



# SHIELDS

HEALTH SOLUTIONS



## Health-System Specialty Pharmacy Exchange: COVID-19

April 24, 2020

### Discussion Objectives

- To provide updates on how COVID-19 is impacting the health-system specialty pharmacy landscape
- To provide actionable insights on operational changes required
- To review a real-world experience dealing with COVID-19 on the front lines of health-system owned specialty pharmacy

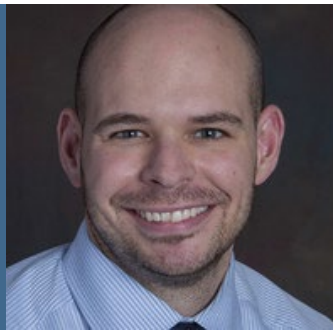
### Meeting Format and Flow

- Casual sharing environment
- Insights gathered from our guest speaker, internal Shields experts, and our partner health-systems will be shared
- Use the chat feature to ask a question or provide additional insight into a topic area
- Meeting is being recorded and a transcript with chat based additions will be made available and shared

### Health-System Strategy Team, Shields Health Solutions



**Erin Hendrick**



**Chris Paciullo**



**Stephen J. Davis**

*With significant input and support provided by our  
expert peers within Shields Health Solutions*

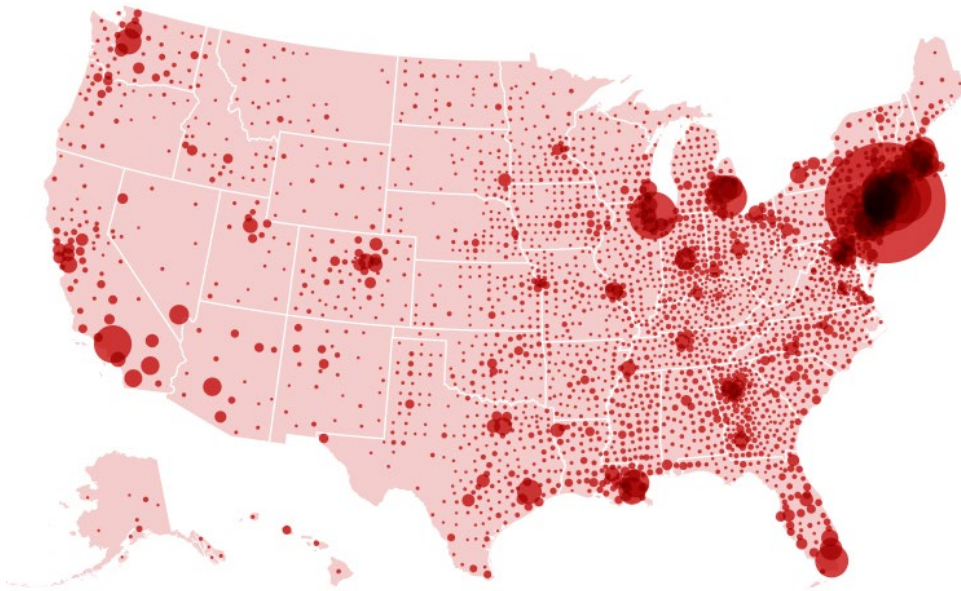
**Ameet Wattamwar**  
**Director of Pharmacy, Specialty Pharmacy Program**  
**NYU Langone Hospitals**



## COVID-19 in the United States

Confirmed cases: 869,006(Today: +164)









Deaths: 49,958 (Today: +4)



- Most states remain under stay-at-home guidance
- A few states, including Georgia, lifting restrictions
- Case volumes continue to rise though the slope of the line appears to be flattening
- A second wave, possibly more severe, has been predicted by the CDC in early winter 2020
- \$484B Stimulus package passed by Senate this week with funding for health-systems
- Over 25M have filed for unemployment since March 15
  - Tenuous summer insurance outlook

Last updated 24 Apr 6:25am EDT Source: Johns Hopkins CSSE \*Note: The CSSE states that its numbers rely upon publicly available data from multiple sources.

## Specialty Pharmacy Has Demonstrated Significant Resiliency to Date

	March	April MTD <sup>^</sup>
Operating Revenue (Rx)*	 25%	 10%
Average Days Supply Dispensed*	 10%	 10%
Total Specialty Appointments (Health System)*	 15%	 30%
New Patient Starts (Rx)*	 <1%	 10%

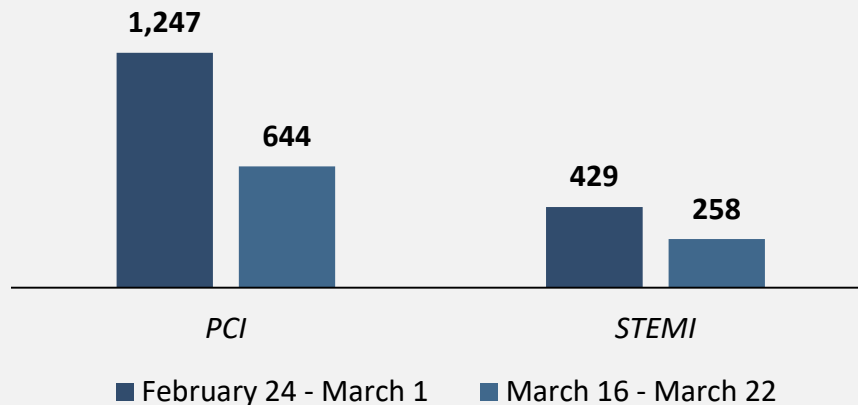
\*compared to January/Feb run rate

<sup>^</sup> as of EOD 4/23/2020

- In March, revenues outpaced the increase in “average days supply dispensed” by a significant amount. This appears to have normalized in April
- Specialty appointments have dropped significantly across all partners. We anticipate some normalization as telehealth gains greater traction and processes such as pulling the appointments through to the schedule are integrated fully
- Our ability to convert new patients to fill within the health-system pharmacy has not yet been impacted by the COVID-19 crisis, in part due to patient dissatisfaction with the typical supply chain options

## Non-COVID-19 Urgent Patient Volumes

**Number of cardiology interventions in Spain before and during COVID-19 epidemic**



- Similar study in US demonstrated a 38% drop in STEMI PCI
- Small studies and anecdotes are demonstrating significant drops in non-COVID 19 urgent and emergent admissions
  - Fewer patients are initiating therapy on new brands across key specialty therapeutic areas
  - Medically administered therapies have seen drops from 5-33% across brands compared to the 2019

<https://doi.org/10.1016/j.jacc.2020.04.011>

## Elective Procedures

- Most health-systems exploring the path to reopening ASCs and elective procedures
- Revenue loss from elective volumes expected to significantly impact HS EBIDTA



## Patient Care First

- Chronic and specialty patients require uninterrupted care
  - Proactive outreach and fills
- Shields is recommending early refills and 60- 90 day fills for multiple month prescriptions for stable patients
  - Utilizing refill overrides: Submission code 13
  - Evaluate the safety and applicability of providing extended fills
  - Contact providers for prescriptions that will expire prior to June 1<sup>st</sup> to obtain a new prescription
- Clinical Pharmacist outreach should include COVID-19 education
  - YouTube taking a tougher stance on false claims videos
- Patients are more likely to be home and more likely to be interested in discussing their specialty prescriptions
  - Monthly clinical check-in calls likely to be extended due to patients seeking conversation
- Though patient availability peaked in March, a slight decline in patient telephone call acceptance has been noted
  - Likely a facet of many companies re-igniting telephone based campaigns



## Pharma

### Drug Efficacy

- Unfortunately, many of the drug therapies, including remdesivir, explored to date have demonstrated little to no efficacy in patient care outcomes to date
  - On a positive, this will help to alleviate some of the concerns for patients chronically using medications such as hydroxychloroquine and tocilizumab

### Drug Availability

- While medications typically used in the critical care setting, including paralytics, remain in critical supply, the specialty supply chain remains mostly uninterrupted
  - Most manufacturing employees considered essential

### Pipeline

- Many new clinical trials have been halted and some in-progress trials suspended, especially in neurology and gene therapy
- Those continuing have allowed for significant protocol deviations
- New launch products delayed (Neurocrine, BMS)
- FDA appears to be moving items along
- Trial result continue to be presented in virtual conferences
- Unclear what the long term impact of some of these issues will be

## HRSA

### ■ Immediate Enrollment

- The Health Resources and Services Administration (HRSA) has announced that, in response to the COVID-19 pandemic, it **“is allowing some entities, upon request and review, to immediately enroll into the 340B Program.”**
  - In a new notice on the 340B Drug Pricing Program homepage, HRSA notes that every Friday, beginning Friday, April 10th, it will post a supplemental **Medicaid Exclusion File** that includes a list of entities who have been approved for immediate enrollment. This list is in addition to the quarterly MEF posted on the 340B Office of Pharmacy Affairs Information System.

#### Abbreviated Health Records

- During this time, an abbreviated health record may be adequate for purposes of the 340B Program. The record should identify the patient, record the medical evaluation (including any testing, diagnosis or clinical impressions) and the treatment provided or prescribed. For purposes of 340B Program eligibility, the record may be a single form or note page.
- In addition, in a situation where volunteer health professionals are providing health care, emergency documentation should be generated to make the relationship between the provider and the covered entity clear and to make clear the covered entity’s responsibility for providing care. This documentation should recognize the emergency nature of the situation, the name and address of the volunteer, and his/her relationship to the clinic, and should be kept on file by the covered entity.

#### Telehealth

- HRSA understands that the use of technology in health care delivery during this time is critical, and that telemedicine is merely a mode by which the health care service is delivered. For the 340B Program, HRSA recommends that covered entities outline the use of these modalities in their policies and procedures and continue to ensure auditable records are maintained for each eligible patient dispensed a 340B drug.  
**\*Make sure your telehealth visits align with your splitter / location file logic\***

#### Audits

- Based on the current COVID-19 pandemic, HRSA is moving towards conducting 340B Program covered entity audits remotely (virtually) for the next several months

## CDC Updates

### Masks

- Everyone entering a pharmacy should wear a face covering regardless of symptoms
- All pharmacists and technicians should wear a facemask while in the pharmacy

### Face to Face Encounters

- Routine clinical preventive services that require face to face encounters, such as adult immunizations, should be postponed and rescheduled

## Co-Located Clinics

- Signs should be posted by the door instructing patients of the clinic with respiratory illness to either return to their vehicles or remain outside, where they should proceed to call the clinic and allow the appropriate triage to be performed before entering the store. If possible, patients with mild symptoms should be managed over the phone and sent home with instructions for care.
- Facemasks or cloth face coverings should be provided for all patients not already wearing one, ideally before they enter.
- If possible, separate entrances for clinic patients should be provided. Otherwise, a clear path should be created to the clinic, with partitions or other barriers to minimize contact with pharmacy customers.

## Other Updates

### Workforce

- Pearson VUE is opening a limited number of testing sites for essential services, including pharmacists
- NABP Passport – temporary authorization that allows pharmacists, techs, interns to obtain temporarily licenses in other states until they can get permanent licensure
- No updates from ASHP on COVID effects on residency

### State Specific

- Some states issuing guidance on:
  - Ordering restrictions (hydroxychloroquine, chloroquine, azithromycin)
  - Compounding hand sanitizer
  - Therapeutic interchange
  - Telehealth services

*For a continually updated list please see  
<https://naspa.us/resource/covid-19-information-from-the-states/>*

## Cold Chain Challenges

- Shipping materials
  - Most have not experienced any shortages in the typical materials needed for cold chain shipping materials
  - Some distributors have requested letters to show that purchases are for “essential services”, which pharmacy falls under
  - Some pharmacies that previously had “cooler” takeback programs have discontinued them
  - Continue to monitor existing supply due to some seeing an increase in shipping due to 90 day prescriptions, early fills, and packaging for maintenance medications

## Clinic Changes

- Significant drops in clinic volumes, even in urgent and time-sensitive disease states
  - 10-50%
- Telehealth
  - Increased utilization
  - HRSA states “telemedicine is merely a mode”
  - Hospitals should address this in their policy and procedures
  - Address how hospitals are responsible for the care of their patients for 340b purposes
  - Meet the steps around access to the medical record and the relationship with the health professional providing the service
- Clinic staffing
  - Some clinics have limited staff on-site to assist with appeals
  - Other clinic specialty pharmacy staff working remotely
- Communication
  - Team conference calls throughout the workday
  - Video conferencing (Wi-Fi bandwidth issues)
  - Adjusting how to work remotely during these times (limited child care options, homeschooling, secure home work spaces, distractions, etc.)

## Accreditation Updates



- Please note, this time frame may change as the situation continues.
  - Through May 15, 2020, URAC will:
  - Suspend all accreditation and certification onsite activities.
  - Transition scheduled validation reviews to virtual where possible.
  - Relax requirements for employment background screening and drug testing/screening from “prior to hire” to completed within 60 days of the date of hire.
  - Evaluate requests for extension for application submission without penalty.
  - Evaluate the need to extend accreditation and certification expiration dates without penalty.
- Temporarily changing certain accreditation policies and procedures in accordance with the latest directives from the Centers for Medicare and Medicaid Services (CMS).
  - Postponing surveys in states identified by the Centers for Disease Control and Prevention (CDC) as having more than 500 reported cases of COVID-19, as well as areas where residents were ordered to shelter in place by authorities.



## NYU Experience

- Overview of NYU/ NYU SP program
- Goals of the NYU SP during the COVID-19 Pandemic
- Impact of COVID-19 on the NYU Specialty Pharmacy Program
  - RX Volume
  - Telehealth
  - 60-90 day fills
- Inventory
  - Leverage distributors/ direct contracts to procure non-SP agents to help your health system fight COVID-19 (NMBA's, inhalers, Hydroxychloroquine etc)
- Operations
  - PPE use within the pharmacy
  - Patient signature requirements
  - Recycling of coolers
- How your SP program can support providers in clinic
  - Prior authorizations, PAP enrollment, patient care coordination
- Business development
  - Cost savings opportunity for self-insured payors

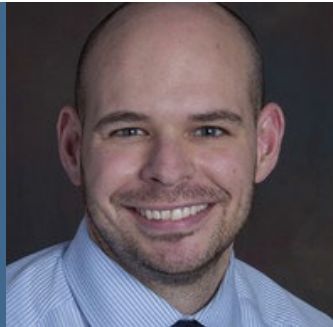


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- Please reach out to us with any information you want to share or questions for the network you may have
- Summary documents will be sent out



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