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For a time, the Commonwealth of Virginia had a prior-authorization regime in place that wrongly restricted patients’ eligibility for certain hepatitis C medications—restrictions that a federal district court and the Department of Health and Human Services (HHS) itself opined violated federal law.

Virginia ultimately abandoned the prior-authorization restrictions. But while they were in place in 2015 and 2016, a clinical pharmacy manager at a Tennessee Walgreens and one of her employees changed data on forms and falsified laboratory test results relating to disease severity and drug and alcohol abstinence. That allowed Medicaid patients in Virginia to obtain prior authorization for hepatitis C medications that their physicians prescribed and that Walgreens provided.

The U.S. government criminally prosecuted the Walgreens employees, and the two ultimately pleaded guilty to health care fraud. But now the government wants to collect treble damages from Walgreens for the nearly $800,000 it paid for the medications dispensed—medications that the patients would have wrongly been denied under the unlawful prior-authorization restrictions.

That can’t be allowed to happen, physicians say. The Litigation Center of the American Medical Association and State Medical Societies, the Medical Society of Virginia (MSV) and the U.S. Chamber of Commerce (Chamber) tell the 4th U.S. Circuit Court of Appeals that there is no basis for the government’s claim under the False Claims Act (FCA) and that it is “contrary to Medicaid’s goal of providing prescription drug coverage to needy citizens.”

Fixing prior authorization is a critical component of the AMA Recovery Plan for America’s Physicians.

Prior authorization is overused and existing processes present significant administrative and clinical concerns. Find out how the AMA is tackling prior authorization with research, practice resources and reform resources.

Find out more about the cases in which the AMA Litigation Center is providing assistance and learn about the Litigation Center’s case-selection criteria.

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Negative impact on patient health

The brief from the AMA Litigation Center, MSV and the Chamber underscores Walgreen Co.’s argument that the lower-court decision that dismissed the lawsuit should stand. The government is asking the appellate court to overturn the decision.

“The government’s argument that an FCA defendant cannot assert the illegality of a funding condition effectively means that states that impose unlawful conditions on the receipt of Medicaid assistance are entitled to keep their ill-gotten gains (and in fact treble them). Accepting those arguments would incentivize governments to impose illegal funding conditions, with the consequence of denying care to patients who depend on Medicaid,” says the amicus brief filed by the AMA Litigation Center, MSV and the Chamber in the case, United States of America and Commonwealth of Virginia v. Walgreen Co.

The brief tells the court that the medical associations oppose prior-authorization requirements like the one Virginia had in place and are concerned about the negative impact on state-federal health care programs if the appellate court overturns the decision.

“In a recent resolution, the AMA House of Delegates surveyed the medical evidence and concluded that ‘there are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successful complete [hepatitis C] therapy’ and ‘that initiating therapy in patients with lower-stage fibrosis augments the clinical and public health benefits of virologic cure, and treatment delay may decrease the benefit of virologic cure,’” the brief says.

Entitled to payments

The FCA’s primary purpose is to make the government completely whole for any losses. But because the Virginia requirements were unlawful, the government didn’t suffer any losses. The brief says federal law “entitled Walgreens to reimbursement for every hepatitis C treatment at issue.”

“Walgreens patients were legally entitled to coverage for the medications that doctors prescribed and Walgreen was legally entitled to reimbursement for providing those medications. Neither this Court nor the Supreme Court has ever ruled that a defendant could be barred from raising such an argument,” the brief says.

Further, the brief says, “no one paid more than they were legally obligated to pay; and Walgreens received nothing more than what it was owed. That is not a scenario in which the FCA’s draconian treble damages remedy applies, nor was it intended to do so. To hold otherwise would create fundamental unfairness for FCA defendants in a wide range of cases involving unlawful payment.
conditions.”