NASP

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

Overview of 2017 Direct and Indirect Remuneration Fees

December 12, 2016

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

Goals

#1

Review 2017 DIR fee developments

#2

Impact of DIR Fees on Beneficiaries

#3

Discuss Statutory, Regulatory & Guidance Insights

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

Review: Flow of Specialty Prescription

PROVIDER

Referral/Prescription

Specialty Pharmacy

- Best in Class
- In Network Payer
- In Network Medication

- Prior Authorization
- Benefits Determination
- Coordination of Benefits
- Communicate status to Provider
- Access to Medication
- Access to Payer Network

- Communicate to Patient
- Clinical Assessment
- Establish pick up/delivery
- Instruct Patient/Caregiver proper use of medication and regimen.
- Provide additional encouragement and support

Coordinate billing to PART D Sponsors contracted PBM / Delivery of Medication

- Patient receives Medication
- 1-3 days post delivery, call to patient
- Adherence Monitoring starts
- Confirm understanding
- Document changes to therapy

- 7-10 Days post delivery
- Confirm understanding with Patient/Caregiver
- Side Effect Management
- Communicate gap information to Provider
- Establish next date/time to call to discuss refill

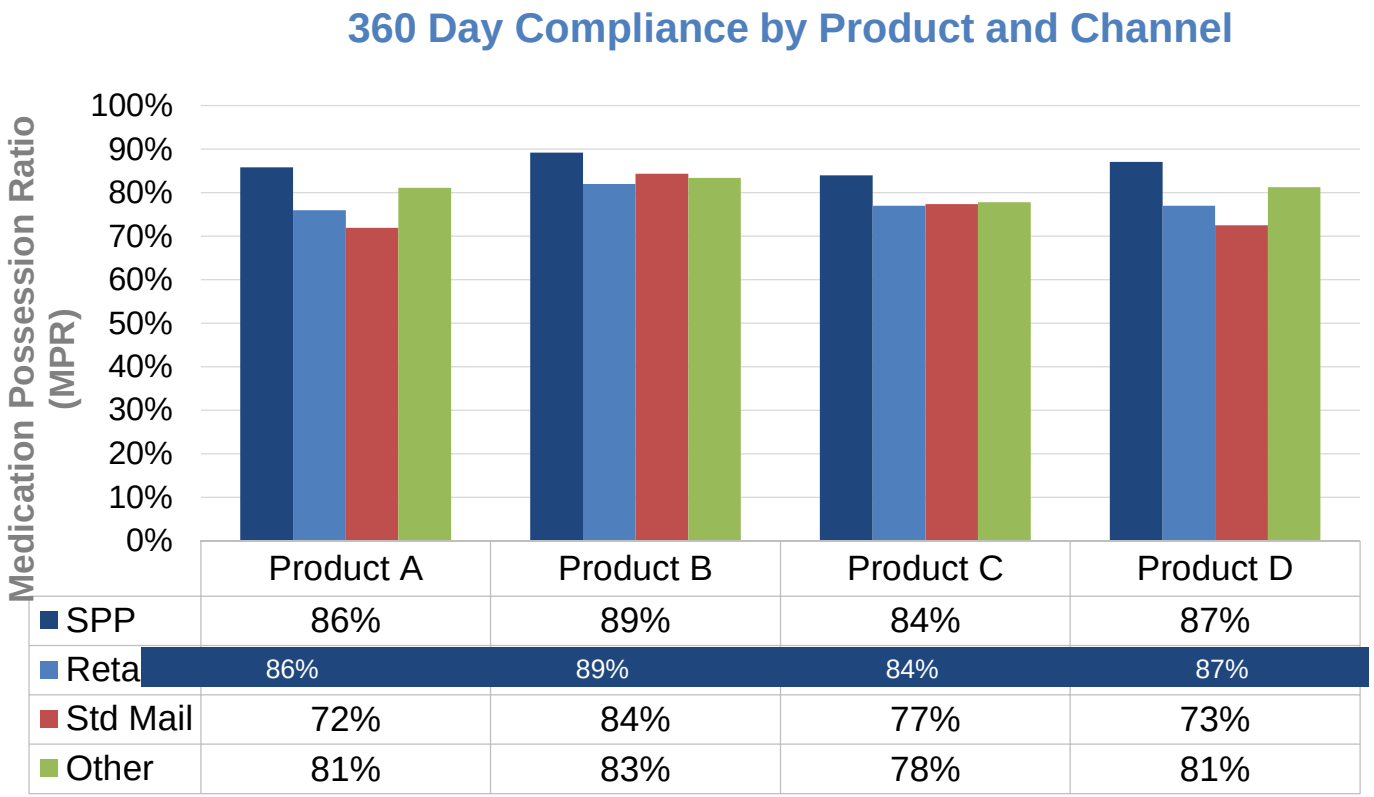
Challenges moving forward

Independent Specialty Pharmacy AND Pharmacy Benefit Manager/Health Plan at market disadvantage when Pharmacy Benefit Manager owns its own Specialty Pharmacy

- Financials
- Moving patient to in house Specialty Pharmacy, post first fill.
- DIR methodology of calculation inconsistent with no ceiling in sight
- Specialty Pharmacy is typically introduced to a PART D network AFTER Sponsor submits to CMS for approval
- Patient Disruption, Pharmacies can not provide service when in the RED
- Methodology for recoupment of DIR FEE's, see next slide

Patient Compliance

Specialty Pharmacies Excel at Driving Engagement and Compliance



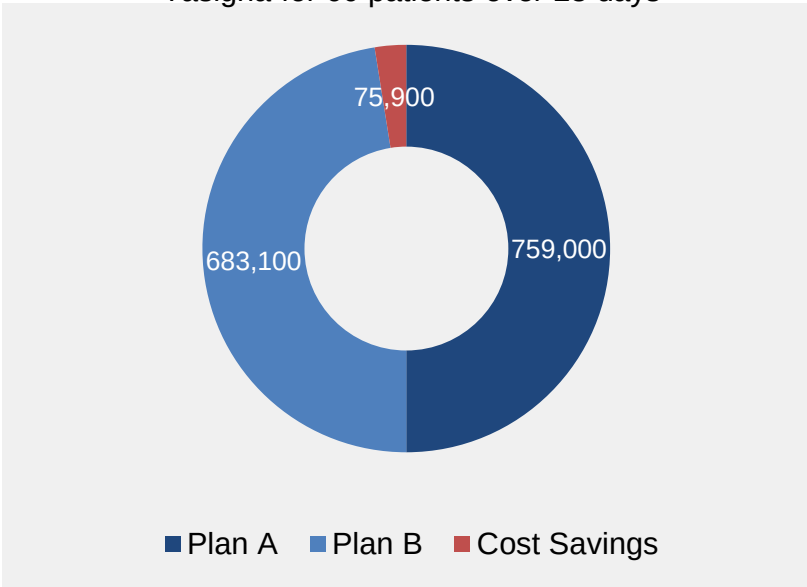
	Product A	Product B	Product C	Product D
SPP	86%	89%	84%	87%
Reta	86%	89%	84%	87%
Std Mail	72%	84%	77%	73%
Other	81%	83%	78%	81%

Source: Understanding and Improving Adherence for Specialty Products, IMS.

SRx Bends the Cost Curve

- Split-fill program – 2-week supply for initial 90-days

Example: Tasigna 200mg
Qty 112/28 day supply- $12,650 [AWP]
Tasigna for 60 patients over 28 days



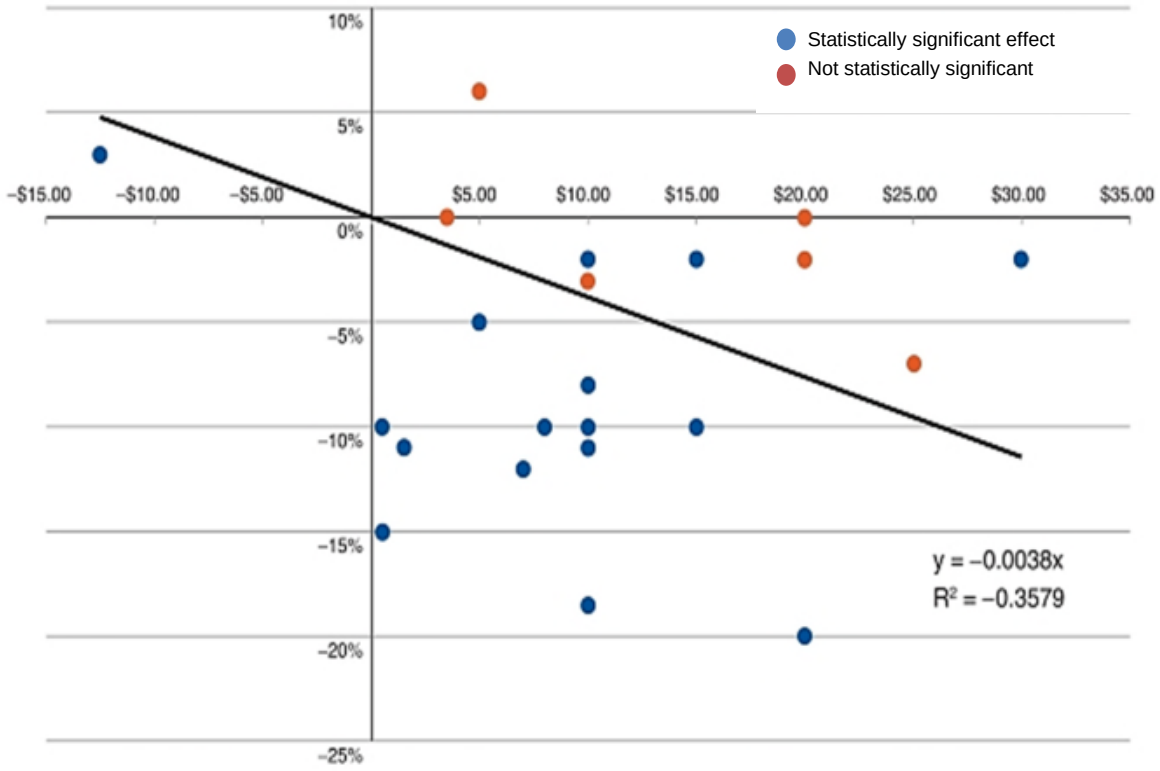
Case Example

Plan A:
- Total plan spend for 28 day supplies for all 60 patients

Plan B:
- Total cost for 14 day increments in 28 days
- Anticipated 10% attrition within 28 days
- **$75,900** potential savings in one month for one drug if utilizing Plan B
- With continued 10% attrituion during first 3-months, potential savings of **$227,700** utilizing Plan B

SRx Supports Patient Access

Patient Success Correlated to Access through Copay Assistance



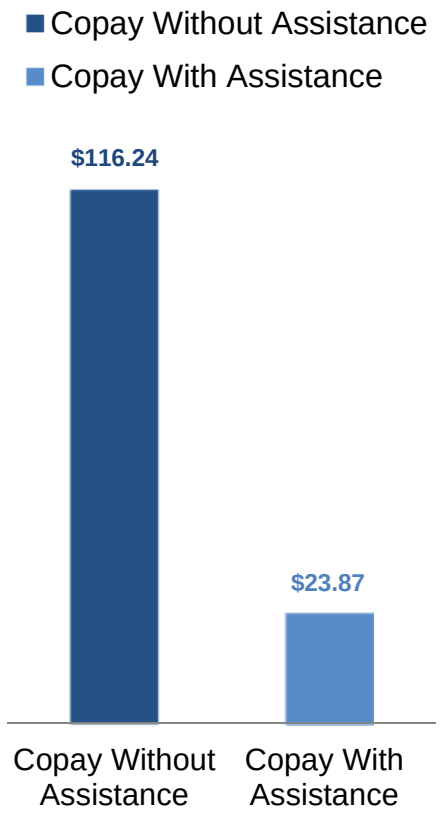


Figure 2

Relationship between changes in patient cost sharing (copays) and medication adherence.

Review DIR Fee Impact 2016 & Beyond

- Imposition of primary care oriented metrics are having an accelerating negative impact on high-touch Specialty Pharmacies (“SRx”) that support patient clinical outcomes and bend the cost curve.
- PBMs have erroneously leveraged CMS provisions intended to assure transparency in the actual cost paid for a Part D drug, including any price concessions applied after the point of sale.
- DIR Fee Schedules applied to Specialty Pharmacy have resulted in negative margin for disease-curing and life-sustaining therapies ***before*** SRx work begins to support patient access to therapy & clinical outcomes.
- Impact is likely to increase as additional PBM-imposed fee programs proliferate and as the models for fee recoupment become more variable

Direct and Indirect Remuneration (DIR)

- Beneficiary pays co-pay or co-insurance at point of sale based on price adjudicated at that moment.

- Up to months later, the PBM collects a DIR Fee on that transaction from the specialty pharmacy thereby reducing the net to the pharmacy but NOT reducing beneficiary cost.

- Final 2014 Part D rule established a new definition of "negotiated price" effective in 2016 to include all pharmacy price concessions which can be reasonably determined at point of sale. "beginning with contract year 2016, Part D sponsors must include in amounts reported as negotiated prices all pharmacy price concessions from network pharmacies and additional contingent amounts that can reasonably be determined at the point-of-sale."

- Fees being applied to SRx related to SRx-specific performance can be reasonably determined at the point of sale, if such fees are consistent with the performance metrics that SRx holds themselves to with Health Plans, Plan Sponsors, Manufacturers, Referring Providers and Patients.

- Term "DIR fee" may have been inappropriately used by PBMs as a result of the structure they imposed in their programs; however, as established, the PBM-sponsored programs create (by content and cadence) unpredictability that the Medicare Part D program seeks to avoid.

DIR Fees measure Primary Care – Not Specialty Pharmacy outcomes

SRx does not manage current **star-ratings** categories.

Performance Criteria	Criteria Weight
ACE / ARB Adherence	20%
Statin Adherence	20%
Diabetes Adherence	20%
GAP Therapy – statin	25%
CMR Completion Rate	5%
% High Risk Medications (HRM)	5%
Formulary Compliance	5%

- All patients are negatively impacted by DIR fees.
- PBM owned specialty pharmacy losses are underwritten by consolidated P&L's.
- Independent SRx losses negatively impact high touch patient support.

Fees Come in a Variety of Flavors

Percent of COGs	
Ingredient Cost including pt. copay	**$15,020.00**
9.5% DIR Fee Ingredient Costs	**$ 1,425.00**
True Reimbursement	**$13,575.00**

Flat Fee	
Ingredient cost Including pt. copay	**$15,020.00**
Flat DIR Fee	**$2.00**
True Reimbursement	**$15,018**

Differential Pricing	
Ingredient cost plus dispense fee ($1)	**$15,001.00**
Contracted reimbursement is $13,000.00 plus dispense Fee ($1)	**$13,001.00**
True Reimbursement	**$13,001.00**

- Many DIR Fees are % of COGs, promoting higher ingredient costs and incentivizing larger DIR fees as a percentage
- DIR fees not capped so that the more volume the more losses.
- SRx are pivoting from managing therapy and patient outcomes to managing DIR fees and referrals out of negative margin therapies.
- Even after dispensing, SRx must assess patient and therapy dispenses due to retroactive DIR fee application.
- Fees imposed after SRx has provided patient support and dispensing therapies.

Lack of Transparency in Costs is Accompanied by Lack of Predictability

01 Fees can be assessed based upon performance criteria for primary care patients which make up a small percentage of total medications dispensed by SRx (oftentimes less than 5%).

02 Fees can be assessed against the entire basket of claims dispensed by the individual SRx or by a network including a small number of SRx but a disproportionately larger percentage of retail pharmacies

03 Fees can be assessed based upon a “curve” in which SRx providers in a network along with retail providers, notwithstanding having achieved ratings in excess of 90%, place lower than others and so have higher fees applied to their entire book of business with the PBM.

Impact of DIR Fees on Beneficiaries

- Beneficiary pays co-pay &/or co-insurance at the point of sale. Up to months later the PBM collects DIR fees on the transaction, resulting in reduced payments to SRx but no reduced beneficiary costs.
- Plan Benefits are increasing patient out-of-pocket expenses for high cost medications, imposing financial and compliance risks
- Loss of access to co-pay assistance, persistency and compliance programs.
- Therapy disruption when the SRx is economically compelled to transfer patients
- Loss of effective patient/provider coordination

Statutory, Regulatory & Guidance Insights

- PBMs have inappropriately applied DIR fees to SRx. 42 USC does not give PBMs statutory authority to levy additional fees after the point of sale.
- Negotiated prices definitions (42 USC 1395w-102 7 141) do not explicitly authorize clawbacks or variable rates.
- CMS Guidance contemplated Sponsors paying enhanced rates or additional payments based upon generic utilization, pharmacy network size or other metrics but did not suggest after-the-fact fees.
- Below cost reimbursement violates AWP (42 USC 1395w-104) because CMS guidance includes "reasonableness" into the applicable terms of a prescription drug plan, including the price of SRx meds.
- Below cost reimbursement limits pharmacies' ability to participate in Medicare Part D networks (42 USC 1395a) thereby limiting beneficiary access under Freedom of Choice provisions.
- DIR clawback methodology after the fact manipulates the Medicare Part D negotiated price and provides less transparency than is intended by the law.
- Variability in Part D sponsor pharmacy price reporting- what is a DIR Fee & how is that different from a price concession?

NASP NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

Performance Measurement Options for Specialty Pharmacies

01

Proportion of Days Covered (PDC)

Formula used to estimate patients' adherence to chronic medications. PDC uses prescription fill data to calculate the percentage of days for which the patient has medication on-hand to take for their chronic conditions

02

Fulfillment of promise to deliver

Assess the percentage of prescriptions that a specialty pharmacy delivers on time, i.e., the percentage of prescriptions that reached patients on the date scheduled for delivery

03

Call Center - Average Speed of Answer

Average wait time of all calls in the period

04

Call Center - Abandonment Rate

The percentage of inbound phone calls made to Avella that are abandoned by the customer prior to speaking to an agent

05

Adverse Drug Event Reporting

Assess the percentage of reported and completed Adverse Drug events within 1 business day

06

Dispensing Accuracy

This six-part measure and composite roll-up assesses the percentage of prescriptions that a specialty pharmacy dispenses inaccurately. Measure parts include: (A) Incorrect Drug and/or Product Dispensed; (B) Incorrect Recipient; (C) Incorrect Strength; (D) Incorrect Dosage Form; (E) Incorrect Instructions; (F) Incorrect Quantity.

07

Dispensing Accuracy – PHI Security

Assesses the percentage of prescriptions delivered to the wrong recipient

08

Turnaround Time

This 3-part measure assesses the average speed with which Avella fills prescriptions. Part A measures prescription turnaround time for refill prescriptions, Part B measures prescription turnaround time for prescriptions that required intervention (PA/FA/MD clarification/PT clarification), and Part C measures prescription turnaround time for all prescriptions.

09

Patient Satisfaction

Assesses patient experience based on survey responses

NASP NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

Summary

- Current PBM-sponsored programs have missed the mark in terms of aligning incentives to recognize and encourage Best-in-Class Specialty Pharmacy services that have documented optimal clinical and cost outcomes.
- As currently structured, DIR Fees have been inappropriately expanded beyond statutory provisions and guidance.
- In addition to being out of scope in terms of structure, transparency and reasonableness, the programs implemented in 2016 will reduce access and increases costs for Medicare beneficiaries.
- SRx providers and NASP seeks to restructure the Network Participation requirements to align Program Quality Metrics to SRx standards and to assure that the value SRx brings to clinical outcomes and bending the cost curve sustain meaningful access to covered beneficiaries. These programs can be structured to be reasonably determined at the point of sale.

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

Next Steps

01

Clarify definitions and terms of Specialty Pharmacy Network Participation Program elements to assure access for beneficiaries to Any Willing Provider.

02

Eliminate percentage DIR on specialty tier drugs.

03

Apply SRx Network Participation Programs to SRx therapies – not all therapies.

04

Create DIR programs that motivate higher levels of clinical and operational performance and allow payment to be rendered based on achievable clinical measures applicable to the practice of specialty pharmacy.

05

Mandate a consistent calculation methodology

06

Re-characterize DIR Fee that allow specialty pharmacies to want to participate in servicing Part D patient Health Care needs.

07

Guidance needed on DIR ceiling.