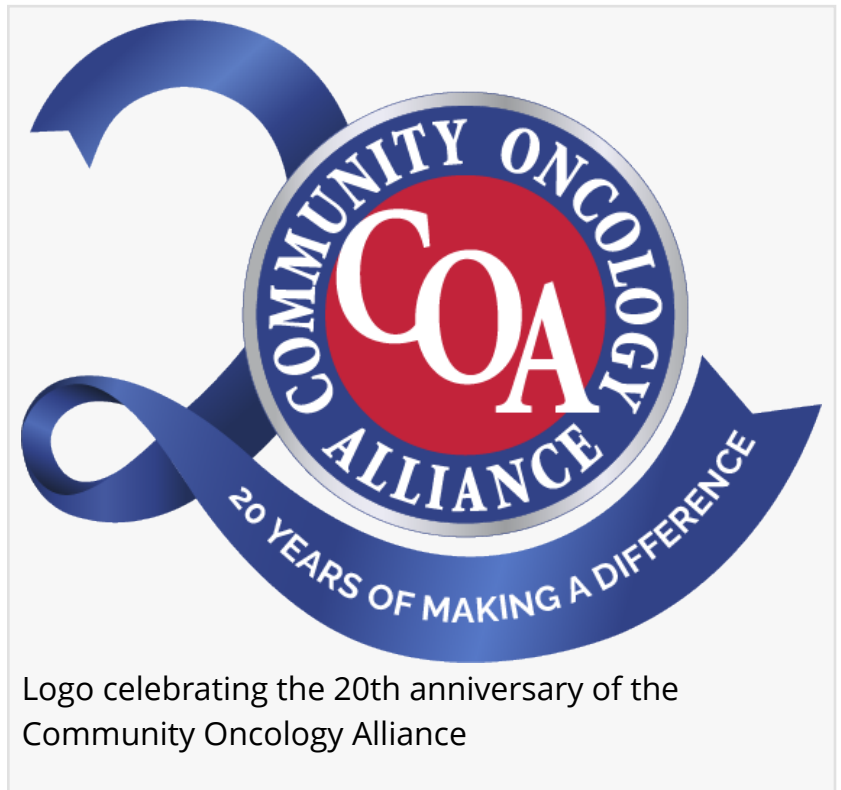


COA Files Lawsuit Against HHS FAQ Limiting Cancer Drug Delivery to Patients

Policy Change Restricting Practice Delivery of Oral Medications is Dangerous Display of Government Overreach, Says Suit

WASHINGTON, D.C., UNITED STATES, July 27, 2023 /EINPresswire.com/ -- The Community Oncology Alliance (COA) has filed a lawsuit on behalf of its members and the patients they serve against the United States Department of Health and Human Services (HHS) to overturn a recent change in federal health policy restricting cancer practices from delivering drugs to patients. The suit calls the change in policy an unconstitutional and dangerous display of government overreach that presents real and irreparable injury to patients.



- [Click here to read the full lawsuit against the HHS drug delivery limits.](#)

Filed this week in the U.S. District Court District of Columbia, COA's suit is in response to a [Frequently Asked Questions \(FAQ\) document](#) issued by the Centers for Medicare & Medicaid Services (CMS) stating that it is a violation of Stark law for independent practices to deliver oral cancer medications to their patients, even if a caregiver picks up a drug for a patient. The guidance was released ahead of the end of the COVID-19 Public Health Emergency (PHE) on May 11, 2023.

"HHS has blatantly and clearly overreached with this FAQ and cancer patients are suffering because of it. COA filed this lawsuit because we cannot let the government simply make unconstitutional rule changes whenever it wants," said Ted Okon, executive director of COA. "By allowing this FAQ to silently become official policy, CMS has courted disaster for cancer patients

and others with serious diseases across the country. The clinical best practices and procedures for patient care, that practices followed forever, are now being upended by bureaucratic edict and putting Medicare seniors at risk.”

The case notes that since the issuing of the FAQ, patients with cancer across the country have faced disruptions to their care. In some cases, patients have been forced by CMS to rely on pharmacy benefit manager (PBM) mail order pharmacies for their treatments, which [COA has long noted](#) are prone to delays, denials, and issues with delivery. The change has been particularly problematic for patients too sick to pick up their drugs, especially in rural or underserved areas, and low-income patients who are now forced to travel, often having to use public transportation to return to the clinic to receive their drug therapies each month.

COA believes that the rule change quietly issued through an FAQ on a website violates the federal rulemaking process required for such a “substantive amendment” to existing rules, in addition to the 10th Amendment to the United States Constitution. The Medicare Act and Administrative Procedure Act require formal notice and comment periods so that stakeholders can be adequately notified and allowed to express their concerns before such major changes to existing rules. Further, the 10th Amendment should protect those States with preexisting physician-dispensed medication mailing rules from interference by the federal government.

The case is Community Oncology Alliance v. Becerra et al., case number 1:23-cv-02168, in the U.S. District Court for the District of Columbia. COA is represented by Jonathan Levitt, Jason Silberberg, and Matthew Modafferi of the law firm Frier Levitt LLC.

Read the full filing at https://mycoa.s3.amazonaws.com/COA_StarkDrugDelivery_HHS-CMS_Lawsuit.pdf.

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About the Community Oncology Alliance: The Community Oncology Alliance (COA) is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. For more than 20 years, COA has been the only organization dedicated solely to community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. More than 5,000 people in the United States are diagnosed with cancer every day and, deaths from the disease have been steadily declining due to earlier detection, diagnosis, and treatment. Learn more at www.CommunityOncology.org. Follow COA on Twitter at www.twitter.com/oncologyCOA or on Facebook at www.facebook.com/CommunityOncologyAlliance.

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