NCPDP EMERGENCY PREPAREDNESS GUIDANCE – COVID-19 VACCINES

VERSION 1.1

This document provides resource information for the pharmacy industry for the COVID-19 pandemic.

February 2021

National Council for Prescription Drug Programs
9240 East Raintree Drive
Scottsdale, AZ 85260

Phone: (480) 477-1000
Fax: (480) 767-1042
Email: ncpdp@ncpdp.org
http: ncpdp.org

NCPDP EMERGENCY PREPAREDNESS GUIDANCE – COVID-19 VACCINES

Version 1.1

NCPDP recognizes the confidentiality of certain information exchanged electronically through the use of its standards. Users should be familiar with the federal, state, and local laws, regulations and codes requiring confidentiality of this information and should utilize the standards accordingly.

NOTICE: In addition, this NCPDP Standard contains certain data fields and elements that may be completed by users with the proprietary information of third parties. The use and distribution of third parties' proprietary information without such third parties' consent, or the execution of a license or other agreement with such third party, could subject the user to numerous legal claims. All users are encouraged to contact such third parties to determine whether such information is proprietary and if necessary, to consult with legal counsel to make arrangements for the use and distribution of such proprietary information.

Published by:
National Council for Prescription Drug Programs

Publication History:
Version 1.0 December 2020
Version 1.1 February 2021

TABLE OF CONTENTS

1. COVID-19 VACCINES CONSIDERATIONS

The federal government is committed to ensuring Americans have access to a COVID-19 vaccine through Operation Warp Speed (OWS), a partnership among the Department of Defense (DOD) and components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA). OWS seeks to accelerate the development, manufacture and distribution of a COVID-19 vaccine to the American people. The OWS goal is to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available within 24 hours of authorization being granted by the FDA. These vaccines will generally be available through the FDA Emergency Use Authorization (EUA) process, and may vary in strength, dose quantity and number of doses to achieve expected efficacy. Additionally, federal, state or local agencies may cover the cost of the vaccine product; however, reimbursement of the professional administration services will be coordinated through existing claim billing processes.

While section 3713 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act refers to a COVID-19 vaccine "licensed under section 351 of the Public Health Service (PHS) Act," Centers for Medicare & Medicaid Services (CMS) could consider any vaccine for which FDA issued an EUA during the public health emergency (PHE) as eligible for coverage and payment. As noted within CMS Interim Final Rule with Comments (IFC) 9912, released on November 6, 2020, qualifying coronavirus preventive services are expected to include vaccine immunizations. Plans and issuers subject to section 2713 of the PHS Act must cover such a vaccine and its administration without cost-sharing, regardless of how the administration is billed and regardless of whether a vaccine requires the administration of multiple doses in order to be considered complete.

In the case of COVID-19, the administration of two doses may align to a unique reimbursement fee per dose, where unique claim billing identifiers may be needed to identify which dose of the series is being administered. If the vaccine product's National Drug Code (NDC) will remain the same for the two doses, an alternate data element within the NCPDP Telecommunication Standard Version D.0 claim request transaction is needed to identify the dose number of the vaccine series. Additional guidance as to the days supply associated to each dose may be necessary to standardize the claim adjudication process and expedite patient access to care. NCPDP has developed the following guidance to expeditiously support standardization within the claim adjudication process to address the unique factors associated with COVID-19 vaccines.

1.1 QUANTITY DISPENSED

To facilitate the use of the Billing (B1) or Rebill (B3) transaction, each individual patient vaccine should be treated as a "milliliter". The Billing Unit (BU) will be a milliliter (ML) for the individual vaccine with the quantity of the number of units dispensed, (e.g., 0.5 mL per individual vaccination).

The billing quantity of each individual vaccine will depend on the product used. In the case of billing a single vaccine from a vial that contains multiple doses in each vial, the metric decimal billing quantity and BU will be the quantity drawn into the syringe (volume post reconstitution or dilution, if required) of the "case or package size" for each individual being vaccinated. The metric decimal quantity will be the amount dispensed with a BU of ML.

EXAMPLE 1: MODERNA COVID-19 VACC (UNAPPROVED) with NDC 80777-0273-10 each vial contains 10 doses of the vaccine. The vial contains 5 mL of product. If there are 10 doses per 5 mL vial, each dose will be 0.5 mL. The BU and quantity recommendation is BU = ML per Section 5.2.2 of the NCPDP Billing Unit Standard (BUS); Quantity Dispensed (442-E7) submitted = 0.5 per dose administered; 10 doses x .5 = 5 ML.

EXAMPLE 2: PFIZER COVID-19 VACC (UNAPPROVED) with NDC 59267-1000-01 each vial contains 6 doses of the vaccine per the product labeling if a low dead space syringe is used. The vial contains 0.45 mL frozen suspension reconstituted with 1.8 mL of saline for 6 doses of 0.3 mL. The BU and quantity recommendation would be BU = ML per Section 5.2.2 of the BUS; Quantity Dispensed (442-E7) submitted = 0.3 per dose administered; 6 doses x .3 = 1.8 ML. Traceable inventory would be either 1 vial or 1.8 x 25 (total volume for that package). This BU assignment recommendation is an exception to the BUS because it is assigned to the volume post dilution.

NOTE 1: In some cases, only 5 doses will be able to be extracted from a vial. The number of doses extracted will be dependent upon the type of syringe used in administration.

NOTE 2: This exception applies to vaccines issued under an EUA during a declared emergency. Once the declared emergency ends or once the product receives an FDA approval such as a Biologics License Application, the BU assignment will be revisited and reassigned if necessary, according to the BUS.

NCPDP anticipates additional products will become available after publication of this guide. Users should confirm with their compendium or drug data provider the appropriate BU and quantity of the specific vaccine being dispensed/administered.

1.2 DAYS SUPPLY

Proper calculation of days supply is a key component to claim billing. Pharmacies should submit a value of "1" in the Days Supply (405-D5) field whether dispensing a single-dose vaccine or a two-dose vaccine. Refer to the NCPDP Telecommunication Version D Questions, Answers and Editorial Updates for examples and additional guidance.

1.3 CLAIM SUBMISSION

In a declared emergency, vaccines may be supplied through the US Strategic National Stockpile (SNS) or other sources with no associated product costs. Refer to Section 6.2.1 of the NCPDP Emergency Preparedness Guidance v1.8 for examples and additional guidance on billing for reimbursement of a free product including an administration fee.

In general, claims submitted for zero-cost vaccines should be submitted on a single B1/B3 billing transaction including the following data elements and values:

- Prescription/Service Reference Number Qualifier (455-EM) of "1" (Rx Billing)
- Product/Service ID Qualifier (436-E1) – usually "03" for NDC
- Product/Service ID (407-D7) containing the NDC number of the vaccine or other product that was administered and obtained at a zero cost
- Quantity Dispensed (442-E7) should be submitted with the value that represents the quantity of drug product administered (see Section 1.1 on quantity dispensed)
- Professional Service Code (440-E5) value of "MA" (Medication Administered)
- Incentive Amount Submitted (438-E3) should be submitted to identify the pharmacy is seeking reimbursement for the administration of the product
- Ingredient Cost Submitted (409-D9) value of $0.00*
- Gross Amount Due (430-DU) value should be submitted to include the Incentive Amount Submitted for the vaccine administration fee and zero cost of the vaccine
- Basis of Cost Determination (423-DN) value of "15" (Free product or no associated cost) should be submitted*

*NOTE: Some systems may not be able to successfully exchange the value of $0.00 as an Ingredient Cost Submitted or do not yet support Basis of Cost Determination (423-DN) value '15'. Trading partners should clearly communicate in advance when alternative values (such as Ingredient Cost Submitted (409-D9) of $0.01 and/or another value for Basis of Cost Determination (423-DN)) are necessary for claims adjudication. Also refer to the section titled "VACCINE SERVICES – PHARMACY BENEFIT BILLING & PROCESSING" within the NCPDP TELECOMMUNICATION VERSION D (Telecommunication Standard) AND ABOVE QUESTIONS, ANSWERS AND EDITORIAL UPDATES.

1.4 VACCINE ADMINISTRATION INDICATORS FOR SINGLE-DOSE AND TWO-DOSE VACCINES

COVID-19 vaccines may require a single dose or a series of two doses to achieve expected efficacy. Reimbursement for administration of these doses may vary for each dose within the series.

Single-Dose Vaccines

Single-Dose vaccines can be identified by the Product/Service ID (407-D7) value, where no additional NCPDP fields or values are necessary to identify it is a single-dose product. Existing data elements and values can be leveraged to apply applicable claim utilization rules.

Two-Dose Vaccines

The Submission Clarification Code (420-DK) field should be used to indicate which dose of a two-dose vaccine is being administered allowing for applicable edits to be invoked and determine proper reimbursement. This guidance applies regardless if the same provider or different providers administer the series of doses.

Use of Submission Clarification Codes (420-DK)

In order to clearly identify whether the claim is for an initial dose or final dose of the vaccine series, a Submission Clarification Code value should be submitted on all claims for two-dose vaccines. The following distinct Submission Clarification Code values should be used to clarify the submission as an initial or final dose:

Initial Dose:

- Submission Clarification Code of **2 "Other Override"** - defined as, "*Used when authorized by the payer in business cases not currently addressed by other SCC values,"* to indicate the first dose of a two-dose vaccine is being administered.

Final Dose:

- Submission Clarification Code of **6 "Starter Dose"** - defined as, "*The pharmacist is indicating that the previous medication was a starter dose and now additional medication is needed to continue treatment,"* to indicate the final dose of a two-dose vaccine is being administered.

Refer to the COVID-19 Vaccine Use Case Examples chart that shows how/when these Submission Clarification Code values can be used within the COVID-19 vaccine claim adjudication process.

1.5 COVID-19 VACCINE USE CASE EXAMPLES

1.5.1 USE OF SUBMISSION CLARIFICATION CODE (420-DK) FOR INITIAL, FINAL AND SINGLE-DOSE IDENTIFICATION

The following use case examples are based on COVID-19 vaccine NDCs associated to the two-dose and single-dose products. Since the NDC by itself does not identify the initial or final dose of a two-dose product, NCPDP recommends Submission Clarification Code (420-DK) value of 2 be used to identify the initial dose and the value of 6 for the final dose. While not required, Submission Clarification Code values of 2 or 6 submitted with single-dose NDCs should not trigger a M/I Submission Clarification Code reject.

The following uses case examples are outlined in the chart below:

1. Two-Dose NDC, SCC = 2
2. Two-Dose NDC, SCC = 6, Fill # = 01, same Service Provider ID
3. Two-Dose NDC, SCC = 6, Fill # = 00, same Service Provider ID
4. Two-Dose NDC, SCC = 6, Fill # = 00, different service Provider ID
5. Two-dose NDC, SCC is BLANK
6. Single-Dose NDC, SCC is BLANK
7. Single-Dose NDC, SCC = 2
8. Single-Dose NDC, SCC = 6

	Request								Response		
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)***	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**	**Incentive Amount Paid (521-FL)**
1. ***Two-Dose NDC, SCC = 2*** a. Provider submits same incentive fee regardless of dose #. b. Payer applies first dose contracted fee	1234567890	1111111	0	MA	2	$28.39	$0.00	15	P	_	$16.94
2. Two-Dose NDC, SCC = 6, Fill # = 01, same Service Provider ID a. Provider submits same incentive fee regardless of dose # b. Payer applies final dose contracted fee	1234567890	1111111	1	MA	6	$28.39	$0.00	15	P	_	$28.39
3. Two-Dose NDC, SCC = 6, Fill # = 00, same Service Provider ID a. Service Provider ID is the same as previous paid claim in payer's claim history, Fill # 00 may indicate pharmacy system's practice to create a new RX # for each dose b. Payer applies second dose contracted fee	1234567890	3333333	0	MA	6	$28.39	$0.00	15	P	_	$28.39
4. Two-Dose NDC, SCC = 6, Fill # = 00, different service Provider ID a. While Fill # = 00, Service Provider ID is different than previous paid claim in payer's claim history b. Payer applies second dose contracted fee based on same NDC and SCC. Refer to	1555555555	2222222	0	MA	6	$28.39	$0.00	15	P	_	$28.39

Use Case	Request								Response		
	Service Provider ID (201-B1)	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)***	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**	**Incentive Amount Paid (521-FL)**
Utilization Guidance section below											
5. Two-dose NDC, SCC is BLANK a. Provider submits same incentive fee regardless of dose # and Professional Service Code MA b. Payer rejects as 34 - M/I SCC as dose number of two-dose NDC is unknown	1234567890	1111111	0	MA	_	$28.39	$0.00	15	R	34 – M/I SCC	
6. Single-Dose NDC, SCC is BLANK a. NDC identifies single-dose product b. Payer applies single-dose contracted fee	1234567890	3333333	0	MA	_	$28.39	$0.00	15	P	-	$28.39
7. Single-Dose NDC, SCC = 2 a. SCC 2 should not trigger a reject, as NDC identifies single-dose product b. Payer applies single-dose contracted fee	1234567890	3333333	0	MA	2	$28.39	$0.00	15	P	-	$28.39
8. Single-Dose NDC, SCC = 6 a. SCC 6 should not trigger a reject, as NDC identifies single-dose product b. Payer applies single-dose contracted fee	1234567890	3333333	0	MA	6	$28.39	$0.00	15	P	-	$28.39

*Please refer to Claim Submission. This applies to all asterisks in the Use Case Example tables.

1.5.2 USE CASES REQUIRING ADDITIONAL DATA

In addition to determining if the submitted claim is for the initial or final dose of a two-dose NDC, claims processing systems may require other data elements before establishing a "clean claim" status.

Prescriber ID Field and Pharmacist Prescriptive Authority:

Based on federal and state regulations, pharmacist prescriptive authority may apply to COVID-19 vaccine prescriptions. Existing NCPDP guidance indicates that for prescriptions initiated by a pharmacy, the pharmacist's Type 1 National Provider Identifier (NPI) would be submitted as the Prescriber ID (411-DB) and Prescription Origin Code (419-DJ) would be 5 – Pharmacy.

If pharmacist NPIs are not included within a payer's prescriber data files used for prescriber ID validation, existing NCPDP guidance indicates that a Submission Clarification Code value of 42 (Prescriber ID Submitted is valid and prescribing requirements have been validated) may be used by payers to override prescriber NPI validation rules. For COVID-19 vaccine claims, in addition to Submission Clarification Code of 42, the values of 2 or 6 would also be submitted to identify the dose number.

Incentive Fee Submitted, Professional Service Code, Fill Number Fields:

NCPDP guidance for vaccine administration uses the Professional Service Code (440-E5) and Incentive Fee Submitted (438-E3) fields to account for the professional services being billed. Claims lacking the required fields may trigger a reject when the payer is unable to validate what items and/or services are being billed. The following use case examples identify common scenarios which may occur with COVID-19 vaccine claims processing and the recommended NCPDP value(s) that should be returned in Reject Code (511-FB) field. Payers may provide additional clarification within the Additional Message Information (526-FQ) field.

The following uses case examples are outlined in the chart below:

1. Two-Dose or Single-Dose NDC,SCC = 2, Professional Service Code = MA, Incentive Fee Submitted value is BLANK
2. Two-Dose or Single-Dose NDC, SCC = 2, Professional Service Code is BLANK, Incentive Fee Submitted value > $0
3. Two-Dose or Single-Dose NDC, SCC = 6, Professional Service Code = MA, Incentive Fee Submitted value is BLANK
4. Two-Dose or Single-Dose NDC, SCC = 6, Professional Service Code is BLANK, Incentive Fee Submitted value > $0
5. Single-Dose NDC, SCC is Blank, Professional Service Code = MA, Incentive Fee Submitted value is BLANK
6. Single-Dose NDC, SCC is Blank, Professional Service Code is BLANK, Incentive Fee Submitted value > $0
7. Two-Dose or Single-Dose NDC, SCC = 2, Prescription Origin Code = 5, Prescriber ID = RPh NPI
8. Two-Dose or Single-Dose NDC, SCC = 6, Prescription Origin Code = 5, Prescriber ID = RPh NPI
9. Two-Dose or Single-Dose NDC, SCC 2 and SCC 42, Prescription Origin Code = 5, Prescriber ID = RPh NPI
10. Two-Dose or Single-Dose NDC, SCC 6 and SCC 42, Prescription Origin Code = 5, Prescriber ID = RPh NPI

11. Single-Dose NDC, SCC = 42, Prescription Origin Code = 5, Prescriber ID = RPh NPI
12. Single-Dose NDC, SCC is BLANK, Prescription Origin Code = 5, Prescriber ID = RPh NPI

	Request								Response	
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)***	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**
1. Two-Dose or Single-Dose NDC, SCC = 2, Professional Service Code = MA, Incentive Fee Submitted value is BLANK a. Payer rejects as E3 – M/I Incentive Fee Submitted	12234567890	1111111	0	MA	2	_	$0.00	15	R	E3 – M/I Incentive Amount Submitted
2. Two-Dose or Single-Dose NDC, SCC = 2, Professional Service Code is BLANK, Incentive Fee Submitted value > $0 a. Payer rejects as E5 – M/I Professional Service Code	1234567890	1111111	0	_	2	$28.39	$0.00	15	R	E5 – M/I Professional Service Code
3. Two-Dose or Single-Dose NDC, SCC = 6, Professional Service Code = MA, Incentive Fee Submitted value is BLANK a. Payer rejects as E3 – M/I Incentive Fee Submitted	1234567890	2222222	0	MA	6	_	$0.00	15	R	E3 – M/I Incentive Amount Submitted
4. Two-Dose or Single-Dose NDC, SCC = 6, Professional Service Code is BLANK, Incentive Fee Submitted value > $0 a. Payer rejects as E5 – M/I Professional Service Code	1234567890	2222222	0	_	6	$28.38	$0.00	15	R	E5 – M/I Professional Service Code
5. Single-Dose NDC, SCC is Blank, Professional Service Code =	1234567890	1111111	0	MA	_	_	$0.00	15	R	E3 – M/I Incentive Amount Submitted

Use Case	Request								Response	
	Service Provider ID (201-B1)	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)***	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**
MA, Incentive Fee Submitted value is BLANK a. Payer rejects as E3 – M/I Incentive Fee Submitted										
6. Single-Dose NDC, SCC is Blank, Professional Service Code is BLANK, Incentive Fee Submitted value > $0 a. Payer rejects as E5 – M/I Professional Service Code	1234567890	1111111	0	_	_	$28.38	$0.00	15	R	E5 – M/I Professional Service Code
7. Two-Dose or Single-Dose NDC, SCC = 2, Prescription Origin Code = 5, Prescriber ID = RPh NPI a. If prescriber ID validation is applicable Payer may reject with Reject Code of 42. Pharmacy must submit an additional SCC of 42 to override.	1234567890	1111111	0	MA	2	$28.39	$0.00	15	R	42 - Plan's Prescriber data base indicates the Prescriber ID Submitted is inactive or is not found
8. Two-Dose or Single-Dose NDC, SCC = 6, Prescription Origin Code = 5, Prescriber ID = RPh NPI a. If prescriber ID validation is applicable Payer may reject with Reject Code of 42. Pharmacy must submit an additional SCC of 42 to override.	1234567890	2222222	0	MA	6	$28.39	$0.00	15	R	42 – Plan's Prescriber data base indicates the Prescriber ID Submitted is inactive or is not found

Use Case	Request								Response	
	Service Provider ID (201-B1)	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)***	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**
9. Two-Dose or Single-Dose NDC, SCC 2 and SCC 42, Prescription Origin Code = 5, Prescriber ID = RPh NPI a. Payer accepts claim leveraging SCC 42 to override prescriber ID validation edit.	1234567890	1111111	0	MA	2, 42	$28.39	$0.00	15	P	N/A SCC 42 Overrides Prescriptive Authority validation, preventing reject code 42 (Plan's Prescriber data base indicates the Prescriber ID Submitted is inactive or is not found) from being returned
10. Two-Dose or Single-Dose NDC, SCC 6 and SCC 42, Prescription Origin Code = 5, Prescriber ID = RPh NPI a. Payer accepts claim leveraging SCC 42 to override prescriber ID validation edit.	1234567890	2222222	0	MA	6, 42	$28.39	$0.00	15	P	N/A SCC 42 Overrides Prescriptive Authority validation, preventing reject code 42 (Plan's Prescriber data base indicates the Prescriber ID Submitted is inactive or is not found) from being returned
11. Single-Dose NDC, SCC = 42, Prescription Origin Code = 5, Prescriber ID = RPh NPI a. Payer accepts claim leveraging SCC 42 to override prescriber ID validation edit.	1234567890	1111111	0	MA	42	$28.39	$0.00	15	P	N/A SCC 42 Overrides Prescriptive Authority validation, preventing reject code 42 (Plan's Prescriber data base indicates the Prescriber ID Submitted is inactive or is not found) from being returned
12. Single-Dose NDC, SCC is BLANK, Prescription Origin Code = 5, Prescriber ID = RPh NPI a. Payer rejects as 42 - Plan's Prescriber data base indicates the Prescriber ID	1234567890	1111111	0	MA	_	$28.39	$0.00	15	R	42 - Plan's Prescriber data base indicates the Prescriber ID Submitted is inactive or is not found

	Request								Response	
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)***	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**
Submitted is inactive or is not found										

1.5.3 UTILIZATION REJECT USE CASES

There are situations which may impact anticipated utilization and patient safety system rules where point of service overrides may be necessary to further clarify the claim request. Utilization and patient safety edits are generally communicated within DUR/PPS Request and Response segments, allowing for override based on professional judgement. Plan quantity and days supply limitations may be communicated through a hard stop type of reject, where prior authorization would be needed for override considerations.

NCPDP recommends CDC guidelines and manufacturer product information be referenced before determining COVID-19 vaccine utilization rules and override processes. Drug Utilization Review (DUR) messaging should be clear and identify any previous provider(s) when duplicate therapies have been identified. Override processes should also be clearly communicated as patient specific circumstances (e.g., allergic reaction, clinical risk factors), product availability (e.g., initial manufacturer inventory shortage) or claims processing anomalies (e.g., gap in timing of reversals for prior claims) may justify the need for subsequent claims.

The following use case examples are outlined in the chart below:

1. Two-Dose NDC, SCC = 6, payer's claim history includes completed vaccine series for same NDC from different service provider ID
2. Two-Dose NDC, SCC = 2, payer's claim history includes paid claim for single-dose NDC from a different service provider ID
3. Single-Dose NDC, payer's claim history includes paid claim for the same NDC and same service provider ID
4. Single-Dose NDC, payer's claim history includes paid claim for same NDC from a different service provider ID
5. Two-Dose NDC, SCC = 6, payer's claim history does not include the initial dose, impacted by effective date gaps
6. Two-Dose NDC, SCC = 2, payer's claim history includes dose 1 from same provider ID, same NDC, date of service less than the second dose date range
7. Two-Dose NDC, SCC = 2, payer's claim history includes dose 1 from same provider, same NDC, date of service aligned to the second dose date range
8. Two-Dose NDC, SCC =6, payer's claim history includes dose 1 from same provider, same NDC, date of service aligned to the second dose date range
9. Two-Dose NDC, SCC = 6, payer's claim history includes dose 1 under a different NDC, DUR Conflict

	Request									Response		
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Reason for Service Code (439-E4)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)***	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**	**Reason for Service Code (439-E4)**
1. Two-Dose NDC, SCC = 6, payer's claim history includes completed vaccine series for same NDC from different service provider ID a. Payer rejects as 76-Plan Limits Exceeded where PA would be required for override, or b. Payer rejects as DUR Reject Code 943 and Reason for Service Code EX – Excessive Quantity where PA would be required for override	1555555555	2222222	1		MA	6	$28.39	$0.00	15	R	76 – Plan Limit Exceeded or; 943 – DUR Reject, Pharmacy Override Using DUR/PPS Not Allowed	and Reason for Service Code EX – Excessive Quantity
2. Two-Dose NDC, SCC = 2, payer's claim history includes paid claim for single-dose NDC from a different service provider ID a. Payer rejects as 76-Plan Limits Exceeded where PA would be required for override, or b. Payer rejects as DUR Reject Code 943 and Reason for Service Code EX – Excessive Quantity where PA would be required for override	1555555555	2222222	1		MA	2	$28.39	$0.00	15	R	76 – Plan Limit Exceeded or; 943 – DUR Reject, Pharmacy Override Using DUR/PPS Not Allowed	and Reason for Service Code EX – Excessive Quantity
3. Single-Dose NDC, payer's claim history includes	1234567890	3333333	1		MA		$28.39	$0.01	01	R	76 – Plan Limit Exceeded	

	Request									Response		
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Reason for Service Code (439-E4)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)***	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**	**Reason for Service Code (439-E4)**
paid claim for the same NDC and same service provider ID a. Payer rejects as 76-Plan Limits Exceeded where PA would be required for override, or b. Payer rejects as DUR Reject Code 943 and Reason for Service Code EX, where PA would be required for override – Excessive Quantity											or; 943 – DUR Reject, Pharmacy Override Using DUR/PPS Not Allowed	and Reason for Service Code EX – Excessive Quantity
4. Single-Dose NDC, payer's claim history includes paid claim for same NDC from a different service provider ID a. Payer rejects as 76-Plan Limits Exceeded where PA would be required for override, or b. Payer rejects as DUR Reject Code 943 and Reason for Service Code EX – Excessive Quantity, where PA would be required for override	1555555555	4444444	0		MA		$28.39	$0.01	01	R	76 – Plan Limit Exceeded or; 943 – DUR Reject, Pharmacy Override Using DUR/PPS Not Allowed	and Reason for Service Code EX – Excessive Quantity
5. ***Two-Dose NDC, SCC = 6, payer's claim history does not include the initial dose, impacted by effective date gaps*** ***a.*** Payer accepts claim as beneficiary's coverage	1555555555	4444444	0		MA	6	$28.39	$0.00	15	P		

	Request									Response		
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Reason for Service Code (439-E4)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)***	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**	**Reason for Service Code (439-E4)**
effective date or plan benefit POS coverage rules where effective is post the initial dose date range												
6. ***Two-Dose NDC, SCC = 2, payer's claim history includes dose 1 from same provider ID, same NDC, but the date of service is the same date of service or immediately after the initial dose*** a. Use reject code 79 – Refill Too Soon when RX # or Fill Number are different or; b. Use reject code 943 – DUR w/o DUR Override and Reason for Service Code ER, EX or ID c. Use DUR reject code 88 – DUR Override allowed	1555555555	4444444	0		MA	2	$28.39	$0.00	15		79 – Refill Too Soon Or 943 - DUR Reject – Pharmacy Override Using DUR/PPS Not Allowed OR 88 – DUR Reject	ER – Overuse EX – Excessive Quantity ID – Ingredient Duplication
7. Two-Dose NDC, SCC = 2, payer's claim history includes dose 1 from same provider, same NDC, date of service aligned to the second dose date range a. Payer rejects claim due to initial dose already paid b. Reject code 34 – M/I SCC	1555555555	4444444	0		MA	2	$28.39	$0.00	15	R	34 – M/I SCC	

	Request									Response		
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Reason for Service Code (439-E4)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)***	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**	**Reason for Service Code (439-E4)**
8. Two-Dose NDC, SCC =6, payer's claim history includes dose 1 from same provider, same NDC and, date of service is aligned to the second dose date range, pharmacy responds to SCC reject a. ***Previous Claim submitted with SCC=2 Rejected with Code 34 – M/I SCC*** b. ***Pharmacy resubmits claim with SCC=6 for final dose***	1555555555	4444444	0		MA	6	$28.39	$0.00	15	P		
9. Two-Dose NDC, SCC = 6, payer's claim history includes dose 1 under a different vaccine manufacturer a. If Payer rejects claim based on a clinical safety alert, the payer must clearly communicate the vaccine manufacturer conflict and include their point of service override procedures	1555555555	4444444	0		MA	6	$28.39	$0.00	15	R	88 – DUR Or	Examples: DD - Drug-Drug Interaction OR DI - Drug Incompatibility OR TD Therapeutic Duplication

	Request									Response		
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Reason for Service Code (439-E4)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)***	**Ingredient Cost Submitted (409-D9)***	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**	**Reason for Service Code (439-E4)**
within the Additional Information Message field (526-FQ). b. If DUR reject is returned, the DUR Professional Service and Result of Service codes would be used as the override c. If an alternate reject code is used, Submission Clarification Code 10 – Meets Plan Limitations, should be used as the override											Alternate reject code, with vaccine manufacturer conflict and override procedure communicated in 526-FQ	

1.5.4 VACCINE ADMINISTRATION NOT COVERED OR OTHER COVERAGE USE CASES

Federal and state regulations and program policies for COVID-19 vaccine administration may result in atypical vaccine administration coverage rules.

1.5.4.1 MEDICARE

For Calendar Years (CYs) 2020 and 2021, Medicare payment for the COVID-19 vaccine and its administration will be made through the original fee-for-service (FFS) Medicare program (Medicare Part B) for all Medicare beneficiaries. The pharmacy should bill FFS in whatever manner they currently bill Medicare FFS

claims. The pharmacy will need the beneficiary's Medicare Beneficiary Identifier (MBI) to bill Part B. However, if the pharmacy does bill the MA-PD or PDP in error, the plan should reject as indicated below in Scenario 1.

1.5.4.2 MEDICAID OR COMMERCIAL

When the COVID-19 vaccine administration is not covered under the plan benefit billed, the plan's rejected claim response must indicate the appropriate plan benefit to bill for the patient out-of-pocket cost to be zero. In addition to the below recommended reject codes, the other payer information should be returned in the Response Coordination Of Benefits/Other Payers Segment and/or the Additional Message Information (526-FQ) field, when available. Note, the Other Payer ID Qualifier (339-6C) field also supports the Other Payer "Name" (value = 10) and "Other" (value = 99) to support medical benefit plan names or their associated Payer ID used for electronic data interchanges, (e.g., ASC X12 270/271, 837, 835).

The following use case examples are outlined in the chart below:

1. Two-Dose or Single-Dose NDC submitted to Medicare Part D BIN/PCN (PDP or MAPD), member's eligibility is active
2. Two-Dose or Single-Dose NDC submitted to Medicaid Managed Care Plan, member's eligibility is active, State Medicaid plan determined COVID-19 vaccine to be a Carve-out to Medicaid FFS
3. Two-Dose or Single-Dose NDC submitted to Commercial RX benefit, Managed Care Plan, member's eligibility is active, health plan determined COVID-19 vaccine to only be covered under medical benefit

	Request								Response	
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)**	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**
1. Two-Dose or Single-Dose NDC submitted to Medicare Part D BIN/PCN (PDP or MAPD), member's eligibility is active a. MAPD rejects as A5 b. PDP rejects as A5 and/or A6 c. Recommend all Part D plans return Additional Message Information "COVID-19 Vaccine should	1555555555	2222222	0	MA	2	$28.39	$0.00	15	R	A5 – Not Covered Under Part D Law A6 – May be covered under Part B Along with Additional Message information "COVID-19 Vaccine should be billed to Medicare Part B FFS"

Use Case	Request								Response	
	Service Provider ID (201-B1)	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)**	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**
be billed to Medicare Part B FFS"										
2. Two-Dose or Single-Dose NDC submitted to Medicaid Managed Care Plan, member's eligibility is active, State Medicaid plan determined COVID-19 vaccine to be a Carve-out to Medicaid FFS a. Payer rejects as 831 - Product Service ID Carve-Out, Bill Medicaid Fee For Service b. Recommend payer return 4RX of Medicaid FFS RX benefit in Response COB Other Payers Segment, or clear message within the Additional Message Information field	1555555555	2222222	1	MA	2	$28.39	$0.00	15	R	831 - Product Service ID Carve-Out, Bill Medicaid Fee For Service
3. Two-Dose or Single-Dose NDC submitted to Commercial RX benefit, member's eligibility is active, health plan determined COVID-19 vaccine to only be covered under medical benefit a. Payer rejects as 817 – Not covered under pharmacy benefit, bill medical benefit	1234567890	3333333	1	MA	6	$28.39	$0.01	01	R	817 - Not covered under pharmacy benefit, bill medical benefit

	Request								Response	
Use Case	**Service Provider ID (201-B1)**	**RX# (402-D2)**	**Fill # (403-D3)**	**Professional Service Code (440-E5)**	**SCC (420-DK)**	**Incentive Amount Submitted (438-E3)**	**Ingredient Cost Submitted (409-D9)**	**Basis of Cost (423-DN)**	**Trans Response Status (112-AN)**	**Reject Code (511-FB)**
b. Recommend payer return medical benefit plan name using Other Payer ID Qualifier of 10 or PAYER ID (Other Payer ID Qualifier of 99) in Response COB Other Payers Segment, or clear message within the Additional Message Information field										

1.6 PRICING CONSIDERATIONS

The pricing fields and values submitted in the pricing fields for a zero-cost drug plus vaccine administration fee claim can differ significantly from a traditional drug claim; however, the NCPDP Telecommunication Standard supports the various contract terms used to determine reimbursement.

Required fields include:

Claim Request	**Claim Response**
Ingredient Cost Submitted (409-D9)	Patient Paid Amount (505-F5)
Gross Amount Due (430-DU)	Total Amount Paid (509-F9)

Example Optional Fields Include:

Claim Request	**Claim Response**
Incentive Amount Submitted (438-E3)	Incentive Amount Paid (521-FL)
Usual and Customary (426-DQ)	Ingredient Cost Paid (506-F6)
Basis of Cost Determination (423-DN)	Basis of Reimbursement Determination (522-FM)

Since the Ingredient Cost Submitted (409-D9) value of $0.00 or $0.01 is used to represent the supply of COVID-19 vaccines provided at zero cost to the pharmacy provider, the Gross Amount Due (430-DU) value will generally represent the Incentive Amount Submitted for the vaccine administration fee.

Two-dose series COVID-19 vaccines introduce a layer of complexity as the product NDC remains the same; however, reimbursement may be based on whether the claim is for the initial or final dose being submitted.

Additionally, vaccines administered at no cost to the patient (including to the uninsured) during stages defined by government agencies may create confusion on the use of Usual and Customary Charge (426-DQ). The Usual and Customary (426-DQ) is defined as the 'Amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed;' this field is used for lower of reimbursement calculations. To ensure continuity in system logic and expeditiously support immunization efforts during these phases, the Usual and Customary Charge must reflect the amount charged to a cash paying customer.

1.7 UNIQUE SETTINGS OF CARE IMPACT ON PLACE OF SERVICE, PATIENT RESIDENCE AND PHARMACY SERVICE TYPE

Certain plan types (e.g., government programs) may leverage a combination of the below fields to determine claim adjudication and reimbursement rules.

- **384-4X Patient Residence:** Code identifying the patient's place of residence. Current External Code List (ECL) values include:
    - 0 = Not Specified
    - 1 = Home
    - 2 = Skilled Nursing Facility
    - 3 = Nursing Facility
    - 4 = Assisted Living Facility
    - 5 = Custodial Care Facility

- 6 = Group Home
- 7 = Inpatient Psychiatric Facility
- 8 = Psychiatric Facility - Partial Hospitalization
- 9 = Intermediate Care Facility/Individuals with Intellectual Disabilities
- 10 = Residential Substance Abuse Treatment Facility
- 11 = Hospice
- 12 = Psychiatric Residential Treatment Facility
- 13 = Comprehensive Inpatient Rehabilitation Facility
- 14 = Homeless Shelter
- 15 = Prison/Correctional Facility

Refer to NCPDP ECL Code List values.

- **147-U7 Pharmacy Service Type:** The type of service being performed by a pharmacy when different contractual terms exist between a payer and the pharmacy, or when benefits are based upon the type of service performed. Current ECL values include:
  - 1 = Community/Retail Pharmacy Services
  - 2 = Compounding Pharmacy Services
  - 3 = Home Infusion Therapy Provider Services
  - 4 = Institutional Pharmacy Services
  - 5 = Long Term Care Pharmacy Services
  - 6 = Mail Order Pharmacy Services
  - 7 = Managed Care Organization Pharmacy Services
  - 8 = Specialty Care Pharmacy Services
  - 99 = Other

- **307-C7 Place of Service:** Code identifying the place where a product or service is administered. ECL values are managed by CMS. Below are some of the CMS place of service values that may apply to vaccine immunization services from a pharmacy provider.
  - 01 = Pharmacy
  - 03 = School
  - 04 = Homeless Shelter
  - 13 = Assisted Living Facility
  - 14 = Group Home
  - 15 = Mobile Unit
  - 18 = Place of Employment, Work-site
  - 31 = Skilled Nursing Facility
  - 32 = Nursing Facility
  - 33 = Custodial Care Facility
  - 51 = Inpatient Psychiatric Facility
  - 54 = Intermediate Care Facility/ Individuals with Intellectual Disabilities
  - 60 = Mass Immunization Center
  - 99 = Other Place of Service

Typically, the Pharmacy Service Type and Place of Service values align to the Patient Residence Code. (Consider a retail pharmacy providing services within the pharmacy for an ambulatory patient with a patient residence of home or a long term care pharmacy providing services from the pharmacy for a patient whose residence is a nursing Facility.) However, vaccine administration will alter these typical relationships and potentially impact current claim adjudication rules, particularly during a declared PHE with restricted distribution.

For example:

#	Patient Residence	Pharmacy Service Type	Place of Service
1	3: Nursing Facility	1: Retail Pharmacy	32: Nursing Facility
2	4: Assisted Living	1: Retail Pharmacy	60: Mass Immunizer Center
3	14: Homeless Shelter	1: Retail Pharmacy	15: Mobile Unit
4	4: Home	5: Long Term Care Pharmacy	15: Mobile Unit
5	6: Group Home	5: Long Term Care Pharmacy	33: Custodial Care Facility

To mitigate patient access to care risks as a result of claim rejections for non-typical settings of care situations, it is recommended validation edits for these fields be bypassed for COVID-19 vaccine claims.

1.8 INNER AND OUTER PACK NDCS

As defined in Billing Unit Standard FAQ:
An inner pack is an additional level of multi-unit packaging within a case, carton or other larger packaging. In situations of an inner and outer pack, the inner NDC is a proportion of the outer NDC and would carry the same billing unit as the outer pack NDC. For example, a package containing 25 individual 10 ML vials of a drug may contain outer and inner pack NDCs. The NDC representing the entire package of 25 vials is considered the "outer" NDC, or "outer pack". The dispensed quantity for the entire package would equal 250 mL. The NDC on the individual 10 ML vial is considered the "inner" NDC, or "inner pack," where the billing unit would also be ML and quantity would represent the total MLs dispensed.

During the PHE, COVID-19 vaccine products are distributed through federal and state programs at no cost to the administering providers. The vaccines are packaged in a manner to support mass immunization, where inner pack and outer pack NDCs may be assigned. Inner-pack NDCs may represent a single multi-dose vial, and the outer pack NDCs may represent a number of vials packaged within a case.

Because the COVID-19 vaccines distributed through federal and state programs have no associated product cost during the PHE, it is recommended that all payers support both the inner pack and outer pack NDCs in order to prevent unnecessary point of service rejects. The dispensed quantity for either remains the same as discussed in Section 1.1.

Once COVID-19 vaccines become available for purchase within the marketplace, they will be packaged accordingly, with distinct NDCs, different from those assigned to the EUA products. Refer to NCPDP WG2 Product Identification as guidance is developed for the industry regarding the transition to the new NDCs.

1.9 SECOND DOSE UTILIZATION EDITS

NCPDP recommends hard stop utilization edits not apply to claims for EUA products until after the final dose has been administered. Examples of these edits may include:

- Refill too Soon (reject 79), when the second dose is earlier than the calculated days from the date of service of the first dose
- Plan Limitations Exceeded, or DUR Utilization edit, when the second dose is later than the calculated days from the date of service of the first dose

This guidance is based on the current state of public health emergency and urgent distribution and administration solutions. CDC guidance remains fluid and is subject to change based upon vaccine availability. The pharmacy industry is encouraged to stay attuned to current CDC guidance[1], HHS guidance and FDA approvals and bring forward any related claims adjudication questions to NCPDP to facilitate standardization.

[1] https://www.cdc.gov/vaccines/covid-19/index.html

2. FAQS

2.1 SHOULD PAYERS/PROCESSORS LEVERAGE THE USE OF THE FILL NUMBER FIELD (403-D3) WHEN PROCESSING CLAIMS FOR COVID-19 VACCINES?

NCPDP recommends payers/processors not leverage the Fill Number Field (403-D3) when processing COVID-19 vaccine claims. Many providers will issue a new prescription for each vaccine administration. Payers/processors should instead leverage the Submission Clarification Code (SCC) field (420-DK) as indicated in the examples in Section Use of Submission Clarification Code (420-DK) for Initial, Final and Single-Dose Identification when processing claims.

2.2 SINCE PAYERS/PROCESSORS DO NOT LEVERAGE THE FILL NUMBER FIELD, WHAT SHOULD BE CONSIDERED A DUPLICATE CLAIM FOR COVID-19 VACCINE CLAIMS?

COVID-19 vaccine claims submitted for the same patient with the same Product ID and same Date Of Service should be considered a duplicate claim and follow existing duplicate claim processing rules. The Date Of Service is imperative in identification of a duplicate claim. See examples outlined in section Utilization Reject Use Cases, Scenario 6.

2.3 WHAT VALUE SHOULD A PAYER/PROCESSOR SUPPORT WHEN THEIR SYSTEM CANNOT ACCEPT THE BASIS OF COST DETERMINATION (423-DN) VALUE = 15 (FREE PRODUCT)?

In instances where systems cannot accept the value = 15, NCPDP recommends payers/processors support Basis of Cost Determination (423-DN) values usually accepted for non-COVID-19 claims. The use of 00 (default) is highly discouraged.

2.4 FOR A TWO-DOSE VACCINE, HOW DOES NCPDP RECOMMEND PAYERS/PROCESSORS HANDLE CLAIMS SUBMITTED WITH THE SCC VALUE = 06 (INDICATING SECOND DOSE) WHEN THERE IS NO PREVIOUS CLAIMS HISTORY ON FILE INDICATING THAT A FIRST DOSE HAS BEEN ADMINISTERED?

NCPDP recommends payers/processors accept and not reject claims submitted with the SCC value = 6 at this time. Pharmacies have indicated they have a backlog of claims due to lack of industry readiness leading to incomplete claims history in payers/processors databases. It has been reported that vaccinations are being administered at multiple locations throughout this emergency. Additionally, end-of-year coverage changes could result in gaps in claim history. As a result, payers/processors may want to re-evaluate any hard-stop edits in place at this time. See Example in Section Utilization Reject Use Cases, Scenario 5.

2.5 SHOULD THE NDC NUMBER CHANGE WHEN THE EMERGENCY USE AUTHORIZATION (EUA) TRANSITIONS TO APPROVAL?

Yes. EUA product is still considered an unapproved drug. The product contains minimal label requirements, and the name is that of the active ingredient. At this point, product should be labeled with an EUA NDC as a product identifier.

There are many changes that occur when a product transitions from EUA to approval, many of which would require NDC changes:

1. Name Change: Ingredient Name to Trade Name
2. Labeling: Product Fact Sheet to Approved Package Insert
3. Artwork: Un-serialized to Serialized product
4. Approval Type: Unapproved Other to NDA/BLA
5. Product Type: Government provided to commercially available

While the Labeler Code represents the company and can remain the same, the product code and/or package size identifiers should change in a way that clearly distinguishes between the unapproved Government provided and approved commercial product. This will also help to track inventory of unapproved drug product that may be in the channel pre- and post-approval.

APPENDIX A – HISTORY OF DOCUMENT CHANGES

VERSION 1.0

New Document

VERSION 1.1

Updates:

- Modified Section 1.1 Quantity Dispensed
    - Modified Example 2 to address vial quantity of 6 doses versus 5 doses per the product labeling if a low dead space syringe is used.
    - Added Note 1
    - Minor clarification to Note 2
- Modified Section 1.3 Claims Submission
    - Bullet point 8 – removed "or $0.01" and "*" to reference NOTE
    - Added "NOTE:" to the end of this section
- All examples (1.5.1 through 1.5.4) modified the fill numbers so the fill number is represented as a non-zero padded value (e.g., "0", "1", "12", "99", etc.)
- Modified Section 1.5.1 examples to ensure the Ingredient Cost Submitted is "$0.00"
- Modified Section 1.5.2 examples to ensure the Ingredient Cost Submitted is "$0.00"
- Modified Section 1.5.3
    - updated the examples table to include the new columns:
        - Request: Reason for Service Code (439-E4)
        - Response: Reason for Service Code (439-E4)
    - examples 1 and 2 modified the Ingredient Cost Submitted to "$0.00"
    - examples 3 and 4 modified Basis of Cost from 15 to 01
    - added examples 5 through 9
- Modified Section 1.5.4:
    - Added Section 1.5.4.1 Medicare
    - Moved wording and examples from previous section 1.5.4 to new section 1.5.4.2 Medicaid or Commercial
        - Made some minor clarifications to the first sentence.
- Added Section 1.8 Inner and Outer Pack NDCs
- Added Section 1.9 Second Dose Utilization Edits
- Added Section 2 FAQs
- Added Appendix A – History of Document Changes