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National Health Care Anti-Fraud Association ("NHCAA")

Part D Fraud Schemes
Fraud Detection & Investigation in Specialty Areas

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November 16th , 2011

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*"Keep your eyes open.
These days
Even the walls have ears.
Chatter and gossip
Go hand in hand with
Treason."*

KEEP YOUR MOUTH SHUT!

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High-Level Overview

Examine recent Part D trends and schemes including the West Hollywood Area Project, overutilization, diversion and counterfeit drugs. Gain investigative ideas through case examples and industry experience from health care fraud specialist focused on Part D investigations.
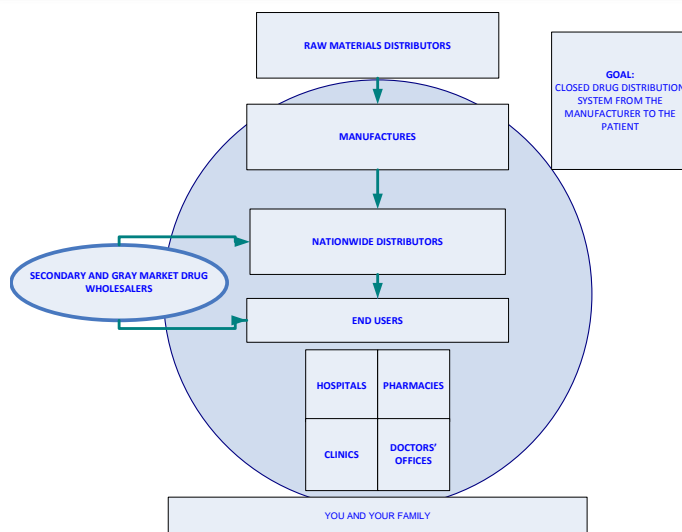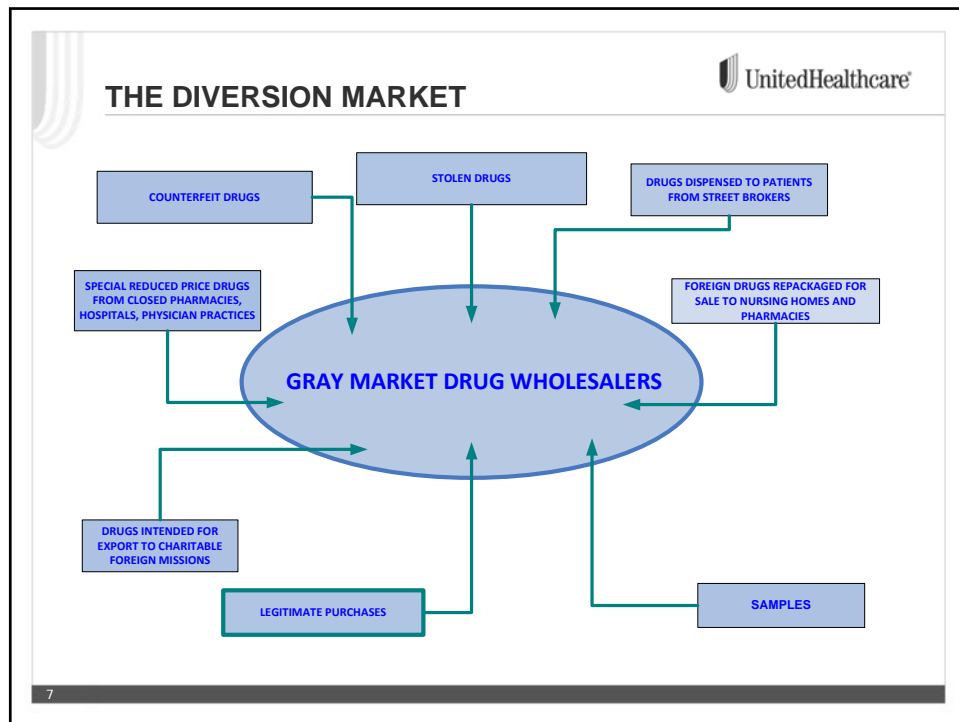
Trends/Schemes

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- Billing several payers for the same prescription
- Prescription drug splitting or shorting
- Forging or altering prescriptions
- Dispensing expired or adulterated prescription drugs
- Incorrectly billing secondary payers
- Billing for nonexistent prescriptions
- Billing for brand-name when generics are dispensed
- Script Mills
- DEA number or prescription pads are stolen
- Using insurance to obtain prescriptions for others
- Selling prescriptions
- Unusual activity or a higher than normal percentage of Part D EOBs

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DRUG DISTRIBUTION

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RAW MATERIALS DISTRIBUTORS

GOAL:
CLOSED DRUG DISTRIBUTION SYSTEM FROM THE MANUFACTURER TO THE PATIENT

MANUFACTURES

NATIONWIDE DISTRIBUTORS

SECONDARY AND GRAY MARKET DRUG WHOLESALERS

END USERS

HOSPITALS PHARMACIES

CLINICS DOCTORS' OFFICES

YOU AND YOUR FAMILY

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THE DIVERSION MARKET

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COUNTERFEIT DRUGS

STOLEN DRUGS

DRUGS DISPENSED TO PATIENTS FROM STREET BROKERS

SPECIAL REDUCED PRICE DRUGS FROM CLOSED PHARMACIES, HOSPITALS, PHYSICIAN PRACTICES

FOREIGN DRUGS REPACKAGED FOR SALE TO NURSING HOMES AND PHARMACIES

GRAY MARKET DRUG WHOLESALERS

DRUGS INTENDED FOR EXPORT TO CHARITABLE FOREIGN MISSIONS

LEGITIMATE PURCHASES

SAMPLES

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Un-Announced (Pharmacy) Compliance Audit – Miami, FL

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Raw Material Distributors – Extended

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- **Manufacturing Globalization**
  - Economics = $
    - Cheaper
    - Greater Profit Margin
  - At least **80%** of all (US) active ingredients or bulk chemicals are manufactured overseas, i.e. China, India, etc.[1]
  - At least **40%** of all (US) finished drugs are manufactured overseas.[2]
  - Limited enforcement of quality standards
  - Limited FDA Inspections[3]
    - Domestic Sites – Every 2 to 3 years
    - Foreign Sites – Every **9** years
  - Lack of federal resources to allow for the FDA to properly monitor and inspect foreign manufacturing drug sites[4]

1. FDA estimates. U.S. Government Accountability Office (September 2010). Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed. Appendix 1: Comments from the Department of Health and Human Services (Publication No. GAO-10-961)
2. FDA estimates. Hamburg, Margaret. Commissioner, U.S. Food and Drug Administration. Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of representatives. April 13, 2011
3. U.S. Government Accountability Office (September 2010). Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed. Appendix 1: Comments from the Department of Health and Human Services (Publication No. GAO-10-961)
4. U.S. Government Accountability Office. (2007, November). Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers. (Publication No. GAO-08-224T)
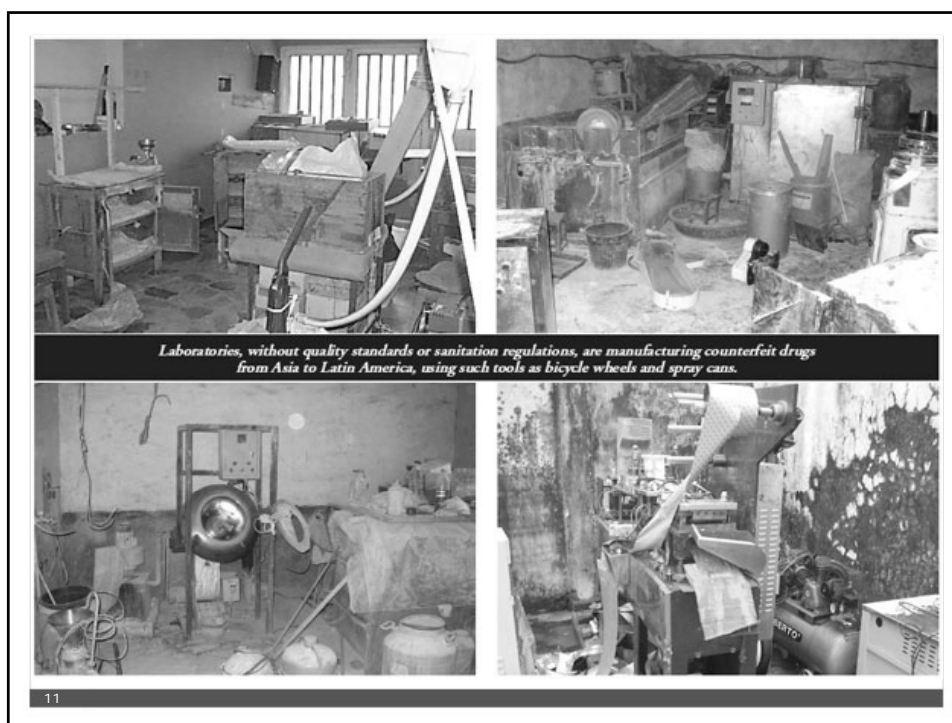
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Counterfeit Drugs - Extended

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- "Counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient. Educating consumers about the risks of counterfeit medicine is an important part in the effort to stop counterfeits from entering the United States' drug supply."*
  - **Conditions**
    - Extremely Poor
    - Dirty and Disgusting
    - Primitive Drug Labs
    - Insects / Contaminants

  - **Ingredients**
    - Inappropriate Quantities of an Active Ingredient
    - Highway Paint
    - Floor Wax
    - Boric Acid
    - Sugar
    - Chalk
    - Non-sterile Water
    - Banned (Toxic) Active Ingredients

  - **Consequences**
    - Death
    - Investigations
      - The FDA opened **72** Counterfeit Drug Investigations in the FY 2010.

REAL   FAKE

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*Acquired via http://www.fda.gov on 9/6/2011

Laboratories, without quality standards or sanitation regulations, are manufacturing counterfeit drugs from Asia to Latin America, using such tools as bicycle wheels and spray cans.

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Counterfeit Drugs – Extended – Cont'd

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Counterfeit (Global) Examples*

Counterfeit Medicine	Country/Year	Report
Anti-diabetic traditional medicine (used to lower blood sugar)	China, 2009	Contained six times the normal dose of glibenclamide (two people died, nine people hospitalized)[1]
Metakelfin (antimalarial)	United Republic of Tanzania, 2009	Discovered in 40 pharmacies: lacked sufficient active ingredient[2]
Viagra & Cialis (for erectile dysfunction)	Thailand, 2008	Smuggled into Thailand from an unknown source in an unknown country[3]
Xenical (for fighting obesity)	United States of America, 2007	Contained no active ingredient and sold via Internet sites operated outside the USA[4]
Zyprexa (for treating bipolar disorder and schizophrenia)	United Kingdom, 2007	Detected in the legal supply chain: lacked sufficient active ingredient[5]
Lipitor (for lowering cholesterol)	United Kingdom, 2006	Detected in the legal supply chain: lacked sufficient active ingredient[6]

1. Deadly counterfeit diabetes drug found outside China's Xinjiang, China View, 5 February 2009.
2. Tanzania Food and Drugs Authority
3. Center for Combating Counterfeit Drug, Thailand
4. US Food and Drug Administration
5. The Medicines and Healthcare products Regulatory Agency, United Kingdom
6. The Medicines and Healthcare products Regulatory Agency, United Kingdom

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Acquire via World Health Organization - http://www.who.int/mediacentre/factsheets/fs275/en/
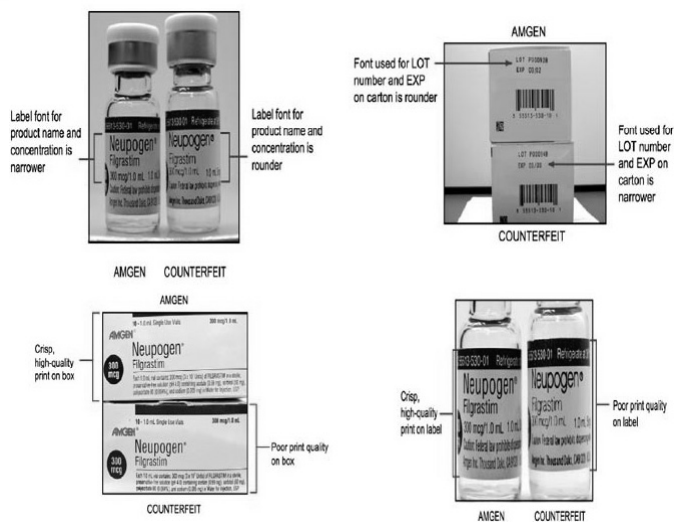
Counterfeit Drug - Examples

Serostim 6 mg

Acquire via Food and Drug Administration - http://www.fda.gov/Drugs/DrugSafety/ucm180899.htm

Counterfeit Drug – Examples – Cont'd

Acquire via Food and Drug Administration - http://www.fda.gov/Drugs/DrugSafety/ucm180899.htm

"The Difficult Fight Against Counterfeit Drugs"

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- (CBS News) 60 Minutes – March 13, 2011 – 5:00PM

- Special Report by CNN's Dr. Sanjay Gupta

- "60 Minutes' nine-month investigation of counterfeit prescription drugs reveals dangerous and sometimes deadly fakes get into the nation's drug pipeline."

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"West Hollywood Area Project"

[WHAP]

Medicare Part D Fraud Scheme
A Plan's Prospective

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"WHAP" – CMS Alert / Overall Summary

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Summary

- "Medical clinics in the West Hollywood area of Southern California have been submitting fraudulent prescriptions for high-cost medications under the **Part D** program. A partial list of these medications include: **Abilify, Advair, Aricept, Celebrex, OxyContin, Effexor, Lipitor, Nexium, Prevacid, Protonix, Tricor, Zetia,** and **Zyprexa.**"

- "Compromised/stolen beneficiary identification numbers (Health Insurance Claim Number [HICN]) have been used in conjunction with compromised/stolen physician identification numbers (National Provider [NPI] and Drug Enforcement Administration [DEA]) numbers to submit the fraudulent prescriptions."

- "**Beneficiaries have become a primary reporting source** of physicians whose identities have been compromised. Calls taken from Medicare beneficiaries reporting this activity should be recognized as having a high fraud potential."*

HOW

- "An individual representing a medical clinic will visit a pharmacy to set up a drop-off and pick-up arrangement for the prescriptions identified above, indicating they will deliver the filled prescriptions to the beneficiaries."

- "**Address** and **telephone** numbers on the prescription forms **will often not match** the address and telephone number of record for the physician in the NPI registry or DEA registration records."

- "An **unusually high number of patients** are prescribed **high-cost drugs** and/or the anti-psychotic medications, **Zyprexa** and **Abilify.**"

- "Although prescriptions will be submitted outside of the Los Angeles area, often the beneficiaries have addresses in the Los Angeles area. In some cases the prescriptions are being **submitted at locations over 100 miles** from the medical clinic location."*

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*Acquired via Centers for Medicare & Medicaid Services ("CMS") - April 7, 2011 Fraud Alert Dissemination

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Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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Center for Program Integrity

Date: April 7, 2011

To: Compliance Officers
          Medicare Advantage Organizations and Medicare Part D Sponsors

From: John Spiegel, Director
          Medicare Program Integrity Group

Subject: Part D Fraud Scheme in Southern California
          AKA: West Hollywood Area Project (WHAP)

This fraud alert serves as notification to compliance officers of a Part D scheme that is being perpetrated in Southern California. Compliance officers should share this information with their appropriate fraud investigation departments. Any information that your organization may have related to this scheme should be promptly reported to the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC–Health Integrity LLC), 1-877-772-3379 (1-877-7SAFERX).

Summary

Medical clinics in the West Hollywood area of Southern California have been submitting fraudulent prescriptions for high-cost medications under the Part D program. A partial list of these medications include: Abilify, Advair, Aricept, Celebrex, OxyContin, Effexor, Lipitor, Nexium, Prevacid, Protonix, Tricor, Zetia, and Zyprexa.

Compromised/stolen beneficiary identification numbers (Health Insurance Claim Number [HICN]) have been used in conjunction with compromised/stolen physician identification numbers (National Provider [NPI] and Drug Enforcement Administration [DEA]) numbers to submit the fraudulent prescriptions.

Beneficiaries have become a primary reporting source of physicians whose identities have been compromised. Calls taken from Medicare beneficiaries reporting this activity should be recognized as having a high fraud potential.

How the Scheme is Perpetrated

- An individual representing a medical clinic will visit a pharmacy to set up a drop-off and pick-up arrangement for the prescriptions identified above, indicating they will deliver the filled prescriptions to the beneficiaries.

- Address and telephone numbers on the prescription forms will often not match the address and telephone number of record for the physician in the NPI registry or DEA registration records.

- An unusually high number of patients are prescribed high-cost drugs and/or the anti-psychotic medications, Zyprexa and Abilify.

- Although prescriptions will be submitted outside of the Los Angeles area, often the beneficiaries have addresses in the Los Angeles area. In some cases the prescriptions are being submitted at locations over 100 miles from the medical clinic location.

Health Integrity LLC may be able to assist you with identification of compromised physicians. The Health Integrity contact, Martina Gilly, can be reached at (678) 402-8514. If you have information related to this scheme, please include copies of a sample subset of the prescriptions for each compromised physician. In most cases the actual prescription forms are indicators of the medical clinic that is producing the fraudulent prescriptions.

If you have any questions regarding this fraud alert, please contact CMS representatives Connie Herbstman at (617) 565-1284 or Bobbie Knickman at (410) 786-4161.

Drug Summary – "WHAP"

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- **Abilify** - *is a psychotropic drug (antipsychotic) that alters brain chemical activity. Abilify is used to treat schizophrenia, mania, depression , bipolar disorders, autistic disorder, and some irritable behavior disorders.*

- **Zyprexa** - *is an atypical antipsychotic medication used to treat schizophrenia and manic episodes of bipolar disorder.*

- **Advair Diskus** – *is a combination of inhaled drugs that is used to treat asthma and chronic bronchitis, including COPD associated with chronic bronchitis.*

- **Actos** – *is a thiazolidinedione and increases the body's sensitivity to insulin. Actos is used for type 2 diabetes, not type 1 or diabetic ketoacidosis.*

- **Aricept** – *is a cholinesterase inhibitor that reduces or prevents acetylcholine breakdown in the brain tissue. Aricept is used to treat mild to moderate dementia like that found in patients with Alzheimer's disease.*

- **Lipitor** – *belongs to a class of drugs referred to as statins. Lipitor is used for the treatment of elevated total cholesterol, LDL, triglycerides, and to elevate HDL cholesterol.*

- Januvia
- Lidoderm
- **Nexium**
- **Plavix**
- Prevacid
- Protonix
- Spiriva
- Seroquel
- Tricor
- Vytorin
- Zetia
- Celebrex
- Diovan
- Effexor
- Femora

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Financial Reimbursement - "WHAP"

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UnitedHealthcare Drug Costs

Drug Name	Paid Amount	Day Supply	Drug Quantity
Zyprexa Tab 20MG	**$775 - $1550**	30 - 60	30 - 60
Zyprexa Tab 15MG	**$608 - $1216**	30 - 60	30 - 60
Abilify Tab 20 MG	**$594 - $1188**	30 - 60	30 - 60
Abilify Tab 15MG	**$423 - $846**	30 - 60	30 - 60

Average prescription contains (at least) one form of Zyprexa and/or Abilify – per month

On average a (one-time) fill may yield a loss of $1,000 (plus)

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Data Analytics – "WHAP"

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- **Proactive Data Analytics:** *Investigative techniques and data mining based on red flags and industry knowledge, specifically as it relates to the WHAP*

  - **Provider Specialty**
    - *Does the provider's specialty coincide with the medications being issued, i.e. an ophthalmologist prescribing high-level antipsychotics*
      - Analytics on provider's specialty code & NDC
  - **Member/Clinic/Pharmacy Location**
    - *Identify geographical abnormalities, i.e. a member "commuting" extended distances (100 miles – plus) to receive and/or fill any of the identified "WHAP" drugs*
      - Analytics on zip codes, states, & NDC
  - **Provider Last Name "A"**
    - *One (industry) hypothesis is that the suspect(s) acquired several prescribing provider DEA # via a free online look-up tool. (Free membership is limited to the first letter of the alphabet, i.e. "A")*
      - Analytics on a provider's last name and/or the standard DEA formula
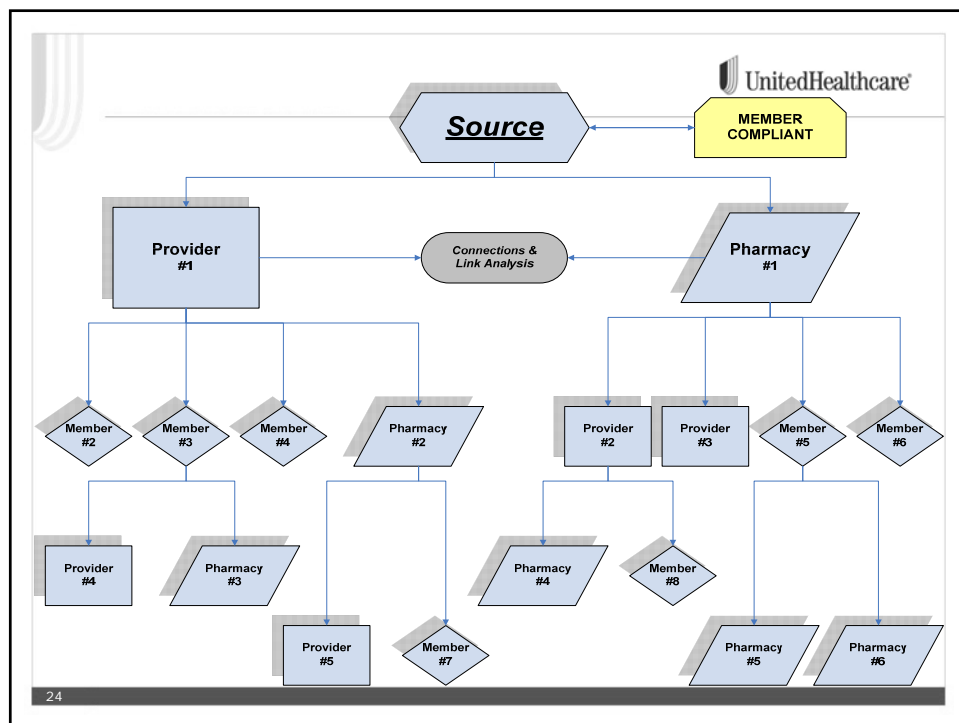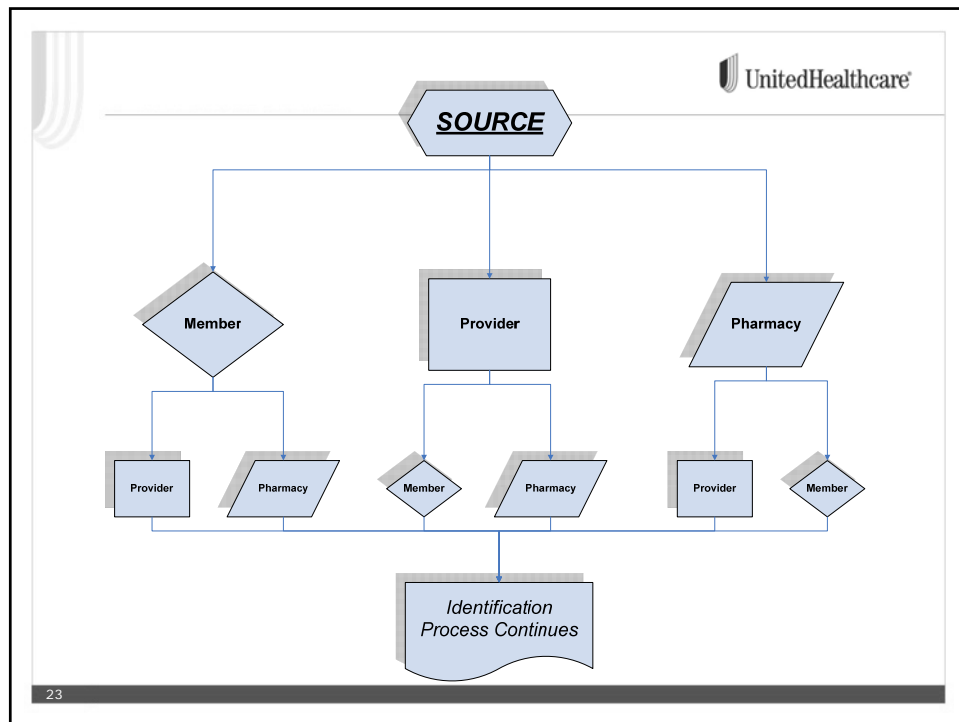 - **High Utilization - WHAP Drugs**

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Data Analytics – "WHAP" Cont'd

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- **Complaint Analytics**: Each complaint received warrants an in-depth analysis and pharmaceutical data extracts. It is crucial for a Plan to exhaust all aspect of the WHAP scheme as well as apply as many investigative techniques deemed appropriate. Please be advised complaints ("source") may include, but are not limited to the following:

  - **Member:** *As per the CMS alert, "Beneficiaries have become a primary reporting source of physicians whose identities have been compromised. Calls taken from Medicare beneficiaries reporting this activity should be recognized as having a high fraud potential."*
    - A member complaint may yield additional providers & pharmacies

  - **Provider**
    - A provider complaint may yield additional members & pharmacies

  - **Pharmacy**
    - A pharmacy complaint may yield additional members & providers

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Proactive / Preventive Queries   UnitedHealthcare®

- Once a subject (member, provider, pharmacy) has been identified it proactive/prevented query building and data analytics becomes a critical step.

- Preventative Query Building & Proposed Algorithms
  – Query #1
     • Member

  – Query #2
     • Provider

  – Query #3
     • Pharmacy

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Data Analytics – Query #1 (Member)   UnitedHealthcare®

- **Objective** (Post Validation and Investigation)
  – Establish a query to proactively monitor "WHAP" compromised member ID's.
  – The sole premise behind this query is to prevent and/or deter additional false claims from being submitted, as well as:
     • Recovery/Reclaim any inappropriate (fraudulent) claims
     • Ensure the accuracy of a member's pharmaceutical claims profile
     • Identify "NEW" scheme trends and shifts
     • Aid in federal/local prosecutions and/or arrests

- **How**
  – A defined user must create and maintain a cumulative filter that encompasses all member ID's compromised by the "WHAP" scheme – append said filter to the user's Medicare Part D claims platform. *Run Regularly*

- *Option(s)*
  – *The above-referenced query can be modified by unique ID's, i.e. one query per member ID (thereby allowing the user to append a date filter and eliminated historic claims)*

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Data Analytics – Query #2 (Provider)   UnitedHealthcare®

- **Objective** (Post Validation and Investigation)
  - Establish a query to proactively monitor "WHAP" compromised provider ID's.
  - The sole premise behind this query is to prevent and/or deter additional false claims from being submitted, as well as:
    - Recovery/Reclaim any inappropriate (fraudulent) claims
    - Ensure the accuracy of a member's & provider's pharmaceutical claims profile
    - Identify "NEW" scheme trends and shifts
    - Aid in federal/local prosecutions and/or arrests

- **How**
  - A defined user must create and maintain a cumulative filter that encompasses all provider ID's compromised by the "WHAP" scheme – append said filter to the user's Medicare Part D claims platform. *Run Regularly*

- *Option(s)*
  - *This can be a unique query – one query per provider ID (thereby allowing the user to append a date filter)*

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Data Analytics – Query #3 (Pharmacy)   UnitedHealthcare®

- **Objective**
  - Establish a query to proactively monitor pharmacies associated to the "WHAP" Scheme.
  - The sole premise behind this query is to prevent and/or deter additional false claims from being submitted, as well as:
    - Recovery/Reclaim any inappropriate (fraudulent) claims
    - Aid in federal/local prosecution

- **How**
  - A defined user must create and maintain a cumulative filters that encompasses all pharmacies linked with the "WHAP" scheme – append said filters to the user's Medicare Part D claims platform. *Run Regularly*

- *Option(s)*
  - *The above-referenced query can be modified by several ways:*
    - *Append the compromised member and/or compromised provider filters*
    - *Append a query that encompasses all suspect NDC Codes (thereby allowing the user to filter the results by suspect drug claims only)*

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"WHAP" – UHC & OptumRx Involvement

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- **Collaborative Investigation**
  - WHAP is a large scale Medicare Part D scheme with the potential to yield high fiscal losses, as well as adversely affect (our) Medicare population. Therefore, to deter such losses and prevent FWA activity a high level of cooperation is needed by all parties.
    - Plans
    - Pharmacy Benefits Manger ("PBM")
    - Health Integrity, LLC. – ("MEDIC")
    - Federal Law Enforcement
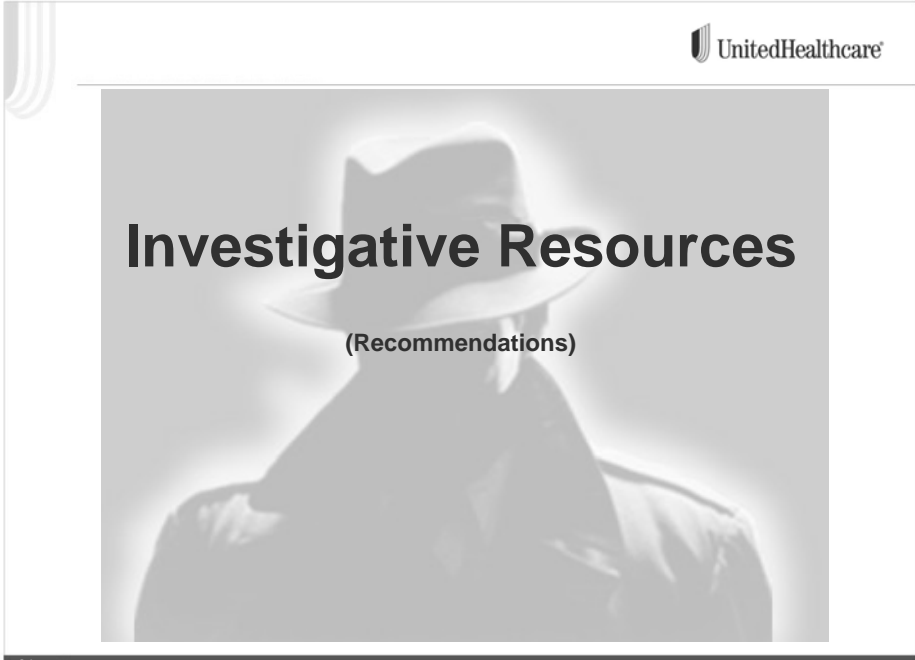   - Local Law Enforcement
    - NHCAA – SIRIS Updates

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Take-Aways

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- **Compromised Beneficiary Information**
  - There is a identity (PHI) risk for all members who fell victim to this scheme. As such, certain actions will be advanced by ("UHC") & ("OptumRx"):
    - Change of ID
    - Cumulative Tracking of All Affected
    - Mailing of Educational Materials
    - Pharmaceutical Claims Monitoring to Deter Future Billings
    - Identity Theft Victim's Complaint & Affidavit *(if applicable)*
    - Credit Monitoring *(if applicable)*
- **Reversal / Recoveries**
  - Correction to our beneficiaries pharmaceutical claims history
  - Recovery of any/all inappropriate (fraudulent) claims
- **Uncalculated (Proposed) Cost Avoidance**
  - Cost avoidance is an accepted methodology used to track moneys saved due to "prevented" actions taken. As it stands ("UHC") is currently determining how to apply the Cost Avoidance methodology to this specific scheme. Because, the deterrence of a high fiscal loss will result in a high fiscal cost avoidance.
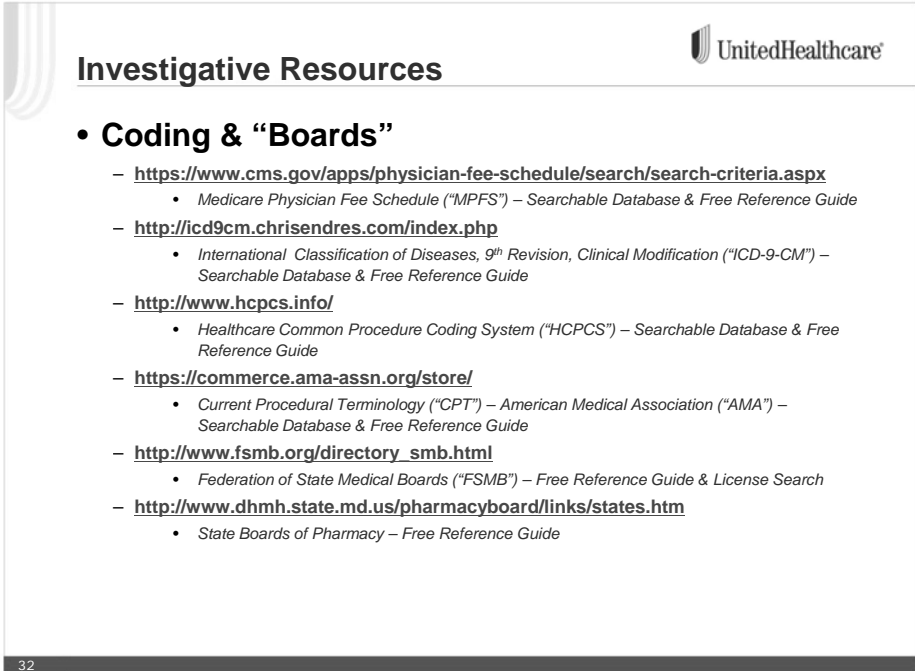
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Investigative Resources

(Recommendations)

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Investigative Resources

- **Coding & "Boards"**
  - **https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx**
    - *Medicare Physician Fee Schedule ("MPFS") – Searchable Database & Free Reference Guide*
  - **http://icd9cm.chrisendres.com/index.php**
    - *International Classification of Diseases, 9th Revision, Clinical Modification ("ICD-9-CM") – Searchable Database & Free Reference Guide*
  - **http://www.hcpcs.info/**
    - *Healthcare Common Procedure Coding System ("HCPCS") – Searchable Database & Free Reference Guide*
  - **https://commerce.ama-assn.org/store/**
    - *Current Procedural Terminology ("CPT") – American Medical Association ("AMA") – Searchable Database & Free Reference Guide*
  - **http://www.fsmb.org/directory_smb.html**
    - *Federation of State Medical Boards ("FSMB") – Free Reference Guide & License Search*
  - **http://www.dhmh.state.md.us/pharmacyboard/links/states.htm**
    - *State Boards of Pharmacy – Free Reference Guide*

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Investigative Resources (Cont'd)   UnitedHealthcare®

- **Drug Resources**
  - http://www.commondatahub.com/static/healthcare/pharmaceutical_codes/
    - *CommonDataHub – Data Standards Repository – National Drug Code ("NDC") – Searchable Repository (Reports) & Free Reference Guide*
  - http://www.deadiversion.usdoj.gov/schedules/#list
    - *U.S. Department of Justice ("DOJ") – Drug Enforcement Administration ("DEA") – Controlled Substance Schedules – List of Controlled Substances & Free Reference Guide*
  - http://www.justice.gov/ndic/
    - *U.S. Department of Justice ("DOJ") – National Drug Intelligence Center ("NDIC") – Reference Guide*
  - http://www.pdr.net/Default.aspx
    - *Physicians' Desk Reference ("PDR") – Searchable Database & Free Drug Reference Tool.*
  - http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
    - *U.S. Department of Health & Human Services ("HHS") – Food and Drug Administration ("FDA") – Drug Evaluation and Research Tool & Free Reference Guide*
  - http://www.namsdl.org/presdrug.htm
    - *National Alliance for Model State Drug Laws ("NAMSDL") – Free Resource Tool*
  - http://www.rxlist.com/script/main/hp.asp
    - *The Internet Drug Index – Searchable Database & Free Drug Reference Tool*

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Investigative Resources (Cont'd)   UnitedHealthcare®

- **Research & Reference**
  - https://www.epls.gov/
    - *Excluded Parties List System ("EPLS") – Searchable Database & Free Reference Tool*
  - http://oig.hhs.gov/exclusions/index.asp
    - *U.S. Department of Health & Human Services ("HHS") – Office of Inspector General ("OIG") – List of Excluded Individuals/Entities ("LEIE") – Searchable Database & Free Reference Tool*
  - http://www.statehealthfacts.org/index.jsp
    - *Henry J. Kaiser Family Foundation – Project - Designed to provide free, up-to-date, and easy-to-use health data for all 50 states*
  - http://www.accurint.com/ (Paid Membership)
    - *LexisNexis – Accurint – Public Records Search and Background Information Tool*
  - https://www.medicare.gov/find-a-plan/questions/home.aspx
    - *Medicare Plan Finder – General Search & Resource Tool*
  - http://www.cms.gov/MCRAdvPartDEnrolData/MEC/list.asp#TopOfPage
    - *Centers for Medicare & Medicaid Services ("CMS") – Medicare Advantage/Part D Monthly Enrollment Data & Free Resource Tool*
  - https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do
    - *National Plan & Provider Enumeration System ("NPPES") – National Provider Identifier Search & Free Research Tool*

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Questions

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