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The *voice* of the  
community  
pharmacist.

# Point-of-Care Testing (Beyond COVID-19)



Ask questions and  
participate in polls  
at [meet.ps/poct](https://meet.ps/poct)

Presentation By: Rannon Ching

*Support for this program provided by Quidel, Inc.*

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## Disclosure

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.



# Pharmacist and Technician Learning Objectives

1. Discuss state variability in scope of practice and requirements for pharmacists to perform point-of-care testing services.
2. Differentiate opportunities in point-of-care testing as it pertains to chronic disease management and acute infectious disease management.
3. Describe successful strategies for increasing point-of-care testing services to make it a sustainable patient care offering.

ACPE UAN: 0207-9999-21-609-L04-P/T | 1.0 contact hours (0.1 CEUs) | Activity Type: Knowledge-Based | Release date: October 9, 2021







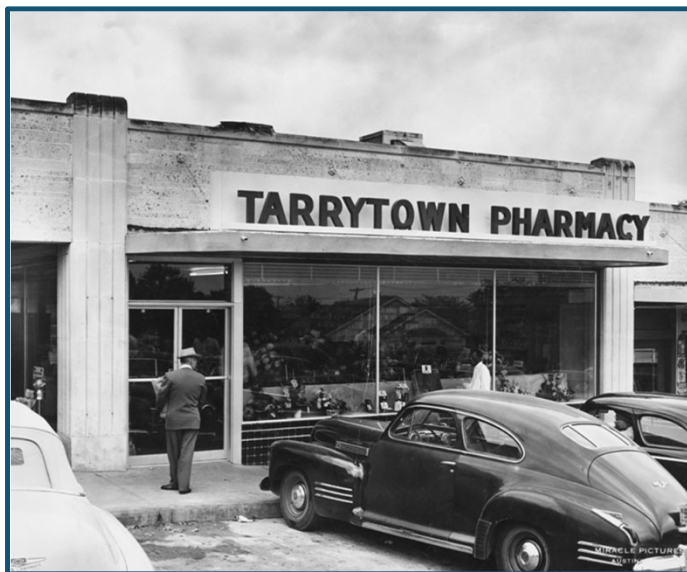
# Introductions

- Rannon Ching
  - Pharmacist-In-Charge at Tarrytown Pharmacy
  - Graduated from UT Austin College of Pharmacy 2014
  - Introduction to Pharmacy
    - Uncle owns independent pharmacy on Oahu (Waimanalo Pharmacy)
    - Started working at Tarrytown Pharmacy Spring 2009 of Freshman year at UT Austin
    - Took over Tarrytown Pharmacy as Pharmacist In Charge in 2016



# The Pharmacy

- Independent Pharmacy located in the Tarrytown Neighborhood of Austin Texas
- Founded December 6<sup>th</sup> of 1941 (over 75 years of serving Austin)
- Classic customer service and offerings
- Progressive Pharmacy practices
- Strong relationships (Professional, Patient, Legislative, University)
- Performing CLIA-waived tests since 2016



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# Point Of Care Testing: The Foundation

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# What is Point-Of-Care Testing?

- Point of Care Testing (POCT) Definition
  - **Medical diagnostic testing at or near the point of care, which is at the time and place of patient care**
    - Also referred to as near-patient testing, bedside testing, remote testing, mobile testing, and rapid diagnostics

# Benefits of POCT



<https://www.pointofcare.abbott/us/en/about-us/benefits-of-point-of-care-testing>

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# What is CLIA?

- **Clinical Laboratory Improvement Amendments (CLIA)**
  - Passed by Congress in 1988
  - Established standards for laboratory testing to:
    - Ensure accuracy, reliability, and timeliness of test results regardless of where or by whom the test was performed.
  - Required for certain diagnostic tests to be performed by a laboratory that meets CLIA standards

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# Enter the CLIA-Waiver

- CLIA-Waived Tests
  - Tests that are exempt from the more stringent requirements set in place by the CLIA
  - Remember: These are tests that have been deemed to be simple and have a low risk for inaccurate results
    - This does not mean they are error-proof!
  - There are a lot of waived tests!
    - Over 1,400 test systems that have been waived
    - List of Waived Tests
      - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>
- CLIA-Waived Tests allow for pharmacies to offer more advanced services than just filling prescriptions!



## Poll Question!

- What is required to offer point of care testing?
  - A. CLIA-waived certificate from CMS
  - B. Completion of a POCT certificate program
  - C. Collaborative Practice Agreement
  - D. None of the Above?
- Answer: A\*\* CLIA-waived certificate from CMS



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## CLIA-Waived Tests

- Defined by CMS as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”
- The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews manufacturer’s applications for test system waiver
- Sites must have a CLIA Certificate of Waiver
  - Certificate allows a “non-clinical” facility to utilize CLIA-waived tests
  - Must apply to CMS for a certificate of waiver
  - Fee for a wavier is \$150
  - Certificate is valid for 2 years, before renewal is needed
- Tarrytown received our CLIA Certificate in 2016 to start offering POC testing to our patients

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# Certificate and Training Programs

- There are organizations that offer a training and/or certificate program for Point Of Care Testing
  - NASPA Pharmacy-based Point-of-Care Testing Certificate Program
  - NCPA to offer virtual training, Dec. 7 – 9 a.m. – 1 p.m. ET
- Not required by state law; FL is the exception to the rule – special Test and Treat Training needed in
- They do offer benefits
  - A great introduction to POCT
  - Learning how to perform POCT with practical hands-on training
  - Helps build confidence in providers that may be more hesitant to test
  - Opportunity to brainstorm and learn from more experienced POCT providers
- Important to start testing and not put it off

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# Acute Infection Point of Care Testing

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# Acute Infection POCT

- Rapid test to detect presence of an active infection
- Popular with patients!
  - Pharmacies are available evenings and weekends
    - When MD Offices are closed
  - High costs associated with Freestanding Emergency Rooms and Urgent Cares

# Popular Point-Of-Care Tests



- Strep and Flu Testing
  - Rapid Flu and Strep tests are a great way to improve access to care
  - Tests performed quickly, only requiring a nasal or throat swab



# Rapid Strep Testing

- Requires a throat swab
- Results in 5 minutes
- Rapid Strep testing supplies are relatively inexpensive
- Strep cases present year-round
  - Great revenue stream throughout the year

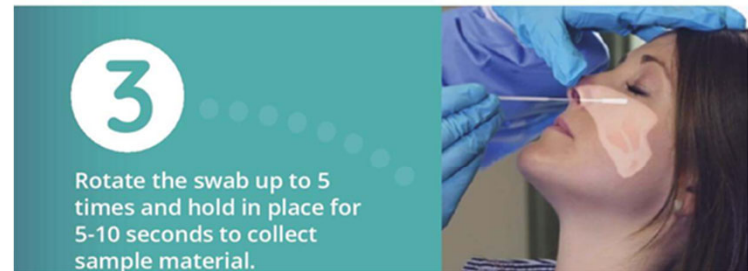
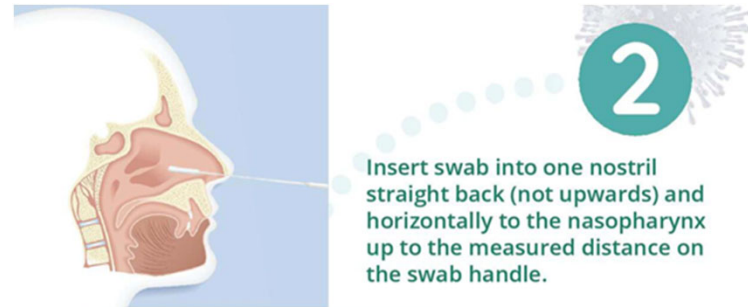
1. The **BD Veritor** System Group A Strep Kit includes sterile swabs with a rayon tip for throat specimen collection.
2. Have the patient open his or her mouth. Depress the tongue completely with a tongue depressor.
3. Swab the posterior pharynx, tonsils, and other inflamed areas. Avoid touching the tongue, cheeks, and teeth with the swab.
4. Withdraw the swab from the mouth. The sample is now ready for processing using the **BD Veritor** System Group A Strep Kit.

[https://www.bd.com/DS\\_POC\\_Veritor-system-Strep-CLIA-kit\\_DF\\_MU](https://www.bd.com/DS_POC_Veritor-system-Strep-CLIA-kit_DF_MU)



# Rapid Flu Testing

- Requires a nasal swab
- Testing takes 10 minutes to get a result
- Rapid Flu testing's supply costs are moderately priced
- Influenza is a great public health risk
- During peak flu season, seeing a provider can be more difficult
- Pharmacies are perfectly poised to provide increased access to care
- Results display which influenza strains are present (A or B)



<https://blog.puritanmedproducts.com/bid/339104/how-to-swab-for-the-flu-flocked-swab-sample-collection>



# COVID-19 Testing

- Brought CLIA-waived testing into the mainstream
- Huge opportunity for community pharmacy
- Amazing financial opportunity for your business

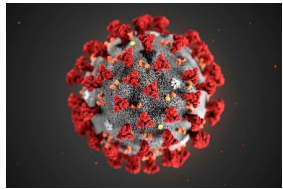


IMAGE FROM  
[https://www.google.com/url?sa=i&url=https://www.newscientist.com/%2Fterm%2F&psig=AOvVaw0WMonZ38h\\_g\\_DQ32-68&usq=159447514855000&source=images&ocid=web&ved=0CAMQJB1q1w1TCJBhPrwuxCF0AAAAAABAJ](https://www.google.com/url?sa=i&url=https://www.newscientist.com/%2Fterm%2F&psig=AOvVaw0WMonZ38h_g_DQ32-68&usq=159447514855000&source=images&ocid=web&ved=0CAMQJB1q1w1TCJBhPrwuxCF0AAAAAABAJ)





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# Chronic Disease Management

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# Chronic Disease Management POCT

- Tests that screen for chronic disease states
  - Diabetes
  - Hypercholesterolemia
- \*\*The future of pharmacy-based disease state management!!

# Chronic Disease POCT

- Blood Glucose
  - One of the most common CLIA-waived tests available and most widely used
  - Important for diagnostics and monitoring
- A1C
  - Great benchmark for diabetes management
  - Diabetes education (DSMES)
  - Opportunity for partnering with physicians to manage diabetic patients



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# Chronic Disease POCT

- Lipid Management
  - Quick finger stick
  - Blood sample collected in a pipette
  - Analyzed sample gives full lipid panel
    - LDL, HDL, TG, TC



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# POCT Beyond COVID

- What do you already offer at your pharmacy? How can POCT help?
  - Prior Authorizations
    - Specialty pharmacy – PA's for PCSK9 inhibitor require LDL lab values
  - Diabetes Management
    - Ability to monitor blood glucose, A1C, and other relevant values
  - COVID-Testing
    - Offer valuable data and care for local community
  - Delivery Services
    - Performing Strep and Flu tests, and allowing patients to go home after testing, and deliver medications to their homes

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# Starting Your POCT Program

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# What do you need to start POCT?

1. Find someone to oversee POCT at your pharmacy (Director)
2. Select which tests you will offer
3. Obtain a CLIA Certificate of Waiver (CW) from CMS
4. Location for testing
5. Educate yourself and/or attend a training program
6. Develop a protocol or instructions for your employees to conduct POCT
7. Start Testing!

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# 1. POCT POC

- Find someone to oversee POCT at your pharmacy (Director)
  - Usually a pharmacist, but doesn't have to be
    - Some states require the director to be a physician (California)
- CMS defines this person as the “Director” of your facility (you'll need this during your application)
- Responsible for maintaining regulatory requirements, certificates, policies and procedures, etc.
- Delegate to a trusted staff member if you are unable to do this yourself!



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## 2. Select your tests

- Research and find the manufacturer and name of the test
  - Required for CLIA-Waiver Certificate Application
  - Example: Quidel Sofia-2 Rapid Strep Test / PTC Diagnostic – A1C now, etc)
- Ask yourself what kind of tests and testing do you want to offer?

### 3. CLIA Certificate of Waiver

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved  
OMB No. 0938-0581

#### CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

##### I. GENERAL INFORMATION

<input type="checkbox"/> Initial Application	<input type="checkbox"/> Survey	CLIA IDENTIFICATION NUMBER	
<input type="checkbox"/> Change in Certificate Type		_____ D _____	
<input type="checkbox"/> Other Changes (Specify) _____		(If an initial application leave blank, a number will be assigned)	
Effective Date _____			
FACILITY NAME _____		FEDERAL TAX IDENTIFICATION NUMBER _____	
EMAIL ADDRESS _____		TELEPHONE NO. (Include area code) _____	FAX NO. (Include area code) _____
FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified		MAILING/BILLING ADDRESS (if different from facility address) send Fee Coupon or certificate	
NUMBER, STREET (No P.O. Boxes) _____		NUMBER, STREET _____	
CITY _____	STATE _____	ZIP CODE _____	CITY _____
SEND FEE COUPON TO THIS ADDRESS		SEND CERTIFICATE TO THIS ADDRESS	
<input type="checkbox"/> Physical		<input type="checkbox"/> Physical	
<input type="checkbox"/> Mailing		<input type="checkbox"/> Mailing	
<input type="checkbox"/> Corporate		<input type="checkbox"/> Corporate	
NAME OF DIRECTOR (Last, First, Middle Initial) _____		CITY _____	STATE _____
		ZIP CODE _____	
CREDENTIALS _____		FOR OFFICE USE ONLY	
		Date Received _____	

##### II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

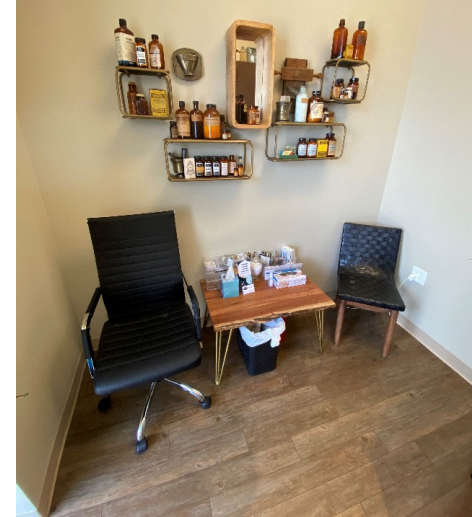
- ☒ Certificate of Waiver (Complete Sections I – VI and IX – X)
- ☐ Certificate for Provider Performed Microscopy Procedures (PPM) ((Complete Sections I-VII and IX-X)
- ☐ Certificate of Compliance (Complete Sections I – X)
- ☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

## Complete a Form CMS – 116

- <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>
  - Select Initial Application
  - Select Certificate of Waiver Requested
  - Complete the rest of the form

## 4. Find a location for testing

- Find an appropriate area or room to perform tests
  - Immunization room or area
  - Private consultation area
  - An area with a privacy barrier
- Keep organized
  - Have plenty of counter space for preparing reagents, documentation, and organizing testing materials
  - Have a dedicated storage and organization of tests, machines, testing supplies (tongue depressors, alcohol swabs, lancets, band aids, etc)



Tarrytown  
Pharmacy Patient  
Room

Tarrytown Drive-Thru COVID Testing



## 5. Educate Yourself

- Pharmacy-based Point-of-Care Testing Certificate Program
  - 20 CE hours (16 hours on-demand)
  - 4 hour virtual, live training – Dec. 7 from 9 a.m. -1 p.m.
  - [www.ncpa.org/poct](http://www.ncpa.org/poct) for more information
- Free information on testing basics and how to apply or update a CLIA waiver:  
[www.ncpa.org/coronavirus](http://www.ncpa.org/coronavirus)

Applying for and Updating a CLIA Certificate of Waiver

Why do COVID-19 Testing?

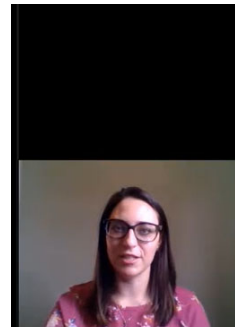
How do I get started?

Which tests can I perform?

What about safety?

Where do I report results?

How do I bill for testing?



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved  
OMB No. 0938-0581

### CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

**I. GENERAL INFORMATION**

☐ Initial Application ☐ Survey

☐ Change in Certificate Type

☐ Other Changes (Specify) \_\_\_\_\_

Effective Date \_\_\_\_\_

CLIA IDENTIFICATION NUMBER \_\_\_\_\_  
\_\_\_\_\_ D \_\_\_\_\_  
(If an initial application leave blank, a number will be assigned)

FACILITY NAME \_\_\_\_\_

FEDERAL TAX IDENTIFICATION NUMBER \_\_\_\_\_

EMAIL ADDRESS \_\_\_\_\_

TELEPHONE NO. (Include area code) \_\_\_\_\_ FAX NO. (Include area code) \_\_\_\_\_

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite)  
If Applicable, Fee Coupon/Certificate will be mailed to this Address unless  
mailing or corporate address is specified

MAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon  
or certificate

NUMBER, STREET \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP CODE \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP CODE \_\_\_\_\_

SEND FEE COUPON TO THIS ADDRESS: ☐ Physical ☐ Mailing ☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS: ☐ Physical ☐ Mailing ☐ Corporate

CORPORATE ADDRESS (If different from facility) send Fee Coupon or certificate

NUMBER, STREET \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP CODE \_\_\_\_\_

NAME OF DIRECTOR (Last, First, Middle Initial) \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP CODE \_\_\_\_\_

CREDENTIALS \_\_\_\_\_

FOR OFFICE USE ONLY

Date Received \_\_\_\_\_

**II. TYPE OF CERTIFICATE REQUESTED (Check only one)** Please refer to the accompanying instructions for inspection and

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## 6. Develop a protocol

- Staff needs to be properly trained
  - Which of your staff will you allow to perform tests?
    - Technically these are OTC tests that can be done by the average consumer
    - Not required to have any special training or certification
      - Certifications and training programs exist and might be helpful. These are **NOT** mandatory to perform POCT
    - Staff need to be trained on use of the POC tests, but this can be formal or informal training
- Protocols maintain consistent quality of experience and more accurate results
  - Intake forms
  - Process of specimen collection and test processing
  - OSHA and other potential safety concerns

# Specimen Processing / Result Reading

- Certain POC tests might require equipment to read results, or interpret results with more accuracy
- Equipment is either purchased or provided by company, depending on what kind of test and which company
- Reading equipment usually takes out the subjective nature of OTC home tests
  - i.e. reading lines on a test strip (pregnancy test, drug test, etc)
- Different types of reading devices





# Testing in action



# Testing In Action





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# Next Steps Post-Results

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# What to do with positive tests?

- When patients test positive for Strep or Flu, or have an elevated reading for blood glucose or A1C?
  - **Test and Treat**
    - Positive tests warrant a treatment
      - i.e. Antibiotics for Strep or UTI, antiviral for Flu
  - **Triage**
    - Identify a concerning POCT value, and notify an appropriate provider
      - i.e. Elevated cholesterol or blood pressure – Primary Care Physician, or elevated A1C – endocrinologist
- Texas pharmacists are not able to prescribe in most community settings
- What are your options?
  - Ask patient's primary care provider to provide a prescription
  - Partner with or employ a prescriber to furnish prescriptions upon a pharmacy's positive test
  - Be innovative

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# Pharmacist Test and Treat!

- **PREP Act Authority**

- On September 9, 2021, the U.S. Secretary of Health and Human Services issued a [9th amendment to the federal COVID-19 Public Readiness and Emergency Preparedness \(PREP\) Act](#), which, subject to certain requirements, authorizes pharmacists to order and administer select COVID-19 therapeutics to populations authorized by the FDA and for pharmacy technicians and pharmacy interns working under the supervision of a pharmacist to administer COVID-19 therapeutics.
  - [Read about these requirements online.](#)

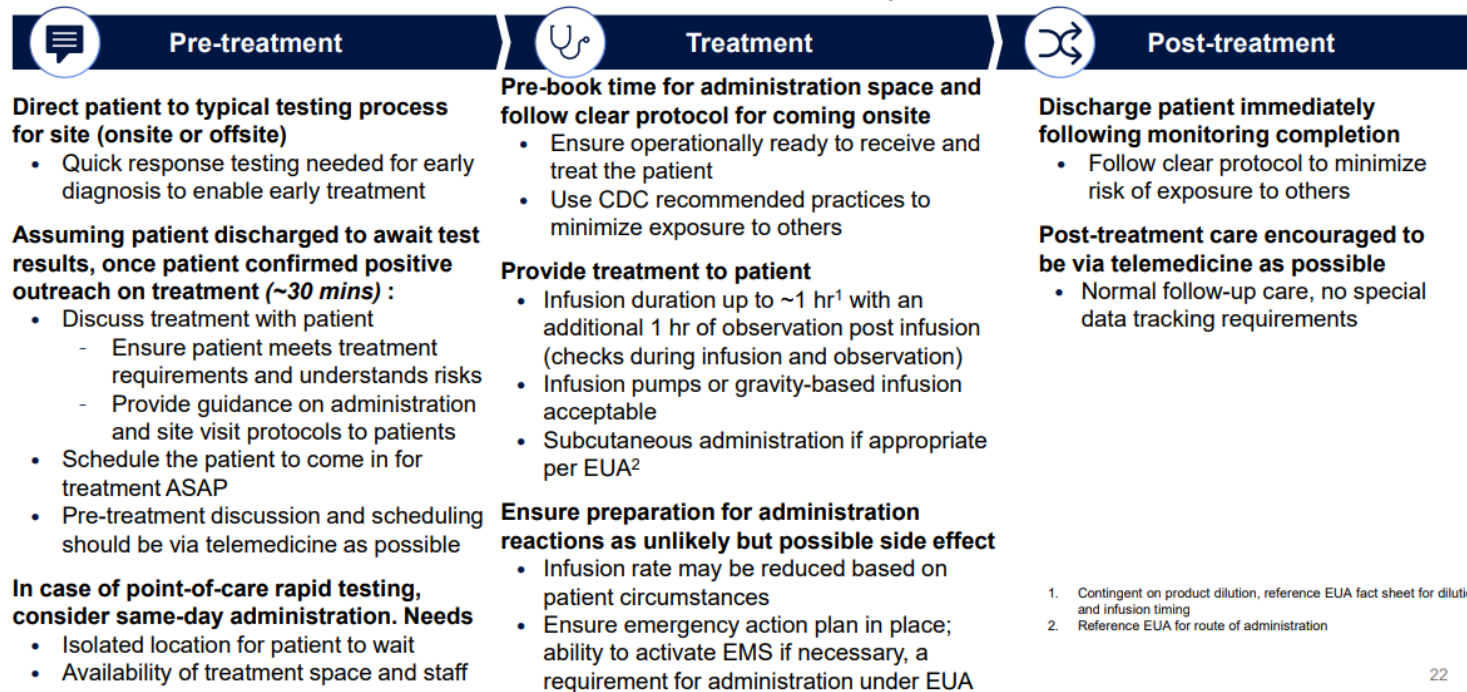
# Pharmacist-Generated Orders

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## Patient Flow for Outpatient mAbs Product

*Scenario 2 and 3: Patient arrives for testing at site with unknown diagnosis*

Same process as Scenario 1



1. Contingent on product dilution, reference EUA fact sheet for dilution and infusion timing
2. Reference EUA for route of administration

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# Test and Treat – CPA's

- Collaborative Practice Agreements (CPA)
  - **Senate Bill 1056 (Sen. Zaffirini/Rep. Raney)**
    - [SB 1056](#) amends the Occupations Code and clarifies that a physician may delegate to any properly qualified and trained pharmacist the implementation and modification of a patient's drug therapy under protocol.
  - **What does this mean for pharmacists?**
    - Pharmacists, particularly those practicing in a community or long-term care setting, can now be part of team-based care through collaborative practice. All pharmacists may now enter into collaborative practice agreements with physicians for their patients and establish protocols to make changes to a patient's drug therapy regimen.
  - **Effective Date:** Not later than December 1, 2019, the Texas State Board of Pharmacy shall adopt rules to implement [signed into law by Governor Abbott]

Referenced from the Texas Pharmacy Association

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## **Test and Treat – CPA's**

- Limitations
  - Patients must already have an established relationship with that provider
  - Not great for a pharmacy demographic that have many different options for healthcare providers (big cities)
  - Smaller demographic areas that only have a handful of providers could accomplish this more easily

Referenced from the Texas Pharmacy Association

# **Test and Treat – Standing Orders**

- Certain states have friendly Test and Treat laws
  - These allow for a standing order to fill prescriptions for antibiotics or antivirals based on POC test results

Referenced from the Texas Pharmacy Association

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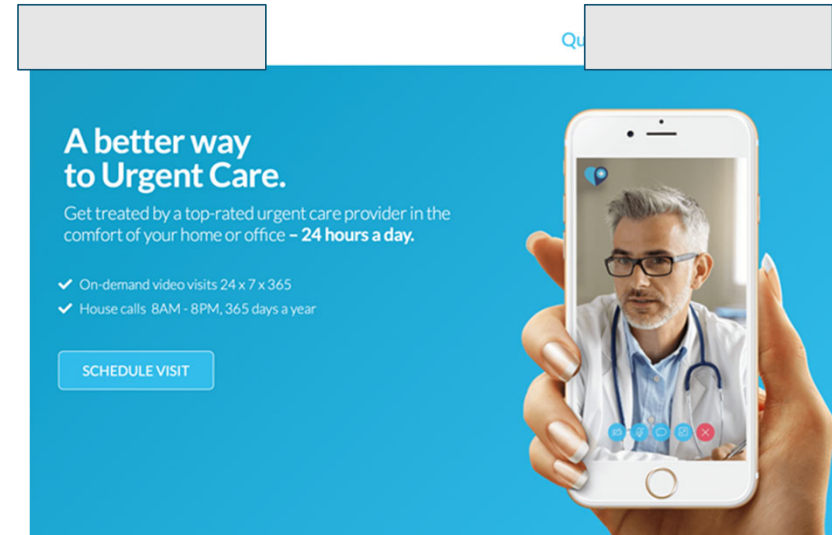
# **Test and Treat: Collaboration**

- Collaborate
  - Work with the patient's current provider
    - Call pediatricians, primary care physicians, to alert them about their patient's positive test
    - Ask if they would be willing to prescribe something over the phone for their patient
  - Pros
    - Helps keep positively identified sick patients out of the doctor's office and prevent spread in the office
    - Easier than setting up a full CPA
  - Cons
    - Prescriber may think you are taking business away from them (you can explain that it is like urgent care)
    - May take longer if you can't get a hold of a provider (nights and weekends)
    - Potentially delays therapy for a sick patient



# Interprofessional Collaboration

- Tarrytown Pharmacy partnered with a local telehealth company
  - An urgent care clinic with telehealth technology
    - \*\*Note: They have changed business models and no longer services the general public**
- Tarrytown Pharmacists recommended visits for positive or negative tests, as appropriate
- Telehealth billed patient's insurance for an office visit copay (many times \$0), or charged a nominal out of pocket fee
- After the video visit, a prescription was called-in to Tarrytown, if appropriate

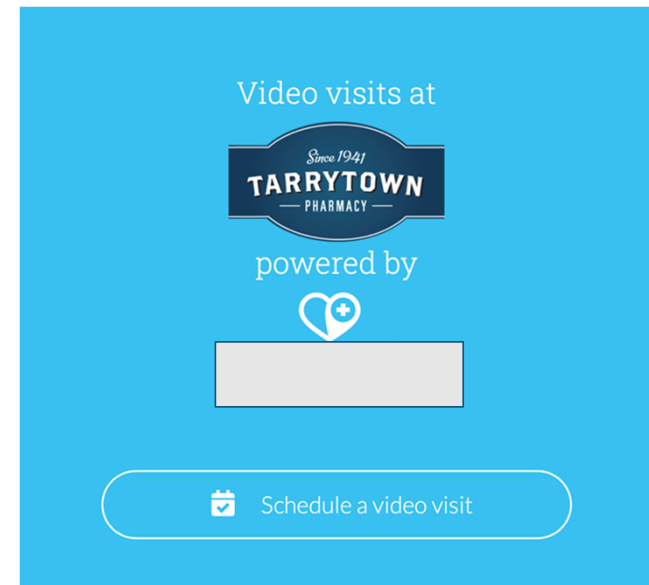


A better way to Urgent Care.

Get treated by a top-rated urgent care provider in the comfort of your home or office – **24 hours a day.**

- ✓ On-demand video visits 24 x 7 x 365
- ✓ House calls 8AM - 8PM, 365 days a year

[SCHEDULE VISIT](#)



Video visits at

**TARRYTOWN**  
PHARMACY

powered by

[Schedule a video visit](#)

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# Pricing and Payment

- How do you get paid?
  - Patient – Cash-based service
    - This is the easiest way to get payment, and the one I recommend
    - Call to various urgent care and big-box chain solutions. Find out what a reasonable comp price would be if the patient went elsewhere
      - ***Many times patients get overcharged at free-standing urgent care clinics!!***
    - Charge the patient a flat fee for the test. Include supplies cost and personnel time!
  - Insurance
    - Submitting claims as an out-of-network provider, or having patients submit superbill
    - This is a work in-progress, but potentially you can get paid by medical insurances
    - Considerations: In-network vs. out of network, pharmacists as providers, deductibles
    - \*\*Medicare – Emergency COVID testing exceptions
  - Other options are available, but not likely to be easy to implement

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# Workflow

- How do you fit POC into your workflow?
  - Put it in line! Just like an immunization or a medication counsel
  - Utilize technicians to help patients complete intake forms, process prescription labels, and prepare the room for whomever will be administering the test
  - For cash-based models, you usually will make a much larger gross profit margin on a POCT than prescriptions
    - Low reimbursement rates on prescriptions, etc.
- Utilize technology and other services
  - Text patients their results, so they don't have to wait in the store
  - Deliver medications to patient's home, if they don't want to drive back to the store

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## **6. Start Testing!**

- Once you have your program in-place, go for it!
- The best way to learn is by doing and adapting

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# **Marketing Considerations**

- If someone does not know who you are and what you do, a service won't be utilized
- Marketing Options
  - Website
  - Banners on pharmacy building\*\*\* (Worked for Tarrytown)
  - Flyers (Direct Mailers, Brochures, Word of Mouth)
  - Reach out to schools, doctor offices, etc
  - Facebook and Instagram (Targeted ads)
  - Hire a marketer
    - Visit MD Offices, drum up potential business



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The *voice* of the  
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[www.ncpa.org](http://www.ncpa.org)

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