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The US Oncology Network's Barry Brooks Testifies Before House Energy & Commerce Health Subcommittee on Site-Neutral Medicare Payment Reform

On May 21, The US Oncology Network's Dr. Barry Brooks, Chairman of the Pharmacy & Therapeutics Committee, testified at a hearing entitled *Keeping the Promise: Site of Service Medicare Payment Reforms* held by the House Energy and Commerce Subcommittee on Health. The hearing focused primarily on proposed site-of-service payment reforms in Medicare.

Dr. Brooks testified about an alarming trend in cancer care, in which outpatient oncology services have begun to shift from community oncology clinics to the more expensive hospital outpatient department (HOPD). Under the current Medicare payment structure, according to Milliman data, HOPD-based chemotherapy costs the Medicare program increased costs of more than $623 million annually.

Dr. Brooks stated in his testimony to the Committee, "Year after year, as I watch colleagues being forced – either for financial or competitive reasons to merge with a hospital, it has become clear that congressional action is necessary to halt the patient access and cost consequences that come along with the shift to hospital-based care. With reduced access to community cancer clinics, not only are patients forced from their preferred treatment setting, forced to drive further and wait longer, they are also charged more for the same service."

Also in his testimony, Dr. Brooks urged lawmakers to support The Medicare Patient Access to Cancer Treatment Act of 2014 (H.R. 2869), a bill to establish payment parity under the Medicare program for cancer care services furnished in the hospital outpatient department and the physician office setting.

The Medicare Payment Advisory Commission (MedPAC) has taken a similar position regarding the alignment of Medicare payments for cancer care services. MedPAC Executive Director Mark Miller also testified at the May 21 hearing, stating, "As billing of services shifts from freestanding offices to OPDs, program spending and beneficiary cost sharing increase without significant changes in patient care. To limit the incentive

to shift cases to higher cost settings, there is a need to align OPD rates with freestanding office rates."

Following the hearing, *Roll Call* published an editorial by Dr. Brooks, highlighting key aspects of his testimony, in which he wrote, "There is simply no clinical justification for continuing to incentivize and enrich hospitals while impoverishing community practices that provide the exact same care at a lower cost. One sensible solution would be for the Congress to pass the Medicare Patient Access to Cancer Treatment Act, which would establish payment equality for the delivery of cancer care across settings to better ensure that community clinics are not forced out of the nation's cancer care delivery system."

To view Dr. Brooks' testimony before the Committee, click here.

Court Decision Calls HRSA 340B Rule-Making Authority Into Question

On May 23, a U.S. district court judge overturned a 340B regulation made by the Health Resources and Services Administration (HRSA), which allowed 340B program discounts for orphan drugs used for off-label treatments. The court found that HRSA did not have the authority to rule on an Affordable Care Act (ACA) provision exempting orphan drugs from the 340B discount program. In its original 2013 rule, HRSA said an exception for orphan drugs only applied to drugs used for on-label conditions.

The court's decision calls into question HRSA's authority to release rules specific to the 340B program. It may require HRSA to ask Congress to give the agency rule-making authority before it issues any future 340B regulations.

The Pharmaceutical Research and Manufacturers of America (PhRMA), the organization that filed the original lawsuit against HRSA, said in its lawsuit, "Congress did not empower HHS or HRSA to promulgate rules interpreting the orphan drug exclusion."

HRSA, the HHS agency that regulates the 340B program, is scheduled to release a comprehensive regulation in June addressing issues regarding the program's parameters, including patient definition, contract pharmacy, hospital eligibility and the eligibility of offsite facilities. The rule has reportedly already been sent to the Office of Management and Budget (OMB) for review.

New Study Examines 340B Hospital Acquisitions of Physician-Based Oncology Practices

On May 29, the Berkeley Research Group (BRG) released a study, *Trends in 340B Covered Entity Acquisitions of Physician-based Oncology Practices*, sponsored by the Biotechnology Industry Organization (BIO), which measures the impact of physician-based oncology practice acquisitions on purchases through the 340B program. The study also examines characteristics of 340B covered entities and acquired physician practices.

The study raises further questions as to whether or not the 340B program is being used to achieve its original intent of helping indigent, uninsured patients access prescription drugs, or if it is being abused in order to achieve financial gain for participating covered entities.

In its statement releasing the report, BIO states, "Distorting the program in this way to create a revenue line—a financial instrument—may comply with the letter of the law, but not the intent of the law. As the Health Resources and Services Administration (HRSA) may not have the tools necessary to bring the program back in alignment with its original intent, Congress must take a closer look at the program to ensure it is used to meet patient needs."

Key findings of the report include:

- Acquisitions of physician-based oncology services by 340B hospitals increased significantly between 2009 and 2012
- The volume of oncology-related 340B chargebacks by hospitals that acquired a physician-based oncology practice grew by 3 times between 2009 and 2012
- 45 percent of 340B covered entities included in the study generated more oncology-related chargebacks than they reported in total charity care costs, indicating that the 340B hospitals were recouping more than their self-reported charity care costs

To read the BIO press release and highlights of the study, click here.

CMS Issues Proposed Rule on "Meaningful Use" Requirements

The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator (ONC) released a proposed rule on May 20, which would give healthcare providers more flexibility in meeting Stage 2 "meaningful use" requirements for use of certified electronic health record technology (CEHRT). The proposed rule would:

- Allow providers to use 2011 CEHRT or a combination of 2011 and 2014 CEHRT for the 2014 reporting period to be eligible for incentive payments
- Require all hospitals and healthcare providers to use 2014 CEHRT to be eligible for incentives beginning in 2015
- Extend Stage 2 requirements through 2016
- Delay Stage 3 requirements from 2016 to 2017

Medicare providers must meet “meaningful use” requirements by October 1, 2014 in order to avoid reductions in their 2015 Medicare reimbursements. Penalties to providers who do not meet the standards will receive a 1 percent reimbursement reduction, which will increase each year a Medicare provider does not exhibit “meaningful use” of CEHRT.

To view the CMS’ statement on the proposed rule, click here.

Senators Urge Medicare to Cover Lung Cancer Test

On May 28, a bipartisan group of 44 members of the U.S. Senate sent a letter to the Centers for Medicare and Medicaid Services (CMS) Administrator Marilyn Tavenner, urging expanded coverage for early lung-cancer CT screening tests under Medicare. Senators Dianne Feinstein (D-CA) and Johnny Isakson (R-GA) led the effort.

The Senators write, “We are writing to urge that the Medicare National Coverage Determination (NCD) for low-dose computed tomography (LDCT) scans for Medicare beneficiaries with a high risk of developing lung cancer be completed expeditiously. With the medical age of lung cancer diagnosis being age 70, it is essential that seniors on Medicare have access to this screening tool.”

In December 2013, the U.S. Preventive Services Task Force (USPSTF) issued recommendations on screening for lung cancer, in which they recommend annual screening for lung cancer with low-dose computed tomography in adults ages 55 to 80 years who are at high risk for lung cancer such as patients who have a 30 pack-year smoking history and currently smoke or have quit smoking within the past 15 years.

The Senators further pointed out that, in regard to the USPSTF recommendations, lung CT screening is now accessible to patients with private insurance while Medicare beneficiaries are still waiting for coverage.

Burwell Vote Likely this Week

The Senate is expected to vote this week on Sylvia Mathews Burwell’s nomination to head the Department of Health and Human Services (HHS). Her confirmation is expected with overwhelming support from both Democrats and Republicans.

The Senate Finance Committee previously held a hearing on May 14, during which the HHS nominee was questioned about a variety of Medicare issues, including how she plans to address the permanent repeal of the SGR payment formula.

While Burwell suggested she would work in coordination with lawmakers on both sides of the aisle to develop a permanent solution, she did not offer any specific policy recommendations. To view the Senate Finance Committee hearing, click here.

President Obama nominated Sylvia Mathews Burwell to be the next HHS Secretary following the resignation of Secretary Kathleen Sebelius. Burwell has served as the Director of the US Office of Management and Budget since April 2013.