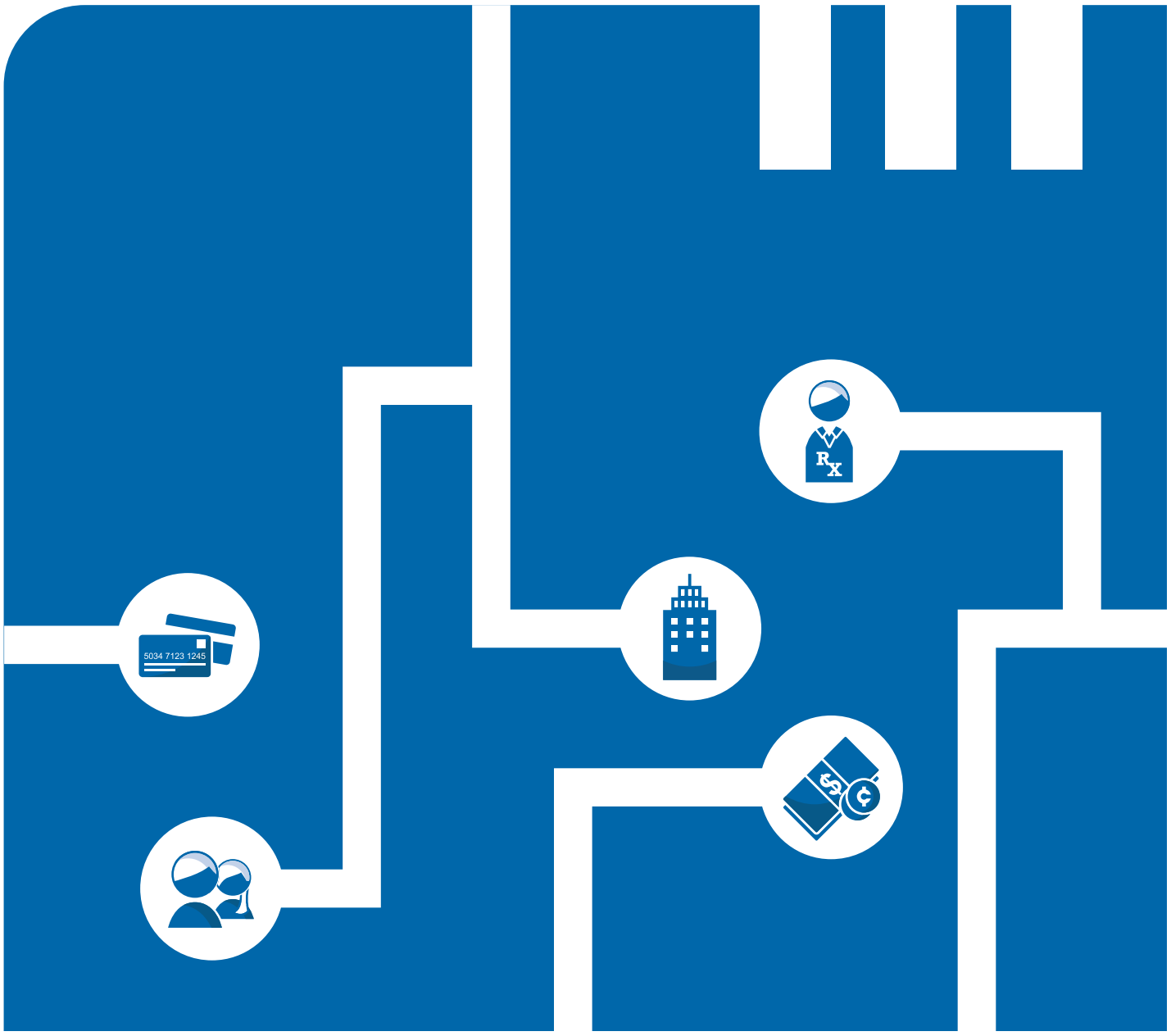
McKESSON

White Paper

Safeguards Manufacturers Can Use Today to Help Support Regulatory Compliance

October 2016



Introduction

On September 18, 2014, the Office of Inspector General (OIG) published its report on a survey of pharmaceutical manufacturers' co-pay savings programs, entitled "Manufacturer Safeguards May Not Prevent Co-payment Coupon Use for Part D Drugs" (OEI-05-12-00540).

The Federal Anti-Kickback Statute (AKS) prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs. Violations may result in criminal and civil prosecution.

The OIG conducted this study to assess the effectiveness of the measures pharmaceutical manufacturers use to prevent their coupon programs from inducing the purchase of medications paid for by Federal health care programs (Federal plans). Findings from the study apply to Medicare Part D as well as other Federal programs such as Medicaid, TriCare, DoD and VA plans.

The OIG found that most of the safeguards manufacturers rely on are not sufficient to prevent the improper use of co-payment coupons for medications paid for by Federal health care programs.

In its supplementary Special Advisory Bulletin, the OIG concludes that manufacturers are ultimately responsible for operating these programs in compliance with Federal law, and must take appropriate steps to prevent coupons from being applied to claims for Federal health care programs. Failure to take such additional steps may be evidence of intent to induce purchase of medications paid for by Federal plans, in violation of the Anti-Kickback Statute.

The OIG found that only one entity has a sufficient level of claims edit data – both primary insurance and coupon information – that more accurately identifies Part D claims. The company the OIG was referring to is RelayHealth, a McKesson joint venture.

It must be understood, however, that no single entity, including RelayHealth, has the ability to exclude all government beneficiaries. As stated on page 17 of the OEI-05-12-00540 report, *Some Claims Processing Edits Use More Accurate Proxies To Identify Part D Coverage, but Cannot Be Used by All Manufacturers.* Claims processing edits that more accurately determine Part D enrollment are imperfect because these edits use information that cannot be obtained by all manufacturers. These edits rely on the more accurate proxies of BIN/PCN and benefit stage information.

While edits that rely on the primary insurer's BIN/PCN are more accurate proxies, access to this combination of information is limited. To access the BIN/PCN, a manufacturer's coupon vendor needs to have access to primary insurance claims as the PCN is not transmitted as part of the coupon claim.

Industry Response to the OIG Report and Special Advisory Bulletin

NCPDP approves formation of WG9 OIG Report OEI-05-12-00540 Task Group

In response to the September 2014 OIG report and supplementary Special Advisory Bulletin, the National Council for Prescription Drug Programs (NCPDP) approved forming a new task group in November 2014 to develop a standard approach to handling cost sharing assistance when the beneficiary is in a government program. The work group is known as the WG9 OIG Report OEI-05-12-00540 Task Group (WG9 Task Group).

The group's objective, as published on the NCPDP website is as follows: The OIG Report OEI-05-12-00540 Task Group will develop recommendations to address the observations and conclusions in the OIG report specifically referencing Medicare Part D as a result of the focus of the executive summary with recommended estimated implementation timelines where available. The task group will identify any assistance needed from the Center for Medicare Services ("CMS") or OIG and the task group will communicate progress to OIG through the task group's CMS representative. If necessary, this task group will address any proposed or new guidance as appropriate.

The goal of the WG9 Task Group is to focus on Medicare Part D as it relates to the OIG report while also evaluating enhancements to the NCPDP standards that could be applicable to other government programs outside of Medicare Part D. McKesson, inclusive of RelayHealth, have been actively engaged in the group's activity and progress since inception.

Potential Solutions Formed in 2015; Prioritized in Early 2016

Throughout 2015, the WG9 Task Group conducted conference calls with industry stakeholders to collaborate and develop recommended potential solutions. By late 2015, the group had defined twenty-one solutions which were prioritized by stakeholder participants considering each solution's potential effectiveness inclusive of level of effort to implement. This was achieved by conducting a survey during December 2015 – January 2016. The survey results were reviewed by the group in January 2016 and the short list of potential solutions was pared down to ten.

One High Priority Solution Selected

The short list was reviewed with CMS in early April 2016. CMS indicated there was one item that appears to provide a solution that is consistent with what the OIG is looking for to help address the observations and conclusions in the OIG report. The solution suggests that the industry utilize a proposed new field "Other Payer Adjudicated Program Type" with payer type values for Medicaid, Medicare, DOD, VA, TriCare, Workers Compensation, and other government funded health plans. This would allow for clearer identification of the payer type for each prescription claim being processed for adjudication and /or pharmacy system edits based on the value in this field.

The Other Payer Adjudicated Program Type solution would require the NCPDP Telecommunication Standard be modified to support a mandated field within the prescription claim that identifies the payer's program type. Standards version changes typically require a 5-7 year period for approval to implementation. With CMS's support, the WG9 Task Group is presently developing use case scenarios, process flow, and a white paper on the proposed solution while advancing a potential change to the NCPDP Telecommunication Standard.

Other Payer Adjudicated Program Type implementation may have a significant impact on industry stakeholders including payers, claims adjudicators, claims "switch" services, coupon vendors, pharmacies, pharmaceutical manufacturers and their respective processing systems. This long-term solution has high potential for effectively addressing the observations and conclusions indicated in the OIG report.

WG9 Task Group – Ongoing Work

The WG9 Work Group will continue to develop other potential solutions with CMS input and support. Overall, the pharmaceutical industry is highly supportive of the work the WG9 Task Group and CMS are doing to help manufacturers comply with the Federal Anti-Kickback Statute. However, many of the solutions being considered, including the Other Payer Adjudication Program Type, will not be available for several years, with current estimates of market availability in 2023.

Safeguards Manufacturers Can Use Today to Help Support Regulatory Compliance

The purpose of this paper is to review solutions which are available today that manufacturers can use to help support regulatory compliance. Several solutions have challenges, which are identified.

It's important to recognize there is no single solution available today that manufacturers can use as a safeguard to ensure that 100% of Federal beneficiaries are excluded from coupon programs. Most manufacturers have recognized that the application of multiple safeguards applied for their co-pay assistance programs provides the best support for regulatory compliance.

Safeguard Review – Current Challenges

As mentioned previously, while edits that rely on the primary insurer's BIN/PCN are more accurate proxies, access to this combination of information is limited. To access the BIN/PCN, a manufacturer's coupon vendor needs to have access to primary insurance claims as the PCN is not transmitted as part of the coupon claim.

Because access to primary insurance claims are limited for most vendors, edits are included using "proxy" values from the claim to approximate Medicare Part D coverage. This is done due to lack of access to the patient's Part D enrollment status or other primary insurance information needed to accurately identify Federal health care claims. Proxy values include:

- The patient's primary insurance BIN as reported in the coupon claim
- The Part D benefit stage information from the primary claim as reported in the coupon claim
- The patient's date of birth

Challenges with Coupon Vendor's Claim Edits

Coupon claim "proxy" values are used to approximate a patient's Part D coverage, but may be unreliable, insufficient, or unavailable to the manufacturer or the coupon vendor due to any of the following factors:

- Varying primary insurance BIN, PCN and Group ID identifier combinations
  - The BIN is the only primary insurance information visible to secondary coupon benefit payers within the coupon claim.
  - CMS regulations require payers that process claims for Commercial and Part D plans to differentiate these claims by BIN and PCN. Other government funded plans are identified by BIN, PCN and Group ID.
  - Primary insurance BINs cannot always identify Part D coverage, and may lack the needed PCN and or Group ID information to determine if a patient is enrolled in a Part D plan or other government plan.
- Inconsistencies in effective use of the Part D Benefit Stage information within a primary claim
  - Per NCPDP HIPAA Standards, the Part D Benefit Stage values may only be submitted on a coordination of benefits ("COB") claim if required for state/federal/regulatory agency programs.
  - The primary claim's Part D Benefit Stage is not indicated in all prescription claims.
  - Medicaid claims can't be identified by the Part D Benefit Stage information.
- Reliance on a patient's date of birth
  - Use of the patient's date of birth to calculate their age may not identify all Part D beneficiaries, as not all covered patients fit a specific age demographic.
    - Per the OIG report, 17 percent of Medicare beneficiaries are disabled and under age 65.
    - As working age continues to increase, Medicare-eligible patients may still be enrolled in commercial plans which cover the pharmacy and/or medical benefit.

The challenges above have led to differentiation in safeguard services currently available to manufacturers.

The OIG identified one entity with access to the BIN/PCN. This entity plays a dual role as a coupon vendor and a switching company that electronically routes claims, giving it access to the primary insurance claim containing the BIN/PCN that indicates Part D insurance. This capability was accessed over 10 years ago to create a solution that would help manufacturers to identify and exclude those patients that were deemed inappropriate based on utilization of government funded plans.

RelayHealth, a McKesson subsidiary, developed Government Plan Exclusion (GPE) technology which utilizes and maintains a robust database of government plan and coupon identifiers to prevent – in real time during claim adjudication – the application of coupons to known Federal health care claims.

Government Plan Exclusion (GPE) technology – Claims Processing Edits for More Accurate Proxies

Unlike other claims edit technologies, GPE has visibility into the primary claim payer information at the BIN/PCN and Group ID levels to block co-pay offers for beneficiaries with known government payer plans. GPE can also be used to verify a patient's eligibility for a co-pay benefit during the enrollment, attestation and card activation process.

Proprietary McKesson Safeguards

Government Plan Exclusion
Unlike other co-pay support providers, McKesson, through its subsidiary RelayHealth, uniquely offers Government Plan Exclusion technology (GPE) to all pharmaceutical manufacturers who have implemented co-pay coupon programs with McKesson. Also, unlike secondary claims edit technologies subject to NCPDP data limitations and permissions, McKesson's pharmacy switch and GPE technology have visibility into the primary claim payer information at the BIN/PCN and Group ID levels. This allows GPE to apply data and deterministic, matching technology to identify known government payer plans during primary claim processing and automatically block secondary co-pay benefits before any medication is dispensed.

This unique safeguard – only available from McKesson – has been used to screen patients for co-pay benefit eligibility for over ten years, serving more than 700 pharmaceutical brands and 140 pharmaceutical manufacturers. GPE claims edits automatically apply for prescription claims processed in over 50,000 pharmacies, which process over 85% of all retail pharmacy prescription claims nationwide. GPE is available without charge to all pharmaceutical manufacturers who have partnered to provide co-pay assistance with McKesson.

GPE tables and technologies are applied several times throughout the enrollment and claims process to provide multiple layers of protection throughout McKesson programs.

GPE@Enrollment – ***Applied During Patient Enrollment Prior to Card Activation***

In an effort to actively prevent application of coupons to Federal health care claims, McKesson is leveraging its proprietary Government Plan Exclusion data and technology to provide screening during the enrollment process. With its GPE@Enrollment solution, McKesson is strengthening its portfolio and market leadership position by delivering a new, unique, solution which:

1. Verifies patient eligibility prior to card activation in real-time.
2. Blocks card activation for patients with known government health plans by leveraging proprietary GPE data.
3. Allows the application of this market-leading safeguard to any patient, using any pharmacy.

GPE@Enrollment can apply within all enrollment channels including web, live agent, IVR and mobile. It can also be applied for direct member reimbursement supporting the patient rebate process for eligible patients not able to receive a co-pay benefit at time of dispensing at their pharmacy.

Here's how GPE@Enrollment works. During the enrollment / card activation process:

1. Patients are asked to provide their primary insurance BIN, PCN and Group ID.
2. When primary insurance information is provided, the solution will compare the health plan information provided to the comprehensive database of known government plans – the same list of payer plans used by GPE logic within the primary claims process in over 50,000 pharmacies nationwide.
3. If there is a match between the patient's health plan information and the GPE payer plan data, the card will not be activated; if there is not a match, the card may be activated.

GPE@Enrollment

Screens patients during patient enrollment and before activation

GPE BIN/PCN/Group Exclusion – *Applied During Claims Processing in Over 50,000 Pharmacies*

The illustration below, shows how GPE works when a Federal health plan is a primary payer on a given prescription claim along with a co-pay offer administered by McKesson and submitted as a secondary claim.

Primary Claim (patient's health insurance plan):

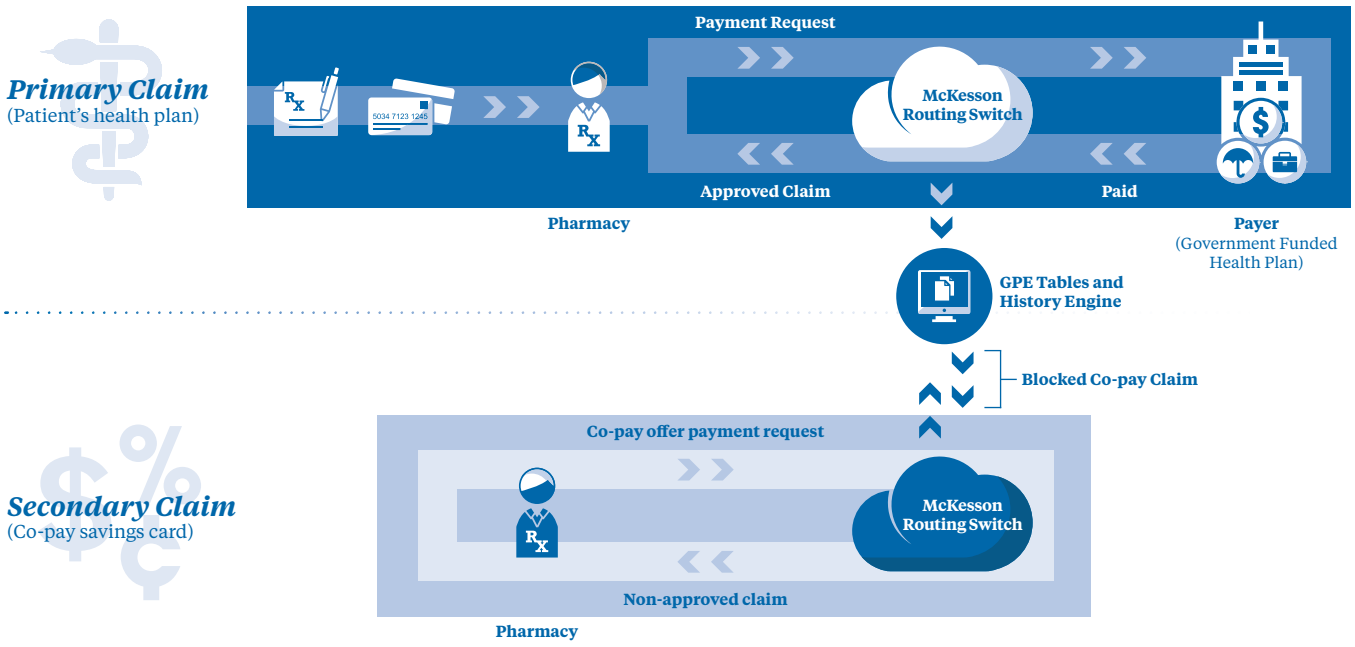
1. Pharmacist submits the primary claim for a patient with a Federal health plan.
2. GPE flags the transaction as a government plan claim within the GPE History Engine.

Secondary Claim: (co-pay savings card program).

1. Pharmacy submits the secondary co-pay coupon claim.
2. GPE performs a History Check to determine if a prior known government health plan claim was processed for that prescription fill.
3. If GPE finds a corresponding claim that was paid by a known government plan, it blocks the secondary claim and that claim is *not* transmitted to McKesson for co-pay benefit payment.
4. GPE sends a message notifying the pharmacist that the co-pay coupon claim cannot be processed because the primary claim was submitted to a known government plan.

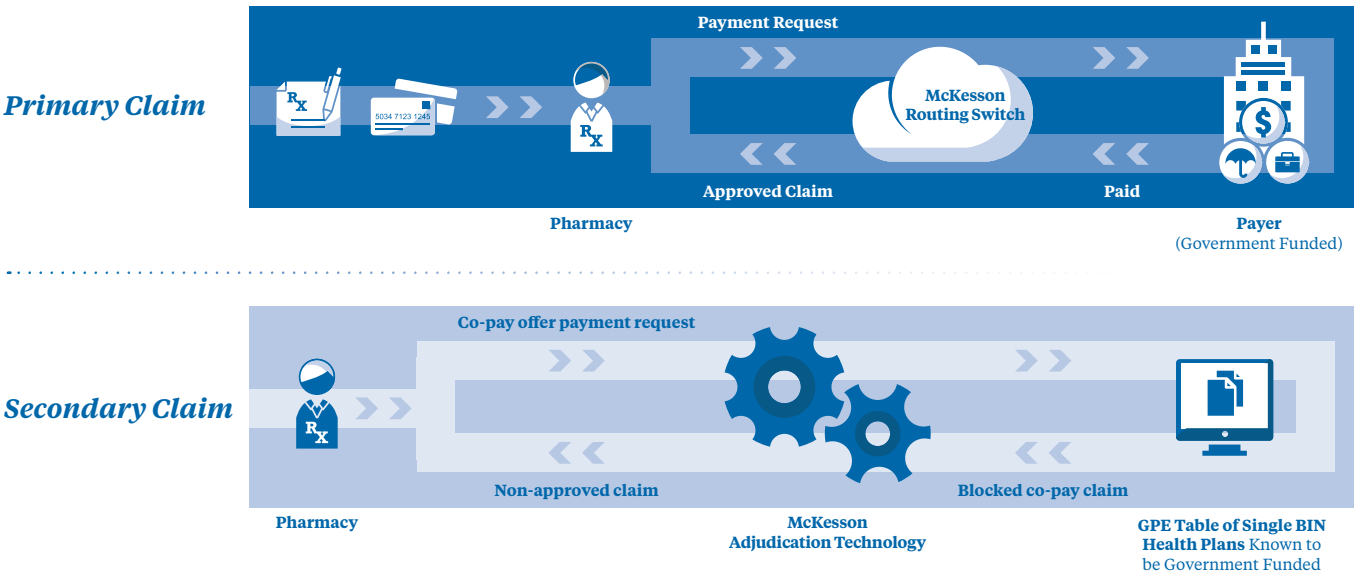
Government Plan Exclusion – Data and Logic

Applied during claims processing at over 50,000 pharmacies nationwide



GPE Single BIN Exclusion

Applied during claims processing at all pharmacies



GPE Single BIN Exclusion – ***Applied During Claims Processing At All Pharmacies***

Leveraging our claims adjudication technology, McKesson's GPE Single BIN Exclusion solution applies during co-pay claims processing at all pharmacies. Within the GPE Table of Health Plans, McKesson has identified a comprehensive list of known government health plans identified by a single BIN. All PCN and/or Group ID combinations within each BIN have been identified as government funded plans and the list is continually maintained by McKesson to help ensure currency. During the secondary claims process, McKesson adjudication technology has visibility to all primary payer BINs, which allows the system to identify these BINs in real-time and block co-pay benefits from applying at any retail pharmacy nationwide.

The illustration above shows a scenario where a primary payer is government funded and is a health plan which can each be identified by a single BIN as a government funded plan. In this scenario, the primary claim is approved, but the secondary claim is instantly blocked by McKesson's adjudication technology if there is a match of the patient's health plan BIN with any known, single BIN health plan.

Summary – Proprietary McKesson Safeguards

Benefits:

- Applies the most comprehensive, accessible list of government known plans
- Eligibility checks can be applied during enrollment, primary and secondary claims processes
- There is no requirement for collection of personal health information
- Public data sources are not required or accessed
- Eligibility checks can be applied to all patients, regardless of pharmacy used

Challenges:

- Proprietary McKesson Safeguards are available only in conjunction with McKesson copay solutions without significant cost to the pharmaceutical manufacturer

In addition to its proprietary safeguards, McKesson applies multiple other layers of safeguards to help ensure awareness and assist manufacturers, pharmacies and patients in determining appropriate eligibility for co-pay assistance programs as directed from the OIG.

What follows are safeguard options that are available at no cost to our manufacturers as a part of every McKesson run program. Cited below, you will find the benefits of these solutions, along with the challenges – specifically if used as a single offering. Although these are not proprietary, they are components that strengthen the overall compliance offering as a part of risk management.

Additional Layers of Safeguards Available from McKesson

Collateral and Exclusion Language – Patients

Printed and digital coupons

Manufacturers can include notices to patients on program materials, cards and coupons stating that co-pay cards and coupons are not permitted for use with prescription claims funded by Federal health care programs. Most, if not all manufacturers, reported using notices to patients stating that co-pay coupons may not be used to purchase medications paid for by Federal health care programs. These notices are widely used on printed and digital coupons.

Benefits:

- Clearly states exclusions for use on program collateral

Challenges:

- Font size and location can impede successful communication

Patient Attestation

During the enrollment process, the patient is asked to confirm their eligibility via specific questions related to their coverage by government-funded plans. Documented responses to the questions are required to proceed to activation of the program. This attestation can be applied across multiple enrollment channels, including live, web, text and IVR.

Benefits:

- Records patient provided confirmations to Federally mandated exclusion criteria

Challenges:

- Patient supplied responses can be open to patient reporting inaccuracies

Collateral and Exclusion Language – Pharmacies

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Manufacturers can include notices to pharmacists on program materials, cards and coupons stating that co-pay cards and coupons are not permitted for use with prescription claims funded by Federal health care programs. Most, if not all manufacturers, reporting using notices to Pharmacies stating that co-payment coupons may not be used to purchase medications paid for by Federal health care programs.

Benefits:

- Clearly states exclusions for use on program collateral

Challenges:

- Exclusion language does not ensure that appropriate exclusions are applied

Part D Benefit Stage Use within the Claim Edit

According to the September 2014 OIG report, twenty percent of manufacturers use claims edits that rely on the Part D Benefit Stage field within the prescription claims. That field contains data if the beneficiary for that claim has a Part D health plan. Claim edits that can identify data in this field can instantly block the coupon from being applied to the claim or send a message to the pharmacist to reverse the claim.

Some coupon vendors may have adjudication systems with limited access to the Part D Benefit Stage identifiers within the prescription claim. Why is the McKesson solution different? McKesson owns its adjudication technology and has optimized this technology to block secondary claims for Medicare Part D transactions by recognizing identified Part D Benefit Stage codes contained within the claim. Like our Government Plan BIN Exclusion solution, this technology can be applied to all secondary claims submitted by all pharmacies participating in co-pay coupon programs with McKesson.

Benefits:

- Provides additional deterministic approach to blocking excluded patients during the claims process

Challenges:

- Per NCPDP HIPAA Standards, the Part D Benefit Stage values may only be submitted on a COB claim if it is required for state/federal/regulatory agency programs
- The primary claim's Part D Benefit Stage is not indicated in all prescription claims
- Medicaid claims can't be identified by the Part D Benefit Stage information

Pharmacist Messaging

Although many pharmacists may be aware that use of co-pay card offers are not permitted for patients with Federal health claim benefits, most adjudication vendors, including McKesson, have claim adjudication technology that automatically sends a message to the pharmacist instructing them to reverse an approved claim if the patient is not eligible for co-pay assistance.

Benefits:

- Co-pay card eligibility requirements are reinforced with each prescription claim processed along with a co-pay card

Challenges:

- Pharmacists are often very busy and may not always read the message or act on it

Summary

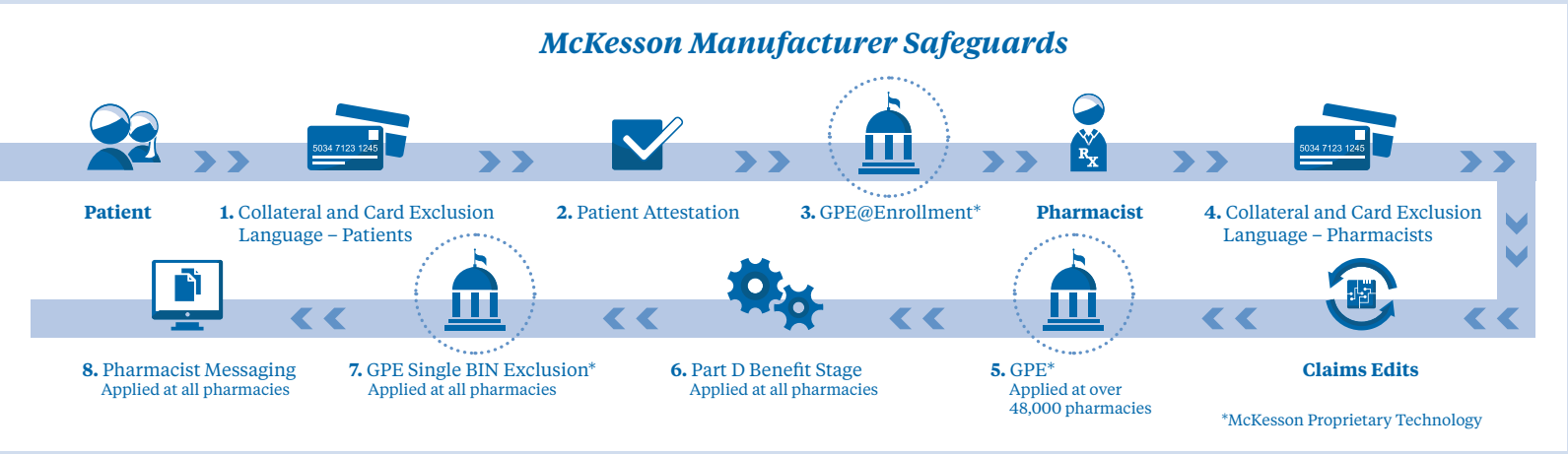
McKesson offers the most comprehensive portfolio of safeguards available in our industry to prevent coupon programs from inducing the purchase of medications paid for by Federal plans. Our portfolio includes eight levels of currently available safeguards to help support manufacturers in their regulatory compliance with patients, pharmacists and within the claims editing process. Although many co-pay solutions providers offer one or more of the safeguards listed above, three of these safeguards are only available from McKesson:

- **Government Plan Exclusion:** uses deterministic logic and comprehensive, known health plan BIN/PCN/Group ID data within the prescription claim edit
- **GPE@Enrollment:** applied during the enrollment process to screen patients prior to card activation and leverages the comprehensive data base on known government funded health plans maintained by RelayHealth, a McKesson joint venture
- **GPE Single BIN Exclusion:** leverages McKesson's claims adjudication technology and comprehensive data base on known government funded health plans to block co-pay offers from applying for beneficiaries with these known health plan at all pharmacies

Below is a graphic of how all 8 safeguards work throughout manufacturer program execution to help protect our customers and the patients they serve:

McKesson will continue to be actively engaged in the NCPDP WG9 OIG Report OEI-05-12-00540 Task Group's activity and progress, working closely with CMS and the OIG to develop solutions that can be used industry-wide to help support pharmaceutical manufacturer compliance with regulatory requirements. Great progress has been made since 2014 but it may be several years before these solutions are generally available for use by the entire market.

McKesson will also continue to fortify our portfolio of safeguards through expanded reach, comprehensive data and advancing technology, ensuring that we continue to lead the market in helping to protect our manufacturer partners in our collective commitment to compliance.



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1 Manufacturer Safeguards May Not Prevent Co-payment Coupon Use for Part D Drugs (OEI-05-12-00540), page 17

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