Thursday, August 16, 2018

Network Practices Host Members of Congress

The Network recently hosted site visits with Congresswoman Susan Brooks (R-IN) and Congressman Jodey Arrington (R-TX). **Read below.**

Brookings Institution Calls for Expansion of Medicare Site Neutral Payment Policies

In a blog post this week, researchers from the USC-Brookings Schaeffer Initiative for Health Policy praised the Center for Medicare & Medicaid Services' (CMS) recent decision to expand site neutral payment for all clinic visits at off-campus hospital outpatient departments in the 2019 outpatient prospective payment system (OPPS) proposed rule. **Read below.**

CMS to Require ACOs to Take on More Risk

Last week, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule to reorganize the Medicare Shared Savings Program Accountable Care Organization (ACO) program. **Read below.**

CMS Releases New Step Therapy Guidance for Medicare Advantage Plans

The Centers for Medicare & Medicaid Services (CMS) announced their intention to rescind prior guidance that had prohibited step therapy for Part B drugs and issued new guidance that will allow Medicare Advantage (MA) plans to apply step therapy for Part B drugs, beginning January 1, 2019. **Read below.**

Bipartisan House Lawmakers Urge HHS to Address Retroactive DIR Fees

A bipartisan group of 83 House lawmakers sent a letter urging Health and Human Services Secretary Alex Azar to address the issue of retroactive direct and indirect remuneration (DIR) fees. **Read below.**

Senator Hatch, Rep. Walden Urge OMB to Rethink Safe Harbor Proposed Rule

Last week, Senator Orrin Hatch, Chairman of the Senate Committee on Finance, and Congressman Greg Walden, Chairman of the House Committee on Energy and Commerce, together sent a letter to Mick Mulvaney, Director of the Office of Management and Budget, urging him to fully consider the implications of a draft regulation removing safe harbor protections for drug rebates. **Read below.**

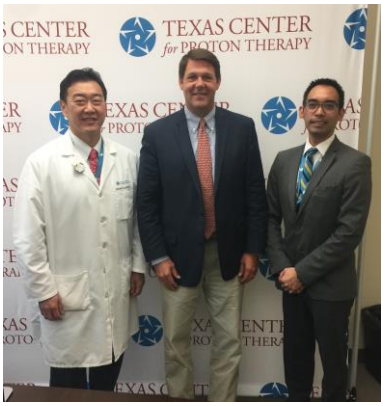
E&C Leaders Request Additional Info from 340B Contract Pharmacies

House Energy and Commerce Committee Chairman Greg Walden, Health Subcommittee Chairman Michael Burgess, and Oversight Subcommittee Chairman Gregg Harper recently sent letters to nine contact pharmacies expressing concern over the growth and lack of oversight of contract pharmacies in the 340B program and asking questions to better understand their role. **Read below.**

Bipartisan House Committee Leaders Send Letters to Opioid Manufacturers

The leaders of the Energy and Commerce Committee recently sent letters to three opioid manufacturers requesting information on each manufacturer's role in the opioid crisis. **Read below.**

Network Practices Host Members of Congress



LEFT: Rep. Susan Brooks with Dr. Mark Lobo at Integrated Cancer Care

RIGHT: Rep. Jodey Arrington at Texas Center for Proton Therapy

On August 7, Congresswoman Susan Brooks (R-IN) visited Integrated Cancer Care in Indianapolis, IN. Congresswoman Brooks represents the 5th district of Indiana and serves on the House Energy and Commerce Committee. The Congresswoman toured the facility and spent time talking with physicians and practice staff about issues impacting community cancer care. Dr. Mark Lobo and staff explained the complex process of delivering patient specific, timely radiation therapy treatment and the importance of patient access to these services in the community setting.

Congressman Jodey Arrington (R-TX) toured the Texas Center for Proton Therapy in Irving, TX on August 10. Congressman Arrington represents the 19th district of Texas and serves on the House Budget and Veterans' Affairs Committees. Dr. Andrew Lee lead the tour of the center and educated the Congressman on advancements in proton therapy treatment including high-quality scanning and digital imaging which allow optimal targeting and treating of tumors. The conversation also touched on reimbursement policies and regulations that disadvantage independent physician practices in favor of large, complex healthcare systems.

If your practice is interested in hosting a visit with your Member of Congress or local legislator, please contact Angela Storseth at Angela.Storseth@McKesson.com.

Brookings Institution Calls for Expansion of Medicare Site Neutral Payment Policies

In a blog post this week, researchers from the USC-Brookings Schaeffer Initiative for Health Policy praised the Center for Medicare & Medicaid Services' (CMS) recent decision to expand site neutral payment for all clinic visits at off campus hospital outpatient departments in the 2019 outpatient prospective payment system (OPPS) proposed rule. The authors argue the current policy should be expanded even further and be applied to a much broader set of clinical services at both off-campus and on-campus HOPDs and at ambulatory surgery centers. The authors cited evidence that the payment discrepancies between different sites of service drive up Medicare costs and create an incentive for large hospital systems to purchase smaller practices and convert them into hospital outpatient departments.

According to the Congressional Budget Office, expanding site neutral payments to existing off-campus HOPDs for all services - rather than just clinic visits - would save Medicare $13 billion over the next ten years.

To read the Brookings Institution's blog post, CLICK HERE.

To read the CBO estimate on site neutral cost savings, CLICK HERE.

CMS to Require ACOs to Take on More Risk

Last week, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule to reorganize the Medicare Shared Savings Program Accountable Care Organization (ACO) program. Starting next year, ACOs participating in the “no-risk” track, which allows providers to share in savings accrued through the program without facing any financial penalty for missing targets, will have to move on to the larger risk sharing track after two years - down from the current six. Additionally, the proposed rule collapses the three current ACO tracks into two - a basic track and an enhanced track - and will move to five-year participation agreements instead of three. ACOs on the “basic” track will be able to share savings with no financial risk for two years before being incrementally exposed to higher risk. The “enhanced” track will essentially mirror the existing “Track 3” option available to ACOs.

The proposal has received pushback from provider organizations, including the American Hospital Association and the National Association of ACOs who claim it will reduce providers’ incentives to participate. While CMS does acknowledge that fewer providers may participate, Administrator Seema Verma argued that the remaining ACOs will be those that drive the biggest savings.

To view CMS’ announcement of the proposed rule, CLICK HERE.

To view the new proposed rule, CLICK HERE.

CMS Releases New Step Therapy Guidance for Medicare Advantage Plans

Earlier this week, the Centers for Medicare & Medicaid Services (CMS) announced their intention to rescind prior guidance that had prohibited step therapy for Part B drugs and issued new guidance that will allow Medicare Advantage (MA) plans to apply step therapy for Part B drugs, beginning January 1, 2019.

The Administration claims that this action is an effort to reduce prescription drug costs through better negotiation, a component of the "American Patients First" drug pricing blueprint released in May.

The Network will closely monitor and examine the impact of this announcement and will work with CMS and MA plans to ensure cancer patients continue to have timely access to appropriate and tailored treatments. Under the new guidance:

- MA plans that choose to apply step therapy to Part B drugs must couple step therapy with broader care coordination activities.
- MA plans will be required to pass along at least 50 percent of the savings from step therapy to beneficiaries.
- MA plans that also offer a Part D benefit will be allowed to manage within their Part B benefit as well as cross-manage across Part B and Part D.
- CMS will consider rulemaking related to step therapy that might be appropriate for 2020 and future years.

Beneficiary Protections:

- If a plan decides to apply step therapy to Part B drugs, it must be explicitly communicated to beneficiaries through the Annual Notice of Change and Evidence of Coverage documents.
- Patients that do not wish to participate in a plan that includes step therapy will have the option to select a different plan during Open Enrollment.

- Once the MA plan year begins, beneficiaries can make a one-time switch to another MA plan or Original Medicare from January 1 through March 31, annually.
- This change will only apply to newly prescribed medications.
- The traditional MA appeals process still applies for instances in which a provider and patient seek an exception to step therapy.

To read the press release from CMS, CLICK HERE.

To read the fact sheet, CLICK HERE.

To read the memo that was sent to Medicare Advantage plans, CLICK HERE.

Bipartisan House Lawmakers Urge HHS to Address Retroactive DIR Fees

A bipartisan group of 83 House lawmakers sent a letter urging Health and Human Services Secretary Alex Azar to address the issue of retroactive direct and indirect remuneration (DIR) fees.

"DIR Fees imposed on pharmacies participating in Medicare Part D networks by plan sponsors and their pharmacy benefit managers (PBMs) have exploded in recent years and have had a crippling impact on patients, Medicare, and pharmacies. The retroactive nature of these fees means beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap (or "donut hole") phase of their benefit," the letter reads. "We ask this Administration to require the reporting of all pharmacy price concessions in the negotiated price at the point of sale."

The lawmakers noted that although CMS collected information on the idea of including rebates and DIR fees at the point of sale and has asserted its authority to address DIR fees through regulation, it has not taken any action to do so. The issue of DIR fees was also noticeably absent from the Administration's *American Patients First* drug pricing blueprint.

To read the lawmakers' letter, CLICK HERE.

Senator Hatch, Rep. Walden Urge OMB to Fully Consider Safe Harbor Proposed Rule

Last week, Senator Orrin Hatch, Chairman of the Senate Committee on Finance, and Congressman Greg Walden, Chairman of the House Committee on Energy and Commerce, together sent a letter to Mick Mulvaney, Director of the Office of Management and Budget, urging him to fully consider the implications of a recent draft regulation removing safe harbor protections for drug rebates.

In the letter, the Congressmen highlight how a proposed rule – "Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection" – could have significant economic implications. Because the proposed rule is economically significant, the Congressmen remind Director Mulvaney a detailed assessment and quantification of likely costs and benefits, as well as an analysis of reasonable alternatives, must be included in the proposed rule. The lawmakers also highlight how removing safe harbor protections for rebates used to purchase prescription drugs would alter a variety of taxpayer-funded programs and raise antitrust concerns within the healthcare space.

To read the letter, CLICK HERE.

E&C Leaders Request Additional Info From 340B Contract Pharmacies

House Energy and Commerce Committee Chairman Greg Walden, Heath Subcommittee Chairman Michael Burgess and Oversight Subcommittee Chairman Gregg Harper recently sent letters to nine contact pharmacies expressing concern over the growth and lack of oversight of contract pharmacies in the 340B program and asking questions to better understand their role.

Since 2010, the number of contract pharmacies in the 340B program has exploded, wrote the lawmakers. Additionally, the lawmakers note, the 340B statute remains silent on many important program requirements, including pharmacy arrangements for covered entities, resulting in many covered entities contracting with multiple external pharmacies in operating their 340B programs. The lawmakers outlined how these policies in the 340B program complicate efforts to prevent drug diversion and duplicate discounts, while also impeding oversight efforts. The letters were sent to the leaders of Accredo Health Group, Albertsons Companies, Avella Specialty Pharmacy, Cains Drug Store, CVS Health, Diplomat Specialty Pharmacy, Kroger Company, Walgreens and Walmart Inc.

The letters asked the leaders of the 340B contract pharmacies specific questions about the number of agreements they have with entities covered by the 340B program, their evaluation process for these contract agreements, the location of contracting entities relative to their pharmacy, fees charged, data tracking and reporting, diversion and duplicate discount prevention efforts, and the policies around the provision of discounts to low-income 340B patients.

To view the Committee's requests, CLICK HERE.

Bipartisan House Committee Leaders Send Letters to Opioid Manufacturers

The leaders of the House Energy and Commerce Committee recently sent letters to three opioid manufacturers requesting information on each manufacturer's role in the opioid crisis. Sent to the Chief Executive Officers of Insys Therapeutics, Mallinckrodt Pharmaceuticals and Purdue Pharma, the letters outline the role of pharmaceutical manufacturers in the opioid crisis before diving into questions more specific to each manufacturer.

- In the letter to Insys, the committee leaders investigate an alleged kickback scheme intended to boost the sales of the company's sublingual fentanyl spray, including questions about the company's speaker's program, internal investigations, training and sales materials, communication channels, quota systems, customer lists, and more.

- The letter to Mallinckrodt centered around questions about the company's efforts to monitor opioid sales for suspicious orders, including requests for copies of internal reports and other company communications.

- In the letter to Purdue Pharma, committee leaders ask when the company first knew about the dangers of OxyContin, requesting information on internal inquiries about the street value of the drug, the promotion of its opioid products to customers, sales incentives for employees, and documents from current and former Purdue Pharma executives on the subject of opioids.

To read the Committee's letters, CLICK HERE.