Executive Summary

Pharmacy Organization's Joint Policy Recommendations to Combat the COVID-19 Pandemic

Major pharmacy organizations, representing the interests of pharmacists in the United States, have released a joint set of policy recommendations critical to addressing the COVID-19 pandemic.

The COVID-19 pandemic continues to put an enormous strain on our nation's healthcare system, and the supply of qualified healthcare providers is becoming increasingly limited. Pharmacists are currently among those healthcare professionals on the front line, providing essential healthcare services during this time.

Pharmacists are among the nation's most accessible healthcare professionals, with 90% of Americans living within 5 miles of a community pharmacy. They are medication experts, providing patient care in a variety of settings, including hospitals, clinics, community pharmacies, long-term care, the medical home, and physician offices.

These four policy recommendations will empower pharmacists to fully and effectively support our nation's COVID-19 response and help to ensure patients get the treatment they need.

In short, the joint statement recommends:

Authorize Test-Treat-Immunize

Allow pharmacists to order, collect specimens, conduct and interpret tests and, when appropriate, initiate treatment for infectious diseases including COVID-19, flu, strep, and interpret and discuss with patients. Expand current state pharmacists immunization authority to include all FDA approved vaccines, including the forthcoming novel vaccine for COVID-19, for all indicated populations.

Ease Operational Barriers to Address Workforce and Workflow Issues

Allow pharmacists and pharmacy technicians with valid licenses to operate across state lines, including telehealth. Authorize pharmacists and pharmacy staff to conduct routine pharmacy tasks remotely as necessary (i.e., prescription data entry and script verification), including those licensed outside the state.

Address Shortages and Continuity of Care

Authorize pharmacists to conduct therapeutic interchange and substitution without physician authorization when product shortages arise. The FDA should identify drugs that are in, or at risk, of shortage and work with firms to extend expiration dates. Require manufacturers to provide the FDA with more information on the causes of shortages and their expected durations and allow public reporting of this information.

Reimburse for Services and Remove Barriers

Provide coverage for services delivered by pharmacists if within scope of practice and covered for other healthcare providers. Remove the specific day's supply requirement from co-pay waivers for essential, life-sustaining medications to ensure continuous access when medication is in shortage or needs to be rationed. Remove restrictions and cover home or mail delivery. Assure access to testing, treatment, and pharmacists services for patients without adequate access to services.

immediately include the Pharmacy and Medically Underserved Areas Enhancement Act in emergency legislation to respond to the COVID-19 crisis.

Pharmacists as Front-Line Responders for COVID-19 Patient Care

As the coronavirus spreads throughout the country and the supply of qualified healthcare providers becomes limited, pharmacists are at the front-line providing essential patient care services during this public health crisis. We applaud the ongoing efforts of the federal government, states, and the private sector to educate, contain, prevent, mitigate, test, treat, and respond to the devastating COVID-19 pandemic that is plaguing our nation and the world. As front-line providers and highly trusted and trained healthcare professionals, pharmacists play a critical role in patient care and public health. Pharmacists around the country are serving their communities and helping patients cope with this pandemic. However, there is much more that pharmacists can do for their patients and ease the burden on the healthcare system if additional authorities are granted and barriers to access for pharmacist patient care services are removed.

Pharmacists are the most accessible healthcare providers and the first touchpoint of patient engagement with the healthcare system. In fact, 90% of all Americans live within five miles of a community pharmacy. In rural and underserved communities and in areas experiencing physician shortages, pharmacists may be the only healthcare provider that is immediately accessible to patients. As of May 2018, according to the Bureau of Labor Statistics, there are over 309,000 employed licensed pharmacists in the United States and its territories. Pharmacists practice in community pharmacies, hospitals, clinics, physician offices, long term care and other settings to provide patient care.

Pharmacists Test and Treat:

Pharmacists are trained to treat infectious diseases and can significantly expand access to care, if barriers are removed. In a growing number of states pharmacists currently have the authority to test for and treat infectious diseases, such as influenza and strep infections. For example, in Idaho, pharmacists are authorized to prescribe products to treat strep/flu pursuant to a rapid diagnostic test using an evidence-based protocol. Florida recently passed a law permitting pharmacists to test and treat for strep, flu and other non-chronic ailments. Additionally, forty-nine states and the District of Columbia allow for pharmacists to practice in collaboration with advanced practice prescribers, , including in several states that allow the ability to test and treat for infectious diseases, prescribe and administer vaccinations, and manage maintenance medication. However, pharmacists' authorities to test and treat are inconsistent across the states. At this time of need, we need consistency in authority across the country for pharmacists to use their training, expertise, and knowledge to test and treat patients.

We urge policymakers to include or authorize pharmacists in testing, interpreting, counseling patients on test results, initiating treatment, and counseling patients when treatments are available, and ensuring the appropriate legal and regulatory authorities support pharmacists call to action to provide this essential patient care.

Pharmacists are Immunizers:

Nearly all practicing pharmacists have been trained to administer vaccines to patients of all ages. Pharmacists play a critical role in increasing influenza vaccination rates across the United States. In 2013, an additional 4.1 million adults were vaccinated because of pharmacists' efforts. These additional vaccinations are estimated to have resulted in 81,000 to 134,000 fewer adult influenza infections that year. Additionally, the odds that an adult would receive the flu shot increased by 7.8 percent in states that allowed pharmacists to be immunizers.

We urge policymakers to include or authorize pharmacists as immunizers when a vaccine for COVID-19 is available and ensure the appropriate legal and regulatory authorities support pharmacists' call to action and appropriate reimbursement to provide this essential patient care.

Pharmacists are Responders:

As medication experts and providers, pharmacists are trained to respond quickly to patient needs - whether it is managing medication, identifying therapeutic needs and alternatives, testing, immunizing, counseling patients, compounding drugs that are in shortage, and more. Pharmacists can help respond to the COVID-19 pandemic by administering tests once they are commercially available, treating COVID-19 when treatments become available, and by testing for and treating influenza and strep throat infections. By testing and treating flu and strep in the pharmacy, the time from symptom development to treatment decreases. Importantly, caring for patients with flu or strep in the pharmacy alleviates some of the burden on hospitals and clinics so they can focus on high-risk COVID-19 patients. Pharmacists are also accessible and can respond to address patient care needs through telehealth and telepharmacy if appropriate authority is provided.

President Trump has declared a national emergency under the National Emergencies Act. The Secretary of Health and Human Services ("HHS") has declared a public health emergency under Section 319 of the Public Health Service Act. The Secretary is thereby authorized to take additional actions in addition to his regular authorities.

Under Section 1135 of the Social Security Act, the HHS Secretary may now temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program ("CHIP") requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods. It also allows providers who provide such services in good faith to be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).

We urge the Task Force and the HHS Secretary to use the full authority of Section 1135 to maximize the use of pharmacists to prevent, treat, and respond to the coronavirus pandemic.

To ensure that pharmacists in their communities are empowered to effectively support the COVID-19 response, we recommend federal and state policymakers take the following steps:

1. **Authorize Test-Treat-Immunize:** Authorize additional pharmacist-provided services.
2. **Ease Operational Barriers:** Address workforce and workflow issues that prevent full and effective pharmacist engagement in COVID-19 response
3. **Address Shortages and Continuity of Care:** Remove barriers for pharmacists to provide continuity of care if a medical product shortage exists
4. **Reimburse for Services:** Remove reimbursement barriers that prevent pharmacists from fully and effectively engaging in COVID-19 response

Specific Recommendations:

1. Authorize Test-Treat-Immunize and other pharmacist-provided services

As health systems become overburdened and reach their capacity for providing care, pharmacists can step in and relieve some of that burden by increasing access and providing faster testing and treatment for patients. Pharmacists are trained and authorized to provide these services in some states, but consistent application across all states is necessary to ensure pharmacists are fully utilized during the pandemic. The following actions should be taken to ensure access to pharmacist patient care services:

- Allow pharmacists to order, collect specimens, conduct, and interpret necessary tests and, where appropriate, initiate treatment for infectious diseases, including but not limited to flu, strep, and COVID-19, and interpret and discuss test results with patients.
- Allow all pharmacies to be granted a CMS certificate of waiver to provide all CLIA-waived point-of-care tests.
- Ensure access to and effective use of personal protective equipment (PPE) by all involved in testing.
- Expand current state pharmacist immunization authority to include all FDA approved vaccines, including the forthcoming novel vaccine for COVID-19, for all indicated populations.
- Allow pharmacists to independently evaluate and manage medications through therapeutic interchange, chronic care dose adjustment, refill authorizations, quantity modifications (e.g., 90-day fills), and other forms of prescription adaptation.
- Allow pharmacists to administer any injectable medication.

2. Ease Operational Barriers to address workforce and workflow issues that prevent full and effective pharmacist engagement in COVID-19 response.

COVID-19 response will strain our healthcare system to the breaking point. Every pharmacist will be needed, so flexible workforce and workflow arrangements will be essential to support healthcare teams. The following actions should be taken to allow providers the maximum flexibility in providing care access and to ensure pharmacists and other clinicians are safe and supported while providing patient care.

- Flexible Pharmacy Staffing:
  - Allow pharmacists and pharmacy technicians with valid licenses to operate across state lines, including via telehealth.
  - Authorize pharmacists and pharmacy staff to conduct routine pharmacy tasks remotely as necessary (i.e. prescription data entry and script verification, medication review and reconciliation), including those licensed outside the state to ensure business continuity.
  - Authorize pharmacies to temporarily operate in a satellite or other location not currently designated by permit (e.g., temporary space to allow pharmacy cleaning, etc.).
  - Authorize central fill operations in areas with pharmacy deserts and pharmacy workforce shortage areas.
  - Waive proof-of-receipt requirements in order to limit unnecessary contact with sick patients.
  - Ensure pharmacists and pharmacy staff that deliver prescription medications are designated essential personnel with freedom of movement during curfews, travel restrictions, or lockdowns.
  - Waive limitations on who can be in the pharmacy department so staff other than pharmacy personnel can assist with non-clinical functions.
  - Waive requirements for prior notification to a board of pharmacy and/or the public when a pharmacy is closed due to an emergency.
  - Provide pharmacy technicians in all practice settings with expanded authority, under a pharmacist's supervision, including authorization to:
    - Transfer prescriptions (excluding controlled substances);
    - Conduct technician product verification for refills (i.e., tech-check-tech); and
    - Administer rapid diagnostic tests for infectious diseases, including flu, strep, and COVID-19 tests, under the supervision of the pharmacist, and ensure that only the pharmacist interprets test results.
  - Waive pharmacy technician ratios.
  - Allow a grace period for pharmacy staff to renew CPR certification and/or renew their licenses or other requirements during emergency period.
- Flexible Medication fills/refills:
  - Allow any pharmacy to provide:
    - Early refills;
    - Prescriptions for greater than 30 days' supply; and
    - Emergency fills for non-controlled medications without a prescription when no refills remain.
- Adequate Workforce Protection:
  - Ensure provision of appropriate and effective personal protective equipment (N-95 masks, gloves, etc.) when necessary, for pharmacists, pharmacy personnel and all other health care professionals providing direct patient care to individuals (including screening and testing), handling hazardous substances and compounding.
- Provide Family Support:
  - During the declared national emergency, provide Federal, state, or public-private partnership funding for childcare and/or eldercare services for clinicians and pharmacy personnel who are unable to make alternative arrangements (e.g., those with school-age children whose schools have been closed) to ensure adequate staffing levels
- Educating Pharmacists:
  - Provide funding for infectious disease and emergency response continuing education to ensure that clinicians are up-to-date on clinical and regulatory changes.

3. Address Shortages and Continuity of Care

In order to care for patients, pharmacists and other clinicians must be able to access the medications and supplies they need. The following actions should be taken to mitigate shortages and strengthen our supply chain to mount the strongest possible COVID-19 response.

- Allow Therapeutic Interchange and Substitution:
  - States and CMS should authorize pharmacists to conduct therapeutic interchange and substitution with notification but without authorization of a prescriber when product shortages arise.
  - Plans should facilitate pharmacist therapeutic interchange and substitution without prior authorization when product shortages arise
- Increased Transparency Regarding Shortages:
  - FDA should be more transparent and timely in reporting drug shortage information under the national emergency, recognizing the sensitivities of preventing hoarding and stockpiling.
  - FDA should provide timely guidance regarding compounding processes and alternative ingredients providers can utilize when ingredients are in shortage.
- Extend Expiration Dates:
  - FDA should proactively identify drugs that are in or at-risk of shortage during the national emergency and urgently work with firms to extend expiration dates for drug products.
- Exercise Enforcement Discretion:
  - FDA should exercise general enforcement discretion over 503A and 503B compounders, except for matters of gross negligence or imminent threat to public health and safety, to allow maximum flexibility during the declared national emergency.
  - FDA should waive the restriction on compounding pharmacies to only ship out of state 5% of their overall prescription volume for specific products in shortage for the duration of the emergency.
  - FDA should use enforcement discretion for dispenser-to-dispenser transactions when there is no specific patient need under section 581(19) of the Federal Food Drug and Cosmetic Act and allow for transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need during the national emergency.
- Supply Chain Security and Integrity:
  - Require manufacturers to provide the FDA with more information on the causes of shortages and their expected durations and allow public reporting of this information.
  - Require manufacturers to publicly disclose manufacturing sites, including use of contract manufacturers, and sources of active pharmaceutical ingredients (APIs).
  - Require manufacturers to conduct periodic risk assessments of their supply chains and establish contingency plans to maintain the supply of a drug in the event of a manufacturing disruption.
  - Require HHS and DHS to conduct a risk assessment of national security threats associated with the manufacturing and distribution of critical drugs.
  - Incentivize domestic, advanced manufacturing capacity.
  - Government authorities (DOJ/HHS/FTC) should hold manufacturers, distributors, providers, and others accountable to state and federal price gouging laws in the sale of those items to pharmacies, hospitals, other healthcare providers, and consumers.
  - Government authorities (DOJ/FDA/FTC) should aggressively enforce laws and regulations against false and misleading claims and adulterated products by entities offering to sell pharmaceutical and medical products to healthcare providers and consumers.

4. Reimburse for Services: Remove reimbursement barriers that prevent pharmacists from fully and effectively engaging in COVID-19 response.

Immediately include the Pharmacy and Medically Underserved Areas Enhancement Act in emergency legislation to respond to the COVID-19 crisis. Pharmacists and pharmacies are vital to meeting public health needs. Financial sustainability is critical to ensuring that they can meet patient and community needs. The following actions must be taken to maintain patient access and keep doors open during this unprecedented crisis:

- Protect Patient Access to Medications:
  - Remove the specific day's supply requirement (e.g., 14-day or 30-day) from co-pay waivers for medications (e.g. insulin, among others) to ensure continuous access when medication is in shortage or has to be rationed.
  - Authorize pharmacy payment without administrative barriers for prescriptions filled at pharmacy of choice including early refills, quantity limits or emergency fills and refills
  - Remove restrictions and cover home or mail delivery by all pharmacies.
  - Suspend all pharmacy direct and indirect remuneration (DIR) fees assessed on all pharmacies immediately.
  - Instruct PBMs to allow 90-day prescription refills for patients by home delivery from any pharmacy of their choice or mail to include commensurate reimbursement
  - Relax prior authorization requirements to eliminate pharmacy and prescriber burden.
  - Assure coverage of testing and treatment services and other pharmacist services for beneficiaries and for patients without adequate healthcare coverage.
- Institute Medicare, Medicaid and Commercial Payor Systems that Ensure Access to Pharmacist Services:
  - Ensure that pharmacists will be paid for services provided:
    - Clarify Medicare and Medicaid authority to reimburse clinical services provided by pharmacists acting within their state scope of practice or as authorized under a national emergency by immediately including the Pharmacy and Medically Underserved Areas Enhancement Act in emergency legislation to respond to the COVID-19 crisis.
    - Issue clarification that physicians and qualified nonphysician practitioners (NPP) are permitted to bill for pharmacists' evaluation and management (E/M) services at higher levels than E/M code 99211 under incident-to physician services requirements to expand access to care.
    - Enable coding and billing infrastructure for pharmacies/pharmacists to receive appropriate coverage and reimbursement for the provision of care services, including screening, testing, immunization, and medication management whether under Medicare Part B, D, or Medicare Advantage.
  - Allow care provision flexibility:
    - Allow pharmacists' E/M services under incident-to physician arrangements to be delivered under general supervision requirements.
    - Allow pharmacists to bill for Medicare telehealth services within their scope of practice.
  - Delay pharmacy audits, which can be time consuming and burdensome, for the duration of the declared state of emergency.
  - PBMs, plans, and other payers should expedite prompt payments and reimbursements to pharmacies.

REFERENCES

[1]NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

[2]https://www.bls.gov/oes/2018/may/oes291051.htm

[3]NASPA. Pharmacist Prescribing: "Test and Treat." February 8, 2019, available at: https://naspa.us/resource/pharmacist-prescribing-for-strepand-flu-test-and-treat/

[4]Centers for Disease Control and Prevention, "Advancing Team-Based Care Through Collaborative Practice Agreements" (2017) www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.

[5]Code of Ala. § 34-23-77 (2019)

[6]Ourth H. Groppi J. Morreale A,. Quicci-Roberts K. Clinical pharmacist prescribing activities in the Veterans Health Administration. American Journal of Health-System Pharmacy, Volume 73, Issue 18, 15 September 2016, Pages 1406–1415, https://doi.org/10.2146/ajhp150778

[7]APhA 2019 Annual Report

[8]Drozd EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clin Ther. 2017 Aug 3. pii: S0149-2918(17)30771-3, available at: https://www.ncbi.nlm.nih.gov/pubmed/28781217

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO
American Pharmacists Association (APhA)

Paul W. Abramowitz, Pharm.D., Sc.D. (Hon.), FASHP
Chief Executive Officer, ASHP
American Society of Health-System Pharmacists (ASHP)

Rebecca P. Snead, RPh, CAE, FAPhA
Executive Vice President/CEO
National Alliance of State Pharmacy Associations

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer
National Association of Chain Drug Stores

Stacy Sochacki
Interim Executive Director
Hematology/Oncology Pharmacy Association (HOPA)

B. Douglas Hoey, RPh, MBA
Chief Executive Officer
National Community Pharmacists Association (NCPA)

Chad Worz, PharmD, BCGP
Chief Executive
American Society of Consultant Pharmacists (ASCP)

Lucinda L. Maine, PhD, RPh
Executive Vice President and CEO
American Association of Colleges of Pharmacy (AACP)

Michael S. Maddux, Pharm.D., FCCP
Executive Director
American College of Clinical Pharmacy

Sheila M. Arguette, RPH
Executive Director
National Association of Specialty Pharmacy

Brenda Schimenti
Executive Director
College of Psychiatric and Neurologic Pharmacists

Jan Engle, PharmD, PhD (HON), FAPhA, FCCP, FNAP
Executive Director
Accreditation Council for Pharmacy Education (ACPE)