



Medication Management Conundrum During the Pandemic

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Baptist Health

- 450 bed teaching hospital
- Two community hospitals
- One behavioral health facility
- Large cancer center
- Specialty pharmacy
- Retail pharmacy



Objectives

- Describe shifts from initial surge to case plateau
- Discuss the role of technology and teamwork to effectively manage medication supply
- Describe sterile product supply challenges encountered and initiatives to manage them



Personal Story: Year 2012

Ascension Health

- 150+ hospitals in 24 States
- 2,600+ site of care
- 1st index case: Fungal meningitis outbreak
- 753 patients in 20 States; 64 deaths

ORIGINAL ARTICLE BRIEF REPORT

The Index Case for the Fungal Meningitis Outbreak in the United States

April C. Pettit, M.D., M.P.H., Jonathan A. Kropski, M.D., Jessica L. Castilho, M.D., M.P.H., Jonathan E. Schmitz, M.D., Ph.D., Carol A. Rauch, M.D., Ph.D., Bret C. Mobley, M.D.,
Xuan J. Wang, M.D., Steven S. Spires, M.D., and Meredith E. Pugh, M.D., M.S.C.I.

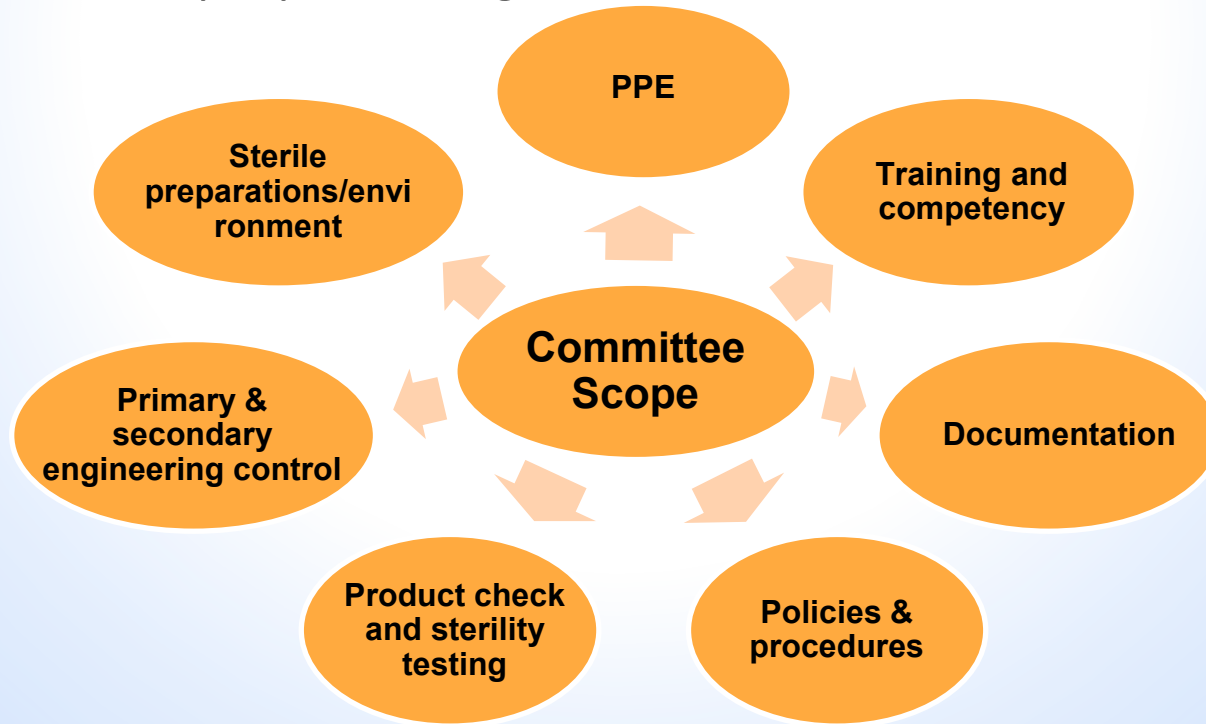
N Engl J Med 2012; 367:2119-2125

Centers for Disease Control and Prevention. Multistate outbreak of fungal meningitis and other infections. Feb 18, 2016. www.cdc.gov/hai/outbreaks/meningitis.html.



Next Step

- Ascension Compounding Subcommittee created on November 2012
- Objectives include:
 - Create standardized guidance on best, safe, and cost-effective compounding practices across the system
 - Provide tools and resources needed to comply with federal and state sterile preparation guidelines





Compounding Pharmacy Conundrum

“We Cannot Live Without Them but We Cannot Live With Them” According to the Present Paradigm

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and Christian Hartman, PharmD, MBA*

Compounding pharmacies serve a critical role in modern health care to meet special patient care needs. Although the US Food and Drug Administration (FDA) has clearly delineated jurisdiction over drug companies and products manufactured under Good Manufacturing Practice (GMP) regulations to ensure quality, potency, and purity, compounding pharmacies are regulated by the State Boards and are not registered by the FDA. In recent years, some compounding pharmacies acted like a manufacturer, preparing large amounts of injectable drugs with interstate activities. Multiple outbreaks have been linked to compounding pharmacies, including a recent outbreak of fungal meningitis related to contaminated methylprednisolone, exposing > 14,000 patients in multiple states. This tragedy underscores the urgency of addressing safety related to compounding pharmacies. There is a call for action at the federal and state levels to set minimum production standards, impose new labeling conditions on compounded drugs, and require large-scale compounders be regulated by the FDA. “Industrial” compounding must come under FDA oversight, require those pharmacies to meet GMP standards, and ensure quality and safe products for patient use. Moreover, compliance with the Institute for Safe Medication Practices 2011 recommendations that any type of sterile compounding must be in compliance with the United States Pharmacopoeia chapter 797 guidelines will reduce the risk of patient harm from microbial contamination. Finally, other critical factors that require close attention include addressing injectable products compounded in hospitals and other outpatient health-care centers. The FDA and State Boards of Pharmacy must be adequately funded to exercise the oversight effectively.

CHEST 2013; 143(4):896-900

FDC Act Amendment: 2013

- Compounding Quality Act (CQA) under Drug Quality and Security Act (DQSA)
- New entity: 503B Outsourcing facilities
- Must meet stringent CGMP quality standards
- Subjected to FDA inspection
- Better communication between the FDA and state pharmacy boards

FDA Drug Quality and Security Act (H.R. 3204). Section 503B of the Food, Drug & Cosmetic Act.

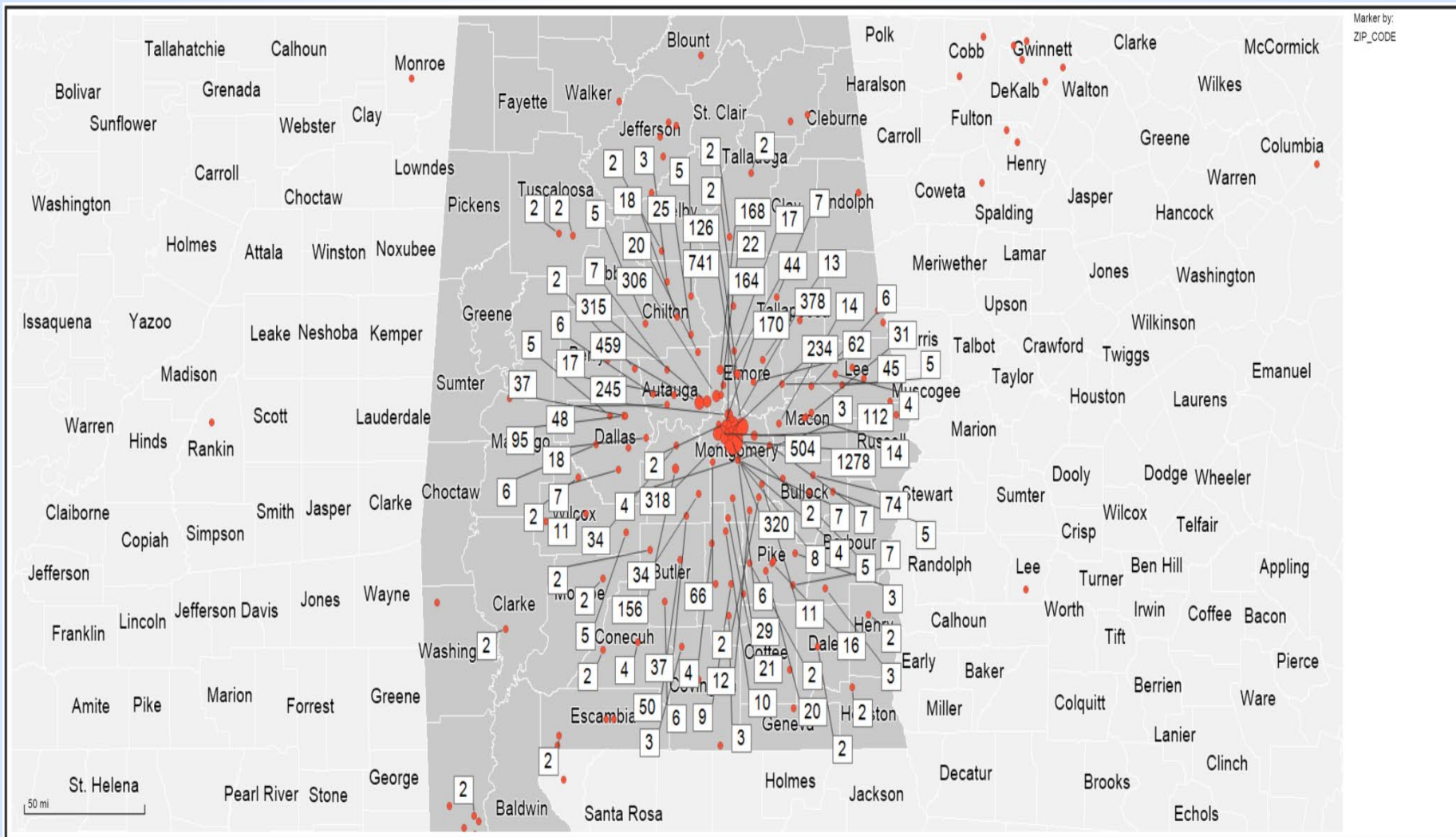
<https://www.fda.gov/media/104094/download>.

OIG Report: 2019

- 89% hospitals obtain non-patient-specific compounded drugs from 503B outsourcing facilities
 - Reasons include: lack of resources, staff competence, quality control, drug shortages, volume surge, crash cart medications, high-risk preparations, facilities without 24/7 pharmacy services
 - Common medications include: patient controlled analgesia (PCA), operating room (OR) syringes, epidurals, critical care infusions, analgesics, and sedatives
- Better communication between the FDA and state pharmacy boards

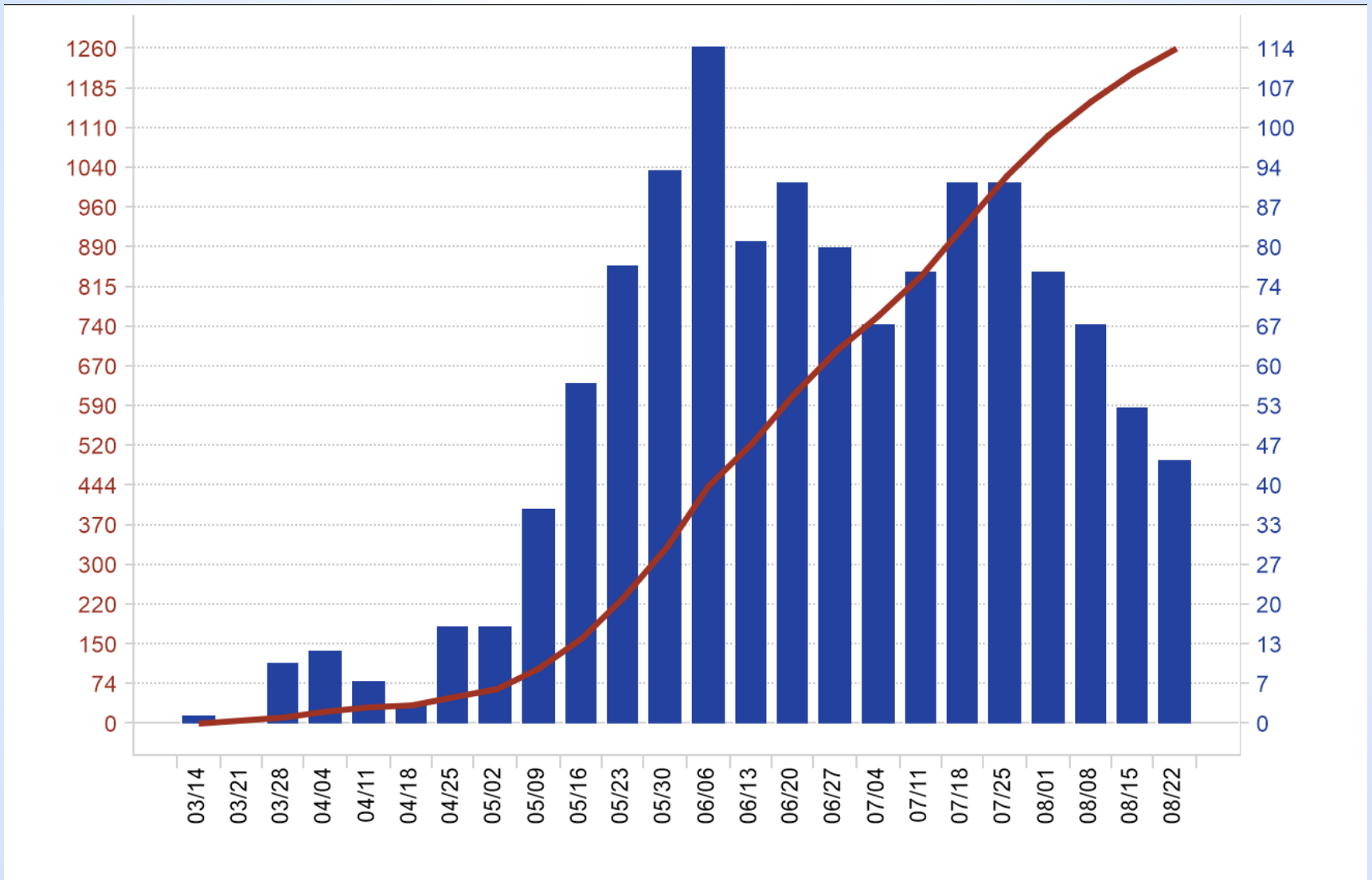
2020 Pandemic Baptist Health

Map of Tests Administered

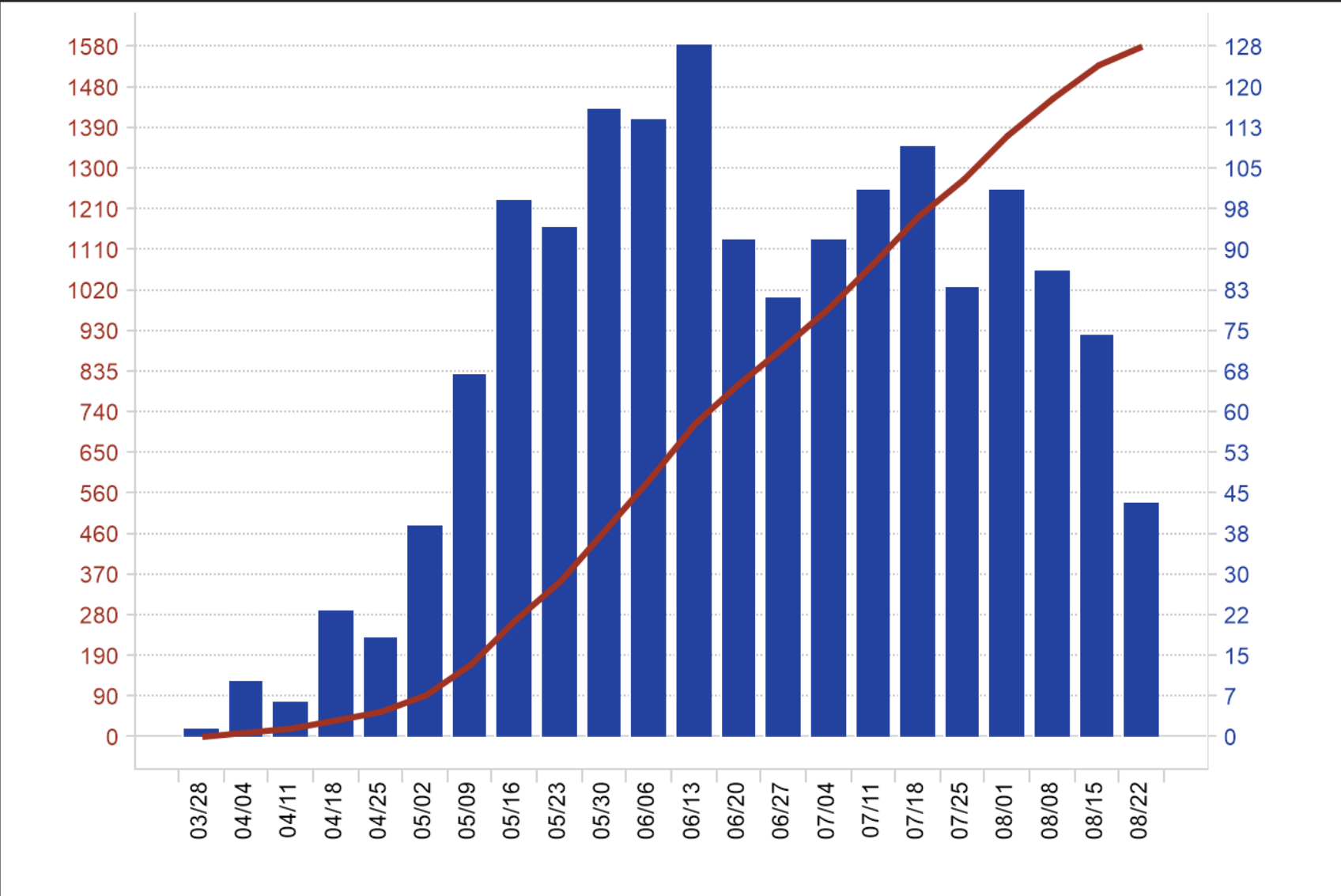


April 21, 2020

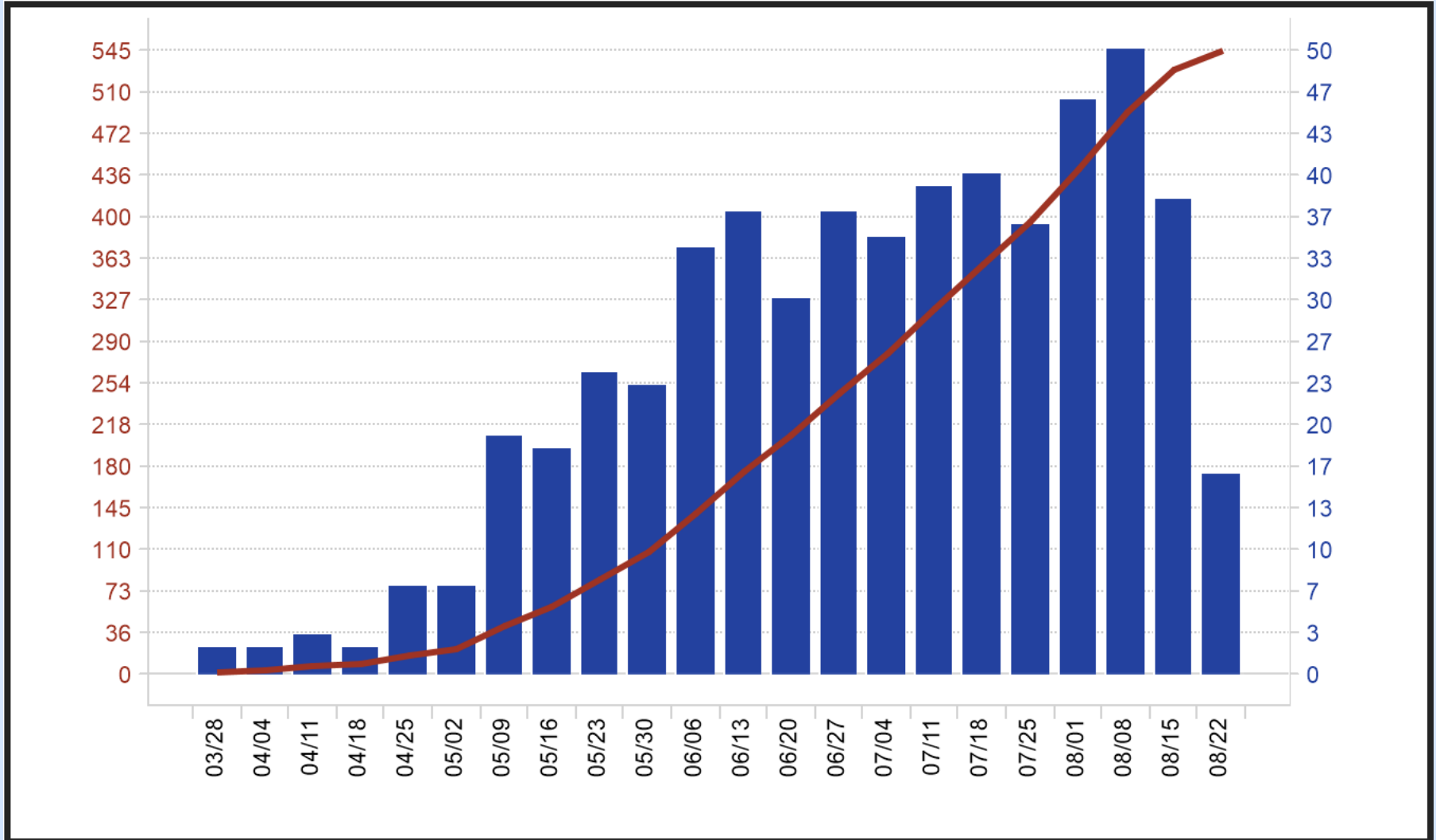
Total Cases and Cases Per Week: East Campus



Total Cases and Cases Per Week: South Campus



Total Cases and Cases Per Week: Prattville Campus



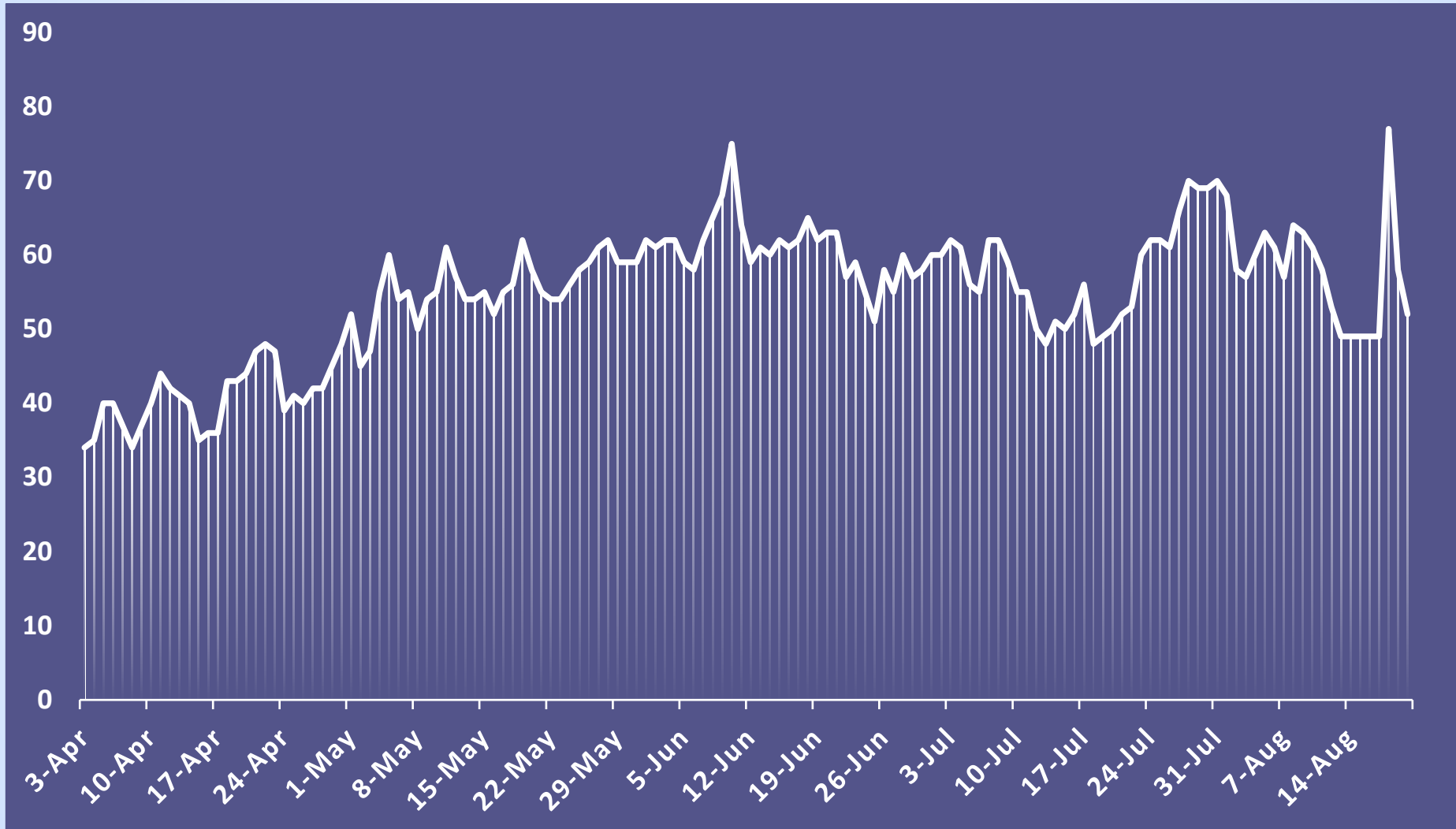
Medication Management

- Planning
- Automated ADC/Carousel inventory of critical drugs: real-time oversight of inventory
- Allocation and limits: paralytic agents, analgesics, sedatives
- Leverage all accounts
- Alternate agents: develop protocols
- Options: wholesaler, direct order, 503B vendor

Medication Management

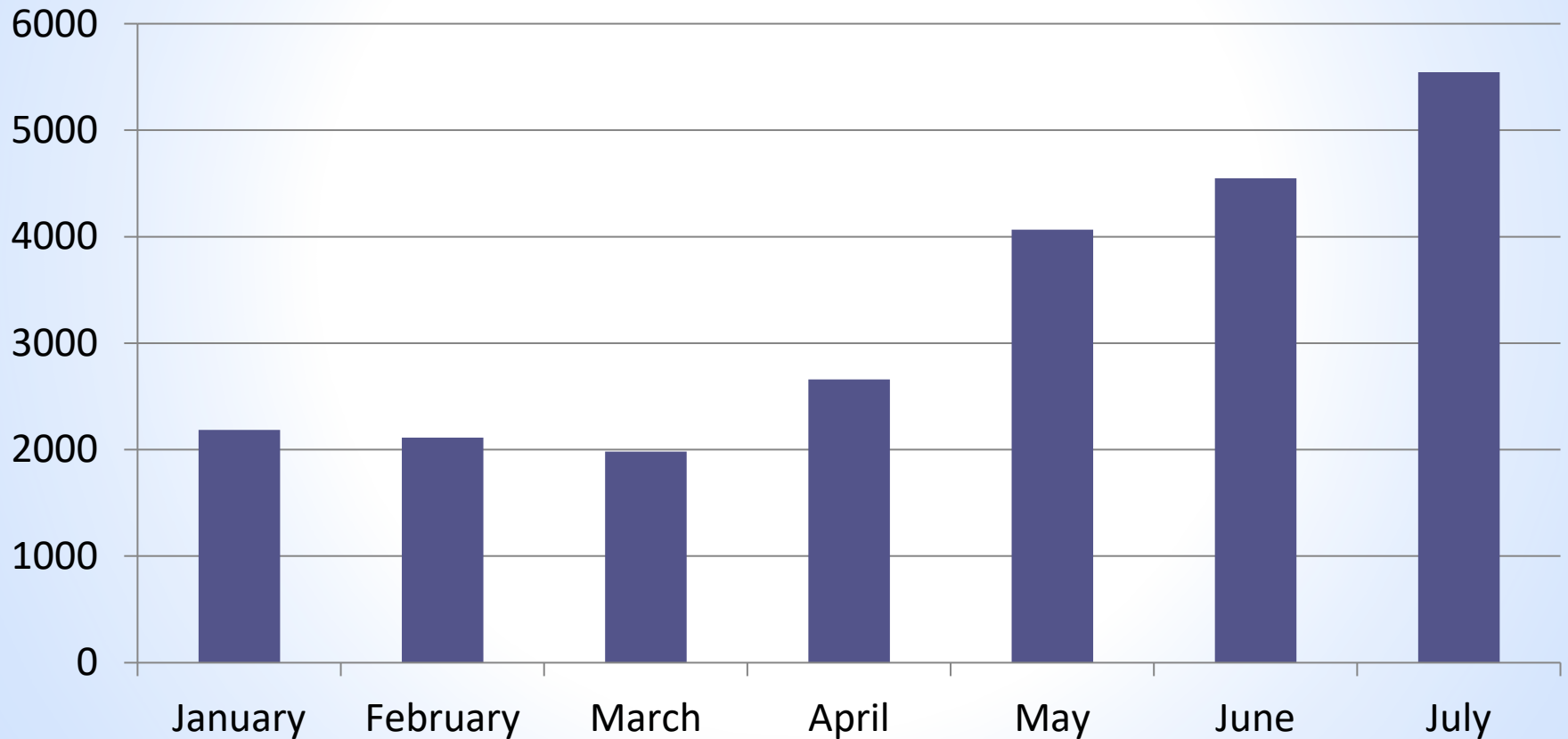
- Develop new protocols/revisions in collaboration with Infectious Diseases (ID), Internal Medicine (IM), and Pulmonary/Critical Care
- Sharing of COVID-19 medication inventory with relevant stakeholders (clinicians, nursing leadership, administration, etc.)
- Continuous evaluation and dissemination of new guidelines or major publications (particularly with treating clinicians)
- Clinical intervention: Who can we switch?
- Buyer: Critical role
- Consolidated medication batching process

Ventilator Usage



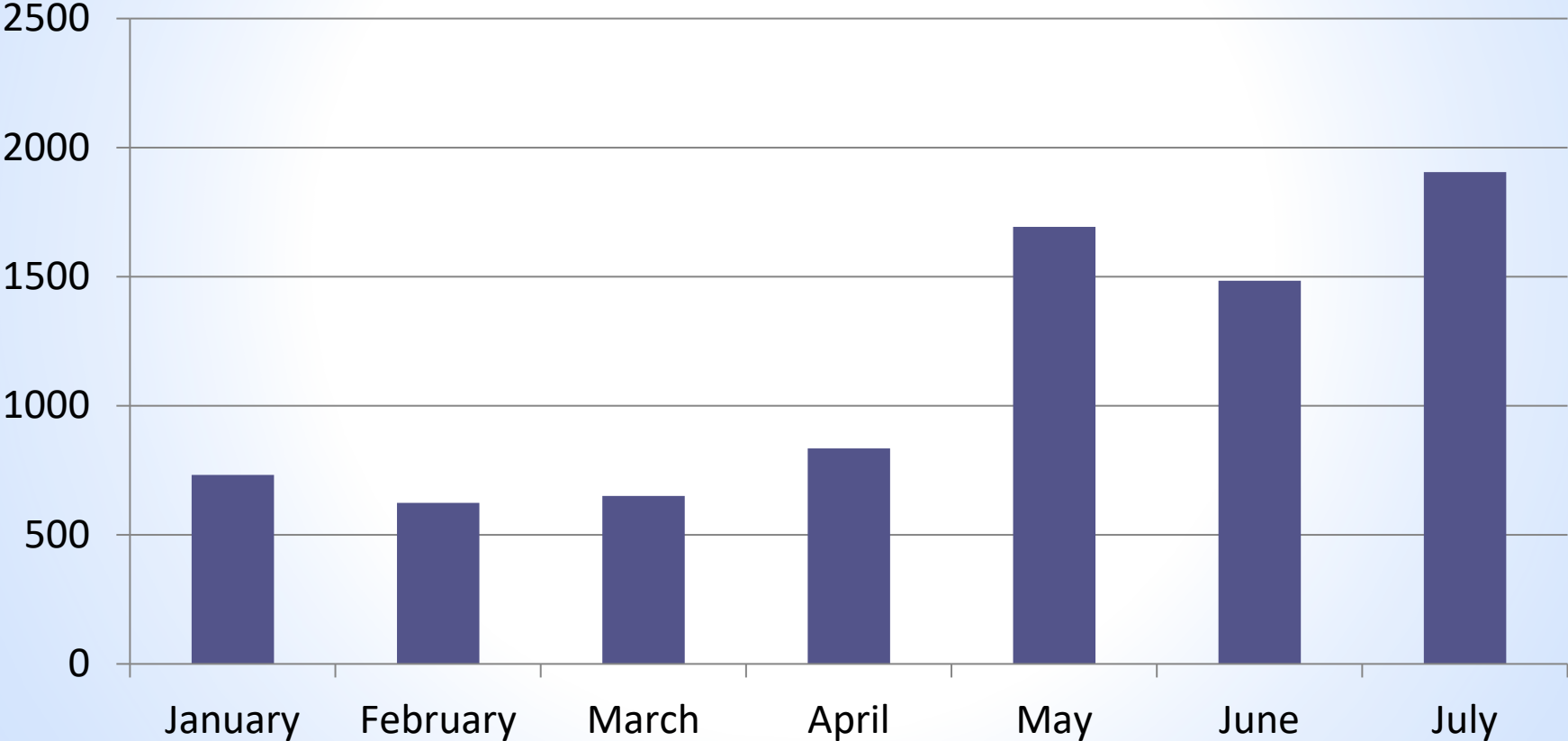
Fentanyl Infusion Usage

Doses Dispensed



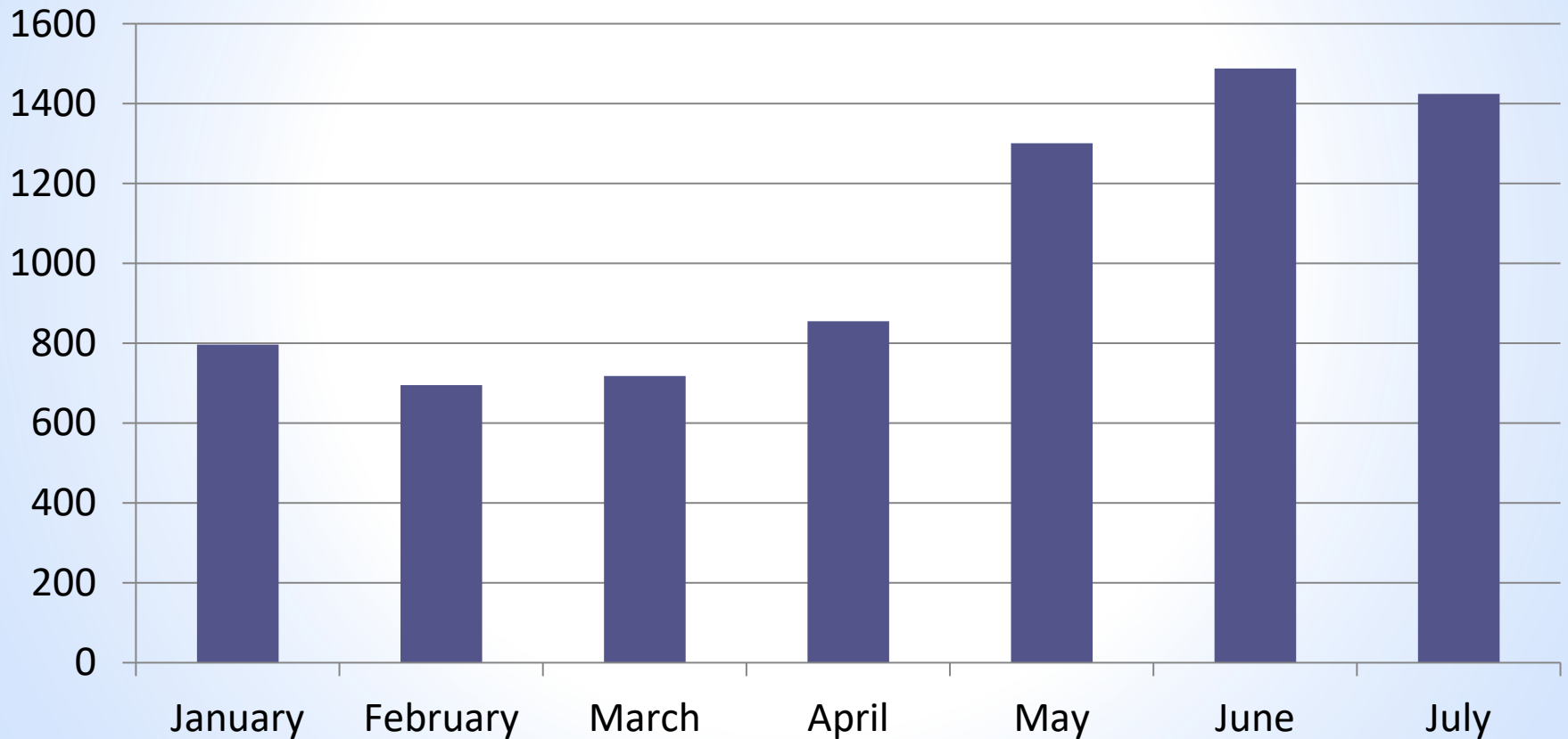
Midazolam Infusion Usage

Doses Dispensed

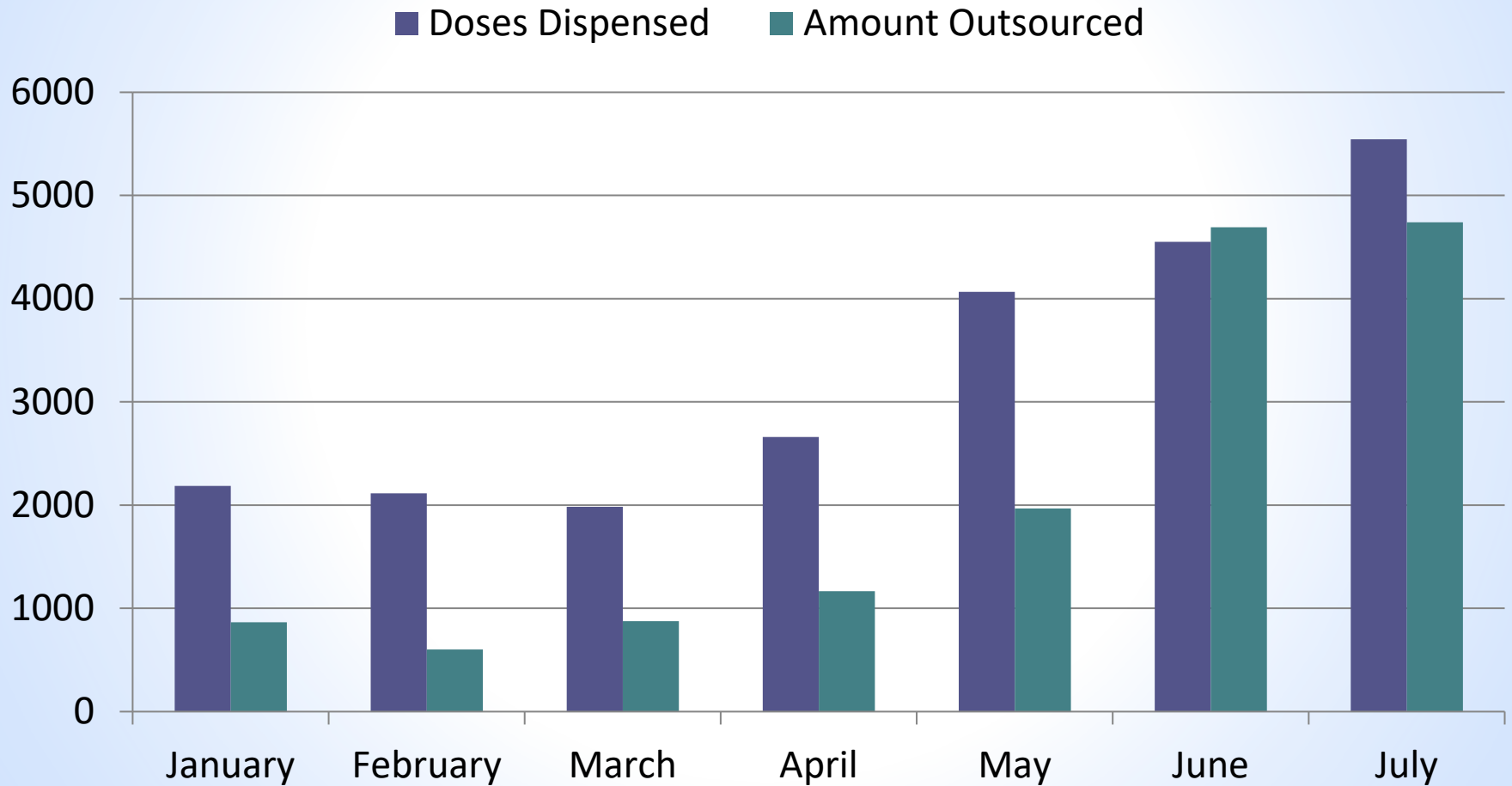


Norepinephrine Infusion Usage

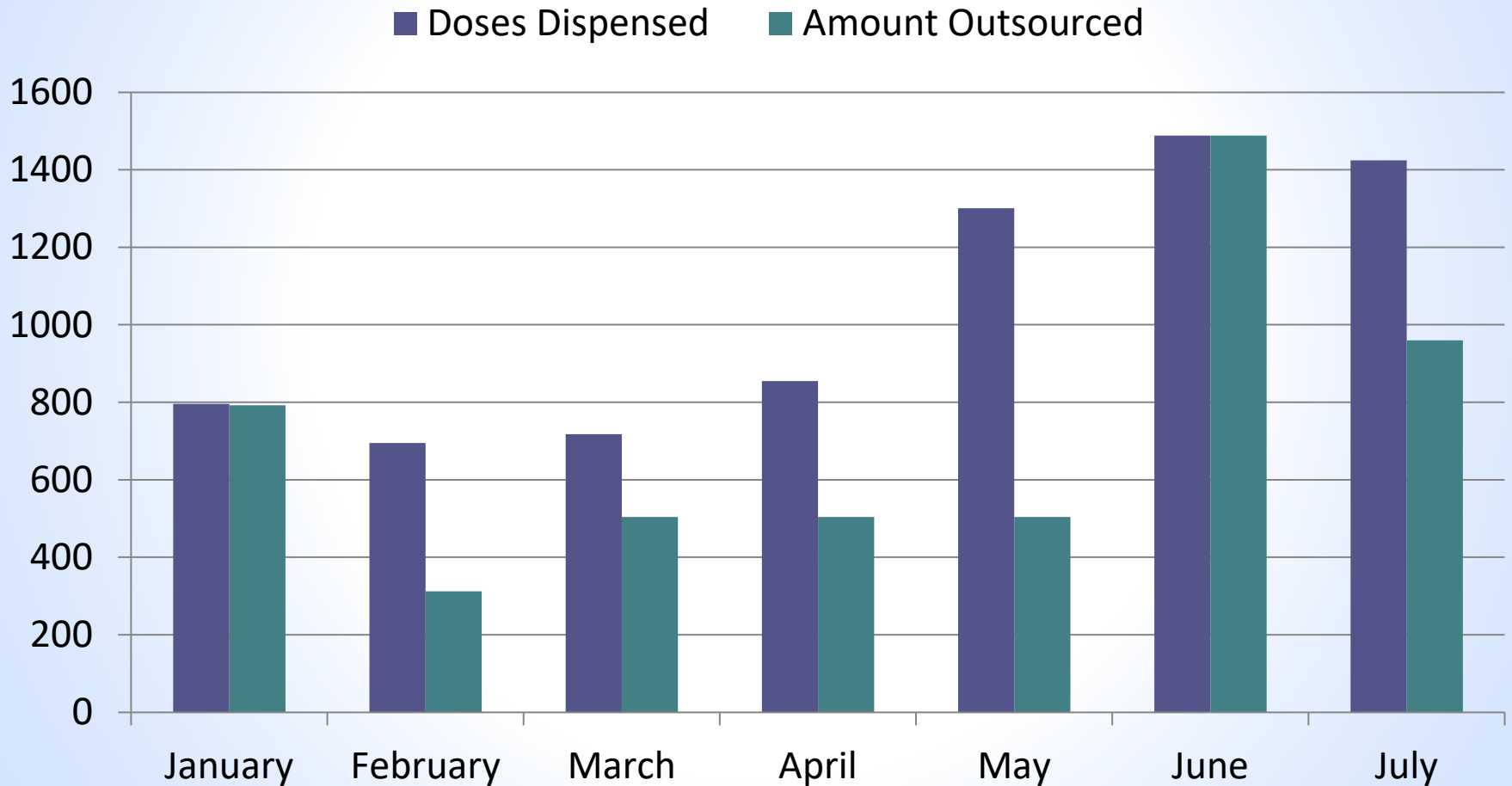
Doses Dispensed



Fentanyl Infusion Usage



Norepinephrine Infusion Usage



Summary

- Significant progress made in the recent years to protect patients from harm
- Patients are safer today than before the DQSA was passed
- 425 FDA inspections between 2014 and 2017: 140 recalls of compounded drugs
- 503B facilities are assets to the US drug supply chain, serving as an essential resource for delivering health care
- 503B facilities are playing a critical role to serve the most vulnerable patients during the COVID-19 pandemic