OMB Control No. 0910-0500 Expiration Date: 9/30/2023

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0500 and the expiration date is 09/30/2023. The time required to complete this information collection is estimated to average 15 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FDA

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov. The survey we are conducting is on behalf of the U.S. Food and Drug Administration (FDA).



Click <u>here</u> to access the portal.

Supported Browsers: Google Chrome*, Mozilla Firefox, Microsoft Edge, and Apple Safari **Preferred for optimal functionality.*

Introduction

The Food and Drug Administration (FDA) plays a vital role in helping to address the Coronavirus Disease (COVID-19) pandemic and recognizes the critical role of your organization. Currently, FDA is working to identify critical care drugs essential for the care and management of hospitalized patients with COVID-19, particularly for those managed in the intensive care units.

Input from you and organizations like yours help to identify drugs that may be at risk of a regional or national shortage. We are requesting for you or another member of your organization to complete a brief survey on a weekly basis. The initial survey will require that you register in FDA's secure portal and complete a quick survey as soon as possible. The information you provide to us should be to the best of your knowledge at the time you complete the survey for the week that the survey is sent, and will be used to help ensure these drugs remain available to meet the needs of your state and our nation.

For any questions or if you would like to speak to someone at the FDA to assist in providing the information in the survey, please reach out to Stephanie Omokaro at the following email: <u>DMPD-COVID-19@fda.hhs.gov</u>.

COVID-19 Critical Care Drug Monitoring Survey



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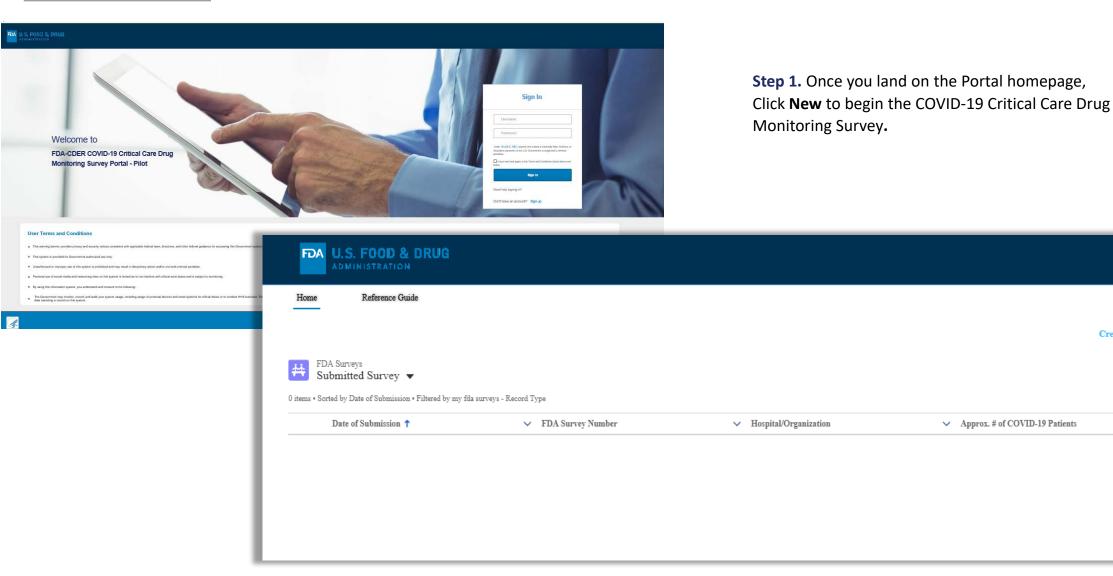
New

Create New Survey Entry All fields with * are required

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Portal Homepage





Hospital/Organization Information

For New Users:

Step 1. Select + New Hospital Organization.

Step 2. From the pop-up window complete the information requested:

- Enter the Hospital Organization name.
- Enter the **Address**.
- Enter the **City**.
- Select the **State** from the dropdown box.
- Enter the **Zip or Postal Code**.

Mandatory fields (*) are required to proceed.

Step 3. Click Save.

For returning users, select the Hospital Organization from the search bar and continue with the survey.

*Hospital/Organization	*Role	
	QNone	
+ New Hospital/Organization	Number of Hospital Beds	
	Critical Care Drug Monitoring	Survey
Net	w Hospital/Organization	
nformation		
nformation *Hospital/Organization		
*Hospital/Organization	Address Ling 2	
	Address Line 2	
*Hospital/Organization	Address Line 2	
*Hospital/Organization Address Line 1	Address Line 2	
*Hospital/Organization Address Line 1	Address Line 2 *Zip or Postal Code	
Hospital/Organization		



Hospital/Organization Information

Step 4. Verify your Hospital/Organization was entered successfully.

Step 5. Complete the information requested:

- Select your **Role** from the dropdown
- Enter the Number of Hospitals/Organization represented in the survey.
- Enter the Number of Hospital Beds.
- Select **Yes or No f**rom the dropdown if there is an Intensive Care Unit (ICU).
- Enter the **Number of ICU Beds**.
- Select the State(s) represented in the survey
 - From the Available column, highlight the State(s). Click forward (▶) arrow to move the selections to the Choose column.
 - To deselect State(s), highlight State(s) from the *Choose* column, hit the **reverse** (
) arrow to move the selections to the *Available* column.
- Enter the Number of ICU COVID-19 Patients non-ventilated
- Enter the Number of ICU COVID-19 Patients ventilated

ADMINISTRATION	New FDA Survey: Critical		
e Reference Guide	*Hospital/Organization	*Role None	Create New Survey Entry All fields with * are required New
• Sorted by Date of Submission • Filtered by my f a Date of Submission ↑	 *# of hospitals represented in survey ? *Does the hospital have an ICU? -None *State(s) represented in this survey ? Available Chosen Alaska Arizona Arkansas 	Number of Hospital Beds Number of ICU Beds	VID-19 Patients V
	* Approx. # of COVID-19 Patients	# of ICU COVID19 Patients non-ventilated # of ICU COVID19 Patients ventilated Cancel Save & New Save	



FDA Critical Care Drug List

Step 7. From the dropdown menu, select the **Number of Days** that correspond to your On-Hand Day Supply for the current week for each drug listed.

Additionally,

- Select the Yes or No checkbox to indicate if your organization has changed its medical practice to manage the inventory for each drug listed.
- Select the Yes or No checkbox to indicate if your organization is experiencing delays in receiving each drug listed.

FDA Critical Care Drug List

Instructions for Completing Survey;

FDA has identified the following drugs as important to the care of hospitalized COVID-19 patients and would like to monitor availability of these drugs

1. Please select from the dropdown the number of days per supply remaining in your inventory for this week.

2. Additionally, if you have changed your current medical practice (e.g., use of second third line drugs or other conservation strategies) to manage your inventory of these drugs, please check the "Yes" box.

3. Also, if you have experienced a delay in receiving any of these drugs, please check the "Yes" box.

All fields with " are required

DrugNames	*What is Your On-Hand Day Supply?		Are you Changing Medical Practice to Manage Supply?	Are you Experiencing Delays in Receiving the Drug?
Rocuronium, Injection	Select One	٠	Ø Yes⊟ No	₩ Yes 🛛 No
Succiny/choline, injection	Less than 2 Days 3 - 6 Days		YesNo	⊖ Yes ⊃ No
Vecuronium, Injection	7 Days or More I am Not Certain		💷 Yez 🖾 No	© Yes ⊠ No
Norepinephrine, Injection	Select One	×	YesNo	UTYES No
Phenylephrine, Injection	Select One	٠	I Yes No	© Yes © No
Vasopressin, Injection	Select One	٠	Yes_No	Ves. No
Azithromycin, Injection	Select One	•	III Yez III No	III Yes III No
Ceftriaxone, Injection	Select One	×	YesNo	Ves_No
Piperacillin/Tazobactam, Injection	Select One	٠	III Yez III No	III Yes III No
Vancomycin, Injection	Select One	*	U/Yes U No	Yes No



Optional Survey

Step 8. Provide information on drugs that are currently on FDA's Drug Shortages List. From the dropdown menu, select the **Number of Days** that correspond to the drug(s) listed with your On-Hand Day Supply for the current week.

Additionally,

- Select the Yes or No checkbox to indicate if your organization has changed its medical practice to manage the inventory for each drug listed.
- Select the Yes or No checkbox to indicate if your organization is experiencing delays in receiving each drug listed.

FDA COVID-19 Critical Care Drug on FDA Shortage List (Optional Survey)

Assist FDA with Monitoring Drugs on the FDA Shortage List

Instructions for Completing Survey:

The following drugs are some of the drugs present on the FDA Drug Shortages list. If you are able, please provide any information on these drugs.

Please complete this survey if you want to report shortages on Cisatracurium, Midazolam, Propofol, Ketamine, Dexmetedomidine, Fentanyl, Hydromorphone, Morphine, Epinephrine, Azithromycin, Cefepime, Cefotaxime, Normal Saline, Dialysis Fluid, Sodium Bicarbonate, Heparin/UFH, and Famotidine.

FDA COVID-19 Critical Care Drug on FDA Shortage List (Optional Survey)

Assist FDA with Monitoring Drugs on the FDA Shortage List

Instructions for Completing Survey:

The following drugs are some of the drugs present on the FDA Drug Shortages list. If you are able, please provide any information on these drugs.

Please complete this survey if you want to report shortages on Cisatracurium, Midazolam, Propofol, Ketamine, Dexmetedomidine, Fentanyl, Hydromorphone, Morphine, Epinephrine, Azithromycin, Cefepime, Cefotaxime, Normal Saline, Dialysis Fluid, Sodium Bicarbonate, Heparin/UFH, and Famotidine.

Drug Names	What is Your On-Hand Day Supply?	Are you Changing Medical Practice to Manage 5	Supply? Are you Experiencing Delays in Receiving the Drug?
Cisatracurium, Injection	Select One	¥ Yes □ No	Yes □ No No
Midazolam, Injection	Less than 3 Days 3 - 6 Days	U Yes No	⊡ Yes ⊃ No
Propofal, Injection	7 Days or More I am Not Certain	I Yes No	S Yes S No
Ketamine, Injection	Select One		⊖Yes⊡ No
Dexmetedomidine, Injection	Select One	₩ Yes © No	□ Yes □ No
Fentanyl, Injection	Select One	Yes⊡ No	⊡ Yes ⊡ No
Hydromorphone, Injection	Select One	▼ Ves □ No	Ves No
Morphine, Injection	Select One	✓Yes No	⊡ Yes □ No
Epinephrine, Injection	Select One	¥ Yes No	S Yes No
Azithromycin, Oral	Salect One	▼ UYesUNo	



Additional Drugs Not Listed

Step 9. Click **New** to report information on Additional Drug(s) not listed.

Step 10. From the pop-up window complete the information requested:

- Enter the Drug Name.
- Select your **On-Hand Day Supply** from the dropdown.
- Click the checkbox to indicate if your organization is changing its medical practice to manage the supply for the drug.
- Click the checkbox to indicate if your organization is experiencing delays in receiving the drug.

Step 11. Click Save.

Additional Drugs Not Listed Please add any additional drugs that your hospital/organization is concerned about. Drugs Name ~ **New Additional Drug Names** * Drug Name What is Your On-Hand Day Supply? Select One Are you Experiencing Delays in Are you Changing Medical Practice to Manage Supply? Receiving the Drug?



COVID-19 Critical Care Drug Monitoring Survey



Additional Comments

Step 12. Add Additional Comments.

Submit the Survey

Step 13. Click the checkbox to verify the information submitted is for the current week.

Step 14. Click Submit Notification of Drug Demand.

Step 15. Click OK to confirm submission.

Receiving Notification(s) from FDA

You will receive an email confirming your submission of the COVID-19 Critical Care Drug Monitoring Survey.

I		Additional Comments			
	Provide any additional comments(maximum of 300 characters)				
	The submission being made at this time reflects information for the current weekly reporting period from Sunday through Saturday (e.g. submission made on April 30, 2020 is a submission made for the week of April 26th to May 2nd). If multiput submissions are made within the week, the most recent submission will be used for reporting purposes. Excedditional questions glasses betweek to EDA at				
		Confirm	n Submission		
	Press OK button below to confirm your submission				
			Cancel		

Thank you for submitting your Critical Care Drug Survey. Your FDA Survey Number is 00000145. Please use this FDA Survey Number to uniquely identify this submission to the FDA. Please log in to the FDA-CDER COVID-19 Critical Care Drug Monitoring Survey Portal-Pilot to review your submission; https://informaticsConnect.fda.gov

Please note that no further action is needed at this time on your end. If you identify changes or corrections are needed, please contact OMP Drugs Team at DMPD-COVID-19@fda.hhs.gov.

For technical support, contact the Informatics Connect Portal Support Team here

** Please do not reply directly to this message. This is an automatically generated email and replies will not be monitored. **