure. These formulations would make it easier for patients to maintain their treatment course and increase adherence rates, leading to greater public health outcomes. But many of these treatment advancements would be subject to higher rebates if CMS finalizes the Medicaid proposed rule, causing manufacturers to potentially halt these research and development efforts.

CMS has the right intention in continuing to seek solutions to reduce health care costs and to clarify the definition of a line extension to minimize inconsistent interpretations of the term. However, the specificity of the rule as it's written has significant implications, and stakeholders must be provided adequate time to consider such implications.

In the midst of COVID-19, the latest pandemic, we cannot lose sight of the long-term solutions that are needed to contain health care costs. But we also can't overlook how certain proposals may inadvertently harm patient access and care. As it's written, this CMS proposed rule is a hurried attempt to patch a broken system while further complicating healthcare for vulnerable communities. CMS must hit pause and realize this too.

This opinion was written by Adrienne Simmons, PharmD, MS, BCPS, AAHIVP, policy manager for the National Viral Hepatitis Roundtable ([NVHR](#)), a national coalition working together to eliminate viral hepatitis in the United States.