Dear COA Members and Supporters,

The first half of 2021 has been a busy one. As the COVID-19 pandemic receded and vaccines succeeded, the Community Oncology Alliance (COA) worked diligently to ensure community oncology was prepared for the return of patients to waiting rooms and treatment facilities. At the same time, our advocacy efforts have made sure your voice has been heard by policymakers and industry giants alike as important issues that impact the future of cancer care are debated.

This 2021 Member Update is a brief glimpse into the work we have done on your behalf over the last six months. Whether it’s working with legislators to introduce important bills, keeping members informed about cancer screening trends, or planning next year’s Conference, this Update contains all the information you need to catch up on COA activities on your behalf. If you have a colleague who wants to know more about COA, this is the perfect document to share.

The rest of 2021 and this pandemic are yet to be written, but rest assured that COA will continue to advocate for strong, sensible policies that benefit community oncology patients and practices. Community oncology is not taking a backseat as the year continues, so stay tuned for more updates and a stronger, better tomorrow.

Kashyap Patel, MD
President
president@COAcancer.org

Ted Okon, MBA
Executive Director
token@COAcancer.org

Mark Thompson, MD
Medical Director for Public Policy
mthompson@COAcancer.org
Oncology Policy & Legislation Updates

2021 opened with a new President and new Congress, and many hoped the reset of the national election would usher in a new era of bipartisanship. Unfortunately, most major legislation and policy decisions have followed the now standard playbook of gridlock along partisan lines. Some items, like prescription drug pricing reform, have even stalled due to intraparty fighting. However, COA is seeing much more activity and success at the state and regional levels. Here are some brief recaps of some of the oncology policy and legislation that COA is tracking.

Stopping Pharmacy Benefit Manager (PBM) Abuses

COA has long focused on fighting the influence of PBMs and securing timely medication access for patients with cancer. In May, Representatives Terri Sewell (D-AL) and Gus Bilirakis (R-FL) introduced H.R. 3258, the Timely Access to Cancer Treatment (TACT) Act of 2021, to the U.S. House of Representatives. This important bill requires PBMs to provide oral cancer medications to patients within 72 hours. If a PBM fails to meet this deadline, patients can then obtain their medication from a licensed dispensing facility of their choice. We are proud to have worked with Reps. Sewell and Bilirakis to bring this bill to the House floor and look forward to other representatives co-signing this important bill.

Hospital Price Transparency

In 2020, the Trump administration implemented a rule requiring hospitals to provide online, indexed lists of the prices they charge for services and medications, designed to help consumers make informed choices about the hospitals they choose. Many hospitals are skirting the rule by embedding code on their websites that prevent the results from appearing in search engines. The fine for noncompliance is $300 per day, a sum that is not an effective deterrent for offending hospitals. In July, President Biden issued an executive order floating the possibility of raising the fine to $2 million per day. COA is following this issue closely and has called for the Department of Health and Human Services (HHS) to substantially increase the penalties for hospitals not complying with price transparency guidelines. We are gratified that HHS is now proposing much higher penalties per COA’s request.
**Fighting DIR Fees & Step Therapy**

In April, COA sent two letters raising the alarm about [direct and indirect remuneration (DIR) fees](#) and step therapy prohibition, respectively. The first letter, sent to the House Energy and Commerce Committee, requested a hearing on DIR fees, arguing that DIR fees are being used by PBMs to increase their own profits at the expense of patients and providers. The second letter, sent to HHS Secretary Xavier Becerra, asked for a reinstatement of step therapy prohibition for Part B drugs in Medicare Advantage plans. The prohibition would allow Medicare patients to access the right drug for their disease the first time, rather than waiting for insurer approval after failing on other therapies.

**Reforming the 340B Drug Pricing Program**

Community oncology practices have long raised the alarm that the 340B Drug Payment Program is broken and has become a lucrative program merely enriching hospitals, fueling the closure and consolidation of independent providers, driving up drug prices, and most importantly, not helping patients in need. COA was pleased that CMS recently announced that they would continue to implement the -22.5 percent adjustment to 340B reimbursement to hospitals, a needed reality check for the hospitals abusing this program.

In addition to advocating for reform and transparency in the 340B program, the COA Board has also been working with stakeholders to put forth an overhaul of the 340B program so that the discounts would “follow the patient.” This program change would ensure that patients benefit from the discounted prescriptions directly, rather than the savings being pocketed by the hospitals. COA is working with key Congressional champions to advance legislation it has crafted to ensure that patients in need have access to 340B drug discounts.

**Mandatory CMMI Alternative Payment Models (APMs)**

The new director of the CMS Innovation Center, Liz Fowler, has proposed making future APMs mandatory. COA has spoken directly with Director Fowler and her team about our fierce opposition to mandatory models, voicing concerns that it would harm patients and practices.

*Oncology Care Model (OCM) & Oncology Care First (OCF)*

The Oncology Care Model was extended until June 2022 due to the COVID-19 pandemic. Although the end of OCM is rapidly approaching, no word has been given yet on the successor model other than the name, Oncology Care First. COA continues to monitor the situation and will provide updates as we receive them.
Radiation Oncology Model

Last fall, CMS announced the Radiation Oncology Model (RO Model or RO-APM), a mandatory, episode-based payment model for radiotherapy (RT) services. The goals of the model are to “improve the quality of care for cancer patients receiving radiotherapy...and move toward a simplified and predictable payment system.” The details of the RO Model, however, were extremely flawed and required several changes to be a truly effective laboratory for care reform. The COA Board joined 27 stakeholder groups in sending a letter to CMMI, providing several suggestions to encourage participation. Due to the pandemic, the RO Model was delayed but it has recently re-emerged with a proposed start date of January 2022. COA is preparing an in-depth analysis of the RO Model and is preparing for a major fight against this mandatory model unless CMS makes significant changes.

Encouraging State Regulation of PBMs

Last year, COA joined an amicus brief in the ultimately successful case of Rutledge v. PCMA, in which the State of Arkansas was attempting to regulate PBMs while the PBM trade lobby (PCMA) fought the issue. The Supreme Court voted unanimously that states do have the right to regulate PBMs which has launched further cases, including the most recent in North Dakota, Wehbi v. Rutledge. Like the Arkansas case, which affirmed that state regulation of PBMs did not violate ERISA, the Wehbi case concerns the ability of states to regulate PBMs, specifically regarding gag clause provisions and spread pricing. COA has also joined an amicus brief in the Wehbi case.

State PBM ‘Wins’ in 2021

Without serious Federal intervention it is increasingly looking like states are the best immediate source for PBM reform and regulation. During the last legislative session, several states passed PBM and related legislation. Here are a few ‘wins’ that COA has tracked so far in 2021:

**Tennessee**

Thus far in 2021, advocacy by state oncology societies in Tennessee, together with strong stakeholder coalitions in each state, has seen PBM reform legislation passed by wide margins. In mid-May, a PBM reform bill passed both houses of the Tennessee legislature, and on June 1, the governor signed it into law.¹

**Wisconsin**

In March 2021, Wisconsin enacted 2021 Wisconsin Act 9, which, among other items, requires a PBM to obtain licensure from the Office of the Commissioner of Insurance. The overwhelming and rare bipartisan support reflects the increased interest that state governments are taking in PBMs’ role in the drug supply chain.²
Texas
Texas signed two bills into law that protect pharmacists and patients from harmful PBM practices. In May 2021, House Bill 1763 was signed, prohibiting clawbacks and preventing PBMs from imposing accreditation or certification requirements above those required by state and federal law. House Bill 1919, which became law in June, “prohibits PBMs from steering patients to their affiliated pharmacies through online or patient-specific messaging. Additionally, it prohibits PBMs from requiring or inducing patients with reduced cost-sharing to use their affiliated pharmacy, prohibits PBMs from using patient-specific prescription information for commercial purposes, and requires patient consent to transfer a prescription.”

Copay Accumulator Legislation
Dozens of states have introduced legislation over the last several months to stop insurers’ use of copay accumulator programs. Kentucky was the first state to have legislation signed into law this year, quickly followed by Oklahoma. They join states like Arizona, Illinois, West Virginia, and Virginia in protecting patients from these harmful payer programs.

Coming Soon: Deeper COA Engagement in State Cancer Policy & Legislation
Recognizing the opportunity to shape state as well as Federal policy, the COA Board of Directors has voted to move into state policy and legislation and approved the hiring of a COA staff member dedicated solely to following issues at the state level.

Committees, Initiatives, & Task Force Updates
Taking a Stand on Important Issues: New COA Position Statements
The pandemic prevented the usual meetings on the Hill, but the COA Government Affairs & Policy (GAP) Committee replaced in-person meetings with Zoom and phone meetings. Much of the GAP Committee’s work was condensed into four Position Statements, each released to address a growing area of concern in public policy: Disparities in Cancer Care, Sequestration Cuts, Oral Parity, and Prior Authorization.

These position statements join the eight other statements COA has released in recent years. As legislative and policy changes occur, the GAP Committee updates COA Position Statements to reflect any changes in COA’s position.
The 2021 Community Oncology Conference: Resilient, Resourceful, Innovative

On April 8 and 9, over 3,400 registrants tuned in to catch the 2021 Virtual Community Oncology Conference. The Conference showcased the resilience, resourcefulness, and innovativeness of the community oncology professionals who provided safe, uninterrupted care throughout the pandemic. Fifty speakers across 24 sessions demonstrated new treatments, technologies, and models that helped practices survive the pandemic and grow into the future. Keynote speaker Sean Swarner, the first cancer survivor to climb Mount Everest, spoke about the miraculous impact that community oncology has had on his life. Attendees left the 2021 Conference with the items they need to face 2021 and 2022 with a bright outlook.

Relaunching the Oncology Medical Home (OMH)

In July, COA and ASCO joined forces to re-launch the Oncology Medical Home (OMH) program. In jointly released new standards that provide a comprehensive roadmap for oncology practices to deliver high-quality, evidence-based cancer care, the COA/ASCO standards will form the foundation of the Patient-Centered Cancer Care program, a two-year, OMH certification pilot. These standards, which were published in JCO Oncology Practice, establish core elements needed to deliver equitable, high-quality cancer care. More details about the pilot sites and future of the OMH program will be announced in the coming months.

Engaging Employers & Self-Insured Payers Through the National Cancer Treatment Alliance (NCTA) & Cancer Pharmacy Network (CPN)

The cost of treating cancer has escalated in recent years for employers as more of their employees are diagnosed with cancer. Additionally, navigating cancer treatment has become significantly more complex for employers. Responding to these challenges, COA created the National Cancer Treatment Alliance (NCTA), a coalition of leading, independent community oncology practices. NCTA will eventually seek to direct contract with employers for cancer drugs and services so that their employees have access to the highest quality, most affordable, and locally accessible cancer care.

As many cancer drugs are available in oral form, NCTA has developed its first contracting subsidiary, the Cancer Pharmacy Network (CPN). CPN will function as a clinically integrated network providing direct contracting between oncology providers and employers for oral cancer drugs, as well as data-backed informational studies that help shed light and transparency on the opaque world of PBM contracting, rebates, and exclusionary pharmacy networks. Unlike PBMs, CPN will create transparency in drug benefit design and delivery where there currently is none.
Fueling Patient Advocacy through CPAN

The COA Patient Advocacy Network (CPAN) continues to grow with 29 chapters in nine states. Despite the pandemic, new chapters were launched and educational events were held while staying in compliance with CDC guidelines. Advocates have also benefited from CPAN's industry leading monthly Advocacy Chats, short virtual educational events held each month and featuring information on everything from clinical trials to social media in cancer care. Community oncology advocates also joined CPAN for its second annual virtual Community Oncology Advocacy Summit, which featured the latest updates and education on key issues impacting cancer care.

Hey America: It's Time to Screen for Cancer!

In April, COA released a study (performed by Avalere Health) that found alarming reductions in breast, colon, prostate, and lung cancer screenings during the pandemic. In response, COA partnered with CancerCare to launch the “Time to Screen” campaign. This national effort aims to raise awareness about missed cancer screenings. It also supports patients in learning more about the importance of screenings, answers any questions, and helps patients find nearby screening locations just by visiting www.TimeToScreen.org or by calling the toll-free hotline at 1-855-53-SCREEN. Joined by two-time Grammy award winner and the “Godmother of Soul” Patti LaBelle, the Time to Screen campaign is taking over the airwaves with public service announcements (PSAs), digital and print advertisements, and so much more.

Your Calendar

As we enter the second half of 2021 and look forward to 2022, we'll mark a (hopeful) return to in-person meetings, including, for the first time since 2019, the 2022 Conference which will take place March 17-18, 2022, at the Gaylord Palms in Kissimmee, FL. Stay tuned for more information!

Additionally, CPAN Advocacy Chats will continue as 30-minute online webinars with leaders from the advocacy community. Chats are the 2nd Wednesday of every month, and information about future chats can be found on CPAN's webpage and COA's Twitter, Facebook, and LinkedIn channels.

2. Ibid.
5. American Medical Association; State Advocacy Update; April 23, 2021.