

# Specialty Pharmaceuticals: Fraud, Waste & Abuse

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## Agenda

- Introduction to specialty pharmaceuticals
- Industry cost containment issues & the impact on fraud investigations
- Key steps in maximizing overpayment identification & recovery
- Case Studies
  - #1 – Infusion Clinic
  - #2 – Large Metropolitan Hospital – Northeast
  - #3 – Large Metropolitan Hospital – Southeast
  - #4 – Drug Company Sales Representatives



## Basic Points

- **Defined:** Injected or infused drugs, many derived or cultured instead of manufactured, used to treat complex, often chronic medical conditions, such as:
  - Cancer – Cisplatin, Avastin, Alimta
  - Multiple Sclerosis – Ampyra, Tysabri
  - Rheumatoid Arthritis – Remicaid, Actemra
  - Immune Deficiency – IVIG, Epogen
- **Expensive:** Treatment of one patient often costs at least \$10-20,000 per treatment cycle and can reach over \$250,000/year.
  - One patient at a hospital in the Northeast - treatment cost \$750k over a 6 month period, and would continue for patient's lifetime
- **Providers:** Physicians, hospitals, home infusion therapy companies, specialty pharmacies, retail pharmacies, mail-order pharmacies

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## Terminology & Acronyms

- **J-Code/Q-Code:** Published by CMS in the "HCFA Common Procedure Coding System" Manual (HCPCS) – identifies drug at relatively high level. Used for professional billing, and *sometimes* facilities too.
- **NDC - National Drug Code:** Unique number assigned by manufacturer/repackager. Identifies manufacturer/distributor of drug + detailed information on strength, dosage and formulation. Primarily used for pharmacy claims.
- **AWP - Average Wholesale Price:** Published by RedBook, First Databank. Based on information gathered from Manufacturers. Originally intended to be wholesale price, but now recognized as more of a "retail" price.
- **ASP - Average Sales Price:** Mandated by CMS, to reflect more accurate information on actual price charged by drug manufacturers. Becoming more common.
- **WAC – Wholesale Acquisition Cost:** Another pricing methodology. Main precursor to ASP. Was better than AWP, but for some drugs, still substantially above true cost.

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## 2010 Trends in the U.S.\*

- Increase in Spending on Specialty Pharmaceuticals is substantially higher than the trend for drugs as a whole
  - Specialty Drugs = 17.4%
  - Overall = 3.7%
- More than 70% of overall trend was from Specialty Drugs
- Driven both by *higher per unit cost* as well as *increased utilization*
  - New drugs & indications *as well as* Price increases (pricing power)
  - Issue with generics – many are new, also unclear can be generics as easily
- This continues trend of last 10+ years, during which specialty drugs have gone from 1-2% of total pharmacy spend, to over 16% today
- It varies by plan, but about ½ of spend is on medical platform, and ½ on pharmacy. There are ongoing discussions about where it is best sited



\* From 2010 Drug Trend Report, published by Medco Health (2011).

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## 2010 Trends in the U.S.\*

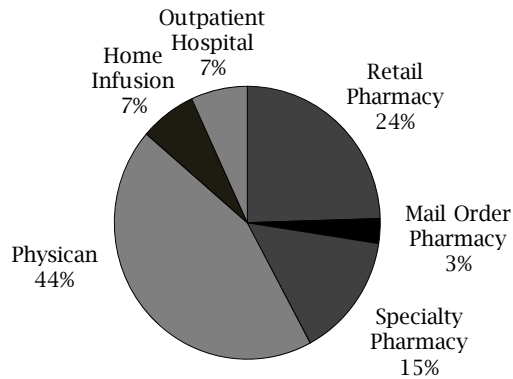
- This is driven by new drugs, as well as new indications for existing drugs
- FDA approved 27 new drugs in 2010 – over half (15) were specialty drugs
  - Examples – *Ampyra* for Multiple Sclerosis, *Actemra* for Rheumatoid Arthritis
  - Some will replace other treatments, and others supplement
- Numerous *new indications* were also approved for existing drugs
  - *Lucentis* – Macular Edema due to central retinal vein occlusion
  - *Botox* – prophylaxis for adults with chronic migraine AND Upper limb spasticity in flexor muscles
- This imbalance towards specialty drugs is expected to continue for at least several years
  - Pipeline is 60+% specialty drugs
  - Many feel that most of the “traditional” drugs have been discovered
  - Focus of many drug companies is on biologics, etc.



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## Distribution Channels

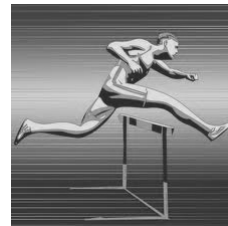


- **Fastest Growing:**
  - Specialty Pharmacy
  - Mail Order Pharm.
  - Outpatient Hospital
- **Highest Cost:**
  - Outpatient Hospital
- **Biggest Risk:**
  - Physician
  - Home Infusion

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## Industry Hurdles

- Payment/claims processing methodologies vary substantially among payers, and some have changed it over time. Examples:
  - Adjudicating claims utilizing NDC codes (39,400 published), versus HCPCS codes (1,800 published). Some use both.
    - Some claims systems have this built in. Others its done in a separate system. Also, even if built in, data might not come out.
  - Fees based on industry drug pricing (AWP, ASP, WAC, etc.) vs. % of billed charges vs. bundled (case rate, DRG) with stop loss, etc.
  - Medical vs. pharmacy vs. a combination.
  - Allow services from all types of providers and places of service vs. try to control/limit POS and provider types.
    - Various techniques – soft v. hard steerage, exclusives, etc.



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## Hurdles to Proving Fraud

- Complexity + lack of industry standardization = widespread billing & payment errors.
  - Claim overpayments may be due to *payer processing error* or *provider billing error/abuse* or *both*
  - Providers can plausibly claim that they did not understand the billing rules generally or for the plan specifically
- Thus, difficult to prove a provider's intent to defraud. Some exceptions:
  - Billing for drug samples/drugs provided for trials
  - Services not rendered (or not rendered as billed)
  - Drug diversion (patient or provider driven)
- Still substantial opportunity to find systemic overpayments = Pattern of abusive billing, etc.



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## Key Steps

- Start with a comprehensive understanding of how the plan manages the services
  - Review benefit coverage(s), adjudication policies & procedures, fee methodologies, provider contracts, special deals, etc.
  - Look for unusual processes (e.g. manual NDC review) or pricing methodologies
- Include all data
  - Provider types – physicians, hospital, ancillary, Specialty Rx
  - Claims systems – medical & pharmacy
  - Places of service – inpatient, outpatient, in office, at home
- Prioritize identification of systemic overpayments that can be addressed pre-payment
  - Processing errors – processing guidelines/weaknesses
  - System errors – contract loading, fee schedules
  - Billing errors – wastage, miscellaneous codes



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## Key Steps (cont.)

- Assign appropriate staff
  - Experienced claims adjudicators
  - Understanding of reimbursement methodologies and any special deals
  - Internal/external clinical expertise
- Run retrospective claims reports to identify target providers & drugs
  - Rank drugs by paid amount
  - Look for provider aberrancies
  - Consider \$ thresholds
- Conduct industry research on drugs within target range (drugcodes.com, CMS, WebMD, etc.)
  - Condition(s) treated
  - Typical dosing / multiple dosing regimens
  - Maximum Units / Flat Dose



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## Key Steps (cont.)

- Talk to internal experts about any adjudication/pricing red flags and start your analysis in those areas
  - Allowing/paying J3490/3590 (misc code) claims
  - Manual process to price claims
  - No front-end controls
- Identify any sensitive providers/provider categories
  - Large Hospital systems – special deals, global settlements
  - “Special relationship” providers – capitated, at risk
  - Certain specialties – Oncology, Rheumatology, Infectious Disease
- Identify and recover some “easy” overpayments to analyze/fine-tune process before implementing large-scale program
- Include periodic review of program goals vs. results, allowing for revised strategy as necessary



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## Case Study # 1 – Infusion Clinic

- Clinic in Southern U.S.; Members with HIV diagnosis.
- All Medicare PFFS Members
  - Despite major commercial presence, no claims on those products
- Services at issue
  - Some PT, OT, etc.
  - Suspicious because primarily Specialty Drugs
- Payments - \$12.8 million over 2 years
  - \$5 Million for Sandostatin LAR (J2353)
  - \$3 Million for Intravenous ImmunoGlobulan
  - Only \$728k for services unrelated to drugs
  - Spend represented over 5% of total drug spend for PFFS membership (about 130k members) over 2 year period



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## Case Study # 1 (cont.)

- Analysis revealed some interesting facts
  - For members receiving drugs, average spend was \$469k (26 members).
  - Drugs used were definitely outside standard regimen for HIV.
  - Members were coming 2-3 times per week for extended period
- We obtained records for a number of the members.
  - Provider billed for incorrect type of Sandostatin.
  - IVIG also looked suspicious.
  - Members all signed, and placed finger print on each page.
- Conclusion – Fraudulent billing. Approached HHS – OIG, and they have an active investigation.
  - Members are involved in the scheme
  - Could be organized crime involvement (doctor only has 10% ownership, others are offshore)



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## Case Study # 1 (cont.)

- Member treated from Nov '08 through Jul '10
- Total paid of \$543k
- \$419k for 3 drugs – Sandostatin LAR (\$207k), IVIG (\$117k), and Neupogen (\$95k)
- Non-drug related = \$16k

Member ID	Member Name	DOS	Qty	CPT	CPT_Desc	Billed Amount	Paid Amount
12345	I A	2/2/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	2/4/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	2/6/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	2/9/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	2/11/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	2/12/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	2/17/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	3/2/2009	20	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$2,076.20	\$2,076.20
12345	I A	5/18/2009	40	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$4,152.40	\$4,152.40
12345	I A	5/20/2009	40	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$4,152.40	\$4,152.40
12345	I A	5/22/2009	40	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$4,152.40	\$4,152.40
12345	I A	5/26/2009	40	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$4,152.40	\$4,152.40
12345	I A	5/28/2009	40	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$4,152.40	\$4,152.40
12345	I A	5/29/2009	40	J2353	INJ OCTREOTIDE DEPOT FORM IM 1MG	\$4,152.40	\$4,152.40

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## Case Study # 2 – Hospital System - Northeast

- Basics
  - Large plan (3+ million lives) concentrated in the Region
  - 2 Hospitals in Major Hospital System in Region
  - Plan's contract with hospitals provided for reimbursement at percent of charges for Rev Code 636 (these drugs)
- Data examined for various drugs, ended up focusing on 4
  - Avastin, Alimta, Eloxatin and Rituxan
  - All "single use" vials
- Industry Standards
  - CMS requires providers to stock both vial sizes, so can get close to required dose (i.e., Avastin 100mg and 400mg vials)
  - They can be used on more than one member, but just cannot be stored for very long (4-24 hours depending on drug).
  - CMS guidance that providers should schedule patients to avoid waste
  - Large hospitals typically will use extra drug on other patients (sister hospital)



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## Case Study # 2 (cont.)

- Provider typically billed what appeared to be correct quantity of drug (not full vials)
  - Avastin – one Jcode unit = 10mg, typical dosing is 50-110 units
  - Rituxan – one Jcode unit = 100mg, typical dosing is 5-10 units
- However, charges told another story – provider was always billing charges for largest full vial, even when smaller vial could have been used
  - Avastin – 41-80 units (most common) = same charge
- Since payment is based on charges not units, result is the same as if units only for largest vial were billed
- Estimated overpayment of \$340k annually (\$2+ million over 6 year period breach of contract period).



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## Case Study # 2 (cont.)

### Avastin

- Available in 100mg and 400 mg “single use” vials
- It is a very common drug, so there are often multiple members treated on the same day
- Record Review confirmed quantities in “Units” field (for RN, CK, etc.)

Member Name	CPT Code	CPT Description	Units	Date of Service	Charges	Paid Amt
R__N__	J9035	INJECTION BEVACIZUMAB 10 MG	66	8/12/2008	\$16,816.80	\$8,408.40
C__K__	J9035	INJECTION BEVACIZUMAB 10 MG	58	8/13/2008	\$16,816.80	\$8,408.40
R__N__	J9035	INJECTION BEVACIZUMAB 10 MG	1	8/14/2009	\$16,816.80	\$8,408.40
R__K__	J9035	INJECTION BEVACIZUMAB 10 MG	80	8/17/2009	\$16,816.80	\$8,408.40
G__C__	J9035	INJECTION BEVACIZUMAB 10 MG	2	8/19/2009	\$16,816.80	\$8,408.40

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## Case Study # 3 – Large Hospital in Southeast

- Plan's contract with Hospital provided for reimbursement at % of charge above certain stop loss limits
- Services at issue – Caspofungin (J0637), used for treatment of sepsis after gastric bypass
  - Caspofungin is an antifungal drug administered intravenously showing activity against infections with *Aspergillus* and *Candida*, and works by inhibiting the enzyme D-Glucan synthase and thereby disturbing the integrity of the fungal cell wall.
- Issue – charges per dose of \$19k v. AWP of \$400
- Caused hospital to pay \$19k per dose, which was 47,500% of AWP. Egregiously above hospital's cost
- Findings – Hospital improperly triggered the stop loss provision in the contract through excessive charges.
- Result – Plan recovered \$6 million



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## Case Study # 4 – Drug Company Sales Reps

### **Issue:** Antiemetics with Chemotherapy

- **Drugs** – Antiemetics – many Chemotherapy regimens can induce nausea and vomiting (CINV). These drugs are given to reduce CINV.
  - Aloxi (Palonosetron) – J2469, manufactured by Helsinn Healthcare
  - Zofran (Ondanestron) – J2405, manufactured by Glaxo Smithkline
  - Aloxi is clinically very similar to Zofran, but is claimed to stay in bloodstream longer.
- Drug sales representatives are encouraging individual doctors to use Aloxi instead of Zofran claiming that it is designed to stay in the bloodstream longer, and therefore is more effective in preventing CINV over longer periods.
- Cost of Aloxi is currently 75x that of Zofran (was over 100x in 2010), with minimal clinical benefit.
- Savings of over \$2.9 M in first year edit in place.



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## Summary

- High trend = Costs increasing rapidly
- Lack of billing & payment consistency within industry
- Difficult to prove fraud, but not to find systemic abuse/overpayments
- Widespread and significant overpayments to providers
- A cost containment/overpayment recovery program will:
  - Lead to significant overpayment identification & recovery
  - Lead to front-end cost containment improvements
  - Establish and maintain sentinel effect with disreputable providers



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## Questions & Answers

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