# **NCPDP EMERGENCY PREPAREDNESS INFORMATION**

# **VERSION 1.7**

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

May 2020

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

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

http: ncpdp.org



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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 medications during declared emergencies, such as but not limited to eligibility and claims processing. 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 plan declared emergency plan billing rules and claim routing information as part of their normal procedures.
- Enrollment files and medication 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 <a href="mailto:ncpdp.org">ncpdp.org</a>, or contact the Council office at 480-477-1000 or via email at <a href="mailto:ncpdp@ncpdp.org">ncpdp@ncpdp.org</a>.

# 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 STATE EMERGENCY DECLARATIONS

#### 2.1.1 AUTHORITY TO DECLARE EMERGENCIES

When conditions warrant, all states have mechanisms that allow government officials to declare a state of emergency, thereby activating authorities and resources that are unavailable in non-emergencies.

#### 2.1.2 Types of State Emergencies

The determination of whether circumstances justify or require the declaration of an emergency depends on conditions set forth in state law. Traditionally, states have a general statute that permits the governor to declare a state of emergency for many types of emergent situations. In the last decade, states have begun to refine their approaches to defining emergencies; a state 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 STATE EMERGENCY DECLARATION PROCESS

While the process is unique to each state, generally the governor may declare 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 state rules and regulations that are waived or suspended during the emergency. For additional state-specific information, please visit the State Governor's Office 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 STATE AND FEDERAL 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 (federal, state, local), can confuse organizations and individuals. Federal declarations

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generally do not alter state legislative and regulatory requirements; however, state law will be preempted to the extent it conflicts with federal law.

# 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

- Based on a request from State or Local authorities or on impending chances of a declared emergency, Healthcare Ready (refer to section <u>Healthcare Ready</u>) may activate <u>Rx Open.org</u><sup>1</sup>. Rx Open provides information on the operating status of certain healthcare facilities in areas impacted by a disaster.
- 2. As each State may invoke 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. Under the <u>Public Health Emergency (PHE) Declarations</u><sup>2</sup> website, the <u>Secretary of HHS</u><sup>3</sup> may issue a <u>PHE Declaration</u><sup>4</sup> 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, the <a href="HHS">HHS</a> in collaboration with <a href="Federal Emergency Management Agency">Federal Emergency Management Agency (FEMA)</a> and upon request by the Governor of impacted states may activate the <a href="Emergency Prescription Assistance Program (EPAP)">Emergency Prescription Assistance Program (EPAP)</a> based on the potential risk for patients' inability to obtain their medication.
- 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

<u>Healthcare Ready</u><sup>8</sup> 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

<sup>&</sup>lt;sup>1</sup> https://www.rxopen.org

<sup>&</sup>lt;sup>2</sup> https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx

<sup>&</sup>lt;sup>3</sup> https://www.hhs.gov/about/leadership/secretary/index.html

<sup>&</sup>lt;sup>4</sup> https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx

<sup>&</sup>lt;sup>5</sup> https://www.hhs.gov/

<sup>&</sup>lt;sup>6</sup> https://www.fema.gov/

<sup>&</sup>lt;sup>7</sup> https://www.phe.gov/Preparedness/planning/epap

<sup>8</sup> https://www.healthcareready.org/emergency-response

public health. Healthcare Ready can be used 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.

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 section <a href="Rx Open">Rx Open</a>). Additional information on Healthcare Ready services during a disaster is available in their <a href="Partner-Playbook">Partner Playbook</a>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 ContactUs@healthcareready.org, alerts@healthcareready.org, or call 866-247–2694. You may also want to refer to the websites: <a href="healthcareready.org">healthcareready.org</a> and <a href="mailto:rxopen.org">rxopen.org</a>.

#### 3.3.1 RX OPEN

When activated, Rx Open (<u>rxopen.org</u>) 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.

Healthcare Ready only activates Rx Open at the request of government officials or following a federally declared emergency. Rx Open provides the tool 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 <a href="mailto:rxopen.org">rxopen.org</a>. 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.

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 Individual Pharmacy Map or County Pharmacy Map.
  - c. The Individual Pharmacy Map displays community pharmacies and American Red Cross shelters in the affected area and is color coded based on operational status.
  - d. The best way to access information in the Rx Open Individual Pharmacy Map is to click on a dot representing a pharmacy; a box containing contact information appears.
  - e. The County Pharmacy 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

<sup>&</sup>lt;sup>9</sup>https://healthcareready.org/wp-content/uploads/2019/12/2018 Partner Playbook - TLP white final.pdf

<sup>10</sup> https://healthcareready.org/

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- 2. Benefits of Rx Open:
  - a. Helps patients have access to critical medicines.
  - b. Assists emergency management and public health responses.
  - c. Helps maintain employment, tax base, and business continuity in a community.

# 4. HEALTHCARE INDUSTRY RESPONSIBILITIES

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. Verify payer/plan declared emergency claims processing information is loaded into pharmacy software and available for use.
- 2. Ensure your pharmacy software system and operational procedures support the implemented NCPDP External Code List values and FAQ 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 history information is contributed regularly, provide up to date, information in a timely manner.
- 5. If participating in a business relationship where medication history information is available upon a declared emergency, verify processes and procedures are in place and executable.
- 6. To receive timely situational awareness updates in the event of a disaster, ensure contact information is current with the Office of the Assistant Secretary for Preparedness and Response 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, see Appendix A.
- 7. It is recommended that all pharmacists obtain their individual NPI to support state emergency refill prescription dispensing. Refer to National Plan and Enumeration System (NPPES)<sup>11</sup>.

#### 4.1.2 DURING DECLARED EMERGENCY

- 1. It may be beneficial to send refill reminders once a pending state/federal emergency has been declared to notify patients to pick up necessary medication. For patient's safety, it is critical they evacuate or shelter in place with an adequate supply of medication.
- 2. If you use auto refill reminders, ensure they direct your patients to pick up their medication from an open pharmacy location.
- 3. Most States have procedures in place that address a pharmacist's ability to dispense an emergency supply of medication 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 Pharmacy's (NABP)<sup>12</sup> 'Model Rules for Public Health Emergencies<sup>13</sup>' that provides 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 see Rx Open.

<sup>11</sup> https://nppes.cms.hhs.gov/#/

<sup>12</sup> https://nabp.pharmacy/

<sup>&</sup>lt;sup>13</sup> https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/

Refer to the <u>Frequently Asked Questions</u> section 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 medication being requested because the medication was lost.
- 2. In Version 2017071 of the NCPDP 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 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 medication 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

 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 NCPDP SCRIPT Standard Version 2017071 supports an urgency indicator within the applicable request messages.

#### 4.3.2 DURING DECLARED EMERGENCY

1. Refer to Rx Open for availability of pharmacy providers.

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- 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 that one of the components (EHR system, E-Prescribing network, Pharmacy system) is down or unavailable, the prescriber would default to writing or phoning in prescriptions, following all Statespecific guidelines.
- 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 <a href="mailto:rxopen.org">rxopen.org</a> (Refer to <a href="Healthcare Ready">Healthcare Ready</a>).

#### 4.3.3 EPRESCRIBING RENEWAL REQUESTS

- 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 medication being requested because the medication was lost.
- 2. In Version 2017071 of the NCPDP 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.

# 4.4 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. 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, notification obtained, contact ContactUs@healthcareready.org to self-report. Refer to Reporting Additional Information on Pharmacy Status.

#### 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.
- 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 report of pharmacies billing prescriptions in the previous 24 hours at 2pm and 8pm ET daily using a FTP process or via email to contactUs@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 counties identified in the declared emergency. 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 contactUs@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 contactus@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 relocated), 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 evacuees 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 <a href="accessorline.ncpdp.org">accessorline.ncpdp.org</a>.
  - c. If these pharmacies move, the pharmacy will log on to <u>accessonline.ncpdp.org</u> and update their physical address. The NCPDP ID and NPI will remain the same.

# 5. MEDICATION 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 Federal, State, and Local 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 evacuees 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 <a href="Emergency Prescription Assistance Program">Emergency Prescription Assistance Program</a> (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 PBMs'/payers' 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:

- Early refills
- Utilization management edit exceptions including but not limited to prior authorization overrides
- Copay waivers
- Prescriptive authority exceptions

Additionally, payers and pharmacies need to be prepared to process claims for products supplied through the <u>SNS</u>. 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 the <a href="Frequently Asked Questions">Frequently Asked Questions</a> section, 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 medication.

	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		0	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 (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:
  - o 13 Payer Recognized Declared Emergency Assistance Request
  - o 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			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: 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 authority rules for emergency

	Claim Segment Segment Identification (111-AM) = "07"			Claim Billing/Claim Rebill
Field #	NCPDP Field Name	Value	Payer	Payer Situation
			Usage	
				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			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). 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. Systems that are not able to accept the value \$0.00 should clearly communicate the use of \$0.01 as the submitted cost. Also refer to section titled "VACCINE SERVICES – PHARMACY BENEFIT BILLING & PROCESSING" within the TELECOMMUNICATION VERSION D AND ABOVE QUESTIONS, ANSWERS AND EDITORIAL UPDATES<sup>14</sup>.

# 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.

<sup>&</sup>lt;sup>14</sup> https://www.ncpdp.org/NCPDP/media/pdf/VersionDQuestions.pdf

- The Product/Service ID Qualifier (436-E1) should be submitted with the correct Product/Service ID Qualifier (in this example "03" (NDC)) and Product/Service ID (407-D7) contains the NDC Number of the vaccine or other product that was administered.
- 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 that the product was administered.
- The Incentive Amount Submitted (438-E3) is submitted to identify 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	Сат	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	М	bbbbbbbbbb					

	CLAIM SEGMENT							
FIELD	FIELD NAME	Сат	VALUE	COMMENTS				
111-AM	SEGMENT IDENTIFICATION	М	07	CLAIM SEGMENT				
455-EM	PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER	М	1	Claim billing				
402-D2	PRESCRIPTION/SERVICE REFERENCE NUMBER	М	7654321					
436-E1	PRODUCT/SERVICE ID QUALIFIER	M	03	NDC				
407-D7	PRODUCT/SERVICE ID	М	66521011510	Fluvirin 2012-2013				
442-E7	QUANTITY DISPENSED	Q	500	0.5 (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	САТ	VALUE	COMMENTS		
111-AM	SEGMENT IDENTIFICATION	М	08	DUR/PPS Segment		
473-7E	DUR/PPS CODE COUNTER	R	1	1 <sup>st</sup> DUR activity		
440-E5	PROFESSIONAL SERVICE CODE	Q	MA	Medication Administered		

	PRICING SEGMENT							
FIELD	FIELD NAME	САТ	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	<i>2</i> 50{	\$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 COSTS) 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 Number 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	Сат	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	М	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	М	4563663111bbbbb					
401-D1	DATE OF SERVICE	М	20200315	March 15, 2020				
110-AK	SOFTWARE VENDOR/CERTIFICATION ID	M	bbbbbbbbbb					

CLAIM SEGMENT				
FIELD	FIELD NAME	Сат	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	М	7654321	
436-E1	PRODUCT/SERVICE ID QUALIFIER	М	03	NDC
407-D7	PRODUCT/SERVICE ID	M	0004080085	Tamiflu 75mg
442-E7	QUANTITY DISPENSED	Q	10	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	Сат	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 the patients on the site when the EPAP is activated.

Upon receipt of an activation notice, the EPAP Processor 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, or 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<sup>15</sup> 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 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, Express Scripts (ESI), the current 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 <u>no</u> 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.
- 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.

<sup>15</sup> https://www.phe.gov/Preparedness/planning/epap/Pages/epap-pharmacies.aspx

7. Eligible patients will receive coverage under the EPAP with **\$0** copayments. Pharmacies will receive reimbursement from FSI.

# 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 NCPDP Telecommunication Standard Eligibility Verification (E1) transaction, web portals connected to centralized locations, medication 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 copays/deductibles, should seek assistance from other disaster relief agencies or local resources. See <a href="Healthcare">Healthcare</a> 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 medication 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	М
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		0

# Patient Segment - Required

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	01=Patient	М
331-CX	Patient ID Qualifier		0
332-CY	Patient ID		0
304-C4	Date of Birth		R

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		0
323-CN	Patient City		0
324-CO	Patient State or Province		0
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	0
384-4X	Patient Residence		R

<sup>\*</sup>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	М
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	М
312-CC	Cardholder First Name		R
313-CD	Cardholder Last Name		R
524-FO	Plan ID		0
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.	М
402-D2	Prescription/Service Reference Number		М
436-E1	Product/Service ID Qualifier	00 = Not specified* 03=National Drug Code	М
407-D7	Product/Service ID		М
442-E7	Quantity Dispensed		R
403-D3	Fill Number	0=Original Dispensing 1 to 99 = Refill number	R
405-D5	Days Supply		R

Field #	NCPDP Field Name	Value	Payer Usage
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)

<sup>\*</sup>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.

## **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		0
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.

<sup>\*\*</sup>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).

481-HA	Flat Sales Tax Amount Submitted*		RW
401-FIA	riat Sales Tax Alliquiit Subillitteu		(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)
Field #	NCPDP Field Name	Value	Payer Usage
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

<sup>\*</sup>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
Field #	NCPDP Field Name	Value	Payer Usage
427-DR	Prescriber Last Name		RW (Prescriber ID Qualifie (466-EZ) =08)

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.

#### DUR/PPS Segment - Situational

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	08=DUR/PPS	М
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**

<sup>\*</sup>Indicates the claim billing includes a charge for administration; leave blank if dispensing without administration.

#### 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	М
450-EF	Compound Dosage Form Description Code		М
451-EG	Compound Dispensing Unit Form Indicator	1=Each 2=Grams 3=Milliliters	М
447-EC	Compound Ingredient Component Count	Maximum 25 ingredients	М
488-RE	Compound Product ID Qualifier	03=NDC	М
489-TE	Compound Product ID	At least 2 ingredients and 2 NDC #s. Number should equal field 447-EC.	М
448-ED	Compound Ingredient Quantity		М
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

<sup>\*</sup> 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 medication.

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

#### **NCPDP EMERGENCY PREPAREDNESS INFORMATION 1.7**

4	491-VE	Diagnosis Code Count	Maximum count of 5	R
4	192-WE	Diagnosis Code Qualifier	02=ICD-10	R
4	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	М
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	М
202-B2	Service Provider ID Qualifier	Same value as in request	М
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	М
504-F4	Message		0

Response Insurance Segment - Required

Field #	NCPDP Field Name	Value	Payer Usage
111-AM	Segment Identification	25=Response Insurance	M
301-C1	Group ID		R
524-FO	Plan ID		0
545-2F	Network Reimbursement ID	Network ID	R*
568-J7	Payer ID Qualifier		0
569-J8	Payer ID		0
302-C2	Cardholder ID		0

<sup>\*</sup>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)

F40.CF	Approved Massage Cada	Г	DW
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			(Current repetition of Additional Message Information (526-FQ) is used and another repetition (526-FQ) follows, and text is continuation of

#### **NCPDP EMERGENCY PREPAREDNESS INFORMATION 1.7**

ſ	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	М
455-EM	Prescription/Service Reference Number Qualifier	1=Rx Billing	M
402-D2	Prescription/Service Reference Number		М
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)
Field #	NCPDP Field Name	Value	Payer Usage
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

Field #	NCPDP Field Name	Value	Payer Usage
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)
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		0
564-J3	Other Amount Paid Qualifier	Occurs up to 3 times	0
565-J4	Other Amount Paid	Occurs up to 3 times	0
566-J5	Other Payer Amount Recognized		0
509-F9	Total Amount Paid		R

Field #	NCPDP Field Name	Value	Payer Usage
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		0
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)

Field #	NCPDP Field Name	Value	Payer Usage
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.)
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)

Field #	NCPDP Field Name	Value	Payer Usage
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)
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)

Field #	NCPDP Field Name	Value	Payer Usage
148-U8	Ingredient Cost Contracted/Reimbursable Amount		RW*
149-U9	Dispensing Fee Contracted/Reimbursable Amount		RW*

<sup>\*</sup>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		0
528-FS	Clinical Significance Code		0
529-FT	Other Pharmacy Indicator		0
530-FU	Previous Date of Fill		0
531-FV	Quantity of Previous Fill		0
532-FW	Database Indicator		0
533-FX	Other Prescriber Indicator		0
544-FY	DUR Free Text Message		0
570-NS	DUR Additional Text		0

#### 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		0

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	М
402-D2	Prescription/Service Reference Number		М
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
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	М
504-F4	Message		0

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	М
Field #	NCPDP Field Name	Value	Payer Usage
547-5F	Approved Message Code Count	Maximum count of 5	RW (Approved Messa Code (548-6F) is used)
548-6F	Approved Message Code		RW (Approved Messa 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		0
550-8F	Help Desk Phone Number		0

Response Claim Segment - Mandatory

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

## FIELD LEGEND FOR COLUMNS

PAYER USAGE COLUMN	Value	Explanation 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
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	ı	The Field is for informational purposes only for the Transaction.	
OPTIONAL	0	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 MEDICATION IN A DECLARED EMERGENCY THROUGH MANUFACTURER PROGRAMS

The Partnership for Prescription Assistance (PPA) helps uninsured and financially struggling patients who lack prescription coverage get access to prescription assistance programs which offer medicines for free or nearly free. The PPA is free, confidential, and assists patients to find programs for which they may be eligible to apply.

Some of the services the PPA offers:

- 1. Offers a user-friendly website (<u>pparx.org</u>) to enable patients to find prescription assistance programs for which they may be eligible to apply. Patients can download and print out patient assistance program applications immediately.
- 2. Patients can call toll free (888-4PPA-NOW) to talk with a trained specialist who will guide them through the application process. The call center accepts calls in English, Spanish, and approximately 150 other languages.
- 3. Offers a single point of access to information on 475 public and private patient assistance programs, including nearly 200 programs offered by pharmaceutical companies.
- 4. Offers more than 2,500 brand-name medicines, including a wide range of generics.
- 5. Helps patients contact government programs such as Medicaid and Medicare.
- 6. Offers more than 40 of the assistance programs focused on the medication and healthcare needs of children.
- 7. Provides information on nearly 10,000 free healthcare clinics and has connected more than 241,000 patients with clinics and healthcare providers in their communities.
- 8. Assists patients with chronic disease in learning about the types of new medicines in development that may help them.

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. COVID-19 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 COVID-19 testing in the pharmacy industry. Continuous review and maintenance of regulations and policies is also important.

## 9.1 EXAMPLES OF TYPES OF TESTS

There are a number of different tests for COVID-19 where the level of complexity, specimen collection and testing procedures vary. Multiple distinct product and/or service identifiers may be required to specifically identify the type of test being performed. Current types of tests available are detailed below. Due to the fluidity of the coronavirus pandemic, other types of tests may be developed and approved at a later date.

- 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.

The FDA has 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: <a href="fda.gov/medical-devices/emergency-use-authorizations">fda.gov/medical-devices/emergency-use-authorizations</a>. The majority of diagnostic tests 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) will be assigned to these tests/test kits, where an alternate product ID may be required on the claim. Alternate IDs may include a NCPDP 11-digit NDC, HCPCS code, or CPT code, where product ID mapping will be required.

Packaging of these tests will also vary. 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 COVID-19 testing in the following ways:

- 1. Assess a patient, and when appropriate, order laboratory testing. 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. Reporting of the test results may include:
  - a. Counseling the patient and/or authorized individual/entities of the results and providing notifications to patients' primary care team as identified by the patient.
  - b. Reporting of results to 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 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, the Centers for Medicare & Medicaid Services (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 COVID-19 tests that are moderate and high complexity that have an EUA designated 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:

- 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, 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 COVID-19 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 COVID-19 testing priority guidelines provided by the CDC at: cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html.

## 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 the <u>Billing For Free Product</u> section.

# 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 field (411-DB). The administering provider would be represented in the

Provider ID field (444-E9). 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 cover items and services provided during a visit that "relate to the furnishing or administration" of COVID-19 diagnostic testing among other things.

Detailed guidance regarding billing of COVID-19 Tests can be found in Section Frequently Asked Questions.

# 10. FREQUENTLY ASKED QUESTIONS

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

# 10.1 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 medication as a result of lost medication, 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.

# 10.2 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 medication?

**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.

# 10.3 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 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 reject with a prescriber validation error, to which SCC 42 would be accepted by the payer, then the claim rejects as refill too soon, requiring both SCC 42 and 13.

# 10.4 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 section <u>Billing</u> <u>for Free Product</u> 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.

# 10.5 BILLING FOR COVID-19 TESTING

**Question**: When billing for a COVID-19 test, what information should be included in a NCPDP B1/B3 claim request?

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

#### 1. Provider Validation:

- a) The Type 2 NPI for the pharmacy contracted for COVID-19 test services should be submitted as the Service Provider ID (201-B1).
- b) Pharmacies should acquire the applicable CLIA Waiver certificate (refer to <u>FAQ: Clinical Laboratory Improvement Amendments (CLIA)</u> 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 NDC format for the Product/Service ID (407-D7) field and associate the Product/Service ID Qualifier (436-E1) of NDC (03).

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cil for Prescription Drug Pro

- 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 field (459-ER) 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 Field (440-E5) to further identify additional services being provided.

MA	Medication Administration
	<b>Business Case:</b> 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
	<b>Business Case:</b> 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 Kit 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.
  - 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) 60 Mass Immunization Center
    - iv) 99 Other Place of Service
- 8. Testing Results:
  - a) If testing results are available prior to the claim request being submitted and the pharmacy wants to communicate them, the applicable ICD-10 code could be submitted in the Diagnosis Code (424-DO) field to indicate the testing results. 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.

## 10.5.1 CLAIM EXAMPLES

## 10.5.1.1 BILLING FOR A PRODUCT WITH AN ASSOCIATED COST AND PROFESSIONAL SERVICE CODE OF MA

In the following example, a pharmacy obtains product with a cost of \$50.00 and administers the test at the pharmacy. The test was ordered by the pharmacist, so the Prescriber segment is submitted with the Pharmacist NPI in the Provider ID (444-E9) field and a Provider ID Qualifier (465-EY) of "5=NPI" along with the Prescription Origin Code (419-DJ) a value of '5' - Pharmacy.

A \$20.00 incentive fee is added to cover the cost of test administration (MA)

Only pertinent segments are shown.

Transactio	Transaction Header Segment						
Field	Field Name	Cat	Value	Comments			
101-A1	BIN Number	М	610066				
102-A2	Version/Release Number	М	D0	Transaction Format			
103-A3	Transaction Code	M	B1	Claim Billing			
104-A4	Processor Control Number	M	1234567890				
109-A9	Transaction Count	М	1	One occurrence			
202-B2	Service Provider ID Qualifier	M	01	National Provider ID			
201-B1	Service Provider ID	M	4563663111bbbb				
			b				
401-D1	Date of Service	M	20200317	March 17, 2020			
110-AK	Software Vendor/Certification ID	M	bbbbbbbbbb				

Patient Seg	Patient Segment					
Field	Field Name	Cat	Value	Comments		
111-AM	Segment Identification	М	01	Claim 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	0	123 Main St			
323-CN	Patient City Address	0	Anywhere			
324-CO	Patient State/Province Address	0	NY			
325-CP	Patient ZIP/Postal Zone	0				
326-CQ	Patient Phone Number	0				
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	М	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	М	03	NDC	

407-D7	Product/Service ID	М	1187700126	ID NOW COVID-19 4 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
419-DJ	Prescription Origin Code	Q	5	Pharmacy

DUR/PPS Segment					
Field	Field Name	Cat	Value	Comments	
111-AM	Segment Identification	М	08	DUR/PPS Segment	
473-7E	DUR/PPS Code Counter	R	1	1 <sup>st</sup> DUR activity	
440-E5	Professional Service Code	Q	MA	Administered Test	

Prescriber :	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 Seg	Pricing Segment					
Field	Field Name	Cat	Value	Comments		
111-AM	Segment Identification	М	11	Pricing Segment		
409-D9	Ingredient Cost Submitted	R	500{	\$50.00		
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	<i>85</i> 0{	\$85.00		
430-DU	Gross Amount Due	R	<i>85</i> 0{	\$85.00		
423-DN	Basis of Cost Determination	Q	01	AWP	·	

## 10.5.1.2 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, 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).

A \$40.00 incentive fee is added to cover cost of services provided by the pharmacy to perform laboratory testing.

Only pertinent segments are shown.

Transaction	Transaction Header Segment					
Field	Field Name	Cat	Value	Comments		
101-A1	BIN Number	М	610066			
102-A2	Version/Release Number	M	D0	Transaction Format		

103-A3	Transaction Code	М	B1	Claim Billing
104-A4	Processor Control Number	М	1234567890	
109-A9	Transaction Count	М	1	One occurrence
202-B2	Service Provider ID Qualifier	М	01	National Provider ID
201-B1	Service Provider ID	М	4563663111bbbbb	
401-D1	Date of Service	М	20200317	March 17, 2020
110-AK	Software Vendor/Certification ID	М	bbbbbbbbbb	

Patient Seg	Patient Segment					
Field	Field Name	Cat	Value	Comments		
111-AM	Segment Identification	М	01	Claim 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	0	123 Main St			
323-CN	Patient City Address	0	Anywhere			
324-CO	Patient State/Province Address	0	NY			
325-CP	Patient ZIP/Postal Zone	0	12345			
326-CQ	Patient Phone Number	0				
307-C7	Place of Service	Q	60	Mass Immunization Center indicates		
				location where service was provided		

Claim Segm	Claim Segment					
Field	Field Name	Cat	Value	Comments		
111-AM	Segment Identification	М	07	Claim Segment		
455-EM	Prescription/Service Reference Number Qualifier	М	1	Claim billing		
402-D2	Prescription/Service Reference Number	М	7654321			
436-E1	Product/Service ID Qualifier	М	03	NDC		
407-D7	Product/Service ID	М	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	М	08	DUR/PPS Segment	
473-7E	DUR/PPS Code Counter	R	1	1 <sup>st</sup> DUR activity	
440-E5	Professional Service Code	Q	PT	Perform Laboratory Test	

Pricing Segment					
Field	Field Name	Cat	Value	Comments	
111-AM	Segment Identification	М	11	Pricing Segment	
409-D9	Ingredient Cost Submitted	R	500{	\$50.00	
412-DC	Dispensing Fee Submitted	Q	150{	\$15.00	
438-E3	Incentive Amount Submitted	Q	400{	\$40.00	
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	М	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	U-07.1	COVID-19 (Optional Field indicating				
				positive COVID-19 test)				

# 10.6 COVID-19 TEST KIT QUANTITY DISPENSED

Question: How do I determine the Quantity Dispensed (442-E7) value when billing a COVID-19 Test?

**Answer:** The COVID-19 Test Kits 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.

The COVID-19 test currently listed with the compendia contains the capacity to test multiple patients within a single test platform and typically include the following:

- Sample Receiver or Platform Device (in multiple quantities depending on the kit)
- Transfer Cartridges (in multiple quantities depending on the kit)
- Test Bases (in multiple quantities depending on the kit)
- Patient Swabs (in multiple quantities depending on the kit)
- Transfer Pipettes (in multiple quantities depending on the kit)
- Lancets (in multiple quantities depending on the kit)
- Test Cartridges
- A Positive Control Swab
- A Negative Control Swab

NOTE: Not all kits contain all items

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.

This is an exception to the Billing Unit Standard to accommodate testing products granted Emergency Use Authorization and 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.

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 1/24<sup>th</sup> 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. We advise you check with your compendium prior to determining the appropriate billing quantity of the specific test being dispensed/administered.

# 10.7 CLAIM RESPONSE FOR COVID-19 TEST CLAIM REQUEST

**Question:** Which Reject Code(s) (511-FB) should be returned on the claim response when the COVID-19 test 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:     Submitted claim is for dispensing test product only AND DUR Professional Service Code does not equal MA or PT
		Result:     O 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
		<ul> <li>Result:         <ul> <li>COVID-19 test product,</li> <li>specimen collection, and</li> </ul> </li> </ul>

			interpretation of results
			are a pharmacy benefit exclusion, however, may be covered under the medical benefit
817	Pharmacy Benefit Exclusion, Covered Under	Scenario:	medical beliefic
	Patient's Medical Benefit	0	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:	
		0	COVID-19 test product, specimen collection, and interpretation of results are a pharmacy benefit exclusion, and is known to be covered under the medical benefit
9C	Professional Service Code Value Not Supported	• Scenario:	
		• Result	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	• Scenario:	
	Medicare Part B	0	Submitted claim is for dispensing of test product, specimen collection, or interpretation of results/reporting DUR Professional Service Code is MA or PT
		• Result:	Dationt is determined to be
		0	Patient is determined to be Medicare Part B eligible, mutually exclusive to plan benefit that was billed

# 10.8 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

**Question:** How does a pharmacy request a CLIA waiver in order to conduct applicable COVID-19 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: <a href="mailto:cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf">cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf</a>. 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 <a href="mailto:ncpa.org/coronavirus-information">ncpa.org/coronavirus-information</a> 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: <a href="mailto:cms.gov/Regulations-and-guidance/Legislation/CLIA/Downloads/CLIASA.pdf">cms.gov/Regulations-and-guidance/Legislation/CLIA/Downloads/CLIASA.pdf</a>.

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 <a href="cdc.gov/clia">cdc.gov/clia</a>

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

# 10.9 EXCHANGE CLINICAL INFORMATION

Question: How do healthcare entities exchange patient clinical information regarding their COVID-19 test?

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: <u>STU</u> 1 Draft) based on <u>FHIR R4</u> may be used as guidance on the exchange of additional COVID-19 clinical information. In addition to this type of information exchange, pharmacies and pharmacists should refer to the CDC web site <u>cdc.gov/</u> and state Departments of Health for information on requirements for reporting patient test results.

# 11. TASK GROUP COMMUNICATION PLAN

# 11.1 REVIEW OF DOCUMENT

Unless there are exceptions as defined in Section 11.3 below, this document will be reviewed and updated by the Emergency Preparedness Task Group no less often than annually based on the following timeline:

- 1. Reconvene Emergency Preparedness Task Group after February Work Group meetings.
- 2. 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.

# 11.2 UPON APPROVAL BY 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 (See Appendix A).
- 3. The updated document will be uploaded to the NCPDP website ncpdp.org.

# 11.3 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 Section 11.2. 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 Section 11.2 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: <u>ama-assn.org/ama</u>

#### **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

#### **AMDIS**

Association of Medical Directors of Information Systems

682 Peninsula Drive Lake Almanor, CA 96137 Phone: 719-548-9360 Email: info@amdis.org Web: amdis.org

#### ΔΡhΔ

American Pharmacists Association 2215 Constitution Avenue NW

Washington, DC 20037

Contact: Michael Baxter, Senior Director, Regulatory Policy

Phone: 800-237-2742 Fax: 202-783-2351

Email: infocenter@aphanet.org Email: mbaxter@aphanet.org

Web: pharmacist.com

#### ASCP

#### **NCPDP EMERGENCY PREPAREDNESS INFORMATION 1.7**

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

ASPR Prescription Medication Preparedness Initiative (PMPI)

Contact: Bruce Dell
Phone: 202-205-4369
Email: Bruce.Dell@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@erxnetwork.com

Web: <u>changehealthcare.com</u>

## 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: <u>Express-Scripts.com</u>

#### **Healthcare Ready**

Healthcare Ready

950 F. Street NW, Suite 300 Washington, DC 20004

Phone: 866-247-2694

Email: ContactUs@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: <u>nacds.org</u>

#### 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: <u>medicaiddirectors.org</u>

#### **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

#### **NCPDP EMERGENCY PREPAREDNESS INFORMATION 1.7**

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
Phone: 202-756-5700
Fax: 202-756-5708

Email: aalexander@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

Phone: 610-205-5581

Email: Stacy.Hopkins@Relayhealth.com

Web: <u>relayhealth.com</u>

## **Surescripts**

Surescripts 2800 Crystal Drive 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 <a href="healthcareready.org/contact-us">healthcareready.org/contact-us</a>."
- 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 contactus@healthcareready.org"
  - Moved Section 4.7 Reporting of Impacted Locations to NCPDP Pharmacy Database Process under section 4.5 as new section 4.5.3

- 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:

- 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.
  - 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.