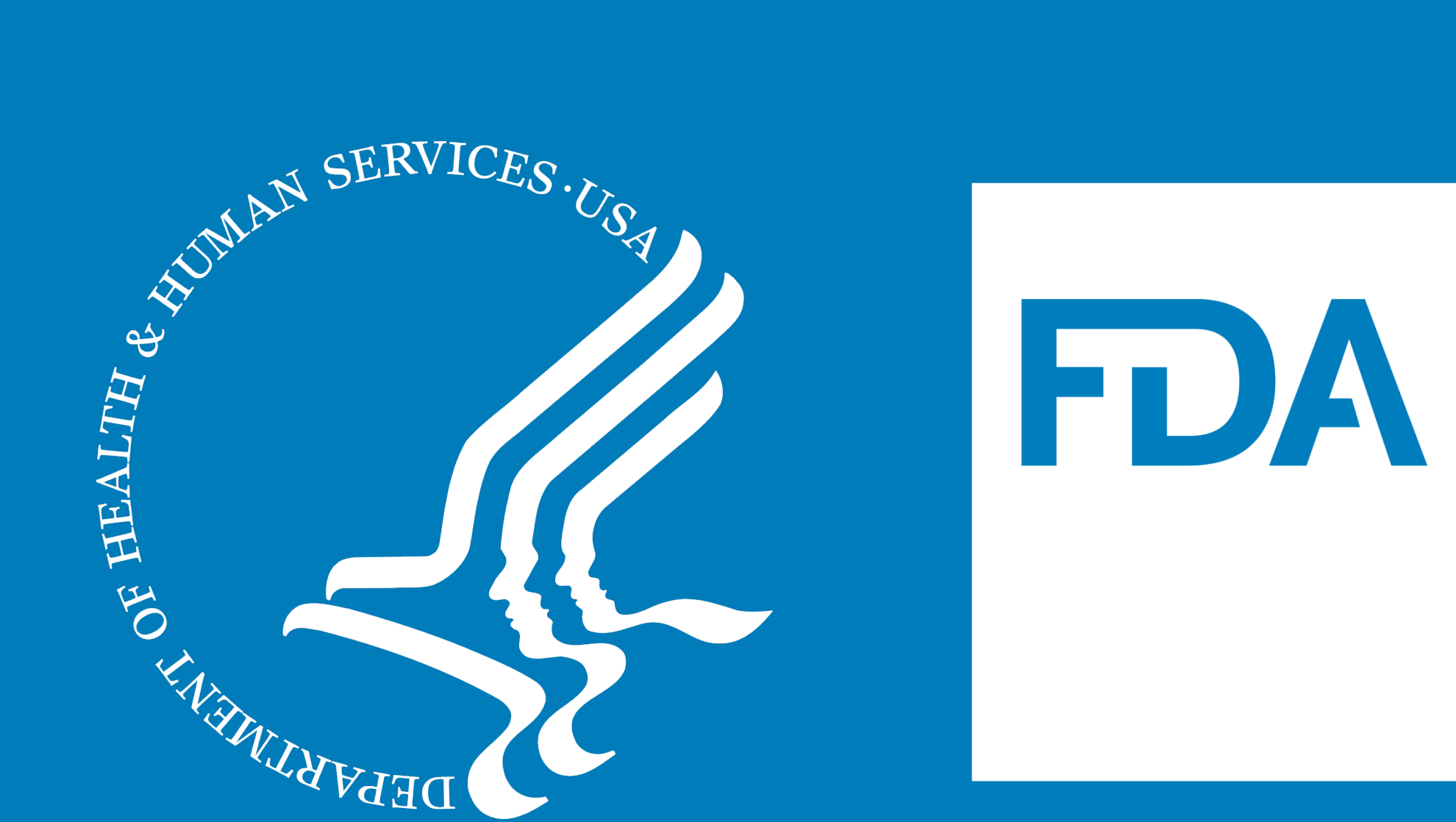


FDA-CDER COVID-19 Critical Care Drug Monitoring Survey Portal

Ongoing Surveillance of Critical Drugs Related to COVID-19 Supply Disruptions



Almeida, Cecilia; Schley, Mignon; Arnett, Tomeka; Omokaro, Stephanie O.

United States Food and Drug Administration, Center for Drug Evaluation and Research: Division of Medical Policy Development, Office of Medical Policy Initiatives, Office of Medical Policy

Abstract

FDA-CDER COVID-19 Critical Care Drug Monitoring Survey Portal (CCDMSP) (est. May 11, 2020) obtains weekly data on U.S. hospital drug inventory. Three years into the COVID-19 public health emergency, this secure online platform (See: <https://informaticsconnect.fda.gov/>) facilitates ongoing reporting of U.S. regional medication needs and monitors significant strains on the supply of certain drugs needed such as those exacerbated by surges in COVID cases and hospitalized patients.

The survey collects information in near real-time about regional drug supply needs and supplements CDER's existing efforts for identifying and mitigating national medication supply disruptions during the pandemic and beyond. To date, over 2300 surveys have been submitted to the Portal from a total of 45 States and highlight the dynamic nature of hospital supply trends over the past 3 years of the COVID-19 pandemic.

Introduction

The pharmaceutical supply chain when disrupted can strain access to critically needed medicines for patients. While the reasons for many drug shortages are largely unknown, factors such as disruptions of global manufacturing, scarcity of active ingredients, extreme weather events and natural disasters, regional spikes in COVID-19 cases, and unprecedented demand surges can play a role in significant supply disruptions. CDER's pandemic preparedness and response activities ensure that safe and effective drugs remain available to treat patients, monitor ongoing supply of needed medicines, and mitigate or prevent drug shortages to protect the nation's health.

The CCDMSP provides CDER with important information on the availability of critical medications, even when those drugs are not in nationwide shortage. This system allows for early recognition of drug vulnerability through collaboration with hospitals and healthcare systems and strengthens FDA's role in securing a safe and adequate drug supply.

Materials and Methods

A repeated cross-sectional mixed-mode hospital survey (i.e., telephone and web) was developed and used to collect information about COVID-19 critical care drugs including the number of days of inventory on hand, changes in medical practice to conserve supply, and experience of shipment delays. Purposive sampling was used to select 3 to 5 hospitals from each of the states and territories in the U.S. at baseline. The first wave of data collection occurred in 2020 and was conducted using a telephone survey at 11 COVID-19 hotspot states, follow-up surveys with hospitals were conducted using a web-based survey instrument and the data was subsequently captured on an ongoing weekly basis using a secure online Portal. Survey responses were aggregated, analyzed, and prioritized based on early signals that considered the number of COVID-19 hotspot states reporting drug accessibility issues, and the availability of substitutable drugs in the same therapeutic class.

A step-by-step guide for registering in the Portal was also created to assist users to create a login/account using multi-factor authentication.

Registered users can enter hospital information, such as number of COVID-19 patients in addition to drug supply. The Portal also allows users to manually enter any drug of concern.

1. See [FD&C Act 506C\(h\)\(2\)](#) (21 U.S.C. 356c(h)(2)) for statutory definition of a drug shortage.

Results and Discussion

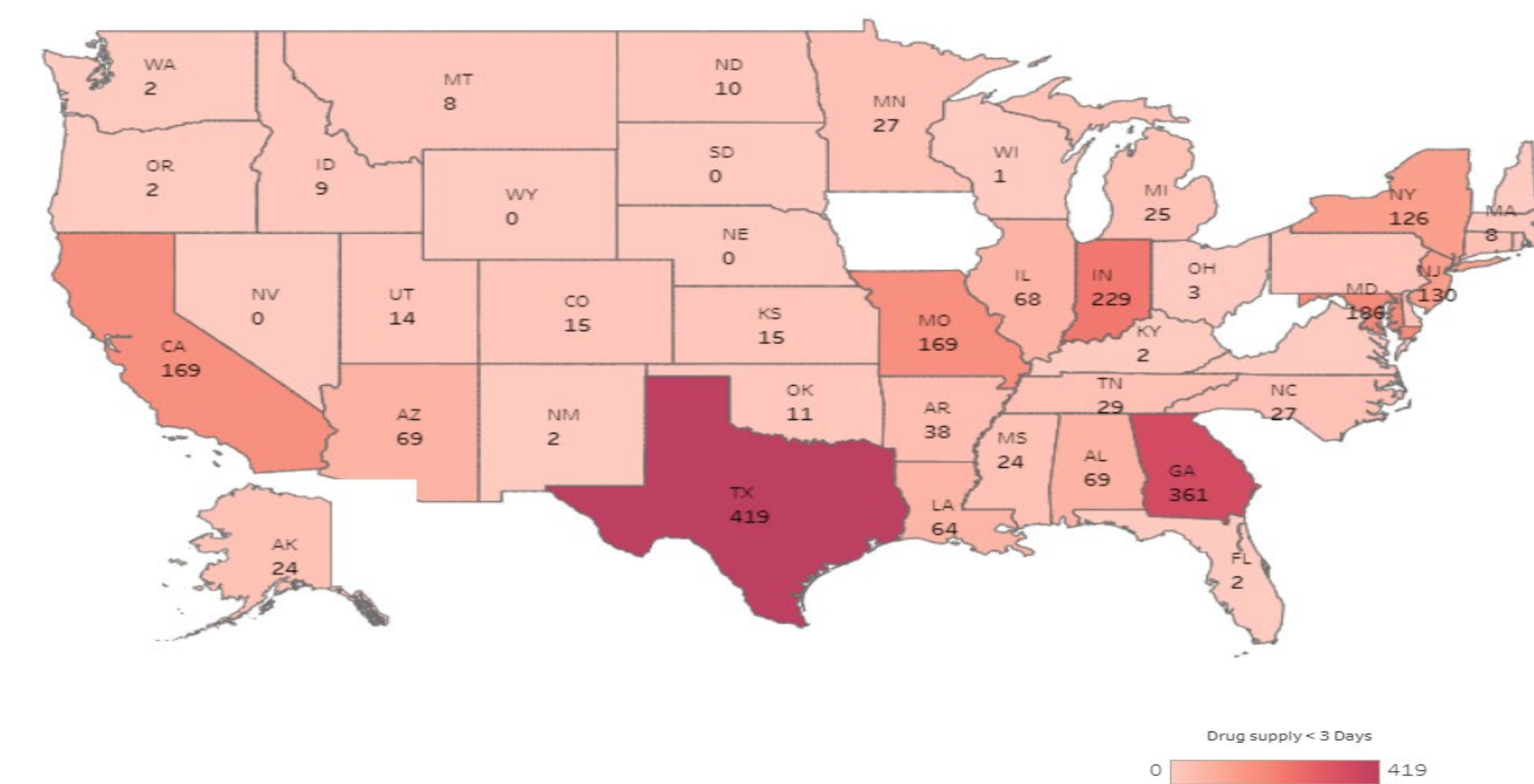


Figure 1. States with Reports of <3 Days Supply (Cumulative)

De-identified and aggregated hospital real world data illustrate dynamic supply trends over time of on-hand days medication inventory. Figure 2 represents the percentage of COVID-19 critical care drugs inventory at each survey over time from May 2020 through December 2022 that were defined as less than 3 days supply, 3-6 days supply, 7 or more days supply, uncertain, or do not stock/not on formulary.

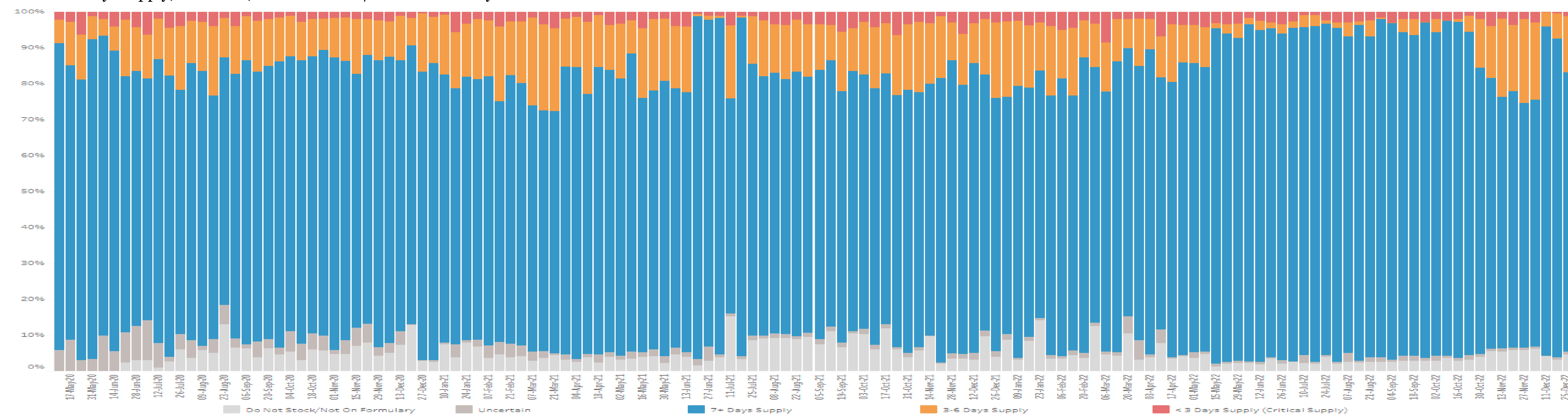


Figure 2. Drug Inventory Over Time May 2020-December 2022

DASHBOARD CAPABILITY

Stakeholder facing dashboard display of supply trends over time and enhanced features to minimize repopulation (i.e., clone functionality) of same data to improve the user experience and reduce overall survey response burden (see Figure 3).

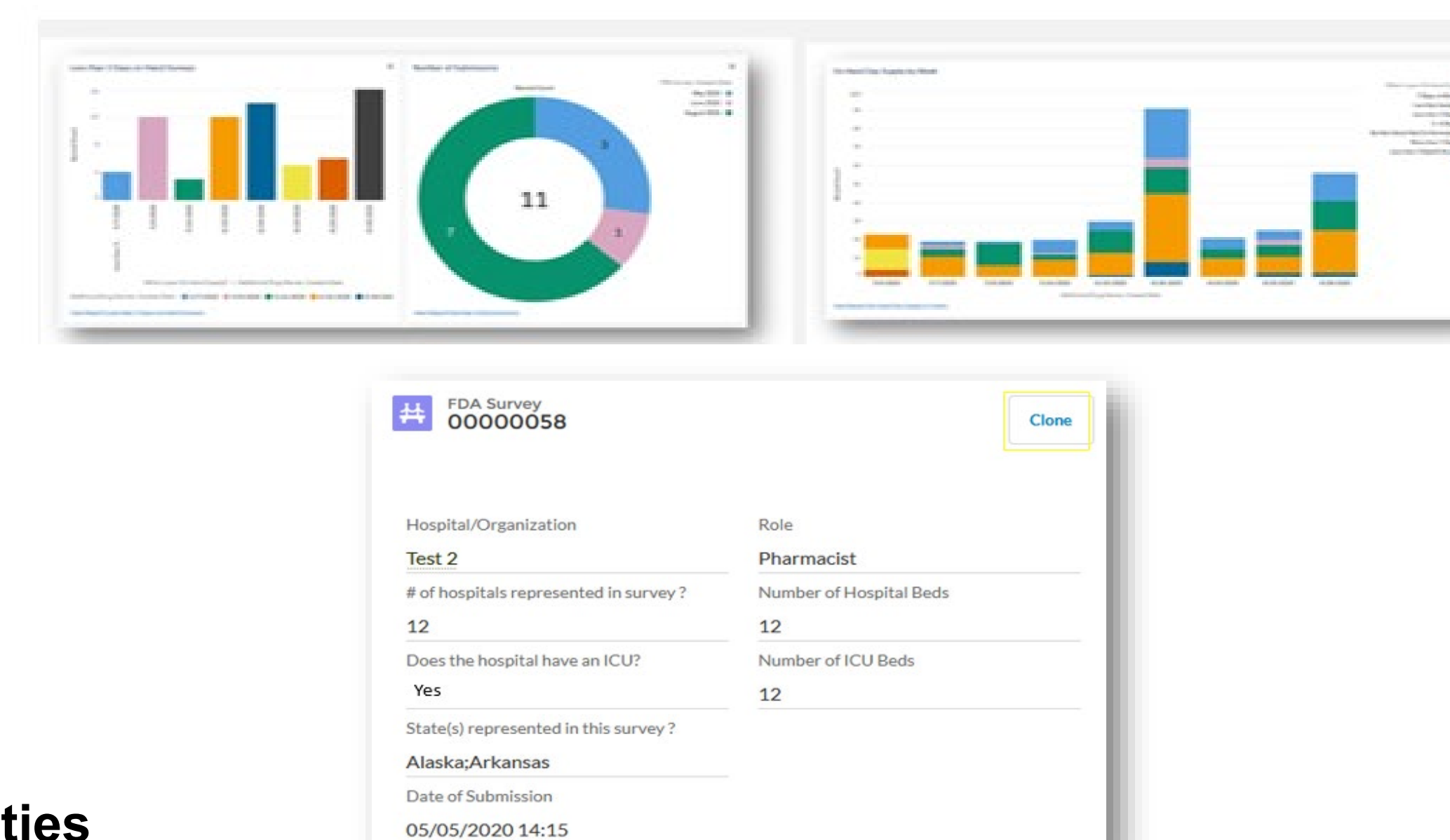


Figure 3. Portal User Capabilities

Conclusion

The CCDMSP provides CDER with vital information on the availability of critical medications. Information provided by U.S. hospitals facilitates early recognition of drug vulnerability for life-saving medications. Portal data on medication supply needs is characterized by trends varying with COVID disease burden and gradually waning reporting frequency over the 3-year duration.

FDA-CDER's role in helping to ensure a safe and sufficient drug supply through several mechanisms including expanding and expediting the generics drug supply and targeting communications with manufacturers and suppliers to focus on critical needs of the American people is strengthened by the CCDMSP. FDA recognizes the indispensable role of hospitals and healthcare organizations in reporting critical drug needs.

Acknowledgments: Thank you to the Frontline hospitals, healthcare workers, and all essential workers across our nation and the globe. Thanks to the FDA and CDER Drug Supply Chain Teams, Quyen Tran, Tala Fakhouri, Adarsh Patel, Seyoum Senay, Katherine McComb, James Zhang, Eric Dzacka, Jeffrey Gruber, Uttara Kelkar, Balaji Bajarang Kharade, Kara Love, Rajesh Vanga, Ashwin Admala, Venu Boppana, Raymond Du, Mathilda Fienkeng, Victor Crentsil, Philip Budashewitz, Karen Hicks, Khair ElZarrad, Mary Ann Slack, and Jacqueline Corrigan-Curay.

Contact FDA if Supply Needed

How to Obtain Supply – Contact FDA Drug Shortage



If you are experiencing drug shortages and need assistance on how to obtain supply, click: Drugshortages@fda.hhs.gov