

FDA COVID-19 Critical Care Drug Monitoring Survey Portal

Rapid Detection of Regional Shortages in Critical Drugs Related to COVID-19 Supply Disruptions

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Abstract

Regional surges in hospitalized patients during the COVID-19 pandemic created significant strain on the supply of certain drugs needed. As a rapid response to the public health emergency, FDA established a secure online voluntary survey platform to monitor drugs identified by healthcare professionals as critical to treating hospitalized patients with COVID-19 at the point of care, providing early warning of drugs vulnerable to supply disruptions (See: <https://informaticsconnect.fda.gov/>).

The goal of this portal is to obtain real-time data on drug supply inventory from hospitals across the U.S. to provide key insights on local and regional drug supply needs to strengthen FDA's existing efforts of identifying drugs needed during the pandemic and beyond.

Introduction

The pharmaceutical supply chain in its usual state is complex for many reasons. Due to the complexity, strain on access to critically needed medicines is exacerbated by factors such as pandemic-related disruptions in global manufacturing and regional spikes in the number of COVID-19 hospitalized patients.

The COVID-19 Drug Monitoring Portal provides FDA with important information on the availability of critical medications, even when those drugs are not in nationwide shortage. This novel system allows early recognition of drug availability issues and strengthens FDA's role in ensuring a safe and adequate drug supply through a proactive stance on preparedness and response activities.

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 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 a weekly basis using a secure online portal. Survey responses were then 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 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 and report on any drug of concern not listed in the survey.

Results and Discussion

Count of Unique Hospitals/Healthcare Organizations

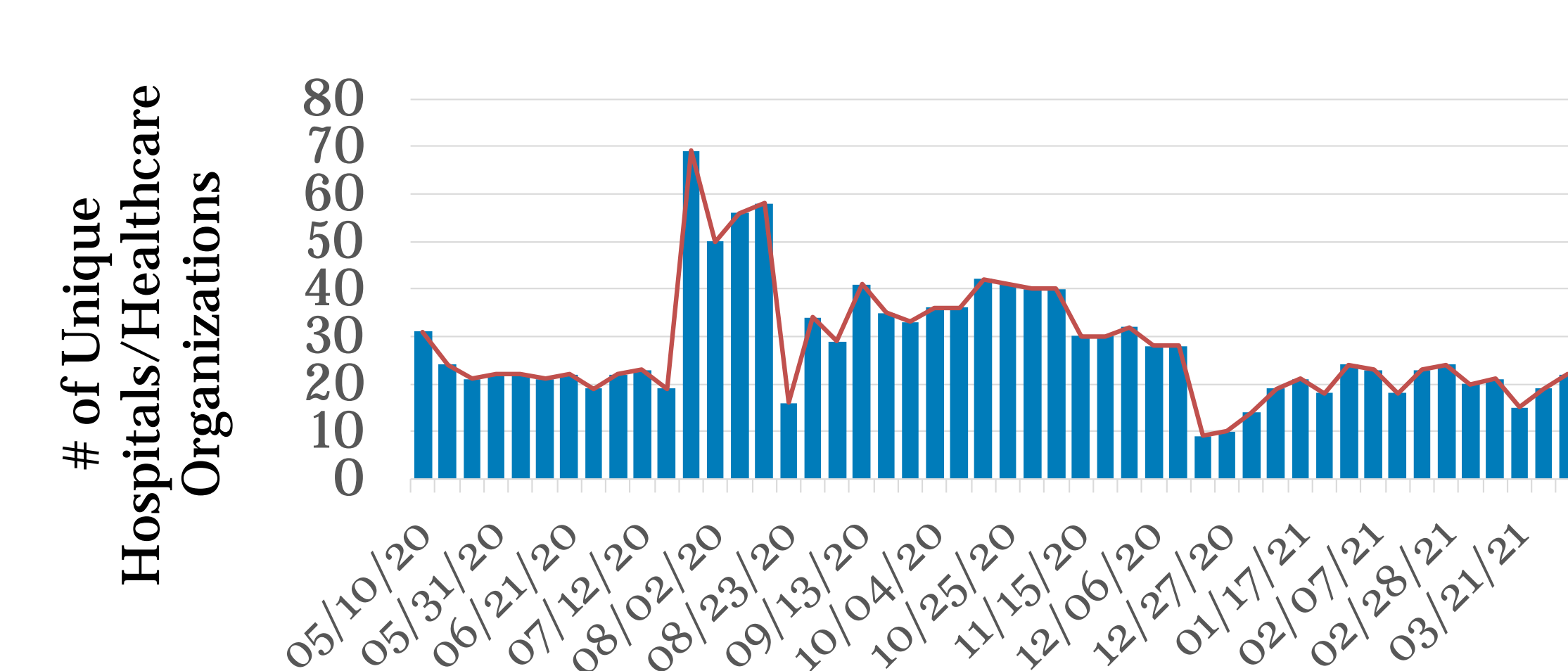


Figure 1. Survey Submissions Over Time

At baseline, 3 to 5 hospitals from each of the US States and Territories were invited to participate. 119 hospitals responded initially [a 43% response rate] (see Figure 1). Weekly follow-up surveys are conducted and over 1375 surveys have been received to date. The number of states reporting ranged from 8 (week of 12/20) to 39 from May to April, with a total of 45 States represented to date. The number of unique hospitals represented weekly ranged from 17 to 648 from May to April. Since May, 42 to 70 drugs were reported per week.

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 that were defined as less than 3 days supply, 3-6 days supply, and 7 or more days supply. Less than 7 days supply was consistently noted for anti-infective, paralytic and sedatives, thrombolytic, and supportive/concomitant medication drug categories.

Aggregated U.S. Hospitals Drug Supply Over Time

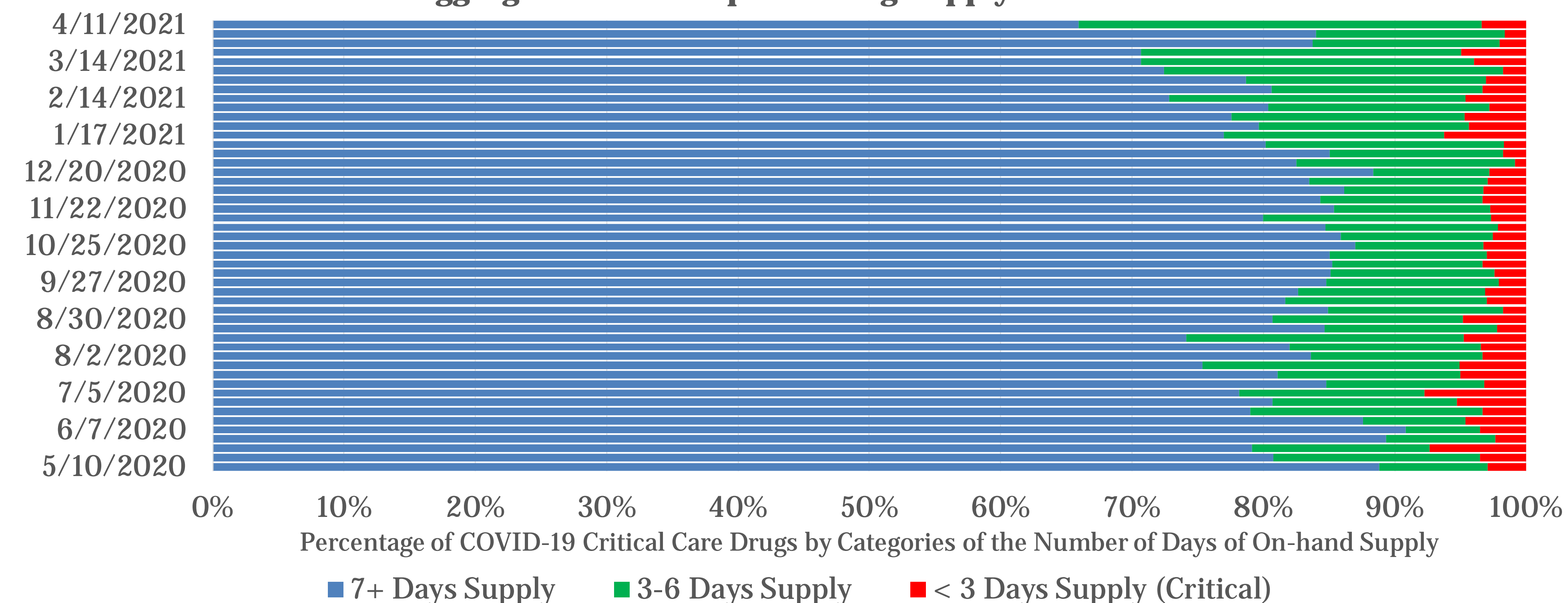


Figure 2. Survey Portal Hospital Supply Trends Over Time

DASHBOARD CAPABILITY

Stakeholder feedback-based enhancements include dashboard display of supply trends over time and features to minimize repopulation of same data to improve the user experience and reduce survey response burden (see Figure 3).



How to Obtain Supply – Contact FDA Drug Shortage



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

Figure 3. Portal User Capabilities

Conclusion

The COVID-19 Drug Monitoring Portal provides FDA with vital information on the availability of medications critical to the care of hospitalized patients with COVID-19.

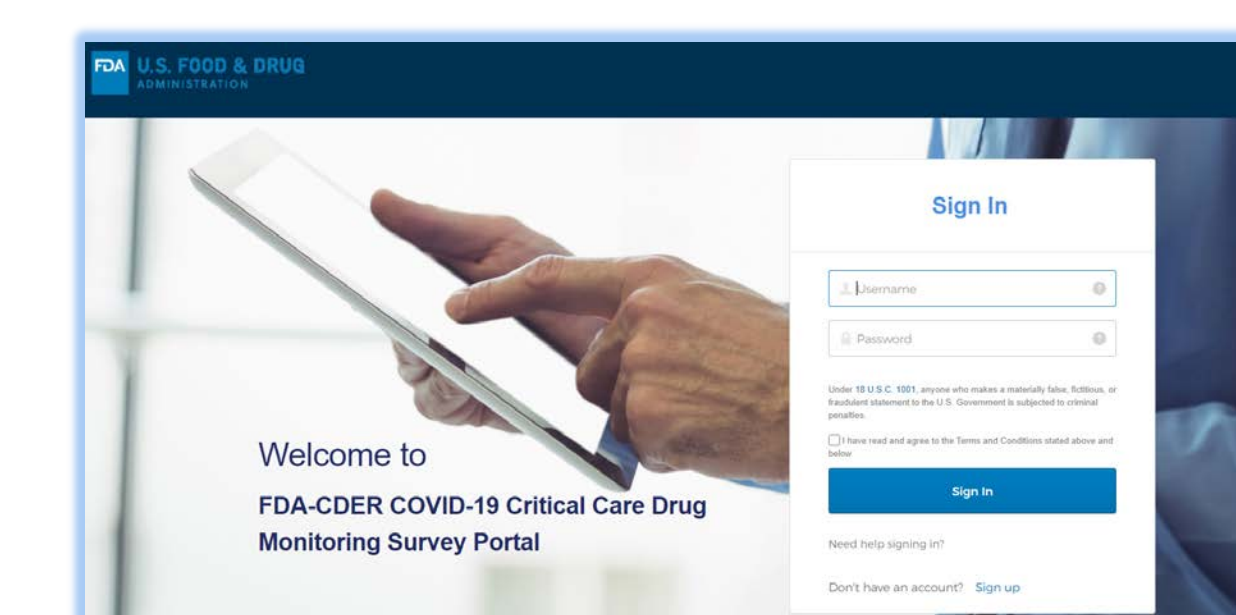
The real-time information provided through collaboration with frontline hospitals across the U.S. allows early recognition of drug availability issues and strengthens FDA's role in helping to ensure a safe and adequate drug supply through usual and novel mechanisms including exercising temporary regulatory flexibility and discretion, expanding the generics drug supply, granting emergency use authorizations, where appropriate, and by targeting communications with manufacturers to focus on critical needs of the American people.

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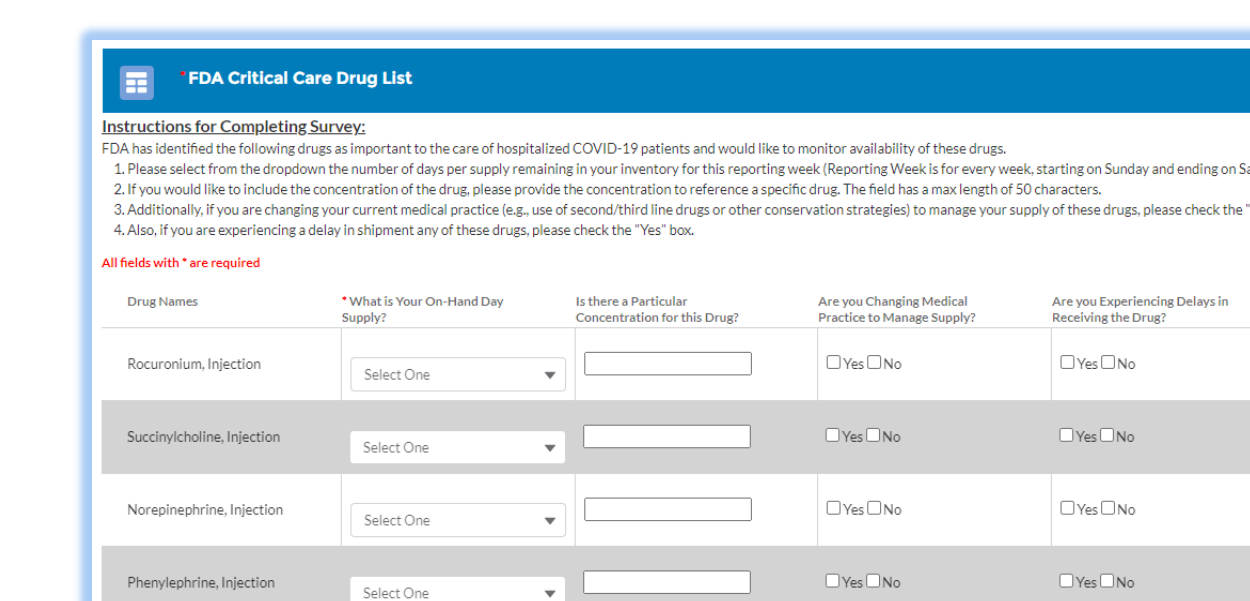
Register Today

If you represent a healthcare organization and are interested in participating, register for the [FDA COVID-19 Critical Care Drug Monitoring Survey Portal](#) (see Figure 4). The survey is intended for pharmacists and administrators familiar with the on-hand days supply of drugs needed by their hospitals or hospital systems.

- 1 Register at URL: <https://informaticsconnect.fda.gov/>



- 2 Enter critical data for the survey



- 3 Submit survey to FDA

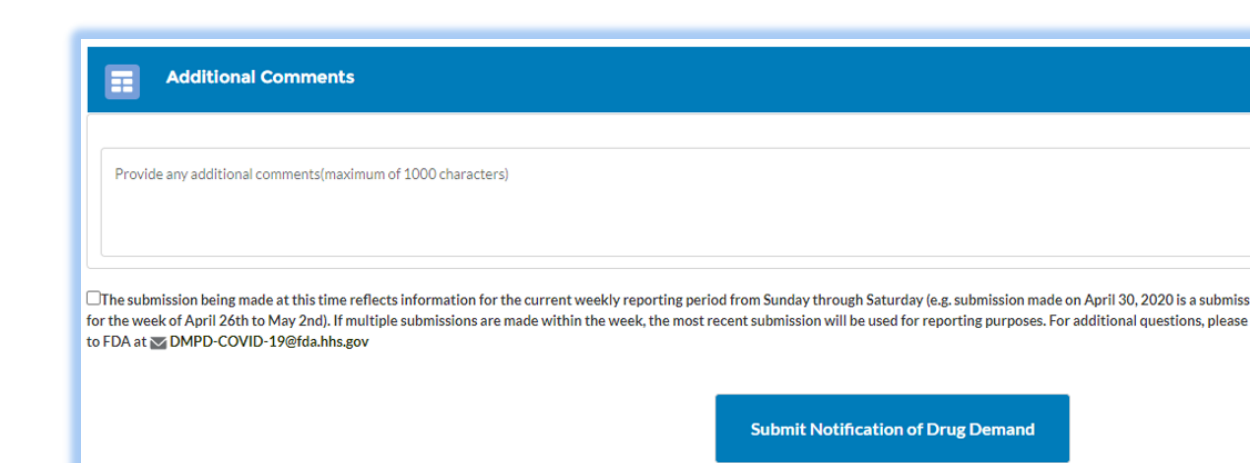


Figure 4. Registration

For any questions or if you would like to speak to someone about survey submission, email us at: DMPD-COVID-19@fda.hhs.gov

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