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In this Issue:

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New Study Finds Shift To Hospital Setting Drives Up Cancer Costs

The Community Oncology Alliance (COA) released a new study entitled "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration," completed by Berkeley Research Group (BRG) on the costs of cancer care, concluding that trends in care delivery and payment are resulting in increased Medicare fee-for-service (FFS) chemotherapy payments.

The study verifies the sizeable shift in cancer care from physician-owned community cancer clinics to hospital outpatient departments (HOPD). BRG found that between 2008 and 2012, claims for chemotherapy services performed in the HOPD setting increased from 1.20 million to 1.94 million, while services performed in the community cancer clinic setting dropped from 5.66 million to 4.72 million.

Under the current Medicare structure, Medicare pays HOPD a higher rate for the exact same chemotherapy services performed at community cancer practices. BRG estimates that Medicare payments were $23.29 million higher between 2009 and 2012 for the services delivered in the HOPD due to hospital acquisition of community cancer practices. Patient costs were also found to be significantly higher, with Medicare beneficiaries paying an additional $4.05 million in out-of-pocket costs during that same timeframe.

Researchers at BRG also examined the expansion of oncology services by 340B hospitals in recent years through the acquisition of community cancer practices, which they concluded leads to higher costs to the Medicare program because of differences in payment for services provided in community cancer clinics as compared to HOPD.

The study found that of the 340B hospitals they identified as acquiring a community cancer practice between 2009 and 2012, Medicare and Medicare beneficiary payments on chemotherapy claims increased by an estimated $167.28 million.

To read COA's press statement on the study findings, click here.

Alliance for Integrity and Reform of 340B Hosts National Leadership Summit to Discuss 340B Reforms

On June 10, the Alliance for Integrity and Reform of 340B (AIR 340B) hosted its inaugural 2014 National Leadership Summit on 340B to discuss challenges in the

federal 340B program and opportunities for reform to ensure it benefits the vulnerable and uninsured patients it is intended to serve.

Dr. Barry Brooks, Chairman of The US Oncology Network's Pharmacy & Therapeutics Committee, participated in the Summit, which engaged a broad spectrum of collaborators to review and discuss the latest data available on the 340B program's impact on patients, costs and its implications on the healthcare delivery system.

Approximately one-third of US hospitals purchase chemotherapy drugs through the 340B program at discounts of up to fifty percent, which result in Medicare margins on chemotherapy drugs of more than 30 percent. Some stakeholders speculate that these high margins are incentivizing hospitals to rapidly increase drug spending and acquire physician practices to drive the delivery of cancer care to the HOPD setting.

An April 2014 Berkeley Research Group (BRG) authored study, "Trends in 340B Covered Entity Acquisitions of Physician-based Oncology Practices," concluded that acquisitions of physician-based oncology services by 340B hospitals increased significantly between 2009 and 2012, tripling the number of oncology-related 340B chargebacks to the point were hospitals chargebacks exceeded the entities' total charity care costs. The study reported that of the eighty-six 340B hospitals that acquired a physician's office during that time, Medicare program spending was $23.29 million higher and Medicare beneficiary costs were $4.05 million higher than they would have been if the services were delivered in the physicians' offices.

Based on this evidence and other research, stakeholders are concerned that the 340B program has departed significantly from its original intent and has led to misuse of the program and unintended consequences for patients. To address these concerns, Summit participants discussed the following 340B policy reforms:

- *Clearer guidance for the definition of the term "patient" to ensure that 340B entities use the program to support the needs of the most medically underserved patients;*
- *Full and transparent accounting for all cost-savings derived from the 340B program; and*
- *Revised hospital eligibility criteria to ensure 340B discounts go to the facilities that are taking care of medically underserved patients and providing appropriate levels of charity care.*

The federal policy dialogue on 340B increased greatly as the Health Resources and Services Administration (HRSA) prepared to release its comprehensive "mega-rule," which is expected to define patient eligibility, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria and hospital off-site facility eligibility. However, a recent decision in the US District Court for the District of Columbia questions HRSA's authority to regulate discounts for orphan drugs under the 340B program, creating uncertainty on the mega-rule's status.

Despite the U.S. District Court's ruling, HRSA announced on June 18 plans to continue allowing certain hospitals to receive discounts on orphan drugs when they are used for non-orphan conditions. A posting on HRSA's website reads, "The Court did not invalidate HRSA's interpretation of the statute. HHS/HRSA continues to stand by the interpretation described in its published final rule, which allows the 340B covered entities affected by the orphan drug exclusion to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation."

It remains unclear how these developments will impact the anticipated mega-rule, however some have speculated that Congress may ultimately have to pass legislation giving HHS authority to interpret the 340B program.

MedPAC Expands Support of Site Neutral Payments

On June 13, the Medicare Payment Advisory Commission (MedPAC) released its June 2014 *Report to the Congress: Medicare and the Health Care Delivery System*, which continues to examine services and conditions for site-neutral Medicare payments across settings of care.

In the previous two years, MedPAC has supported site-neutral payment policies across outpatient settings, acknowledging that hospital outpatient departments are often paid significantly more for delivering the same services as those provided in physician offices, including a wide array of cancer care services. The report released June 13 of this year focuses specifically on the concept of site-neutral payment policy in post-acute care settings such as skilled nursing facilities (SNFs).

The MedPAC criteria used in selecting services and conditions for site-neutral payments included:

- **Service is frequently furnished in the lower-cost setting**: MedPAC examined ambulatory services furnished in the physician's office more than 50 percent of the time.
- **Patient severity**: Patients' health status was of similar severity across settings.
- **Comparable service unit**: Payment for the service in each setting covers the same services.
- **Literature on quality and outcomes**: MedPAC reviewed literature comparing outcomes and quality across settings.
- **High volume/high spending**: MedPAC identified services that constitute a sizeable amount of Medicare spending to determine if site-neutral payments

could reduce spending.

In addition, the report further addresses the need to reconcile quality performance incentives and payment rules across Medicare payment models including fee-for-services (FFS), accountable care organizations (ACO) and Medicare Advantage (MA) plans.

To read MedPAC's press release on the recent report, click here.

The House Ways and Means Committee will hold a hearing on the MedPAC report on June 18. MedPAC Executive Director Mark Miller will be the sole witness.

Large Bipartisan Group of Lawmakers Urge Medicare Decision on Low-Dose CT Scans For Lung Cancer Screening

A bipartisan group of 179 lawmakers in the US Senate and House of Representatives is asking the Centers for Medicare & Medicaid Services (CMS) to make a Medicare coverage decision for lung cancer screening with the use of low-dose computed tomography (CT). Many lawmakers are urging CMS to make a decision in line with The US Preventive Services Task Force (USPSTF) recommendation despite opposition from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).

The USPSTF has recommended lung cancer screening for high-risk patients. Under the Affordable Care Act, this recommendation requires private insurers, but not those covered by Medicare, to provide lung-cancer screening for high-risk groups including patients with a 30-pack a year history of smoking beginning in 2015.

A Senate letter currently has 45 signatures and is led by Senators Dianne Feinstein (D-CA) and Johnny Isakson (R-GA). The House letter currently has 134 signatures and is led by Representatives Charles Boustany (R-LA), John Barrow (D-GA), Jim Renacci (R-OH), and Richard Neal (D-MA).