ARKANSAS REGISTER



Transmittal Sheet

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Secretary of State

John Thurston

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For Office Use Only: Code Number Effective Date Name of Agency Department of Human Services Department Division of Medical Services E-mail Mac.E.Golden@dhs.arkansas.gov Phone 501.320.6383 Contact Mac E. Golden Statutory Authority for Promulgating Rules Arkansas Code §§ 20-76-201, 20-77-107, and 25-10-129 Rule Title: National Drug Code(NDC) Billing Updates Intended Effective Date Date (Check One) September 25, 2022 Emergency (ACA 25-15-204) October 24, 2022 10 Days After Filing (ACA 25-15-204) Final Date for Public Comment Other $\frac{01\text{-}01\text{-}2023}{\text{(Must be more than 10 days after filing date.)}}$ December 16, 2022 Reviewed by Legislative Council..... January 01, 2023 Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218) 12-16-2022 Lisa Teague lisa.teague@dhs.arkansas.gov Contact Person E-mail Address

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature
501-244-3944 elizabeth.pitman@dhs.arkansas.go
Phone Number E-mail Address
Director, Division of Medical Services
Title
12-16-2022
Date

TOC not required

242.400 Drug Procedure Codes and National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005 for drugs. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on or after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The *Labeler termination date* indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the *termination date*.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the NDC termination date. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for

Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA-assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78
LABELER	PRODUCT CODE	PACKAGE CODE
CODE	(4 digits)	(2 digits)
(5 digits)	` , ,	` , ,

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	123456789 0 1
1111-2222-33	0 1111222233
01111 456 71	01111 0 45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

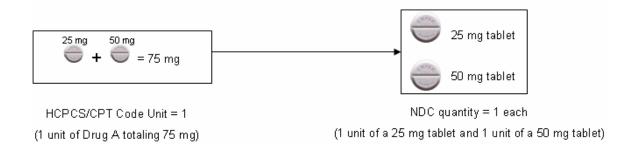
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

C. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

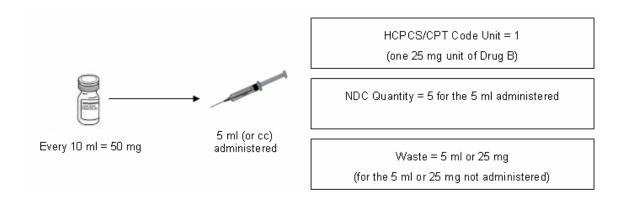
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug, whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets D (Electronic Claims Filing) and E (Paper Claims Filing) below.

Diagram 5



D. Electronic Claims Filing 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier

- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- E. Paper Claims Filing CMS-1450 (UB-04)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

Diagram 6

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0636	N4 12345678912 UN 1.00	Z1234 KP	01/01/22	1	2500			1
2	0636	N4 01111222233 UN 1.00	Z1234 KQ	01/01/22	1	2500			2
э	0636	N4 44444455506 ML 3.00	Z1234 KQ	01/01/22	3	7500			э
4	0636	N4 44444455506 ML 2.00	Z1234 JW	01/01/22	2	5000			4
5									5
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F. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

G. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, disputes or review issues, appeal hearings, investigations, or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing the purchase of drugs and documentation showing what drug (name, strength, and amount) was administered and on what date, to the beneficiary in question.

242.410 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

- A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges 96365 through 96379.
- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description, the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials:** Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

ARKids First-B Section II

TOC not required

262.431 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.

View or print the procedure codes for ARKids First-B procedures and services.

- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description, the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials:** Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

TOC not required

272.531 National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The Labeler termination date indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the termination date.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the *NDC termination date*. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for

Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78		
LABELER	PRODUCT	PACKAGE		
CODE	CODE	CODE		
(5 digits)	(4 digits)	(2 digits)		

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345-6789-1	123456789 0 1
1111-2222-33	0 1111222233
01111-456-71	01111 0 45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

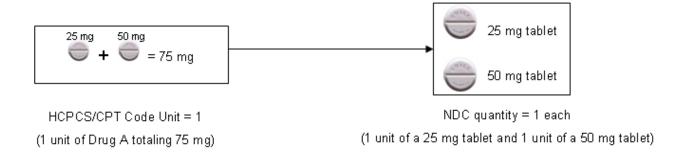
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

I. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

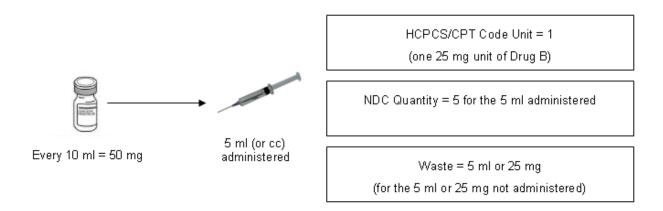
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets A (Electronic Claims Filing) and B (Paper Claims Filing) below.

Diagram 5



A. Electronic Claims Filing – 837P (Professional) and 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- B. Paper Claims Filing CMS-1500

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 6

24. A	From	ATE(S)	OF SER	VICE To		B. PLACE OF	C.	D. PROCEDUR (Explain U	ES, SERI	VICES, O	R SUPPLIES	S E. DIAGNOSIS	F.	G. DAYS	H. EPSOT	ID.	J. RENDERING
MM	DD	YY	MM	DO	YY.	SERVICE	EMG	CPT/HCPCS	1	MODE	RER	POINTER	\$ CHARGES	UNITS	Pan	QUAL	PROVIDER ID. #
N4	1234	1567	8912	UN	1.00												123456789
01	01	22	01	01	22	11		Z1234	KP			1	25 00	1		NPI	
N4	011:	1122	2223	UN	1.00												123456789
01	01	22	01	01	22	11		Z1234	KQ			1	25 00	1		NPI	
N4	4444	1445	5506	ML	3.0												123456789
01	01	22	01	01	22	11		Z1234	KQ			1	75 00	3		NPI.	
N4	4444	1445	5506	ML	2.0												123456789
01	01	22	01	01	22	11		Z1234	JW			1	50 00	2		NPI	
						-				100						NPI	
															-		
					1	-			1000			110 25 100	and the second			NP1	
25. F	FDFRA	TAX	D: NUM	WER	555	FIN	26	PATIENTS ACCOU	INT NO	197	ACCEPT A	CCC/SAMENT?	26 TOTAL CHARGE	1.9	9 AAAC	NINT P	AID 30 Roud by NI ICC use

II. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

III. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, dispute or review issues, appeal hearings, investigations, or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing purchase of drugs and documentation showing what drug (name, strength, and amount) was administered and on what date, to the beneficiary in question.

See Section 272.533 for additional information regarding drug code billing.

272.533 Injections, Therapeutic and/or Diagnostic Agents

1-1-23

A. Providers billing the Arkansas Medicaid Program for covered injections should bill the appropriate CPT or HCPCS procedure code for the specific injection administered. The procedure codes and their descriptions may be found in the Current Procedure Terminology (CPT) and in the Healthcare Common Procedural Coding System Level II (HCPCS) coding books.

Injection administration code is payable for beneficiaries of all ages. May be used for billing the administration of subcutaneous and/or intramuscular injections only. This procedure code cannot be billed when the medication is administered "ORALLY." No fee is billable for drugs administered orally.

Cannot be billed separately for Influenza Virus vaccines or Vaccines for Children (VFC) vaccines.

Cannot be billed to administer any medication given for family planning purposes. No other fee is billable when the provider decides not to supply family planning injectable medications.

Cannot be billed when the drug administered is not FDA approved.

Covered drugs can be billed electronically or on paper. If requested, additional documentation may be required to justify medical necessity. Reimbursement for manually priced drugs is based on a percentage of the average wholesale price.

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs. See Section 272.531 for further information.

Administration of therapeutic agents is payable only if provided in a physician's office, place of service code "11." These procedures are not payable to the certified nurse-midwife if performed in any other setting. Therapeutic injections should only be provided by certified nurse-midwives experienced in the provision of these medications and who have the facilities to treat patients who may experience adverse reactions. The capability to treat infusion reactions with appropriate life support techniques should be immediately available. Only one administration fee is allowed per date of service unless "multiple sites" are indicated in the "Procedures, Services, or Supplies" field in the CMS-1500 claim form. Reimbursement for supplies is included in the administration fee. An administration fee is not allowed when drugs are given orally.

Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges for therapeutic and chemotherapy administration procedure codes.

B. For consideration of payable unlisted CPT/HCPCS drug procedure codes:

1. The provider must submit an electronic or paper claim that includes a description of the drug being represented by the unlisted procedure code on the claim form.

- 2. Documentation that further describes the drug provided must be attached and must include justification for medical necessity.
- 3. All other billing requirements must be met in order for payment to be approved.

C. Immunizations

Physicians may bill for immunization procedures on the CMS-1500 claim form. <u>View a CMS-1500 sample form.</u>

Coverage criteria for all immunizations and vaccines are listed in the <u>Procedure Code</u> <u>Tables – Arkansas Department of Human Services</u>.

Influenza virus vaccine through the Vaccines for Children (VFC) program is determined by the age of the beneficiary and which vaccine is used.

The administration fee for all vaccines is included in the reimbursement fee for the vaccine CPT procedure code.

D. Vaccines for Children (VFC)

The Vaccines for Children (VFC) Program was established to generate awareness and access for childhood immunizations. Arkansas Medicaid established new procedure codes for billing the administration of VFC immunizations for children under the age of 19 years of age. To enroll in the VFC Program, contact the Arkansas Department of Health. Providers may also obtain the vaccines to administer from the Arkansas Division of Health. View or print Arkansas Department of Health contact information.

Medicaid policy regarding immunizations for adults remains unchanged by the VFC Program.

Vaccines available through the VFC Program are covered for Medicaid-eligible children. Administration fee only is reimbursed. When filing claims for administering VFC vaccines, providers must use the CPT procedure code for the vaccine administered. Electronic and paper claims require modifiers **EP** and **TJ**. ARKids First-B beneficiaries are not eligible for the VFC Program; however vaccines can be obtained to administer to ARKids First-B beneficiaries who are under the age of 19 by contacting the Arkansas Department of Health and indicating the need to order ARKids First-B SCHIP vaccines. View or print the Department of Health contact information.

When vaccines are administered to beneficiaries of ARKids First-B services, only modifier **SL** must be used for billing. Any additional billing and coverage protocols are listed under the specific procedure code in the tables in this section of this manual. See Part F of this section.

E. Billing of Multi-Use and Single-Use Vials

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

- Multiple units may be billed when applicable. Take-home drugs are not covered.
 Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.
- When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.

a. **Single-Use Vials:** If the provider must discard the remainder of a **single-use vial** or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.

- b. **Multi-Use Vials** are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
- c. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

See Section 272.531 for additional information regarding National Drug Code (NDC) billing.

F. Process for Obtaining a Prior Authorization (PA) Number from the DHS contracted Prior Authorization vendor.

Covered drugs may be billed electronically or on a paper claim. Additionally, these procedure codes requiring a PA will no longer require manual review during the processing of the claim.

A PA must be requested before treatment is initiated for any drug, therapeutic agent or treatment that indicates a PA is required in a provider manual or an official Division of Medical Services correspondence.

The PA requests should be completed using the approved contracted vendor PA request form (View or print PA form.)

A decision letter will be returned to the provider by fax or *e-mail* within five (5) business days.

If approved, the Prior Authorization number must be appended to all applicable claims, within the scope of the approval and may be billed electronically or on a paper claim with additional documentation when necessary.

Denials will be subject to reconsideration if received by the contracted vendor with additional documentation within fifteen (15) business days of date of denial letter.

A reconsideration decision will be returned within five (5) business days of receipt of the reconsideration request.

G. Contact Information for Obtaining Prior Authorization

<u>View or print contact information to obtain the DHS or designated vendor step-by-step process for requesting prior authorization.</u>

H. All family planning procedures require an FP modifier and a primary family planning diagnosis on the claim.

*Procedure code requires paper billing with applicable attachments and must follow NDC protocol. (See Section 272.531 for NDC protocol.)

See Section 240.000-240.200 for prior authorization procedures.

List 603 diagnosis codes include: (<u>View ICD Codes</u>.) Diagnosis List 603 restrictions apply to ages twenty-one (21) years and above unless otherwise indicated in the age restriction column.

TOC not required

242.141 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

- A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.
 - <u>View or print the procedure codes and modifiers for Child Health Services/Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services.</u>
- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description, the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

TOC not required

272.102 Drug Procedure Codes and National Drug Codes (NDC)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005 for drugs. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on or after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. The effective date is when a manufacturer entered into a rebate agreement with CMS. The Labeler termination date indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the termination date. For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the NDC termination date. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA-assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 1 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 1

00123	0456	78		
LABELER CODE		PACKAGE CODE		
(5 digits)	(4 digits)	(2 digits)		

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 2 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 2

	Required 11-digit NDC
10-digit FDA NDC on PACKAGE	(5-4-2) Billing Format
12345 6789 1	12345678901
1111-2222-33	01111222233
01111 456 71	01111045671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

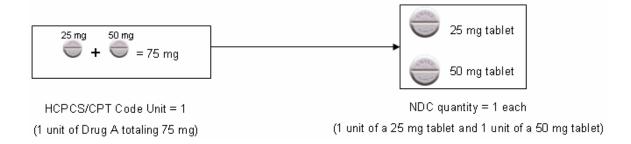
Exception: There is no requirement for an NDC when billing for vaccines.

C. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

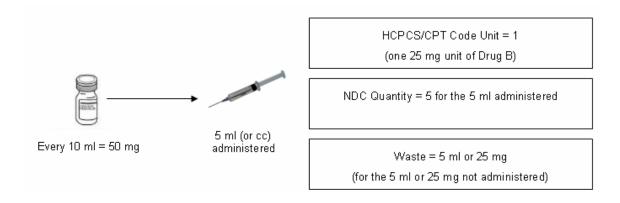
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug, whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example, whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 3.

Diagram 3



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. For billing wastage, see bullets D (Electronic Claims Filing) and E (Paper Claims Filing) below.

Diagram 4



D. Electronic Claims Filing 837I (Outpatient)

Providers are instructed to bill as follows:

- o 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- o 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- o 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- o 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- E. Paper Claims Filing CMS-1450 (UB-04)

Providers are instructed to bill as follows:

- o 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- o 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- o 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- o 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier

o Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 5

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0636	N4 12345678912 UN 1.00	Z1234 KP	01/01/22	1	2500			ŀ
2	0636	N4 01111222233 UN 1.00	Z1234 KQ	01/01/22	1	2500			2
э	0636	N4 44444455506 ML 3.00	Z1234 KQ	01/01/22	3	7500			э
4	0636	N4 44444455506 ML 2.00	Z1234 JW	01/01/22	2	5000			4
5									5
									4

F. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

G. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, disputes or review issues, appeal hearings, investigations, or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing the purchase of drugs and documentation showing what drug (name, strength, and amount) was administered and on what date, to the beneficiary in question.

See Section 272.510 for additional information regarding National Drug Code (NDC) billing.

272.510 Injections, Radiopharmaceuticals and Therapeutic Agents

1-1-23

1. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

TOC not required

262.441 National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The *Labeler termination date* indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the *termination date*.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the *NDC termination date*. The NDC termination date represents

the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78
LABELER	PRODUCT	PACKAGE
CODE	CODE	CODE
(5 digits)	(4 digits)	(2 digits)

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	123456789 0 1
1111-2222-33	0 1111222233
01111 456 71	01111 0 45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

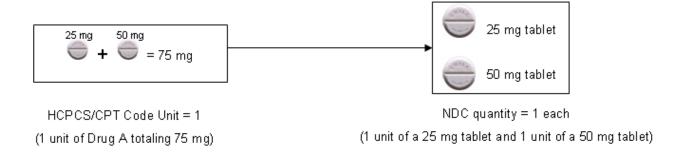
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

I. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

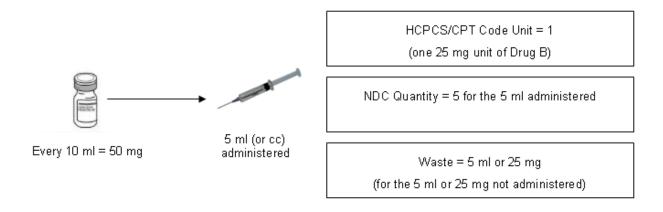
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets A (Electronic Claims Filing) and B (Paper Claims Filing) below.

Diagram 5



A. Electronic Claims Filing – 837P (Professional) and 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- B. Paper Claims Filing CMS-1500

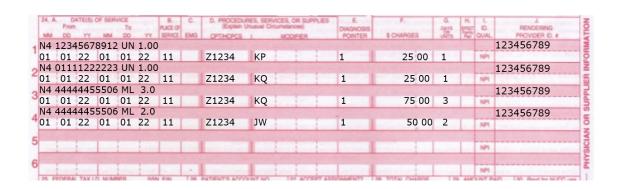
Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 6



II. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

III. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, dispute or review issues, appeal hearings, investigations or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing purchase of drugs and documentation showing what drug (name, strength and amount) was administered and on what date, to the beneficiary in question.

262.442 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.

<u>View or print the procedure codes for Federally Qualified Health Center (FQHC)</u> services.

- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description, the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

See Section 262.441 for additional information regarding National Drug Code (NDC) billing.

242.143 National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. The effective date is when a manufacturer entered into a rebate agreement with CMS. The Labeler termination date indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the termination date. For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the NDC termination date. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA-assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 1 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 1

00123	0456	78
LABELER	PRODUCT CODE	PACKAGE CODE
CODE	(4 digits)	(2 digits)
(5 digits)	, ,	, ,

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 2 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 2

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	12345678901
1111-2222-33	01111222233
01111 456 71	01111045671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

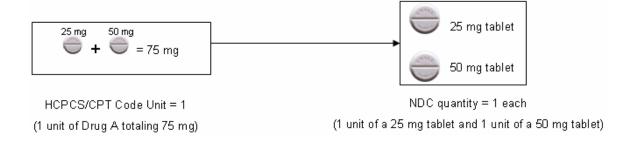
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

C. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug, whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example, whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 3.

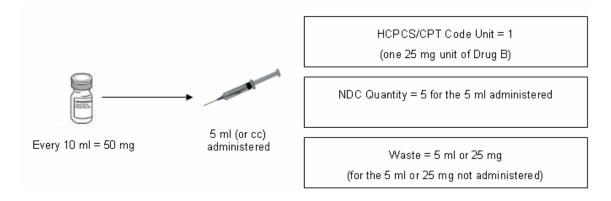
Diagram 3



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be

documented as wasted. For billing wastage, see bullets D (Electronic Claims Filing) and E (Paper Claims Filing) below.

Diagram 4



D. Electronic Claims Filing 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- E. Paper Claims Filing CMS-1450 (UB-04)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 5

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0636	N4 12345678912 UN 1.00	Z1234 KP	01/01/22	1	2500			1
2	0636	N4 01111222233 UN 1.00	Z1234 KQ	01/01/22	1	2500			2
3	0636	N4 44444455506 ML 3.00	Z1234 KQ	01/01/22	3	7500			э
4	0636	N4 44444455506 ML 2.00	Z1234 JW	01/01/22	2	5000			4
5									5
								4	4

F. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

G. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, disputes or review issues, appeal hearings, investigations, or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing the purchase of drugs and documentation showing what drug (name, strength, and amount) was administered and on what date, to the beneficiary in question.

242.144 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.

View or print the procedure codes for Home Health services.

- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description, the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - 1. Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.

2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.

3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

See Section 242.143 for additional information regarding National Drug Code (NDC) billing.

TOC not required

242.401 National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The *Labeler termination date* indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the *termination date*.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the *NDC termination date*. The NDC termination date represents

the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78
LABELER	PRODUCT	PACKAGE
CODE	CODE	CODE
(5 digits)	(4 digits)	(2 digits)

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	123456789 0 1
1111-2222-33	0 1111222233
01111 456 71	01111 0 45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

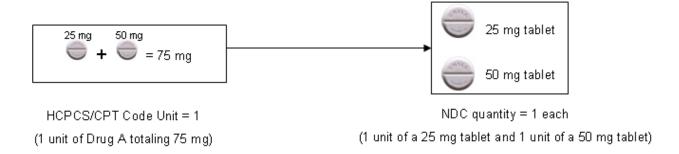
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

I. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

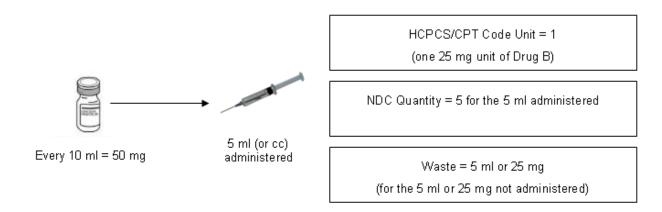
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets A (Electronic Claims Filing) and B (Paper Claims Filing) below.

Diagram 5



A. Electronic Claims Filing – 837P (Professional) and 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim

Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- B. Paper Claims Filing CMS-1500

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 6

24. A.	From	E(S)	OF SERI	To		PLACE OF	C	D. PROCEDU (Explain U	RES, SERV	ACES, OR S cumelances	SUPPLIES	E. DIAGNOSIS	F.	G. DAYS	H, EPSOT	ID.	RENDERING
MM	DD	YY	MM	DO	YY	SERVICE	EMG	CPT/HCPCS	1	MODIFIE	R	POINTER	\$ CHARGES	UNITS	Pan	QUAL	PROVIDER ID. #
14 1	2345	67	8912	UN	1.00												123456789
1	01 2	2	01	01	22	11		Z1234	KP			1	25 00	1		NPI	
14 0	1111	22	2223	UN	1.00												123456789
1	01 2	2	01	01	22	11		Z1234	KQ			1	25 00	1		NPI	
14 4	4444	45	5506	ML	3.0												123456789
1	01 2	2	01	01	22	11		Z1234	KQ			1	75 00	3		NPI.	
14 4	4444	45	5506	ML	2.0												123456789
)1	01 2	2	01	01	22	11		Z1234	JW			1	50 00	2		NPI	
					-						4				P		
									_							NPI	The second second second
	-				-				-	-	-	-	-		P		
			100		4	-				100	-	200	median endian		100	NPI	AND REAL PROPERTY AND ADDRESS.

II. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

III. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, dispute or review issues, appeal hearings, investigations or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing purchase of drugs and documentation showing what drug (name, strength and amount) was administered and on what date, to the beneficiary in question.

242.402 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.

View or print the procedure codes for Hyperalimentation services.

- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

Nurse Practitioner Section II

TOC not required

252.438 National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The *Labeler termination date* indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the *termination date*.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the *NDC termination date*. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for

Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78
LABELER	PRODUCT	PACKAGE
CODE	CODE	CODE
(5 digits)	(4 digits)	(2 digits)

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	123456789 0 1
1111-2222-33	0 1111222233
01111 456 71	01111 0 45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

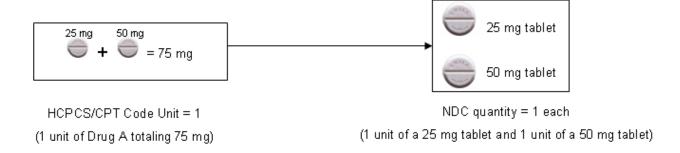
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

I. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

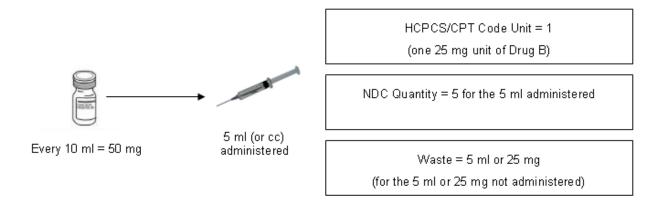
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets A (Electronic Claims Filing) and B (Paper Claims Filing) below.

Diagram 5



A. Electronic Claims Filing – 837P (Professional) and 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim

Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- B. Paper Claims Filing CMS-1500

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 6

24. A.	From Prom	OF SEF	To		B. PLACE OF	C.	D. PROCEDUI (Explain U	RES, SERI Inusual Cir	VICES, OR SI cumetances)	UPPLIES	E. DIAGNOSIS	F.	G. DAYS OR	H, EPSOT Family	ID.	RENDERING
14 1	123456	7891	2 UN	1.00	SEMPLE	EMIG	CPT/HCPCS		MODIFIER		POINTER	\$ CHARGES	UNITS	Pacific	JUAL	123456789
)1	01 22	01	01	22	11		Z1234	KP			1	25 00	1		NPI	
N4 C	11112	2222	3 UN	1.00												123456789
1	01 22	01	01	22	11		Z1234	KQ			1	25 00	1		NPI	
14 4	144444	5550	5 ML	3.0												123456789
1	01 22	01	01	22	11		Z1234	KQ			1	75 00	3		NPI.	
14 4	144444	5550	5 ML	2.0												123456789
1	01 22	01	01	22	11		Z1234	JW			1	50 00	2		NPI	
															NPI	
								1							NP1	

II. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

III. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, dispute or review issues, appeal hearings, investigations or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing purchase of drugs and documentation showing what drug (name, strength and amount) was administered and on what date, to the beneficiary in question.

252.439 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.

View or print the procedure codes for Nurse Practitioner services.

- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

TOC not required

242.450 National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare & Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The *Labeler termination date* indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the *termination date*.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the *NDC termination date*. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78
LABELER	PRODUCT	PACKAGE
CODE	CODE	CODE
(5 digits)	(4 digits)	(2 digits)

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	123456789 0 1
1111-2222-33	0 1111222233
01111 456 71	01111 0 45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPC/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

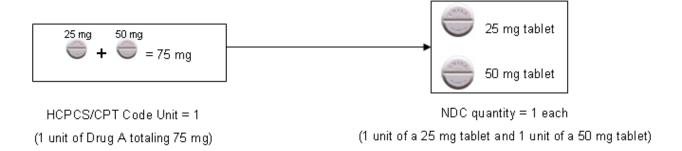
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

I. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

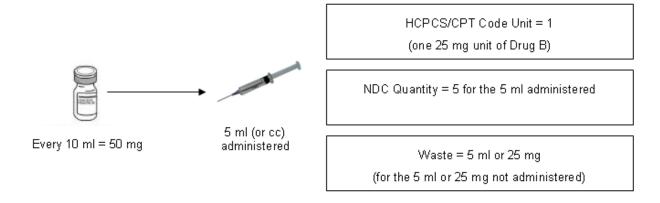
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets A (Electronic Claims Filing) and B (Paper Claims Filing) below.

Diagram 5



A. Electronic Claims Filing – 837P (Professional) and 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

B. Paper Claims Filing – CMS-1500 and CMS-1450 (UB-04)

Arkansas Medicaid will require providers billing drug HCPCS/CPT codes including covered unlisted drug procedure codes to use the required NDC format.

See Diagram 6 for CMS-1500 and Diagram 7 for CMS-1450 (UB-04).

CMS-1500

For professional claims, CMS-1500, list the qualifier of "N4", the 11-digit NDC, the unit of measure qualifier (F2 - International Unit; GR - Gram; ML - Milliliter; UN - Unit), and the number of units of the actual NDC administered in the shaded area above detail field 24A, spaced and arranged exactly as in Diagram 6.

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 6



For institutional outpatient claims on the CMS-1450 (UB-04), use the locator field 43 (Description) to list the qualifier of "N4", the 11-digit NDC, the unit of measure qualifier (F2 - International Unit; GR - Gram; ML - Milliliter; UN - Unit), and number of units of the actual NDC administered, spaced, and arranged exactly as in Diagram 7.

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 7

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0636	N4 12345678912 UN 1.00	Z1234 KP	01/01/22	1	2500		
2	0636	N4 01111222233 UN 1.00	Z1234 KQ	01/01/22	1	2500		
3	0636	N4 44444455506 ML 3.00	Z1234 KQ	01/01/22	3	7500		
4	0636	N4 44444455506 ML 2.00	Z1234 JW	01/01/22	2	5000		
5								

II. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

III. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, disputes or review issues, appeal hearings, investigations, or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer. At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include NDC invoices showing the purchase of drugs and documentation showing what drug (name, strength, and amount) was administered and on what date, to the beneficiary in question.

TOC not required

242.401 National Drug Codes (NDCs)

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Health Care Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The *Labeler termination date* indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the *termination date*.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the *NDC termination date*. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code, and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78		
LABELER	PRODUCT	PACKAGE		
CODE	CODE	CODE		
(5 digits)	(4 digits)	(2 digits)		

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	123456789 0 1
1111-2222-33	0 1111222233
01111 456 71	01111 0 45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

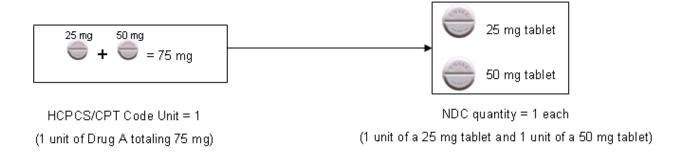
Exception: There is no requirement for an NDC when billing for vaccines, radiopharmaceuticals, and allergen immunotherapy.

I. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

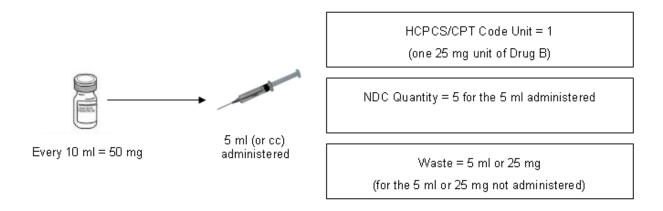
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets A (Electronic Claims Filing) and B (Paper Claims Filing) below.

Diagram 5



A. Electronic Claims Filing – 837P (Professional) and 837I (Outpatient)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage
- B. Paper Claims Filing CMS-1500

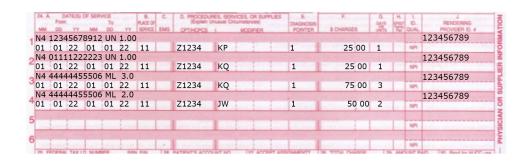
Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 6



II. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

III. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, dispute or review issues, appeal hearings, investigations or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing purchase of drugs and documentation showing what drug (name, strength and amount) was administered and on what date, to the beneficiary in question.

242.402 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.

<u>View or print the procedure codes and modifiers for Durable Medical Equipment</u> (DME), oxygen equipment and supplies, orthotic appliances, prosthetic devices and medical supplies, procedures and services.

- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

Rural Health Clinic Section II

TOC not required

252.103 Billing of Multi-Use and Single-Use Vials

1-1-23

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.

View or print the procedure codes for Rural Health Clinic (RHC) services.

- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

TOC not required

252.100 Ambulance Procedure Codes

1-1-23

The covered ambulance procedure codes are listed below.

View or print the procedure codes for Transportation (Ambulance) services.

Drug procedure codes require National Drug Codes (NDC) billing protocol. See Section 252.110 below.

*Procedure code can be billed <u>only</u> in conjunction with procedure code (please keep all documentation supporting the medical necessity of all codes billed for retrospective review of claims).

Arkansas Medicaid follows the billing protocol per the Federal Deficit Reduction Act of 2005 for drugs.

- A. Multiple units may be billed when applicable. Take-home drugs are not covered. Drugs loaded into an infusion pump are not classified as "take-home drugs." Refer to payable CPT code ranges.
- B. When submitting Arkansas Medicaid drug claims, drug units should be reported in multiples of the dosage included in the HCPCS procedure code description. If the dosage given is not a multiple of the number provided in the HCPCS code description the provider shall round up to the nearest whole number in order to express the HCPCS description number as a multiple.
 - Single-Use Vials: If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Arkansas Medicaid will cover the amount of the drug discarded along with the amount administered. Discarded drugs shall be billed on a separate detail line with a JW (Drug wastage) modifier.
 - 2. **Multi-Use Vials**: Multi-use vials are not subject to payment for any discarded amounts of the drug. The units billed must correspond with the units administered to the beneficiary.
 - 3. **Documentation:** The provider must clearly document in the patient's medical record the actual dose administered in addition to the exact amount wasted and the total amount the vial is labeled to contain.

Remember to verify the milligrams given to the patient and then convert to the proper units for billing.

Follow the Centers for Disease Control (CDC) requirements for safe practices regarding expiration and sterility of multi-use vials.

252.110 National Drug Codes (NDC) Billing Protocol

1-1-23

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid implemented billing protocol per the Federal Deficit Reduction Act of 2005. This explains policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes with dates of service on and after January 1, 2008.

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Healthcare Common Procedure Coding System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare and Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each state a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first five (5) digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first five (5) digits of the NDC) to the list of covered labelers which is maintained on the DHS contracted Pharmacy vendor website.

A complete listing of "Covered Labelers" is located on the website. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The Labeler termination date indicates that the manufacturer no longer participates in the federal rebate program, and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the termination date.

Diagram 1

Labeler ID	Labeler Name	Contract Begin Date	Contract End Date
00002	ELI LILLY AND COMPANY	01/01/1991	01/01/3000
00003	E.R. SQUIBB & SONS, LLC.	01/01/1991	01/01/3000
00004	GENENTECH, INC.	01/01/1991	01/01/3000
00006	MERCK SHARP & DOHME CORP.	01/01/1991	01/01/3000
00007	GLAXOSMITHKLINE LLC	01/01/1991	01/01/3000
80000	WYETH PHARMACEUTICALS LLC,	01/01/1991	01/01/3000
00009	PHARMACIA AND UPJOHN COMPANY LLC	01/01/1991	01/01/3000
00013	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00014	PFIZER, INC	01/01/1991	01/01/3000
00015	MEAD JOHNSON AND COMPANY	01/01/1991	01/01/3000
00023	ALLERGAN INC	01/01/1991	01/01/3000
00024	SANOFI-AVENTIS, US LLC	01/01/1991	01/01/3000
00025	PFIZER LABORATORIES DIV PFIZER INC	01/01/1991	01/01/3000
00026	BAYER HEALTHCARE LLC	01/01/1991	01/01/3000
00032	ABBVIE INC.	01/01/1991	01/01/3000

For a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the NDC termination date. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three (3) segments or codes: a 5-digit labeler code, a 4-digit product code and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero (0) in one (1) of the three (3) segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as five (5) digits with leading zeros; the product code as four (4) digits with leading zeros; the package code as two (2) digits without leading zeros, using the "5-4-2" format.

00400	0.450	70
00123	0456	78
LABELER CODE	PRODUCT CODE	PACKAGE CODE
(5 digits)	(4 digits)	(2 digits)

NDCs submitted in any configuration other than the 11-digit format will be rejected/denied. NDCs billed to Medicaid for payment must use the 11-digit format without dashes or spaces between the numbers.

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid.

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC
	(5-4-2) Billing Format
12345 6789 1	12345678901
1111-2222-33	01111222233
01111 456 71	01111045671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

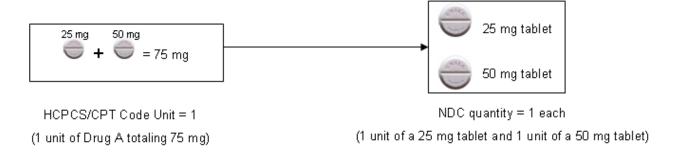
HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPCS/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one (1) labeler to another, from one (1) package size to another, and from one (1) time period to another.

Exception: There is no requirement for an NDC when billing for vaccines.

I. Claims Filing

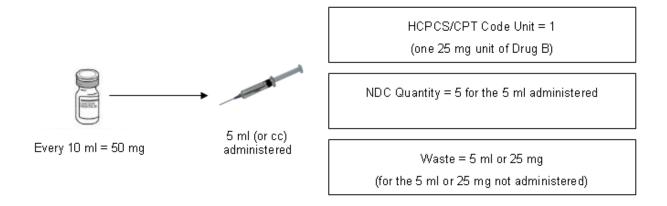
The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5. For billing wastage, see bullets A (Electronic Claims Filing) and B (Paper Claims Filing) below.

Diagram 5



A. Electronic Claims Filing – 837P (Professional)

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure submit via paper claim
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: The NDCs listed above are not the same (unless with a JW modifier). Same NDCs shall be billed on a single line with appropriate units.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation

- JW = Drug wastage
- B. Paper Claims Filing CMS-1500

Arkansas Medicaid will require providers billing drug HCPCS/CPT codes including covered unlisted drug procedure codes to use the required NDC format.

See Diagram 6 for CMS-1500.

CMS-1500

For professional claims, CMS-1500, list the qualifier of "N4", the 11-digit NDC, the unit of measure qualifier (F2 – International Unit; GR – Gram; ML - Milliliter; UN – Unit), and the number of units of the actual NDC administered in the shaded area above detail field 24A, spaced and arranged exactly as in Diagram 6.

Providers are instructed to bill as follows:

- 1 NDC for a procedure 1st/only detail shall be billed with no modifier
- 2 NDCs for same procedure 1st detail shall be billed with a KP and 2nd gets billed with a KQ modifier
- 3 NDCs for same procedure 1st detail shall be billed with a KP and 2nd & 3rd detail get billed with a KQ modifier
- 4 or more NDCs for same procedure 1st detail shall be billed with a KP and 2nd and subsequent details shall be billed with a KQ modifier
- Wastage of each NDC shall be billed on a separate line with a JW modifier.

NOTE: CMS definitions of modifiers:

- KP = First drug of a multiple drug unit dose formulation
- KQ = Second or subsequent drug of a multiple drug unit dose formulation
- JW = Drug wastage

Diagram 6



II. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

III. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, dispute or review issues, appeal hearings, investigations or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing purchase of drugs and documentation showing what drug (name, strength and amount) was administered and on what date, to the beneficiary in question.

See Section 252.100 for additional information regarding drug code billing.