Bureau of TennCare
Policy Manual

Policy No: BTC-Pol-Enc-200701-001	
Subject: NDC Submission for HCPCS Drug Claims	
Approval: Encounter Policy Workgroup	**Date: 09/07/2012**

PURPOSE OF POLICY STATEMENT: To clarify TennCare's position on the submission of encounters that must include the National Drug Code (NDC) for Physician administered drugs submitted on the CMS-1500/837P and UB04/837I formats.

The Deficit Reduction Act (DRA) of 2005 contains requirement for state Medicaid agencies to require claims with information necessary to pursue drug rebates for physician administered drugs or face losing Federal Financial Participation for those claims. Many states including Tennessee have issued instructions on how to report information required for drug rebate processing. The required information includes NDC, quantity and unit of measurement. TennCare issued instructions and modification in 2007 that became effective for services billed on professional claim forms (837P or CMS1500) on or after July 1, 2007and institutional claim forms (837I or UB04) on or after January 1, 2008. This document will define both the provider reporting and TennCare Managed Care Contractor (MCC) processing instructions for drug related claims.

The Patient Protection and Affordable Care Acts (ACA) from March, 2010 increase the Medicaid drug rebate percentages for most drugs. ACA also allows the Federal government to receive a portion of drug rebate funds regardless of their collection status by the Medicaid agency. In order to minimize losses of drug rebate funds, TennCare will enforce the requirement of drug information reporting on all drug related 837I outpatient claims processed on or after January 1, 2011 per DRA and ACA legislation. 837P reporting requirements implemented on July 1, 2007 will not change.

POLICY:

In conjunction with the DRA of 2005 and ACA of 2010, TennCare requires all Physician administered drugs, submitted on the CMS-1500/837P and UB04/837I format, to be reported using NDC codes in conjunction with Healthcare Common Procedure Coding System (HCPCS) Codes (i.e. J codes).

PROCEDURES:

Encounters must include the following information on the 837 for drugs administered:

Data Element	837 Loop	Companion Guide Name	837P Seg.	837I Seg.
Drug Ingredient Billed Amount	2400	Line Item Charge Amount (Unit Price)	SV102	SV203
HCPCS Unit of Measure	2400	Unit or Basis for Measurment Code	SV103	SV204
HCPCS Quantity	2400	Quantity	SV104	SV205
NDC Qualifier of N4	2410	Product or Service ID Qualifier	LIN02	LIN02
NDC -11 digit level	2410	National Drug Code (NDC)	LIN03	LIN03
NDC Quanity	2410	Quantity	CTP04	CTP04
NDC Unit of Measure	2410	Unit or Basis for Measurment Code	CTP05-1	CTP05-1
Drug Ingredient Paid Amount	2430	Service Line Paid Amount	SVD02	SVD02

The X12 837 Institutional (837I) and Professional (837P) claim formats support the reporting of the required drug rebate information in the 2410 loop which can be repeated up to 25 times to match how NCPDP retail pharmacy claims support the reporting of compound drugs and their components. The HCPCS code should be in 837P 2400 SV101-2 or 837I 2400 SV202-2, the provider's charge for the drug in 837P 2400 SV102 or 837I 2400 SV203 and the associated units in 837P 2400 SV104 or 837I 2400 SV205. The NDC number must be is 2410 LIN03 and the associated NDC quantity in 2410 CPT04 with the NDC unit of measure in 2410 CTP05-1. The NDC unit price(s) has been removed in the ASC X12N 5010 transaction versions. These fields are required per the 837s TR3 situational rule under 2410 LIN – "Required when government regulation mandates that prescribed drugs and biologics are reported with NDC numbers."

When billing using the CMS1500 paper claim form the NUCC has issued instructions to report the drug information in the upper half of Box 24 beginning with the N4 qualifier (from the 837) immediately followed by the 11 character NDC followed by three spaces followed by the unit of measurement qualifier (F2 - International Unit, GR - Gram, ME- Milligram, ML - Milliliter, or UN - Unit) followed immediately by the quantity. The NUCC Instructions Manual includes the drug description following the NDC but this is not a TennCare requirement. These instructions basically follow the 837P with Box 24 being specified and the number of spaces between the NDC and the unit of measure qualifier.

The NUBC has issued instructions for the reporting of the required drug rebate information on the UB04 paper claim form using form locator 43. TennCare has adopted these recommendations. The reporting incorporates utilizing the N4 qualifier

followed by the 11 character NDC followed by the unit of measurement qualifier (same as used in the 837I, 837P and CMS1500) followed immediately by the quantity.

The required drug rebate information is still required on a claim even if Medicaid is a secondary or tertiary payer. The final DRA rule states that Medicaid agencies are entitled to drug rebates if they pay any amount for a qualifying drug. Therefore, the required drug rebate information must be present on all claims except those excluded by the DRA. The NDC level information is not required for Inpatient Services, Immunizations and Radiopharmaceuticals. Effective for dates-of-service on or after July 1, 2007 for 837P/CMS1500 and January 1, 2008 for 837I/UB04 providers must bill with the appropriate NDC number when billing for a drug.

Each J-code submitted must have a corresponding NDC on each claim line. If the drug administered is comprised of more than one ingredient (i.e. compound drugs, same drug different strengths, etc.), each NDC must be represented. For the same drug with different strengths the J-code should be repeated as necessary to cover each unique NDC. For compound drugs each NDC should be represented via repeating the appropriate NDC or utilizing the compound drug section of the claim whichever is appropriate for the given claim form.

A valid NDC must be used on all J-code drugs. To be considered valid, a NDC must be present in the correct field, in the correct format, using the 5-4-2 HIPAA standard 11-digit code, and be found on TennCare's drug file. TennCare receives and updates a drug list from First Data Bank on a weekly basis.

Some NDCs are displayed on drug packaging in a 10-digit format. Proper HIPAA billing of a NDC requires an 11-digit number in a 5-4-2 format. Converting NDCs from a 10-digit to an 11-digit format requires a strategically placed zero, dependent upon the 10-digit format. The following table shows common 10-digit NDC formats indicated on packaging and the associated conversion to an 11-digit format using the proper placement of a zero. The correctly placed additional "0" is in a **bold font and underlined** in the examples. Note that hyphens indicated below are used solely to illustrate the various formatting examples for NDCs. **Do not use hyphens when entering the actual data in a claim.**

Converting NDCs from 10-digits to 11-digits:

10-digit Format on Package	10-digit Format Example	11-digit Format	11-digit Format Example	Actual 10-digit NDC Example	11-digit Conversion of Example
4-4-2	9999-9999-99	5-4-2	**0**9999-9999-99	0002-7597-01 Zyprexa® 10mg vial	**0**0002-7597-01
5-3-2	99999-999-99	5-4-2	99999-**0**999-99	50242-040-62 Xolair® 150mg vial	50242-**0**040-62
5-4-1	99999-9999-9	5-4-2	99999-9999-**0**9	60575-4112-1 Synagis® 50mg vial	60575-4112-**0**1

UB04 instructions when billing for a drug.

1. Report the required drug related information in form locator 43.
2. Enter the NDC qualifier of N4, followed by the 11-digit NDC number and the unit of measurement followed by the metric decimal quantity or unit. Do not enter a space between the qualifier and NDC. Do not enter hyphens or spaces within the NDC number. The NDC number being submitted to TennCare must be the actual NDC number on the package or container from which the medication was administered.
3. Enter the NDC unit of measurement code and numeric quantity administered to the patient.
4. Enter the actual metric decimal quantity (units) administered to the patient. If reporting a fraction of a unit, use the decimal point. The unit of measurement codes are as follows:
   a. F2 - International Unit
   b. GR – Gram
   c. ME - Milligram
   d. ML - Milliliter
   e. UN – Unit

   Note currently ME – Milligram is not available on the UB04 paper form.

CMS1500 instructions when billing for a drug.

1. Box 24a
   a. Unshaded area: Enter date of service in the block, MMDDYY.
   b. Shaded area: Enter the NDC qualifier of N4, followed by an 11-digit NDC number. Do not enter a space between the qualifier and NDC. Do not enter hyphens or spaces within the NDC number. The NDC number being submitted to TennCare must be the actual NDC number on the package or container from which the medication was administered**.** The NDC description is optional data that may follow the NDC number.
2. Box 24d
   a. Unshaded area: Enter the 5-digit CPT-4 or HCPCS procedure code that describes the procedure performed. If service provided requires modifier(s), enter up to 3 modifiers in the column(s) provided following the CPT-4 or HCPCS code. If more than 3 modifiers apply, enter modifier 99 first.
   b. Shaded area (note this shaded area is a continuation of the area above 24a through 24h): Enter 3 blank spaces from the end of the character string from 24a above then enter the NDC unit of measurement and numeric quantity administered to the patient. Enter the actual metric decimal quantity (units) administered to the patient. If reporting a fraction of a unit, use the decimal point. Nine numbers may precede the decimal point and three numbers may follow the decimal. The unit of measurement codes are as followed:
      i. F2 - International Unit
      ii. GR - Gram
      iii. ME – Milligram
      iv. ML - Milliliter
      v. UN - Unit

Note currently ME – Milligram is not available on the CMS1500 paper form.

Exceptions:

- Vaccines for children which are paid as an administrative fee
- Inpatient administered drugs
- Radiopharmaceuticals unless the drug is billed separately from the procedure

DEFINITIONS:

CMS – Centers for Medicare & Medicaid Services.
EDI – Electronic Data Interchange
HIPAA – Health Insurance Portability and Accountability Act.
NDC – National Drug Code
TCMIS – TennCare Management Information System
TennCare or TennCare Program **–** The program administered by the single state agency, as designated by the state and CMS, pursuant to Title XIX of the Social Security Act and the Section 1115 research and demonstration waiver granted to the State of Tennessee and any successor programs.

REFERENCE DOCUMENTS:

Deficit Reduction Act of 2005
Patient Protection and Affordable Care Acts (ACA) of 2010
NUBC UB04 Manual 2012
NUCC CMS1500 Claim Form v7 – 07/11
ASC X12 Health Care Claim: Professional (837) 005010X222A1
ASC X12 Health Care Claim: Institutional (837) 005010X223A2
TennCare HIPAA Companion Guides

OFFICES OF PRIMARY RESPONSIBILITY:

- TennCare IS Division—to ensure that encounters are submitted to TennCare in the approved format
- Information Systems Management Contractor – to process encounters through the TCMIS system
- MCCs - to follow transaction requirements

Legal basis for this requirement.

Federal law requires that NDC information be submitted for covered outpatient drugs, in order for there to be Federal Financial Participation (FFP) for payment for those drugs. **42 USCA 1396r-8(a)(7) ; 42 CFR 447.520.** TennCare rule says any service for which there is no FFP is an excluded service which TennCare will not pay for. **TennCare rule 1200-13-13-10(1).** Therefore, the MCO is not permitted to offer non-covered services. **CRA 2.6.6.6.**

Tennessee statute requires TennCare to have a uniform claims process which the MCOs must use.**TCA 71-5-191.** Tennessee statute requires the MCO's to follow the uniform claims procedure as set up by TennCare, and lists various performance requirements re processing time and notice requirements. **TCA 56-32-126.** As part of the uniform claims process, MCOs are required in the CRA to submit encounter data as defined by TennCare that comply with standard code sets. **CRA 2.23.4.2.1.**
A clean claim is one that *requires no further information, adjustment, or alteration by the provider of the services* in order to be adjudicated **The Contractor risk agreement (CRA) Section 1 Definitions.** Providers are required in their provider agreements to submit clean claims in order to be paid.**CRA 2.12.9.29**

Taking these all these provisions together it is clear that 1) MCOs only are to provide services for which there is FFP and 2) to get FFP Federal law requires certain data (namely NDC codes), which Tennessee state law and the CRA require the MCO to obtain from the Provider and pass on to the State**. Failure to supply a clean claim leads directly to loss of FFP for that service, and therefore these claims must be correctly resubmitted, as is mandated under the terms of both the provider agreement and the Contractor Risk Agreement. MCOs should not make payments including partial payments on unclean claims. Failure to properly submit the required NDC information may result in the imposition of a Corrective Action Plan and potential liquidated damages as required by the CRA, and possibly other penalties at the discretion of the Commissioner of the Department of Commerce and Insurance.**