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The Honorable Congressman Peter Roskam  
Chairman, House Ways and Means Health Subcommittee  
United States House of Representatives  
2246 Rayburn House Office Building  
Washington, DC 20515

05/01/2018

Dear Congressman Roskam,

Thank you for taking the time to visit Illinois Cancer Specialists – Fox Valley on April 24<sup>th</sup>, 2018. Following up on the conversation regarding the impact of Direct and Indirect Remuneration (DIR) fees, Pharmacy Benefit Managers (PBM) and site-neutral payments on Oncology practices, we have provided some additional information below for your review and perusal.

**Pharmacy Benefit Managers (PBM) & Direct and Indirect Remuneration (DIR) fees:**

Physician dispensing is a critical part of ensuring safe pharmacy practice in medicine. Literature has proven that patients receiving medications directly from their treating physician receive the medications in a timely fashion,<sup>1</sup> have higher adherence rates,<sup>2</sup> and demonstrate improved outcomes.<sup>3</sup> This is particularly true in oncology, where complex cancer treatments with serious side effects require unabating skilled physician attention for regular visits and chemotherapy. Over the past decade, the availability and use of oral oncolytic medications (chemotherapy, biotherapy, and immunotherapy) has significantly increased. Payments for these medications are made under Medicare Part D through PBMs. Currently, five PBMs control network access for more than 80% of the covered lives in the United States.<sup>4</sup>

The Centers for Medicare and Medicaid Services (CMS) initially created DIR fees to track manufacturer rebates and other price adjustments to PBMs for the Medicare Part D medications. The savings from rebates received by the PBM are therefore passed on to CMS. However, over time, DIR fees have morphed from a rebate the PBM pays to the payer (CMS) to encompass a myriad of fees the participating pharmacy/dispensing physician pays the PBM (PBM “claw-back” of the rebate from the pharmacy/dispensing physician). These fees can be:

- a. The cost a pharmacy pays to participate in a PBM’s network (not just Medicare Part D),
- b. The adjustment of reimbursement rates the pharmacy receives for a medication, and
- c. The fees levied on a pharmacy based on certain quality measures.

The DIR fees can have a significant negative impact on the pharmacy or dispensing physician when considering specialty medications, such as oral oncolytic drugs. To secure access to the network patients, pharmacies have historically assumed the DIR fees as the cost of doing business. However, recent changes to the DIR calculation methodology has made the fiscal impact on dispensing physicians and pharmacies unbearable. DIR fees can be assessed in a variety of methods: as a percent of the cost of goods (COG), as a flat fee, or as an adjustment to the reimbursement fee schedule. DIR fees levied as a percent of the COGs significantly impact specialty medications (oral oncolytic drugs) which cost anywhere from a few thousand to tens of thousands of dollars for a month’s therapy. These fees are levied retrospectively, sometimes several months after the medication has been dispensed. The retrospective levy of such fees creates unpredictability for pharmacies at the time and point of sale. DIR fees applied to specialty medications have often resulted in negative net cost recovery for disease-curing and life sustaining cancer treatments. Underwater reimbursement on expensive medications limits pharmacies’/dispensing physicians’ ability to continually provide services to Medicare Part D patients, thereby limiting beneficiary access. Further, fees that are assessed based on quality measures focus entirely on primary care measures, and do not apply to specialty medications.

Example scenario:

Cost of Goods (COG)	\$15000
Reimbursement @ Point of Sale	\$15350 PBM payment = \$15150 Patient Co-pay = \$200
DIR fee levied	\$675 (at 4.5%) (3-11% of the COG)
Net payment to the pharmacy	(\$325)

**Proposed solution:** In the interest of preserving physician dispensing and community pharmacy practice, we urge Congress to consider eliminating retroactive levy of DIR fees, to increase transparency and provide greater predictability to pharmacies.

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**Site-neutral payments:**

Community based oncology care has been historically provided by independent oncology providers/practitioners and oncology group practices operating independent of a hospital. Such providers/practices are reimbursed for the services rendered using the Medicare Physician Fee Schedule (PFS). Currently, Medicare's payments for out-patient services are based on the site of service rather than the type of care provided. While the practices are reimbursed using the PFS, similar services provided at hospital out-patient departments (HOPD) are reimbursed under the Hospital Outpatient Prospective Payer System (HOPPS). HOPDs bill for and collect facility fees from patients who receive care at their facilities. The fees reflect a service charge for the patient's use of the hospital facilities and equipment. This results in patients and payers (Medicare) paying more when the same services are delivered in the HOPD instead of independent physician practices for a wide variety of services. A simple comparison shows that physician visits cost \$51 more when performed in a HOPD.<sup>8</sup> Literature suggests that facility fees can increase the total cost of a service by three to five times when compared to the same service provided by an independent physician. Patients with high out-of-pocket expenses (co-pay and co-insurance) often become responsible for the payment of such additional costs. Over a three-year period, Medicare paid an additional \$2.7 billion on services and patients spent \$411 million more in out-of-pocket costs when services were delivered in a hospital-owned setting.<sup>9</sup>

**Example cost comparisons:**

Service	Independent Practice	Hospital Out-patient Department
Chemotherapy <sup>6</sup>	\$136	\$281
Cardiac Imaging	\$655	\$2078
Colonoscopy <sup>7</sup>	\$625	\$1383

Hospitals can also charge patients facility fees if they see physicians who work in an off-campus office that is owned by the hospital. This also encourages the acquisition of office-based physician practices by hospitals, further restricting patient access to care in the lower cost community setting.<sup>10</sup> As a testament to this shift, data shows that hospital ownership of physician practices has steadily increased to 1 in 4 in 2015, making it difficult for patients to find an independent physician. From July 2014 to January 2015 alone, 13,000 physician practices were acquired. Since 2008, there has been a 172% increase in community-based cancer clinics acquired by hospitals.<sup>11</sup>

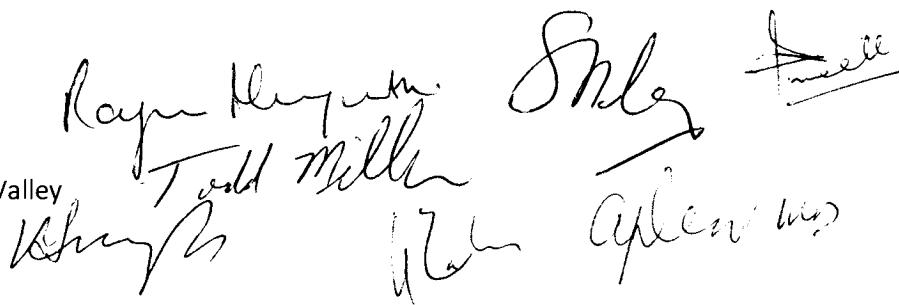
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The Bipartisan Budget Act of 2015 (BBA) aligns payments for certain provider-based off-campus HOPDs with payments to physician practices. However, this only applies to newly acquired provider-based off-campus facilities. All existing off-campus HOPDs continue to bill at the much higher HOPPS rate for the same services. The 21st Century Cures Act further exempts certain facilities from the site neutral payment law.

**Proposed solution:** Recognizing the value and quality of care provided by community based, independent physicians/practices, we urge Congress to consider site-neutral payment policies for all facilities irrespective of site of service.

Sincerely,

  
Illinois Cancer Specialists – Fox Valley



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