NCPDP EMERGENCY PREPAREDNESS GUIDANCE

VERSION 1.12

This document provides resource information for the pharmacy industry for a declared emergency.

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1. INTRODUCTION

Declared emergencies, such as weather-related events (e.g., hurricanes, fires, floods, etc.), natural disasters (e.g., earthquakes) or pandemics (e.g., H1N1, COVID-19), have led to the creation of this document. This document provides guidance to the pharmacy industry for resources available during a declared emergency. The intended audience is healthcare providers who would need resource information for assisting patients in accessing their products and services provided by pharmacies during declared emergencies. This document will be updated as new information is available.

Additionally, this document addresses certain emergency preparedness processes and procedures that could be established as daily occurrences to be invoked at a moment's notice, mitigating urgent training for emergency situations. For example:

- Payers/pharmacy benefit managers should have declared emergency criteria established within standard plan benefit templates.
- Pharmacy systems should support declared emergency plan billing rules and claim routing information as part of their normal procedures.
- Enrollment files and product history are routinely updated and should be accessible during a declared emergency.

Pharmacies, payers and prescribers should review this document to ensure they are able to assist in a declared emergency.

If you have any questions regarding the availability or content of this document, visit ncpdp.org or contact the Council office at 480-477-1000 or via email at ncpdp@ncpdp.org.

2. DISASTER DECLARATION PROCESS

If and when a state of emergency is declared, it will determine the legal and operational resources available to respond to a declared emergency and has implications for governments, the private sector and the public. Understanding the scope of local, state and federal emergency authorities and how they interact is an important part of preparing for and responding to a declared emergency.

2.1 *EMERGENCY DECLARATIONS*

2.1.1 AUTHORITY TO DECLARE EMERGENCIES

When conditions warrant, all jurisdictions have mechanisms that allow government officials to declare a state of emergency, thereby activating authorities and resources that are idle under normal conditions.

2.1.2 TYPES OF EMERGENCIES

The determination of whether circumstances justify or require the declaration of an emergency depends on conditions set forth in the relevant jurisdictional laws. Traditionally, various jurisdictions have a general statute that permits the governor or other authority to declare a state of emergency. States and local jurisdictions have refined their approaches to defining emergencies; the relevant jurisdiction may have one or more statutory definitions related to emergencies, including disaster, emergency and pandemic/epidemic. For purposes of this document, we will be using the term "**declared emergency**" to include any type of disaster, emergency or pandemic/epidemic.

2.1.3 EMERGENCY DECLARATION PROCESS

Generally, the governor or other authority declares an emergency by issuing an executive order or other declaration to that effect. The declaration addresses the effective dates and duration of the declaration, geographic areas of the state covered, conditions giving rise to the emergency and the agency or agencies leading the response activities. The declaration may also identify specific rules and regulations that are waived or suspended during the emergency. For additional information, please visit the state governor's or other jurisdiction's website.

2.2 *FEDERAL EMERGENCY DECLARATIONS AND AUTHORITIES*

As with the states, federal law imbues designated federal officials with broad powers that allow them to respond to and assist states and localities in responding to emergencies even without a federal emergency declaration. Thus, the Secretary of the U.S. Department of Health and Human Services (HHS) has broad authority under Sections 301 and 311 of the Public Health Service Act to provide assistance to states and localities. Federal law also provides the President and other federal officials with authority to declare emergencies under specified conditions.

2.3 *IMPLICATIONS OF EMERGENCY DECLARATIONS AND AUTHORITIES*

A declared emergency can change the legal and operational landscape in which governments, private organizations and the public operate during a declared emergency. Emergency declarations, especially if they occur at multiple levels (local, state, federal), can confuse organizations and individuals. When conflicting or overlapping declarations exist, the most restrictive takes precedence.

3. ACTIVATION OF EMERGENCY RESPONSE

Once an emergency has been declared, local, state and federal authorities have the ability to activate emergency response procedures.

3.1 *STATE AND LOCAL*

1. Healthcare Ready (refer to Healthcare Ready) may activate Rx Open[1] upon request by a state or local authority or due to an anticipated declared emergency. Rx Open provides information on the operating status of certain healthcare facilities in areas impacted by a disaster.
2. As each state or local authority invokes its own programs, it is recommended the applicable state Medicaid agencies, state boards of pharmacy or state emergency agencies be contacted for specific details.

3.2 *FEDERAL*

1. In addition to state and local authorities, the federal government may declare a federal emergency as a result of a terrorist incident, pandemic or natural disaster.
2. On the Public Health Emergency (PHE) Declarations[2] website, the Secretary of HHS[3] may issue a PHE Declaration[4] when, under the U.S. Public Health Service section 319, there is a determination that: a) a disease or disorder presents a PHE; or b) that a PHE, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. Examples of what may be implemented following a 319 declaration include:
    a. Waiver or modification of certain Medicare, Medicaid, Children's Health Insurance Program (CHIP) and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requirements.
    b. Adjustments to Medicare Part B fee schedules.
    c. Modifications to the practice of telemedicine.
3. After a federal emergency has been declared, HHS[5] in collaboration with Federal Emergency Management Agency (FEMA)[6] and upon request by the governor of impacted states may activate the Emergency Prescription Assistance Program (EPAP),[7] based on the potential risk for patients' inability to obtain their products or services.
4. Additionally, the federal government may decide to release needed materials from the Strategic National Stockpile (SNS) after receiving a request from a state, local, tribal or territorial entity. The SNS is the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to be depleted.

3.3 *HEALTHCARE READY*

[1] https://www.rxopen.org
[2] https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx
[3] https://www.hhs.gov/about/leadership/index.html
[4] https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx
[5] https://www.hhs.gov/
[6] https://www.fema.gov/
[7] https://www.phe.gov/Preparedness/planning/epap

Healthcare Ready[8] is a national non-profit organization that provides an information-sharing and problem-solving forum for members of the private pharmaceutical supply chain system, disaster response, relief agencies and government to help ensure the continued delivery of critical medicines during any event impacting healthcare or public health. Healthcare Ready can be contacted for support during all hazards, including a severe natural disaster, a large-scale terrorist attack or a pandemic/epidemic, that creates disruptions to the normal supply of essential medicines and/or delivery of healthcare.

The organization provides a single point of contact for the private sector pharmaceutical supply system, enabling requests for information, pharmaceutical supply status or pharmacy status through the Rx Open map (refer to Rx Open). Additional information on Healthcare Ready services during a disaster is available in their Partner Playbook[9].

Healthcare Ready activates whenever there is a potential wide-spread impact to healthcare supply chains and/or community well-being. Activation is determined on a case-by-case basis. Examples of some of the triggers considered before activation are:

- Disaster declaration by a governor or the President.
- Department of Homeland Security (DHS) Threat Advisory Red/Severe Classification.
- Health and well-being of a significant number of persons is materially threatened or affected.
- Local, regional, national or global healthcare infrastructure is significantly compromised.

Contact Healthcare Ready at alerts@healthcareready.org or call 866-247–2694. You may also want to refer to the websites: healthcareready.org and rxopen.org.

3.3.1 RX OPEN

When activated, Rx Open (rxopen.org) is a way for the public to locate nearby open pharmacies in a declared emergency-impacted area to gain access to needed medicines. A map marks the location and operating status (open, closed or unknown) of those pharmacies. It also maps open Red Cross shelters and dialysis centers.

Healthcare Ready activates Rx Open at the request of government officials, following a federally declared emergency, and/or if a hazard is expected to occur that will impact regional healthcare delivery. Healthcare Ready activates the Rx Open map specifically for the impacted area and updates the tool daily until the crisis has stabilized.

While your 2-1-1 call center manager may alert you that Rx Open has been activated, you can also check at Rx Open. If it is activated, interactive maps will be available. Activations will also be announced via a message sent to partners in affected states and on Twitter @HC_Ready[10].

Healthcare Ready also sends out email notifications when Rx Open is being enabled. Sign up to receive email notifications at healthcareready.org/contact-us.

1. How to use Rx Open:
    a. Go to rxopen.org.
    b. Scroll down to use the map, which includes two tabs for two different map views – Facilities or Counties.
    c. The Facilities Map displays community pharmacies and dialysis centers in the affected area and is color coded based on operational status.
    d. The Search bar at the top left corner of the map can be used to center the map around a location or locate a pharmacy by name or address.

[8] https://www.healthcareready.org/emergency-response
[9] https://healthcareready.org/wp-content/uploads/2019/12/2018_Partner_Playbook_-_TLP_white_final.pdf
[10] https://twitter.com/HC_Ready

   e. To access information in the Rx Open Facilities Map, to click on a dot representing a pharmacy; a box containing contact information appears.
   f. The Counties Map displays the percent of pharmacies open by county and includes four thresholds:
      i. greater than 90% of facilities open
      ii. 75% to 90% of facilities open
      iii. 50% to 74% of facilities open
      iv. less than 50% of facilities open
2. Benefits of Rx Open:
   a. Helps patients have access to critical medicines.
   b. Assists emergency management and public health responses in understanding where critical healthcare infrastructure is impacted.
   c. Helps maintain employment and business continuity in a community.

4. HEALTHCARE INDUSTRY AREAS OF CONSIDERATION

During a declared emergency, many important steps must occur. This section provides a high-level list of items to assist with industry notification and processing of claims during a declared emergency.

4.1 *PHARMACIES/AUTHORIZED REPRESENTATIVE OF PHARMACIES*

An authorized representative of a pharmacy (e.g., the pharmacy owner or a representative of the chain or network headquarters) should leverage this document at the time of or in preparation for a declared emergency to support necessary emergency pharmacy services.

4.1.1 PREPARATION STEPS

1. Ensure your pharmacy software system is prepared to submit emergency claims in accordance with payers/processors' and/or the Centers for Medicare & Medicaid Services (CMS) specified requirements.
2. Ensure your pharmacy software system and operational procedures support the implemented NCPDP External Code List values and FAQ or special guidance, where specific fields and code set values may be dedicated to emergency situations.
3. Establish a provider directory reporting status with your claim adjudication intermediaries for open locations to be listed within Healthcare Ready's Rx Open system.
4. If participating in a business relationship where medication or product history information is available upon a declared emergency, verify processes and procedures are in place and executable.
5. If participating in a business relationship where medication or product history information is contributed regularly, provide up-to-date information as warranted.
6. To receive timely situational awareness updates in the event of a declared emergency, ensure contact information is current with the Office of the Assistant Secretary for Preparedness and Response (ASPR) Division of Critical Infrastructure Protection - the government lead for the healthcare and public health sector partnership. Private sector partners can also join the partnership via the Sector Coordinating Council. The ASPR Prescription Medication Preparedness Initiative is an additional source for updates; refer to Appendix A.
7. It is recommended all pharmacists obtain their individual National Provider Identifier (NPI) to support state emergency refill prescription dispensing. Refer to National Plan and Enumeration System (NPPES)[11].
8. To ensure patients and healthcare providers can find and confirm their active status during a declared emergency, pharmacies should verify they have completed any needed authorization. If the authorization form was not completed and notification obtained, contact alerts@healthcareready.org to self-report. Refer to Reporting Additional Information on Pharmacy Status.

4.1.2 DURING DECLARED EMERGENCY

1. It may be beneficial to send reminders once a pending emergency has been declared to notify patients to pick up necessary product. For patients' safety, it is critical they evacuate or shelter in place with an adequate supply of product.
2. If you use auto refill reminders, ensure they direct your patients to pick up their product from an open pharmacy location.
3. Most states have procedures in place that address a pharmacist's ability to dispense an emergency supply of product per the defined state board of pharmacy rules. All pharmacists should be familiar with their individual state's declared emergency procedures. Refer to the National Association of Boards of

[11] https://nppes.cms.hhs.gov/#/

Pharmacy's (NABP)[12] '*Model Pharmacy Act/Rules*[13]' for guidance to state boards of pharmacy on implementing rules applicable to cases of declared emergencies.

4. To locate the nearest open pharmacy location or update your pharmacy status, please refer to Rx Open.

Refer to Frequently Asked Questions for additional information regarding billing using a Pharmacist (Type 1) NPI or Pharmacy (Type 2) NPI during a declared emergency.

4.1.3 EPRESCRIBING RENEWAL REQUESTS

1. If a patient loses a non-refillable prescription (e.g., a controlled substance) during a declared emergency, a Renewal Request (RxRenewalRequest) may be sent by the pharmacy. The request should include a message in the <Notes> of MedicationDispensed explaining the declared emergency and the number of days of product being requested because the product was lost.
2. In the NCPDP SCRIPT Standard version 2017071 (SCRIPT Standard), UrgencyIndicator is valued with "X" to communicate an urgent refill request to the prescriber. The request should include a message in the <Notes> of MedicationDispensed explaining the urgency is due to the declared emergency and other relevant information.

4.2 *PAYERS*

4.2.1 PREPARATION STEPS

1. Verify payer/plan sheets for processing requirements for a declared emergency are up-to-date and available to industry participants.
2. Ensure your claims processing system and operational procedures support the implemented NCPDP External Code List values and FAQ or special guidance, where specific fields and code set values may be dedicated to emergency situations.
3. Current information should be provided if participating in a business relationship where product history information is regularly contributed.
4. To receive timely situational awareness updates in the event of a declared emergency, ensure contact information is current with the Office of the Assistant Secretary for Preparedness Response Critical Infrastructure Protection for the Healthcare and Public Health Sector (refer to Appendix A).

4.2.2 DURING DECLARED EMERGENCY

1. Keep your pharmacy network up to date with plan notifications and point-of-service messaging for emergency plan benefit adjustments.
2. Refer to Rx Open for availability of providers.

4.3 *PRESCRIBERS*

4.3.1 PREPARATION STEPS

1. Ensure your EHR system and operational procedures support the most current NCPDP SCRIPT Implementation Guide, where specific fields and code set values may be dedicated to emergency situations. For example, the SCRIPT Standard supports an urgency indicator within the applicable request messages.

[12] https://nabp.pharmacy/
[13] https://nabp.pharmacy/resources/model-pharmacy-act/

4.3.2 DURING DECLARED EMERGENCY

1. Refer to Rx Open for availability of pharmacy providers.
2. Electronic Health Record (EHR) vendors and pharmacies supporting electronic prescribing would continue to do so if their systems are up and available in a declared emergency.
3. In the event one of the components (EHR system, E-Prescribing network, pharmacy system) is down or unavailable, the prescriber would default to writing, faxing or phoning in prescriptions, following all applicable regulations.
4. Prior to sending any prescription (electronic, paper or verbal), it is recommended the prescriber verify operational status of the intended pharmacy. If the prescriber still has internet access during the declared emergency, this may be accomplished by accessing Rx Open (Refer to Healthcare Ready).

4.3.3 EPRESCRIBING RENEWAL REQUESTS

1. If a patient loses a non-refillable prescription (e.g., a controlled substance) during a declared emergency, a Renewal Request (RxRenewalRequest) may be sent by the pharmacy. The request should include a message in the <Notes> field of MedicationDispensed explaining the declared emergency and the number of days of product being requested because the product was lost. This request should include an UrgencyIndicator is valued with "X" to communicate an urgent refill request to the prescriber. The request should include a message in the <Notes> of MedicationDispensed explaining the urgency is due to the declared emergency and other relevant information.

4.4 *INTERMEDIARIES*

Intermediaries have developed a process for reporting active pharmacies to the Healthcare Ready tool Rx Open. In some cases, the pharmacy needs to authorize its intermediary to send active claim status to Healthcare Ready in order to ensure the pharmacy's information shows as "active" during a declared emergency.

Intermediaries may need to develop reporting based on the type of emergency. For example, during the COVID-19 pandemic, intermediaries developed processes for CMS to allow reporting of Medicare Part-B COVID-19 vaccine data to Medicare Part-D sponsors.

4.5 *PHARMACY STATUS REPORTING*

4.5.1 AUTOMATED PHARMACY STATUS REPORTING

1. As part of initial declared emergency activation, Healthcare Ready will contact participating intermediaries for activation of pharmacy status reporting. Basic information on the nature and scope of the event, as well as the geographic location, will be included in the request. A Presidential emergency declaration is considered the baseline trigger for activation of the pharmacy status reporting, although incidents that do not rise to the level of a federal response may be considered if there is a request for pharmacy status reporting from state or local public health or emergency management officials or if Healthcare Ready anticipates a hazard that will have region-level impacts.
2. NCPDP will provide Healthcare Ready access to the NCPDP DataQ pharmacy database for baseline data on pharmacies in the impacted area(s).
3. Intermediaries will provide a twice daily report of pharmacies billing prescriptions in the previous 24 hours using a FTP process or via email to alerts@healthcareready.org. For the purposes of information sharing, it is assumed pharmacies that have billed for prescriptions are open for business. Fields included in the pharmacy status report:
    a. NCPDP ID

b. National Provider ID
c. Store Name
d. Physical Address
e. City
f. State
g. ZIP/Postal Code
h. Phone

Reporting will be limited to the states identified in the declared emergency or have otherwise been determined to be threatened by a major hazard. Temporary pharmacies that have applied for and received a NCPDP ID number will be automatically included in the pharmacy status reporting. PLEASE NOTE: If you experience any issues using Rx Open or find a pharmacy status is not accurate, please email alerts@healthcareready.org for assistance.

4.5.2 REPORTING ADDITIONAL INFORMATION ON PHARMACY STATUS

If you are an authorized representative of a pharmacy and have additional information to report about a pharmacy impacted by a declared emergency, please contact the Healthcare Ready Operations Center at 866-247-2694 or email alerts@healthcareready.org. Please be prepared to provide the pharmacy status report information listed above, as well as additional information you wish to provide on pharmacy status, such as temporary location (tied to an existing NCPDP ID) or barriers to continuing service (e.g., deliveries are not able to gain access to the declared emergency area).

4.6 *REPORTING OF IMPACTED LOCATIONS TO NCPDP PHARMACY DATABASE PROCESSES*

Notifications of pharmacies significantly impacted by a declared emergency (closed long term or temporarily re-located), are used by NCPDP to update the NCPDP pharmacy database (DataQ) in the following ways:

1. List of closed or destroyed pharmacies in the area.
    a. If your pharmacy has been closed or destroyed due to the natural disaster, you can log on to accessonline.ncpdp.org and request deactivation of your pharmacy. If you do not have computer access, you can call NCPDP at 480-734-2870 (phone is manned during regular business hours and a voicemail for non-business hours). If your pharmacy is scheduled to reopen, your NCPDP number will be reinstated at no charge.
    b. Deactivation will avoid the potential for fraudulent activity or inaccurate status reporting using that pharmacy's identifier.
2. List a temporary location for an existing pharmacy (with a valid NCPDP ID number) where patients can call to get existing prescriptions refilled and pick them up.
    a. The temporary address as well as the permanent address from the NCPDP pharmacy database (the "Database") should be included. The mailing address of the pharmacy in the Database may or may not change, depending on the wishes of the pharmacy.
    b. When and if the store moves back to the previous location, or any other location, the physical location will be changed in the Database.
3. Information on new locations of new temporary or mobile pharmacies.
    a. These pharmacies will receive a NCPDP ID number from NCPDP at no charge and be added to the Database.
    b. If these pharmacies are eventually closed, the pharmacy must deactivate their NCPDP ID (and NPI) by logging on to accessonline.ncpdp.org.
    c. If these pharmacies move, the pharmacy will log on to accessonline.ncpdp.org and update their physical address. The NCPDP ID and NPI will remain the same.

5. MEDICATION (PRODUCT) HISTORY INFORMATION

The capability to adequately deliver medication history to prescribers on a nationwide basis exists today through ePrescribing networks, pharmacy benefit manager claim databases and retail pharmacy databases. To access medication history, EHR vendors must have an established relationship with one of these data sources.

5.1 *CONNECTIVITY*

EHR vendors that have established connectivity with the various medication history databases will allow healthcare settings the ability to request medication history for treatment purposes. Depending on the medication history service(s) with whom the vendor is connected, the data should be delivered on a real-time basis for one patient at a time or on a bulk download basis for selected populations of patients within 24-hours. Patients who seek care from physicians who have already deployed such technology will have the ability to access medication history in the normal course of workflow. In a declared emergency, this connectivity would remain the same unless systems on either end are down or network infrastructure has been impacted. If systems are down, medication history would be unavailable unless the individual vendors have manual workarounds in place.

5.2 *AUTHENTICATION*

In order to comply with local, state and federal security and privacy laws, authentication of the medication history requester is necessary. For those prescribers using a certified and connected technology vendor, user authentication is the responsibility of the application vendor and is well managed today. In a declared emergency, authentication methods would remain the same unless systems on either end are down or network infrastructure has been impacted. In this case, medication history would be unavailable unless the individual vendors have manual workarounds in place, including manual authentication verification.

5.3 *ADDITIONAL LIVES*

Following a declared emergency, some payers and pharmacies not connected to a network or hub to transfer medication history may want to contribute medication history. It is recommended these entities have the applicable processes and procedures in place and tested so they can provide medication history information for the requested areas in a timely manner once an emergency is declared. This rapid inclusion of additional lives would allow access by clinicians and pharmacies seeing patients in need of care.

6. EMERGENCY PREPAREDNESS PRESCRIPTION CLAIMS PROCESSING GUIDANCE

This section is specific to processing claims to a patient's current prescription benefit. Refer to Emergency Prescription Assistance Program (EPAP) for declared emergency situations where a patient does not have a prescription benefit.

A declared emergency may impact prescription claims processing in various ways. A PBM's/payer's standard payer sheets aligned with NCPDP guidance should identify the applicable fields and code set values necessary to override standard claims processing rules to support declared emergency situations. These emergency preparedness claims processing procedures may include, but are not limited to:

- Utilization management edit exceptions, such as:
  - Early Refills
  - Prior Authorization overrides
  - Coverage for non-formulary therapeutic substitutions
- Copay waivers
- Prescriptive authority exceptions

Additionally, payers and pharmacies need to be prepared to process claims for products supplied through the SNS. The SNS's role is to supplement state and local supplies during public health emergencies. Many states have products stockpiled as well. The supplies, medicines and devices for life-saving care contained in the SNS can be used as a short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available. When products billed to a prescription benefit are sourced from the SNS, the value submitted in the Ingredient Cost Submitted (409-D9) and Basis of Cost Determination (423-DN) may need to be adjusted.

The following guidance should be used when drafting standard payer sheets to be prepared for emergency declarations as they occur.

6.1 *OVERRIDING STANDARD CLAIMS PROCESSING RULES*

Payer required use and support of specific fields and code set values necessary to identify and apply declared emergency claims processing rules should be communicated in the 'Payer Requirement' section of the payer sheet. The following fields are based on current NCPDP emergency preparedness guidance and code set value definitions. Also refer to Frequently Asked Questions, as new and updated business cases may be addressed.

Patient ZIP/Postal Code (325-CP)

- This field is used in demographic-specific declared emergency situations to identify the patient's original area from which an evacuation may be necessary and require emergency overrides to dispense required product.

	Patient Segment **Segment Identification (111-AM) = "01"**			**Claim Billing/Claim Rebill**
Field	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
325-CP	PATIENT ZIP/POSTAL CODE		O	*Imp Guide:* Optional. *Example Payer Requirement:* • (any unique payer requirements)

	Patient Segment **Segment Identification (111-AM) = "01"**			**Claim Billing/Claim Rebill**
Field	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
				• Declared Emergency Situations: Required, submit patient's ZIP/postal code from which they were displaced

Prescription Origin Code (419-DJ)

- This field may be used to identify new prescription numbers generated by the pharmacy as represented under the value of 5 – Pharmacy, when state emergency prescription declarations allow the pharmacy/pharmacist to authorize a prescription refill when the prescriber cannot be contacted.

Submission Clarification Code (SCC) (420-DK)

- This field may be used to identify a declared emergency situation to request an override to standard plan benefit rules (e.g., refill too soon, plan limitations, prescriptive authority). For example:
  - 13 - Payer Recognized Declared Emergency Assistance Request
  - 42 - Prescriber ID Submitted is valid and prescribing requirements have been validated

	Claim Segment **Segment Identification (111-AM) = "07"**			**Claim Billing/Claim Rebill**
Field #	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
419-DJ	PRESCRIPTION ORIGIN CODE		Q***R***	*Imp Guide:* Required if necessary for plan benefit administration. *Example Payer Requirement:* • (any unique payer requirement(s)) • Declared Emergency Situations: Required, submit the value of *5 – Pharmacy*, for emergency RX refills as authorized by state declared emergency protocol

420-DK	SUBMISSION CLARIFICATION CODE		Q***R***	*Claim Billing/Encounter:*
				Required if clarification is needed and value submitted is greater than zero (0). Occurs the number of times identified in Submission
				Clarification Code Count (354-NX).
				
				Example Payer Requirement:
				• *(any unique payer requirement(s))*
				• *Declared Emergency Situations: Specific values required as follows:*
				  ○ *13 – Payer Recognized Declared Emergency Assistance Request* used to override designated plan benefit rules e.g., refill too soon
				  ○ *42 - Prescriber ID Submitted is valid and prescribing requirements have been validated*, used to request an override to prescriptive

	Claim Segment **Segment Identification (111-AM) = "07"**			**Claim Billing/Claim Rebill**
Field #	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
				authority rules for emergency Rx refills where the pharmacist Type 1 NPI or pharmacy Type 2 NPI is submitted as the prescriber ID

Prescriber ID (411-DB)

- When a prescriber ID is required and default prescriptive authority claim adjudication rules apply, specific payer requirements should be noted for declared emergency situations to indicate if/when the pharmacist Type 1 NPI or pharmacy Type 2 NPI can be submitted.

	Prescriber Segment **Segment Identification (111-AM) = "003"**			**Claim Billing/Claim Rebill**
Field #	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
411-DB	PRESCRIBER ID		Q***R*****	*Imp Guide:* Required if this field could result in different coverage or patient financial responsibility. Required if necessary for state/federal/regulatory agency programs. *Example Payer Requirement:* • (any unique payer requirement(s)) • Declared Emergency Situations: Pharmacist Type 1 NPI or pharmacy Type 2 NPI may be submitted as allowed under state emergency Rx refill protocol

6.2 *BILLING FOR FREE PRODUCT*

During a declared emergency, pharmacies may obtain product with zero cost from the SNS or other sources. Claims submitted for zero cost products may include other charges for dispensing and/or administration fees (e.g., vaccine administration, specimen collection). Refer to the following two examples and associated claims processing guidance. In both examples, NCPDP recommends the use of a single B1/B3 billing transaction with the Basis of Cost Determination value "15" (Free product or no associated cost), with an associated Ingredient Cost Submitted (409-D9) value of $0.00.

NOTE: Some systems may not be able to successfully exchange the value of $0.00 as an Ingredient Cost Submitted (409-D9) 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 STANDARD VERSION D (Telecommunication Standard) AND ABOVE QUESTIONS, ANSWERS AND EDITORIAL UPDATES[14].

NOTE: For specific guidance on COVID-19 vaccines, see COVID-19 Vaccines Considerations section.

6.2.1 BILLING FOR REIMBURSEMENT OF A FREE PRODUCT (NO ASSOCIATED COST) INCLUDING AN ADMINISTRATION FEE

- The submitted Transaction Code (103-A3) is a "B1" (Claim Billing).
- The submitted Prescription/Service Reference Number Qualifier (455-EM) is a "1" (Rx Billing).
- The claim pricing segment follows the prescription claim request formula.
- The Product/Service ID (407-D7) should be submitted with the correct Product/Service ID Qualifier (436/E1) (in this example "03" (NDC)).
- Product/Service ID (407-D7) contains the NDC of the vaccine or other product that was administered and obtained at zero cost.
- The Days Supply (405-D5) should be submitted with a value of "1".
- The Quantity Dispensed (442-E7) should be submitted with the value that represents the quantity of drug product administered.
- The DUR/PPS Segment, with a "MA" (Medication Administered) in the Professional Service Code (440-E5), is submitted to identify the product was administered.
- The Incentive Amount Submitted (438-E3) is submitted when the pharmacy is seeking reimbursement for the administration of the product.
- Basis of Cost Determination (423-DN) should be submitted with the value "15" (Free product or no associated cost).

Only pertinent segments are shown.

TRANSACTION HEADER SEGMENT				
FIELD	**FIELD NAME**	**CAT**	**VALUE**	**COMMENTS**
101-A1	BIN NUMBER	M	*610066*	
102-A2	VERSION/RELEASE NUMBER	M	*D0*	Transaction Format
103-A3	TRANSACTION CODE	M	*B1*	Claim Billing
104-A4	PROCESSOR CONTROL NUMBER	M	*1234567890*	
109-A9	TRANSACTION COUNT	M	*1*	One occurrence
202-B2	SERVICE PROVIDER ID QUALIFIER	M	*01*	National Provider ID
201-B1	SERVICE PROVIDER ID	M	*4563663111bbbbb*	
401-D1	DATE OF SERVICE	M	*20200317*	March 17, 2020
110-AK	SOFTWARE VENDOR/CERTIFICATION ID	M	*bbbbbbbbbb*	

CLAIM SEGMENT				
FIELD	**FIELD NAME**	**CAT**	**VALUE**	**COMMENTS**
111-AM	SEGMENT IDENTIFICATION	M	*07*	CLAIM SEGMENT
455-EM	PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER	M	*1*	Claim billing
402-D2	PRESCRIPTION/SERVICE REFERENCE NUMBER	M	*7654321*	
436-E1	PRODUCT/SERVICE ID QUALIFIER	M	*03*	NDC
407-D7	PRODUCT/SERVICE ID	M	*12345678901*	Zero cost vaccine
442-E7	QUANTITY DISPENSED	Q	*1000*	1 (ML)
403-D3	FILL NUMBER	Q	*0*	Original dispensing for RX#
405-D5	DAYS SUPPLY	Q	*1*	1 Days supply
414-DE	DATE PRESCRIPTION WRITTEN	Q	*20200315*	March 15, 2020

DUR/PPS SEGMENT				
FIELD	**FIELD NAME**	**CAT**	**VALUE**	**COMMENTS**
111-AM	SEGMENT IDENTIFICATION	M	*08*	DUR/PPS Segment
473-7E	DUR/PPS CODE COUNTER	R	*1*	1st DUR activity
440-E5	PROFESSIONAL SERVICE CODE	Q	*MA*	Medication Administered

PRICING SEGMENT				
FIELD	**FIELD NAME**	**CAT**	**VALUE**	**COMMENTS**
111-AM	SEGMENT IDENTIFICATION	M	*11*	PRICING SEGMENT
409-D9	INGREDIENT COST SUBMITTED	R	*0{*	$0.00
412-DC	DISPENSING FEE SUBMITTED	Q	*50{*	$5.00
438-E3	INCENTIVE AMOUNT SUBMITTED	Q	*200{*	$20.00
426-DQ	USUAL AND CUSTOMARY CHARGE	Q	*350{*	$35.00
430-DU	GROSS AMOUNT DUE	R	*250{*	$25.00
423-DN	BASIS OF COST DETERMINATION	Q	*15*	Free product or no associated cost

6.2.2 BILLING FOR REIMBURSEMENT OF A FREE PRODUCT (NO ASSOCIATED COST) WITH NO ADMINISTRATION FEE

- The submitted Transaction Code (103-A3) is a "B1" (Claim Billing).
- The submitted Prescription/Service Reference Number Qualifier (455-EM) is a "1" (Rx Billing).
- The claim pricing segment follows the prescription claim request formula.
- The Product/Service ID Qualifier (436-E1) should be submitted with a value of the correct product (in this example "03" (NDC) and the Product/Service ID (407-D7) contain the NDC of the product).
- The Days Supply (405-D5) should be submitted with appropriate value.
- The Quantity Dispensed (442-E7) should be submitted with the value that represents the quantity of product dispensed.
- The Dispensing Fee Submitted (42-DC) field is submitted to identify the pharmacy is seeking reimbursement for the agreed upon dispensing fee of the free product.
- Basis of Cost Determination (423-DN) should be submitted with the value "15" (Free product at no associated cost).

Only pertinent segments are shown.

TRANSACTION HEADER SEGMENT				
FIELD	**FIELD NAME**	**CAT**	**VALUE**	**COMMENTS**
101-A1	BIN NUMBER	M	*610066*	
102-A2	VERSION/RELEASE NUMBER	M	*D0*	Transaction Format
103-A3	TRANSACTION CODE	M	*B1*	Claim Billing
104-A4	PROCESSOR CONTROL NUMBER	M	*1234567890*	
109-A9	TRANSACTION COUNT	M	*1*	One occurrence
202-B2	SERVICE PROVIDER ID QUALIFIER	M	*01*	National Provider ID
201-B1	SERVICE PROVIDER ID	M	*4563663111bbbbb*	
401-D1	DATE OF SERVICE	M	*20200315*	March 15, 2020
110-AK	SOFTWARE VENDOR/CERTIFICATION ID	M	*bbbbbbbbbb*	

CLAIM SEGMENT				
FIELD	**FIELD NAME**	**CAT**	**VALUE**	**COMMENTS**
111-AM	SEGMENT IDENTIFICATION	M	*07*	CLAIM SEGMENT
455-EM	PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER	M	*1*	Claim billing
402-D2	PRESCRIPTION/SERVICE REFERENCE NUMBER	M	*7654321*	
436-E1	PRODUCT/SERVICE ID QUALIFIER	M	*03*	NDC
407-D7	PRODUCT/SERVICE ID	M	*12345678901*	Zero cost product
442-E7	QUANTITY DISPENSED	Q	*10000*	10.0 (EA)
403-D3	FILL NUMBER	Q	*0*	Original dispensing for RX#
405-D5	DAYS SUPPLY	Q	*5*	5 Days supply
414-DE	DATE PRESCRIPTION WRITTEN	Q	*20200315*	March 15, 2020

PRICING SEGMENT				
FIELD	**FIELD NAME**	**CAT**	**VALUE**	**COMMENTS**
111-AM	SEGMENT IDENTIFICATION	M	*11*	PRICING SEGMENT
409-D9	INGREDIENT COST SUBMITTED	R	0*{*	$0.00
412-DC	DISPENSING FEE SUBMITTED	Q	*50{*	$5.00
438-E3	INCENTIVE AMOUNT SUBMITTED	Q	0*{*	$0.00
426-DQ	USUAL AND CUSTOMARY CHARGE	Q	*50*{	$5.00
430-DU	GROSS AMOUNT DUE	R	50*{*	$5.00
423-DN	BASIS OF COST DETERMINATION	Q	*15*	Free product or no associated cost

7. EMERGENCY PRESCRIPTION ASSISTANCE PROGRAM (EPAP)

After a request from the governor of an affected state, the EPAP must be activated by the U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) before it can be used. It is event specific and will not be automatically activated, even when a presidential declaration is made. Currently, the EPAP covers uninsured patients and the standard formulary is prescription drugs, medical supplies, durable medical equipment and vaccines. The EPAP website is phe.gov/EPAP and there will be a communication section for patients on the site when the EPAP is activated.

Upon receipt of an activation notice, the EPAP Processor (currently Express Scripts (ESI)) will inform the providers of the activation. If you have questions regarding EPAP activation information, eligibility, covered drugs and durable medical equipment, claim submission requirements, your pharmacy provider eligibility status, or if you would like to inquire how your pharmacy can become a contracted provider for the EPAP, please see EPAP for Pharmacies[15] or contact the **EPAP help line at 855-793-7470** for more information.

The EPAP payer sheet provides the general guidance for entities to use common requirements, to establish the declared emergency plan in their system ahead of time and to insert the particular declared emergency parameters when the declared emergency is activated by the HHS/ASPR.

7.1 *EPAP ACTIVATION PROCEDURE*

1. Once ASPR has released the applicable notification, the EPAP processor has 24 hours to activate EPAP coverage for the impacted area(s) within the U.S. and U.S. territories.
2. ESI has provided the broadest pharmacy network with over 70,000 stores nationwide which should include all active and credentialed pharmacies. Any pharmacies wishing to participate, but not in Express Scripts National Plus network, should contact ESI directly to start the credentialing process.
3. Within 24 hours of program activation, pharmacy communications will be faxed or emailed via existing communication processes from ESI to EPAP network pharmacies.
4. The pharmacy communication will include:
    a. Federal declared emergency EPAP start date and time.
    b. Impacted ZIP/Postal codes.
    c. Contract number and group numbers to be used (these vary per declared emergency).
    d. Method of claim adjudication (electronic versus manual depending on the claim). Example, Durable Medical Equipment (e.g., canes) will be processed via manual claim because it does not have an NDC in the pharmacy system, therefore, it cannot process electronically.
    e. EPAP eligibility information (e.g., impacted individuals living in the defined declared emergency area and having no pharmacy insurance, are qualified for the program).
    f. Payer information is:
        i. IIN (BIN): 003858
        ii. PCN: A4
        iii. Group: Changes per declared emergency
        iv. EPAP member services number: 855-793-7470
5. Patients **must first call** ESI at 855-793-7470 to have their EPAP eligibility checked and be enrolled in the EPAP benefit before they can have a claim processed. The enrollment process takes a few minutes to complete.

[15] https://www.phe.gov/Preparedness/planning/epap/Pages/epap-pharmacies.aspx

6. NOTE: Only those who live in a FEMA designated area (fema.gov/disasters), and have no other pharmacy benefit coverage, are eligible for the EPAP. A search will be conducted by ESI during EPAP registration to determine if the patient is eligible.
7. Eligible patients will receive coverage under the EPAP with **$0 copayments**. Pharmacies will receive reimbursement from ESI.

7.2 *EPAP ELIGIBILITY*

If EPAP has been activated, uninsured individuals must contact and enroll with EPAP prior to picking up prescriptions. EPAP is the payer of last resort, therefore the pharmacy must use all tools available to validate insurance availability prior to sending claims to the EPAP Processor. The Telecommunication Standard Eligibility Verification (E1) transaction, web portals connected to centralized locations, product history and payer help desks are tools used by the industry to determine eligibility.

The following steps need to occur before billing an EPAP transaction:

1. Ask the patient for their pharmacy ID card(s).
2. If the patient does not have any pharmacy ID card, perform the applicable eligibility request (E1) transaction(s). If no eligibility is returned, inform the patient to contact EPAP to see if they quality for the program.
3. The transaction should be billed to the EPAP only if the patient is *from a declared emergency area* identified by the EPAP's Processor, Express Scripts, Inc. (ESI). Refer to the EPAP's payer sheet and instructions sent by the EPAP Processor.

Patients with insurance, who due to the declared emergency do not have the ability to pay their co-pays/deductibles, should seek assistance from other disaster relief agencies or local resources. Refer to Healthcare Ready for additional options.

7.3 *COORDINATION OF BENEFITS*

Currently, HHS/ASPR does not allow the EPAP to cover out-of-pocket costs for patients with insurance.

7.4 *NCPDP EMERGENCY PRESCRIPTION ASSISTANCE PROGRAM (EPAP) PAYER SHEET*

This payer sheet is used in a declared emergency when the provider has determined the patient does not have private insurance, such as an individual health insurance policy or employer-sponsored coverage, public healthcare coverage, such as Medicare or Medicaid, or other third-party pharmaceutical coverage. All providers should ensure their pharmacies know how to process claims during a declared emergency and providers should have the plan preloaded in their systems to be ready to activate in the case of a declared emergency.

The EPAP payer sheet is used to standardize claim billing processes to provide product and limited durable medical equipment to eligible patients affected by the declared emergency.

The allowable dates of service will be determined on an event-by-event basis. Refer to EPAP claims processing guidance associated to specific fields within the payer sheet.

EPAP Payer NCPDP Emergency Preparedness Payer Sheet

Revision 07/2018

This payer sheet is used in declared emergencies when the provider has determined the patient does not have private insurance, such as an individual health insurance policy or employer-sponsored coverage, public healthcare coverage, such as Medicare or Medicaid, or other third-party coverage.

The use of the payer sheet is to standardize a declared emergency payer process to provide medication to displaced patients who do not have any financial means of paying for prescriptions.

The standard procedures are to clarify the use of the BIN Number, patient address, submission clarification codes and the prescriber ID when the pharmacy is the prescriber.

General Information:

Payer Name: Express Scripts	Date: **April 2020**
Processor: Express Scripts	Version/Release Number: D.0
Effective: January 1, 2020	NCPDP External Code List Version Date: **October 2018**
NCPDP Data Dictionary Version Date: **July 2007**	NCPDP Emergency External Code List Version Date: **July 2019**
Contact/Information Source: Express-Scripts.com	
Pharmacy Help Desk Info During Declared Emergency: (855) 793-7470	
Network Contracting and Management: (888) 571-8182	
Pharmacist Resource Center: https://prc.express-scripts.com	

Note: All fields requiring alphanumeric data must be submitted in UPPER CASE.

BIN/PCN Table

Plan Name/Group Name	BIN	PCN/GROUP
EPAP	003858	A4/Group will vary per disaster/emergency

Section I: Claim Billing (In Bound)

Transaction Header Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
101-A1	BIN Number	See BIN/PCN table, above	M
102-A2	Version Release Number	D0=Version D.0	M
103-A3	Transaction Code	B1=Billing	M
104-A4	Processor Control Number	As indicated above	M
Field #	**NCPDP Field Name**	**Value**	**Payer Usage**
109-A9	Transaction Count	1 = One Occurrence 2 = Two Occurrences 3 = Three Occurrences 4 = Four Occurrences	M
202-B2	Service Provider ID Qualifier	01=NPI	M
201-B1	Service Provider ID	Pharmacy NPI	M
401-D1	Date of Service		M
110-AK	Software Vendor/Certification ID		O

Patient Segment – Required

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	01=Patient	M
331-CX	Patient ID Qualifier		O
332-CY	Patient ID		O
304-C4	Date of Birth		R

Field #	NCPDP Field Name	Value	Payer Usage
305-C5	Patient Gender Code	1=Male 2=Female	R
310-CA	Patient First Name	Example: John	R
311-CB	Patient Last Name	Example: Smith	R
322-CM	Patient Street Address		O
323-CN	Patient City		O
324-CO	Patient State or Province		O
325-CP	Patient Zip/Postal Code		R*
307-C7	Place of Service	01 = Pharmacy	R
335-2C	Pregnancy Indicator	Blank = Not Specified 1=Not Pregnant 2=Pregnant	O
384-4X	Patient Residence		R

*****For Emergency/Natural Disaster claims, enter the current ZIP code of displaced patient in conjunction with an SCC of 13 = Payer-Recognized Emergency/Disaster Assistance Request.

Insurance Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	04=Insurance	M
302-C2	Cardholder ID	Beneficiary's First Initial of First Name + First Initial of Last Name + Year (YYYY) of Birth + Month (MM) of Birth + Day (DD) of Birth	M
312-CC	Cardholder First Name		R
313-CD	Cardholder Last Name		R
524-FO	Plan ID		O
301-C1	Group ID	Per Disaster/Emergency	R
303-C3	Person Code	001-010 Code assigned to specific person in a family	R
306-C6	Patient Relationship Code	1=Cardholder – The individual that is enrolled in and receives benefits from a health plan 2=Spouse – Patient is the husband/wife/partner of the cardholder 3=Child – Patient is a child of the cardholder 4=Other – Relationship to cardholder is not precise	R

Claim Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	07=Claim	M
455-EM	Prescription/Service Reference Number Qualifier	1=Rx Billing* *Pharmacist should enter "1" when processing claim for a drug and administration.	M
402-D2	Prescription/Service Reference Number		M
436-E1	Product/Service ID Qualifier	00 = Not specified* 03=National Drug Code	M
407-D7	Product/Service ID		M
442-E7	Quantity Dispensed		R
403-D3	Fill Number	0=Original Dispensing 1 to 99 = Refill number	R

Field #	NCPDP Field Name	Value	Payer Usage
405-D5	Days Supply		R
406-D6	Compound Code	1=Not a Compound 2=Compound*	R
408-D8	Dispense as Written (DAW)/Product Selection Code		R
414-DE	Date Prescription Written		R
415-DF	Number of Refills Authorized	00 =No refills authorized 01 - 99, with 99 as unlimited refills	R
419-DJ	Prescription Origin Code	0=Not known 1=Written 2=Telephone 3=Electronic 4=Facsimile 5=Pharmacy	R
354-NX	Submission Clarification Code Count	Maximum count of 3	RW (Field 420-DK is sent)
420-DK	Submission Clarification Code	See ECL for available values	RW (Clarification is needed)
460-ET	Quantity Prescribed		RW (As of 9/21/20 - Required for Schedule II drugs)
454-EK	Scheduled Prescription ID Number		RW (Must be provided when State Medicaid Regulations require this information)
600-28	Unit of Measure	EA = Each GM = Grams ML = Milliliters	R
418-DI	Level of Service		RW (This field could result in different coverage, pricing or patient financial responsibility)
461-EU	Prior Authorization Type Code	0 = Not specified 1 = Prior Authorization 2 = Medical Certification 8 = Payer Defined Exemption	RW (When value 1 or 8 is used in conjunction with Prior Authorization ID Submitted (462-EV)
462-EV	Prior Auth ID Submitted	Submitted when requested by processor Examples: Prior authorization procedures for physician authorized dosage or day supply increases for reject 79 'Refill Too Soon'	RW (461-EU = 1 or 8)

Field #	NCPDP Field Name	Value	Payer Usage
357-NV	Delay Reason Code**		RW (Needed to specify the reason that submission of transaction has been delayed)
995-E2	Route of Administration		RW (Required for Compounds)
147-U7	Pharmacy Service Type	01 = Community/Retail Pharmacy Services 03 = Home Infusion Therapy Services 05 = Long Term Care Pharmacy Services	R
456-EN	Associated Prescription/Service Reference Number		RW (Field 343-HD = P or C)
457-EP	Associated Prescription/Service Date		RW (Field 343-HD = P or C)
343-HD	Dispensing Status	P = Partial C = Complete	RW (Partial fill or completion of a fill)
344-HF	Quantity Intended to be Dispensed		RW (Partial fill or completion of a fill)
345-HG	Days Supply Intended to be Dispensed		RW (Partial fill or completion of a fill)

*The Product/Service ID (407-D7) must contain a value of "0" and Product/Service ID Qualifier (436-E1) must contain a value of "00" when used for multi-ingredient compounds. Partial fills are **not** allowed for Multi-Ingredient Compound claims.

**For Field 357-NV (Delay Reason Code), all valid values are accepted. Values of 1, 2, 7, 8, 9, 10 may be allowed to override Reject 81 (Claim Too Old).

Pricing Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	11=Pricing	M
409-D9	Ingredient Cost Submitted		R
412-DC	Dispensing Fee Submitted		R
433-DX	Patient Paid Amount Submitted		O

Field #	NCPDP Field Name	Value	Payer Usage
438-E3	Incentive Amount Submitted		RW (Value has an effect on Gross Amount (430-DU) calculation) Use when submitting claim for drug and administrative fee together.
481-HA	Flat Sales Tax Amount Submitted*		RW (Value has an effect on Gross Amount (430-DU) calculation)
482-GE	Percentage Sales Tax Amount Submitted*		RW (Value has an effect on Gross Amount (430-DU) calculation)
483-HE	Percentage Sales Tax Rate Submitted*		RW (Percentage Sales Tax Amount Submitted (482-GE) and Percentage Sales Tax Basis Submitted (484-JE) are used or if needed to calculate Percentage Sales Tax Amount Paid (559-AX)
484-JE	Percentage Sales Tax Basis Submitted		RW (Percentage Sales Tax submitted (482-GE) and Percentage Sales Tax Rate Submitted (483-HE) are used)
426-DQ	Usual and Customary Charge		R
430-DU	Gross Amount Due		R
423-DN	Basis of Cost Determination		R

*It is not permissible to submit Sales Tax unless required by State law.

Prescriber Segment – Required

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	03=Prescriber	M
466-EZ	Prescriber ID Qualifier	01=NPI 08=State License 12=DEA (Drug Enforcement Administration) 17 = Foreign Prescriber	R
411-DB	Prescriber ID	NPI*	R
427-DR	Prescriber Last Name		RW (Prescriber ID Qualifier (466-EZ) =08)

Field #	NCPDP Field Name	Value	Payer Usage
367-2N	Prescriber State/Province Address		RW (Prescriber ID Qualifier (466-EZ) = 08, 12)

Express Scripts edits the qualifiers in Field 466-EZ. A valid Prescriber ID is required for all claims. Claims that cannot be validated may be subject to post-adjudication review.

* For vaccines or other products not requiring a prescription, an individual NPI is required. It may be the prescriber who wrote the prescription or alternate care provider (pharmacist, nurse practitioner, etc.) who administered the vaccine or dispensed the product.

DUR/PPS Segment – Situational

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	08=DUR/PPS	M
473-7E	DUR/PPS Code Counter	Maximum of 9 occurrences	R
439-E4	Reason for Service Code	Refer to ECL	R
440-E5	Professional Service Code	00=No intervention M0=Prescriber consulted MA=Medication administration* P0=Patient consulted R0=Pharmacist consulted other source (Refer to ECL for other available values)	R
441-E6	Result of Service Code	Refer to ECL	R
474-8E	DUR/PPS Level of Effort	11=Level 1 (Lowest) 12=Level 2 13=Level 3 14=Level 4 15=Level 5 (Highest)	RW**

*Indicates the claim billing includes a charge for administration; leave blank if dispensing without administration.

**When submitting a compound claim, Field 474-8E is required; using the values consistent with your contract.

Compound Segment – Situational

(Required when submitting a compound claim. Will support only one transaction per transmission)

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	10=Compound	M
450-EF	Compound Dosage Form Description Code		M
451-EG	Compound Dispensing Unit Form Indicator	1=Each 2=Grams 3=Milliliters	M
447-EC	Compound Ingredient Component Count	Maximum 25 ingredients	M
488-RE	Compound Product ID Qualifier	03=NDC	M
489-TE	Compound Product ID	At least 2 ingredients and 2 NDC #s. Number should equal field 447-EC.	M
448-ED	Compound Ingredient Quantity		M
449-EE	Compound Ingredient Drug Cost		R
490-UE	Compound Ingredient Basis of Cost Determination		R

Clinical Segment – Situational

May be required as determined by benefit design. When the segment is submitted, the fields defined below are required.

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	13=Clinical	M
491-VE	Diagnosis Code Count	Maximum count of 5	R
492-WE	Diagnosis Code Qualifier	02=ICD-10	R
424-DO	Diagnosis Code		R

Section II: Response Claim Billing (Out Bound)

Response Header Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
102-A2	Version Release Number	D0 =Version D.0	M
103-A3	Transaction Code	B1=Billing	M
109-A9	Transaction Count	Same value as in request	M
Field #	**NCPDP Field Name**	**Value**	**Payer Usage**
501-FI	Header Response Status	A=Accepted R=Rejected	M
202-B2	Service Provider ID Qualifier	Same value as in request	M
201-B1	Service Provider ID	Same value as in request	M
401-D1	Date of Service	Same value as in request	M

Response Message Segment – Situational

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	20=Response Message	M
504-F4	Message		O

Response Insurance Segment – Required

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	25=Response Insurance	M
301-C1 **Response**	Group ID		R
524-FO	Plan ID		O
545-2F	Network Reimbursement ID	Network ID	R*
568-J7	Payer ID Qualifier		O
569-J8	Payer ID		O
302-C2	Cardholder ID		O

*Only Returned on a Paid Response

Response Status Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	21=Response Status	M
112-AN	Transaction Response Status	P=Paid D=Duplicate of Paid R=Reject	M
503-F3	Authorization Number		RW (Transaction Response Status = P)

Field #	NCPDP Field Name	Value	Payer Usage
547-5F	Approved Message Code Count	Maximum count of 5	RW (If Approved Message Code (548-6F) is used)
548-6F	Approved Message Code		RW (If Approved Message Code Count (547-5F) is used)
510-FA	Reject Count	Maximum count of 5	RW (Transaction Response Status = R)
511-FB	Reject Code		RW (Transaction Response Status = R)
546-4F	Reject Field Occurrence Indicator		RW (If repeating field is in error to identify repeating field occurrence)
130-UF	Additional Message Information Count	Maximum count of 9	RW (Additional Message (526-FQ) is used)
132-UH	Additional Message Information Qualifier		RW (Additional Message (526-FQ) is used)
526-FQ	Additional Message Information		RW (Additional text is needed for clarification or detail)
Field #	**NCPDP Field Name**	**Value**	**Payer Usage**
131-UG	Additional Message Information Continuity		RW (Current repetition of Additional Message Information (526-FQ) is used and another repetition (526-FQ) follows, and text is continuation of the current)
549-7F	Help Desk Phone Number Qualifier		O
550-8F	Help Desk Phone Number		O
987-MA	URL		R* (*Only returned on a rejected response)

Response Claim Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	22=Response Claim	M
455-EM	Prescription/Service Reference Number Qualifier	1=Rx Billing	M
402-D2	Prescription/Service Reference Number		M

Field #	NCPDP Field Name	Value	Payer Usage
551-9F	Preferred Product Count	Maximum count of 6	RW (Based on benefit and when preferred alternatives are available for the submitted product service ID)
552-AP	Preferred Product ID Qualifier		RW (Preferred Product ID (553-AR) is used)
553-AR	Preferred Product ID		RW (If a product preference exists that needs to be communicated to the receiver via an ID)
556-AU	Preferred Product Description		RW (If a product preference exists that either cannot be communicated by the Preferred Product ID (553-AR) or to clarify the Preferred Product ID (553-AR)

Response Pricing Segment – Mandatory
(This segment will not be included with a rejected response)

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	23=Response Pricing	M
505-F5	Patient Pay Amount		R
506-F6	Ingredient Cost Paid		R
507-F7	Dispensing Fee Paid		R
557-AV	Tax Exempt Indicator		RW (If sender and/or patient is tax exempt and exemption applies to this billing)
558-AW	Flat Sales Tax Amount Paid		RW (If Flat Sales Tax Amount Submitted (481-HA) is greater than zero (0) or if Flat Sales Tax Amount Paid (558-AW) is used to arrive at the final reimbursement)

Field #	NCPDP Field Name	Value	Payer Usage
559-AX	Percentage Sales Tax Amount Paid		RW (If Percentage Tax Amount Submitted (482-GE) is greater than zero (0) or Percentage Sales Tax Rate Paid (560-AY) and Percentage Sales Tax Basis Paid (561-AZ) are used)
560-AY	Percentage Sales Tax Rate Paid		RW (If Percentage Sales Tax Amount Paid (559-AX) is greater than zero (0)
561-AZ	Percentage Sales Tax Basis Paid		RW (If Percentage Sales Tax Amount Paid (559-AX) is greater than zero (0)
521-FL	Incentive Amount Paid		RW (If Incentive Amount Submitted (438-E3) is greater than zero (0)
563-J2	Other Amount Paid Count		O
564-J3	Other Amount Paid Qualifier	Occurs up to 3 times	O
565-J4	Other Amount Paid	Occurs up to 3 times	O
566-J5	Other Payer Amount Recognized		O
509-F9	Total Amount Paid		R
522-FM	Basis of Reimbursement Determination		R
523-FN	Amount Attributed to Sales Tax		RW (If Patient Pay Amount (505-F5) includes sales tax that is the financial responsibility of the member but is not also included in any of the other fields that add up to Patient Pay Amount)
514-FE	Remaining Benefit Amount		O

Field #	NCPDP Field Name	Value	Payer Usage
517-FH	Amount Applied to Periodic Deductible		RW (Patient Pay Amount (505-F5) includes deductible)
518-FI	Amount of Co-pay		RW (Patient Pay Amount (505-F5) includes co-pay as patient financial responsibility)
520-FK	Amount Exceeding Periodic Benefit Maximum		RW (Patient Pay Amount (505-F5) includes amount exceeding periodic benefit maximum)
571-NZ	Amount Attributed to Processor Fee		RW (If customer is responsible for 100% of the prescription payment and when the provider net sale is less than the amount the customer is expected to pay)
575-EQ	Patient Sales Tax Amount		RW (Necessary to identify Patient's portion of the Sales Tax)
574-2Y	Plan Sales Tax Amount		RW (Used when necessary to identify Plan's portion of Sales Tax)
572-4U	Amount of Coinsurance		RW (Patient Pay Amount (505-F5) includes coinsurance as patient financial responsibility)
392-MU	Benefit Stage Count		RW (Benefit Stage Amount (394-MW) is used.)

Field #	NCPDP Field Name	Value	Payer Usage
393-MV	Benefit Stage Qualifier		RW (Benefit Stage Amount (394-MW) is used)
394-MW	Benefit Stage Amount		RW (Medicare Part D payer applies financial amounts to Medicare Part D beneficiary benefit stages. This field is required when the plan is a participant in a Medicare Part D program that requires reporting of benefit stage specific financial amounts.)
577-G3	Estimated Generic Savings		RW (Patient selects brand drug when generic was available)
128-UC	Spending Account Amount Remaining		RW (If known when transaction had spending account dollars reported as part of patient pay amount)
129-UD	Health Plan-Funded Assistance Amount		RW (Patient meets the plan-funded assistance criteria to reduce Patient Pay Amount (505-F5)
134-UK	Amount Attributed to Product Selection/Brand Drug		RW (Patient Pay Amount (505-F5) includes an amount that is attributable to patient's selection of a Brand drug)

Field #	NCPDP Field Name	Value	Payer Usage
133-UJ	Amount Attributed to Provider Network Selection		RW (Patient Pay Amount (505-F5) includes an amount that is attributable to a cost share differential due to the selection of one pharmacy over another)
135-UM	Amount Attributed to Product Selection/Non-Preferred Formulary Selection		RW (Patient Pay Amount (505-F5) includes an amount that is attributable to a patient's selection of a non-preferred formulary product)
136-UN	Amount Attributed to Product Selection/Brand Non-Preferred Formulary Selection		RW (Patient Pay Amount (505-F5) includes an amount that is attributable to a patient's selection of a Brand non-preferred formulary product)
137-UP	Amount Attributed to Coverage Gap		RW (Patient's financial responsibility is due to the coverage gap)
148-U8	Ingredient Cost Contracted/Reimbursable Amount		RW*
149-U9	Dispensing Fee Contracted/Reimbursable Amount		RW*

*Basis of Reimbursement Determination (522-FM) is 14 (Other Payer-Patient Responsibility Amount – 352-NQ) or 15 (Patient Pay Amount – 505-F5) unless prohibited by state/federal/regulatory agency.

Response DUR/PPS Segment – Situational

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	24=Response DUR/PPS	M
567-J6	DUR/PPS Response Code Counter	Maximum 9 occurrences supported	RW (Reason for Service Code (439-E4) is used)
439-E4	Reason for Service Code		O
528-FS	Clinical Significance Code		O
529-FT	Other Pharmacy Indicator		O
530-FU	Previous Date of Fill		O
531-FV	Quantity of Previous Fill		O
532-FW	Database Indicator		O
533-FX	Other Prescriber Indicator		O
544-FY	DUR Free Text Message		O
570-NS	DUR Additional Text		O

Response Prior Authorization Segment – Situational
(Provided when the receiver has an opportunity to reprocess claim using a Prior Authorization Number)

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	26=Response Prior Authorization	M
498-PY	Prior Authorization ID - Assigned		RW (Receiver must submit this Prior Authorization Number in order to receive payment for the claim)

Section III: Reversal Transaction (In Bound)

Transaction Header Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
101-A1	BIN Number	BIN used on original claim submission	M
102-A2	Version Release Number	D0=Version D.0	M
103-A3	Transaction Code	B2=Reversal	M
104-A4	Processor Control Number	PCN used on original claim submission	M
109-A9	Transaction Count	1=One occurrence per B2 transmission	M
202-B2	Service Provider ID Qualifier	01=NPI	M
201-B1	Service Provider ID	NPI	M
401-D1	Date of Service		M
110-AK	Software Vendor/Certification ID		O

Note: Reversal window is 90 days.

Insurance Segment – Required

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	04=Insurance	M
302-C2	Cardholder ID	ID assigned to the cardholder	M
301-C1	Group ID		R

Claim Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	07=Claim	M
455-EM	Prescription /Service Reference Number Qualifier	1=Rx Billing	M
402-D2	Prescription/Service Reference Number		M
436-E1	Product/Service ID Qualifier	Value used on original claim submission	R
407-D7	Product/Service ID		R
403-D3	Fill Number		R
308-C8	Other Coverage Code	Value used on original claim submission	R

Section IV: Reversal Response Transaction (Out Bound)

Response Header Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
102-A2	Version Release Number	D0=Version D.0	M
103-A3	Transaction Code	B2=Reversal	M
109-A9	Transaction Count	1=One Occurrence, per B2 transmission	M
501-FI	Header Response Status	A=Accepted R=Rejected	M

Field #	NCPDP Field Name	Value	Payer Usage
202-B2	Service Provider ID Qualifier	01=NPI	M
201-B1	Service Provider ID	NPI	M
401-D1	Date of Service		M

Response Message Segment – Situational

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	20=Response Message	M
504-F4	Message		O

Response Status Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	21=Response Status	M
112-AN	Transaction Response Status	A=Approved R=Rejected	M
Field #	NCPDP Field Name	Value	Payer Usage
547-5F	Approved Message Code Count	Maximum count of 5	RW (Approved Message Code (548-6F) is used)
548-6F	Approved Message Code		RW (Approved Message Code Count (547-5F) is used)
510-FA	Reject Count	Maximum count of 5	RW (Transaction Response Status=R)
511-FB	Reject Code		RW (Transaction Response Status=R)
549-7F	Help Desk Phone Number Qualifier		O
550-8F	Help Desk Phone Number		O

Response Claim Segment – Mandatory

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	22=Response Claim	M
455-EM	Prescription/Service Reference Number Qualifier	1=Rx Billing	M
402-D2	Prescription/Service Reference Number		M

FIELD LEGEND FOR COLUMNS

PAYER USAGE COLUMN	Value	Explanation	Payer Situation Column
MANDATORY	**M**	The Segment is mandatory for the Transaction or The Field is mandatory for the Segment for the designated Transaction. Mandatory elements have structural requirements.	No
SITUATIONAL		The Segment has been further designated for usage for the Transaction or The Field has been further designated for usage for the Transaction.	
REQUIRED	**R**	The Field has been designated with the situation of "Required" for the Segment for the designated Transaction.	No

PAYER USAGE COLUMN	**Value**	Explanation	Payer Situation Column
REQUIRED FOR MEDICAID SUBROGATION ONLY	**RM**	The Field has been designated with the situation of "Required" for the Segment for the Transaction for Medicaid Subrogation usage only.	
QUALIFIED REQUIREMENT	**Q**	The situations designated have qualifications for usage ("Required if x", "Not required if y").	Yes
QUALIFIED REQUIREMENT FOR MEDICAID SUBROGATION ONLY	**QM**	The situations designated have qualifications for usage ("Required if x", "Not required if y") for Medicaid Subrogation.	
INFORMATIONAL ONLY	**I**	The Field is for informational purposes only for the Transaction.	
OPTIONAL	**O**	The Field has been designated as optional usage (situations were not intentionally defined).	
NOT USED	**N**	The Segment is not used for the Transaction or The Field is not used for the Segment for the Transaction. Not used are shaded for clarity.	
REPEATING	***R***	The three asterisks, "R", and three asterisks designates a field is repeating. Example "Q***R***" means a situationally qualified field that repeats. Example "N***R***" means a not used field that repeats when used.	

8. OBTAINING PRODUCT IN A DECLARED EMERGENCY THROUGH MANUFACTURER PROGRAMS

Pharmaceutical Research and Manufacturers of America (PhRMA) has created the Medicine Assistance Tool (MAT) to provide a dedicated search engine that allows users to search for financial assistance resources available to them, their loved ones or patients in their lives through the various biopharmaceutical industry programs available for patients who are eligible.

MAT is a search engine that contains information on approximately 900 public and private assistance programs that help those with financial need get access to their prescription. MAT is not its own patient assistance program, but rather a search engine for many of the patient assistance resources that the biopharmaceutical industry offers. Patients and health care provider can access MAT at: https://medicineassistancetool.org/

Note: This program does not offer immediate assistance for patients during a short-term declared emergency but may play a role as a long-term solution.

9. DIAGNOSTIC TESTING CONSIDERATIONS

Since a pandemic, such as COVID-19, creates significant volatility throughout the healthcare system, it is important to outline various components of testing that may result in an impact on the billing of test products and services. The following are some of the components that should be considered to support diagnostic testing in the pharmacy industry. Continuous review and maintenance of regulations and policies are also important.

9.1 *EXAMPLES OF TYPES OF DIAGNOSTIC TESTS*

There are a number of different diagnostic tests for COVID-19 currently on the market for which the level of complexity, specimen collection and testing procedures vary. Multiple distinct product/service identifiers may be required to specifically identify the type of test being performed. Current examples of tests available are detailed below.

- Molecular in-vitro testing, authorized for high complexity and/or moderate complexity and/or waived (e.g., rapid results test) lab settings.
- Serological testing authorized for high complexity and/or moderate complexity lab settings.

Beginning in the spring of 2020, the Food and Drug Administration (FDA) granted Emergency Use Authorizations (EUA) for COVID-19 diagnostic tests and tests to detect antibodies to the coronavirus. The full list of tests that have received an EUA is available here: fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices. The majority of diagnostic tests for COVID-19 that have been granted an EUA can only be performed in settings authorized to perform "high complexity" or "moderate complexity" lab tests.

Unique Device Identifiers (e.g., GTIN 14) are assigned to tests/test kits, where an alternate product ID may be required on the claim. Alternate IDs may include a NCPDP 11-digit Product Service Identifier, HCPCS code or CPT code, where product ID mapping will be required.

Packaging of diagnostic tests also varies. Tests that require multiple products (e.g., swabs, swab covers, control solution) may or may not be included in the larger test kit package and may require calculations to derive the quantity dispensed and associated unit cost of an individual test.

9.2 *TYPES OF SERVICES*

It is assumed pharmacies/pharmacists will participate in diagnostic testing, such as COVID-19, in the following ways:

1. Assess a patient, and when appropriate, order laboratory testing. Federal or state law or executive order may authorize a pharmacist to be the clinician who assesses the patient and orders the test.
2. Dispense an individual test kit to a patient, upon the order of a clinician.
3. Administer a test through the collection of a specimen and deliver that specimen to the appropriate lab for analysis.
4. Perform a test as allowed by the pharmacy's Clinical Laboratory Improvement Amendments (CLIA) waiver.
5. Interpret and report test results as authorized by state law. Reporting of the test results may include:
    a. Counseling the patient and/or authorized individual/entities of the results and providing notifications to the patient's primary care team as identified by the patient.
    b. Reporting of results to local, state and federal designated entities (e.g., Department of Health, Centers for Disease Control and Prevention (CDC), etc.)

All the services required to complete the assessment, ordering, dispensing, specimen collection, interpreting and reporting of the results may require multiple billings and possibly occur at separate times. For example, the furnishing of the test and specimen collection may occur on a different date of service and by a different provider than the examination of the specimen collected and reporting the results.

In addition, certain test results may require additional testing with the same or different type of test. As a result, payer edits for duplicative services may need to be bypassed and/or applicable code values may need be developed to identify the initial test and the re-evaluation test. Recurrence of a pathogen, like COVID-19, within the same plan benefit year may also require adjustments to any annual testing benefit restrictions.

9.3 *TESTING CERTIFICATIONS*

The tests themselves are categorized by the FDA in the EUA for one or more of the following settings: high complexity, moderate complexity or waived laboratories. All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Pharmacy providers need to obtain the applicable CLIA certifications for the specific tests they administer.

Three federal agencies are responsible for CLIA: the FDA, CMS and the CDC. Each agency has a unique role in assuring quality laboratory testing. The FDA is the agency that categorizes tests based on complexity (from the least to the most complex: waived tests, moderate complexity tests and high complexity tests), reviews requests for Waiver by Application and develops rules/guidance for CLIA complexity categorization.

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The FDA has also authorized diagnostic tests (like some for COVID-19) that are moderate and high complexity that have an EUA designation as a waived test authorized to be distributed and used in patient care settings outside of the clinical laboratory environment. The FDA determines which tests meet these criteria when it reviews manufacturer's applications for test system waiver. For waived testing, CLIA requires you to:

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturer's instructions for the waived tests you are performing; and
- Notify your state agency of any changes in ownership, name and address or laboratory director within 30 days, or if you wish to add tests that are more complex.

9.4 *PATIENT ASSESSMENT CRITERIA FOR ORDERING DIAGNOSTIC TESTS*

Clinicians should use their professional judgment to determine if a patient should be tested. For specific guidance, clinicians may refer to recommendations supplied by state or local health jurisdictions or diagnostic testing priority guidelines provided by the CDC.

9.5 *TEST PRODUCT SUPPLY*

In a declared emergency, test products may be supplied through the SNS or other source, with no product costs to the clinician administering the test. The zero-product cost would be represented in the claim, but other fees may apply as outlined in Billing For Free Product.

9.6 *ORDERING PROVIDER/ADMINISTERING PROVIDER VALIDATION*

When a pharmacist is ordering a test, collecting a test specimen or interpreting the results, the individual performing these services may need to be identified on different fields in the claim request. The ordering provider would be represented in the Prescriber ID (411-DB) field. The administering provider would be represented in the Provider ID

(444-E9) field. The ordering and administering provider(s) should have a Type 1 NPI for provider validation and enrollment purposes.

9.7 *PAYER CONSIDERATIONS*

The information submitted on a claim for a specified test may be determined by the requirements of the different payers and whether the payer requires processing and payment of the claim under the medical or prescription benefit. The appropriate code set values and clear messaging should be returned on the claim response to communicate plan benefit rules and coverage criteria.

Federal and state regulations may also impact the claim billing process. For example, the Families First Coronavirus Response Act (FFCRA) requires plans and issuers to cover items and services provided to a patient that "relate to the furnishing or administration" of COVID-19 diagnostic testing among other things.

Detailed guidance regarding billing of diagnostic tests can be found in Frequently Asked Questions.

10. 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 HHS, including the CDC, the FDA, the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA). OWS seeks to accelerate the development, manufacturing 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 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," CMS could consider any vaccine for which the FDA issued an EUA during the 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 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.

10.1 *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.

10.2 *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.

10.3 *CLAIM SUBMISSION*

In a declared emergency, vaccines may be supplied through the SNS or other sources with no associated product costs. Refer to Billing For Free Product 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 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 10.1 on quantity dispensed)
- Professional Service Code (440-E5) value of "MA" (Medication Administered)
- Incentive Amount Submitted (438-E3) should be submitted when 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 (409-D9) 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 STANDARD VERSION D (Telecommunication Standard) AND ABOVE QUESTIONS, ANSWERS AND EDITORIAL UPDATES.

10.4 *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.

The submission of the NDC and the Professional Service Code (440-E5) of MA may be sufficient where dose differentiation indicated by a SCC (420-DK) value is not necessary. However, processor system limitations may require submission of a SCC (e.g., SCC = 6). Plans are reminded to communicate any plan specific claims submission requirements.

Two-Dose Vaccines

The SCC 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 of the same provider or different providers administering 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/second dose of the vaccine series, a SCC value should be submitted on all claims for two-dose vaccines. The following distinct SCC values should be used to clarify the submission as an initial or final/second dose:

Initial Dose:

- SCC 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/Second Dose:

- SCC 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/second dose of a two-dose vaccine is being administered.

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

10.5 *ADDITIONAL DOSE OR BOOSTER DOSE*

An **additional dose** may be administered to an individual patient based on patient-specific criteria found in the EUA, FDA-approved label or Advisory Committee on Immunization Practices (ACIP) recommendations. According to the CDC, an additional dose is defined as another dose of vaccine given to a fully vaccinated targeted population.

When a patient requires an additional dose of a specific Product/Service ID (407-D7), an additional identifier within the claim request may be necessary to specify the additional dose situation. NCPDP recommends the use of the following Submission Clarification Codes (SCC) for dose identification.

a. SCC 7 (Medically Necessary):
    i. Additional dose for targeted population, where days between additional dose and last dose of series is no less than the dose series time period.

A **booster dose** is a single dose of the vaccine that may be administered to individuals in accordance with CDC guidance.

When a patient requires a booster dose of a specific Product/Service ID (407-D7), an additional identifier within the claim request may be necessary to specify the additional dose situation. NCPDP recommends the use of the following Submission Clarification Code (SCC) for dose identification.

a. SCC 10 (Meets Plan Limitations):
    i. Booster dose for population with waning immunity.

Refer to the specific manufacturer's fact sheet for recommendations on the timeline of administration.

FDA and ACIP booster guidance may incur variability and changes over time, where days post last dose, dose quantity, patient age, patient eligibility and homologous/heterologous criteria will require flexibility within claim adjudication processes.

If payers cannot immediately support SCC 10, NCPDP recommends an interim solution where both SCC 7 and 10 would be used. This would allow SCC 7 to trigger existing logic and SCC 10 could be used to support any additional override logic for reporting to identify a booster. Payers should notify their pharmacy networks as to these temporary claims processing requirements and when their systems will be able to support just SCC 10 for boosters.

Due to the ever-changing environment of the COVID-19 pandemic, please ensure your organization is monitoring all available resources such as the FDA, CDC and NCPDP. Any new formulations or concentrations of the vaccine will have a different NDC and do not constitute an additional dose under this definition. Plans are reminded to communicate any plan-specific claims submission requirements. The use of ICD-10 codes as the sole means of communicating an additional dose is discouraged. The CDC encourages the industry to be flexible with edits since guidance is very fluid at this time.

New formulations or concentrations of the vaccine will have distinct NDCs (i.e., different from the existing) where the Product/Service ID (407-D7) value would identify the product administered as a distinct product. Existing logic for single or multiple doses should be leveraged to apply applicable claim utilization rules. Rejecting claims for therapeutic duplication based on prior claims for a different NDC is discouraged.

Note: Based on CDC guidelines, booster dose may be required to be administered at a lower dose/reduced quantity than the original dose series. This does not impact the SCC guidance as outlined above. A reduced quantity should not impact the administration fee.

10.6 *COVID-19 VACCINE USE CASE EXAMPLES*

NOTE: Dollar amounts shown in all examples are for illustrative purposes only. Reference CMS website for current prices.

10.6.1 USE OF SUBMISSION CLARIFICATION CODE (420-DK) FOR INITIAL, FINAL/SECOND, ADDITIONAL 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/second dose of a two-dose product, NCPDP recommends SCC (420-DK) value of 2 be used to identify the initial dose, the value of 6 for the final/second dose and the SCC value of 7 for any additional doses. While not required, SCC 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
9. Two-Dose NDC, SCC = 2, Incentive Amount Submitted = 40.00
10. Two-Dose NDC, SCC = 6, Fill # = 01, same Service Provider ID, Incentive Amount Submitted = 40.00
11. Single-Dose NDC, SCC is BLANK, Incentive Amount Submitted = 40.00
12. Additional-Dose SCC = 7 following Two-Dose NDC
13. Booster-Dose SCC = 10 following Single-Dose NDC
14. Booster-Dose SCC = 10 following Two-Dose NDC

	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 number 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 number b. Payer applies final/second 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	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)**
same NDC and SCC. Refer to Utilization Guidance section below											
5. Two-dose NDC, SCC is BLANK a. Provider submits same incentive fee regardless of dose number 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
9. *Two-Dose NDC, SCC = 2*	1234567890	1111111	0	MA	2	$40.00	$0.00	15	P	_	$40.00

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)**
a. Provider submits same incentive fee regardless of dose number b. Payer applies appropriate rate that's agnostic of dose number											
10. Two-Dose NDC, SCC = 6, Fill # = 01, same Service Provider ID a. Provider submits same incentive fee regardless of dose number b. Payer applies appropriate rate that's agnostic of dose number	1234567890	1111111	1	MA	6	$40.00	$0.00	15	P	_	$40.00
11. Single-Dose NDC, SCC is BLANK a. NDC identifies single-dose product b. Payer applies appropriate rate that's agnostic of dose number	1234567890	3333333	0	MA	_	$40.00	$0.00	15	P	-	$40.00
12. Additional-Dose SCC = 7 following Two-Dose NDC a. NDC identifies two-dose product b. Payer applies appropriate rate that's agnostic of dose number	1234567890	1111111	1	MA	7	$40.00	$0.00	15	P	_	$40.00
13. Booster-Dose SCC = 10 following Single-Dose NDC a. NDC identifies single-dose product	1234567890	3333333	0	MA	10	$40.00	$0.00	15	P	-	$40.00

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)**
b. Payer applies appropriate rate that's agnostic of dose number c. *Heterologous interchange is allowed.*											
14. Booster-Dose SCC = 10 following Two-Dose NDC a. NDC identifies two-dose product b. Payer applies appropriate rate that's agnostic of dose number c. *Heterologous interchange is allowed.*	1234567890	1111111	1	MA	10 During transition plans may require a 10 and 7	$40.00	$0.00	15	P	_	$40.00

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

10.6.2 USE CASES REQUIRING ADDITIONAL DATA

In addition to determining if the submitted claim is for the initial or final/second 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 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 SCC 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 SCC value 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

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)**
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 = MA, Incentive Fee Submitted value is BLANK a. Payer rejects as E3 – M/I Incentive Fee Submitted	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)**
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
9. Two-Dose or Single-Dose NDC, SCC 2 and SCC 42, Prescription Origin Code = 5, Prescriber ID = RPh NPI	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

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)**
a. Payer accepts claim leveraging SCC 42 to override prescriber ID validation edit.										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 Submitted is inactive or is not found	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

10.6.3 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.

Now that additional doses or booster doses are expected to be provided to fully vaccinated patients, NCPDP recommends payers/processors reconsider any hard stops (i.e., indicating a non-overridable rejection) that may prevent administration of additional doses (SCC=7) as well as interchange of manufacturers as the CDC continues to issue guidance and provide appropriate timelines for administration of these doses.

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 paid claim for the same	1234567890	3333333	1		MA		$28.39	$0.01	01	R	76 – Plan Limit Exceeded or;	

Use Case	Request									Response		
	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)**
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											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 effective date or plan	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)**
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	
8. Two-Dose NDC, SCC =6, payer's claim history	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)**
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/second dose***												
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 within the Additional	1555555555	4444444	0		MA	6	$28.39	$0.00	15	R	88 – DUR Or Alternate reject code, with vaccine manufacturer conflict and override procedure communicated in 526-FQ	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)**
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												

10.6.4 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.

10.6.4.1 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 Medicare Advantage prescription drug (MA-PD) plan or prescription drug plan (PDP) in error, the plan should reject as indicated below in Scenario 1.

10.6.4.2 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

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)**
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 be billed to Medicare Part B FFS"	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"
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

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)**
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 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	1234567890	3333333	1	MA	6	$28.39	$0.01	01	R	817 - Not covered under pharmacy benefit, bill medical benefit

10.7 *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 (438-E3) 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/second 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.

10.8 *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[16]. 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
  - 12 = Home
  - 13 = Assisted Living Facility
  - 14 = Group Home
  - 15 = Mobile Unit
  - 18 = Place of Employment, Worksite
  - 31 = Skilled Nursing Facility
  - 32 = Nursing Facility
  - 33 = Custodial Care Facility
  - 51 = Inpatient Psychiatric Facility
  - 54 = Intermediate Care Facility/ Individuals with Intellectual Disabilities

[16] https://www.cms.gov/medicare/coding/place-of-service-codes

- 60 = Mass Immunization Center
- 99 = Other Place of Service

Typically, the Pharmacy Service Type (147-U7) and Place of Service (307-C7) values align to the Patient Residence (384-4X). (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 (e.g., Retail Pharmacy providing services from the patient's Home).

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	1: Home	5: Long Term Care Pharmacy	15: Mobile Unit
5	6: Group Home	5: Long Term Care Pharmacy	33: Custodial Care Facility
6	1: Home	1: Retail Pharmacy	12: Home

To mitigate patient access to care risks resulting from claim rejections for non-typical settings of care situations, it is recommended that validation edits for these fields be by-passed for COVID-19 vaccine claims unless the Place of Service (e.g., home) results in a rate of reimbursement distinct from all other places of services.

10.9 *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 to prevent unnecessary point of service rejects. The dispensed quantity for either remains the same as discussed in the section Quantity Dispensed.

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.

10.10 *SECOND DOSE/ADDITIONAL DOSE/BOOSTER DOSE UTILIZATION EDITS*

NCPDP recommends hard stop utilization edits not apply to claims for EUA products. 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
- Refill too Soon when the additional dose or booster dose is earlier than the calculated days from the date of service of the final dose of previously administered vaccine
- 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
- Plan Limitations Exceeded or DUR Utilization edit, when the additional dose or booster dose is different than the calculated days from the date of service of the final dose of previously administered vaccine

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[17], HHS guidance and FDA approvals and bring forward any related claims adjudication questions to NCPDP to facilitate standardization.

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

11. FREQUENTLY ASKED QUESTIONS

The following questions and answers provide additional guidance on billing of claims during time of emergency.

11.1 *PLAN LIMITATION OVERRIDE CODES*

Question: Which NCPDP fields and code set values should be used during a declared emergency to request an override to a plan limitation reject such as refill too soon, where the patient requires an additional supply of previously dispensed product as a result of lost product, evacuation, quarantine or other applicable situations?

Answer: Submission Clarification Code (420-DK) value of 13 (Payer-Recognized Emergency/Disaster Assistance Request - The pharmacist is indicating an override is needed based on an emergency/disaster situation) should be used in a declared emergency situation to request an override to plan limitation rules.

11.2 *EMERGENCY DISASTER LOCATIONS*

Question: What patient information is required to identify a declared emergency situation where the patient has been displaced and requires an additional supply of previously dispensed product?

Answer: The Patient ZIP/Postal Code (325-CP) is required and should represent the location from where the patient was displaced. The combination of the submitted ZIP/Postal code, claim date of service and Submission Clarification Code (420-DK) value of 13 can be used by the payer to apply applicable plan benefit overrides.

11.3 *EMERGENCY RX REFILLS PRESCRIBER IDS AND OVERRIDE CODES*

Question: What information is needed within the claim request for payers to apply the applicable claim adjudication rules to support state emergency declarations that allow for a pharmacist to extend a prescription refill for specified products (e.g., maintenance medications/products) when the original prescriber is not available to authorize a renewal?

Answer: Based on each entity's interpretation of the board of pharmacy rules, the emergency Rx could be an extension of the original prescription where the original prescriber ID would be associated to the claim, or the pharmacist Type 1 or pharmacy Type 2 NPI could be submitted as the Prescriber ID (411-DB). In both situations, this would be a new prescription number, where Prescription Origin Code (419-DJ) should be submitted with a value of '5'.

- Prescription Origin Code (419-DJ) value of '5'– Pharmacy
    - *Pharmacy - This value is used to cover any situation where a new Rx number needs to be created from an existing valid prescription such as traditional transfers, intrachain transfers, file buys, software upgrades/migrations and any reason necessary to "give it a new number." This value is also the appropriate value for "Pharmacy dispensing" when applicable such as BTC (behind the counter), Plan B, established protocols, pharmacist's authority to prescribe, etc.*

When the pharmacist or pharmacy NPI is submitted, Type 1 NPI and prescriptive authority validation rules may apply. While various methods may be employed by payers to override these system rules, adhering to the following recommendations will promote standardization of processes and expedite patient access to care. Also refer to CMS HPMS Memo published April 3, 2020 *(Notification of PDE Prescriber ID Editing and*

States of Emergencies) and trading partner agreements to validate specific claims processing expectations. When prescriber validation results in a point of service (POS) reject, one or both of the below Submission Clarification Codes may be necessary to override prescriber validation rules as a result of the emergency Rx situation.

- Submission Clarification Code (420-DK)
    - 13: *Payer-Recognized Emergency/Disaster Assistance Request - The pharmacist is indicating that an override is needed based on an emergency/disaster situation recognized by the payer*
    - 42: *Prescriber ID Submitted is valid and prescribing requirements have been validated*

If plan benefit rules apply after the prescriber validation step, multiple Submission Clarification Codes may be needed. For example, the emergency Rx could initially be rejected with a prescriber validation error, in which case Submission Clarification Code 42 would be accepted by the payer, then the claim would be rejected as refill too soon, requiring both Submission Clarification Code 42 and 13.

11.4 *BILLING FOR A FREE PRODUCT WITH NO ASSOCIATED COST*

Question: How do I bill for a test with no associated cost?

Answer: When pharmacies obtain a test with zero cost from the SNS or other source, refer to Billing for Free Product for examples and additional guidance.

Claims submitted for zero-cost tests may include other charges for dispensing and/or incentive fees for administration and/or interpretation and reporting of tests.

NCPDP recommends the use of a single B1/B3 billing transaction with the Basis of Cost Determination (423-DN) value "15" (Free product or no associated cost), with an associated Ingredient Cost Submitted (409-D9) value of $0.00. Systems that may not be able to accept the value $0.00 should clearly communicate the use of $0.01 as the submitted cost.

11.5 *BILLING EXAMPLE FOR DIAGNOSTIC TESTS*

Question: When billing for diagnostic tests, such as COVID-19, what information should be included in a NCPDP B1/B3 claim request?

Answer: When diagnostic tests, such as COVID-19, are covered under the pharmacy benefit, the following guidance should be used to allow processing of the claim using the Telecommunication Standard Claim Billing (B1/B3) format.

1. Provider Validation:
    a) The Type 2 NPI for the pharmacy contracted for providing testing services should be submitted as the Service Provider ID (201-B1).
    b) Pharmacies should acquire the applicable CLIA Waiver certificate (refer to FAQ: Clinical Laboratory Improvement Amendments (CLIA) below). This information may need to be communicated through trading partner agreements to allow for provider validation.
2. Product/Service Identifiers:
    a) Test kits will contain a Universal Product Code (UPC) or Unique Device Identifier (UDI) code. Convert the code assigned to the test kit product to the NCPDP 11-digit Product Service Identifier for the Product/Service ID (407-D7) field and associate the Product/Service ID Qualifier (436-E1) of NDC (03).

b) Alternatively, payers may require a Healthcare Common Procedural Coding System (HCPCS) code in which case use the Product/Service ID Qualifier (436-E1) of HCPCS (09) and the applicable HCPCS code as the Product/Service ID (407-D7). HHS may also assign a qualifier(s) to allow more specificity to be used in the Procedure Modifier Code (459-ER) field in the Claim segment.

c) When only dispensing a test kit to the patient, upon the order of a clinician other than the pharmacist, additional service identifiers may not be required (e.g., Professional Service Code (440-E5) would be blank).

NOTE: When the ordering provider is the pharmacist, the dispensing of a test would also include assessment.

d) When the pharmacist is administering the test (collecting the specimen) and/or interpreting and reporting the results, the following codes should be submitted in the Professional Service Code (440-E5) field to further identify additional services being provided.

MA	*Medication Administration* **Business Case:** Indicates that the test has been administered. Submission of this code assumes the kit has also been dispensed as defined in c) above.
PT	*Perform Laboratory Test* **Business Case:** Indicates that test analysis has been performed and results have been interpreted. Submission of this code includes services as defined in MA above in addition to informing the patient of test results and reporting the results to designated entities, when required.

3. Unit of Measure:
   a) Refer to FAQ: COVID-19 Test Quantity Dispensed below.
4. Product Costs and Associated Fees:
   a) The cost of the individual test kit should be submitted in the Ingredient Cost Submitted (409-D9) field. Based on how/who supplied the test kit, this could be $0.00. Products with a cost of $0.00 must have a distinct product identifier that is only associated to the no-cost product.
   b) The cost of dispensing the test kit should be submitted in the Dispensing Fee Submitted (412-DC) field.
   c) The fee for any associated services (e.g., specimen collection or interpretation and reporting of results) should be captured in the Incentive Amount Submitted (438-E3) field.
5. Prescriber ID:
   a) The NPI of the provider authorized to order the test should be submitted as the Prescriber ID. In some cases, this may be the pharmacist or pharmacy NPI. When submitting a pharmacy/pharmacist NPI, the Prescription Origin Code (419-DJ) value of 5-Pharmacy must also be submitted.
6. Provider ID:
   a) The NPI of the authorized provider administering the test may be submitted in the Provider ID (444-E9) field.
7. Place of Service:
   a) Indicates the location the service was provided. When required, the applicable value should be submitted in the Place of Service (307-C7). For example:
      i) 01 Pharmacy
      ii) 15 Mobile Unit
      iii) 32 Nursing Facility
      iv) 60 Mass Immunization Center
      v) 99 Other Place of Service
8. Diagnosis Code:
   a) The Diagnosis Code (424-DO) field can be used by the pharmacy to communicate either the reason for performing the test or testing results by submitting the applicable ICD-10 code.

b) The CDC has provided guidance as to applicable ICD-10 codes cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf.

This FAQ will be updated as more information becomes available.

11.5.1 CLAIM EXAMPLES

11.5.1.1 BILLING FOR A PRODUCT WITH NO ASSOCIATED COST AND ADMINISTRATION CODE OF MA (COLLECTION OF A SPECIMEN)

In the following example a pharmacy collects the specimen from the patient and transfers it to a lab for processing. The pharmacy does NOT perform the testing. The product service identifier (407-D7) field submitted is reflective of the supplies assembled by the pharmacy for collection of the specimen. There are various specimen collection supplies available in the marketplace, all of which may not yet have a GTIN product identifier. As a result of a declared state of emergency, when the specimen collection supplies are not associated to a manufacturer and assigned product ID, the value of 99999-0992-11 (COVID-19 Test Specimen Collection) can be submitted as the Product/Service ID with the Product/Service ID Qualifier (436-E1) of 03 "National Drug Code".

The Professional Service Code (440-E5) field should include the value of MA – Medication Administered to represent the specimen collection. The associated charges for the professional service should be submitted in the Incentive Fee Submitted (438-E3) field. Based on trading partner agreements, additional charges may be submitted and represented in the applicable fields e.g., Dispensing Fee Submitted (412-DC), Other Amount Claimed Submitted (480-H9).

Transaction Header Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
101-A1	BIN Number	M	*610066*	
102-A2	Version/Release Number	M	*D0*	Transaction Format
103-A3	Transaction Code	M	*B1*	Claim Billing
104-A4	Processor Control Number	M	*1234567890*	
109-A9	Transaction Count	M	*1*	One occurrence
202-B2	Service Provider ID Qualifier	M	*01*	National Provider ID
201-B1	Service Provider ID	M	*1112223333*	
401-D1	Date of Service	M	*20200317*	March 17, 2020
110-AK	Software Vendor/Certification ID	M	*bbbbbbbbbb*	

Patient Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*01*	Patient Segment
304-C4	Date of Birth	R	*19631105*	November 5, 1963
305-C5	Patient Gender Code	R	*2*	Female
310-CA	Patient First Name	Q	*Mary*	Patient first name
311-CB	Patient Last Name	R	*Smith*	Patient last name
322-CM	Patient Street Address	O	*123 Main St*	
323-CN	Patient City Address	O	*Anywhere*	
324-CO	Patient State/Province Address	O	*NY*	
325-CP	Patient ZIP/Postal Zone	O		
326-CQ	Patient Phone Number	O		
307-C7	Place of Service	Q	*01*	Pharmacy indicates location where service was provided

Claim Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*07*	Claim Segment
455-EM	Prescription/Service Reference Number Qualifier	M	*1*	Claim billing

402-D2	Prescription/Service Reference Number	M	*7654321*	
436-E1	Product/Service ID Qualifier	M	*03*	National Drug Code
407-D7	Product/Service ID	M	*99999099211*	COVID -19 Test Specimen Collection
442-E7	Quantity Dispensed	Q	*1*	1 (EA)
403-D3	Fill Number	Q	*0*	Original dispensing for RX#
405-D5	Days Supply	Q	*1*	1 Days supply
414-DE	Date Prescription Written	Q	*20200315*	March 15, 2020
419-DJ	Prescription Origin Code	Q	5	Pharmacy

DUR/PPS Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*08*	DUR/PPS Segment
473-7E	DUR/PPS Code Counter	R	*1*	1st DUR activity
440-E5	Professional Service Code	Q	*MA*	Medication Administration (Specimen collection)

Prescriber Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*03*	Prescriber Segment
466-EZ	Prescriber ID Qualifier	Q	*01*	NPI
411-DB	Prescriber ID	Q	*1234567890*	Pharmacist NPI (ID of clinician who ordered the test)

Pricing Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*11*	Pricing Segment
409-D9	Ingredient Cost Submitted	R	0a	$0.01
412-DC	Dispensing Fee Submitted	Q	*50{*	$5.00
438-E3	Incentive Amount Submitted	Q	250{	$25.00
426-DQ	Usual and Customary Charge	Q	260{	$26.00
430-DU	Gross Amount Due	R	*300a*	$30.01
423-DN	Basis of Cost Determination	Q	*01*	AWP

11.5.1.2 BILLING FOR A PRODUCT WITH AN ASSOCIATED COST AND PROFESSIONAL SERVICE CODE OF PT

In the following example, a pharmacy obtains product with a cost of $50.00, administers and performs the test and interprets the results. Submission of this code (PT) includes MA services provided in addition to interpreting the test results, informing the patient and reporting the test results to designated entities, when required. In this example, the test was ordered by another clinician (Prescriber segment is not shown). The test was administered and interpreted by the pharmacist at the point of care, so the Provider segment is submitted and includes the Pharmacist NPI in the Provider ID (444-E9) field with a Provider ID Qualifier (465-EY) of "5=NPI". Additionally, the pharmacy wants to report the positive testing results of the patient so the appropriate Diagnosis Code (424-D0) is submitted in the Clinical Segment (this is an optional field and is sent at the discretion of the pharmacy).

Any incentive fee to cover cost of services provided by the pharmacy is added in the Pricing Segment (438-E3).
Only pertinent segments are shown.

Transaction Header Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
101-A1	BIN Number	M	*610066*	
102-A2	Version/Release Number	M	*D0*	Transaction Format
103-A3	Transaction Code	M	*B1*	Claim Billing
104-A4	Processor Control Number	M	*1234567890*	
109-A9	Transaction Count	M	*1*	One occurrence
202-B2	Service Provider ID Qualifier	M	*01*	National Provider ID
201-B1	Service Provider ID	M	*1112223333*	
401-D1	Date of Service	M	*20200317*	March 17, 2020
110-AK	Software Vendor/Certification ID	M	*bbbbbbbbbb*	

Patient Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*01*	Patient Segment
304-C4	Date of Birth	R	*19631105*	November 5, 1963
305-C5	Patient Gender Code	R	*2*	Female
310-CA	Patient First Name	Q	*Mary*	Patient first name
311-CB	Patient Last Name	R	*Smith*	Patient last name
322-CM	Patient Street Address	O	*123 Main St*	
323-CN	Patient City Address	O	*Anywhere*	
324-CO	Patient State/Province Address	O	*NY*	
325-CP	Patient ZIP/Postal Zone	O	*12345*	
326-CQ	Patient Phone Number	O		
307-C7	Place of Service	Q	*60*	Mass Immunization Center indicates location where service was provided

Claim Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*07*	Claim Segment
455-EM	Prescription/Service Reference Number Qualifier	M	*1*	Claim billing
402-D2	Prescription/Service Reference Number	M	*7654321*	
436-E1	Product/Service ID Qualifier	M	*03*	NDC
407-D7	Product/Service ID	M	*11877001126*	ID NOW COVID-19 24 Test Kit
442-E7	Quantity Dispensed	Q	*1*	1 (EA)
403-D3	Fill Number	Q	*0*	Original dispensing for Rx#
405-D5	Days Supply	Q	*1*	1 Days supply
414-DE	Date Prescription Written	Q	*20200315*	March 15, 2020

DUR/PPS Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*08*	DUR/PPS Segment
473-7E	DUR/PPS Code Counter	R	*1*	1st DUR activity
440-E5	Professional Service Code	Q	*PT*	Perform Laboratory Test

Pricing Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*11*	Pricing Segment
409-D9	Ingredient Cost Submitted	R	500*{*	$50.00
412-DC	Dispensing Fee Submitted	Q	*50{*	$5.00
438-E3	Incentive Amount Submitted	Q	*500{*	$50.00 ($10 assessment and $40 for administration of test)
426-DQ	Usual and Customary Charge	Q	*1050{*	$105.00
430-DU	Gross Amount Due	R	1050*{*	$105.00
423-DN	Basis of Cost Determination	Q	*01*	AWP

Pharmacy Provider Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*02*	Pharmacy Provider Segment
465-EY	Provider ID Qualifier	Q	*05*	NPI
444-E9	Provider ID	Q	*01234567890*	NPI of Pharmacist who performed the test

Clinical Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*13*	Clinical Segment
491-VE	Diagnosis Code Count	Q	1	
492-WE	Diagnosis Code Qualifier	Q	*02*	ICD-10-CM
424-DO	Diagnosis Code	Q	*Z11.59*	COVID-19 (value Z11.59 - no known exposure to the virus and the test results are either unknown or negative)

11.6 *COVID-19 TEST QUANTITY DISPENSED*

Question: How do I determine the Quantity Dispensed (442-E7) value when billing a COVID-19 Test from a package containing multiple tests and supplies?

Answer: To facilitate the use of the B1 or B3 transaction, each individual patient test should be treated as a "kit". The Billing Unit (BU) will be an EACH (EA) for the individual test with the quantity of "1" each[18].

The COVID-19 Test have a UPC or UDI assigned to the product and are converted by the drug data compendia to the NCPDP 11-digit Product Service Identifier that should be used for claims adjudication.

Billing each individual test will depend on the product used. In the case of billing a single test from a kit that contains 24 test swabs and covers, the metric decimal billing quantity and BU will be 1/24th of the "case or package size" or a single kit = 1 swab and cover for each individual being tested. The metric decimal quantity = 1 with a BU of EA.

EXAMPLE: The Globally Unique Identifier (GUID) for ID NOW™ COVID-19 24 Test Kit is 10811877011269. When reformatted to an 11-digit NCPDP Product Service Identifier as per the Product Identification Standard, the resultant identifier is 11877-0011-26 and a Product Service Identifier Qualifier = 03 (NDC).

ID NOW™ COVID-19 carton with NDC 11877-0011-26 contains 24 Sample Receivers, 24 Transfer Cartridges, 24 Test Bases, 24 Patient Swabs and 24 Transfer Pipettes plus 2 Control Swabs. The "case size" is 24 and the billing unit for each individual patient test = 1 each.

NOTE: The actual metric decimal quantity will vary depending on product selection. NCPDP anticipates additional products will become available after publication of this guide which may include kits (1 swab and 1 cover) with individual testing capacity. Validate with your compendium the appropriate billing quantity of the specific test being dispensed/administered.

11.7 *CLAIM RESPONSE FOR EXAMPLE DIAGNOSTIC TEST CLAIM REQUEST*

Question: Which Reject Code(s) (511-FB) should be returned on the claim response when the diagnostic test (e.g., COVID-19) kit or professional services of specimen collection or interpretation or results/reporting are not covered under the pharmacy benefit?

Answer: The type of payer adjudicating the claim and the specific components of the pharmacy benefit will impact the use of the specific reject code(s) that should be returned when the submitted products and/or services are not covered. The below chart recommends the use of the following reject codes that are currently available.

Reject Code	Original Description	Business Case:
70	Product/Service Not Covered – Plan/Benefit Exclusion	• **Scenario:**

[18]This is an exception to the Billing Unit Standard to accommodate testing products granted Emergency Use Authorization and to facilitate the individual tests that will be administered when there is more than one test in the box and there are other materials such as laboratory devices and control swabs also included in the carton but used for multiple patients or tests.

		○ Submitted claim is for dispensing test product only AND DUR Professional Service Code does not equal MA or PT • **Result:** ○ COVID-19 test product is a pharmacy plan benefit exclusion
816	Pharmacy Benefit Exclusion, May Be Covered Under Patient's Medical Benefit	• **Scenario:** ○ Submitted claim is for dispensing of test product, specimen collection or interpretation of results/reporting and DUR Professional Service Code is MA or PT • **Result:** ○ COVID-19 test product, specimen collection and interpretation of results are a pharmacy benefit exclusion, however, may be covered under the medical benefit
817	Pharmacy Benefit Exclusion, Covered Under Patient's Medical Benefit	• **Scenario:** ○ Submitted claim is for dispensing of test product, specimen collection or interpretation of results/reporting AND DUR Professional Service Code is MA or PT • **Result:** ○ COVID-19 test product, specimen collection and interpretation of results are a pharmacy benefit exclusion and are known to be covered under the medical benefit
9C	Professional Service Code Value Not Supported	• **Scenario:** ○ Submitted claim is for dispensing of test product, specimen collection or interpretation of results/reporting and DUR Professional Service Code is MA or PT • **Result**

		○ COVID-19 test specimen collection and interpretation of results are a pharmacy benefit exclusion, other coverage not known
A6	This Product/Service May Be Covered Under Medicare Part B	• **Scenario:** ○ Submitted claim is for dispensing of test product, specimen collection or interpretation of results/reporting and DUR Professional Service Code is MA or PT • **Result:** ○ Patient is determined to be Medicare Part B eligible, mutually exclusive to plan benefit that was billed

11.8 *CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)*

Question: How does a pharmacy request a CLIA waiver in order to conduct applicable testing within the authorized settings?

Answer: Pharmacies can request a CLIA waiver by completing and submitting the CLIA Application for Certification form. The form is available at: cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf. The form is used for different types of labs, so the National Community Pharmacists Association (NCPA) has made a short video to show how a pharmacy would likely want to complete the form. The video link can be found near the top of the NCPA Coronavirus Information ncpa.org/coronavirus-information page.

The completed CLIA application should be forwarded to the address of the local state agency for the state in which your laboratory resides. Pharmacies should also check with their state authorities to ensure all necessary requirements are met. A list of state agencies can be found here: cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf.

Question: How does a payer know the pharmacy has obtained a CLIA waiver?

Answer: Payers who intend to validate that a pharmacy has received a CLIA waiver will need to confirm the existence of the waiver by either reviewing the CLIA file they receive or checking via the online database cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Laboratory_Demographic_Information.

More information is available at cdc.gov/clia.

The FDA has provided a resource page regarding COVID-19 tests: fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2.

11.9 *EXCHANGE CLINICAL INFORMATION*

Question: How do healthcare entities exchange patient clinical information regarding their diagnostic tests?

Answer: Health plans, pharmacies and other authorized healthcare providers may exchange information a number of different ways. The HL7 Pharmacist Care Plan FHIR® IG (v0.2.0: STU 1 Draft) based on FHIR® R4 may be used as guidance for the exchange of clinical information. In addition to this type of information exchange, pharmacies and pharmacists should refer to the CDC web site cdc.gov/ and state departments of health for information on requirements for reporting diagnostic test results.

11.10 *EMERGENCY USE PRODUCT SERVICE IDENTIFIER FOR COVID-19 TEST SPECIMEN COLLECTION*

Question: When the COVID-19 test specimen collection product does not have a product ID which should be submitted, what should be submitted as the Product/Service ID (407-D7) for a specimen collection claim represented with the Professional Service Code (440-E5) value of MA – Medication Administered (Specimen Collection)?

Answer: If there is no product identifier on the product being used to collect the specimen during a declared emergency, the Product/Service ID of 99999-0992-11 (COVID-19 Test Specimen Collection), with the Product/Service ID Qualifier (436-E1) of 03 – National Drug Code can be used.

Note: This identifier is only for COVID-19 Test Specimen Collection. To obtain an identifier for another emergency situation contact ncpdp@ncpdp.org.

NDC	99999-0992-11
Product Name	COVID-19 Test Specimen Collection
Rx or OTC	OTC
Package Size (ml, gm, each)	1 each
Manufacturer's Suggested Wholesale Price (SWP)	$0.01
1st Ship Date (New products)	6/19/20
Active Ingredients & Strengths	Does not apply
Labeler/Manufacturer Name	NCPDP Emergency Preparedness

11.11 *INCENTIVE FEE*

Question: Which pricing fields can be used when a payer is unable to support the Incentive Fee Submitted (438-E3) field for claims that include both a Product/Service ID (407-D7) and a Professional Service Code (440-E5) e.g., MA – Medication Administered (specimen collection)?

Answer: The submitted claim must balance the Gross Amount Due (430-DU) value to the sum of the components and at a minimum include the Ingredient Cost Submitted (409-D9) and Gross Amount Due required fields. The Gross Amount Due field is comprised of the Ingredient Cost Submitted, Dispensing Fee Submitted (412-DC), Incentive Amount Submitted (438-E3), Other Amounts Claimed Submitted (480-H9) and tax fields. If the payer cannot support any of the component fields to Gross Amount Due, the payer should ignore and must not reject these component fields and use the submitted Pricing Segment Fields such as Gross Amount Due and Usual and Customary Charge (426-DQ) for financial calculations as dictated by trading partner agreement.

Claim Billing Request:

Pricing Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*11*	Pricing Segment
409-D9	Ingredient Cost Submitted	R	*a*	$0.01
412-DC	Dispensing Fee Submitted	Q	*{*	$0.00
438-E3	Incentive Amount Submitted	Q	*260{*	$26.00
426-DQ	Usual and Customary Charge	Q	*250{*	$25.00
430-DU	Gross Amount Due	R	*260a*	$26.01
423-DN	Basis of Cost Determination	Q	01	AWP

Claim Billing Response:

In instances where the payer does not support all components of Gross Amount Due (430-DU), such as Incentive Fee Submitted (438-E3), the payer still must return a balanced response including Patient Pay Amount (505-F5) and Total Amount Paid (509-F9) along with applicable component pricing fields. Below is an example of how the payer may respond to the above request.

Note: Since Incentive Fee is not supported by the payer, Incentive Amount Paid (521-FL) is not included in the response.

Response Pricing Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*11*	Pricing Segment
505-F5	Patient Pay Amount	R	*{*	$0.00
506-F6	Ingredient Cost Paid	Q	*{*	$0.00
507-F7	Dispensing Fee Paid	Q	*250{*	$25.00
509-F9	Total Amount Paid	R	*250{*	$25.00
522-FM	Basis of Reimbursement Determination	Q	8	Contract Pricing

11.12 *TRANSPORTATION COSTS*

Question: Within a claim billing request for a specimen collection, which field(s) should be used to submit a transportation charge applicable to the transfer of the specimen collection from the pharmacy to the laboratory completing the diagnostic test?

Answer: The Other Amount Claimed Submitted (480-H9) field should be used with the value of (02) Shipping Cost in the Other Amount Claimed Submitted Qualifier (479-H8) field. The shipping cost is a component of the Gross Amount Due (430-DU) but is not included in the Usual and Customary Charge (426-DQ) as Usual and Customary is defined as 'Amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed.'

Pricing Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*11*	Pricing Segment
409-D9	Ingredient Cost Submitted	R	*0a*	$0.01
412-DC	Dispensing Fee Submitted	Q	*50{*	$5.00
438-E3	Incentive Amount Submitted	Q	*250{*	$25.00

478-H7	Other Amount Claimed Submitted Count	Q	*1*	1 occurrence
479-H8	Other Amount Claimed Submitted Qualifier	Q	*02*	Shipping Cost (transportation cost)
480-H9	Other Amount Claimed Submitted	Q	*50{*	$5.00
426-DQ	Usual and Customary Charge	Q	*300a*	$30.01
430-DU	Gross Amount Due	R	*350a*	$35.01
423-DN	Basis of Cost Determination	Q	*01*	AWP

11.13 *ADMINISTRATION OF MONOCLONAL ANTIBODY PRODUCT*

What minimum necessary information is needed in the claim request to standardize the NCPDP claim adjudication process for COVID-19 monoclonal antibody product administration claims?

Billing for Reimbursement of REGEN-COV co-formulated product and REGEN-COV (casirivimab and imdevimab) to be administered subcutaneously with No Associated Drug Cost With an Administration Fee

- The submitted Transaction Code (103-A3) is a "B1" (Claim Billing).
- The submitted Prescription/Service Reference Number Qualifier (455-EM) is a "1" (Rx Billing).
- The claim pricing segment follows the prescription claim request formula.
- The Product/Service ID Qualifier (436-E1) and the Product/Service ID (407-D7) should be submitted with the value of the dispensed product (in this example "03" (NDC) and the NDC of the product).
- The Days Supply (405-D5) should be submitted with appropriate value.
- The Quantity Dispensed (442-E7) should be submitted with the value that represents the quantity of product dispensed.
- The Incentive Fee Amount Submitted (438-E3) is submitted when there are professional service charges associated with any unique dispensing requirements with the applicable Professional Service Code (440-E5).
- Basis of Cost Determination (423-DN) should be submitted with the value "15" (Free product at no associated cost).
- In situations where a different incentive fee is offered based on the service location, the Place of Service (307-C7) field maybe required.

Only pertinent segments are shown.

Transaction Header Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
101-A1	BIN Number	M	*610066*	
102-A2	Version/Release Number	M	*D0*	Transaction Format
103-A3	Transaction Code	M	*B1*	Claim Billing
104-A4	Processor Control Number	M	0123456789	
109-A9	Transaction Count	M	*1*	One occurrence
202-B2	Service Provider ID Qualifier	M	*01*	National Provider ID
201-B1	Service Provider ID	M	*4563663111bbbbb*	
401-D1	Date of Service	M	*20210908*	September 8, 2021
110-AK	Software Vendor/Certification ID	M	*bbbbbbbbbb*	

Claim Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*07*	Claim Segment
455-EM	Prescription/Service Reference Number Qualifier	M	*1*	Claim billing
402-D2	Prescription/Service Reference Number	M	*7654321*	
436-E1	Product/Service ID Qualifier	M	*03*	NDC
407-D7	Product/Service ID	M	*61755003901*	REGEN-COV

442-E7	Quantity Dispensed	Q	*10000*	10.0 (mL)
403-D3	Fill Number	Q	*0*	Original dispensing for RX#
405-D5	Days Supply	Q	*1*	1 Days supply
414-DE	Date Prescription Written	Q	*20210908*	September 8, 2021

DUR/PPS Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*08*	DUR/PPS Segment
473-7E	DUR/PPS Code Counter	R	*1*	1st DUR activity
440-E5	Professional Service Code	Q	*MA*	Medication Administration

Pricing Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*11*	Pricing Segment
409-D9	Ingredient Cost Submitted	R	0{	$0.00
412-DC	Dispensing Fee Submitted	Q	*0{*	$0.00
438-E3	Incentive Amount Submitted	Q	4500{	$450.00
426-DQ	Usual and Customary Charge	Q	50{	$5.00
430-DU	Gross Amount Due	R	4500{	$450.00
423-DN	Basis of Cost Determination	Q	*15*	Free product or no associated cost

Patient Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*01*	Patient Segment
307-C7	Place of Service	Q	*32*	Nursing Facility

11.14 *BILLING OF OTC PRODUCTS DURING AN EMERGENCY*

Question: When an OTC product, such as COVID 19 Home Test and Collection Kits, has been deemed as covered during an emergency, what NPI should be included in the Prescriber ID field for submission on a claim?

Answer: If the emergency order specifies the OTC product requires a prescription order:

The Prescriber ID (411-DB) value would represent the Type 1 NPI of the clinician with the applicable prescriptive authority. Based on federal and state regulations during the state of emergency, pharmacist prescriptive authority may apply to OTC prescriptions. Existing NCPDP guidance indicates that for prescriptions initiated by a pharmacy, the pharmacist's Type 1 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 SCC value of 42 (Prescriber ID Submitted is valid and prescribing requirements have been validated) may be used by payers to override prescriber NPI validation and prescriber enrollment rules.

Refer to existing NCPDP guidance under section OVERRIDING STANDARD CLAIMS PROCESSING RULES and USE CASES REQUIRING ADDITIONAL DATA of the Emergency Preparedness document, as well as section "6.15 EMERGENCY FILL" of the NCPDP TELECOMMUNICATION STANDARD VERSION D (Telecommunication Standard) AND ABOVE QUESTIONS, ANSWERS AND EDITORIAL UPDATES.

If the emergency order specifies the OTC product does not require a prescription, the Prescriber ID (411-DB) field is not required.

In the situation when the plan benefit or emergency order covers a product without a prescription, neither a Prescriber ID nor Prescriber ID Qualifier should be sent. If the processor requires the submission of a

Prescriber ID due to editing rules, use Qualifier ID value "14" – Plan Specific with the plan defined value. NCPDP recommends as a best practice a single value of zero (0) in the Prescriber ID field for this situation. Alternatively, based upon trading agreement, the Pharmacy NPI (Type 2) and the Qualifier of "01" may be submitted as the Prescriber ID. Since a prescription is not required, prescriber enrollment validation should not apply to any prescriber ID value that may be submitted.

Refer to existing NCPDP guidance section 3.8 PRESCRIBER SEGMENT of the NCPDP TELECOMMUNICATION STANDARD VERSION D (Telecommunication Standard) AND ABOVE QUESTIONS, ANSWERS AND EDITORIAL UPDATES.

Question: When an OTC product, such as COVID 19 Home Test and Collection Kits, has been deemed as covered, what fee(s) should be included in the claim?

Answer: The following fees should be included in the claim when an OTC product has been deemed as covered:

- The Dispensing Fee Submitted (412-DC) is submitted when the pharmacy is seeking reimbursement for the agreed upon dispensing fee.
- The Incentive Amount Submitted (438-E3) is submitted when:
    - There are professional service charges associated with any unique dispensing requirements (e.g., free product) with the applicable Professional Service Code (440-E5) value, or
    - There are charges associated with the professional service of test administration with the applicable Professional Service Code (440-E5) value.
    - See Billing of a Self-Administered Free Product During an Emergency for additional details.

Question: When an OTC product, such as COVID 19 Home Test and Collection Kits, has been deemed as covered, what product identifier should be included in the claim?

Answer: For the purposes of claims submission during a State of Emergency for an OTC product such as a COVID home test kit or collection kit, the appropriate product service identifier must be submitted.

These products should have a recognizable industry identifier assigned prior to distribution, such as an UPC, GTIN or UDI. Products without a valid NCPDP-recognized identifier will not process in pharmacy systems.

For further information on proper formatting of these Identifiers, see NCPDP Product Identifiers Standard Version 1.5.

11.15 *BILLING OF A SELF-ADMINISTERED FREE PRODUCT DURING AN EMERGENCY*

Claims for products that incur no product cost may be submitted to the patient's prescription benefit plan. The claim request would use the standard fields with applicable pricing and professional service identifiers to support the unique dispensing needs. The following claims processing guidance should be used to support rapid adoption of Federal emergency authorizations of self-administered free products and associated policies.

- The submitted Transaction Code (103-A3) is "B1" (Claim Billing).
- The submitted Prescription/Service Reference Number Qualifier (455-EM) is "1" (Rx Billing).
- The claim pricing segment follows the prescription claim request formula.
- The Product/Service ID Qualifier (436-E1) and the Product/Service ID (407-D7) should be submitted with the value of the dispensed product (in this example "03" (NDC) and the NDC of the product).

- The Days Supply (405-D5) should represent the number of days the dispensed quantity will last based on the prescribed dose.
- The Quantity Dispensed (442-E7) should be submitted with the value that represents the quantity of product dispensed.
- Professional Service Code (440-E5) value of "AS" - Patient Assessment should be submitted to identify the professional services associated with the unique dispensing requirements. If payers cannot immediately support "AS", NCPDP recommends an interim solution where the value of "MA" is accepted. This would allow payers to trigger existing incentive fee logic. Payers should notify their pharmacy networks as to these temporary claims processing requirements and when their systems will be able to support the value of "AS" in the Professional Service Code (440-E5).
- The Ingredient Cost Submitted (409-D9) for the free product should be submitted as $0.00.
    - NOTE: Some systems may not be able to successfully exchange the value of $0.00 as an Ingredient Cost Submitted (409-D9) 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.
- Basis of Cost Determination (423-DN) should be submitted with the value "15" (Free product at no associated cost).
- The Dispensing Fee Submitted (412-DC) is submitted when the pharmacy is seeking reimbursement for the agreed upon dispensing fee of the free product.
- The Incentive Amount Submitted (438-E3) is submitted when there are professional service charges associated with the unique dispensing requirements.
- The Gross Amount Due (430-DU) field is required and represents the sum of the component fields.
- Payer response should follow the NCPDP prescription pricing formula, including the corresponding response pricing fields to the submitted fields, (e.g., Ingredient Cost Paid (506-F6), Dispensing Fee Paid (507-F7), Incentive Amount Paid (521-FL)).

Only pertinent segments are shown.

Transaction Header Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
101-A1	BIN Number	M	*610066*	
102-A2	Version/Release Number	M	*D0*	Transaction Format
103-A3	Transaction Code	M	*B1*	Claim Billing
104-A4	Processor Control Number	M	*1234567890*	
109-A9	Transaction Count	M	*1*	One occurrence
202-B2	Service Provider ID Qualifier	M	*01*	National Provider ID
201-B1	Service Provider ID	M	*4563663111bbbbb*	
401-D1	Date of Service	M	*20211212*	December 12, 2021
110-AK	Software Vendor/Certification ID	M	*bbbbbbbbbb*	

Claim Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*07*	Claim Segment
455-EM	Prescription/Service Reference Number Qualifier	M	*1*	Claim billing

402-D2	Prescription/Service Reference Number	M	*7654321*	
436-E1	Product/Service ID Qualifier	M	*03*	NDC
407-D7	Product/Service ID	M	*12345678901*	self-administered free product
442-E7	Quantity Dispensed	Q	*10000*	10
403-D3	Fill Number	Q	*0*	Original dispensing for RX#
405-D5	Days Supply	Q	*5*	5 Days supply
414-DE	Date Prescription Written	Q	*20211212*	December 12, 2021

DUR/PPS Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*08*	DUR/PPS Segment
473-7E	DUR/PPS Code Counter	R	*1*	1st DUR activity
440-E5	Professional Service Code	Q	*AS*	Patient Assessment

Pricing Segment				
Field	**Field Name**	**Cat**	**Value**	**Comments**
111-AM	Segment Identification	M	*11*	Pricing Segment
409-D9	Ingredient Cost Submitted	R	*0{*	$0.00
412-DC	Dispensing Fee Submitted	Q	*150{*	$15.00
438-E3	Incentive Amount Submitted	Q	*200{*	$20.00
426-DQ	Usual and Customary Charge	Q	*350{*	$35.00
430-DU	Gross Amount Due	R	*350{*	$35.00
423-DN	Basis of Cost Determination	Q	*15*	Free product or no associated cost

NOTE: Recommendation when covered by Medicare Part D – Incentive payments made to pharmacies for dispensing activities associated with ensuring possession of the appropriate covered Part D drug is transferred to a Part D enrollee, such as the dispensing of generic drugs, are part of the dispensing fee component of gross covered prescription drug cost. Plans will need to aggregate any amounts paid (incentive fee and/or dispensing fee) and report them as dispensing fees for the purposes of Prescription Drug Event (PDE) reporting.

11.16 *NEW NDCS FOR COMMERCIAL COVID-19 VACCINE PRODUCTS*

Question: Will a new NDC be required for COVID-19 vaccines or products as they become available for purchase after the EUA expires?

Answer: Once FDA approved COVID-19 vaccines or products 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.

12. TASK GROUP COMMUNICATION PLAN

12.1 *REVIEW OF DOCUMENT*

Unless there are exceptions as defined in Declared Emergency: Publication Exception to Annual Review below, this document will be reviewed and updated by the MC Emergency Preparedness Task Group no less often than annually based on the following timeline:

1. Reconvene MC Emergency Preparedness Task Group after February Work Group meetings.
2. MC Emergency Preparedness Task Group will review this document for accuracy and modify as necessary.
3. Reviewed document will be presented for approval at May Work Group meetings.

12.2 *UPON APPROVAL AT MAY WORK GROUP*

Once the document has been approved at the May Work Group meeting:

1. The document will be reviewed and approved by the Standardization Co-Chairs.
2. NCPDP will redistribute the updated document to all stakeholders (Refer to Appendix A).
3. The updated document will be uploaded to the NCPDP website ncpdp.org.

12.3 *DECLARED EMERGENCY: PUBLICATION EXCEPTION TO ANNUAL REVIEW*

In the case of a recently declared emergency, the Task Group leaders may meet to discuss the relevance of the most recent document to the declared emergency and determine whether modification is necessary.

If modifications are necessary, the Task Group will begin meeting to determine what information contained in this document needs updating and what information relevant to the specific situation should be added. The Task Group will meet in accordance with the urgency of the situation to update the document for industry. The document will be reviewed and approved by the Standardization Co-Chairs and NCPDP will publish and post the document as detailed in Upon Approval At May Work Group. After publication, the document will be presented at the next Quarterly Work Group meeting as an emergency revision and publication of the document.

To assure critical information is kept current and accurate for the duration of the declared emergency, the Task Group will maintain the currency of the document by continuing to meet and update the document for the duration of the declared emergency. Updates will be approved and published in accordance with Upon Approval At May Work Group but not less often than quarterly. The most recent document update will be presented at the next Quarterly Work Group meeting as an emergency revision(s) and publication(s) of the document.

APPENDIX A – STAKEHOLDERS

AHIP
America's Health Insurance Plans
601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, DC 20004
Phone: 202-778-3200
Contact: Kate Berry, Senior Vice President Clinical Affairs and Strategic Partnerships
Phone: 202-778-3229
Email: kberry@ahip.org
Web: ahip.org

AMA
American Medical Association
AMA Plaza
330 N. Wabash Avenue, Suite 39300
Chicago, IL 60611-5885
Phone: 800-621-8335
Email: tyler.scheid@ama-assn.org
Web: ama-assn.org/ama

AMCP
Academy of Managed Care Pharmacy
675 North Washington Street, Suite 220
Alexandria, VA 22314
Phone: 703-684-8600
Fax: 703-684-2651
Email: mdonahue@amcp.org
Web: amcp.org

APhA
American Pharmacists Association
2215 Constitution Avenue NW
Washington, DC 20037
Contact: Karin Bolte, JD, Director, Health Policy
Phone: 800-237-2742
Fax: 202-783-2351
Email: infocenter@aphanet.org
Email: kbolte@aphanet.org
Web: pharmacist.com

ASCP
The American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, VA 22314
Contact: Arnold E. Clayman, PD, FASCP, VP of Pharmacy Practice & Government Affairs
Phone: 703-739-1316
Email: aclayman@ascp.com
Web: ascp.com

ASHP
American Society of Health-System Pharmacists
4500 East-West Highway, Suite 900
Bethesda, MD 20814
Phone: 866-279-0681
Email: custserv@ashp.org
Web: ashp.org

ASPR
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response
200 Independence Avenue, S.W.
Washington, DC 20201

- Division of Critical Infrastructure Protection (CIP)- government lead for the Healthcare and Public Health Sector
  Email: cip@hhs.gov
- Strategic National Stockpile
  Contact: Ron Ottem - Chief, Strategic Logistics Branch
  Phone: 404-639-2576
  Email: rco9@cdc.gov

Web: phe.gov

Change Healthcare
Change Healthcare Corporation
3055 Lebanon Pike
Nashville, TN 37214
Phone: 615-932-3000
Email: Jason.grantham@changehealthcare.com
Web: changehealthcare.com

ESI
Express Scripts, Inc.
1 Express Way
St. Louis, MO 63121
Contact: Laurie A. Littlecreek
Phone: 800-282-2881
Email: LALittlecreek@express-scripts.com
Web: Express-Scripts.com

Healthcare Ready
Healthcare Ready
1325 G Street NW, Suite 500
Washington, DC 20004
Phone: 866-247-2694
Email: alerts@healthcareready.org
Web: healthcareready.org

NABP
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

Phone: 847-391-4406
Fax: 847-375-1114
Email: ExecOffice@nabp.pharmacy
Email: help@nabp.pharmacy
Web: nabp.pharmacy

NACDS
National Association of Chain Drug Stores
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
Phone: 703-549-3001
Fax: 703-836-4869
Email: contactus@nacds.org
Web: nacds.org

NAMD
National Association of Medicaid Directors - State Medicaid Directors
444 North Capitol Street, Suite 524
Washington, DC 20001
Contact: Matt Salo, Executive Director
Phone: 202-403-8620
Email: matt.salo@medicaiddirectors.org
Email: tess.moore@medicaiddirectors.org
Web: medicaiddirectors.org

NCPA
National Community Pharmacists Association
100 Daingerfield Road
Alexandria, VA 22314
Phone: 703-683-8200
Voice: 800-544-7447
Fax: 703-683-3619
Email: lschwartz@ncpanet.org
Web: ncpanet.org

NGA
National Governors Association
Hall of the States
444 North Capitol Street, Suite 267
Washington, DC 20001-1512
Phone: 202-624-5300
Fax: 202-624-5313
Web: nga.org

PCMA
The Pharmaceutical Care Management Association
325 7th Street, NW, Suite 900
Washington, DC 20004
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Fax: 202-756-5708
Email: kbass@pcmanet.org
Web: pcmanet.org

RelayHealth
Relay-Health
1564 Northeast Expressway
Atlanta, GA 30329-2010
Phone: 888-743-8735
Contact: Amy Valli, Manager, Public Relations
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Email: Catherine.romanick@relayhealth.com
Web: relayhealth.com

Surescripts
Surescripts
2550 South Clark Street
Arlington, VA 22202
Phone: 703-921-2121
Fax: 703-921-2191
Web: Surescripts.com

APPENDIX B – HISTORY OF DOCUMENT CHANGES

VERSION 1.1

Section *NCPDP Emergency Preparedness Payer Sheet for the Emergency Prescription Assistance Program (EPAP) Payer* has been updated to include the possibility of using a "Red Cross ID". This section has been updated to change from the Patient's Social Security Number to the Patient's "Red Cross ID".

Section *Eligibility Information* has been added.

VERSION 1.2

Information on Healthcare Ready has been added.
Reporting functionality to NCPDP has been modified.
Modifications to notification of closed pharmacies have been made with the incorporation of Healthcare Ready processes.
Emergency Prescription Assistance Program (EPAP) information has been updated.

VERSION 1.3

EPAP information has been updated to change from CMS references to the Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR).

References to ICERx have been removed as this program is no longer operating.

VERSION 1.4

For Version 1.4 there were many updates and additions to the document such as:

1. Updated general grammar, fonts and font size and spacing throughout the document
2. Updated Hyperlinks throughout the document
3. Update all references of RxResponse to Rx Open Links
4. Updated Copyright details
5. Added Section 2 – What Triggers an Emergency Response
6. Added 3.1.2 – Ongoing item 4
7. Added Section 3.1.3 – Pharmacists Prescribing and 3.1.4 – ePrescribing Renewal Request
8. Update Section 3.2.1 – During Emergency To Reference Rx Open
9. Added Section 3.3 Prescribers
10. Modified Section 3.4 – Switch/Clearinghouse Reporting of Healthcare Ready
11. Modified Pharmacy Status Reporting to Section 3.4.1 – Rx Open
12. Modified Section 3.5 – Concepts of Operations – Automated Pharmacy States Reporting, added item 4 – How To Use Rx Open
13. Updated Section 3.7 – Report Impact Of Disaster Impacted Locations to NCPDP Pharmacy Database Processes
14. Modified Section 4 – Medication History Information
15. Combined Section 2 – What Do I Need To Do and Section 3 – Pharmacy Status Reporting into Section 3 – What Do I Need To Do
16. Removed Section 4.2 – Portal
17. Modified Section 5 – Eligibility Verification for Billing/Payment

18. Added Section 7.1 – EPAP Activation Procedure
19. Update Section 3.1.1 – During Emergency To Reference Rx Open
20. Modified Section 8.1 – NCPDP Emergency Preparedness Payer Sheet For Patient's Current Payer
21. Modified Section 9.1 – RxResponse to 9.1 – HealthcareReady
22. Clarifications to Section 10.1 – The Partnership For Prescription Assistance (PPA)
23. Added Section 11 Task Group Communication Plan
24. Added Section 13 – Appendix B Stakeholders

VERSION 1.5

For Version 1.5 there were many updates and additions to the document:

1. Initial page
    a) Updated NCPDP Logo.
    b) Updated the description to add "or Pandemic/Epidemic".
2. Introduction page
    a) Modified the first three paragraphs into one.
    b) Changed disaster to emergency throughout the remaining introduction.
3. Section 2.2 – Added item 2.
4. Section 3.1.1 – Added items 1 – 3.
5. Section 3.1.3 – Modified the paragraph to include "as well as controlled substances".
6. Section 3.1.4 – Modified the first sentence, reorganized the words to read better.
7. Section 7 – Added "After a request from the Governor of an affected State" at the beginning of the first paragraph.
8. Section 7.1 – Added "once the Secretary for Emergency Preparedness activates" to item 1.
9. Section 8 – Modified the following:
    a) Removed "Emergency" from the title of the section
    b) Removed "emergency" from the section description
    c) Added 3. NCPDP Pandemic/Epidemic Payer Sheet for Patient's Current Payer link
10. Section 8.1 – Modified the following:
    a) Modified "prior authorization numbers" to "submission clarification code" in the second paragraph
    b) Added link to Patient Segment
    c) Added link to Prescriber Segment
    d) Modified "reject overrides during emergency/disaster requesting additional fills" to "override various rejections such as "refill too soon" during emergency/disaster situations" in the last paragraph
11. Section 8.2 – Modified the following:
    a) Added link to Patient Segment
    b) Added link to Prescriber Segment
12. Section 8.3 – Added
13. Section 8.4 – Modified the following:
    a) Added section number 8.4 to the "NCPDP Emergency Preparedness Payer Sheet for Patient's Current Payer"
    b) Updated the Revision Date
    c) Modified Field 461-EU changed Payer Usage from Null to "N"
    d) Modified Field 462-EU changed Payer Usage from Null to "N"
    e) Updated the legend to match NCPDP Telecommunication Standard Implementation Guide Version D.0
    f) Updated/inserted the values in the Payer Usage column to match NCPDP Telecommunication Standard Implementation Guide Version D.0
14. Section 8.5 – Modified the following:

a) Added section number 8.5 to the "NCPDP Emergency Preparedness Payer Sheet for the Emergency Prescription Assistance Program (EPAP) Payer"
b) Updated the Revision Date
c) Updated the legend to match NCPDP Telecommunication Standard Implementation Guide Version D.0
d) Updated/inserted the values in the Payer Usage column to match Telecommunication Implementation Guide v D.0

15. Section 8.6 – Added
16. Section 9 – Added email contact of alerts@healthcareready.org to the last paragraph.
17. Removed prior Section 10 and incorporated it under section 9.
    a) Section 10.1 becomes 9.2
18. Appendix B Section 12.1 Stakeholders – Added/modified the following:
    a) With the changes in in 17 above, this section is changed from 13.1 to 12.1
    b) Added the following new stakeholders:
        (1) AHIP
        (2) APhA
        (3) ASCP
        (4) EPAP Processor
        (5) ESI
    b) Modified the following stakeholders:
        (1) Updated AMA to include their Suite
        (2) Updated AMDIS to reflect name on their website.
        (3) Updated ASHP to include their website.
        (4) Updated ASPR to include their website.
        (5) Updated NAMD to include their address; updated their phone number and added an additional contact email.
        (6) Updated PCMA to include their Suite number.

VERSION 1.6

For Version 1.6 there were many updates and additions to the document:

1. Appendix A History of document changes switched with Appendix B Stakeholders. All links pointing to Appendix B Stakeholders have been updated to point to new Appendix A Stakeholders.
2. Made updates to contacts in Appendix A Stakeholders.
3. Section 2.1.3 added the following text to the end of the section "For additional state specific information please visit the State Governors Office".
4. All references to "Prescription Medication Preparedness Initiative programs" have been removed.
5. Section 4.4.1 Rx Open – added the following text to the end of the section "Healthcare Ready also sends out email notifications when Rx Open is being turned on. Sign up to receive email notifications at healthcareready.org/contact-us."
6. Section 4.5 title changed to "Pharmacy Status Reporting"
    a) Created Section 4.5.1 Automated Pharmacy Status Reporting, previously part of section 4.5
        i) Under How to Use Rx Open – Added references to Country Pharmacy Map.
        ii) Under How to Use Rx Open – Added new sub section 'e' – The County Pharmacy Map displays the percent of pharmacies open by county and includes four thresholds.
    b) Moved Section 4.6 Reporting Additional information on Pharmacy status under section 4.5, as new section 4.5.2
        i) Added "or email alerts@healthcareready.org"
    c) Moved Section 4.7 Reporting of Impacted Locations to NCPDP Pharmacy Database Process under section 4.5 as new section 4.5.3

   i) Updated title to "Reporting of impacted locations to NCPDP Pharmacy Database Processes", previously "Report of Declared Emergency on Impacted locations to NCPDP Pharmacy Database Processes".
7. Section 8.2 removed (National Stockpiled product is not used) from the initial sentence.
8. Section 8.3 added "and used when submitting claims using National stockpiled products as authorized to be distributed by the CDC" at the end of the first sentence.
9. Section 9 renamed Obtaining Medication in a Declared Emergency Through Manufacturer Programs.
10. Section 9.1 Role of Healthcare Ready moved to Section 3.3. All links in the document pointing to Healthcare Ready were updated to the new location.
11. Appendix A –
    a) Modified title to include Stakeholders
    b) Removed the numbered list of Stakeholders
    c) Modified several contact information.
    d) Added contact for ASPR for National Stockpile – Need to review annually. The contact person can change every time there's a change in Administration or HHS Secretary.

VERSION 1.7

Updates and additions to the document:

1. Made clerical updates (minor word changes and punctuation) throughout the document to read better.
2. Section 1 Introduction –
    a) added "weather related events" along with examples and several clarifications in the first two paragraphs.
    b) Paragraph 1, third sentence – added "assisting patients in accessing their medications during declared emergencies, such as but not limited to claims processing."
    c) Paragraph 3 – Example created bullet point and additional clarifications.
3. Section 3.1 State & Local –
    a) Added footnotes for websites.
    b) Updated links throughout the section.
    c) Added description for RxOpen
4. Section 3.2 Federal –
    a) Broke item 1 into 3 items.
    b) Changed 'Local declared emergencies' to 'Local authorities'.
    c) Moved 'upon request by the Governor of impacted states' within the sentence.
    d) Changed 'after receiving a state request' to 'after receiving a request from a state, local, tribal or territorial, entity'
    e) Modified Strategic National Stockpile as SNS.
    f) Removed Note: REMOVED AFTER A DISASTER IS DECLARED. From the end of the section.
    g) Added footnotes for websites.
5. Section 3.3 Healthcare Ready –
    a) Added footnotes for websites.
    b) Minor clarifications throughout the section.
    c) Updated link for Partner Playbook and added footnote.
    d) Moved Rx Open from old section 4.4
        i) Moved How to Use RxOpen from section 4.5.
            (1) Added sub bullet #3
        ii) Moved Benefits of RxOpen from section 4.5.
        iii) Added
6. Section 4.1 Pharmacies/Authorized Representative of Pharmacies – Total rewrite. Reorganized the entire section, added multiple steps and clarifications throughout the section.

7. Section 4.2 Payers –
    a) Added 4.2.1 Preparation Steps.
    b) Removed Ongoing section.
    c) Total rewrite of the section.
8. Section 4.3 Prescribers –
    a) Added 4.3.1 Preparation Steps.
    b) Removed Ongoing section.
    c) Total rewrite of the section.
9. Section 4.4 Intermediaries –
    a) Changed name from Intermediaries Reporting to Healthcare Ready
    b) RxOpen moved to section 3.3.1
    c) Reorganization and clarification of the entire section performed.
10. Section 4.5 Pharmacy Status Reporting –
    a) Moved How to use RxOpen and Benefits of RxOpen to section 3.3.1 RxOpen
11. Section 4.5.1 Automated Pharmacy Status Reporting
    a) 4.e – Added:
        i) greater than 90% of facilities open
        ii) 75% to 90% of facilities open
        iii) 50% to 74% of facilities open
        iv) less than 50% of facilities open
12. Section 5.1 Connectivity –
    a) Second sentence: May changed to should in the following “the data should be delivered”.
    b) Forth sentence: added “, or network infrastructure has been impacted” to the end of the sentence.
    c) Additional clarification.
13. Section 5.2 Authentication –
    a) Third sentence: added “, or network infrastructure has been impacted” to the end of the sentence.
14. Section 6 Emergency Preparedness Prescription Claims Processing Guidance –
    a) Total rewrite of this section.
    b) Added section 6.1 Billing for Reimbursement of a Free Product (No Associated Cost) Including an Administration Fee.
    c) Added section 6.2 Billing for Reimbursement of a Free Product (No Associated Cost) with no Administration Fee.
15. Section 7 Emergency Prescription Assistance Program (EPAP) – Removed the last paragraph.
16. Section 7.1 EPAP Activation Procedure – Added clarifications throughout and added item #7.
17. Section 7.2 EPAP Eligibility – New Section
18. Section 7.4 Updated NCPDP Emergency Prescriptions Assistance Program (EPAP) Payer Sheet - Updated the entire payer sheet using section 8.2.
19. Removed old Section 8 Payer Sheet Templates
20. Merged old Section 8.1 NCPDP Declared Emergency Payer Sheet for Patient’s Current Payer into section 6
21. Changed ‘National Stockpile’ to SNS throughout the document.
22. Old Section 8.2 becomes Section 7.4 –
    a) Removed paragraph 3 and 5 to 8.
23. Removed old Section 8.3 NCPDP Pandemic/Epidemic Payer Sheet for Patient’s Current Payer
24. Removed old Section8.4 payer sheet
25. Removed old Section 8.6 NCPDP Pandemic/Epidemic Payer Sheet for Patient’s Current Payer
26. Add the following new sections:
    a) Section 9 COVID-19 Testing Considerations
    b) Section 10 Frequently Asked Questions section
27. Modified Section 11 Task Group Communication Plan

a) Changed title of 11.1 from Review Document on an Annual Basis to Review Of Document
b) Added new section 11.3 Declared Emergency: Publication Exception to Annual Review.
c) Modified section 11.1 to add in language regarding exceptions based on 11.3.

28. Modified Appendix A Stakeholders
    a) Contact updates:
        i) AMCP - mdonahue@amcp.org
        ii) APhA – Michael Baxter mbaxter@aphanet.org
        iii) NGA – need contact
        iv) Relay Health - Stacy Hopkins (Stacy.Hopkins@Relayhealth.com)
    b) Removed the following from Surescripts: "Learn more about Surescripts at surescripts.com/action-plans-disaster-response/"
    c) Removed hyperlinks for contact emails in this section and throughout the document.

VERSION 1.8

Updates and additions to the document:

1. Throughout the document:
    a) Changed title from NCPDP Emergency Preparedness Information to NCPDP Emergency Preparedness Guidance.
    b) Updated "medication" to "product" where applicable.
    c) Updated all references to Local, State and Federal to be in that specific order.
    d) Added footnotes throughout to reference various websites.
    e) Updated Healthcare Ready contact from contactus@healthcareready.org to alerts@healthcareready.org per Healthcare Ready.
    f) Updated "disaster" to "declared emergency" where applicable.
    g) Updated all references to sections within the document to reflect the name of the section as opposed to the section number because the numbers were changing so frequently.
    h) Listed the full name of the SCRIPT and Telecommunication standard and referenced the name SCRIPT or Telecommunication in the remaining spots in the document.
    i) Update "COVID-19 testing" to "diagnostic testing" where appropriate. And added "Such as COVID-19" where appropriate.
    j) Update "NCPDP 11-digit NDC" to "NCPDP 11-digit Product Service Identifier"
    k) Update all field names to the following format "Field Name (XXX-XX) field"
2. Section 1 – Introduction:
    a) Added "and services provided by pharmacies" and removed "such as but not limited to eligibility and claims processing" from the 3rd sentence.
    b) Second bullet removed "plan" before "declared emergency plan billing rules" as redundant.
3. Section 2.1 removed "Local and State" from the title
4. Section 2.1.1:
    a) Changed "all states" to "all jurisdictions"
    b) Changed "unavailable in non-emergencies" to "idle under normal conditions"
5. Section 2.1.2:
    a) Removed 'State' from the title.
    b) Address the various jurisdictions to make it more universal.
6. Section 2.1.3:
    a) Removed 'State' from the title.
    b) Made clarifications throughout the paragraph.

c) Address the various jurisdictions to make it more universal.

7. Section 2.3:
   a) Removed “Local, State and Federal” from the title.
   b) Modified the last sentence to reflect “When conflicting or overlapping declarations exist, the most restrictive takes precedence”.
8. Section 3.1 State and Local:
   a) Modified item 1 for clearer understanding.
   b) Removed .org from RxOpen here and throughout the document.
   c) Item 2 added “or local authority” after “As each state…”.
9. Section 3.3 Healthcare Ready - made minor updates so the section so it reads better.
10. Section 3.3.1 Rx Open:
    a) Added “and dialysis centers” to the end of the first paragraph.
    b) Added “, and/or if a hazard is expected to occur that will impact regional healthcare delivery. Healthcare Ready activates the” to the end of the first sentence and beginning of the second sentence in the 2nd paragraph.
    c) Several updates were made to the “How to use Rx Open” for clarification, based on feedback from Healthcare Ready.
11. Section 4 changed “Responsibility” to “Areas of Consideration” in the title.
12. Section 4.1.1 Preparation Steps
    a) Several modifications were made to this section
       i) Rearranged some steps
       ii) Added new steps
       iii) Clarifications made throughout.
13. Section 4.1.2 During Declared Emergency
    a) Made several capitalization corrections.
14. Section 4.3.2 During Declared Emergency
    a) Changed “State specific guidelines” to “applicable regulations”.
15. Section 4.3.3 ePrescribing Renewal Requests
    a) Combined the two paragraphs and added “This request should include an” to the beginning of the third sentence.
16. Section 4.4 Intermediaries
    a) Move the last two sentences to Section 4.1.1 Preparation Steps.
17. Section 4.5.1 Automated Pharmacy Status Reporting
    a) Added “or if Healthcare Ready anticipates a hazard that will have region-level impacts” to the end of item 1.
    b) Item 3 replaced the specific time references with “twice daily” for reports.
    c) In the last paragraph, changed “counties” to “states” and added “or have otherwise been determined to be threatened by a major hazard” at the end of the first sentence.
18. Section 4.6 – Item 2, changed “evacuees” to “patients”.
19. Section 5 Added “(Product)” after Medication in the title.
20. Section 5.3 Additional Lives - changed “evacuees” to “patients” at the end of the paragraph.
21. Section 6 –
    a) Modified bullet points,
       i) rearranged items

ii) moved early refills under “Utilization management edit exceptions” and added “Prior Authorization overrides” and “Coverage for non-formulary therapeutic substitutions”.

22. Section 6.2 Billing for Free Product
    a) Added “specimen collection” to the end of the first sentence.
    b) Added the Note section in place of the second paragraph.
23. Section 6.2.1 added field numbers after the field names in the fourth bullet. Also added “and obtained at zero cost” to the end of the fourth bullet.
    a) Update the example: generalized the Product/Service Identifier and Quantity Dispensed.
24. Section 6.2.2 - Update the example: generalized the Product/Service Identifier and Quantity Dispensed.
25. Section 7 – Updated the first sentence of the second paragraph to include “(currently Express Scripts (ESI))”.
26. Section 8 – updated the title and changed “Medication” to “Product”.
27. Section 9 – Updated the title and changed “COVID-19” to “Diagnostic” and within the paragraph.
28. Section 9.1 – Added “Diagnostic” to the title and within the paragraph. Modified the paragraph to read more clearly.
29. Section 9.2 Types of Service – Added “as authorized by state law” to the fifth item.
30. Section 9.4 – Updated the title to change “COVID-19” to “Diagnostic” and removed the CDC link at the end of the paragraph.
31. Section 9.7 Payer Considerations – Updated the last sentence of the second paragraph to replace “during a visit” with “to a patient”.
32. Section 10.5 –
    a) Modified the title to add in “Example” and change “COVID-19 Testing” to “Diagnostic Test”.
    b) In the answer – Added “Products with a cost of $0.00 must have a distinct product identifier that is only associated to the no-cost product.” to the end of item 4-a
    c) Added item 8 Diagnosis Code.
33. Section 10.5.1 Claim examples –
    a) Switched the test administration section “MA” (new Section 10.5.1.1 previously Section 10.5.1.2) example in front of “PT” (new Section 10.5.1.2 previously Section 10.5.1.1)
    b) Made major rewrites of section 10.5.1.1 and updates to several fields within the example.
    c) Section 10.5.1.2 – updates to several fields within the example.
34. Section 10.6
    a) Removed “Complex”, “Kit” and “Example” from the title.
    b) Major rewrite of this section based on new information.
35. Section 10.7 Updated title to add “Example” and change “COVID-19” to “Diagnostic Test”
36. Added the following new sections:
    a) 10.10 through 10.12
37. Appendix A Stakeholders:
    a) Updated APhA contact and email
    b) Healthcare Ready address and email
    c) Surescripts address

VERSION 1.9

Updates and additions to the document:

1. Section 3.3 Healthcare Ready
   a) Updated footnote #3 hyperlink.
2. Section 3.3.1 Rx Open
   a) Item 1-c: Removed American Red Cross from the list.
   b) Item 2-b: Added "in understanding where critical healthcare infrastructure is impacted".
   c) Item 2-c: Removed Tax base from the list.
3. Section 4.1.2 During Declared Emergency
   a) Updated hyperlink for Footnote #14.
4. Section 4.1.1 Preparation Steps
   a) Step 1: Added "and/or the Centers for Medicare & Medicaid Services (CMS)"
5. Section 4.4 – Added second paragraph
6. Section 6.2 Billing for Free Product
   a) Rewrote the 2nd paragraph.
   b) Added the 3rd paragraph (Second Note).
7. Section 9.1 Examples of Type of Diagnostic Tests
   a) Updated the hyperlink in the 2nd paragraph.
8. Section 10 COVID-19 Vaccines Considerations – Added the entire section
9. Appendix A Stakeholders
   a) Removed AMDIS as a stakeholder
   b) Updated ASPR contacts
   c) Updated Change Healthcare contacts
   d) Updates PCMA contacts
   e) Updated RelayHealth Contacts

VERSION 1.10

Updates and additions to the document:

1. Added new section 10.5 Additional Doses
2. Updated all references of "final dose" to "final/second dose" throughout the document
3. Section 10.6.1 Use of Submission Clarification Code (420-DK) for Initial, Final/Second, Additional and Single-Dose Indication
   a) Modified the title to include "/Second, Additional"
   b) Added reference of "SCC Value of 7 for any additional dose"
   c) Added Examples 12 and 13

VERSION 1.11

Updates and additions to the document:

1. Section 10.5 Additional Dose or Booster Dose
   a) Add or Booster Dose to the title
   b) Major modifications throughout the section to add SCC 10 with clarifications for booster shots.
2. Section 10.6.3 Utilization Reject Use Cases
   a) Added the third paragraph for Additional Dose or Booster Dose.
3. Section 10.10 Second Dose/Additional Dose/Booster Dose Utilization Edits
   a) Update the title to include "Additional Dose or Booster Dose"

   b) Removed "until after the final/second does has been administered" from the first paragraph, end of the first sentence.
   c) Add bullets 2 and 4.
4. Added Section 11.13

VERSION 1.12

Updates and additions to the document:

1. Section 10.3 Claim Submission added hyperlink to the NCPDP TELECOMMUNICATION VERSION D (Telecommunication Standard) AND ABOVE QUESTIONS, ANSWERS AND EDITORIAL UPDATES document.
2. Section 10.5 Additional Dose or Booster Dose
   a) Modified the definition of booster dose to say "in accordance with CDC guidance"
   b) Removed the age examples
3. Section 10.6.1
   a) Removed "Additional-Dose SCC = 7 following Single-Dose NDC" example
   b) Added two booster dose examples
4. Section 10.10 Second Dose/Additional Dose/Booster Dose Utilization Edits
   a) Modified the last bullet point to reflect "when the additional dose or booster dose is different than the calculated days from the date of service of the final dose of previously administered vaccine", previously said "when the additional dose or booster dose is later than the calculated days from the date of service of the final dose of previously administered vaccine"
5. Section 11.13
   a) Modified the fourth bullet to match wording in section 11.14
   b) Modified the seventh bullet to have it correctly reflect "when there are professional service charges associated with any unique dispensing requirements with the applicable Professional Service Code (440-E5)"
6. Added FAQ 11.14 Billing of OTC Products During an Emergency
7. Added FAQ 11.15 Billing of a Self-Administered Free Product During an Emergency
8. Added FAQ 11.16 New NDCs for Commercial COVID-19 Vaccine Products