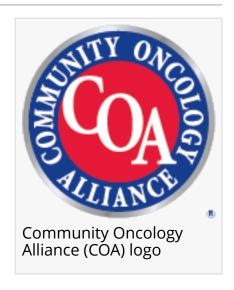


COA: CMS Allows Middlemen to Force Patients to "Fail First" While Paradoxically Keeping Cancer a Protected Class

Final Part D Rule Means All Medicare Patients with Cancer Will Face a More Dangerous Nightmare of Denials and Delays to Physician-Prescribed Treatments

WASHINGTON, DISTRICT OF COLUMBIA, UNITED STATES, May 23, 2019 /EINPresswire.com/ -- The Centers for Medicare & Medicaid Services (CMS) recently released its final rule for Medicare Part D that will maintain the status of cancer as a "protected class" in Medicare Advantage (MA). The Community Oncology Alliance (COA) commends CMS for this decision; however, and paradoxically, in the final rule, CMS codified its decision to allow MA plans to use "fail first" step therapy for new starts of Part B drugs for cancer and other serious diseases. The Trump administration's decision to finalize step therapy in MA plans means that Medicare patients with cancer will face nightmares of delays and denials while trying to access their physician-prescribed treatments.



As COA noted in our strong opposition and <u>comments to the original decision on "fail first" step</u> therapy, the Trump administration has perpetuated a nightmare for Medicare patients with cancer. We are already seeing patients facing significantly increased difficulty accessing the



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evidence-based treatments that trained oncologists have prescribed for their individual cancers. This final rule puts medical decision making in the hands of middlemen – health plans and pharmacy benefit managers (PBMs) – who can force use of older, less-appropriate cancer treatment or drugs simply because of cost.

Step therapy requirements are driven by financial interests to save money and not by what is in the best interest of a patient with cancer. They leave patients at the whim of MA health plans and PBMs that are more concerned with their financial well-being than patient outcomes and side

effects. Additionally, far from a focus on saving money, COA has seen several examples where step therapy decisions are made to push the drug that will provide the middlemen the maximum rebate, not necessarily the lower cost. This includes plans preferring expensive brand name drugs where generics or biosimilars are available, all because of secret contracts and formularies that earn the middlemen more in rebates.

Even with the status quo in which cancer remains a protected class, middlemen-dictated restrictions on drug access already cause patients extreme difficulty, which can result in lengthy delays and questionable denials for access to life-saving treatment. Countless times, bureaucratic middlemen delays have meant that patients with cancer must postpone treatment that would give them their best chance at battling this devastating disease. COA has highlighted numerous PBM horror stories in a series of papers, pulled from our extensive and ever-growing

database of real stories submitted by practices across the country. Giving MA plans more authority to place hurdles between patients and their prescribed therapies shifts decision making away from the clinical expertise of providers and instead places it with financially motivated corporate middlemen.

Even though CMS proposes patient safeguards, such as an appeals process, it is incomprehensible to require patients receiving cancer treatment, or their already overwhelmed and distressed family members and/or caregivers, to first fail on inferior, sometimes inappropriate cancer therapy, let alone navigate a bureaucratic appeals process. Moreover, allowing broader use of prior authorization and "fail first" step therapy for protected classes, places an additional administrative burden on providers to sort through utilization management processes in order to ensure access to cancer treatment in a timely manner. It is not uncommon for community oncology practices to spend many valuable hours on overcoming PBM and plan sponsor denials of medication needed by critically ill patients.

"Oncologists are challenged every day by our patients who present with complex cancer cases. Each of these require individualized, evidence-based treatment plans that are informed by our years of education, experience, and most importantly, firsthand observations of that particular patient," said Michael Diaz, M.D., a practicing medical oncologist at Florida Cancer Specialists & Research Institute, and COA president. "CMS' final rule means that oncologists will face more barriers to providing cancer patients with the treatments that they need, when they need them. At a time when we are trying to improve the health care system, it is unconscionable that the administration would finalize such a dangerous proposal that will only make patient care more difficult and complex."

"There is only one word for 'fail first' step therapy for patients with cancer: inhumane," said Ted Okon, executive director of COA. "Anyone who has experienced cancer knows that dealing with middlemen who come between them and their treatments is a true nightmare. Worst of all, the dirty little secret is that it isn't in the best interest of patient care or outcomes – it is all to save middlemen corporations a buck while patients suffer. The administration has made a huge mistake with moving this final rule forward and we implore them to reconsider."

COA implores the Trump administration to rescind this final rule and reconsider allowing "fail first" step therapy in Medicare. As noted in our original comment letter on this proposed rule, we recommend that treatments prescribed in line with provider-developed clinical guidelines, pathways, or evidence-based protocols should be made available with minimal middleman interference and on the lowest or preferred tiers. This would better align all health care stakeholders and incentivize high-value care.

COA commends and continues to support the Trump administration's efforts to achieve lower drug prices and reduce cancer care costs for Medicare and beneficiaries. However, this cannot come by putting the health of Medicare seniors with cancer and other serious diseases in jeopardy. Middlemen should not be empowered to make or deny individualized, evidence-based treatment decisions for patients with cancer. The proposed rule will have a tremendous impact on patient outcomes, the physician-patient relationship, and administrative burdens, all of which our government should be seeking to improve, not worsen.

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The Community Oncology Alliance (COA) is a non-profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA leads community cancer clinics in navigating an increasingly challenging environment to provide efficiencies, patient advocacy, and proactive solutions to Congress and policymakers. Learn more about COA at www.communityOncology.org.

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