

## **NCPA summary of key changes for Community Pharmacy in the Medicare Part D program to Begin in 2010**

- **Prompt Payment of Retail Pharmacy Claims and Submission of LTC Pharmacy Claims**

Pursuant to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), effective January 1, 2010, CMS' contract with Part D sponsors must include (as must the sponsors' contracts with pharmacies or other providers, first tier, downstream, and related entities) provisions requiring:

- 1) PDPs and MA-PDs to transmit payment to pharmacies for all clean claims submitted within 14 calendar days for electronic claims and 30 days for claims submitted otherwise. A "clean claim" is defined as a claim that has no defect or impropriety that prevents timely payment from being made. A claim is deemed clean if the plan does not provide the pharmacy notice of any deficiency within 10 days for an electronic claim and within 15 days for claims transmitted otherwise.
- 2) This requirement does NOT apply to mail order and long-term care pharmacies. CMS also stated that on the submission side, LTC pharmacies have not less than 30 days, nor more than 90 days, to submit claims to the sponsor for reimbursement.

- **Medication Therapy Management Program Requirements**

The MTM program targets beneficiaries who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the CMS Secretary. The existing \$4,000 threshold will be lowered to \$3,000 for 2010. Plans will evaluate beneficiaries at least on a quarterly basis for automatic inclusion in the program. The beneficiary may choose to opt-out of the MTM program. The services provided in the MTM program, at a minimum, include: an annual comprehensive medication review (CMR), no less than quarterly targeted medication reviews, provider interventions to resolve medication-related problems or other opportunities to optimize the targeted beneficiary's medication use.

- **FDA-CMS Non matched NDC list**

Beginning January 1, 2010, CMS will begin rejecting prescription drug event (PDE) submissions with NDCs for which FDA is unable to provide regulatory status determinations through their regulatory process. These edits will only apply to PDEs with dates of service on or after January 1, 2010. CMS has released a non-matched NDC list for plans to compare against the FDA's NDC Directory. Part D plans are likely to begin rejecting prescription claims containing NDCs that are included on CMS's non-matched list. Based on CMS' list, over 7,000 NDCs are affected and many of them are generics. Pharmacies can take steps to prepare, including working with suppliers to ensure unlisted products are not offered to Medicare beneficiaries.

CMS plans to update the list at least twice during the 2010 plan year by deleting NDCs that have been registered and listed with the FDA since the fall 2009 posting of the list and removing associated PDE edits. Removal of edits will apply both retrospectively and prospectively for all dates of service, and additional NDCs will not be added to the CY 2010 Non-matched NDC list during the 2010 plan year.

- **Prescription Origin Code**

Beginning in 2010, CMS requires that Part D sponsors must obtain the Prescription Origin Code and report this code on their prescription drug event (PDE) only for new prescriptions submitted in Standard format (currently Standard format is NCPDP 5.1). Pharmacies must report this information for new Part D prescriptions. The

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Prescription Origin Code will remain optional for all PDEs for refills submitted in the Standard format and for all PDEs submitted in the Non-Standard Format. While use of the prescription origin code is designed to monitor increase in E-prescribing, this code must be reported on all PDEs for new prescriptions submitted in Standard format.

- **Fraud, Waste and Abuse**

CMS rules require each plan sponsor to adopt a comprehensive program to prevent, detect, and correct fraud, waste and abuse, and ensure that its first tier, downstream and related entity has completed compliance training. By the end of 2009, pharmacies must have completed this training. Pharmacies may continue to meet CMS's rules by certifying or attesting to plans that the pharmacies have completed their own training. Plans may seek such attestation from pharmacies as part of their network contracts. The training programs should address the following topics listed in an August 2009 CMS memorandum:

- Laws and regulations related to MA and Part D fraud, waste and abuse (i.e., False Claims Act, Anti-Kickback statute, HIPAA, etc.)
- Obligations of the first tier downstream, and related entities to have appropriate policies and procedures to address fraud, waste, and abuse
- Process for reporting to the MAO or PDP sponsor suspected fraud, waste and abuse in first tier, downstream, and related entities
- Protections for employees of first tier, downstream, and related entities who report suspected fraud, waste and abuse
- Types of fraud, waste and abuse that can occur in first tier, downstream, and related entities

- *Background and additional considerations*

In October 2008, CMS issued a memorandum suggesting that in order to meet the FWA training requirements, pharmacies should not develop their own training; that plans should provide the training; and that CMS would help the industry develop a standardized training program. CMS has since stated several times that it would clarify this policy and has stated that it will issue FAQs soon. The following information, based on the latest communications with CMS, is therefore non-binding on the agency.

- Despite the 2008 and 2009 memorandums, the 2006 Medicare Manual policy permitting pharmacies to implement their own training or take the training offered by Part D plans is not superseded.
- Plans bear the responsibility of ensuring that pharmacies have completed training.
- At this time, CMS is not requiring Part D plans to attest to CMS that pharmacies have completed training. However, plans may be required to provide evidence of compliance during a plan audit. Plans may use pharmacy attestations, among others, as such evidence.
- Given the delay in releasing its guidance and the looming December 31, 2009, deadline, CMS has agreed to consider pharmacy's request for CMS to exercise enforcement discretion until the 2010 plan year. **We continue to, however, strongly urge pharmacies to meet the December 31, 2009, deadline.**

- **Negotiated Pricing (Pass through v. Lock-in pricing)**

A January 6, 2009 final rule by CMS requires plan sponsors to treat the differential between the lock-in price and the pass-through price (referred to by CMS as the "risk premium") as an administrative cost, and not a drug cost. Effective for the 2010 plan year, plan sponsors must report the amount ultimately received by the pharmacy or other dispensing provider ("pass through pricing") as the basis for determining beneficiary cost sharing and for reporting a plan's drugs costs to CMS, rather than the amount the plan sponsor pays to an intermediary contracting organization, such as a PBM. (Prior to the change, plan sponsors could use either pricing metric as

the basis for determining beneficiary cost sharing and for reporting drug costs under Part D). So while plans sponsors may continue to use the lock-in model with their PBMs, they must reveal to CMS the price actually paid to the pharmacy as the negotiated price – the difference must be reported as an administrative cost. All should benefit from this basic level of PBM transparency.

- **Claims for Drugs Prescribed by Excluded Providers**

CMS has indicated that PDP plans may not pay claims from Medicare Excluded providers, and the agency requires plans to have processes to identify these individuals and entities, and to regularly update their systems with this information -- including requesting that network pharmacies obtain prescribers' national provider identifier (NPI) (when prescribers have one). Pharmacies thus need to ask for and include NPI data on all claims when prescribers have this data.