

## Pharmacy Generated NDC Numbers

There are a least two primary situations where the NDC number system doesn't not quite fit real world pharmacy experience.

They are;

- 1) Partial doses of;
  - a. Tablets
  - b. Oral liquids
  - c. Injectables
  - d. IV's
  
- 2) Compounded medications
  - a. Single Active Ingredient
    - i. Injectables
    - ii. IV's
    - iii. Oral
    - iv. Topical
  
  - b. Multiple Active Ingredients
    - i. Injectables
    - ii. IV's
    - iii. Oral
    - iv. Topical

Before we have a discussion on a several possible means of adapting the current NDC numbering system to cover these situations we should 1<sup>st</sup> review the components of an NDC number.

### Definitions:

1) **NDC number** - National Drug Code, a unique 10 digit identification number, assigned by the Food and Drug Administration (FDA), to every prescription medication and product and to some non-prescription medications and products. It is made up of 3 parts;

1<sup>st</sup> part - a 4 or 5 digit Manufacturer Identification number

2<sup>nd</sup> part - a 3 or 4 digit Product Identification number made by the manufacturer

3<sup>rd</sup> part - a 1 or 2 digit product Container Size ID number

This makes three 10 digit NDC number sequences possible (dashes are space holders only to aid in visualization of the three parts. They are not actually in the bar code data)

1234 -1234 -12  
12345 -123 -12  
12345 -1234 -1

This came about because the 4 digit Manufacturer ID ran out of available numbers. To keep with-in the original 10 digit length the FDA lets the manufacturer choose to either shorten the product ID or Container size code by one character. Because of the confusion this can cause, the health care industry commonly expands these 3 possible sequences into an 11 digit number by padding with a zero the part of the 10 digit NDC that doesn't match a full 5-4-2 sequence.

This makes the three sequences above look like the following: (with the added zero underlined and bolded for ease of identification)

**0**1234 - 1234 - 12  
12345 - **0**123 - 12  
12345 - 1234 - **0**1

This expanded 11 digit NDC number format is what is most commonly used to bill, track and order prescription items.

For example:

FDA 10 digit NDC # is 63653-1171-1

63653 = Sanofi-Synthelabo, 1171 = PLAVIX<sup>®</sup> 75mg, 1 = bottle size of 90

Expanded 11 digit format NDC # is 63653-1171-01

63653 = Sanofi-Synthelabo, 1171 = PLAVIX<sup>®</sup> 75mg, 01 = bottle size of 90

*Important points:*

- 1) *It is the combination of the Manufacturer ID and the Product ID that defines a unique product. The Product ID by itself can represent many different products depending on who the manufacturer is. For example a product ID of 3872 could represent atenolol by one manufacturer and glucophage by another manufacturer.*
- 2) *There is no national container size ID numbering standard that all manufactures use. For one manufacturer a size ID of 11 could be 100 tablets and for another manufacturer it could mean 1000 tablets*

With this information we can now define some issues to consider when pharmacy generating NDC numbers

- 1) Should the pharmacy use the 11 digit ( 5-4-2) format
- 2) Should it uniquely identify the Pharmacy to at least the organization using the products
- 3) Should it uniquely identify the Product to at least the organization using the products
- 4) There is no national standard for container size ID's
- 5) Will automated allergy and disease warning applications need to use the NDC #

So what are some possible methods we can use to generate NDC #'s?

NOTE:

- A) These various methods make for a unique number that follows the basic NDC number layout logic
- B) Methods 1 and 2 make a NDC that for your users identifies your pharmacy as the packager.
- C) All of these methods have pro's and con's.

Your job is to determine which of them are better than your current practices, which often consist of having one made up NDC # to identify all partials and maybe a different one for all compounds etc. or a pharmacy Med ID that does not distinguish between the different sources of the same medication. **This can be a serious problem if you need to identify which patients received a particular brand of medication or is required as part of the billing requirements.**

**Method 1 - Manufacture code + Product and Strength indicating Product Code + Container Size ID code**

**Caution:** Automated allergy, disease and dosage warning by NDC # is not a requirement or you can add the warning logic for the active ingredient with this new NDC into the warning system.

Step:

- 1) Assign the pharmacy a unique 5 digit Manufacturer ID.
  - a. Historically pharmacies have often used 99999 to indicated compounded products; however, this has now been assigned to a manufacturer.
  - b. You can use any 5 digit number as long as it is not being used now or would be anticipated to be used in the future by a FDA approved manufacturer. Define a policy for your pharmacy, you could use a 5 digit number for compounds and partials or you could use a 5 digit number for compounds and different 5 digit number for partials.

For example;

Suggested Hospital Compounded /Repackaged Manufacturer ID's	
Stock IV Solutions	99997
Partial tablets/oral doses when not using Method # 3	99996
Oral Solution compounds	99995
Weight based dosing mg / kg	99994
Topical	99993

- 2) Assign a unique product ID to each product.
  - a. The 4 digit Product ID code allows us to have 9,999 unique products.
    - i. Each unique **Product and Strength** combination can have its own Product ID.

For example Partial;

ATENolol 25 mg doses such as

1. ½ tablet ( 12.5 mg ) could be 1232
2. ¼ tablet ( 6.25 mg ) could be 1234

metFORMIN 500 mg doses such as

1. ½ tablet ( 250 mg ) could be 1236
2. ¼ tablet ( 125 mg ) could be 1237

PROPRANolol 40 mg doses such as

1. ½ tablet ( 20 mg ) could be 1238
2. ¼ tablet ( 10 mg ) could be 1239

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3) Assign a unique Container Size code

- a. This allows the pharmacy to develop its own container size sequence. Remember there is no national container size ID standard. 100 different size ID's are possible. See pages 7 and 8 for a suggest list of size ID's.

For example;

01	1 tablet or capsule or 1 mL
05	5 mL
10	10 mL
15	15 mL
30	30 mL
60	60 mL or 60 doses
31	100 mL or doses
35	500 mL or doses
49	1000 ml or doses

For example; (dashes for reading convenience only)

Using the ATENolol 25 mg example the NDC #'s would look like

1. ½ tablet (12.5 mg) could be 99999-1235-01
2. ¼ tablet (6.25 mg) could be 99999-1234-01

metFORMIN 500 mg could be

3. ½ tablet ( 250 mg ) could be 99999-1236-01
4. ¼ tablet ( 125 mg ) could be 99999-1237-01

PROPRANolol 40 mg could be

3. ½ tablet ( 20 mg ) could be 99999-1238-01
4. ¼ tablet ( 10 mg ) could be 99999-1239-01

**Method 2 – Manufacture code + Full Dose Product Code + Container code that also indicates partial dose size**

**Caution:** Automated allergy, disease and dosage warning by NDC # is not a requirement or you can add the warning logic for the active ingredient with this new NDC into the warning system.

Step:

- 1) Assign the pharmacy a unique 5 digit Manufacturer ID just like in Method 1
- 2) Assign a unique product ID to each product.
  - a. The 4 digit product ID code allows us to have 9,999 unique products.
    - i. Each FULL dose (e.g. tablet, capsule) for each unique product and strength can have its own Product ID.

For example;

If we start with atenolol 25 mg

1. 1 tablet of ATENolol 25 mg could be 1235
2. 1 tablet of ATENolol 50 mg could be 1236

- 3) Assign a unique Container Size ID that may also indicate a **Partial** Dose Size, (100 codes possible.)

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- a. This allows the pharmacy to develop its own container size sequence. Remember there is no national container size ID standard. In this example the 01 means 1 whole solid dose product, the 62 means 1/2 of a solid dose product, the 63 means 1/3 of a solid dose product etc.

For example;

01	1 tablet or capsule or 1 mL
62	1 / 2 tablet or 2 mL
63	1 / 3 tablet or 3 mL
64	1 / 4 tablet or 4 mL
05	5 mL or 5 doses
10	10 mL or 10 doses
15	15 mL or 15 doses
30	30 mL or 30 doses
60	60 mL or 60 doses
31	100 mL or doses
35	500 mL or doses
41	1000 ml or doses

For example; (dashes for reading convenience only)

Using the ATENolol 25 mg example again the NDC #'s would look like

1. 1/2 tablet (12.5 mg) could be 99999-1235-62
2. 1/4 tablet (6.25 mg) could be 99999-1235-64

Using the 1 tablet of ATENolol 50 mg the NDC #'s would look like

1. 1/3 tablet (16.67 mg) could be 99999-1236-63
2. 1/4 tablet (12.5 mg) could be 99999-1236-64

**Method 3 - 1<sup>st</sup> nine digits of the original NDC number plus a new unique container size ID**

- 1) Resolves the requirement of using an automated warning system that requires a product's NDC # for Allergy and Disease warnings so long as they only need the 1<sup>st</sup> 9 digits of the NDC # to identify the product. Remember, the 1<sup>st</sup> 9 digits uniquely identify the product including its strength and dosage form.
- 2) It will not solve the problem of Dosage warnings unless you can add the strength into the database the system uses and link it to the complete 11 digit NDC #.

Step:

- 1) Use the original Manufacturer ID
- 2) Use the original product ID
- 3) Assign a unique Container Size ID that also indicates Partial Dose Size, (100 codes possible.)

- a. This allows the pharmacy to develop its own container size sequence. Remember there is no national container size code standard.

For example;

01	1 tablet or capsule or 1 mL
62	1 / 2 tablet or 2 mL
63	1 / 3 tablet or 3 mL
64	1 / 4 tablet or 4 mL
05	5 mL or 5 doses
10	10 mL or 10 doses

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15	15 mL or 15 doses
30	30 mL or 30 doses
60	60 mL or 60 doses

For example; (dashes for reading convenience only)

The ATENolol 25 mg with an original NDC # of 00182-8235-00 and container size of 1 would become for a single partial dose;

1. ½ tablet (12.5 mg) could be 00182-8235-62
2. ¼ tablet (6.25 mg) could be 00182-8235-64

metFORMIN 500 mg original NDC # of 00087-6060-10 and container size of 500 would become for a single partial dose;

3. ½ tablet ( 250 mg ) could be 00087-6060-62
4. ⅓ tablet ( 166.67 mg ) could be 00087-6060-63

**Method 4 - NDC numbers with a suffix addendum**

- 1) Resolves the requirement of using an automated warning system that requires a product’s NDC # for Allergy and Disease warnings so long as they can work with an ID that starts with a length greater than the normal 11 digits of the NDC #. Systems may do this by simply working with only the first 11 digits of the ID.
- 2) It will not solve the problem of Dosage warnings unless you can add the new strength into the database the system uses and link it to the new 11 digit NDC number plus its suffix addendum.

Step:

- 1) Use the original Manufacturer NDC number
- 2) Assign a suffix addendum to it that represents another diluent and a new container size or just a new container size, in the format xyy or yy

x = diluent and yy = container size

For example diluent codes could be:

3 digit product ID suffix – 1st digit is a diluent code		
nothing just different volume	0	A
0.9 % Normal Saline	1	B
D5W	2	C
0.45 % Normal Saline	3	D
Sterile Water	4	E

Use the container codes as discussed in Method 3 and in the container size table discussed on pages 7 and 8 in the container size ID suggestion section.

- e.g. 55390-0340-10 – 005 for a non diluted 5 mL container of esmolol HCl injection  
55390-0340-10 – 150 for a 50 mL container of esmolol HCl injection diluted in 0.9% Normal saline  
55390-0340-10 – B50 for a 50 mL container of esmolol HCl injection diluted in 0.9% Normal saline  
55390-0340-10 – 05 5 mL container of esmolol HCl injection with no diluent code used

*You can easily adopt the logic behind these 4 methods for dilutions of liquids and/or partial dispensing (repackaging) from the original manufacturer containers.*

These Methods

- 1) Can also be applied to single and multiple active ingredient compounds where you
  - a. Do not need to apply some automated allergy, disease or dosage warning system that uses the NDC #.
  - b. Want to simply identify the unique product for your BPOC, CPOE or billing systems.
- 2) They can also be used if the warning system is user friendly enough to allow you to define NDC #'s and enter all of the active ingredients with strengths. For these systems to be truly "health system" friendly the end user needs to be able to add information into the warning application and receive the same type of warnings received when the information has been entered by the application vendor.

*Another advantage of adopting a structured NDC # identification system for your pharmacy is that now you can assign unique billing ID to each product which should improve billing and inventory accuracy.*

To review these methods are ways that you may use to identify products with a unique ID number:

- 1) That follows the basic NDC number layout logic
- 2) That may be specific to your pharmacy.

### **Addendum: Container Size ID Suggestions**

On the flowing pages is a more expansive listing of suggested Container Size ID's for use when generating your own NDC numbers. These may be applied to any of the three Methods for generating NDC #'s discussed.

However, in Method 3 the size ID's can only be used if the manufacture has not all ready used the selected size ID for one of their NDC numbers for the same medication you are making a new NDC number for.

The most recent release of the *RxScan NDC Smart Label Design & Print™* software helps you select an appropriate container size ID number when using it to make NDC #'s.

Some of the logic behind the new Container Size ID's possibilities listed below is;

- A) Container/Quantity/Volume Size of 1 to 9 = 1 digit number, start them with a 0 e.g. 05 for a qty of 5
- B) Container/Quantity/Volume Size of 10 to 99 are common quantities so make them the actual quantity # or if needed since they are 2 digit numbers start their ID with a 2, using a combination not already used.
- C) Container/Quantity/Volume Size of 100 to 999 = 3 digit number start them with a 3
- D) Container/Quantity/Volume Size of 1000 to 9999 = 4 digit number start them with a 4
- E) Partial tablets start with a 6
- F) Decimal point containing volumes start with a 7 e.g.  $\underline{2}.5 = 7\underline{2}$ ,  $\underline{3}.5 = 7\underline{3}$ ,  $7.5 = 7\underline{7}$  in these cases I used the first # of the quantity to be the last number of the ID; this may need modification as we find more examples.
- G) Others quantity ID's not in the list should start with an 8 or 9. Use up the 8# combinations first then move to 9#.
- H) Remember; DO not assign a quantity to a size ID combination already assigned to a different unique quantity.

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Suggested Container Size ID's			
Container Quantity/Volume Size	Size ID #	Container Quantity/Volume Size	Size ID #
0.1 mL	81	36 tablets or capsules or mL's	96
0.2 mL	82	40 tablets or capsules or mL's	40
0.3 mL	83	45 tablets or capsules or mL's	45
0.4 mL	84	50 tablets or capsules or mL's	50
0.5 mL	85	55 tablets or capsules or mL's	55
0.6 mL	86	60 tablets or capsules or mL's	60
0.7 mL	87	67.5 mL's	97
0.8 mL	88	70 tablets or capsules or mL's	70
0.9 mL	89	75 tablets or capsules or mL's	75
1/4 tablet	64	80 tablets or capsules or mL's	80
1/3 tablet	63	90 tablets or capsules or mL's	90
1/2 tablet	62	100 tablets or capsules or mL's	31
2/3 tablet	66	105 tablets or capsules or mL's	51
3/4 tablet	67	110 tablets or capsules or mL's	52
1 tablet or capsule or 1 mL	01	115 tablets or capsules or mL's	53
2 tablets or capsule or 2 mL	02	120 tablets or capsules or mL's	61
2.5 mL or g	72	124 tablets or capsules or mL's	54
3 tablets or capsule or 3 mL	03	143 tablets or capsules or mL's	68
3.5 mL or g	73	200 tablets or capsules or mL's	32
4 tablets or capsules or mL's	04	240 tablets or capsules or mL's	65
4.4 mL's	44	250 tablets or capsules or mL's	66
5 tablets or capsules or mL's	05	280 tablets or capsules or mL's	28
6 tablets or capsules or mL's	06	286 tablets or capsules or mL's	69
7 tablets or capsules or mL's	07	300 tablets or capsules or mL's	33
7.5 mL or g	77	400 tablets or capsules or mL's	34
8 tablets or capsules or mL's	08	500 tablets or capsules or mL's	35
9 tablets or capsules or mL's	09	560 tablets or capsules or mL's	56
10 tablets or capsules or mL's	10	600 tablets or capsules or mL's	36
13 tablets or capsules or mL's	13	700 tablets or capsules or mL's	37
15 tablets or capsules or mL's	15	800 tablets or capsules or mL's	38
20 tablets or capsules or mL's	20	900 tablets or capsules or mL's	39
21 tablets or capsules or mL's	21	1000 tablets or capsules or mL's	41
25 tablets or capsules or mL's	25	Unknown	00
30 tablets or capsules or mL's	30		

The following are container size ID's not yet used in the suggested container size ID list. These are available for your own use.							
Container Quantity/Volume Size	ID #	Container Quantity/Volume Size	ID #	Container Quantity/Volume Size	ID #	Container Quantity/Volume Size	ID #
	11		24		48		78
	12		26		49		79
	14		27		55		91
	16		29		57		92
	17		42		58		93
	18		43		59		94
	19		44		71		95
	22		46		74		98
	23		47		76		99

To help you generate NDC numbers for your compounds and partial tablets, the **RxScan Smart Label Design & Print™** software has a wizard section that walks you through the self-generation of NDC numbers.

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