PHARMACY COMPLIANCE GUIDE™
FDA, DEA, USP, PBMs, Medicare Part B, C, and D, patient safety, and audits are changing the face of pharmacy as we know it. Pharmacy compounding and USP <800> compliance will move to state-level enforcement. Medicare Part D auditors are increasing enforcement activities for Fraud, Waste and Abuse (FWA), HIPAA Compliance and pharmacy credentialing. Medicare continues to focus on Star Ratings for Medicare Part D plans. There is a disconnect in the understanding of medication adherence between Part D auditors and pharmacies. New USP <800> Hazardous Drug regulations going into effect at the end of 2019 are creating a lot of uncertainty and angst. In addition, the Cures Act goes into effect on January 1, 2020. That’s a lot to think about!

The goal of this guide is to help you make sense of the multitude of changes that are occurring in the compliance world, recognize how these changes impact the way you do business, and offer suggestions and solutions that you can implement to ensure that your pharmacy remains in compliance. For more information on the individual topics discussed in this pharmacy compliance guide, we encourage you to visit our blog or consult one of our Compliance Strategists. Our Compliance Strategists are trained to listen, help you identify compliance gaps, and guide you in eliminating these gaps so that your pharmacy is not only in compliance with existing regulations but also prepared in advance for the implementation of new and changing regulations.

WE’RE HERE TO KEEP YOU STRESS FREE AND IN COMPLIANCE! (TM)
# Table of Contents

1. **Medicare Part D in 2019:**
   What are the Regulations and How Do They Apply to My Pharmacy?
   - P. 4

2. **Medication Adherence:**
   How Can My Pharmacy Benefit from a Medication Adherence Program?
   - P. 10

3. **Audits and Inspections:**
   What Should I Expect When an Auditor Comes to My Pharmacy?
   - P. 14

4. **Competitive Bid Suspension:**
   How Should My Pharmacy Respond to the Suspension of Competitive Bid?
   - P. 18

5. **USP <800> Hazardous Drugs:**
   What Impact Will USP <800> Have on Daily Operations in My Pharmacy?
   - P. 21

6. **Final Thoughts**
   - P. 25
MEDICARE PART D IN 2019:
WHAT ARE THE REGULATIONS
AND HOW DO THEY APPLY
TO MY PHARMACY?
Did You Know...
No Pharmacy is Safe from a Compliance Inspection?

Did you know that PBM auditors have the right to enter your pharmacy to validate that required trainings are occurring and exclusion verification documents are being completed? Annual credentialing documentation is used to verify that the information you provide is accurate. Auditors from OptumRx and CVS/Caremark are requesting OIG reports by specific dates (month and year). OptumRx auditors will require you to provide documentation confirming that patients are receiving CMS-10147 when a “569” error for a non-formulary drug occurs.

Failure to comply with regulatory requirements or falsifying records to document completion of necessary trainings and verifications can result in auditors pulling all of your Medicare Part C and Part D reimbursements. These reimbursements can account for 40-50% or more of your prescriptions for any given year. A penalty of this magnitude would be catastrophic for most independent pharmacies and small, independent chain pharmacies.

In the following pages we will examine regulatory requirements and best practices to establish and maintain compliance. We will offer information and suggestions to proactively address regulatory changes on the horizon in 2019. Additionally, we will discuss some of the options and customized solutions that R. J. Hedges & Associates can provide to solve your most troubling compliance challenges.
Ensuring HIPAA Documents are Up-to-Date: The U.S. Department of Health & Humans Services (HHS)/Office for Civil Rights (OCR) and PBM auditors are checking for specific HIPAA documents in your pharmacy. They will ask to see your Risk Analysis, Risk Management, and Disaster Recovery Plan documents, as well as your Business Associate Agreements, Offshore Attestations, and annual Privacy and Security Assessments.

R.J. Hedges & Associates examines risk potential specific to your location and develops a risk management and disaster recovery plan that is customized for your pharmacy.

Securing Business Associate Agreements (BAAs)/Offshore Attestations: HIPAA regulations require and PBMs verify that you obtain BAAs/Offshore Attestations for any person/organization accessing/utilizing the Protected Health Information (PHI) you maintain on your patients. In an audit situation, you will be required to produce these documents for inspection.

R.J. Hedges & Associates can assist you in identifying your Business Associates, provide BAAs/Offshore Attestation ready for signature, and generate an annual reminder for BAA review and update.

Attestations are legally-binding statements that verify completion of Medicare Part D employee training requirements. Both the training and attestation to the training must be completed annually. Unfortunately, and to their detriment in an audit situation, many pharmacies sign the annual attestations without completing the required training.

R.J. Hedges & Associates has employee training programs available to assist you in meeting these requirements, checklists to walk you through completion of most PBM attestations with ease, and a system in place to provide you with annual reminders to ensure that completion of these requirements is not overlooked in the busy day-to-day operation of your business.

If you’ve done one have you really done them all? NCPDP is attempting to develop a standardized system for everyone to use. Many PBMs are using NCPDP’s data. However, several PBMs, like Express Scripts and CVS/Caremark, are mandating use of their own system, and Express Scripts even charges you for use of their system! Unfortunately, in these instances, the best course of action is to comply with PBM requirements. Otherwise, they can and will drop you from their plan.

R.J. Hedges & Associates has policies, procedures, and checklists in place to assist you in successfully navigating the process of securing credentialing/re-credentialing approval.
**PERFORMING EXCLUSION VERIFICATIONS**

FWA regulations require you to complete monthly exclusion verifications for all of your employees and “entities.” In simple terms, entities are HIPAA-defined business associates and any vendors you purchase products from and dispense to a Medicare patient. Verifications must be performed and completed on both the OIG and SAM websites and records maintained for 10 years, which can be a daunting, time-consuming task.

R.J. Hedges & Associates has developed an automated database system that streamlines this process, allowing for completion of the monthly verification requirement for both employees and entities in seconds (literally) vs. the time-consuming manual process of data input into two different websites. See “How do I check the Exclusion List” under “Frequently Asked Questions” at the end of this section for additional details.

**PROVIDING CMS-10147 FORMS**

If you receive a “569” error for a non-formulary drug, a CMS-10147 document must be given to the patient notifying them of their right to appeal. It is extremely important that you document provision of the CMS-10147 to patients, either in the patient notes, prescription history, or within the pharmacy software. If the individual prescription does not permit a note, then place it in the patient profile with the Rx number, date, and make comment that the CMS-10147 was provided.
FREQUENTLY ASKED QUESTIONS

CAN I LOSE MY MEDICARE REIMBURSEMENTS?

If a pharmacy employee – from the owner down to a 1099 contractor – is found on the OIG/SAM Exclusion List, auditors can revoke any or all Part D reimbursements for every day that the excluded employee worked in the pharmacy. In some instances, Part B and Part C reimbursements can also be revoked. To put it in perspective, the average pharmacy in the United States dispenses a Medicare prescription for a patient every five minutes! Take a moment to consider how many Medicare patients your pharmacy serves and the repercussions that losing Medicare reimbursements would have on your business. Additionally, when the Cures Act goes into effect on January 1, 2020, these requirements will also apply and impact your Medicaid reimbursements.

WHAT IS THE EXCLUSION LIST?

According to the Office of the Inspector General (OIG) website, the “List of Excluded Individuals/Entities (LEIE) provides information to the healthcare industry, patients, and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid, and all other federal health care programs.” Some of the most common reasons people are on the OIG Exclusion List are Medicare or Medicaid fraud, patient abuse or neglect, and felony convictions for healthcare-related fraud, theft, or other financial misconduct. For additional information on the OIG/SAM Exclusion List or LEIE and recommendations that will help you stay in compliance and protect your pharmacy, check out our Compliance Blog, “Staying off the Naughty List.”

WHAT HAPPENS IF MY EMPLOYEE IS ON THE EXCLUSION LIST?

An employee on the Exclusion List must be terminated immediately; this includes owners, employees, and 1099 contractors. Failure to take action poses a serious risk of losing all reimbursements for every Medicare Part B, C, and D customer served while the individual was employed.

HOW DO I CHECK THE EXCLUSION LIST?

Non-Clients:
The monthly verification process requires you to go to the OIG website. Click “Search for Multiple Individuals,” which allows you to enter a maximum of 5 names at a time. If you have an employee who has used multiple names in the past, including different surnames, each variation will need verified. Repeat this process as necessary until all of your employees and HIPAA-defined entities have been verified. The entire process must then be completed on the SAM website as well. Unfortunately, this can be a rather tedious and time-consuming process each month.

Clients:
If you are an R.J. Hedges & Associates client, you have access to our automated database system through our Compliance Portal®. Our process safeguards your reimbursements by ensuring that your employees, owners, vendors, and other business associates are in the clear in a fraction of the time (literally about 20 seconds) that it takes to manually input information into both the OIG and SAM websites. Your project manager will enter all of your employees and HIPAA-defined business entities into our system. Once your custom-
ized verification list has been created, all you need to do each month is log into the Compliance Portal®, click “OIG - SAM Exclusion Verification,” print out the generated report, and keep a copy for your records. Remember, an auditor can request proof that OIG/SAM verifications have been performed for any month/year within the past 10 years.

If our system identifies a potential red flag for an employee or entity, we have a process in place to confirm that there is indeed a problem. Just because a name is on the exclusion list does not mean it is your employee or entity. A simple call to your Project Manager will put the process in motion. With information you provide, your Project Manager will be able to fully investigate and determine whether the employee or entity is or is not on the Exclusion List. In those rare instances when an employee or entity is on the Exclusion List, you will be personally contacted by our President/CEO, Jeff Hedges, who will discuss and advise you on the steps that need to be taken to resolve the problem and protect your business.

VISIT OUR WEBSITE TO LEARN MORE ABOUT HAVING A CUSTOM-TAILORED PROGRAM CREATED FOR YOUR PHARMACY THAT WILL KEEP YOU COMPLIANT, HELP YOU PASS AUDITS AND INSPECTIONS, AND ALLOW YOU TO FOCUS MORE OF YOUR ATTENTION ON DAY-TO-DAY OPERATIONS AND LESS ON THE RED TAPE OF REGULATORY COMPLIANCE.
MEDICATION ADHERENCE: HOW CAN MY PHARMACY BENEFIT FROM A MEDICATION ADHERENCE PROGRAM?
If you haven’t fully embraced medication adherence, now is the time to start. Medication adherence plays an important role in improving STAR ratings and raising EQuiPP scores. Implementing a Medication Adherence Program increases patient engagement with pharmacy personnel. Increased patient engagement improves pharmacy-patient-physician relationships, strengthens patient loyalty, and fosters improved patient medication adherence. Pharmacies focusing on how to succeed using medication adherence are considered high-performing pharmacies and will continue to succeed.

WHAT IS MEDICATION ADHERENCE?

Simply stated, medication adherence is filling a patient’s prescriptions at the same time each month, either once a month or bi-monthly if a patient is struggling to financially afford synchronizing medication refills to a single transaction each month. Medication adherence also requires pharmacies to communicate and educate patients in regard to medication usage and to coordinate with the patient’s physician as necessary.

WHY PARTICIPATE IN MEDICATION ADHERENCE?

Pharmacies that have a successful Medication Adherence Program in place are very desirable to Part D plans. By syncing patient medications and participating with Medication Therapy Management (MTM) and required documentation in OutcomesMTM or Mirixa software, pharmacies are planting seeds for improved patient care and additional billable services which have the potential to positively impact a pharmacy’s bottom line. Pharmacies that are not moving toward medication adherence risk being dropped from their PBM networks resulting in loss of patients and decreased revenue.
WHAT ARE THE ADDED BENEFITS OF A MEDICATION ADHERENCE PROGRAM?

There are four distinct benefits of a Medication Adherence Program:

1. DEVELOPMENT OF A PERSONAL RELATIONSHIP WITH YOUR PATIENTS

Statistics show that when a patient feels valued, they tend to be more loyal. It only takes a few minutes to show your patient that you care and are willing to go the extra mile. In return, they will be less likely to shop around.

2. IMPROVEMENT OF STAR RATINGS AND EQUIPP SCORES

Achieving high Star Ratings requires pharmacist, patient, and physician involvement in overall patient care and medication adherence. Third-party plans seek to partner with high-performing pharmacies in order to boost their Star Ratings. As your pharmacy’s rating increases and the insurance company is at a five-star level, they are permitted to market their healthcare plan year-round rather than only during the open enrollment period. Studies prove that high Star Ratings positively impact patient health and help drive down healthcare costs.

3. MAXIMIZATION OF REVENUE

When it comes to refilling prescriptions, there is a 2-day average lapse between the time a patient requests a refill and the time the prescription is actually picked up by the patient. This translates into 24 days of lost product and lost revenue each year. Implementing a Medication Adherence Program, provides a pharmacy with at least one additional fill annually, minimizes the amount of lost revenue, and ultimately changes a pharmacy’s growth from reactive to proactive.

4. OPTIMIZATION OF WORKFLOW

Gone are the days of waiting for physicians to call, fax or eScript prescriptions into the pharmacy or waiting for patients to call in refills, leaving you at the mercy of the phone and fax machine. When you have a good Medication Adherence Program, everything is scheduled resulting in improved workflow, better staff organization, and maximization of staff labor.
### WHAT IS INVOLVED IN PUTTING MEDICATION ADHERENCE INTO PRACTICE?

Medication adherence should NOT be complicated! The following scenario demonstrates medication compliance in action:

On Monday, Pharmacy Tech Smith calls Ms. Jones to let her know that her prescription refills will be ready for pick-up on Thursday. While speaking with Ms. Jones, Pharmacy Tech Smith asks her the following questions:

- Have you been in the hospital recently?
- When did you last see your doctor?
- Have you started taking any new prescription or over-the-counter medicines?
- Do you have any questions or concerns about your medications?

Pharmacy Tech Smith wishes Ms. Jones a good day, ends the call, and documents the conversation by entering notes in her chart in the pharmacy’s software.

A key difference between this type of patient contact and having an auto-fill system in place is that the pharmacy can be made aware of changes in the patient’s medical history and/or changes in medication. The pharmacist is readily available to intervene during the call to answer questions or alleviate any concerns the patient may have. This ensures that the patient is receiving the most up-to-date refills, highlights possible drug interactions, builds patient rapport, and allows opportunity for patient education and service recommendations with the goal of improving patient outcomes and increasing your pharmacy’s business.

---

**IF YOU ARE INTERESTED IN FURTHER EXPLORING HOW TO IMPLEMENT A MEDICATION ADHERENCE PROGRAM IN YOUR PHARMACY, CONSULT A COMPLIANCE STRATEGIST AT R.J. HEDGES & ASSOCIATES TODAY.**

**OUR PHARMACY COMPLIANCE PROGRAM INCLUDES:**

- Detailed medication adherence program set-up procedures;
- Customized marketing materials for your pharmacy;
- Patient enrollment policies, procedures, and support documents; and
- Patient management processes.

---

**MEDICATION ADHERENCE: HOW CAN MY PHARMACY BENEFIT FROM A MEDICATION ADHERENCE PROGRAM?**
AUDITS AND INSPECTIONS:
WHAT SHOULD I EXPECT WHEN AN AUDITOR COMES TO MY PHARMACY?
The largest concern in the regulatory world for pharmacy owners is the dreaded audit. The dramatic increase in the frequency of audits is negatively impacting community pharmacies. Following is a summary of the information and documentation you and your staff will need to have available in preparation for an audit.

**NOTE:** Due to the stringent nature of these audits, the following information is based on OptumRx audit requirements.

**WHAT IS AN AUDIT?**

PBM audits are a Medicare Part D audit. In relation to the information and documentation you will be required to produce, these audits are best described as a combination of a CMS on-site visit, a state board inspection, and a Medicare accreditation survey all rolled into one.

**HOW DO I KNOW IF I’M BEING AUDITED?**

You will usually receive a notice approximately two weeks in advance of your scheduled audit. The notice will provide you with the specific date and time when the auditor will visit your pharmacy.

**WHAT WILL THE AUDITOR LOOK FOR?**

The list below provides a summary of the items and documentation that need to be made readily available for the auditor’s review upon request in order to avoid non-conformances and potential penalties:

1. **Current licensure for the staff and pharmacist-in-charge.**

2. **Evidence of CMS-10147 adherence:** The auditor will request documentation demonstrating that CMS-10147 was provided to patients informing them of their right to appeal for all transactions that generated a “569” non-formulary drug error within an auditor-identified timeframe. This documentation can occur in 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 a note that the CMS-10147 was offered to the patient.
3. Documentation of compliance with HIPAA regulations: The auditor will examine your HIPAA compliance program including establishment of required policies and procedures and documented proof that annual employee training requirements are being met. NOTE: In addition to OptumRx/PBM audits, HIPAA inspectors for OCR have increased the number of on-site inspections being performed and have also started performing desk audits. If you receive notice of an OCR Desk Audit, the following items will be requested:
   - Notice of Privacy Practices (NOPP)
   - Risk analysis
   - Risk management plan
   - Disaster recovery plan
   - Annual privacy/security assessments
   - Policies and procedures.

4. Documentation of FWA training: The auditor will ask to see training logs and signed certificates confirming that you and your staff have completed annual FWA training requirements. Your records will be used to validate the information you provided on your annual FWA Attestation.

5. Confirmation of OIG/SAM exclusion verification: The auditor will request documentation that OIG/SAM exclusion verifications are being completed on a monthly basis for all of your employees and HIPAA-defined entities. Be sure to retain an actual hard copy of the printed record for at least one year. Records may then be kept electronically and must be retained for 10 years. The auditor will not consider an email stating that you have no one on the exclusion list to be adequate documentation.

6. Confirmation of record retention: The auditor will verify that records are being retained for the required amount of time. Requirements for retention include:
   - State Pharmacy Board and DEA – 2 years
   - HIPAA only – 6 years
   - Medicare Part B – 7 years
   - Medicare Part D, HIPAA, and FWA (training and OIG reports) – 10 years.
Records do not have to be located on-site. They can be stored in a secure, off-site storage location. After 2 years, electronic record storage is also a viable, acceptable option in most instances as long as you have a good back-up system. However, confirmation that electronic record storage is permissible in your state is advised prior to implementing this storage method.

7. Verification of mail-order volume and compounding volume: The auditor will check your mail-order volume, i.e., the number of prescriptions you are sending by mail. Additionally, if you are a compounding pharmacy, the auditor will compare the percentage of compounding performed with the overall percentage of your business.

8. Supporting policies and procedures: The auditor will confirm that policies and procedures are in place including but not necessarily limited to the following topics:
   - Generic/brand price disclosures
   - Inventory evaluation
   - Medication expiration
   - Medication refill
   - Mis-fills
   - Patient counseling
   - Return to stock
   - Demographics and allergy captures.

9. Prescription review: The auditor will present a list of prescriptions for review. Usually the number of prescriptions requested is between 50-100, but this number can be lower or higher at the auditor’s discretion.
WHAT ARE THE RAMIFICATIONS OF FAILING AN AUDIT?

Discrepancies found during an audit can trigger a number of responses ranging from a simple warning to complete cancellation of your contract. The most severe penalties are issued for failing to conduct FWA training, HIPAA training, and OIG/SAM exclusion verifications. Failure to prove that you are running the OIG/SAM exclusion every month, can result in a 100% pull back of Part D reimbursements. Worse yet, in this situation, there is no appeal process.

WHAT CAN I DO TO CONFIDENTLY PREPARE FOR AN AUDIT?

Advance preparation is key. The repercussions for being ill-prepared for an audit can be catastrophic for your pharmacy. The reality is that it is no longer “if” an auditor walks into your pharmacy but “when” an auditor walks into your pharmacy. After reviewing the above information, if you are confident that you have all the components in place to successfully satisfy the requirements of an audit, great!
COMPETITIVE BID SUSPENSION:
HOW SHOULD MY PHARMACY RESPONS
TO THE SUSPENSION OF COMPETITIVE BID?
Competitive Bidding was suspended nationwide on December 31, 2018. It is unclear at this time whether we will see Competitive Bid dropped as a failed experiment or reinstituted with a larger product line. However, at a minimum, CMS expects this gap in the Competitive Bid Program to last until December 31, 2020. This provides pharmacies and DME facilities located in competitive bid zones the opportunity to re-enter the full DME market. Another important date is January 1, 2020, which is when the Cures Act will go into full force. The Cures Act will require state Medicaid programs to follow all Medicare requirements, including fee schedules and possibly accreditation.

**WHAT DO I NEED TO DO TO START DISPENSING ITEMS THAT WERE OFF LIMITS DUE TO COMPETITIVE BID?**

The process to be granted approval to dispense and bill Medicare for products/services previously off limits due to Competitive Bid varies depending on accreditation status and PTAN status. Pharmacies will fall into one of following categories:

1. **Exempt**

Exempt pharmacies are those who have either been grandfathered into the program many years ago OR have been granted exemption after 5 years of accreditation with billing for DMEPOS of less than 5% of pharmacy sales. In order to begin providing products previously on the Competitive Bid List, an exempt pharmacy will simply need to identify the products/services they wish to dispense, complete any necessary training or licensures requirements for the products/services (this information can be found on the NSC website), and submit an updated CMS-855S. Upon approval, the pharmacy can begin dispensing and billing Medicare.
2  ACCREDITED

Pharmacies currently accredited by one of the 9 Accreditation Organizations are able to follow the same simple process as exempt pharmacies, described above. The big difference is that accredited pharmacies must first contact their Accreditation Organization and have the products/services added to their accreditation certificates prior to submitting the CMS-855S. NOTE: The Accrediting Organization may require a small processing fee and/or another on-site survey.

3  PHARMACEUTICAL PTAN ONLY

Pharmacies with a pharmaceutical PTAN only have never been accredited or dispensed DMEPOS items before but have completed a CMS-855S for Non-Accredited Drugs. The good news is there is already a PTAN in place that will simply need updated using the same process as Exempt and Accredited pharmacies, described above. The bad news, is that application for accreditation will need to be made and approved before the update to the CMS-855S can occur. The accreditation process can take a minimum of 45 days and often longer.

4  LOOKING TO ENTER THE DMEPOS MARKET FOR THE FIRST TIME

Our fourth and final category is for those pharmacies looking to enter the DMEPOS market for the first time. It can take up to a full year to work through the process of obtaining accreditation and a PTAN before any products/services can be dispensed or billed to Medicare.

IF YOU ARE A CLIENT OF R.J. HEDGES & ASSOCIATES AND ARE INTERESTED IN DISPENSING DMEPOS ITEMS FOR THE FIRST TIME OR ADDING TO THE PRODUCTS/SERVICES YOU CURRENTLY DISPENSE, CONTACT YOUR PROJECT MANAGER WHO WILL BE HAPPY TO GUIDE YOU THROUGH THE PROCESS.

IF YOU ARE NOT A CLIENT BUT ARE INTERESTED IN MORE INFORMATION ON BECOMING ACCREDITED, APPLYING FOR A PTAN, OR ADDING DMEPOS SERVICES, CONTACT US. OUR HIGHLY-QUALIFIED TEAM IS READY TO DISCUSS THE RIGHT SOLUTION FOR YOUR PHARMACY!
USP <800> HAZARDOUS DRUGS: WHAT IMPACT WILL USP <800> HAVE ON DAILY OPERATIONS IN MY PHARMACY?
USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings has been posted and will go into effect on December 1, 2019. While the National Institute for Occupational Safety and Health (NIOSH) defines criteria and identifies Hazardous Drugs (HDs), it is USP who develops standards for safe handling of HDs and minimization of public health risks. It is important to begin taking steps in advance of the official implementation date to ensure your pharmacy is prepared to comply with <USP> 800 standards.

WHAT IS USP <800>? 

USP <800> is a set of standards developed to help increase awareness, provide uniform guidance, protect patients, and reduce occupational risks for healthcare workers managing hazardous drugs.

WHO WILL BE AFFECTED BY USP <800>? 

Many people believe USP <800> will only affect compounding activities. However, the reality is that every pharmacy dispenses HDs listed on the NIOSH list and will be affected.

WHAT STEPS SHOULD I BE TAKING NOW TO ENSURE THAT MY PHARMACY IS PREPARED FOR THE IMPLEMENTATION OF USP <800>? 

The upcoming months are going to be all about preparation. We’ve passed along some preliminary information and a few initial steps to our clients to get things rolling:

1. Regardless of type of pharmacy you operate, the first step to begin preparing for USP <800> is to segregate all HDs within the pharmacy and start an inventory. Segregation can be as simple as a dedicated shelf on a shelving unit or as complex as a dedicated segregation room depending on the individual pharmacy’s operation.

2. Safety Data Sheets (SDSs) must be acquired for each HD in order to identify safety requirements and need for personal protective equipment.

3. Pharmacies dispensing HDs that are only counted and re-packaged from a manufacturer’s container, must complete an Assessment of Risk. The HD can then be prepared for dispensing with no further containment requirements. NOTE: All HDs are prohibited from being placed in automated medication machines (robots) or run through pill counters. Pharmacies dispensing more than standard tablets and capsules will see a larger impact on daily operations from USP <800>.
R.J. HEDGES & ASSOCIATES HAS BEEN PREPARING FOR USP <800> FOR SOME TIME NOW. THE POLICIES AND PROCEDURES AFFECTED BY USP <800> HAVE BEEN INTEGRATED INTO OUR PHARMACY PROGRAM AND COMPOUNDING PROGRAM LOCATED ON THE COMPLIANCE PORTAL® TO ENSURE OUR CLIENTS ARE UP-TO-DATE AND PREPARED.

EACH MONTH BETWEEN NOW AND THE LAUNCH DATE FOR USP <800>, OUR MONTHLY CLIENT TASK LISTS WILL WALK OUR CLIENTS STEP-BY-STEP THROUGH THE IMPLEMENTATION PROCESS, AND OUR MONTHLY CLIENT NEWSLETTER WILL HIGHLIGHT A DIFFERENT ASPECT OF HOW PHARMACY OPERATIONS WILL BE IMPACTED.

IN ADDITION, OUR KNOWLEDGEABLE TEAM IS AVAILABLE TO ANSWER QUESTIONS AND ASSIST OUR CLIENTS.
6 FINAL THOUGHTS
Is your pharmacy 100% compliant?

Go to www.rjhedges.com to take our FREE assessments and find out!

Keeping up-to-date with compliance standards to meet insurance, state, and federal requirements can feel like a second job. R.J Hedges & Associates has been providing compliance solutions to pharmacies, small and large, for over 14 years. Compliance services include Pharmacy, DMEPOS, HIPAA, Medicare Part D, OSHA, Compounding, FWA, Immunizations, Diabetic Shoes, and more. We’re here to help you protect your pharmacy with one-on-one personal support, compliance training, customized programs, and policies, procedures, and supporting documentation that can be accessed 24/7.

GIVE US A CALL AT (724) 357-8380 OR VISIT OUR WEBSITE TO SPEAK WITH A COMPLIANCE STRATEGIST TODAY!