

### Description

A 71-year-old female, Nancy Peters, visits a small rural vaccination clinic in Western Pennsylvania to be given a COVID-19 vaccine on 1/7/2021. A clinic staff member collects basic patient demographic information including name, date of birth, and sex. A clinic provider, Lisa Bonn (physician ID 546), reviews the patient's medical history and orders the Pfizer vaccine for her. The patient is given the EUA patient factsheet for the vaccine, which replaces the Vaccine Information Sheet (VIS), to review. After reading it, the patient agrees to receive the recommended vaccine, but does not want the data to be shared once it is incorporated into the local IIS and does not want reminders and recalls. An appropriate dose of the COVID-19 Pfizer vaccine is selected from the clinic's stock of vaccines. A clinician, Macy Jane Rogers (ID 8247), prepares and administers the dose to the patient and then enters the data into the sending application and transmits it to the IIS. The patient is told to return for the 2nd dose of the Pfizer vaccine in 3 weeks. She is given a CDC COVID-19 Vaccination Record Card and instructed to bring it when receiving the 2nd dose of the vaccine.

### Comments

The dates used in the test story and test messages are examples and can be changed to reflect appropriate current dates.

### Pre-condition

Sending systems should have the capability of sending an HL7 v2.5.1 standard-based Immunization Message Z22 Profile-VXU Message.

### Post-Condition

No Post Condition

### Test Objectives

This test case assesses the ability of the sending application:

- To create a vaccine administration message for an adult who received the 1st dose of the Pfizer COVID-19 vaccine.
- To include a patient factsheet instead of a VIS in the message.
- To support no consent for sharing data.
- To support no for reminders and recalls.
- To support vaccination series status as incomplete (Dose 1 of 2)
- To support sending middle names.

### Evaluation Criteria

Message Validation Report

### Notes

The use of CVX 213 "SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED" is prohibited for the current administration of a COVID-19 vaccine.

COVID-19 vaccines have received Emergency Use Authorization (EUA) by the FDA. Per the CDC, the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS. These codes were developed in advance of potential EUA decision by FDA for each vaccine.

Per the ONC 2015 Edition HIT Certification Criterion §170.315(f)(1) Transmission to immunization registries, codes from the NDC Directory are required for vaccines in new vaccine administered records in Z22 VXU messages. However, for this test plan either an NDC, a CVX, or both can be messaged. Best practice is to send both.

