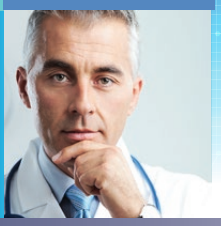
# RJ Health Systems

## Fraud, Waste and Abuse (FWA) Issues and Avoidance Specific to Medical Drug Claims







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## FRAUD

**The intentional deception or misrepresentation that an individual knows, or should know, to be false, or does not believe to be true, and makes, knowing the deception could result in some unauthorized benefit to himself or some other person(s).[1]**

"NJ Physician faces fraud charges on accusations of overbilling insurer…a doctor who practices in East Brunswick, N.J., was arrested and charged with health care claims fraud and insurance fraud on allegations that he overbilled a private insurer, according to prosecutors. [The doctor named]…is accused of receiving overpayments from Horizon Blue Cross Blue Shield after submitting claims that included wrong diagnoses for patient visits from February 2010 to May 2015."
NHCAA Smart Brief 9/7/2017

## WASTE

**"Waste includes overusing services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare Program. Waste is generally not considered to be caused by criminally negligent actions but rather by the misuse of resources."[2]**

"Providers reported units of service for the entire vial instead of units of service for the amount of Herceptin actually used…Providers blamed the overpayments on clerical errors and automated billing systems that can't prevent or detect problems with billing for units of service. First Coast says it overpays 'because neither the Fiscal Intermediary Standard System nor the CWF had sufficient edits in place during our audit period to prevent or detect the overpayments.'" [3]

## ABUSE

**A range of the following improper behaviors or billing practices including, but not limited to:**

- **Billing for a non-covered service;**
- **Misusing codes on the claim (i.e., the way the service is coded on the claim does not comply with national or local coding guidelines or is not billed as rendered); or**
- **Inappropriately allocating costs on a cost report [1]**

"CMS has safeguards to prevent and recover Medicare payments made on behalf of deceased beneficiaries; however, it inappropriately paid $23 million (less than one-tenth of a percent of total Medicare expenditures) in 2011 after beneficiaries' deaths" [4]

# Fraud, Waste and Abuse (FWA) Issues and Avoidance Specific to Medical Drug Claims

Fraud, waste and abuse is a diverse topic that spans all parties involved in the delivery and payment of healthcare services. Due to the depth of this topic, we have divided this paper into three distinct parts. Each part is independent of one another and may be reviewed based on the individual's needs.

**Part I** contains a primer on fraud, waste and abuse including estimated U.S. volume, definitions, investigative bodies and potential impact. Compliance issues specific to the medical drug claim are introduced.

**Part II** narrows the topic specific to medically administered drug claims, with compliance monitoring suggestions for providers.

**Part III** discusses leveraging data external to standard claim fields to identify and monitor for claim outliers with suggestions for implementation.



## Part I – Primer on Fraud, Waste and Abuse

**Overview**

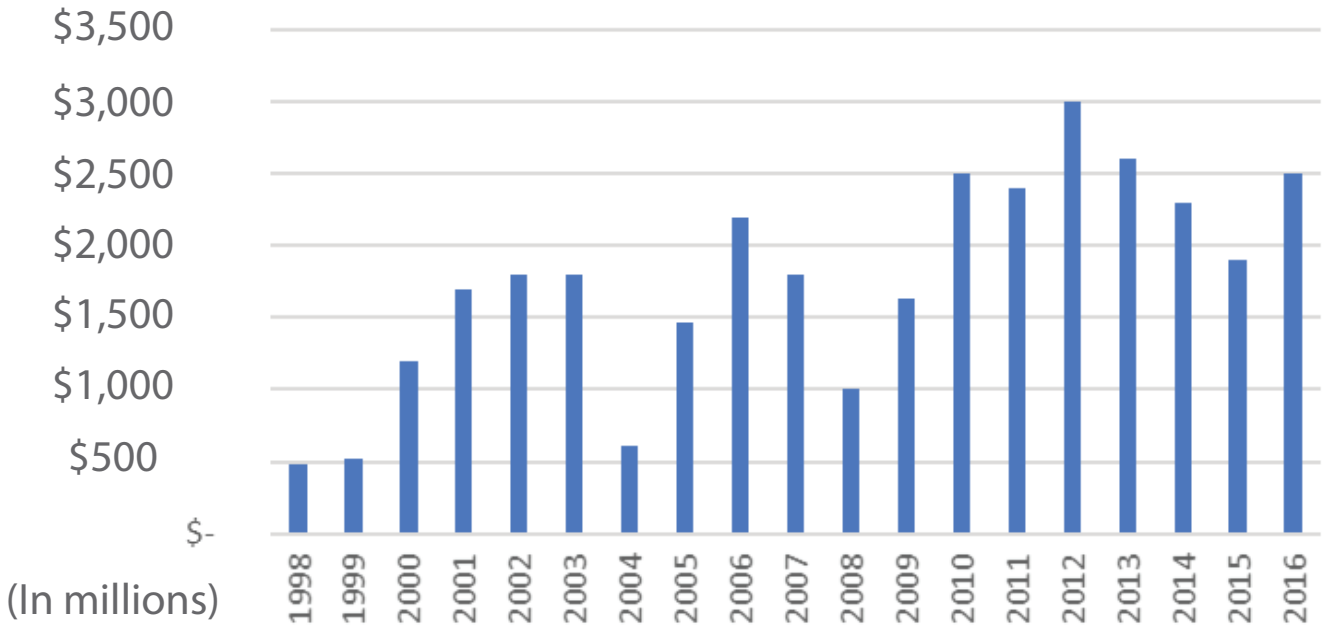
Per the United States Department of Justice Health Care Fraud Unit web page, "Health care fraud costs the United States tens of billions of dollars each year."

The Department of Health and Human Services (HHS) and The Department of Justice (DOJ) Health Care Fraud and Abuse Control Program (HCFAC) Annual Report for Fiscal Year (FY) 2016 states that during FY 2016, "The Federal Government won or negotiated over $2.5 billion in health care fraud judgments and settlements" verses a total of over $1.9 billion in FY 2015. [5, 6] The amount appears to change annually due to multiple factors including the budget and objectives of the various departments, partners and stakeholders. This annual report quantifies and qualifies the works of multiple U.S. federal agencies annual efforts to combat healthcare fraud, waste and abuse. Some salient data includes 3,635 as the number of individuals and entities HHS-OIG excluded from participation in Medicare, Medicaid, and other federal health care programs in FY2016 and $31 billion equaling the total monies returned by the HCFAC account to the Medicare Trust Funds since the inception of the Program in 1997.

While the National Health Care Anti-Fraud Association (NHCAA) estimates the annual health care fraud in the United States at about $68 billion, the amount of monies won or negotiated by the federal government contained in this report has exceeded 1 billion annually since FY2005 as plotted in table 1.

> **"The Federal Government won or negotiated over $2.5 billion in health care fraud judgments and settlements versus a total of over $1.9 billion in FY 2015.[5, 6]**

**Table 1** - Judgement and Monies Returned to the Federal Government or by Private Persons (By FY)




Data obtained from The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Reports FY1998 through 2016.



In the following pages we will provide a brief introduction to the concept and actions which may be taken for detection and prevention of fraud, waste and abuse (FWA). Traditional approaches to prevention and resolution of FWA and non-compliance are discussed.

Much of available FWA education and management literature primarily focuses on the pharmacy benefit within the pharmacy setting. Due to this, we chose to limit our review to medically administered drug claims in the office and outpatient settings.

**Differentiating Fraud, Waste and Abuse:**

When differentiating fraud from waste and abuse, the important distinctions are intent and benefit which are both required to meet the definition of fraud. Abuse and the resultant waste are often the result of poor practices and mistakes, representing opportunities for process improvement and education. An example of fraud is to purposely bill for services that were never given or to bill for a service that has a higher reimbursement than the service provided. Abuse may include payment for items or services that are billed by mistake by providers, but should not be paid for by the plan. Billing for a brand drug when a generic was administered is a mistake that could result in abuse. While waste can result from providing more medication than is necessary for the treatment of a specific condition.

When differentiating fraud from waste and abuse, the important distinctions are intent and benefit

Most Providers in the United States (US) are ethical practitioners who are not intending to misrepresent their practice through false claims. They intend to provide quality care to patients and may unintentionally submit incorrect or undocumented claims which may result in waste or abuse potentially through non-compliance with a payors policy. However, fraud may occur by anyone in daily practice due to employee's and sub-contractor's unfamiliarity with payor restrictions. What may be interpreted as a mistake may be pursued as fraud based on patterns of behavior. Per CMS, some examples of fraud would be to bill Medicare for an appointment the patient did not keep, knowingly up coding a service, billing for services not furnished or falsifying records to show delivery, as well as paying for referrals.[8] Abuse may include billing for unnecessary services, excessive charging, miscoding and unbundling codes.[8] An example of waste would include over-utilization or incurring unnecessary costs potentially through services which are not medically necessary.

These activities may result from simple mistakes to a mentality of 'bending the rules'. However, all could result in criminal or civil liability.

While there are multiple definitions of fraud, waste and abuse, what can differentiate fraud is intent and knowledge. Did a provider knowingly intend to submit a claim for the incorrect units or double bill a medication that was supplied and billed by a specialty pharmacy and brought in by a patient for administration at the prescriber's office? If the answer is yes, these actions may be considered fraud. Examples of actual cases and proposed recoveries are quoted in text boxes throughout the remainder of this paper.

What you interpret as a mistake may be pursued as fraud based on patterns of behavior.

**Who investigates FWA?**

Federal and State Oversight Authorities include:

- The Office of Inspector General (OIG)
- U.S. Department of Health and Human Services (HHS)
- Department of Justice (DOJ)
- Centers for Medicare & Medicaid Services (CMS)
- Office of the State Attorney General (AG)
- State Medicaid Agencies
- Medicaid Fraud Control Units (MCFU)
- The Office of the State OIG and Medicaid OIG

Improper payment prevention and recoupment is one way to curtail fraud, waste and abuse. Approaches include the implementation of pre-payment edits and review and post payment review, auditing and redetermination based on under or overpayment. Per CMS common causes of overpayment include the following.

- Billing for excessive or non-covered services
- Duplicate submission and subsequent payment of the same service or claim
- Payment for excluded or medically unnecessary services
- Payment for services that were furnished in a setting that was not appropriate to the patient's medical needs and condition
- Payment to an incorrect payee[9]

While CMS contracts payment integrity services for their Medicare fee-for-service medical claims with internal oversite by the Center for Program Integrity (CPI), other payors follow a similar process either by mandate or necessity. State Medicaid programs have specific legal obligations to protect Federal tax dollars used to fund each state run Medicaid program. Since each state oversees and runs their own program based on individual state needs the investigation and enforcement is also state dependent. States with Managed Care contracts may pass the obligation to the contracted Managed Care Organization (MCO), subcontract out program integrity or manage it internally.

> "Delaware did not bill manufacturers for some rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations. As a result, Delaware did not collect an estimated $127,000 (Federal share) in rebates."[10]

These disparate programs and routes of enforcement may leave a provider wondering "Hey, didn't I just get reviewed/audited/investigated by you guys?" That may be the case. Some States run Medicaid programs that operate under both a Managed Care Organization (MCO) and a fee-for-service (FFS) design. In this case a provider could be subject to review from both organizations under the single State Medicaid program. There is also the potential to be audited by both a Medicare and Medicaid contractor. Each may use the same audit contractor representing different payors with their own universe of claims. Providers should always clarify what payor or payor subcontractor is performing the audit, claim review or investigation, what dates of service are involved and what is the basis of the review.

In some cases, a review could escalate to an audit, investigation or both. As a review gets upgraded, the organization performing the service may change as well. For example, in the case of a complaint, it may first be investigated directly by the payor then referred for a comprehensive audit by the agency or a sub-

contractor. If credible evidence of fraud is discovered during the process, further referral to the State Attorney General's (AG) office or Medicaid Fraud Control Units (MFCU) or the Office of the Inspector General (OIG) for programs sponsored by the Department of Health & Human Services (HHS) may occur. While such escalation is not common, in the first half of FY 2016, the OIG reported expected recoveries of more than $2.77 billion, 428 criminal actions and 383 civil actions.[11]

**OIG/GSA Exclusion Lists**

CMS receives assistance from other Federal agencies including The Office of the Inspector General (OIG) and the General Services Administration (GSA). OIG protects programs within Health and Human Services (HHS) by performing audits and investigations in addition to other activities including oversite and certification of state MFCU offices and the operation and maintenance of the individual and entity exclusion program. The GSA assists with the management and support of federal agencies including centralized procurement. The GSA maintains the System for Award Management (SAM) including the excluded parties list containing information on entities that are debarred, disqualified, excluded and suspended from conducting business with various Federal agencies. The GSA exclusion list will include information from the OIG excluded program list but is more comprehensive for all Federal agencies.

Excluded individuals are barred from receiving payments from Federal health care programs. This includes payment for goods or services prescribed by an excluded individual. This exclusion includes billing for the individuals' services under a group practice or by an employer. CMS requires participating providers to screen employees and contractors against the exclusion lists. Screening must occur monthly and any discoveries must be reported to the appropriate agency.

In addition to individuals, provider organizations or entities may also be excluded from participating in federal programs due to convictions including fraud, patient abuse, or by Office of the Inspector General (OIG) discretion for other offences. Excluded providers may not participate in Federal health care programs for a period designated by the OIG.

Excluded individuals are barred from receiving payments from Federal Health care programs. This includes payment for goods or services prescribed by an excluded individual.

In addition to Federal exclusion lists, some states also maintain a separate exclusion list which must also be reviewed. Check with your individual state laws, provider manuals and agreements for further guidance.

> "Atlanta Medical Clinic, which is a pain management clinic, and owner Timothy Dembowski, DC, have agreed to pay the federal government $250,000 to resolve False Claims Act allegations, according to the Department of Justice. According to the government, AMC and Dr. Dembowski submitted fraudulent claims to Medicare for services performed by a physician who worked at the pain clinic and was suspended from the Medicare program."[12]

## What could be the impact of FWA?

Federal laws governing Medicare fraud and abuse include the following:

- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral Law (Stark Law)
- Social Security Act
- United States Criminal Code[8]

Examples of violations of each and the potential penalty are summarized in table 2.

**Table 2** - Examples of Fraud and Abuse of Federal Programs[8]

| False Claims Act | Anti-Kickback Statute | Physician Self-Referral Law | United States Criminal Code |
|---|---|---|---|
| Description: Knowingly submits or causes the submission of a false claim | Description: Knowingly and willfully receiving remuneration for referrals | Description: Referral to an entity in which the physician or an immediate family member has an ownership or investment | Description: Knowingly and willfully executing a scheme in connection with a service delivery to defraud a program or obtain property owned by a program |
| Example: Knowingly submitting a claim for a higher level of service than provided or documented | Example: Provider receives cash or lower rent in exchange for referrals | Example: Provider refers a patient to a service where the provider has an investment interest | Example: Prescribers and clinics conspire a scheme to submit claims for wheelchairs that were not medically necessary |
| Civil penalties: Up to 3x the damages sustained plus up to $21,563 (2016) per false claim | Civil penalties: Up to $73,588 (2016) per kickback plus 3x the kickback amount | Civil penalties: Up to $23,863 (2016) for each service, repayment of claims and potential exclusion | Civil Penalties: N/A |
| Criminal penalties: Fines, imprisonment or both | Criminal penalties: Fines, imprisonment or both | Criminal penalties: Fines | Criminal penalties: Fines, imprisonment or both |

Specific to the US Criminal Code example above, Per Title 18 of the United States Code Section 1347. Health Care Fraud "Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice— (1) to defraud any health care benefit program; or (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both." If the violation results in death, imprisonment may be extended to life.

## Examples of FWA in the Medical Drug Claim

Prevention of fraud, waste and abuse is the responsibility of the entire health care system from the payor down to the recipient. Occurrences may be identified at every level. Some examples are listed below.

| Sponsor Level: | Provider Level: | Recipient Level: |
|---|---|---|
| Failure to approve Prior Authorization (PAs) when medically necessary | Writing or filling prescriptions and refills for medically unnecessary drugs | Client misrepresentation of eligibility |
| Making payment for excluded services | Submitting claims for unnecessary, unprovided services | Identity theft |
| Enrolling members without consent | Submitting claims for up coded services/units | Client prescription altering |
| | Substituting claims for a covered item or rebateable NDC when providing a noncovered item or nonrebateable NDC | |
| | Administering expired or improperly prepared or inventoried medication | |
| | Double billing with a pharmacy for the same client | |
| | Double billing using the same medication for a different client | |

> "Medicare contractors in 13 jurisdictions overpaid providers $35.9 million for selected outpatient drugs from July 1, 2009, through June 30, 2012. For 88 percent of the overpayments, providers billed either incorrect units of service or, otherwise, a combination or incorrect units of service and incorrect Healthcare Common Procedure Coding Systems codes. The Medicare claims processing systems did not have sufficient prepayment edits in place to prevent all overpayments."[6]

## Compliance and FWA

Many of the laws and requirements presented here are specific to federal programs such as Medicare, Medicare Advantage Plans and Medicaid. Private payor sponsors and employer groups will also have requirements and policies for the prevention of fraud, waste and abuse. Prevention and detection of fraud, waste and abuse is often achieved through compliance programs. Generally, compliance is acting with conformity to a set standard, policy, demand or legal requirement.

Aside from direct reporting to the government agencies, provider and sponsor/payor compliance departments are typically where suspected fraud, waste and abuse is reported, investigated and corrected. Compliance may fall under the auspices of multiple departments working together within a health care plan such as Quality Assurance, Provider Relations, Customer Relations, Specialty Investigations Unit, IT/Analytics, Training/Education, Policy and/or Complaints. Each plan may have a different structure and set up for the detection and correction of non-compliance, with the same goal of reducing overall health care cost through the prevention, detection and elimination of fraud, waste and abuse.



## Potential Consequences of FWA and Non-compliance

Suspected fraud will be handled differently depending on the policies of the payor. If any funding of the program is from CMS, credible cases will be referred for a specialty investigation and potentially involve MFCU for the Medicaid program, the OIG or the State's Attorney General. Penalties can be monetary and/or result in jail time. Additions of the involved party(ies) to the exclusion list for a specified period may also result. Check with your individual payor for specific corrective actions plans and/or remediation options.

Waste and abuse are typically identified on a per claim basis through post payment activities including claim reviews, desk and on-site audits of single, targeted or a universe of claims or through specialty investigations. Remediation may include partial or full recoupment of payment potentially extrapolated to all claims within the reviewed period depending on applicate state laws and payor policy. Other payor specific requirements may include retraining, a corrective action plan or contract termination.

A system of progressive discipline is usually followed prior to provider disenrollment. Proactively investigate and work cooperatively with the payor to explore all options to remedy or prevent such actions.

Payors evaluate program compliance through several methods of claim and document evaluation including self-assessments, surveys, document requests, attestation requests as well as on-site or desktop audits. Non-compliance could result in actions similar to FWA depending on the severity and preponderance of the identified issue.

# Part II – Fraud, Waste, Abuse and Compliance for medical drug claims

**Practice areas at risk for FWA/Compliance (FWA-C) issues for medically administered drugs**

To avoid FWA-C issues, services should be delivered by the billing institution in compliance with the physician's order. Services billed for should be appropriate, documented and rendered to a covered patient. Claims data should be supported by the medical record and ancillary supporting documentation such as physician orders and the Medication Administration Record (MAR) or electronic MAR (eMAR).

Internally to identify practice areas at risk for FWA and non-compliance specific to a provider, their compliance officer and/or team may regularly conduct internal audits. For our topic, the internal audit would include a review of claims submitted under the medical drug benefit. This process of internal validation of claim accuracy and identification of outliers may be followed by re-education to current policy and procedure in addition to corrective actions to include policy review and revision. Leveraging data such as maximum doses for billing codes and FDA approved and compendia reviewed diagnoses can aid in making the process of claim outlier identification more efficient.

External to the provider to identify areas at risk for FWA and non-compliance, payors, plan sponsors and their subcontractors will conduct claims analysis, audits, investigations or claim reviews. Depending on the tool used and areas of interest, this process may not be restricted to billing practices and can include requests for documentation involving general areas of practice in support of claims. Some specific areas of interest during the review process have been highlighted.

*General areas of practice*

General standards of the practice may be reviewed by an auditor or payor agent as it relates to payor policy and legal requirements. Proper licensing, accurate and up to date provider agreements and enrollment including practice ownership and locations, required training and employee screening as well as HIPAA requirements are examples of items which may be reviewed for compliance. Standard organizational policies and procedures may also be reviewed in support of claims.

*Incorrect Claim Submission*

Claims containing data elements required by the payor to support the claim are reviewed against all supporting documentation including medical/health records, physician orders, lab reports, organizational policy and procedure, invoices, MAR (eMAR) and nursing notes. Elements from claims should be supported by these records. If not, an adjustment to the claim including non-payment may result. Examples include submission of a non-matching or not provided HCPCS/CPT code or NDC (if required), incorrect or miscalculated billing units or strength, incorrect NPI, non-matching or not supported diagnosis or administration code, non-matching date(s) of service, incorrect patient, improper billing of waste, billing waste for non-qualified vials and/or duplicate claims.

> "A review of the Medicare Part B data reveals that more than $420 million in trastuzumab charges were filed in 2010, with $500,000 billed [incorrectly] under the JW modifier, indicating drug waste." [13]

*Non-compliance with Payor Policy*

Audit findings for non-compliance are typically based on the provider not following the requirements for a valid, medically supported claim. Policy requirements of the payor which are not fulfilled can result in recoupment of the claim upon audit. Requirements for payment of a medical drug claim may include execution of a proper PA, submission of a covered diagnosis, incorrect submission of usual and customary pricing or exceeding the published fee schedule, individual claims for drugs subject to bundling, claims not submitted to the primary payor for a secondary payor and claims exceeding the limits of the program. Claims may be fully recouped or recouped up to the limited amount.

*Non-compliance with acceptable standards of practice*

In some cases, non-compliance is not based on an individual payor's policy or provider's practice but an accepted practice standard defined by a third party. Such is the case with conventional coding policies. These policies are developed by organizations such as the American Medical Association (AMA) in their Current Procedural Terminology (CPT) Manual and coding guidelines developed by national societies and standard practices.

> "It is important for medical oncologists to be aware that J9999 is not a catch-all for every chemotherapy drug without a CPT assignment. Experimental drugs are not covered by J9999, and Medicare pays close attention to all 'unclassified' claims to ensure sufficient documentation and demonstrable medical necessity."[13]

*Non-compliance with Federal or State Law*

Examples of non-compliance wth Federal or State law include unsanitary drug preparation and administration conditions, improper needle/waste disposal, improper drug storage and improper handling of controlled substances

Upon audit, non-compliance with a Federal or State law can result in total or partial recoupment of an entire claim. Depending on the payor and severity or risk to the patient, non-compliance could also result in litigation and disenrollment. Examples include unsanitary drug preparation and administration conditions, improper needle/waste disposal, improper drug storage and handling or improper handling of controlled substances. All orders should be executed by a practitioner legally able to prescribe per State regulations in compliance with State collaborative agreements.

> "...a jury convicted [the Defendant]... of receipt and delivery of misbranded drugs, smuggling goods into the United States, health care fraud and mail fraud. She formerly operated East Lake Oncology, where she administered at least $700,000 worth of the foreign drugs, then billed Medicare as if she had used the higher-priced U.S. versions. She obtained the drugs - which had names like MabThera, Eprex, Ribomustin, Neulastim, and Zometa - from distributors in the United Kingdom and Canada."[14]

*Poor or Missing Documentation*

If it's not documented, it was not performed/administered. An auditor or investigator cannot take a verbal rational at face value. They need access to consistent, clear, dated and signed documentation supporting the order and administration of the drug. The order should be complete supporting all required information for a claim including client demographics (including current weight if weight based dosing is used), dose, frequency, timing of and route of administration of the drug with appropriate signatures and dates. If an appropriate diagnosis, PA, statement of medically necessity for off label dosing or use is required for payment, that should also be documented. In addition to a complete signed and dated MAR (eMAR), record of purchase, receipt and/or drug inventory to support the claim should also be maintained. Be sure to always check with the individual payor for additional required documentation. For example, there may be limited or non-acceptance of records which appear to be cloned or copy and pasted to a new record or limitations on orders by residents lacking a supporting supervising physician document and signature. The claim for an incorrect, incomplete or unsupported order and or administration may be completely recouped by a payor or adjusted for any difference between a submitted code and the correct code or the amount in excess of what was actually ordered.

If it's not documented, it was not performed / administered. An auditor or investigator cannot take a verbal rational at face value.

*Brown/White Bagging*

Brown bagging is when a patient brings a medication dispensed by a pharmacy to the physician's office for administration. White bagging is when the physician receives a medication from the pharmacy and the patient comes to the physician's office for administration. Each carries a risk of FWA in the form of double billing of the drug by both the prescriber and pharmacy, payment for a drug not administered to the patient and drug paid for by two plans when not administered to the first patient while being used for and paid again for a second patient in another plan.

Areas of interest to an auditor will include proper storage and sequestration of the medication from inventory owned by the hospital or medical office, receipt records, refill requests and waste from over dispensing in vial sizes exceeding the total ordered dose and underutilization/waste of remaining doses in multiple dose vials. The provider should understand payor policy on possible return, reuse and pre-ordering of medications ultimately not administered to the patient. Communication and documentation between the pharmacy, ordering physician and place of administration, in addition to understanding payor policy, is key to preventing FWA for this drug delivery model. One suggestion for minimizing the risk of billing medication which is not administered would be to prescribe in single dose quantities and dispense only after continuation of therapy is confirmed with the prescriber.

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**Figure 3** - Brown Bagging Methods

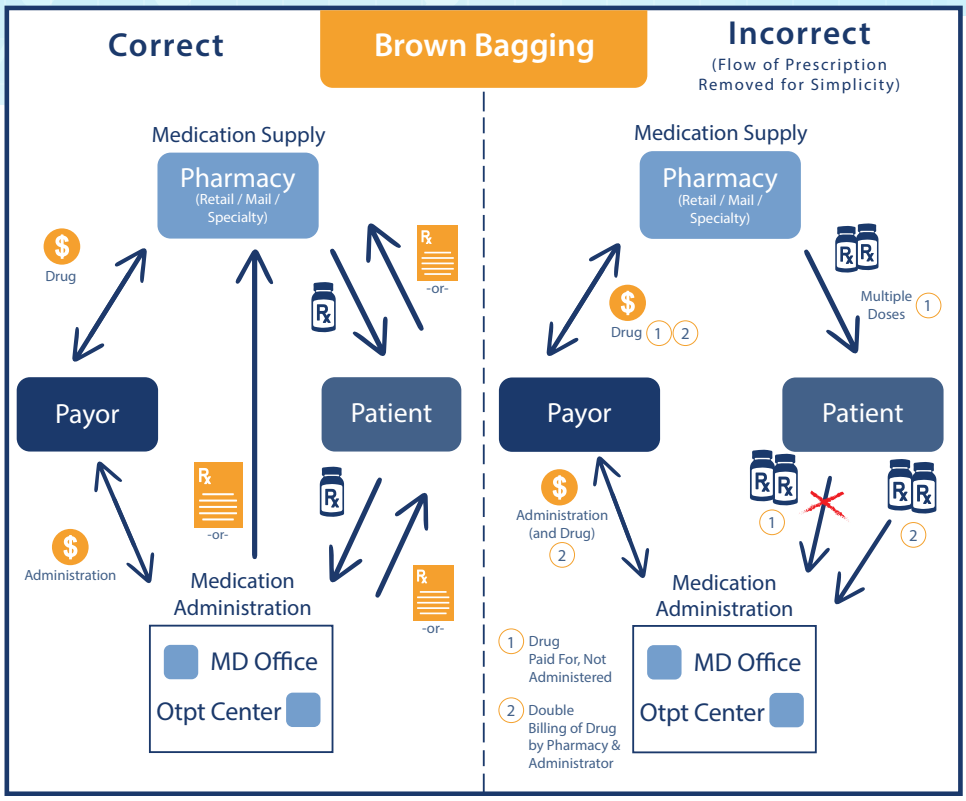
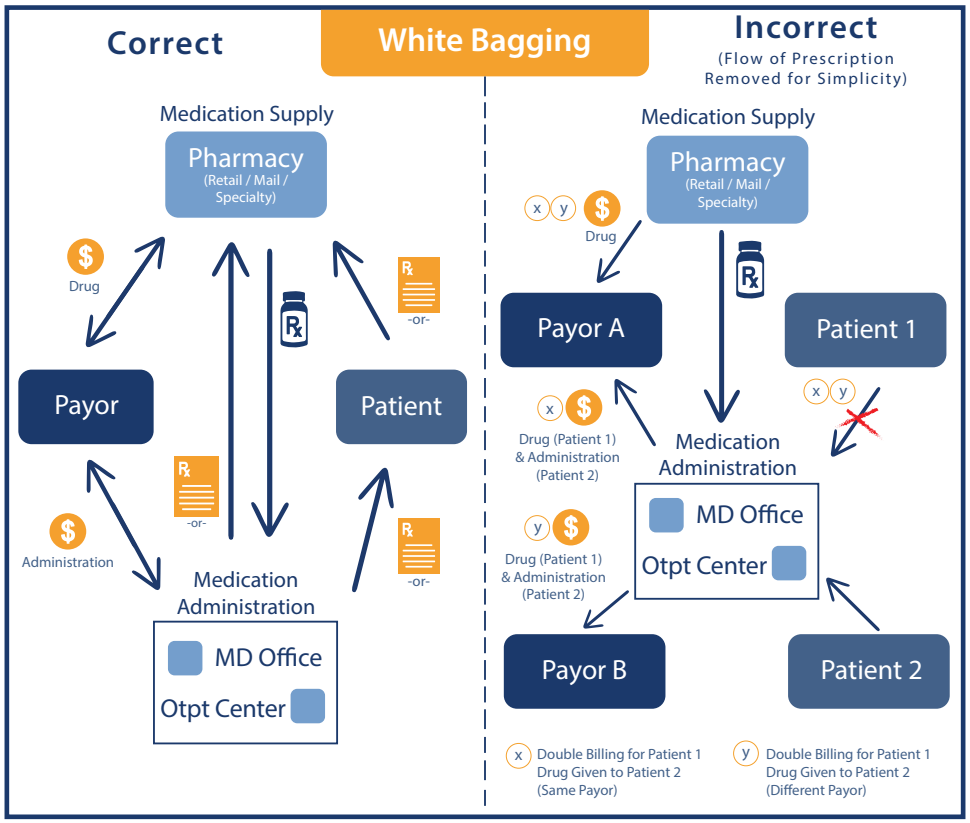



**Figure 4** - White Bagging Methods



## Corrective Action Plans

Sponsors and payors may require a corrective action plan in response to an investigation or compliance audit. Actions included in a corrective action plan should identify and resolve the cause of non-compliance. Corrective action should be continuous and include a monitoring plan. Corrective action may include one or more of the following.

- Education / Training
- Disciplinary action
- New/Revised policies and procedures
- Documentation reviews
- Pre-payment edits
- Post-payment reviews/ self-audits

## Advice to Providers

***Be Proactive***

Read and follow the requirements of Payor Provider Agreements and Manuals. Ensure you are subscribed to update notifications and have a system in place to effectively communicate internally and to subcontractors any resulting changes to your practice.

Keep up to date with laws and regulations.

Invest in and institute FWA and compliance training for all employees. This should include ethics and standards of conduct.

***Set Policies***

Institute practice site FWA/compliance policies including the appointment of an individual responsible for oversight. Include required activities such as screening of new hires, contractors and employees against exclusion lists.

Require the same standards of conduct and training of any subcontractors used by your practice and include as a stipulation in your contact.

***Document***

Always document what you do

Know and follow the payor's documentation retention requirements

***Perform Self-Audits/Internal-Audits***

Ensure proper claims submission.

Perform self-audits or internal-audits. In addition, investigate potential, acceptable self-audit options with payors.

Have a process for and encourage employees to report FWA and issues of non-compliance. Openly discuss these issues within your practice.

When FWA/compliance issues are discovered work with payors to proactively resolve the issue.

***Seek Assistance***

Determine resources within your state and area of practice for assistance with FWA and compliance issues involving their prevention and resolution.

Work with your claims processor to determine options for identification of claim outliers prior to submission.



In all cases, refer to your Provider Agreements and Policy Manuals for individual requirements for each payor plan. When setting an internal practice standard or policy, it is advisable to go with the strictest guidance. Also, be familiar with and follow all Federal and State statutes and regulations as applied to your practice. When faced with conflicting legislation the best approach is to follow the more stringent requirement.

Document, Document, Document (If the document does not exist to support your actions, then you did not do it.)

***Report it!***

If you identify or suspect FWA please report it to all affected payors. Each payor should have one or several methods for reporting including phone, e-mail, on-line form submittal and/or facsimile forms. There should be an option for an anonymous report if desired, however this does limit the investigative options for the payor. For the best results, supply as much specific information as possible about the FWA.

# Part III – Leveraging data to identify medical claim outliers to assist in the identification of FWA

**Leveraging drug specific pricing and clinical data to address FWA-C issues**

In the FWA arena there are several potential applications of drug specific pricing and clinical edit data which assists in the facilitation of the identification of medical claims and providers which may be candidates for further evaluation.

***For Payors***

*Medical Claim Pre-payment*

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The greatest benefit of the use of drug data and edits is in the prevention of FWA. Maximum units per billing code data should be utilized to set a threshold dose beyond which claims will be diverted from the automatic approval/payment process to manual evaluation. Organizations may approach exceeded doses in multiple ways including provider document requests, claim denial notices and provider claim review and resubmission requests. Threshold dosing edits may also be set to initiate a prior authorization (PA) process or the requirement for additional documentation on the claim, such as a required diagnosis.

Organizations may approach exceeded doses in multiple ways including provider document requests, claim denial notices and provider claim review and resubmission requests.

In addition, FDA and compendia diagnosis codes may be used in a similar manner selecting claims in a predetermined high-risk drug category with an off-label diagnosis for submission into a PA process or selecting clients for recommendation to an appropriate Clinical Case Management Program. In this case, an organization can determine whether a drug claim is for a usage that is non-reimbursable. Additionally, checking claims which had previously received a PA approval for appropriate diagnosis, ensures that the claim is being submitted accurately.

Assessment of claim pricing against an industry standard that is customized to set a maximum allowed amount for each billing code, can identify and prevent risk of overpayment on claims from out of network providers whose usual and customary pricing exceeds the plan's desired maximum reimbursement policies.

> "CMS developed the National Correct Coding Initiative (NCCI) to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Medicare claims. The use of the NCCI edits saved the Medicare program $681.9 million in FY 2014. NCCI savings are from Medicare Part B Medically Unlikely Edits (MUEs). and Part B Procedure-to-Procedure (PTP) Edits."[6]

Examples of data features which may be utilized in claim edits include the following:

- HCPCS/CPT maximum units with both FDA and compendia limits rounded to single dose vial units
- NDC to HCPCS code crosswalk including NDCs without a HCPCS code with the recommended NOC (not otherwise classified) code
- Single vs multi-dose vial indicators by NDC to identify those acceptable for billing with waste modifiers according to payor policy

There exists multiple modalities of accessing and utilizing data which should be selected based on compatibility with your claims review process:

- Data files for direct integration into your organizations claim processing system
- Web-based SaaS application which contains interfaces for manual data look up and claim screening
- Claims screening supplied through a call and answer process within your system via API configuration or batch processing review

Also of interest to both payors and provider are claims check tools. Claims data entered into an on-line form can be verified against multiple clinical data sets to identify non-matching NDCs, inappropriate units, off-label diagnosis codes and inappropriate administration codes in one check.

*Payment Policy*

Drug level data and edits may be utilized by plan sponsors to ensure compliance to payor policy. If payor policy includes a NDC mandate, claims can be screened pre- or post-payment for the presence of an appropriate NDC that aligns with the submitted code. A non-matching NDC could result in several actions by the plan to include claim denial pre-payment or letters requesting claim correction by the provider.

*Post-Payment*

Incorporation of pricing thresholds into post payment review can assist a plan's internal auditors identify claims which are not reimbursed at rates established by provider contracts.

Analysts and auditors can incorporate pricing and clinical data sets into their tools to assist in the identification of outlier claims. Analysts can group and sort outlier claims by provider, group or place of service to identify areas at risk for overpayment or inappropriate claim activity. Data can be further utilized in provider and claim benchmarking processes. Auditors can incorporate maximum units into their auditing package to call attention to records requiring additional scrutiny thereby effecting a more efficient and effective claim review process.

The use of drug and code level data sets and application of an error count threshold per claim may be used to identify providers who may require additional education on proper claim submission and payor policy.

### *For Providers*

For large health providers with compliance teams performing internal or self-audits, analytics can screen claims with units submitted below the minimum or above the maximum units, with off-label diagnosis codes, non-matching NDCs or improper administration codes for each HCPCS/CPT code which contains clinical data. This targeted list of claims may result in more efficient and effective self/internal audits allowing for increased training and claim error reduction.

Providers can likewise utilize data to accomplish the following.

Screen claims prior to submission to assist with compliance and outlier avoidance.

Identify NDCs which are payable by the Medicaid program.

Review current and historical pricing including AWP, WAC and ASP (Medicare Allowable) rates to assist with selection of the most economical NDC for purchase and to gain understanding of contracted reimbursement rates.

Utilizing data in this manor, providers can potentially benefit from decreased underpayments, non-payment or repricing of claims resulting from incorrect claim submission. Claims screening by providers prior to submission may also reduce the cost of responding to claim inquiries from the payor.

## Examples of RJ Health Systems Data Solutions

RJ Health Systems' suite of offerings can empower organizations in the identification and management of potential FWA. RJ Health Systems maintains a library of data files, including pricing, dosing units and diagnosis, which can be incorporated into FWA-C identification and prevention. Table 5 below lists a few examples of how data has been applied to historical claims to detect both specific claim opportunities and trends. It serves as an introductory review of some of the data available.

**Table 5** - RJ Health Systems applied to historical claims identifies potential FWA and non-compliance

| Activity / Opportunity | RJ Health Systems Data File | Examples from Recent Historical Claims Analysis |
|---|---|---|
| Upcoding Units | Min/Max Plus: Maximum Dose Units | A claim exceeding maximum units by over 500 units resulted in an overpayment exceeding $21,000. |
| Miscalculated Units | Min/Max Plus: Maximum Dosing Units | |
| Incorrect NDC on claim | Pricing/Crosswalk: NDC Crosswalk | Over 15,000 claims related to HCPCS to NDC mapping issues were identified. A claim for a NDC with an IV route submitted under the SC code resulted in an overpayment of over $68,000. |
| Incorrect HCPCS on claim | Pricing/Crosswalk: NDC Crosswalk | |
| Upcoding Administration Code | Administration Codes | An administration code missing from claims resulted in payment under an incorrect HCPCS code. 16 claims exceeding maximum units were paid at over $15,000. |
| Incorrect Administration Code | Administration Codes | |
| Medical Necessity | Diagnosis Codes, Min/Max Plus and Age/Gender | Claim units from provider NPIs from same provider group exceeded all other NPIs combined by 10%. |
| Improperly Billed Waste | Pricing/Crosswalk: NDC Crosswalk | Not observed: Modifier codes not available during analysis. See Herceptin example under reference 9 below. |
| PA Diagnosis Not Validated on Claim | Diagnosis Codes, Min/Max Plus | Claims with off label use for J1745 exceeded 300 paid at over $2,500,000 despite PA program in place. |
| Inflated usual and customary pricing | Custom File | Autoimmune class: Allowed amount would have to exceed AWP + 50% to justify allowed amount paid for over $54,000 in claims. |
| Payment for unapproved use | Diagnosis Codes | Off label diagnosis codes included over 30 claims valued at around $200,000. |
| Overbilling of drug not administered | Min/Max Plus: Maximum Dose Units | Over $28 million in medical claims originating at pharmacies exceeded maximum units: dispensing multiple doses at one time risks overpayment for medication not administered |

Min/Max Plus Data:

Claims with potential up coding of units can be identified by comparing claim units to the maximum allowable unit data. Several data fields are available at the HCPCS level and may be implemented based on payor goals.

A claims data analysis using the Min/Max Plus file revealed the place of service for the most frequent units exceeded outlier for one drug was at pharmacies verses professional or outpatient locations.

Maximum units are available based on both FDA approved indications and compendia approved indications. Each is further subdivided for pediatric and adult indications. Data is rounded to both the standard HCPCS billing units and to the smallest available single-dose vial where applicable. While

multiple examples of units exceeding the maximum were identified in a claim review recently performed, a stand out was for Benlysta. With dosing set at 10mg/kg and billable units also at 10mg, the client would need to weigh over 600kg to justify the units billed on the claim.

Pricing/NDC crosswalk:

In another historical claim analysis 15,000 claims where identified with HCPCS to NDC mapping issues. For payment based at the HCPCS level, this activity may result in claim overpayment. One such example included a claim where the IV version of a drug was billed under the SC route HCPCS code. Since HCPCS reimbursement per billable unit was higher for the SC code the claim was overpaid. Two claims with this error resulted in a total overpayment of about $69,000.

Diagnosis codes:

During a recent claim review, HCPCS code J1745 was selected for prioritized review for an off-label detection solution. Diagnosis codes submitted on claims were reviewed against RJ Health Systems diagnosis code data associated with approved FDA and compendia indications. Over $2,500,000 in paid claims were identified with off-label diagnosis codes submitted on the claim. The same company who processed prior authorizations (PA) for the drug was also an approved supplier. Requiring an approved diagnosis code on the claim was discussed as a second point of validation for appropriate PA program approval.

Faced with multiple FWA and non-compliance issues, it is fortunate that the same data file may be used to identify and solve for multiple issues. For example, a claims data analysis using the Min/Max Plus file revealed the place of service for the most frequent units exceeded outlier for one drug was at pharmacies versus professional or outpatient locations. Payor policy required billing of the medically administered drugs under professional claims versus the NCPDP standard. Pharmacies dispensing greater than one dose at a time for administration at the doctor's office or an outpatient location (brown bagging or white bagging) results in the risk of waste of medication already paid for never being administered to the patient. Review of claims data against the Min/Max Plus file revealed this as an opportunity for policy review with the Min/Max Plus file also offering a claims screening solution upon policy change.

Not sure where to start? One option would be to provide RJ Health Systems with historical professional drug claims data for review and analysis. Analysis of historical claims data utilizing our various files is beneficial to many payors in determining a benchmark for potential opportunities and in identification of outliers. Through insight into specific therapeutic classes and drugs where issues exist, a plan is in a better position to determine strategy and goals to address these issues. If your objectives are already set, choose the data file and drug class which would best support your current program goals. Data is available for direct integration into your current systems, on-line for manual review or for screening against claims data via an API.

## Conclusion

Health care fraud estimates in the United States exceeds $68 billion annually. This does not include the concomitant cost of waste, abuse and non-compliance. One approach to prevention is a rigorous application of pre-payment pricing and clinical edits utilizing claim line thresholds to identify outliers. Identified claims may be addressed through a mix of manual review, prior authorization programs or additional claim requirements. Post-payment claim review, audit and analytics at both the payor and provider identifies outliers after the fact with an added benefit of claim grouping into categories of risk and benchmarking activities. Data containing clinical and reimbursement thresholds may be incorporated into this process to assist in a more efficient and effective claim review.

One approach to prevention is a rigorous application of pre-payment pricing and clinical edits utilizing claim line thresholds to identify outliers.

Incorporating reimbursement and clinical data into medical drug claims systems pre- and post-payment is one way both payors and providers can prevent, identify and resolve issues related to medical drug claim fraud, waste, abuse and non-compliance. RJ Health Systems provides pricing and clinical drug information for medically covered pharmaceuticals at the HCPCS/CPT code and NDC level that can be integrated into your systems, reviewed on-line as SaaS or utilized through an API protocol.



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**FWA-C Resources:**

*Additional training and resources are available from CMS and OIG.*

*CMS: "Compliance and Fraud and Abuse Related Resources" https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html*

*OIG: "A Roadmap for New Physicians Avoiding Medicare and Medicaid Fraud and Abuse" https://oig.hhs.gov/compliance/physician-education/index.asp*

*OIG: "Compliance Education Materials for Physicians" https://oig.hhs.gov/compliance/101/index.asp*

## About the Author

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Prior to joining RJ Health Systems in May of 2017, Laura Benson obtained pharmacy practice experience at multiple practice sites including hospital, long term care and retail settings. Most recently she worked for the State of CT Department of Social Services QA Department performing activities related to compliance to the State Medicaid program. There she was nominated to attend the National Advocacy Center for two specialized training programs on Medicaid compliance audits and Fraud, Waste and Abuse specific to drug claims. Laura currently works under the tutelage of Todd Cooperman in the RJ Health Systems Analytics Department. Laura earned a Bachelor's degree in Industrial Distribution from Clarkson University and a Doctorate in Pharmacy from Virginia Commonwealth University's Medical College of Virginia.

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Todd Cooperman joined RJ Health Systems in June 2016 as Vice President, Clinical Analytics. As Vice President, Todd has extensive input to the development and maintenance of RJ Health System's drug information databases. Additionally, Todd oversees the development of analytic methodology, implementation, and reporting for our various clients.

Todd has an extensive background in all aspects of managed care and specialty pharmacy including: utilization review, Pharmacy and Therapeutics Committee oversight, predictive and pharmacoeconomic modeling, rules engine development, formulary management, business operations, benefit design, drug information and claim databases, patient education, and clinical practice.

Todd earned a Bachelor's in chemistry from Binghamton University, Doctorate in Pharmacy from Northeastern University, and a Masters of Business Administration from the University of Hartford. Todd completed a pharmacy practice residency at Saint Francis Hospital and University of Connecticut. He is a Registered Pharmacist in the State of Connecticut and is a member of the Academy of Managed Care Pharmacy.

# RJ Health Systems

## About RJ Health Systems

We offer a proprietary methodology and related solutions for reducing medical drug spend. We provide industry standard pricing, coding, dosing, weight, age and diagnosis information for those drugs administered in professional settings. Using our uniform product suite of tools, analyses and data, we help you save time and money.

We offer solutioins that guide our client's management of drug trend in the most efficient way:

- Software as a Service (SaaS) applications for pharmacy, claims and finance staff.
- Customizable data that clients can integrate into operational systems for strategic enterprise initiatives.
- Analytics on unit cost (fees/costs/pricing) and clinical utilization to analyze, forecast and manage upward drug spend trends.
- Services for pharmaceutical manufacturers connecting them to our vast coverage of the payor market which ultimately improves reimbursement accuracy and relationships.

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