

DIR Fees Increase Medicare Beneficiary and Medicare Program Costs for Specialty Drugs

Background

The Centers for Medicare & Medicaid Services (CMS) have developed numerous quality measures by site of care and provider type that are used to support the delivery of quality healthcare to Medicare beneficiaries. The agency and its partners, however, have not yet developed robust and relevant quality measures for beneficiaries that access specialty therapies.¹ Rather, the current quality measures related to the dispensing of drugs at the pharmacy focus on generic utilization rate, statin cholesterol management, diabetes management, rate of 90 day fills, and managing high blood pressure. Unfortunately, Pharmacy Benefit Managers (PBMs) are now using these quality measures in their network contracts with specialty pharmacies.² NASP believes that the use of these quality measures on specialty pharmacies for the population that they serve is misguided and must be stopped given the financial ramifications that this is having on the Medicare beneficiary, the specialty pharmacy, and the Medicare Program.

Issue

Starting with contract year 2016, CMS informed Part D sponsors that they are to evaluate what can be reasonably determined at the point of sale and include those amounts in the negotiated price. Amounts that cannot be reasonably determined at the point of sale must be reported as a Direct or Indirect Remuneration (DIR) fee, which can include but are not limited to, rebates subsidies, or other price concessions that serve to decrease the costs incurred by the Part D plan for a drug.

¹ Specialty therapies are more complex than most prescription medications and are used to treat patients with serious and often life threatening conditions. These medications may be taken orally but often must be injected or infused and may have special administration, storage and delivery requirements. Many of these injectable medications are self-administered in the patient's home. Specialty prescription medications cannot be routinely dispensed at a typical retail community pharmacy because the therapy typically requires special handling as well as significant patient education regarding appropriate utilization. Typical retail pharmacies are not designed to provide the patient care or other services that specialty medications require. http://naspnet.org/wp-content/uploads/2016/06/633570_864cb572b8b042909a3f207eaf764d7a.pdf

² A specialty pharmacy is a state licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. In addition to being state-licensed and regulated, specialty pharmacies should be accredited by independent third parties such as URAC®, the Accreditation Commission for Health Care (ACHC), the Center for Pharmacy Practice Accreditation (CPPA) or the Joint Commission, in order to ensure consistent quality of care. http://naspnet.org/wp-content/uploads/2016/06/633570_864cb572b8b042909a3f207eaf764d7a.pdf

In response, PBMs started tying DIR fees to the quality measures stated above that are not at all related to the complex specialty drugs dispensed by the specialty pharmacy or the Medicare population that the specialty pharmacy serves. This process is inconsistent with current CMS approach and philosophy for the value of quality measures. CMS uses quality measures as a tool that helps measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. These goals include: effective, safe, efficient, patient-centered, equitable, and timely care. NASP supports these goals, however, only when they are relevant to the practice of specialty pharmacy for Medicare beneficiaries. This is NOT the current situation.

How DIR/Administrative Fees Work

As demonstrated further in the attached example, failure to meet any one of the quality measures mentioned above results in the specialty pharmacy paying a DIR fee³ back to the PBM. DIR fees can also be assessed to specialty pharmacies by PBMs for a variety of other reasons including network participation and payment rate reconciliation. A Medicare beneficiary's co-pay or co-insurance, however, is calculated at the point of sale when the specialty pharmacy adjudicates the claim and NOT when the claim is finally adjudicated between the specialty pharmacy and the PBM. The DIR fee is typically a percentage of the ingredient cost of the drug. The higher the ingredient cost of the drug, the higher the DIR fee to the PBM. As a result of the DIR fee, both the Medicare beneficiary and the Medicare program pay more for the drug under the current standard typical DIR arrangement. None of these fees relate to providing quality care or improving outcomes.

The DIR fees are problematic for many reasons. First, specialty pharmacies cannot determine their actual reimbursement rate until well after they have dispensed the medication causing significant commercial uncertainty and the inability to sometimes provide needed services to Medicare beneficiaries. Second, this post claim adjudication recoupment of fees by the PBM of the specialty pharmacy is quickly driving independent specialty pharmacies out of business because the additional payments drive the drug transaction under water. Finally, and most significantly, both the Medicare beneficiary and the Program spend more money on specialty therapies.

CMS and Congress have expressed a willingness to address this problem, however, without finalizing any policy changes, specialty pharmacies remain

³ Some in-network contracts call this fee an administrative fee, but the intent is the same. The specialty pharmacy winds up paying back the PBM money because it failed to meet a quality measure that should not apply to the service it provides to the beneficiaries it serves.



inappropriately at risk and beneficiaries and the Program continue to pay more for medications.

Next Steps/Solutions

NASP appreciates recent Congressional efforts to curtail the use of DIR fees within the Improving Transparency and Accuracy in Medicare Part D Spending Act (S. 3308 / H.R. 5951) and CMS' proposed 2014 guidance, *Guidance on Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions*. The legislation is a good starting point but unfortunately, the legislation does not fully address the needs of specialty pharmacies because it excludes mail order claims and does not address the definition of negotiated price.

NASP believes that CMS and Congress should continue to work together to protect the Medicare beneficiary by suspending the application of all DIR and other fees attached to achieving quality measures until those quality measures have been independently developed and validated much in the same manner as other quality measures in the Medicare program. Until then, the Medicare beneficiary and the Part D Program will continue to overpay for life saving specialty drugs.