

2015

THE PHARMACY OWNER'S COMPLIANCE PLAYBOOK



INTRODUCTION

Medicare Part B, Part C and Part D; Food and Drug Administration (FDA), patient safety and compounding regulations are changing the face of pharmacy as we know it. Pharmacy compounding compliance is moving to a State-level enforcement. Medicare Part B is moving into its sixth year of accreditation. Medicare Part D auditors are increasing their responsibilities of enforcement of Fraud, Waste & Abuse, HIPAA Compliance and new pharmacy requirements from third party plans. At the same time, Medicare is rating Medicare Part D Plans under the Star Rating system, which depends on pharmacist, patient and physician involvement with patient care and medication adherence.

However, there is a disconnect between Part D auditors and Part D Medication Adherence requirements. The trick is understanding both sides of the requirements and using them to your advantage. Pharmacies focusing on how to succeed using Medication Adherence are the pharmacies that are considered high performing pharmacies and will remain in business in 2016 and beyond.

This playbook is a quick guide to what compliance strategies you need to implement immediately to stay protected. For more information on items mentioned in this playbook, we invite you to visit www.RJHedges.com/blog or schedule a consultation with our Compliance Advisors at www.RJHedges.com/calendar. As the nation's leading compliance and accreditation experts, we are here to help you stay stress-free and protected.

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An elderly couple is sitting on a brown leather couch in a bright room with large windows. The woman, on the left, has short grey hair and wears glasses and a red scarf. The man, on the right, is balding and wears a grey vest over a light-colored shirt. They are both looking at a laptop on the couch. The woman is holding a white paper. A blue semi-transparent banner is overlaid across the middle of the image, containing white text.

KICKING OFF MEDICARE PART D IN 2015

4 MEDICARE PART D CHANGES YOUR PHARMACY NEEDS TO IMPLEMENT

In 2013, new Medicare Part D changes went into affect with the full support of the U.S. Department Health & Human Services to uphold them. There are more auditors enforcing these continuously changing regulations. It's starting to make the previous years seem like "the good ole days."

4 PROCESSES YOU NEED TO ESTABLISH IN YOUR PHARMACY

1. **Training Record** - Have Fraud, Waste & Abuse prevention training records, training certificates and training logs for all your staff and document they have been completed every year.
2. **Updated HIPAA** - Have an updated HIPAA program in place...auditors have been specifically instructed to ensure your independent pharmacy has a new HIPAA program. Auditors can tell if you have a new program if your Notice of Privacy Practice has a date prior to 2013, you have not updated your program.
3. **Exclusion Verifications** - As part of the new Fraud, Waste and Abuse regulations, you need to be able to prove that you've been doing monthly exclusion verifications. The monthly verification involves going into the OIG website, GSA website, and SAM website and typing in all the names and businesses and printing reports for each name/business. The other, less time-consuming option is to use the automated system that we have within the R.J. Hedges Compliance Portal™ which will process everything and print out a report within 20 seconds. Our database is updated every time the GSA, SAM and the Office of the Inspector General update their database.
4. **Catamaran Checklist** - When a Catamaran, Humana or other Medicare Part D auditor arrives at your pharmacy, make sure you are keeping up with the CMS-10147 adherence documentation. If you receive a 569 error from your computer system because the transaction was rejected and the patient was not eligible to receive Part D coverage, this CMS-10147 document needs to be given to the patient to notify them of

what appeal rights they have. Catamaran auditors want you to document that you gave the patient the 10147 form, either in their patient notes, prescription history or within your pharmacy software. If the individual prescription does not permit a note, then place it in the patient profile with the RX number, date and note that you offered the 10147 document. That's all you need to do but be sure to add this to your to-do list! See page 12 for our Catamaran Play-by-Play Breakdown.

Following these simple steps, whether an auditor comes in or not, will get you on the path to compliance and help you avoid costly fines.

COACH'S TIPS: DID YOU KNOW?

NO PHARMACY IS SAFE FROM INSPECTION...

Part D auditors from the PBMs or Medicare Part D plans, now have ability to come into your pharmacy and validate that these training and exclusion verification documents are being completed. In the past, pharmacies were only required to say that they had completed these tasks, and no one came to double check these records in your pharmacy. In 2014, this changed. **Auditors will now come into your pharmacy to review all your documentation.**

If they do an audit and you fail to comply with any or all of these items or if say you did complete the trainings and verifications but actually did not, these auditors now have the ability to pull all your Medicare Part C and Part D reimbursements, **which can be anywhere from 40 - 50% of your prescriptions for that year.** This could be very devastating. Most independent pharmacies would not be able to survive a penalty like this, thus, it's extremely important your OIG/GSA/SAM checks are completed properly every single month. We have made our system as simple as possible in order to make running your business easier. Visit www.RJHedges.com to learn more about this great feature.

HOW CAN A PHARMACY LOSE MEDICARE REIMBURSEMENTS?

If a pharmacy has any employee, in any capacity, that is found on the OIG Exclusion list, the OIG or Part D auditors can pull back any and all Part D, and in certain instances Part B and Part C, reimbursements for every day the excluded employee has worked at the pharmacy. This means that the Office of the Inspector General has the right to demand the return of all reimbursement money you received for as long as that employee was on the exclusion list. To put it in perspective, on average in the United States, a Medicare prescription is filled for a patient every 5 minutes! How many Medicare patients does your business serve and how much money would you lose?

WHAT IS THE EXCLUSION LIST?

According to the Office of the Inspector General's site:

"OIG's List of Excluded Individuals/Entities (LEIE) provides information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid and all other Federal health care programs." The most common reasons people are on the OIG Exclusion list are for Medicare or Medicaid fraud, patient abuse or neglect, and felony convictions for health-care related fraud, theft or other financial misconduct.

WHAT HAPPENS IF AN EMPLOYEE IS ON THE EXCLUSION LIST?

The employee must be terminated immediately. If an employee is on the exclusion list and no action is taken, there is a very serious risk of losing all reimbursements for every Medicare Part D customer that employee has served.

The screenshot shows the official website of the Office of Inspector General, U.S. Department of Health & Human Services. The header includes the OIG seal and a search bar for reports, topics, and keywords. A navigation menu lists various sections: About OIG, Reports & Publications, Fraud, Compliance, Recovery Act Oversight, Exclusions, and Newsroom. The main content area is titled 'Search the Exclusions Database' and features a search form for individuals. The form includes fields for 'Last Name' and '(and/or) First Name', and buttons for 'Search' and 'Clear'. There are also links for 'Search For Multiple Individuals', 'Search For A Single Entity', and 'Search For Multiple Entities'.

HOW DO I CHECK THE EXCLUSION LISTS?

There are two ways you can check the exclusion lists:

- ☐ If you are an R.J. Hedges & Associates client with FWA access, log into the Compliance Portal™, click on the "OIG, GSA, SAM Exclusion Program" button, and click the "Print" link. Your project manager has already entered all your employees in the database so all you have to do each month is click the "Print" link, print and keep the documents in your binder. **The process is complete in just about 20 seconds.**
- ☐ If you are not an R.J. Hedges client, the process is tedious, but can still be accomplished. Go to <http://exclusions.oig.hhs.gov> and click "Search for Multiple Individuals." You can type in up to five individuals. Don't forget, if you have an employee that has used multiple names in the past, such as those with new surnames, you'll need to search those variations as well. Remember, the same process must be completed with the GSA and SAM website every month as well.

SCORING BIG IN 2015 AND BEYOND WITH MEDICARE ADHERENCE



WHY START A MEDICATION ADHERENCE PROGRAM?

Pharmacies that are doing a Medication Adherence program and doing it well, will succeed at the end of this year and continue thriving in 2016. The bad side to Medication Adherence is for the pharmacies that aren't doing a program. This seems to be about 50% of pharmacies currently. **If they continue to not participate and not embrace these changes, in 2016 and 2017, the Part D plans are going to drop these pharmacies from their network and these pharmacies will lose their patients.**


WHAT IS MEDICATION ADHERENCE?

Medication Adherence is simply having a patient have all of their prescriptions filled at the same time, or if they can't afford to have it in one batch, then at two times a month. This create a monthly schedule for the patient and pharmacy. The other requirement to Medication Adherence is that the pharmacist talk to the patients and their physicians and coordinate with their physician.

HOW TO PUT MEDICATION ADHERENCE TO PRACTICE:

Here's an example: Bob Smith, ABC Pharmacy's pharmacist, is planning to fill his patient's medications on Friday. According to ABC Pharmacy's Medication Adherence schedule, Bob calls his patient on Monday to have the following dialogue, "This is Bob at ABC Pharmacy. On Friday, we're filling your prescriptions in accordance with the adherence program. Have their been any changes? Have you been in a hospital? Have you seen your doctor? Has your doctor given you any new prescriptions? And do you have any questions?"

The patient gives Bob any feedback at that point in time and Bob documents that he spoke to the patient. Bob can do this in a patient chart or in the patient notes within his pharmacy software, whichever is convenient. Bob notifies the patient that their prescriptions will be ready on Friday so they can come into the pharmacy to pick them up. If the patient says, "I'm sorry, I can't be there on Friday," Bob can say, "Would you like us to deliver them to you Friday evening?" And at that point, the patient says, "Sure, send them to the house". In this example, the pharmacist is having



a conversation with the patient, providing helpful services, asking questions and asking if they need anything else. There is no downside here.

In the case of this patient and with most seniors that are getting 10+ medications, instead of getting a phone call a multiple times of month, and filling the prescription inefficiently, your pharmacy adherence schedule can now fill for Friday and do all 10 prescriptions at once.

BENEFITS OF A MEDICATION ADHERENCE PROGRAM - STAR RATINGS & EQUIPP SCORES

A key benefit of a Medication Adherence Program is having your EQuIPP scores rise, making your pharmacy more attractive to third party plans. Starting in late 2015 and specifically 2016, these third party plans are going to want high performing pharmacies so their Star Ratings increase. If their Star Rating is a 2 or lower, that insurance company's plan will be decertified by the Federal Government. However, if your Star Rating increases at the third party level and they are at a 5 star level, the insurance company will be allowed to market their healthcare plan year-round, which is a major change and a major advantage to them.

BENEFITS OF A MEDICATION ADHERENCE PROGRAM - PHARMACY PROFITS

From an adherence point of view, when a patient currently picks up their prescriptions, normally during a 30 day cycle, they typically call your pharmacy when they are out of their medication. In the case of Bob's patient, this would cause a long term issue without an adherence program. For example, today is Saturday and Bob's patient calls into the pharmacy to get her prescriptions refilled. Bob's patient leaves her prescription numbers, but does not pick them that day, leaving her without any medication. Bob's patient doesn't come in until Monday. For the pharmacy, Bob just lost 2 days on those prescription items. If Bob's patient continues to call when out of medication every month, that's 24 days of lost product during a year. Many pharmacies find situations where the patient is typically longer than 3 days without medication. With an Medication Adherence program, Bob's pharmacy can increase their fill for that patient by at least one additional fill per year. That is revenue that the pharmacy would have lost and now has picked up. And the patient continues to stay with Bob's pharmacy. This is a key point to the pharmacy's growth by changing from being reactive to proactive.

PLAY-BY-PLAY BREAKDOWN CATAMARAN AUDITS



The latest fear for pharmacy owners in this regulatory world is the Catamaran audit. Having shown up on the scene 2 years ago, Catamaran audits are impacting community pharmacies in a BIG way. To further keep you stress-free and in compliance, here's a breakdown of what you and your pharmacy staff need to know to prepare for a Catamaran audit and avoid penalties.

1. WHAT IS A CATAMARAN AUDIT?

Catamaran audits are a Medicare Part D auditor. The best way to explain a Catamaran audit is as a combination of a CMS onsite, state board inspection, and medicare accreditation survey all wrapped into one.

2. HOW DO I KNOW IF I'M GETTING A CATAMARAN AUDIT?

You'll receive a notice roughly two weeks before your scheduled audit with a specific date and time for when your auditors will visit your pharmacy.

3. WHAT WILL THE CATAMARAN AUDITOR LOOK FOR?

This list below will give you a good idea of the items you need to have in order right away and to avoid the severe penalties.

- **Licensure for the staff and pharmacist-in-charge**
- **CMS-10147 Adherence** - If you receive a 569 error from your computer system because the transaction was rejected and the patient was not eligible to receive Part D coverage, this CMS-10147 document needs to be given to the patient to share what their appeal rights are. The Catamaran auditor wants you to document that you gave the patient the 10147 form, either in their patient notes, prescription history or within your pharmacy software. If the individual prescription does not permit a note, then place it in the patient profile with the RX number, date and note that you offered the 10147 document. That's all you need to do but be sure to add this to your to-do list!
- **HIPAA Security** - The Catamaran auditor will look at how your HIPAA Compliance program is established including if you have the proper policies and procedures and if you and your staff doing the required training.



- **Fraud, Waste & Abuse Training** - The Catamaran auditor will check that you and your staff have conducted your annual training and have your training certificates and training logs.
- **OIG/GSA/SAM Validation** - The auditor will want to see that you have checked the OIG exclusions through all three entities, OIG, GSA, and SAM, every month. You'll also need to document that you have done these checks for every employee, every month. Fortunately, we have a very simple process within our Compliance Portal™ that shortens this task to only 20 seconds each month.
- **AHCA Compliance (for Florida only)** - If you are in the state of Florida, the Catamaran auditor is going to require you to have an accreditation and confirm that all criminal background checks have been completed. This is a Florida Medicaid requirement.
- **Pharmacy Insurance Coverage**
- **Agreements with Wholesalers** - Are your wholesalers listed in your Disaster Recovery Plan as required in your HIPAA Compliance program? Do you have an agreement between the pharmacy itself and the wholesalers that shows they are going to be your wholesaler? The auditor will also want to verify that your wholesalers as well as your business associates are listed on your OIG report for verification.
- **Record Retention** - The Catamaran auditor will also look at the record retention of your documents. Each organization has its own record retention requirement:
 - 2 years - State Pharmacy Board
 - 6 years - HIPAA Compliance
 - 7 years - Medicare Part B
 - 10 years - Medicare Part D (Catamaran)

Your records don't have to be located onsite. You can have them in another offsite and secured storage location or you can scan the records after two years and store them electronically as long as you have a good backup system.
- **Mail Order Volume and Compounding Volume** - As the audit continues, the Catamaran auditor will look at your mail order volume, meaning how many prescriptions are you sending by mail. For compounding pharmacies, they will be looking at how much compounding you are doing in a percentage basis compared to the rest of your business.
- **Specific Policies & Procedures** - And lastly, the Catamaran auditor will verify that you have specific policies and procedures including ones for:
 - inventory evaluation
 - patient counseling
 - mis-fill procedures
 - medication refill procedures

- medication expiration procedures
- return to stock
- generic/brand price disclosures
- demographics and allergy captures

A big change for most pharmacies in the country is that they have never had specific policies and procedures for their day-to-day operations. Catamaran is constantly adding additional procedure requirements to their audit checklist that many pharmacies will need to add these specific policies and procedures.

4. WHAT ARE THE RAMIFICATIONS OF FAILING A CATAMARAN AUDIT?

If discrepancies are found during your Catamaran audit, you may find your pharmacy facing a simple warning to 100% of your reimbursements being pulled. The most severe penalties are for not conducting your Fraud, Waste and Abuse, HIPAA training and OIG exclusion verification. If you cannot prove that you are running the OIG exclusion every month, Catamaran will report it back and the third party can pull 100% of the Part D reimbursements that you received for the period of time you were not doing the OIG exclusion. The worst part of this situation is that there is no appeal. **Most pharmacies could not withstand that loss and stay in business.**

5. WHAT CAN I DO TO CONFIDENTLY PREPARE FOR A CATAMARAN AUDIT?

At R.J. Hedges & Associates, we have created a thorough checklist to prepare you for the Catamaran audit. Your R.J. Hedges Project Manager will guide you through this process. It's ready for our clients to use immediately and included in our Fraud, Waste and Abuse Program. If you are not a current R.J. Hedges client and are not confident your pharmacy can pass a Catamaran audit, go to www.RJHedges.com/calendar to schedule a time to speak with our team to find the right solution for your pharmacy.

Preparing for a Catamaran audit is very important as the repercussions can be drastic. Right now, it's just a matter of time until a Catamaran auditor walks into your pharmacy. Several of our clients have already been audited, and while one did receive a warning for not documenting the CMS-10147 form, none had any penalties. R.J Hedges will continue to keep you informed so you can pass the Catamaran audit seamlessly as well.



As the nation's leading compliance experts, we at **R.J. Hedges & Associates** offer solutions for HIPAA, Medicare Part D, OSHA, Compounding, Fraud, Waste & Abuse, Immunization, Diabetic Shoes and more. We're here to help you protect your pharmacy with one-on-one personal support, compliance training, customized programs and documentation that can be accessed 24/7 and compliance standards created with your pharmacy business in mind.

Give us a call at **724.357.8380** or
[visit www.RJHedges.com/calendar](http://www.RJHedges.com/calendar) to meet with our compliance advisors.