



Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacists

May 28, 2020



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Dean and Professor
Loma Linda University School of Pharmacy
President, APhA

Host and Moderator

Today's Focus:

Discuss recommendations for pharmacists providing immunizations during the pandemic, considerations for the upcoming fall season, and an update on COVID-19 vaccine development.

Discuss billing and payment for COVID-19 testing in the Medicare program.



L.J. Tan, MS, PhD
Chief Strategy Officer
Immunization Action Coalition

Guest Speaker



Mitchel Rothholz, RPh, MBA
Chief Strategy Officer
American Pharmacists Association

Guest Speaker



Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice
and Government Affairs
American Pharmacists Association

Guest Speaker



Anne Burns, RPh
Vice President, Professional Affairs
American Pharmacists Association

Guest Speaker



Daniel Zlott, PharmD, BCOP
Vice President
Professional Education Resources
American Pharmacists Association

Subject Matter Expert: Q&A

Format for Today's Webinar

- 1:00 pm:** Introductions
- 1:05 pm:** Discussion with L.J. Tan, Chief Strategy Officer, Immunization Action Coalition and Mitch Rothholz, APhA Staff
- 1:20 pm:** Discussion with Ilisa Bernstein and Anne Burns, APhA Staff
- 1:30 pm:** Open Forum: A Minute for Your Thoughts
- 1:55 pm:** Wrap Up: Review of APhA's Ongoing Activities and What's Coming

Discussion with L.J. Tan and Mitch Rothholz

Recommendations for pharmacists providing immunizations during the pandemic, considerations for the upcoming fall season and update on the anticipated COVID-19 vaccine

Planning for Influenza 2020-21 Season

Things to Consider...

- **Focus on Increasing seasonal influenza vaccination to Decrease healthcare utilization**
- **Focus on adults at higher risk from COVID-19**
 - **Staff/residents of PTCF; adults with chronic underlying illnesses; adults 65 and older; African-Americans, Hispanics; adults who are part of critical infrastructure**
- **Plan:**
 - **Outreach to those at higher risk**
 - **Additional infection prevention control measures**
 - **Address social distancing**
 - **Align with COVID messaging and messages from Public Health**
- **Timing of Influenza Vaccination**
 - **Ideally, vaccinate by end of October, but continue vaccinating as long as vaccine is available**
 - July/August probably too early in most seasons, especially among older adults
 - Start vaccinating in September

2020-2021 Influenza Vaccine Projected Supply

Company	Products	Projected Doses for 2020-2021	Timing of Dose Availability
Astra Zeneca	Flumist	8.75 million	Early August (75% by end of Sept)
GlaxoSmithKline (GSK)	Fluarix Quad, FluLaval Quad	50 million	Same as 2019-2020 season
Sanofi Pasteur	Fluzone HD Quad, Flublok	75 million	Same as 2019-2020 season
Seqirus	Fluad, Flucelvax, Afluria	55 million	Same as 2019-2020 season
TOTAL		188.75 doses	
	2019-2020----->	175 million	



Source: NAIIS Summit Webinar “Influenza Prevention in the Era of COVID-19”, May 21, 2020 – Update from manufacturers

Polling Question

During the COVID-19 pandemic, how comfortable are you and/or your pharmacy staff in administering vaccines in your practice?

- A. Very comfortable
- B. Somewhat comfortable
- C. Not too comfortable
- D. Not at all comfortable
- E. Does not apply (do not administer vaccines in my practice)

Discussion with Ilisa Bernstein and Anne Burns

An update on billing and payment for COVID-19 testing in the Medicare program

Pharmacist COVID-19 Testing

Per HHS: During the public health emergency, licensed pharmacists in any state can order and administer COVID-19 tests authorized by FDA

- How?
 - Obtain CLIA certificate of waiver
 - Enroll with Medicare as an independent clinical laboratory
- Which tests?
 - FDA authorized
 - Allowed in “patient care settings” (see FDA website)
- Payment?
 - Not very straightforward
 - Depends on whether Medicare, Medicaid, private, or uninsured
 - Depends on what services you are providing:
 - Assessing, ordering, specimen collection, conduct test, interpret results, notify patient, report to authorities

FDA Authorized COVID-19 Tests

W = pharmacy setting

¹ Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

04/02/2020	Becton, Dickinson & Company (BD)	BD MAX SARS-CoV-2 Reagents for BD MAX System	Molecular	H, M	HCP, Patients, IFU	None
04/01/2020	Ipsium Diagnostics, LLC	COV-19 IDx assay	Molecular	H	HCP, Patients, EUA Summary	None
04/01/2020	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test	Serology IgM and IgG	H, M	HCP, Patients, IFU	None
03/30/2020	QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel	Molecular	H, M	HCP, Patients, IFU	None
03/30/2020	NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay	Molecular	H, M	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 23, 2020)
03/27/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay	Molecular	H	HCP, Patients, IFU	None
03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19	Molecular	H, M, W	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 21, 2020)
03/26/2020	BGI Genomics	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2	Molecular	H	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 24, 2020)
		AvellinoCoV2 test	Molecular	H	HCP, Patients, EUA Summary	None
		PerkinElmer New Coronavirus Nucleic Acid Detection Kit	Molecular	H	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 1, 2020)
		Accula SARS-Cov-2 Test	Molecular	H, M, W	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 30, 2020)
03/23/2020	BioFire Defense, LLC	BioFire COVID-19 Test	Molecular	H, M	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 23, 2020)

COVID-19 Testing: Payment Opportunities for Pharmacists Under Medicare

Payment for conducting the test – to the pharmacy



PHARMACY

- Medicare will pay for COVID-19 tests performed by pharmacists as part of a Medicare-enrolled laboratory.
- A pharmacist also may furnish basic clinical services, such as collect lab samples, under contract with a doctor or practitioner, in accordance with a pharmacist's scope of practice and state law.
- Beneficiaries can get tested at "parking lot" test sites operated by pharmacies consistent with state requirements.

**There is no beneficiary cost sharing for COVID-19 testing and services during the public health emergency

Payment for COVID-related testing *services* – to the physician for the pharmacists' services

Payment for Conducting COVID-19 Tests

- Obtain CLIA Certificate of Waiver
- Enroll **pharmacy** in Medicare as an Independent Clinical Laboratory – Form 855-B to the local Medicare Administrative Contractor (MAC)
 - Pharmacy will receive PTAN – Provider Transaction Access Number (Medicare provider number)
- Pharmacist performs test and bills the appropriate billing code
 - COVID-19 test
 - **Influenza and/or RSV – if performed with COVID-19 test

CMS Form 855-B

TYPE OF SUPPLIER: *(Check one only)*

- | | |
|--|--|
| <input type="checkbox"/> Ambulance Service Supplier | <input type="checkbox"/> Mass Immunization (Roster Biller Only) |
| <input type="checkbox"/> Ambulatory Surgical Center | <input type="checkbox"/> Pharmacy |
| <input type="checkbox"/> Clinic/Group Practice | <input type="checkbox"/> Physical/Occupational Therapy Group in Private Practice |
| <input type="checkbox"/> Hospital Department(s) | <input type="checkbox"/> Portable X-ray Supplier |
| <input type="checkbox"/> Independent Clinical Laboratory | <input type="checkbox"/> Radiation Therapy Center |
| <input type="checkbox"/> Independent Diagnostic Testing Facility | <input type="checkbox"/> Other <i>(Specify):</i> |
| <input type="checkbox"/> Intensive Cardiac Rehabilitation | <input type="text"/> |
| <input type="checkbox"/> Mammography Center | |

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf>

Example COVID-19 Test Billing Codes

COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE*

Updated May 12, 2020

CPT/HCPCS Code	Laboratory Code Long Descriptor	Code Category
COVID-19 Related Codes		
U0001	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	COVID-19
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	COVID-19
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), 2 amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R	COVID-19
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	COVID-19
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	COVID-19
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	COVID-19

Code used depends on type of test conducted

Code that can be used for a variety of tests

Payment for COVID-19 Testing-Related Services – CMS Interim Final Rule –2*

- Patient assessment and specimen collection (basic clinical services) – state scope of practice applies
- Pharmacists are considered auxiliary or clinical staff in the Medicare program – not recognized “providers” who can bill for services
- “Incident to physician services arrangement” between pharmacist and physician or other qualified nonphysician practitioner (NPP) - **physician or NPP bills for pharmacist’s basic clinical services**
 - Financial relationship must be in place
 - Supervision requirement during public health emergency (PHE)- physician or NPP must be immediately available using real-time audio and visual technology

Evaluation and Management Services CPT Code 99211 is to be used to bill for COVID-19 testing-related services provided by clinical staff (pharmacists) to new and established patients during the PHE per CMS

*<https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf>

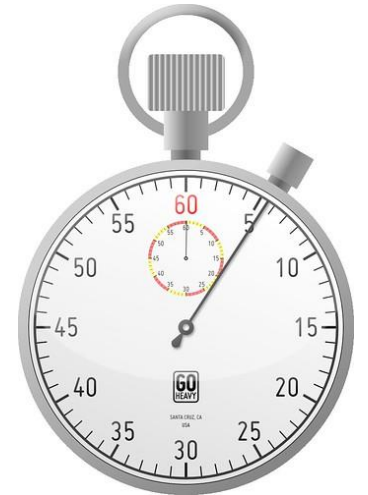
Other COVID-19 Testing-Related Services in Medicare – CMS Interim Final Rule-2*

- Specimen collection in a Hospital Outpatient Department – HCPCS Code C9803 can be used when clinical staff conduct assessment and specimen collection leading to an order or administration of a COVID-19 test
- Specimen Collection by a Laboratory – HCPCS Codes G2023 and G2024 can be used by Medicare laboratories for specimen collection in a patient’s home OR for an individual in a skilled nursing facility (SNF)/by a home health agency (HHA) respectively. Specific requirements apply

**APhA and other national pharmacy organizations continue to clarify details regarding payment for COVID-19 testing and advocate for sustainable payment models for pharmacists’ services in Medicare, Medicaid and private sector programs

Open Forum Ground Rules

- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion
- Individuals whose submissions are selected will be asked by the moderator to state the comment or question for the audience. The line for the individual will be unmuted to read their comment or question.
- To maximize the number of questions/comments addressed, a **60-second time limit** will be in effect for everyone to state their question or comment.
- We will try to get to as many comments and questions as possible. We have created a new forum for COVID-19 discussions where further discussion post-webinar. Information on participating in this forum will be provided at the end of the open forum.



Open Forum Discussion: A
Minute for Your Thoughts
Comments, Questions, Feedback

Review of APhA's Ongoing Activities and What's Coming

NEW Episodes – APhA’s 15 on COVID-19

An education series designed to help you sort COVID-19 fact from fiction. Each episode is 15-20 minutes and provides CPE.

Episode 16: Anticoagulation in COVID-19

<http://elearning.pharmacist.com/products/6106/15-on-covid-19-05-14-2020-anticoagulation/>

Episode 17: Antibody Development and Reinfection

<http://elearning.pharmacist.com/products/6110/15-on-covid-19-05-18-2020-antibody-development-and-reinfection>




Practical Information for Pharmacists to Know Now



Check out the [practice resources here](#)

- Vaccines in Development for COVID-19
- Demystifying Testing for SARS-CoV-2 Virus: Frequently Asked Questions
- Operational Approaches for Health-System Pharmacy Practice During the COVID-19 Pandemic: Lessons on Preparing and Adapting Your Health-System Pharmacy in the COVID-19 Crisis
- New resources weekly!




COVID-19: Demystifying Testing for the SARS-CoV-2 Virus

Frequently Asked Questions About COVID-19 Testing

Testing for COVID-19, caused by the SARS-CoV-2 virus, is rapidly evolving. As pharmacists work on the front line of the COVID-19 response, it is important to understand testing options, how to know which tests are recognized by FDA, and what qualifies a test to be provided in a pharmacy setting. The FDA's [FAQs on Diagnostic Testing for SARS-CoV-2](#) serves as a primary source for information on approval of COVID-19 tests.

What types of specimen are used to determine if someone has COVID-19?



Vaccines in Development for COVID-19

Vaccine development for COVID-19 is under way, with numerous vaccine candidates being studied in clinical trials. Pharmacists are health care providers on the front lines in the nation's response to COVID-19. As the most highly accessible immunizers in communities across America, pharmacists may play a key role in administering immunizations against the SARS-CoV-2 virus, when a vaccine becomes available. The chart below summarizes a sampling of vaccine candidates that are being studied or have been announced as of April 13, 2020. Note that it may not be all-inclusive of trials or vaccine candidates that have been announced. For the most current information, [search clinicaltrials.gov using the condition "COVID-19" and other term "vaccine."](#)

Trial	Location	Phase	Key Study Dates	Estimated Enrollment	Primary Outcome Measure(s)
Evaluating the Safety, Tolerability, and Immunogenicity of Bar-TEC-301a Vaccine for Prevention of COVID-19	Canada	Phase 1	Study Start: 4/20/20 Primary Completion: 8/31/21 Study Completion: 12/31/21	84	• Frequency of adverse events
Safety and Immunity of Covid-19 aAPC Vaccine	China	Phase 1	Study Start: 2/15/20 Primary Completion: 7/31/23 Study Completion: 12/31/24	100	• Frequency of vaccine events • Frequency of serious vaccine events • Proportion of subjects with positive T cell response
A Phase II Clinical Trial to Evaluate the Recombinant, Novel Coronavirus Vaccine (Adenovirus Vector (CTL-nCoV))	China	Phase 2	Study Start: 4/12/20 Primary Completion: 1/31/21 Study Completion: 1/31/21	500	• Occurrence of adverse reactions • Anti SARS-CoV-2 S antibody response • Neutralizing antibody response to SARS-CoV-2
A Phase I Clinical Trial in 18-60 Adults (APIC-1a)	China	Phase 1	Study Start: 3/6/20 Primary Completion: 12/30/20 Study Completion: 12/30/22	108	• Safety indexes of adverse reactions
BCG Vaccination to Protect Healthcare Workers Against COVID-19 (BRACE)	Australia	Phase 3	Study Start: 3/30/20 Primary Completion: 10/30/20 Study Completion: 3/30/22	4170	• COVID-19 disease incidence • Severe COVID-19 disease incidence

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APhA

AMERICAN PHARMACISTS ASSOCIATION

Tell Congress Pharmacists Can Help Fight COVID-19 & Influenza



American Pharmacists Association



Congress is currently crafting new emergency legislation to address the COVID-19 pandemic. Please contact your federal legislators immediately and ask them to allow pharmacists to test Medicare patients for COVID-19 and influenza.

You can personalize the message by editing the content to share a relevant personal experience related to patient care. Legislators value real life examples of pharmacists helping patients. Remember to be polite and include your name and the city of your residence or pharmacy practice.

GO TO: actioncenter.pharmacist.com

Take Action Now!

Congress is currently crafting new emergency legislation to address the COVID-19 pandemic. Please contact your federal legislators immediately and ask them to allow pharmacists to test Medicare patients for COVID-19 and influenza.

Next

Allow American Pharmacists Association to contact me about important future issues



Powered by OneClickPolitics

22%

2259 people took action

Post on **ENGAGE**

Pharmacy's Response to COVID-19

POST your questions

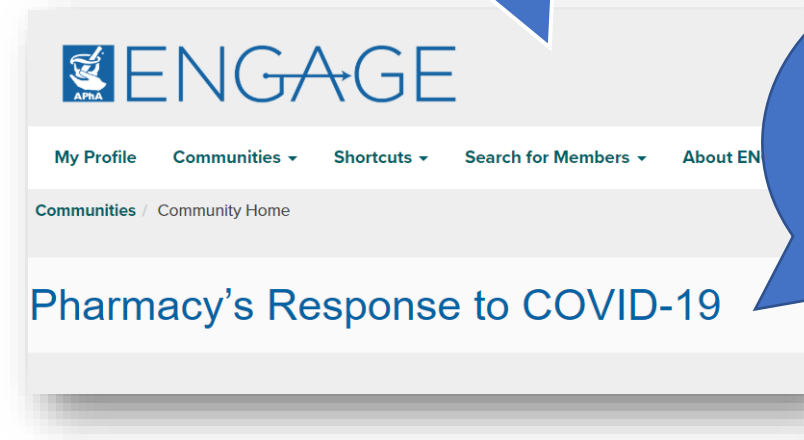
SHARE your lessons learned

SUPPORT your colleagues

ACCESS the latest information

What questions have you received from patients about getting immunized?

What is the demand for immunizations like at your pharmacy?



Join Us

Same day, Same time, Same Place

- Weekly webinar will be on **Thursday, June 4th, from 1-2 pm ET**
- The webinar recording and slides will be available within 24 hours

COVID-19 Resources and Training for You



Webinars

Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacists are weekly webinars conducted every Thursday from 1:00 pm–2:00 pm ET. Each open forum webinar is moderated by APhA President Michael Hogue.

- May 28: **Register for the webinar.** This webinar will address national recommendations for pharmacists providing immunizations during the pandemic, considerations for the upcoming fall season, and an update on COVID-19 vaccine development. APhA staff will also provide an update on billing and payment for COVID-19 testing. Our guest speaker is Dr. L.J. Tan, Chief Strategy Officer for the Immunization Action Coalition.
- May 21: **Access the recording and view the slides.** We focused on the latest information for antibody testing, how to evaluate antibody tests, and implications for pharmacists. Our guest speakers included Dr. Paul Herrmann, MD, PhD, of Loma Linda University, and Dr. Dan Zlott, APhA Vice President, Professional Education Resources.
- May 14: **Access the recording and view the slides.** This week focused on pharmacist well-being and resilience during COVID-19. Our featured speaker Dr. Ken Duckworth, Chief Medical Officer, joined us from the National Alliance on Mental Illness (NAMI).
- May 7: **Access the recording and view the slides.** Two front-line practitioners shared their perspectives on pharmacy practice during COVID-19 in both the community and health-system settings. The webinar also addressed the latest information on the clinical and regulatory fronts.
- April 30: **Access the recording and view the slides.** An overview of compounding, including how it relates to drug shortages, featured three FDA representatives from the Center of Drug Evaluation and Research (CDER) in the Office of Compliance.
- April 23: **Access the recording and view the slides.** This webinar provided an update on the most recent evidence

<https://www.pharmacist.com/coronavirus/resources-training>