

Rx Response State Emergency Management Response Protocol

Draft Version: May 2010



State emergency management departments play a critical role in responding to disasters and lessening negative impacts on public health. However, a major issue many states face in responding to a disaster is enabling communication and problem-solving with private sector entities positioned to provide resources and information.

In order to support public-health related response, members of the biopharmaceutical supply system sponsored the development of an unprecedented program called Rx Response. Rx Response provides an information-sharing and problem-solving forum for the private biopharmaceutical supply system, disaster relief agencies and government to help ensure the continued delivery of critical medicines to patients whose health is threatened by a severe public health emergency. The cornerstone of Rx Response is the reliance on the existing biopharmaceutical supply system to provide for the continued flow of medicine in a major public health emergency; Rx Response can be used during a severe natural disaster, a large-scale terrorist attack, or a pandemic that creates disruptions to the normal supply of essential medicines.

This document is meant to be added as an annex to State Disaster plans to summarize the Rx Response program as it relates to state emergency management. *NOTE: This document is intentionally left in draft form for now; please feel free to suggest modifications that would better integrate into your existing policies and operations, and better serve your needs.*

Program Description

This program provides a single point of contact for the private sector biopharmaceutical supply system, enabling requests for information, biopharmaceutical supply status, or pharmacy status. The members of the Rx Response coalition (referred to in this document as “member organizations”) include:

- American Hospital Association (AHA)
- American Red Cross
- Biotechnology Industry Organization (BIO)
- Generic Pharmaceutical Association (GPhA)
- Healthcare Distribution Management Association (HDMA)
- National Association of Chain Drug Stores (NACDS)
- National Community Pharmacists Association (NCPA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)

As all member organizations (except the American Red Cross) are trade groups, each represents a number of private companies in their respective specialties. In this document, these private companies are referred to as “member companies”.

Resources Available

1. Rx Response produces a biopharmaceutical supply system status report available at <http://infocenter.rxresponse.org> during emergency activations. An abbreviated status report is also publicly available at www.rxresponse.org. Status report information includes events impacting critical medication supply in the following areas:
 - a. Manufacturing (e.g., a facility that produces a critical medicine has been flooded and will not be operational)
 - b. Distribution (e.g., road closures or credentialing barriers that prevent delivery of biopharmaceuticals)

Medicines to patients in times of emergency

- c. Dispensing (e.g., community pharmacies that have re-opened in the impacted area)
- 2. Rx Response supports a communications network to the biopharmaceutical system that can broadcast product, resource, or information requests on behalf of State Emergency Management and Public Health. Examples of communications may include (but are not limited to):
 - a. Manufacturing:
 - i. Requests for biopharmaceutical product
 - b. Distribution:
 - i. Requests for biopharmaceutical product
 - ii. Requests for assistance in distribution capability (trucks, storage facilities, etc)
 - c. Dispensing:
 - i. Requests for biopharmaceutical product
 - ii. Requests for mobile pharmacy placement in an Area of Operations
 - iii. Information to pharmacies regarding patient assistance programs, executive orders that affect pharmacy refills, or public health emergency orders.
- 3. Rx Response can provide a liaison, if requested, for staffing at the State EOC, Health Operations Center, or Business Operations Center, as appropriate.
- 4. The program's Pharmacy Status Reporting Tool is activated when large-scale infrastructure impacts may affect community pharmacies from opening. This mapping tool of pharmacies that have had prescription billing activity is available to the public at www.rxresponse.org and to State Emergency Management and Public Health at infocenter.rxresponse.org. There is also an FAQ on the Pharmacy Status Reporting Tool available on the Rx Response website. This resource will assist with situational awareness for Emergency Management and Public Health, as well as serve as a resource for the public seeking pharmacy services.

Contact information

| | |
|------------------------------------|--|
| Web Sites | www.rxresponse.org and http://infocenter.rxresponse.org (login required) |
| Email Addresses | alerts@rxresponse.org : Email address for disaster-related information, product requests, or requests for information. |
| | reports@rxresponse.org : Email address for recurring reports such as situation reports. |
| | contactus@rxresponse.org : General outreach to Rx Response program, and non-disaster related communications. |
| | admin@rxresponse.org : Email address to assist users with website access or functionality. |
| Operations Center Phone | 866-247-2694 202-715-7200 |
| Operations Center Fax | 202-715-7124 |
| Primary Operations Center Location | 950 F Street, NW (Suite 300) Washington D.C. 20005 |

Activation Process

The program will proactively activate to support state and federal emergency public health and medical personnel (e.g. ESF8) as well as clinical providers & organizations, or to support the private biopharmaceutical supply sector's return to service operations. Because existing relief plans and emergency medical service programs are sufficient to address local or smaller regional public health emergencies, the Rx Response program will focus on addressing major domestic public health emergencies of national significance rather than those emergencies that affect a limited population or geographic area. While public health emergencies will be determined on a case-by-case basis, there are a number of existing mechanisms that will be used by Rx Response to help guide decision-making:

- Disaster declaration by a Governor or the President; and/or
- DHS Threat Advisory Red/Severe Classification; and/or
- Health and well being of a significant number of persons is materially threatened or affected; and/or
- Local, regional, national, or global healthcare infrastructure is significantly compromised; and/or
- Ability to provide ample biopharmaceuticals in sufficient quantities or in a timely fashion is challenged; and/or
- The underlying disaster dynamics are not quickly or simply resolved (e.g. within several days or through normal business practices by individual companies); and/or
- Requests by the media for information on greater than normal demand or shortages within the biopharmaceutical supply system; and/or
- Other situations warranting a response as determined by the respective decision-making bodies within the represented industry groups

| Event Description | Effect on Biopharmaceutical Product | Rx Response Strategy |
|--|--|---|
| Localized Events (e.g., tornado, localized bombing, flu outbreak) | Minimal; normal supply system expected to address limited barriers (if any) | <ul style="list-style-type: none"> • Monitor and report event-specific information, as appropriate |
| Regional Natural Disasters (e.g., earthquakes, fires, floods and hurricanes) | Potentially significant; biopharmaceutical product may not be able to reach disaster area or cannot be prescribed or dispensed. | <ul style="list-style-type: none"> • Activate the program • Monitor the situation • Share information with partners • Identify and resolve barriers, where possible and appropriate |
| Large-Scale Acts of Terrorism | Potentially significant; biopharmaceutical product may not be able to reach disaster area or cannot be prescribed or dispensed. | <ul style="list-style-type: none"> • Activate the program • Monitor the situation • Share information with partners • Identify and resolve barriers, where possible and appropriate |
| Pandemic Events | Collective forum to work with government agencies to address barriers to critical product delivery; voice to HHS response leadership and DHS Critical Infrastructure | <ul style="list-style-type: none"> • Activate the program • Monitor the situation • Share information with partners |

| | | |
|--|---------|---|
| | Program | <ul style="list-style-type: none"> Identify and resolve barriers, where possible and appropriate |
|--|---------|---|

Timelines

- Monitoring will begin 72-96 hours pre-impact for with-notice events.
- No-notice events will require at least 24-48 hours for assessments to be conducted and reported.
- Communications to member organizations (Coordinating Body members) and member companies (private biopharmaceutical supply system companies represented by Coordinating Body members) can be completed 1-2 hours from time of request.
- Product or resource delivery timelines are dependent on the specific companies that are responding to the request.

Notifications

- State Emergency Management or ESF8 should contact the Rx Response program (alerts@rxresponse.org) 72-96 hours pre-impact for with-notice events.
- State Emergency Management or ESF8 information for partners such as situation reports, incident action plans, or press releases that involve biopharmaceuticals or pharmacy operations should be sent to alerts@rxresponse.org.
- Product, resource or information requests can be inputted on the Rx Response website (<http://infocenter.rxresponse.org>), emailed to alerts@rxresponse.org, or phoned into the Operations Center at 866-247-2694.

Potential Requests for Information

The following table contains information essential to public health emergency response. Although Rx Response member companies may provide some of the information below, states are encouraged to provide situation reports and other spot reports with any of the data noted below.

| | |
|---|---|
| Road closures | Airport / port closures |
| Hospital status | Pharmacy status |
| Fuel issues | Security exposures |
| Open alternate medical treatment facilities and other locations where medical treatment is taking place | Disaster declarations |
| Infrastructure damage impacting the storage of biopharmaceutical product | Anticipated alternate standards of care and impact on product need |
| Statutes and regulations activated specific to public healthcare delivery (licensing and liability) | Credentialing requirements for Critical Infrastructure workers seeking access to impacted areas |

Limitations

- Member companies act as first-line responders. Rx Response cannot act as a broker/vendor or direct operations of member companies.
- As a coalition of trade associations, Rx Response cannot collect proprietary information that would violate anti-trust laws such as inventory and/or manufacturing capacity. However, Rx Response can



communicate requests for information on behalf of emergency management and public health to the appropriate owner/operators.



InfoCenter Access Instructions for State Emergency Management/Public Health Officials

To access the site go to:

- <http://infocenter.rxresponse.org>



Please Sign In to Access InfoCenter

Email Address:

Password:

Keep me signed in automatically for two hours (only select if you are at a private computer)

[Forgot Password?](#) | [Request Access to RxResponse.org InfoCenter](#)

- If you do not already have access to the site, click on “Request Access to RxResponse.org InfoCenter” to fill out a form and request access.
- Once your access has been approved and you have received login information, enter your email address as the User ID (xxxxx@xxx.xxx) and the password you set up when requesting access. If it is your first time logging in, you will be redirected to a screen showing the terms and conditions of use, which you must accept to log in.

Although most users provided some contact information to Rx Response, which may be maintained in InfoCenter already, we ask that all members ensure their contact information is up-to-date and complete.

- Please consider providing the following information:
 - Work phone, address and email (mandatory)
 - Home phone (strongly recommended) and alternate email
 - Mobile phone (strongly recommended)
 - Company (strongly recommended)
 - Profile Group (strongly recommended)

Note: If you check “Hide from Public View,?” this information can still be used for automated telephonic and email notification without being displayed to the Rx Response community.

- To update and add contact information, please follow this instruction:
 - On the main page, click on the link “My Profile” in the top right side of the screen, as shown below:



- Update any fields in this screen which require updating. Again, if you check “Hide from Public View?” on any available fields, this information can still be used for automated notification without being displayed to the Rx Response community.

The screenshot shows the 'Rx RESPONSE INFOCENTER' interface. At the top, there are navigation links: Home, Emergencies, Calendar, Documents, Contacts, Profiles, Site Administration, and a search bar. Below this, the page title is 'RxResponse.org InfoCenter'. The main content area displays a contact record for 'stacy.gardner@control-risks.com'. The form has several sections: 'First Name' (Stacy), 'Last Name' (Gardner), 'Full Name' (Stacy Gardner), 'Email Address *' (stacy.gardner@control-risks.com), and 'Company' (Control Risks). There is also a 'Hide from public view?' section with an unchecked checkbox. At the top right of the form are 'OK' and 'Cancel' buttons. At the top left of the form are 'Delete Item' and 'Spelling...' options. A note at the top right of the form states '* indicates a required field'.

- Once you click “OK” to save changes, you will then be redirected back to the main page.

InfoCenter During an Incident

During an emergency, Rx Response will create an emergency specific page to capture all activities and information relevant to the specific incident. This page will include various information-sharing modules, including a document repository, discussion board, relevant links and announcements. In addition to these modules, InfoCenter also has three extremely important information-sharing capabilities: a situation report, product request process and information request process. Each module is discussed below.

Situation Report Overview

The Rx Response Situation Report contains predefined fields to which all participants can contribute relevant information, when logged on to the private InfoCenter site. All information must be reviewed by administrators, as well as a legal representative, before it is approved to be viewed by general users. The situation report summarizes the situation at a high level, including key facts, government actions, barriers to protecting public health, and more. All fields of the situation report that contain information are automatically displayed on the emergency homepage. A scaled down, public version of the situation report is also displayed on the “Emergency Management” link on the main page of www.RxResponse.org.

Situation Report

Status

Crisis Criteria

An Executive Order declaring a state of emergency has been signed.

Gov. Charlie Crist asked the president on Friday for federal aid to remove debris and repair roads, bridges and other public property ravaged by storms and floodwaters across 11 North Florida counties. In a letter to President Barack Obama, the governor also requested hazard mitigation grants for the entire state and direct federal assistance to save lives and property where needed, including flood plain mapping assistance, swift water rescue support and food and water for flood victims. But Crist signaled he would probably expand his request later because the flooding isn't over.

Evacuation

A few low-lying areas are following evacuation orders.

Please see the latest [Florida Disaster Incident Report](#) for the detailed list.

Facts

Weather Summary

-A strong storm system will affect North Florida Monday April 13 through Tuesday morning. A squall line of strong to severe thunderstorms is expected to strengthen as it traverses the Interstate 10 corridor from Monday evening into the overnight hours. Severe thunderstorms will be possible across the Florida Panhandle, spreading east toward the Big Bend and Northeast Florida Peninsula later this afternoon and tonight.

-Damaging winds, large hail and isolated tornadoes will be possible and the Storm Prediction Center has placed much of North Florida in a slight risk area for severe thunderstorms

To add information to the situation report, log in to InfoCenter (<http://infocenter.rxresponse.org>), click on the emergency name and then "Situation Report" in the left side of the screen. Once the page refreshes, click on the name of any section of the situation report you would like to edit, then click on "Edit Item" next to the item you'd like to update, make the appropriate updates, then click "OK". Rx Response administrators will automatically be notified of your submission. Until they approve or reject the content, it will only be visible to you and administrators. The list below captures all standard topics in the situation report:

- Credentialing Issues
- Crisis Criteria
- Distributor Status
- Energy
- Evacuation
- Event Duration
- Facts
- Fuel Issues
- Government Actions
- Hospital Status
- Human Health Impact
- Licensing Issues
- Objectives
- Other
- Payment Issues
- Personnel Needs in the Disaster Area
- Pharmaceutical Manufacturing Status
- Pharmacy Status
- Pharmacy Warehouses Status
- Public Authority in Charge
- Shelter Openings
- Special Needs Shelter Openings

Product Request Overview

Rx Response has developed a product request process that enables state emergency management to submit requests for biopharmaceutical products, if the normal biopharmaceutical supply system is unable to meet the need. Once submitted, the product request will be communicated to all Rx Response participants who have subscribed to receive alerts. The member companies will be responsible for contacting the requestor directly to coordinate filling the product request. If a member company is able to fill the product request, either they or the requestor will need to alert Rx Response that the request has been completed.

In order to submit a product request, log in to the InfoCenter site (<http://infocenter.rxresponse.org>). Click on the active emergency name, then click “Product Requests”. The page will refresh and display any submitted product requests, as well as the status of each. To submit a new product request, click on “New”, and then “New Product Requests”. The page will refresh and display the product request form. Fill out the form, making sure to complete any mandatory fields (indicated with an asterisk), then click “OK” when finished.

| Field | Explanation |
|--|---|
| Title * | Detailed title description of the request (treat like a subject line of an email) |
| Requester Name, Phone, Email, Agency Affiliation, Title* | Contact information for the person making the request, for clarifications and follow-up. Please note that notifications of changes to your product request will be based on this information and not your InfoCenter contact information. |
| Requester Tracking Number * | Facilitates follow-up to ensure that requests have been answered. |
| Secondary Requester Name, Phone, Email Address | While not required, an additional contact will be extremely helpful to expedite requests in case the Requester is not available. |
| Minimum Required Quantity * | Minimum acceptable amount of product |
| Maximum Required Quantity | (not a required field) – if you have storage or other concerns about receiving too much product |
| Type of Medication | Be as specific as possible. Drug name, strength, dosage form and package size, if known |
| Units | e.g., each / case / pallet |
| Delivery Site Contact Name, Phone, Email Address, Title * | Contact information to facilitate delivery |
| Delivery Site Alternate Contact Name, Phone, Email Address, Title | While not required, an additional contact will be extremely helpful to expedite delivery in case the primary contact is not available (e.g., day vs night shift). |
| Delivery Site Street, City, State, Zip * | Location to which the product should be delivered |
| Affiliated Medical Facility Fields | If the delivery site is acting under the license and authority of an existing medical facility (e.g. request is to supply a hospital Alternate Medical Treatment Site that is not located on the campus of the hospital), please provide as much information about the affiliated facility as possible. |
| When is it needed? | Normal biopharmaceutical deliveries can be delivered next business day. Please account as much as possible for delivery delays which may occur during disaster (such as road closures, excessive traffic, multiple credentialing checks). |
| Comment Box | Any additional relevant information, such as acceptable substitutes, preferred delivery times, access routes, storage challenges (refrigerators/freezers), or a more complete description of the need which may assist the member companies in determining how best to fill your needs. |

While entering the product request on the Rx Response website will be the method that is likely to result in the fastest response, product requests can also be submitted over the telephone by calling the Rx Response operations center (866-247-2694 or 202-715-7200), or via email to alerts@rxresponse.org.

Information Requests

Rx Response has also developed an information request process to communicate and track information requests, submitted either by Rx Response participants or state Emergency Management. Similar to the product request process, a requestor need only fill out a form, which will then be communicated out to either a select group of Rx Response participants, as appropriate, or all members of the Rx Response program. The fields are shown below:

| Field | Explanation |
|---|--|
| Title * | Detailed title description of the request (treat like a subject line of an email) |
| Requester Name, Phone, Email, Agency Affiliation, Title* | Contact information for the person making the request, for clarifications and follow-up. Please note that notifications of changes to your information request will be based on this information and not your InfoCenter contact information |
| Requester Tracking Number * | Facilitates follow-up to ensure that requests have been answered |
| Secondary Requester Name, Phone, Email, Agency Affiliation, Title* | While not required, an additional contact will be extremely helpful to expedite requests in case the primary requester is not available |
| Request | Be as specific as possible in capturing the information requested from the Rx Response program |
| Target Completion Date | Date when the information is needed by |
| Request Comments | Any additional relevant information or a more complete description of the information request which may assist the program in determining how best to respond to your request |

While entering the information request on the Rx Response website will be the method that is likely to result in the fastest response, information requests can also be submitted over the telephone by calling the Rx Response operations center (866-247-2694 or 202-715-7200), or via email to alerts@rxresponse.org.

Pharmacy Status Reporting Tool

In response to the known knowledge gap of open pharmacy awareness in public health emergency response, Rx Response has developed an innovative Pharmacy Status Reporting Tool in collaboration with its partner, the National Council for Prescription Drug Programs (NCPDP). This tool - which works on a GIS mapping format and is updated daily during emergencies - allows citizens and government officials alike a means to determine which pharmacies are open and operational in affected disaster areas. The goal of this tool is both to restore an avenue for patients to get their critical medicines and give emergency management officials more raw data on where power restoration is taking place -- which in turn allows EM officials to better track repatriation levels and trends.

| Pharmacy Reporting Tool Functionalities | | |
|--|--------------|---|
| # | Action | Description |
| 1 | Green Icons | These represent presumed open pharmacies. Rx Response presumes pharmacies are open if they are billing prescriptions (information provided by NCPDP). Hovering over an icon prompts a pop-up box that displays the pharmacy's contact & location information. |
| 2 | Yellow Icons | These represent pharmacies with unknown operating statuses. Though Rx Response has verified these pharmacy locations through NCPDP, pharmacy switches have not received billing information from these pharmacies. Hovering over an icon prompts a pop-up box that displays the pharmacy's contact & location information. |
| 3 | Red Circles | These represent issues reported by pharmacies to Rx Response that hinder reopening. This function is currently being developed and should be operational in the summer of 2009. Hovering over an icon prompts a pop-up box that displays the pharmacy's contact & location information (<i>not shown in the image below</i>). |



| Pharmacy Reporting Tool Functionalities | | |
|---|--------------------------|---|
| # | Action | Description |
| 4 | Search Box | This box allows users to input a location (address, zip code, city, or state), and view a downloadable list of open pharmacies within a range of that location. |
| 5 | Download the entire list | This allows users to download a list of all pharmacies for which Rx Response has information. State government officials can then input this information into their own GIS tracking tools. |

Here is an example of the Pharmacy Status Reporting Tool and its functionalities:

If your state is experiencing an emergency and would like to request that Rx Response activate the Pharmacy Status Reporting Tool for your area, please send an email to alerts@rxresponse.org.

Key Response Procedures

| Non-Crisis Actions | | |
|--------------------|--|---|
| # | Procedure Description | Communications Process |
| 1 | On a regular basis, log in to InfoCenter and verify / update your contact information. Review the information posted to your state profile for accuracy and completeness. Periodically review the on-line InfoCenter training to stay familiar with key functionality. | http://infocenter.rxresponse.org |



| | | |
|---|---|---|
| 2 | When coordinating a crisis management exercise, consider inviting Rx Response to participate as a representative of the private sector. | Email to contactus@rxresponse.org |
| 3 | As you are made aware of laws or legislation for your state that relate to public health in time of disaster, consider notifying Rx Response. | Email to contactus@rxresponse.org |
| 4 | Consider adding this document as an annex to your state crisis management plan, with appropriate customizations addressing your unique process. Share any revisions with Rx Response, which will be posted to your state profile. | Email to contactus@rxresponse.org |
| 5 | Consider working with Rx Response to include biopharmaceutical product preparedness in proactive awareness materials targeting the state's population, including the use of the wallet card found on www.rxresponse.org . | Email to contactus@rxresponse.org |

| <i>In Time of Crisis Actions</i> | | |
|---|---|---|
| # | <i>Procedure Description</i> | <i>Communications Process</i> |
| 1 | Once you are made aware of a disaster, consider notifying the Rx Response program director (the Rx Response staff member responsible for the program on a day-to-day basis) to expedite response to protect the biopharmaceutical supply chain. | Email to alerts@rxresponse.org |
| 2 | Visit InfoCenter and review updated information postings, including the situation report, discussion board, calendar and product request page. <i>If this is a "with notice" event (e.g. a hurricane), the situation report will address assumptions regarding issues affecting patents' ability to proactively obtain additional biopharmaceutical product and pharmacy closure plans.</i> | http://infocenter.rxresponse.org |
| 3 | Include Rx Response in any mailing lists for communicating situation reports and/or other documents relevant to response efforts. Information deemed helpful to position Rx Response as an effective response partner include: <ul style="list-style-type: none"> ▪ The state's "reentry" plan, inclusive of FEMA, State and County plans (where shelters may be setup, where alternate treatment facilities may operate, and locations where DMATs and FMSs will function) ▪ At a high level, the size, location and characteristics of vulnerable populations, priority for response and relocation areas ▪ State plan information and need (inclusive of local information summarized): <ul style="list-style-type: none"> ○ Local assumptions ○ Local population profile ○ Local consequences projections ○ Local resource needs ○ Local gap analysis (Pods, SNS, FMS, DMAT, etc.) <p>[This information should be communicated via email and product request functionality on InfoCenter]</p> <ul style="list-style-type: none"> ▪ Security issues impacting the ability to move and position biopharmaceutical product | Email to reports@rxresponse.org |

| | | |
|---|---|--|
| | <ul style="list-style-type: none"> ▪ The process by which healthcare workers enter the disaster area and generally where they are performing mass treatment ▪ Alternate standards of care and the implications to biopharmaceutical product supply (anticipated) ▪ Issues with power and/or the sourcing of refrigeration / climate controlled storage for biopharmaceutical product | |
| 4 | Consider inviting an Rx Response member to participate in person or virtually at your EOC operations, as appropriate. | Email to alerts@rxresponse.org |
| 5 | Consider inviting Rx Response participants to participate via conference call in your EOC meetings, and participate where possible in the Rx Response conference calls (see the InfoCenter calendar for dates and times). | Email to alerts@rxresponse.org ; information will then be posted on InfoCenter |
| 6 | Communicate any biopharmaceutical product or pharmacy supply system information needs that the individual members of Rx Response may be positioned to address. Information needs may include resupply requests for DMATs and FMSs. | http://infocenter.rxresponse.org (Product Request Page) Email to : alerts@rxresponse.org Phone in requests: 866-247-2694 202-715-7200 |
| 7 | Participate in Rx Response lessons learned meetings to discuss program enhancement opportunities. | Meetings or conference calls |

Continuing Outreach and Next Steps

Though Rx Response will work to keep information up to date, state emergency management can assist in this effort by notifying Rx Response when key contact members change or laws pass which affect health care delivery in each state, especially regulations and statutes affecting licensing and liability. As states conduct crisis management exercises, it will be mutually beneficial to include Rx Response, as it will educate both parties on the resources the other group can offer in an actual event, as well as familiarize participants with tools such as InfoCenter or the structure of the state’s emergency management and public health departments.

This document is meant to provide a high-level overview of the Rx Response program as it relates to state emergency management. If more in-depth questions arise, or additional outreach is needed, please contact an Rx Response representative at contactus@rxresponse.org.

