2012 Checklist for Community Pharmacy

Medicare Part D-Related Information

Medicare Part D Valid Prescriber Identifiers

For 2012, CMS will continue to permit the use of any one of four types of prescriber identifiers (NPI, DEA number, UPIN, or state license number). Note that some plans may already require pharmacies to use the NPI as the only allowed identifier on Medicare Part D prescriptions. CMS has instructed plans to not reject a pharmacy claim solely on the basis of an invalid identifier unless the issue can be resolved at point-of-sale. However, if a valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire a valid ID of one of the four acceptable types. Sponsors have the option to either build their own systems or contract with commercial vendors for prescriber ID validation services. CMS expects that network pharmacies will either contractually agree to provide some of the prescriber ID validation services themselves or will fully support any retroactive review of the prescription and other pharmacy records by the Part D sponsor necessary to retrospectively identify the prescriber and obtain a valid identifier. **Pharmacies must submit valid prescriber identifiers with all Medicare Part D claims in accordance with the contractual terms of your agreements.**

Note that for 2013, CMS plans to accept only valid NPI numbers on Part D PDE records and will not accept any other valid prescriber identifier. Nonetheless, CMS will not require hard edits at the point of sale, and therefore will require Part D sponsors to allow pharmacies the opportunity to retrospectively correct any identifier errors.

Valid DEA Numbers on Medicare Part D Prescriptions

Effective January 1, 2012 Part D sponsors will be required to confirm the validity of prescriber DEA numbers on Medicare Part D Schedule II-V drug claims or map NPIs on these claims to the prescriber's DEA numbers. In addition, sponsors will be required to confirm that the controlled substance is within the prescriber's scope of practice to prescribe. CMS has clarified that the scope of practice requirements are no more extensive than those federal and state requirements that are already in place. **Pharmacists should take care to confirm the validity of prescribers' DEA numbers and confirm that controlled substances are within the prescriber's scope of practice. Failure to do so may open the pharmacy up to potential audits and recoveries by Part D sponsors.**

New Special Election Periods for Medicare Beneficiaries

In 2012, CMS will establish a Special Election Period (SEP) that will allow non-LIS Medicare beneficiaries to change their current plan one time to enroll in a 5-star MA-PD or PDP plan. The annual SEP became available December 8, 2011. Enrollment requests made using this SEP will be effective the first of the month following the month the enrollment request is received (January 1–December 1). Once an individual enrolls in a 5-star MA plan or PDP using this SEP, the individual's SEP ends for that plan year, and the individual will be limited to making changes only during other applicable election periods (e.g., annual enrollment period or another valid SEP). Individuals enrolled in a plan with a 5-star overall rating may also switch to a different plan with a 5-star overall rating. Note that the following are the only four 5-star PDP plans and none of them are national PDP's: Simply Prescriptions, HMSA's Medicare Rx Plan, MedicareBlue Rx, and ODS Health Plan, Inc. **Pharmacists should be aware and prepared that some beneficiaries will be changing PDPs in 2012 under the new SEP rules.**

New Adherence Measures Used to Calculate Medicare Part D Plan Ratings

CMS is using a new star rating system to rate Part D plans. In 2012, plan ratings measures will be weighted more on outcomes and patient experience measures such as medication adherence, along with process-based measures such as customer service waiting times. There are three new measures included in the new plan ratings related to medication adherence, which will be measured by a proportion of days covered methodology developed by the Pharmacy Quality Alliance (PQA). More specifically, CMS is adding the medication adherence measures to the star rating analysis in the following three therapeutic categories: Cholesterol (statins), Hypertension (ACEI or ARB) and Oral Diabetes Medications. As the star rating system matures, plans will be focusing on their network pharmacies in terms of performance related to adherence measures. **Pharmacists should work with all Medicare Part D patients to ensure proper adherence.**

Co-branding Requirements Now Prohibit PBM Names on Part D Member ID Cards

For the 2012 plan year, CMS will prohibit PBMs from including their names on Part D member ID cards. Additionally, Part D plans are prohibited from including a pharmacy's name or logo on their member ID cards, even if the pharmacy is a preferred network pharmacy. **Pharmacists should be aware of these rules and report to NCPA any Part D member ID cards with PBM names, pharmacy names, or pharmacy logos on them.***

Monitor Your Patients to Ensure That They Are Part D Patients and Not Hospice Patients

For 2012, CMS has instructed Part D plans that they should not be paying for claims for medications that are the responsibility of a hospice provider, particularly in long-term care facilities. However, CMS suggests that unless the plan has information available at point-of-sale to determine payment responsibility, Part D sponsors should pay the claims for drugs furnished to members enrolled in a hospice program that may be covered under the hospice benefit and retrospectively determine payment responsibility. This means that Part D sponsors may seek recoupment from the pharmacies if the claims are processed incorrectly through Part D. CMS will be providing future guidance regarding how sponsors should identify hospice drugs and whether sponsors should establish a point-of-sale prior authorization edit, or pay the claim at point-of-sale and make a retrospective Part A vs. D payment determination. **To avoid potential recoupment, pharmacists should work with their patients to determine, to the best of their ability, whether or not a patient is a hospice patient or Part D patient.**

Standardized Notice Must Be Distributed by Pharmacies to Part D Patients When Prescriptions Are Denied at Point of Sale

In prior years, when a Part D beneficiary's prescription could not be filled, the pharmacist was required to direct the patient to a posted sign in the pharmacy, which detailed the patient's appeal rights. For 2012, CMS is requiring pharmacies to print, at the point of sale, a standard form notice, in 12-point font, detailing the Part D beneficiary's appeal rights when a claim is denied. This is only applicable when a prescription cannot be covered and the patient's claim is completely rejected at the point of sale. Please work with your pharmacy management system vendor to see if the notice can be automatically generated. The plan is responsible for notifying the pharmacy that the claim is denied and a notice is required, but the pharmacy bears the responsibility for printing out and providing the notice to patients.

A finalized version of the notice will be available at: *http://www.cms.gov/MedPrescriptDrugApplGriev/14_PlanNoticesAndDocuments.asp#TopOfPage*.

Also be aware that in the LTC context, CMS expects pharmacists to contact the prescriber or appropriate LTC staff person to resolve Part D coverage denial issues, obviating the need for delivery of the notice to the patient. **Pharmacists must be prepared to distribute the standardized notice for Part D patient coverage denials starting no later than 90 days after the final notice has been approved. Note that CMS has yet to approve the final notice.**

Medicare Part D Sponsors Must Use a Written Model Transfer Letter to Transition Patients to a Different Network Pharmacy

Medicare Part D plans are increasingly using various methods to transition patients away from their current community pharmacies and into mail order or preferred pharmacies. Some Part D plans may be violating CMS guidance by automatically transferring patients without their consent or by making outbound phone calls to beneficiaries encouraging them to transfer prescriptions to mail. CMS guidance requires that plans must send model transfer letters to Part D beneficiaries to choose whether to accept the transfer or not. CMS originally implemented this policy in 2009, and the policy requires Part D plans to send a written notice to beneficiaries to seek their consent to transition their medications to a new pharmacy. The Part D plan cannot transfer a beneficiary's medications to a new pharmacy unless the beneficiary provides permission by calling the plan or pharmacy or via written statement sent in the mail. **Pharmacists should be aware of this policy and report any violations to NCPA.***

Computer Generated Fax Transmissions for Transmitting Part D Prescription Information

Presently, entities that transmit prescriptions or prescription-related information for Part D covered drugs prescribed for Part D eligible individuals by means of computer generated fax are exempt from the requirement to utilize the NCPDP SCRIPT standard. However, this computer generated fax exemption will be eliminated on January 1, 2012. However, e-prescribing remains voluntary for prescribers and pharmacies. **If the prescriber has adopted e-prescribing and the pharmacy is enabled and is accepting Part D prescriptions electronically, then the pharmacy must also send refill requests electronically and not via computer generated faxes. Pharmacies should work with their pharmacy management system vendors to verify system capabilities.**

Compliance With NCPDP Telecommunications Standard D.0

Pharmacies and other health care providers and payers must be prepared to use the updated X12 Version 5010 and National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard D.0 in HIPAA standard transactions starting January 1, 2012. As of that date, NCPDP version D.0 becomes the mandatory HIPAA standard for submitting pharmacy claims electronically. Pharmacies that submit an electronic claim in 2012 using NCPDP version 5.1 will receive a reject message. Despite January 1 being the compliance date, CMS has stated it will not initiate enforcement action until March 31, 2012, with respect to any HIPAA-covered entity not in compliance with the ASC X12 Version 5010 (Version 5010), NCPDP Telecom D.0 (NCPDP D.0) and NCPDP Medicaid Subrogation 3.0 (NCPDP 3.0) standards. Please click here to access the NCPDP Version D.0 Editorial Document: *http://www.ncpdp.org/members/pdf/VersionD.Editorial.pdf*. **Pharmacies must work with their pharmacy management system vendors to ensure that all electronic transactions meet the new standards.**

Medicare Part D Unique BIN/PCN Combinations

Because pharmacies cannot routinely distinguish Medicare Part D claims from other types of prescription drug coverage when the same routing information ("RxBIN and RxPCN") is used for all lines of business managed by a single processor, CMS is requiring, as of January 1, 2012, that plan sponsors and their intermediary processors use unique RxBIN or RxBIN/RxPCN combinations to identify all Medicare Part D member claims, as well as to assign unique "RxID" identifiers to individual Part D beneficiaries. NCPA supported this change as it will make the reconciliation process easier, as an example. During reconciliation, pharmacies will be able to more clearly differentiate their Part D patients and line of business from their other patients and lines of business. **Pharmacists should be aware of this transition to unique BIN/PCN combinations and be prepared to update patient insurance profiles with this new information.**

Submission of 4Rx Data on All Part D Claims

Because starting January 1, 2012 all Part D plans must have a unique BIN or BIN/PCN for only Part D business, CMS has directed that specific data elements must be submitted via every Part D pharmacy claim. The term "4Rx" is being used to describe these elements that must match what is submitted to CMS via the MARx file for all transactions. The term "4Rx" refers to four elements:

- RxBIN—Part D Rx Bank Identification Number (BIN)
- RxPCN—Part D Rx Processor Control Number (PCN)
- RxGroup—Part D Rx Group (Group ID) and
- RxID—Part D Rx ID for the beneficiary (Cardholder ID).

The intent of the directive is to ensure that: 1) Pharmacies can routinely identify situations in which they are billing a Medicare Part D claim, and 2) Payers supplemental to Medicare Part D can properly coordinate benefits on Part D claims.

Where possible, pharmacies should input numbers for all four elements of 4Rx data on submitted claims and apply it to the patient profiles in their systems. Note that some plans may not have all four elements. If the pharmacy suspects the member has Medicare coverage, and does not receive 4Rx data from the processor in the response to a rejected claim, the pharmacy should check the OHI (other health information) field for clarification information, seek the correct information from the plan, request a member ID card, or perform an Eligibility Verification transaction through an E1 query to update patient profiles.

Please note that CMS has announced that it will delay the mandate to provide all four 4Rx data elements until April 1, 2012. **Individual plans may start implementing 4Rx hard edits before April 1, 2012, but the CMS directive is not effective until April 1, 2012. When possible, pharmacists should update the patient profile proactively and work with their pharmacy management system vendor to ensure the smoothest transition. Please note that while this requirement is specific to Medicare Part D, it will impact commercial and other payers supplemental to Part D.**

Medicare Part B-Related Information

Medicare Part B DME Accreditation Exemption Reminder

As a reminder to pharmacies that are Part B DME suppliers, if you are a currently accredited pharmacy that will meet the accreditation exemption criteria in the near future and you wish to apply for the accreditation exemption, you may submit a signed copy of the accreditation exemption statement as of the date of your 5-year anniversary of enrollment in Medicare. You cannot sign the statement before the 5-year anniversary date. It is important that you are certain that you qualify for the exemption prior to terminating your accreditation. Therefore, it is recommended that you continue accreditation until you have received notice of acceptance of your accreditation exemption statement from the National Supplier Clearinghouse.

The accreditation exemption form is located at: *https://www.cms.gov/MedicareProviderSupEnroll/Downloads/PharmacyAccreditationExemptionStatementFactSheet.pdf.*

There is no express requirement for periodic resubmission of an accreditation exemption application form. However, CMS will conduct annual audits on a sample of pharmacies to verify eligibility, so pharmacies should monitor whether or not they lose eligibility for the exemption. A pharmacy that is currently exempt would lose eligibility for exemption if that store's DMEPOS sales over the past 3 years are more than 5% of the store's total sales, the store receives an unrescinded final adverse action, or there is a change in ownership. Also, remember, that each new store location must independently meet the exemption criteria.

New Fraud, Waste and Abuse Screening Requirements for Medicare Suppliers

CMS has created the following fraud, waste and abuse risk categories for pharmacies enrolling through a CMS 855B—Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers and/or a CMS 855S—Medicare Enrollment Application for DMEPOS Suppliers:

Fraud, Waste and Abuse Screening for DME Suppliers

Limited Risk	Moderate Risk	High Risk
Newly enrolling and revalidating pharmacies that enroll or revalidate using the 855B form	Currently enrolled and revalidating Form 855S DME suppliers	Newly enrolled Form 855S DME suppliers and new Form 855S DME supplier locations

Each risk category is subject to new screening requirements. Limited Risk Suppliers are subject to: 1) Verification that the pharmacy meets the applicable federal regulations or state requirements for pharmacies; 2) Licensure verification; and 3) Pre- and post-enrollment database checks to ensure that suppliers continue to meet enrollment criteria. Moderate Risk Suppliers are subject to limited risk screening plus unscheduled or unannounced site visits. High Risk Suppliers are subject to limited risk and moderate risk screening plus criminal background checks and fingerprinting for owners, authorized or delegated officials or managing employees. Note that the background checks and fingerprinting provisions will be implemented at an unidentified later date. **Pharmacists should be aware of and be prepared to be subject to new fraud, waste and abuse screening requirements when you are enrolled in Medicare through an 855B and/or 855S application form.**

Revalidation of Medicare Part B Enrollment and Revalidation Fees

Between 2012 and 2015, CMS contractors will be sending out revalidation notices to pharmacies enrolled through a CMS 855B—Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers and/or a CMS 855S—Medicare Enrollment Application for DMEPOS Suppliers. This revalidation effort will only impact pharmacies that enrolled through these forms prior to March 25, 2011. Pharmacies are not to take any action until they receive the revalidation notice from their contractor. CMS recommends submitting your revalidation through the internet-based PECOS system. Note that for 2012, you will be required to pay a $523 fee for revalidating through Form 855S and an additional $523 for revalidating through Form 855B, assuming you are enrolled through both forms. NCPA is trying to work with CMS to require a single payment for both forms. Note that pharmacies that are both Medicare Part B and Medicaid providers only have to pay one fee. You have 60 days from the date of the revalidation notice to submit complete enrollment forms. Failure to submit the enrollment forms as requested may result in the deactivation of your Medicare billing privileges.

To see the listing of revalidation notices, click on "Revalidation Phase 1 Listing" in the Downloads section of the following website: *https://www.cms.gov/MedicareProviderSupEnroll/11_Revalidations.asp#TopOfPage*.

You must widen each column in the spreadsheet to view the contents. CMS will be updating this list monthly. If you are listed, and have not received the request, please contact your Medicare contractor. Their toll free number may be found at *http://www.cms.gov/MedicareProviderSupEnroll/downloads/contact_list.pdf*.

Pharmacists must make sure that you revalidate your 855B and 855S enrollment once you receive your revalidation notice between 2012 and 2015.

HIPAA-Related Information

HIPAA Privacy and Security Compliance Audits

The Office of Civil Rights (OCR) recently announced that it has begun a pilot program to perform up to 150 audits of covered entities to assess privacy and security compliance. Audits began in November 2011 and will conclude by December 2012. OCR plans to share best practices as a result of this audit process and guidance targeted to observed compliance challenges. OCR (through audit contractor, KPMG) plans to audit as wide a range of types and sizes of covered entities as possible. Entities selected for an audit will be informed of their selection and asked to provide documentation of their privacy and security compliance efforts. During site visits, auditors will interview key personnel and observe processes and operations to help determine compliance. Following the site visit, auditors will develop and share with the entity a draft report. At this point it is unclear whether an audit could subject the target entity to potential enforcement, such as civil penalties or a consent agreement, in the event significant HIPAA violations are discovered. **Pharmacists should ensure that their HIPAA privacy and security compliance efforts are up-to-date.**

★ As NCPA advocates on Capitol Hill and interacts with federal agencies on important issues affecting your business, it is helpful to provide real-life examples of PBM abuse, antitrust concerns, or unfair trade practices, or instances of unfair audits and recoupment. If you are experiencing problems with Medicaid, Medicare, or PBM practices please submit your complaint so NCPA staff can track and report to the appropriate entities. To submit a complaint, please visit the Take Action section of the NCPA Advocacy Center homepage at http://www.ncpanet.org/index.php/advocacy-center.