



November 23, 2009

Charlene Frizzera, Acting Administrator
Centers for Medicare and Medicaid Services
Room 314-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: 2010 Non-matched NDC List

Dear Acting Administrator Frizzera:

We want to applaud your efforts to increase transparency and clarity with respect to the regulatory status of prescription drug products covered under Medicare Part D. As representatives of industries that help ensure the safe and secure delivery and dispensing of prescription medications, we strongly support efforts that contribute to the success of the Medicare Part D program. Although we appreciate CMS' outreach efforts in engaging and preparing stakeholders for the upcoming January 1, 2010, implementation date for the CMS Non-matched NDC requirement, we are writing you today to bring to your attention additional issues that we feel still need to be addressed and that CMS may not have fully considered.

As indicated, we appreciate CMS' outreach to stakeholders in the supply chain and pharmacy community, and have taken measures to ensure our respective memberships are aware and prepared for the impending January 1, 2010, deadline. We have encouraged our respective members to work closely with their supply chain partners; however, there are unique circumstances and situations that can only be addressed by manufacturers and Part D plans. We hope CMS will take under careful consideration the following issues in order to ensure a smooth implementation process and minimize disruptions to beneficiaries during implementation.

- **Patient Disruption** - There is a potential that medications that patients have been receiving regularly will suddenly not be covered. For brand drugs, there may not be an equivalent. We recommend that CMS and FDA work together to initiate and continue to provide additional outreach to affected parties, including manufacturers and beneficiaries.

We are concerned that patients may not understand why they can no longer obtain the drug which they have obtained under Part D for the past three years. Beneficiaries are likely to believe that they have been obtaining potentially unapproved drugs, causing unnecessary alarm in their minds, and placing pharmacists in the difficult position of having to explain this very complicated issue to the Part D population. In addition, there is a considerable amount of confusion regarding the difference in a product not being approved by the FDA versus not being listed with the FDA. Clarification on this point in regard to stakeholder and beneficiary outreach and education would be greatly appreciated. We recommend that CMS create a standard fact sheet, brochure, flyer, or something similar that could be posted to the CMS Web site and made available to our pharmacy members. Such a tool would serve as a reference for pharmacists to use and/or give to patients when explaining why a previously covered drug is no longer covered under the beneficiary's Part D plan.

- **Supply Chain Concerns** - If a generic drug product is included on the Non-matched NDC list, there may be equivalents available in the marketplace. However, if the generic product is a primary contract item on a wholesaler's generic formulary, there may not be sufficient supply of alternative products in the wholesalers supply chain to meet increased demand as pharmacists across the country switch to the alternative products. Such supply chain issues may limit beneficiary access to covered drugs.
- **Inconsistent Implementation by Plans** - We are concerned that some plans may have in place a point-of-sale (POS) edit at the pharmacy level to block drugs on the Non-matched list from being dispensed, while others do not have such edits for the same exact drug. In other cases, some plans may remove POS edits as the FDA updates its NDC list on a monthly basis, while others will simply rely on CMS' bi-annual update of the Non-matched NDC list for POS edit purposes. Such inconsistency could make it difficult for pharmacies to implement this policy at the pharmacy level, and places pharmacists in a difficult position to explain to Part D patients why their plan no longer pays for the drug while others do. We recommend that CMS either update the Non-matched NDC list on a more frequent basis or require plans to utilize the FDA's NDC list to place and remove POS edits.
- **Retroactive Reversal of Claims** - CMS has suggested that it cannot require plans to put in place POS edits for drugs that appear on the Non-matched NDC list, leaving it up to the plans to decide whether they place edits for NDCs that appear on the list. We are concerned that plans that do not place POS edits could potentially retroactively reverse approved claims. Once a pharmacy dispenses a drug, it would be unfair to have the claim reversed for the plan's failure to have effective edits at the point of sale. Therefore, we urge CMS to prohibit plans from retroactively reversing approved claims for NDCs that appear on the Non-matched list.

In addition to consideration of the foregoing, we strongly encourage you to continue outreach to manufacturers whose products are on the Non-matched list as well as Part D plans. We also strongly urge CMS to consider holding an open door forum as soon as possible in order to capture concerns of all interested stakeholders. Although we have communicated with our

respective supply chain partners, ultimately, the manufacturer bears the responsibility to register their products appropriately with the FDA and with Part D plans to ensure their formularies and edits reflect CMS policies in a timely fashion. We strongly encourage CMS to continue its outreach work with the manufacturer community and Part D plans to ensure that this happens and to help ensure smooth implementation of this initiative.

Thank you again for considering our comments.

Sincerely,

American Pharmacists Association
Food Marketing Institute
Healthcare Distribution Management Association
National Association of Chain Drug Stores
National Community Pharmacists Association