**Purpose:** The purpose of this tool is to provide best practice recommendations and a comprehensive template for manufacturer communication of National Drug Code (NDC) changes to appropriate stakeholders when allowing transfer of accumulations from existing NDC(s) to new NDC(s).

Included within this tool are the following recommendations and resources for this type of communication:

* Details to include
* Process for communicating
* Sample letter for notification of stakeholders

**Background:** Covered entities may use a replenishment inventory model to dispense drugs to both 340B eligible and ineligible patients using one physical inventory. Replenishment models operate on a neutral inventory premise where the inventory that is purchased “replenishes” a dispensing/administration activity that already occurred in the past.

Split-billing software is often used to help covered entities manage a replenishment inventory model. The entity tracks data feeds (such as inpatient or outpatient status, patient and prescriber eligibility, clinic location, Medicaid status, drug identifier, and quantity dispensed) and loads these data points into split-billing software. This software uses logic based on configurations, chosen by the entity, to virtually separate 340B from non-340B transactions after they occur. The software then determines from which account each transaction should be reordered.

The term “split-billing” is used to describe this software, which “splits” a purchase order into two or three different accounts (e.g., 340B, GPO, non-GPO/WAC). This software can help the entity place orders in appropriate accounts while maintaining auditable records of the accumulations and purchases.

Because accumulations are established in each of the accounts by using an 11-digit NDC match for replenishment, purchase of new NDCs typically begins a new replenishment cycle. Existing accumulations are not able to be used toward the purchase of new NDCs. If there is a change in NDC for a given product, manufacturers may elect to allow for transfer of accumulations from existing NDCs to the new NDC. To support program integrity and compliance, manufacturers that wish to allow this type of accumulation transfer should provide written communications to the appropriate stakeholders.

**Details to Communicate:**

* Date of communication
* Effective date
* Statement of approval to honor accumulations of existing NDC(s) toward the purchase of new NDC(s)
* Product description (including existing NDC[s] and new NDC[s])
* Expected timeline for transition of product in the supply chain
* Manufacturer contact information in case of questions

**Instructions:**

1. Use the NDC Change Notification Template on the following pages to draft communication to allow for the transfer of accumulations for the existing NDC(s) to the new NDC(s).
	1. Orange font indicates prompts for modification.
2. Send the finalized document to the following stakeholders:

|  |  |
| --- | --- |
| Stakeholder Group | Notes |
| Covered entities | * Contact information for covered entities can be found at 340bopais.hrsa.gov.
* Notify covered entities of NDC change and allowance of transfer of accumulations.
* The document will serve as written record to promote 340B Program integrity and compliance for the covered entity.
	+ It is the covered entity’s responsibility to notify its third-party administrator, if applicable.
 |
| HRSA/Office of Pharmacy Affairs (OPA) | * Request to post to [Manufacturer Notices to Covered Entities](https://www.hrsa.gov/opa/manufacturer-notices) webpage.
* Office of Pharmacy Affairs

Health Resources and Services Administration340BPricing@hrsa.gov  |
| Prime Vendor Program (PVP), managed by Apexus | * For manufacturers with contracts with the PVP, send the notification to the portfolio executive (PE) contact.
* If there is no PE contact, send the notification to Apexus Answers.

Email >[Chat >](https://www.340bpvp.com/chat) |

**NOTE:** You may consider including the finalized document as part of your usual communication process for NDC change notification to wholesalers. It is important to note that this document is not meant to replace wholesaler notification for NDC changes; rather, it is intended to supplement your current process to create a comprehensive communication plan.

# NDC Change Notification Template

[Place letter on Manufacturer letterhead]

Date: [Date]

[Manufacturer] **Notice Regarding** [Drug Name(s)]
**National Drug Code Numbers Update and Impact on 340B Virtual Inventory Management**

[Manufacturer] has asked the Office of Pharmacy Affairs (OPA) to post this notice on the OPA’s public website to notify 340B covered entities that the National Drug Code (NDC) numbers for [Drug Name(s) (generic name)] for [Drug Route] are being transitioned to new NDCs on [effective date] as follows:

These NDC changes [will/will not] be accompanied by product packaging changes [explain if changes to occur].

|  |  |  |  |
| --- | --- | --- | --- |
| **Product Description** | **Old/Existing NDC** | **New/Replacement NDC** | **Effective Date** |
|  |  |  |  |
|  |  |  |  |

The new NDC(s) will not signify any change in product form, strength, or composition. Because each new [Drug Name] NDC represents the same product as the corresponding old NDC, [Manufacturer] will permit eligible 340B covered entities that use a compliant 340B inventory replenishment model to count accumulations of each old NDC toward replenishment of equal quantities for each corresponding new NDC*.*

The new NDCs will be available as early as [date]. [Manufacturer] will sell its remaining inventory of each old NDC until it is exhausted, at which point [Manufacturer] will begin distributing the corresponding new NDC. [Manufacturer] or your distributor will communicate further information regarding the availability of each new NDC. Chargebacks and returns will continue to be processed for the old NDCs.

For any questions regarding this notice contact [Manufacturer contact information].

Thank you for your attention.