

August 9, 2019

Dear Colleagues,

The first half of 2019 has seen incredible activity on many fronts for the Community Oncology Alliance (COA) in our advocacy for patients with cancer and the community oncology teams that care for them. What follows is an update of all of COA's efforts, initiatives, committees, and publications so far this year.

The COA team is always in Washington keeping our eyes on legislation and proposals, ensuring that the concerns of community oncology are well heard. Policymaking in Congress is fluid and liable to change day to day as deals are cut, particularly with oncology, as the ASP reimbursement system is always a tempting target in budget negotiations. Furthermore, we are often up against multibillion-dollar corporations, such as PBMs, that wield incredible power. That is why it is so important for COA to stay vigilant and ready to act when necessary!

If you have any questions about the specific updates or need to bring an issue to our attention, please do not hesitate to get in touch. We are here to serve you, your practice, and your patients.

Sincerely,



Michael Diaz, MD
President
mdiaz@coacancer.org



Ted Okon
Executive Director
tokon@coacancer.org

COA is YOUR Voice in Washington, Helping Shape Policy

As the only voice dedicated solely to independent community oncology interests in Washington, DC, COA's legislative team has been very busy over the past six months. President Trump's "Blueprint for Reducing Drug Prices" certainly has influenced our work as we have commented on nearly every proposal related to drug pricing.

So far this year, we have been asked to meet with the White House, Department of Health & Human Services, Centers for Medicare & Medicaid Services (CMS), and the major Congressional committees of jurisdiction to discuss drug prices and costs, patient access to cancer treatment—especially new therapies—and strategies for reforming the payment system to control Medicare & seniors' costs.

The fact that Washington policymakers are looking for solutions to the high cost of prescription drugs and are listening to COA has given us a tremendous opportunity to influence discussion and shape legislation.



Here are some practice-impacting highlights of COA's policy advocacy efforts and challenges from just the first half of 2019:

- **ASP Reform** — With the increased utilization of expensive immunotherapy and targeted therapies for cancer drugs, the current ASP reimbursement model is not sustainable. Congress is working on legislation to alter the current ASP formula (currently ASP + 6% but is actually 4.3% due to the ongoing application of the sequester to reimbursement) created in the Medicare Modernization Act of 2003.

One ASP reform being floated in DC is a flat dollar fee add-on for drugs; however, COA is opposed to that because it would leave the fee up to annual review in the Medicare Physician Fee Schedule (MPFS) which would be a moving target for cuts every year.

COA has proposed a tiered ASP add-on percentage approach for drugs, starting lower for expensive drugs and increasing for lower priced drugs. This would also be tied to clinically appropriate utilization management (i.e., pathways). The latest news before the August Congressional recess is that our concerns have been heard and the flat fee is no longer being considered. We will keep you posted on this critically important negotiation.

- **Stopping PBM Abuses** — Legislatively, we are working on a bill that would require PBMs to fill cancer drug prescriptions within 72 hours or permit patients to obtain the drug at a pharmacy of their choice at in-network reimbursement rates. The Improving Patient Access to Cancer Treatment (IMPACT) Act, is currently under review with the House Office of Legislative Counsel and is expected to be introduced in the next legislative session.

Another bill COA is pursuing would require PBMs to have quality indicators specific to the specialty of the provider (e.g. oncology) if it charges direct and indirect remuneration, and would require PBMs to reward pharmacies for high performance and be penalized for poor performance, while providing specific details as to why a pharmacy scored lower allowing them to improve for future reporting periods.

Currently, PBMs charge "DIR fees" of up to 12% under the guise of providing quality performance programs, allowing PBMs to "clawback" millions of dollars from pharmacies on medications that have already been dispensed, increasing their profits at the expense of Medicare and its beneficiaries. Almost all of these quality programs assess pharmacy performance against dispensing completely unrelated medications, such as statins and diabetes drugs. Community oncology pharmacies are not being assessed on the quality performance on oncology specific measures. This proposed legislation would stop that practice.

- **"Fail-First" or Step Therapy Protocols** — Starting this year, CMS administrative rule allowed Medicare Advantage (MA) plans to initiate a fail-first or step therapy approach to cancer management. Although the final rule doesn't eliminate cancer



drugs' protected class status as was put forth initially in the proposed rule (see [COA's Jan. 25th letter to CMS](#) regarding the initial proposal), it paradoxically puts medical decision making in the hands of middlemen—health plans and PBMs—who can force the use of older, less-appropriate cancer treatment or drugs simply because of cost. Until now, protected classes of drugs, such as those for treating cancer, have been exempt from step therapy policies. [COA has come out strongly against fail first step therapy](#), which damages the patient-physician relationship and leaves patients at the whim of insurers and PBMs that are more concerned with their financial well-being than patient outcomes and side effects.

- **Clearing the Way for Value-Based Contracting** – In January, we saw the introduction of the Patient Affordability, Value and Efficiency Act (PAVE Act), bipartisan legislation which would remove legal barriers to value-based contracts for prescription drugs. COA submitted formal [comments](#) in support of the PAVE Act, noting that it is particularly important in cancer care where patients often face high-cost, complex treatments. We outlined the regulatory impediments to value-based contracts, including the Anti-Kickback Statute (“AKS”) and Stark Law constraints, and we recommended that the proposed legislation exclude drugs purchased through value-based arrangements from the ASP statute and also protect manufacturer ASP calculations to promote greater participation in innovative arrangements that can reduce costs and improve patient care.
- **Safe Harbor Legislation** – In April, COA [commented](#) in support of a proposed rule titled “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees”, but we cautioned that without safeguards implementation of the rule could negatively affect patients with cancer.
- **340B Drug Discount Program**—The climate in Congress to address the 340B program has changed with the House and Senate unable to agree on a path forward for reforming the program. Despite this environment, COA continues to highlight how the 340B program has been a driver of consolidation, as well as the high prices of Part B drugs. Legislatively, we are advocating a “follow the patient” fix to 340B where the drug discount should be applied to the drugs purchased by patients in need rather than hospitals, regardless of where the patient is treated. In addition, we continue to push for more hospital program reporting and transparency, as other grantees in the 340B program already do.
- **Biosimilars**—The standing COA Biosimilars Committee continues to consider the complex issue of biosimilars, develop education campaigns for oncologists and other community oncology professionals, and support biosimilars (although not any specific agent) as an appropriate treatment option. In April, COA released a [position statement](#) in which we expressed our commitment to advancing knowledge and acceptance of biosimilars as an important, promising element in reducing drug costs and overall health care spending, and the financial toxicity of cancer care for



patients. Going forward, COA will work to support biosimilars and innovative biosimilar (biologic) development with all stakeholders.

- **CAR-T Therapy in the Community Setting** — This year, COA also established a CAR-T Task Force to define principles for administering CAR-T therapy in the community setting and to ensure that community practices are not excluded from providing this highly innovative and promising treatment option for patients with cancer. Through insights from this expert panel, COA [commented](#) in March on CMS’s language in the national coverage determination for CAR-T therapy to ensure that qualified community sites are not excluded from providing this therapy since many community oncology practices have the experience and capabilities to administer CAR-T therapy.

COA continues to serve as a resource for members of Congress, and we have aided in the construction of multiple pieces of legislation, including the Recovering Excessive Funds for Unused and Needless Drugs (REFUND) Act, which sought to reduce waste associated with large, single-use drug vials, and the Improving Seniors’ Timely Access to Care Act of 2019, which sought to set standards for electronic requests for prior-authorization in the Medicare Advantage program.

The standing Government Affairs and Policy (GAP) Committee is in the process of finalizing official COA position statements on additional areas of importance. These living documents can be updated as policies change and evolve. These will include white and brown bagging, the 340B program, site neutral payments, and much more.

Charting a Future of Oncology Payment Reform: COA’s OCM 2.0 Model

In early May, COA submitted [a payment reform application to the Physician-Focused Payment Model Technical Advisory Committee](#). The application outlines COA’s vision for an alternative payment model that improves cancer care, reduces costs, and offers additional benefits. Known as “OCM 2.0,” the application includes numerous improvements and enhancements to CMMI’s Oncology Care Model (OCM) and includes a proposal for value-based cancer drug selection and pricing. Although initially targeted at the Medicare population, the OCM 2.0 application includes provisions for its universal adoption in commercially insured populations.

COA is working to continue the success of our [Oncology Medical Home \(OMH\) program](#) through a new partnership with the American Society of Clinical Oncology (ASCO). OMH accreditation would certify a practice’s ability to participate in payment reform plans, including the universal payment reform plan “OCM 2.0” that we recently proposed. Stay tuned for much more on this.

At the same time, COA continues to lead practices participating in the OCM to ensure their ongoing success. Through our OCM Support Network, COA provides technical assistance to participating practices and identifies key issues that CMS needs to address. These observations led COA to submit a [letter to CMMI](#) in May with detailed



explanations for how the OCM could and should be improved. Based on our learnings from the COA-hosted OCM Support Network, the letter identifies four areas—Price prediction; Risk adjustment; Attribution and Monthly Enhanced Oncology Services (MEOS) Payment Recoupment; and Timeliness of Data/Information — and suggests solutions to the specific challenges that practices face in these areas. Of note, there is a greater than one-year delay in reporting which limits practices' ability in determining whether they can participate in two-sided risk.

Keeping the Pressure on Pharmacy Benefits Managers (PBMs)

COA remains a strong advocacy against PBMs with a sharp focus on exposing PBM abuses. In April, we published [Part V of our series, "Pharmacy Benefit Manager Horror Stories,"](#) and in May we launched a major national campaign to stop PBM abuses. The PBM Abuses campaign includes an interactive patient stories website at www.PBMAbuses.org; video education; storytelling online and across the [Community Oncology TV network](#); a strong digital media presence; and COA's grassroots networks.

The PBM Abuses campaign was launched in conjunction with a community oncology Hill Day during which advocates from across the country—physicians, pharmacists, nurses, administrators, patients, caregivers, family members, and survivors from 15 states—attended meetings with senators, representatives, and their staffs to ask lawmakers to take concrete steps to stop PBM abuses that are hurting patients with cancer. In February, COA members and leadership were featured in a Medscape Medical News article, ["PBM Delays for Cancer Drugs May Risk Lives, Warn Oncologists,"](#) about the negative impact PBMs are having on the lives of patients with cancer.

The Community Oncology Pharmacy Association (COPA) continues to address, through legal means, PBM barriers to physician dispensing. One notable recent success was getting OptumRx to reverse its policy that required physician dispensing pharmacies to be accredited and retail pharmacies to have dual accreditation in order to participate in UnitedHealthcare's Medicare & Reimbursement network. COPA is currently challenging Prime Therapeutics' decision to not allow physician dispensing pharmacies into network as of January 2018, as well as its decision to terminate physician dispensing pharmacies that were previously in network.

Supporting the Entire Community of Cancer Care Providers & Professionals

COA continues its more than 16 years of providing resources to every member of the community oncology care team. Much of this work takes place through our initiatives which provide free, focused, private, peer-to-peer networks.

- **COA's Administrators' Network (CAN)** facilitated near monthly virtual discussions, webinars, and a half-day workshop for practice administrators to network and learn more about legislative issues affecting cancer care, best practices, and reform efforts.



- In early March, the **Community Oncology Pharmacy Association (COPA)** sponsored an education webinar for administrators and pharmacists on USP 797 Pharmaceutical Compounding–Sterile Preparations and USP 800 Hazardous Drugs–Handling in Healthcare Settings. The webinar included participation by the three largest group purchasing organizations in oncology—Cardinal Health, McKesson Specialty Health, and Oncology Supply.
- COA launched the **COA Oncology Patient Navigator Network (COPNN)**. Navigators guide and support cancer patients through the maze and complications within the health care delivery system. It was launched after we realized navigators were attending COA workshops and conferences. COPNN seeks to serve all types of navigators—patient, clinical, nurse, and financial navigators—to provide peer-to-peer support and best-practices guidance.
- **The COA Advanced Practice Provider Network (CAPP)** was launched to support nurse practitioners and physician assistants through a closed communication network for these important members of the cancer care team. With the shortage of oncologists, advanced practice providers continue to take on increasing responsibilities in cancer care, and COA is helping advanced practice providers grow as leaders and stay current on the latest patient care developments.
- Our patient “advocates for the care” remain a powerful force through the **COA Patient Advocacy Network (CPAN)**, having hosted 23 advocacy events across the country in just the last six months, as well as participating in COA’s annual conference and our May visit to Capitol Hill. This summer, CPAN chapters will host elected officials for COA’s signature “Sit in My Chair” advocacy event where they see community oncology and the great care that our practices provide firsthand.
- **The COA Fellows Initiative**, which seeks to engage and educate oncology/hematology fellows about practicing in the community setting, began partnering with medical schools across the country who are interested in developing or enriching their oncology/hematology fellows’ programs. Educational sessions have been conducted with more than 24 medical schools across the country. At these free sessions, fellows learn about career choices in the community setting and issues in oncology and health policy. Fellows are also given valuable advice for negotiating contracts and interviewing. A number of the participants have gone on to be hired by COA member practices.
- The annual **Community Oncology Conference** held April 4-5 in Orlando, Florida with nearly 1,600 attendees was COA’s largest annual conference to date. The conference featured two days of learning and networking with community oncology practices and allied professionals. In addition to clinical, business, and advocacy tracks, this year’s conference included a full pharmacy track for the second year in a row. Save the date for #COA2020 taking place April 23-24, 2020, once again at the Walt Disney World Dolphin Hotel in Orlando, Florida.



COA Policy Comment Letters, Statements, Publications, & Reports

Here is a list of all COA publications so far this year. If you would like to be added to our distribution lists, please sign up on the COA website at www.CommunityOncology.org.

- **July 29:** [Statement on Proposed Physician & Hospital Payment Rules for 2020](#)
- **July 23:** [Including Patient Financial Assistance in ASP a Dangerous Proposal](#)
- **July 12:** [Killing Medicare Part D Rebate Rule a Huge Gift to Pharmacy Benefit Managers \(PBMs\)](#)
- **July 11:** [Statement on Proposed Radiation Oncology Alternative Payment Model](#)
- **June 11:** [Community Oncology Alliance Announces ‘OCM 2.0’ Proposal, an Ambitious Reform Model to Improve Cancer Care and Reduce Costs](#)
- **June 7:** [Comments on the ICER Value Assessment Framework](#)
- **May 31:** [Letter to CMMI Regarding Challenges That Need to Be Addressed in the OCM and Future Payment Reform Models](#)
- **May 23:** [CMS Allows Middlemen to Force Patients to “Fail First” on Cancer Drugs While Paradoxically Keeping Cancer a Protected Class](#)
- **May 15:** [COA Launches Major National Campaign to Stop PBM Abuses and Highlight Patient Horror Stories](#)
- **April 30:** [CPAN at 10: A decade of Education, Advocacy, and IMPACT](#)
- **April 19:** [Cost Differential of Immuno-Oncology Therapy Delivered at Community Versus Hospital Clinics](#)
- **April 8:** [Formal Comment Letter on Proposal to Remove the Safe Harbor Protection From the Federal Anti-Kickback Statute](#)
- **April 4:** [Pharmacy Benefit Manager Horror Stories – Part V](#)
- **April 4:** [COA Biosimilars Position Statement](#)
- **March 15:** [Formal Comment Letter on CMS Proposed Decision Memo for Chimeric Antigen Receptor \(CAR\) T-Cell Therapy for Cancers](#)
- **February 19:** [Formal Comment Letter on the Patient Affordability, Value and Efficiency \(PAVE\) Act](#)
- **February 6:** [Community Oncology Alliance: 2018 Year in Review](#)
- **January 25:** [Formal Comment Letter on CMS Plans To “Modernize” The Part D Program And Medicare Advantage \(MA\) Plans](#)
- **January 1:** [Formal Comments on Medicare International Pricing Proposal](#)

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