March 23, 2020

COVID-19 has now been detected in 173 countries/regions internationally, with 33,276 cases confirmed in the United States as of the evening of March 22. Additionally, on March 11, the World Health Organization (WHO) made the assessment that COVID-19 can be characterized as a pandemic.

Vizient continues to monitor the rapidly evolving situation and provide general updates as we learn new information. Below are high-level insights into how the disease is impacting the supply, pharmaceutical and clinical environments as well as opportunities to register for educational web offerings.

Note: In response to multiple member inquiries regarding challenges accessing the supplies needed to care for patients, Vizient has implemented a COVID-19 Disaster Response War Room. Should you require assistance during these challenging times, we stand prepared to assist your efforts. Please contact us at DisasterResponse@vizientinc.com

Medical/Surgical Supply Impact:

As the pandemic continues, we are seeing a few emerging trends across the market:

- **Suppliers focused on existing customers** – Given the increasing acuteness of supply shortages and the ongoing rise in the number of COVID-19 cases in the U.S., we have heard from suppliers that they are now focusing on honoring their commitments with their existing customers.

- **Gray market activity on the rise**
  
  - Product availability scams for specific products in high demand (masks, gloves, sanitizer, etc.), large quantities of product and product at unrealistic prices.
  - Cyber and phishing scams with similar internet sites and email domains.
  - Vizient has received 17 requests from members to review companies who claim they may be able to provide members with needed supplies including lab tests, swab tests, PPE, gloves, N95 masks, hand sanitizer, and general medical and dental supplies.
    - We have reviewed and recommended against moving forward with two companies.
    - 15 reviews remain are underway (8 with Vizient team and 7 with suppliers for their response).
  - We encourage members to remain vigilant to ensure that products are from establishments properly registered by the Food and Drug Administration (FDA) and that include the accompanying FDA device listing.
  - Pursuant to a contract award, Vizient requires the following up-front information from all suppliers:
    - A copy of the Establishment Registration Number or Firm Establishment Number as assigned by the FDA.
    - A copy of the [Device Listing](#) along with the Regulation Number of the specific device.
Both of the above documents can be printed in PDF format directly from the FDA’s website. Without this information, we are unable to determine that the supplier is properly registered and the device is available for commercialization by that specific supplier. Lack of this basic documentation is a “red flag” of potential gray market activity.

- If you receive an offer to purchase high-demand products (masks, gloves, sanitizer, etc.), large quantities of product and/or products at unrealistic prices, please contact us for help in vetting suspicious establishments at DisasterResponse@vizientinc.com.

Below are manufacturing status updates as of March 23:

- **PPE** – We are seeing a surge in demand and, with much of the industry’s manufacturing in China (where lines have been down and product has been kept in country), there is a significant shortage situation. There will be some added supply to the market as China is beginning to release some product for shipment, but it will likely take 30 days (or more) for this product to be manufactured, processed and shipped to the United States (even with air freight). Even when this product is shipped, the demand is so significant that there will continue to be an acute shortage issue for the foreseeable future. Our war room continues to advocate on behalf of our members with distributors and suppliers and to date we have successfully adjudicated over 850 member issues. However, our backlog of open member issues is large and growing due to the significant mismatch between supply and demand – just over the last week it has become increasingly and exceedingly difficult to influence movement of PPE as there is just not enough product in the system to address the overwhelming need. We continue to look for additional viable sources of product, identify emerging practices in conservation and identify substitutes. We also continue to urge the Federal Government to step into this issue and are starting to see accelerated focus on these challenges from the Administration.

- **AMD** – Medicom, Inc. PPE Gowns
  - Supplier is at 100% allocation and not taking on new business at this time. Expecting to be able to take on new business in mid-June.

- **Cardinal**
  - With current demand, Cardinal expects extremely limited supply of masks by the end of April.
  - All Cardinal PPE is manufactured in China and with halted production, no product is

- **Encompass**
  - PPE stock out expected in next two months with declining inventory. Allocation based on historical usage.

- **O&M Halyard**
  - Halyard is deploying orders weekly at 100%.
  - Current increased demand has led to isolated processing delays.
  - Halyard is limiting direct dropships as this interferes with the deployment of full-truck-load processing.

- **ICP Medical**
  - PPE allocating 100% to current customers based on four-month usage history; not accepting new customers.

- **Medline**
  - China-based factories are actively loading containers, which will be air-freighted to the U.S. at +700% cost. These deliveries may not meet current demand, but will ensure continued supply in the months to come. The recent stoppage of production/exporting will affect short-term allocations, but to what degree is unknown.
– Current exam gloves at 100% allocation.
– They are ramping up on surgical gowns, and customers should see relief in 30-45 days.
– N95 masks have been unavailable since January.
– Procedure masks with ear loops at 65% of volume. If April shipment is on track, masks should arrive early-to-mid May.
– Surgical masks remain at 100% allocation.
– PPE currently at 100% allocation on existing business, however, because all are made in China, the situation could change.

**Tronex**
– PPE gowns anticipate supply chain to be restored to normal levels in Q3 2020.

**3M (Non-contracted supplier)**
– N95 masks are being produced at full capacity. 400% of capacity since February.
– 3M does not ship direct.
– Huge shipment went to DCs on west coast.
– Manufacturing facility in South Dakota to move to 3 shifts, 7 days a week. Hiring folks on the spot.
– Currently not shipping anything outside U.S. that is manufactured in U.S.

**IVs**
stock. Protective allocation percentages are as follows:

No negative impacts thus far and all facilities have been working extra shifts to build up safety

– Baxter 150% of last 6 months
– ICU 125% of last 6 months
– Braun 105% of last 6 months

**Lab**

**Production lags need by half** – Suppliers of testing materials (BD, Copan, Remel, Puritan and Starplex) met with Vice President Pence over the weekend. While the U.S. needs 1.2M tests per week, suppliers are currently only creating about half that amount. The government has enacted the FDA Emergency Use Authorization (EUA) to help manufacturers and members fast-track all diagnostic tests for COVID-19. Below is what we know of the two components associated with lab testing (testing materials and diagnostic tests):

– **Testing materials to obtain samples from patients** – Testing requires two swabs per patient (one for the nose and one for the throat). Below is what we know about the manufacturers of testing materials and additional FDA recommendations:

  – **Copan** – Copan is the major manufacturer in Milan, Italy, an epicenter for COVID-19. The U.S. government is currently working with Copan to expedite supply to the US, but it’s not yet known when the supplies will arrive or where they’ll be disseminated.
  – **Remel** – We understand that this manufacturer has very little (if any) product available but hear that they are ramping up production with 24/7 shifts and reducing manufacturing of other non-Covid-19 related products. Timing of delivery is currently unknown.
  – **BD** – Another manufacturer, whose products are currently on allocation.
- **Puritan** – Puritan Medical Products is no longer accepting orders for their UniTranz (UT) products. Any order submitted before March 13 has been entered and processed, with a current estimated lead time of 10-12 weeks. All orders submitted on or after March 13 have been cancelled.

- **FDA alternatives** – The FDA has recently made available FAQs on Diagnostic Testing for SARS-CoV-2, which include alternatives for viral transport media/universal transport media (VTM/UTM) and a flocked nasopharyngeal swab, which offers instructions for making product if product remains unavailable.

— **Diagnostic tests to determine if patients are positive or negative for COVID-19** — Below is what we know about key manufacturers of diagnostic tests:

- **All suppliers are on allocation** - While most existing suppliers continue to ramp up production, all product remains on allocation.

- **Diagnostic tests only run on proprietary equipment** – All tests made by suppliers are for use on their specific instruments only, and only those members who have each suppliers’ specific instruments can use those tests to report results. For instance, The Roche Cobas 6800/8800 System can only run tests from Roche and the provider must also have Roche’s instruments to use Roche’s product (if they have access to it).

- **EUA to clear additional suppliers** – We expect the EUA will make it possible for several additional suppliers to sell products shortly. Currently there are twelve approved EUAs for suppliers including GenMark Diagnostics and DiaSorin Molecular who gained approvals on March 20 and Cepheid gained approval on March 21. There are also at least three other suppliers who have tests in development. As those suppliers come online, the ability to test becomes much broader across different proprietary instruments. The list of members who are creating their own EUA testing is growing, as noted on the FDA website.

0 **Government agencies to determine dissemination product** – Several suppliers have been working with the White House and other government agencies to determine where limited lab testing resources will make the greatest impact on public health (CDC, then national reference laboratories, then regional laboratories followed by testing sites and facilities that already have the equipment needed in geographic areas with higher infection rates).

- **Food**

  o **Market trends** – Due to consumer stock-up and the change in purchasing patterns regarding food, our contracted food distributors (US Foods and Sysco) are preparing to experience some food product shortages. This is a new and developing situation and we will start collecting information on particular SKUs. Once collected, we will publish to membership.

  o **Suppliers** – US Foods delivery demands on Wednesday and Saturday have decreased significantly. Distributor is re-aligning delivery schedules to meet shifting demand and be more efficient as they anticipate increased demand with acute care facilities in the near future.

- **Ventilators** – **Anticipated to be in short supply in the coming weeks**

  o Concerns about ventilator shortages similar to PPE are anticipated. If the spread of COVID-19 maintains its current trajectory and more cases shift to the ICU, the concerns are more than warranted. Shortages are now being felt more acutely in the U.S. because earlier ventilator shipments were directed to countries whose COVID-19 cases spiked earliest. Here’s what we know at this moment:
- There are about 100K ICU beds in the US, which represent about 10% of all staffed beds, each with a ventilator in place.

- Vizient contracted suppliers and members report a ramp-up of ventilator orders to support the anticipated influx of COVID-19 patients.

- Rental company inventories are impacted with little likelihood of replacement stock as manufacturers re-direct ventilators to acute care health systems.

- While some suppliers have been reluctant to share projections, Draeger and Hamilton have been very transparent. They are ramping up manufacturing and increasing shifts to mitigate lead times and increase production.

- Draeger shared its plans to communicate with customers an off-label vent application for Draeger Anesthesia machines. These machines are equipped with an “ICU” ventilator, and as ORs temporarily delay elective surgeries, health systems with Draeger anesthesia machines could shift the operational use to caring for COVID-19 patients.

- FDA issues guidance on ventilators: On March 22, the FDA issued an immediately in effect guidance outlining a policy intended to help increase the availability of ventilators and their accessories as well as other respiratory devices during the COVID-19 pandemic. Specifically, this policy creates more flexibility for manufacturers that make device modifications (i.e., changes to ventilator motors, changes in ventilator tubing) to address current manufacturing limitations and supply shortages. For details, see Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency.

- Weekly essential products and contracts list
  - Vizient posts weekly a list of essential products and contracts (identified by category, contract number, supplier, product and product number, where available) that are impacted by the COVID-19 pandemic. The list, now with 1,000+ products, also identifies those products on allocation. Members can find the list on the Vizient Disaster Preparedness site under the Updates and Resources tab.

- National stockpile access
  - Before seeking access to the national stockpile, providers must always exhaust local options for obtaining product through your distributor or contracted supplier.

- Make a request through your state and make sure to develop a “case of need” for those supplies once they arrive at the state level. Include how many cases you currently have, how many you anticipate caring for, how many are currently under investigation and use rate. Please access the resources below for more information:

  - Link: ASTHO Authorization Toolkit
  - Link: HHS Strategic National Stockpile
Labor Impact:

• Labor shortages

  o As health systems continue to experience increased patient volumes and in some instances even quarantine staff, we have started to see staff shortages. We are working with staffing agencies to help our members rapidly deploy contract labor to address the impact of COVID-19.

  o Please reach out to your local Vizient representative or DisasterResponse@vizientinc.com if we can be helpful.

Pharmaceutical Impact:

This week marks the signs of lower fill rates and tighter allocations on some products, not driven by supply issues, but by demand. Below are the latest product status updates as of March 23:

• Chloroquine
  o All suppliers are on allocation at all distributors, and Vizient is working with all suppliers to increase production.

  o Bayer is coming to market and is set to donate 3 million tablets of Resochin (chloroquine phosphate) by the end of March.

• Hydroxychloroquine
  o All suppliers are on allocation at all distributors and Vizient is working with all suppliers to increase production.

  o Teva, Mylan and Novartis and additional suppliers are coming to market and project to make over 100 million doses before the end of May.

• Metered Dose Inhalers (MDI)
  o Due to the concern about infection control with the use of nebulizers for COVID-19 patients, MDIs of all types are beginning to be put on allocation at all distributors given the increased demand.

  o Vizient is working with all MDI suppliers to increase production and the Vizient Center for Pharmacy Practice Excellence is finalizing a full report on best clinical practices and where and how nebulizers can be appropriate based upon the available literature and member insight.

• Actemra
  o Primarily used in rheumatoid arthritis, it has experienced a significant spike in purchasing since being identified as having off-label use for treating COVID-19.

  o Genentech has stated there are no supply issues, and there is enough volume to cover the current patients who were taking prior to this outbreak.
o Genentech is going to work with the federal government on making additional product available and if any Vizient members have issues ordering, please contact Genentech at (800) 551-2231 or go to www.gene.com/covid19.

Vizient is continuing to monitor products that are now being utilized by providers to manage the symptoms and impact of COVID-19 as well as those essential medications that hospitals rely on for the delivery of patient care. This includes daily monitoring of fill rates and/or allocation changes. Please continue to visit the Pharmacy Update tab on the Vizient Disaster Preparedness site for the latest updates.

Continued advocacy for change

As President Trump announced on March 19, chloroquine phosphate – an anti-malaria drug and hydroxychloroquine sulfate – also used for rheumatic diseases – will now be available to more Americans. In recent weeks, these two drugs, which have been available for decades, have shown initial positive results in the management of symptoms of COVID-19. Both products are currently on contract through the Vizient non-injectable generics program. This significant announcement is aligned to the pharmacy sourcing strategy recommendations that Vizient provided to Vice President Pence and the Trump administration earlier this week, including the following: Prioritize approval of pending applications for “essential” medications subject to shortage.

We are pleased to see that the FDA has taken action, especially related to expediting the approval of non-U.S. pharmaceuticals for importation if necessary due to severe supply constraint. As the media has reported, Bayer announced the donation of 3 million tablets of the drug Resochin (chloroquine phosphate). This drug was previously not approved in the U.S., and the FDA has taken swift measures to make this approval happen quickly.

Another key recommendation provided last week includes: Provide the Drug Enforcement Administration (DEA) the support needed to adjust aggregate production quotas (APQ) of controlled substances. Given the anticipated higher demand for many inpatient, critical drugs due to increases in hospitalization, we encouraged removing barriers that prevent adequate supply of these medications being readily available to providers and patients. In a written statement to Vizient this week, the DEA has communicated significant willingness in support of these efforts.

Building transparency

Vizient’s pharmacy sourcing team also continues to make significant progress in bringing much-needed transparency across the pharmaceutical supply chain. As mentioned before, Vizient, during its continuous bid process, has required suppliers to provide the manufacturing location of finished products since 2018, and this data shows that none of these products are experiencing disruption due to COVID-19.

In addition, Vizient is now expanding its requirement of the disclosure of API origination during the continuous bid process, and for all contracted suppliers of Vizient’s identified Essential Medications. We already know the API source for any products in Novaplus Enhanced Supply (NES), which shows no disruption due to COVID-19.

Finally, through a supplier survey that is in the field now, we are also identifying current API sources and manufacturing locations for all contracted drugs included in the Vizient Essential Medications review, as well as the suppliers’ capacity to service current contracted customers for these products for 6 or 9 months. The survey closes this week. This information will be analyzed and shared back with both the FDA and our Vizient membership.

Additional pharmacy areas of focus
The Vizient Center for Pharmacy Practice Excellence clinical pharmacy team is quickly developing an analysis of COVID-19 clinical treatment information. The pharmacist team is currently reviewing information regarding direct antivirals associated with COVID-19 management and is conducting a field pharmacotherapy survey to our members. We will look to share this information on the March 25 member webinar. This team is also developing a Nebulizers vs. Meter Dose Inhalers report, which will be available very soon.

We also want to bring to our members’ attention to an update of a recent article from our USP expert, Katrina Harper. Titled The Effect of COVID-19 PPE Supply Shortages on USP Compliance: Recommendations for Management, this article has received tremendous feedback from members. It now includes important links, such as the recommendation letter on surgical mask and gown conservation strategies and the FDA guidance allowing pharmacists to compound alcohol-based hand sanitizers. The updated article also includes state Pharmacy Boards’ guidance on USP compliance. This is located on the Pharmacy Update tab of the Vizient Disaster Preparedness website and will be updated on a weekly basis.

As a reminder, if you have any questions, please refer to the Pharmacy Update tab on the Disaster Preparedness web page on Vizientinc.com or send your questions directly to our pharmacy team at DisasterResponse@vizientinc.com

Clinical Impact:

This week, Vizient members have been connecting through our networks, using our listservers, virtual communities and weekly COVID-19 webinars to ask questions and share emerging practices that are showing promise within their organizations. If you have missed any of our webinars so far, which have featured Emory University, the University of Washington, the Miriam Hospital and the University of Chicago Medicine, the webinars are available on demand here.

This past week, members were sharing practices and discussing the following critical strategies to prepare for the coming surge of COVID-19 patients.

**Elective surgery and procedure cancellations to prepare for COVID-19 surge**

Many members announced this week that they are cancelling or postponing elective surgeries and procedures. Vizient has created a map to show the facilities that have announced this step. We will be updating it continuously as we hear from members. The American College of Surgeons also issued this guidance.

**Visitation restriction**

Members are widely restricting visitation, only allowing visitors in emergency departments for critical patients for compassionate care or to accompany minors. Long-term care facilities have also restricted visitation to protect their vulnerable patients. See guidance here from the CDC. You can also view the UW Medicine visitor policy that was shared on our March 11 webinar.

**Alternate site of care planning for surge capacity**

Many members are inventorying available sites for triaging suspected cases of COVID-19 for isolation or to prepare for a coming surge. Some strategies include triaging patients by utilizing closed inpatient units, adjacent warehouses, setting up surge tents or checking local closed colleges for dorm room capacity. These are some of the strategies we are compiling and posting to our Disaster Preparedness page as described below.
COVID-19 FAQs

We have assembled FAQs that include collected emerging practices from members and industry resources, organized in the following categories: managing critical supplies, care pathways, testing, PPE conservation, triage practices, surge capacity, staff impact and visitation.

Please continue to share the critical information that is working for your organizations through our network channels, and we'll continue to share it broadly with our members. We have set up a short survey to make sharing these practices easy, and you can access that here.

Joint Commission suspends surveys through May 1

Joint Commission has been keeping abreast of the recommendations from CDC related to the COVID-19 virus and the burden this is placing on health care organizations to meet their community needs and implement safe practices for their staff. They will be sending out a formal announcement to their clients later today or early tomorrow suspending all surveys except for initial hospital and critical access hospital surveys through May 1.