November 18, 2019

Dear Colleagues:

The COA Legislative Team and the members of the Government Affairs and Policy (GAP) Committee continue to serve as the voice of community oncology in Washington and across the country. By the end of 2019, we estimate that our members and advocates will have had almost 500 meetings with policymakers to discuss pressing community oncology issues and legislation.

This quarterly GAP update is not meant to be an exhaustive explanation of every piece of legislation but rather a quick update on the big issues we are tracking across the country and in Washington.



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Oncology Care First: A Last-Minute Surprise

Just as we were going to print with this update, CMS announced a massive new oncology reform model known as the "Oncology Care First" (OCF) model.

- New and distinct from the OCM, the OCF is meant to build on stakeholder feedback and lessons-learned from the ongoing OCM 1.0.
- OCF will be a voluntary, 5-year national model slated to begin January 2021.
- Under pressure to move forward with the model, CMS gave less than three weeks for feedback on the initial OCF proposal. COA responded that a major proposal like the OCF requires thoughtful consideration which would have been difficult to do in the short time before comments were due.
- COA advocacy was instrumental in getting CMS to significantly extend the feedback period for the OCF to December 13th.
- COA is working with CMS to ensure full input by community oncology. Stay tuned for updates – we are all over this!

Stopping CON Restrictions on Cellular Therapies – BIG Win!!!

The Committee has been working with practices in Michigan to stop the state Certificate of Need (CON) Commission from restricting use of CAR-T and other cellular therapies.

- Despite the big health systems essentially controlling the MI CON Commission, we want to stop CON limitation in MI, as it is bad for patient access and practices.

- We also wanted MI to be a firewall to stop this kind of restriction in any other states; the idea of CON being used to regulate drug access is chilling, and we did not want this to be an example.
- Thanks to Stuart Genschaw, Cancer & Hematology Centers of Western Michigan for being active in the fight and lending his voice to local advocacy efforts; and thanks to Dr. Jeffrey Patton, Tennessee Oncology, who volunteered one of his oncologists to provide expert testimony to the MI state legislators on the safe use of CAR-T in the community setting.
- *BREAKING NEWS*: Community oncology had a big win as the MI State Legislature stopped the CON Commission from blocking CAR-T access!

Step Edits for Antiemetics: An Emerging Issue?

In recent months, COA has received reports of insurers and/or pharmacy benefit managers (PBMs) implementing mandatory, double fail-first step edits for antiemetics to control chemotherapy induced nausea and vomiting (CINV).

- This is despite NCCN and ASCO practice guidelines recommending the specific treatments as part of the standard of care for patients.
- In particular, COA has seen this policy with practices in Tennessee through the PBM Magellan and Blue Cross Blue Shield of Tennessee.
- COA has been working with practices and Congressional offices to have these policies rolled back. We have been told the policy is being rescinded, but we are keeping a close eye on them to ensure this is actually the case.

Changes to ASP Reimbursement

The COA team and GAP Committee has been working hard to oppose and deflect multiple proposals to majorly change or lower the ASP reimbursement. For example, we have seen proposals to change ASP to a flat fee and/or reduce it to ASP+3 percent. For a number of practical reasons, these changes would be disastrous to practices and COA worked overtime to get them stopped.

- In the House, there has been interest in a tiered ASP that may be incorporated into the House drug pricing bill (in Speaker Pelosi's bill).
- In the Senate, there is interest for a cap on ASP on the most expensive drugs (in the Grassley/Wyden bill).
- COA has worked to advance interest in tiered ASP, with interest in both houses for ASP+8 percent on Biosimilars to encourage their use and stimulate a robust biosimilars marketplace.

Proposed Mandatory Models by CMMI

There is ongoing discussion in Washington regarding implementing "guardrails" or restraints around the use of mandatory models by CMMI. Earlier this summer CMMI proposed a mandatory Radiation Oncology model, tentatively set to launch in January 2020 and run for five years. As you well know, COA is adamantly opposed to mandatory, forced CMMI models.

- There has been some interest on the Hill in allowing mandatory models only in very controlled smaller studies or after a phase 1 trial has been tested, but lawmakers are also hesitant to restrict CMMI.
- There is concern on the Hill that without some authority to force model participation, there will be inadequate support and/or participation.
- COA continues to impress upon Congress that CMMI needs to be reined in and mandatory, national phase 1 models taken off the table. A well-designed model will have significant, voluntary participation.

Bills of Note: Passed or With Legs in Congress

Many stand-alone bills have been introduced on both sides of the aisle regarding drug pricing, drug waste, Medicaid reform, and surprise billings for emergency out-of-network services. Such bills are often introduced to put on the record language to be incorporated later into larger packages

- H.R. 3, "Lower Drug Costs Now Act of 2019"
    - This is the House Democrats' version of a drug price bill and allows for the Secretary of HHS to negotiate Medicare prices on the top 250 priciest drugs.
    - Has inflationary caps on drug price increases with steep manufacturer penalties; some drug indexing to international price; limit out of pocket expenses for patients in Part D; and significantly shifts the catastrophic coverage to plan sponsors and manufacturers and away from Medicare.
    - This bill is contentious even within the Democrats who are facing pressure from progressive members to make it stronger. It will likely pass the House along partisan lines but will not advance in the Senate.

- S.2543, "Prescription Drug Pricing Reduction Act of 2019"
    - Senate Finance Committee drug pricing bill.
    - Includes alterations to Part B, Part D, Medicaid, and rebate programs; greater drug pricing transparency; sets inflationary caps on drug manufacturer price increases; and mandates greater transparency in both the PBM discount and rebate programs.
    - Has good points and not so good points for oncology; the GAP team has actively lobbied against Section 102 of this bill which, as written, would essentially kill need-based drug price assistance from manufacturers; this bill is not expected to come to the floor during this Congress, even though it has passed out of the Senate Finance Committee.

- H.R. 2115, "Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act"
    - This bill, which points to the bipartisan support for PBM scrutiny, amends the Social Security Act to provide greater transparency for discounts provided by manufacturers to PBMs.
    - It passed the House on October 28th and was referred to the Senate.

- H.R. 1781, "Payment Commission Data Act of 2019"
    - This bill amends the Social Security Act to allow MedPAC, Medicaid, and CHIP access to drug payment information, especially drug discounts, to provide more transparency to PBM related issues.
    - It passed the House on October 28th and was referred to the Senate.

Bills in Congress COA Supports and is Advancing

COA has been active working with Congressional offices on both sides of the aisle to advance a number of important bills addressing PBM abuses that hurt patients, improving the pre-certification process, and fixing the broken 340B Program.

- H.R. 3107, "Improving Senior's Timely Access to Care Act of 2019"
    - Establishes pre-certification standards and transparency for Medicare Advantage plans. COA sees this as a first step in the right direction.
- 340B legislation in the House and Senate
    - Senate and House bills currently being written would alter the 340B program to make it "follow the patient" as was the original intent of the program.
    - COA hopes to see this legislation introduced this year but, as always, 340B is an issue with little bipartisan agreement, so its chances of moving forward are unknown.
- Two bills, being drafted with COA support and which should be introduced in this session of Congress, scrutinize PBMs and remain of interest on the Hill.
    - First, would require that PBMs fill a specialty Rx for antineoplastic agents within 72 hours or allow the patient to fill the Rx wherever he/she prefers and PBMs would have to cover the cost as if in-network.
    - Second bill is regarding DIR fees that would require any "quality" programs tied to DIR fees be specific to oncology and have an upside, not just a downside, for those who perform well.

Hill Lobby Days: Advocating for Community Oncology

In addition to the ongoing meetings with legislators, policy makers, and staff, COA held two Hill Days in the last four months attended by practice representatives, members of the GAP Committee, the COA Board, and patient advocates.

- The July Hill Day was devoted exclusively to PBM issues as part of COA's campaign to educate legislators on ongoing PBM abuses and patient horror stories.
- The September Hill Day focused wholly on opposition to Section 102 of S.2543, Prescription Drug Pricing Reduction Act of 2019, which, as written, would essentially end need-based financial assistance to patients from manufacturers.
- COA is working to stop any legislation that would limit access to need-based financial assistance programs for patients with cancer.

Don't Miss the 2020 Community Oncology Conference!

The Community Oncology Conference is the essential annual meeting for everyone in our field. Whether you are an oncologist/hematologist, practice administrator, pharmacist, patient advocate, or industry expert, the Conference helps you seize opportunities.

- The Community Oncology Conference is easily the most comprehensive meeting of the year for community oncology professionals and stakeholders.
- From Washington policy updates, to the latest on genomic testing and CAR-T, to strategies to overcome PBM challenges and pharmacy operations, it focuses on the real-world issues we face every day.
- #COA2020 is April 23-24, 2020 in Orlando. Learn more at COAConference.org.

Presidential Candidates Health Care and Drug Pricing: Where do They Stand?

It is a busy and chaotic presidential primary season, with numerous candidates and even more debate about what to do with our health care system. Besides "Medicare for all" where do the candidates stand? We thought it would be helpful to share the latest health care and drug pricing plans of the major Democratic presidential candidates.

- Joseph R. Biden, Jr. https://joebiden.com/healthcare/
- Bernie Sanders https://berniesanders.com/issues/medicare-for-all/
- Elizabeth Warren https://elizabethwarren.com/plans/health-care
- Kamala Harris https://kamalaharris.org/issue/health-care/
- Amy Klobuchar https://amyklobuchar.com/issue/health-care/

Mark's Predictions: What Happens Next?

"My sense is that by years end, we will see H.R. 3 pass the House as political posturing going into an election year with no hope that it will go anywhere in the Senate. As citizens, we will see nothing of significance passed in Congress. There is another Continuing Resolution needed in November to fund the government and we will need to diligently watch to make certain some crazy provision doesn't end up in that package."

"As of today, the House has 12 legislative days and the Senate has 15 legislative days before the end of the year. It has been a busy few months, but the GAP Committee will continue to work on behalf of every COA member. As the year wraps up, we will begin to focus on our 2020 plan for the key issues affecting community oncology."

If you have questions, know of pressing issues that are starting to impact your practice and/or patients, or have suggestions to share, please don't hesitate to contact COA at (202) 729-8147 or send us an email at info@coacancer.org.