

COVID-19 PERSONNEL AND SAFETY ISSUES

PREPARED FOR NASP
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Introduction

It is an understatement to see that what the country is experiencing is unprecedented—there is no playbook on how to respond. The law is frantically trying to catch up with events unfolding on the ground. Everything we can say herein is the best information we had as of this morning—it will change and may have already changed. Be sure to continue to monitor developments and seek additional information.

This white paper will present information and ideas designed to help pharmacies navigate the COVID-19 crisis. The motivation for pharmacies to successfully navigate this crisis are obvious but worth restating: (i) the pharmacy wants to take care of its patients; (ii) the pharmacy wants to take care of its employees; (iii) the pharmacy wants to keep its doors open; and (iv) sadly, but predictably, plaintiffs' attorneys will likely come out of the woodwork six months from now and will contemplate suing pharmacies for negligence; the attorneys will attempt to argue that the pharmacies did not take all reasonable steps to protect patients and employees; by following the steps set out in this white paper, pharmacies can argue that they took reasonable steps to protect patients and employees.

What to Do If Owner or Employee is Exhibiting COVID-19 Symptoms

There is no requirement to close the pharmacy if the owner or an employee is exhibiting symptoms or tests positive for COVID-19. Instead, an owner or employee should self-quarantine for 14 days or until he/she tests negative for COVID-19. It will be a best practice to notify employees immediately if the owner or an employee tests positive for COVID-19 or if he/she is exhibiting symptoms consistent with COVID-19.

However, this notification should be reasonably limited. We suggest that notification to those working closely with the individual should include more information than an announcement to those who may have had distant contact. Further, for larger or multi-location entities there may be no need to notify those who had no contact. An entity should perform enhanced cleaning and disinfection after the owner or an employee is suspected/confirmed to have COVID-19 and continue to routinely clean and sanitize all frequently touched surfaces in the pharmacy, such as workstations, keyboards, telephones, countertops, restrooms, shared spaces, doorknobs, etc. The pharmacy should have a sufficient stock of soap, hand sanitizer, and other supplies for employees to regularly sterilize throughout the day.

A pharmacy should prepare now for a scenario in which the owner or a key employee is quarantined. Specifically, the pharmacy should identify alternate key employee(s) to run essential business functions and maintain critical operations. The pharmacy should ensure that the employee is familiar and understands the pharmacy's policies and procedures, especially with respect to COVID-19 issues. The employee (i) will need to monitor ongoing public health recommendations and make sure pharmacy policies and practices are consistent with the recommendations; (ii) should stay in contact (*via* video or telephone conference) with the owner

or key employee to keep him/her updated on business operations; and (iii) will need to educate pharmacy employees about how they can reduce the spread of COVID-19.

How do I handle a patient that exhibits symptoms or that may have a positive diagnosis?

The pharmacy should establish a standard protocol to minimize contact with the patient but ensures that he/she still receives necessary medications.

A pharmacy may adopt a protocol that states that when a patient has symptoms but no diagnosis; then: (i) if the patient is high risk (e.g., elderly), the pharmacy will advise the patient to be tested as soon as possible; (ii) the pharmacy will encourage the patient to minimize contact with others (e.g., enroll the patient in medication synchronization and home delivery); and (iii) the pharmacy will provide education to the patient on prevention/mitigation measures (e.g., frequent handwashing, social distancing).

A pharmacy should develop a protocol for patients who have tested positive for COVID-19. This policy may include: (i) minimizing interaction with the patient (e.g., home delivery using e-signing measures); (ii) establishing a protocol for interacting with the patient to minimize risk of exposure (e.g., gloves, no contact, sanitizing areas after interaction); (iii) encouraging the patient to minimize contact with others (e.g., enroll the patient in medication synchronization and home delivery); and (iv) providing education to the patient on prevention/mitigation measures (e.g., frequent handwashing, social distancing).

A pharmacy should develop a protocol for symptomatic patients who enter the pharmacy. This policy may include: (i) isolate the patient to minimize his/her interaction with others by calmly approaching the patient and asking to speak with him/her privately (employee should use protocols to minimize exposure such as wearing gloves and mask); (ii) escort the patient to an area without others to determine the patient's needs; (iii) have the patient wait separately for his/her medications (e.g., ask the patient to wait in the car); (iv) encourage enrollment in home delivery or similar service for future pharmacy needs while the patient remains symptomatic; (v) sanitize any areas the patient came into contact with upon his/her departure; (vi) advise the patient to be tested; and (vii) provide the patient with education on minimizing exposure of others.

Asking a symptomatic or positive diagnosed patient to leave the pharmacy without providing services raises legal issues and should generally be avoided. Some states permit pharmacies to refuse fills but may require that the prescription be transferred to another pharmacy. Other states may require service to the patient or may allow the refusal of service for any reason. Where, however, a patient becomes hostile/violent in response to a pharmacy's reasonable protocol, it is acceptable to ask the patient to leave to mitigate harm to staff and other patrons. If the patient threatens violence or attempts to harm anyone, the pharmacy should call the police.

Obviously, the above only begins to demonstrate the depth of issues facing pharmacies in these uncertain times. Best practice demands the adoption of a solid policy and the use of common sense and empathy – empathy for patients, staff and others. The pharmacy should act with good reason and common sense and should document everything.

Federal Employment Law Addressing the COVID-19 Crisis

Below is a brief summary of recent employee leave laws including the Emergency Paid Sick Leave Act and the Emergency Family and Medical Leave Expansion Act. Both were passed as part of the Families First Coronavirus Response Act and become effective on April 2, 2020.

Emergency Paid Sick Leave Act - All employees are eligible regardless of their length of service, but the Department of Labor (“DOL”) may exclude certain health care providers and emergency responders. Employers with fewer than 500 employees must provide paid sick leave, but the DOL may exclude certain small businesses with fewer than 50 employees if providing paid sick leave would jeopardize the business as a going concern. For full-time employees, 80 hours of sick leave is available. For part-time employees, the average number of hours the employee works in a two-week period of sick leave is available. For example, if a part-time employee regularly works 25 hours per week, he/she would be eligible for 50 hours of paid sick leave. Sick leave must be made available immediately. Employers cannot require waiting periods and cannot require employees to use other available PTO or sick time first.

The following are the circumstances in which the Emergency Paid Sick Leave Act allows an employee to use emergency sick leave:

1. The employee is subject to a federal, state, or local quarantine or isolation order concerning COVID-19.
2. The employee has been advised by a health care provider to self-quarantine due to concerns related to COVID-19.
3. The employee is experiencing symptoms of COVID-19 and is seeking medical diagnosis.
4. The employee is caring for someone subject to an order of quarantine or isolation or someone who has been advised by a health care provider to self-quarantine due to concerns related to COVID-19.
5. The employee is caring for his/her minor child whose daycare or school has been closed or whose childcare provider is unavailable due to COVID-19.
6. The employee is experiencing any other substantially similar condition specified by the Secretary of Health and Human Services.

Employers must only provide paid sick leave to employees who are unable to work or telework due to one of the covered reasons above. For items 1 – 3 above, employers must pay the greater of the minimum wage *or* the employee’s regular rate of pay up to a cap of \$511 per day or a total of \$5,110. Most employers will pay the employee’s regular rate of pay. The minimum wage provision was likely included for tipped employees like waiters who are paid less than minimum wage. For reasons 4 – 6 above, employers must pay 2/3 of an employee’s regular rate of pay up to a cap of \$200 per day or \$2,000 total.

Emergency Family and Medical Leave Expansion Act - All employees are eligible who have been employed for at least 30 days, but the DOL may exclude certain health care providers and emergency responders. Employers with fewer than 500 employees must provide expanded FMLA leave, but the DOL may exclude certain small businesses with fewer than 50 employees if providing paid sick leave would jeopardize the business as a going concern. 12 weeks of FMLA leave is available, which is the same as traditional FMLA leave. An employee can use expanded FMLA when he/she is unable to work (or telework) due to a need to care for his/her minor child whose school or daycare has been closed due to a public health emergency declared by a federal, state, or local authority related to COVID-19. The first 10 days may be unpaid under this Act, but note that employees are entitled to two weeks (10 workdays) of emergency paid sick leave under the prior Act. The next 10 weeks of leave are paid at 2/3 of an employee's regular rate of pay, up to a cap of \$200 per day or \$10,000 total.

The law protects employees if a child is home due to a school or daycare closure, but not necessarily if the employee's child is sick. The law on its face does not protect the employee if he/she is sick or if a member of the employee's family is sick. It is important that a pharmacy factor in the employee's other available leave after the 10 days and consider concessions made previously for other employees. Pharmacies may also furlough and consider Unpaid Leave of Absence for sick employees. Flexibility and open communication are vital.

Initial guidance from the U.S. Department of Labor ("DOL")

Set out below is initial guidance from the DOL pertaining to the Emergency Paid Sick Leave Act and the Emergency Family and Medical Leave Expansion Act. Such guidance is in the form of FAQs found on the DOL's website.¹ Selected sections that we find particularly applicable to NASP members are highlighted below. Please note these FAQs are not legally enforceable, do not constitute legal advice, and do not carry the weight of regulations. However, they are meant to be instructive and provide a good roadmap for decision-making.

4. If providing child care related paid sick leave and expanded family and medical leave at my business with fewer than 50 employees would jeopardize the viability of my business as a going concern, how do I take advantage of the small business exemption?

To elect this small business exemption, you should document why your business with fewer than 50 employees meets the criteria set forth by the Department, which will be addressed in more detail in forthcoming regulations.

9. May I take 80 hours of paid sick leave for my self-quarantine and then another amount of paid sick leave for another reason provided under the Emergency Paid Sick Leave Act?

No. You may take up to two weeks—or ten days—(80 hours for a full-time employee, or for a part-time employee, the number of hours equal to the average number of hours that the employee works over a typical two-week period) of paid sick leave for any combination of

¹ <https://www.dol.gov/agencies/whd/pandemic/ffcr-a-questions>

qualifying reasons. However, the total number of hours for which you receive paid sick leave is capped at 80 hours under the Emergency Paid Sick Leave Act.

10. If I am home with my child because his or her school or place of care is closed, or child care provider is unavailable, do I get paid sick leave, expanded family and medical leave, or both—how do they interact?

You may be eligible for both types of leave, but only for a total of twelve weeks of paid leave. You may take both paid sick leave and expanded family and medical leave to care for your child whose school or place of care is closed, or child care provider is unavailable, due to COVID-19 related reasons. The Emergency Paid Sick Leave Act provides for an initial two weeks of paid leave. This period thus covers the first ten workdays of expanded family and medical leave, which are otherwise unpaid under the Emergency and Family Medical Leave Expansion Act unless you elect to use existing vacation, personal, or medical or sick leave under your employer's policy. After the first ten workdays have elapsed, you will receive 2/3 of your [regular rate of pay](#) for the hours you would have been scheduled to work in the subsequent ten weeks under the Emergency and Family Medical Leave Expansion Act.

Please note that you can only receive the additional ten weeks of expanded family and medical leave under the Emergency Family and Medical Leave Expansion Act for leave to care for your child whose school or place of care is closed, or child care provider is unavailable, due to COVID-19 related reasons.

38. Assuming I am a covered employer, which of my employees are eligible for paid sick leave and expanded family and medical leave?

Both of these new provisions use the [employee definition](#) as provided by the Fair Labor Standards Act, thus all of your U.S. (including Territorial) employees who meet this definition are eligible including full-time and part-time employees, and “joint employees” working on your site temporarily and/or through a temp agency. However, if you employ a health care provider or an emergency responder you are not required to pay such employee paid sick leave or expanded family and medical leave on a case-by-case basis. And certain small businesses may exempt employees if the leave would jeopardize the company's viability as a going concern. See [Question 58](#) below.

There is one difference regarding an employee's eligibility for paid sick leave versus expanded family and medical leave. While your employee is eligible for paid sick leave regardless of length of employment, your employee must have been employed for 30 calendar days in order to qualify for expanded family and medical leave. For example, if your employee requests expanded family and medical leave on April 10, 2020, he or she must have been your employee since March 11, 2020.

56. Who is a “health care provider” who may be excluded by their employer from paid sick leave and/or expanded family and medical leave?

For the purposes of employees who may be exempted from paid sick leave or expanded family and medical leave by their employer under the FFCRA, a health care provider is anyone

employed at any doctor's office, hospital, health care center, clinic, post-secondary educational institution offering health care instruction, medical school, local health department or agency, nursing facility, retirement facility, nursing home, home health care provider, any facility that performs laboratory or medical testing, pharmacy, or any similar institution, employer, or entity. This includes any permanent or temporary institution, facility, location, or site where medical services are provided that are similar to such institutions.

This definition includes any individual employed by an entity that contracts with any of the above institutions, employers, or entities institutions to provide services or to maintain the operation of the facility. This also includes anyone employed by any entity that provides medical services, produces medical products, or is otherwise involved in the making of COVID-19 related medical equipment, tests, drugs, vaccines, diagnostic vehicles, or treatments. This also includes any individual that the highest official of a state or territory, including the District of Columbia, determines is a health care provider necessary for that state's or territory's or the District of Columbia's response to COVID-19.

To minimize the spread of the virus associated with COVID-19, the Department encourages employers to be judicious when using this definition to exempt health care providers from the provisions of the FFCRA.

58. When does the small business exemption apply to exclude a small business from the provisions of the Emergency Paid Sick Leave Act and Emergency Family and Medical Leave Expansion Act?

An employer, including a religious or nonprofit organization, with fewer than 50 employees (small business) is exempt from providing (a) paid sick leave due to school or place of care closures or child care provider unavailability for COVID-19 related reasons and (b) expanded family and medical leave due to school or place of care closures or child care provider unavailability for COVID-19 related reasons when doing so would jeopardize the viability of the small business as a going concern. A small business may claim this exemption if an authorized officer of the business has determined that:

1. The provision of paid sick leave or expanded family and medical leave would result in the small business's expenses and financial obligations exceeding available business revenues and cause the small business to cease operating at a minimal capacity;
2. The absence of the employee or employees requesting paid sick leave or expanded family and medical leave would entail a substantial risk to the financial health or operational capabilities of the small business because of their specialized skills, knowledge of the business, or responsibilities; or
3. There are not sufficient workers who are able, willing, and qualified, and who will be available at the time and place needed, to perform the labor or services provided by the employee or employees requesting paid sick leave or expanded family and medical leave, and these labor or services are needed for the small business to operate at a minimal capacity.

59. If I am a small business with fewer than 50 employees, am I exempt from the requirements to provide paid sick leave or expanded family and medical leave?

A small business is exempt from certain paid sick leave and expanded family and medical leave requirements if providing an employee such leave would jeopardize the viability of the business as a going concern. This means a small business is exempt from mandated paid sick leave or expanded family and medical leave requirements only if the:

- employer employs fewer than 50 employees;
- leave is requested because the child’s school or place of care is closed, or child care provider is unavailable, due to COVID-19 related reasons; and
- an authorized officer of the business has determined that at least one of the three conditions described in Question 58 is satisfied.

The Department encourages employers and employees to collaborate to reach the best solution for maintaining the business and ensuring employee safety.

Tax Credits - The government is helping offset the cost of the above programs. Employers are permitted a tax credit in an amount equal to 100% of the qualified sick leave wages and qualified family leave wages paid per calendar quarter, up to the applicable caps. The pharmacy may want to create separate pay codes for emergency paid sick leave wages and expanded family leave wages in order to track expenditures accurately².

How to Handle a Decline in Business

Employers have several options if there is not enough work for employees. These include:

- Temporary lay offs
 - Employees are eligible for unemployment compensation.
 - These employees would be “off the books,” and not eligible for continuing benefits.
- Temporary furloughs
 - Furloughs should be for a stated period of time.
 - The employee remains on the books (and should still be eligible for health insurance).
 - Employees may also be eligible for unemployment compensation, depending on state laws.
- Reduced Work Hours
 - Non-exempt, hourly employees need only be paid for hours actually worked.
 - Exempt employees must be paid their full weekly salary for every week in which they perform any work.

² While we note the importance of this credit, we also acknowledge that pharmacies may opt out of the new paid leave requirements contained herein. In that case, some of this analysis will not be relevant. It is provided, however, because it is important to consider all options when making decisions such as whether to allow employee leave. We encourage readers to consult with their attorneys before making any decision on whether to opt out of the requirements of the Emergency Paid Sick Leave Act and the Emergency Family and Medical Leave Expansion Act.

- Consider one week on, one week off schedules for exempt employees.

What are PBMs doing in response to COVID-19?

PBMs are relaxing rules contained in their network agreements and policy manuals, including: (i) waiving early refill limits on prescriptions; (ii) encouraging 90-day supplies for maintenance medications; (iii) waiving home delivery fees; (iv) relaxing mail order restrictions; (v) suspending field and desk audits (but not fraud and abuse audits); and (vi) loosening signature requirements from patients.

For example, CVS/Caremark is: (i) waiving early refill limits on 30-day prescription maintenance medications; (ii) encouraging physicians to write prescriptions for 90-day supplies for maintenance medications; (iii) expanding the ability of pharmacies to mail or deliver medications by waiving some provisions of network agreements; and (iv) relaxing signature log requirements.

Express Scripts is permitting early refills for prescriptions but has warned that overrides will be monitored and may be audited. Express Scripts has also stated that “Pharmacies are NOT required to obtain signatures from patients during this unprecedented pandemic, unless required by law.” Express Scripts provides alternate means of satisfying signature requirements, including:

- Use of logbook that includes prescription number and date of service.
- Cash register receipts that include prescription number.
- Text message or email from patient.
- Note on the hard copy.
- Electronic annotation in the pharmacy system.

Express Scripts is suspending all network pharmacy field and desk audits. However, Express Scripts noted that its suspension of audits does not apply to fraud, waste and abuse investigations or other exceptions that may be required by law.

Leadership and Documentation

Patients, employees, and the general public are scared. Calm and confident leadership and demeanor can go a long way. The pharmacy needs to document all of its efforts in order to explain decisions that may be questioned in the future.

Emergency Declarations

All 50 states and the District of Columbia have declared a State of Emergency for COVID-19. Many of these declarations have effects on pharmacy practice. Changes include relaxed

standards on refills, use of pharmacy technicians, licensing, and remote practice of pharmacy. States continue to add/modify to their state of emergency declarations which may affect pharmacy practice. Pharmacies should check their State Pharmacy Board and Department of Public Health websites daily for up-to-date information on changes affecting their practice.

Hydroxychloroquine and Chloroquine Prescription Restrictions

Hydroxychloroquine and Chloroquine prescriptions have been on the rise for the prevention and treatment of COVID-19. Several states including New York, Ohio, and Arkansas have implemented heightened restrictions or recommendations pertaining to filling prescriptions for these drugs. Some restrictions may include permitting the dispensing of these drugs only for FDA-approved indications, as part of a state-approved clinical trial for COVID-19, or for patients who have tested positive for COVID-19. Pharmacies should check their State Board of Pharmacy website to determine whether their states have implemented restrictions on dispensing these drugs.

Infection Control Procedures

Alternative Patient Servicing Methods

Many states have recommended that pharmacies either implement or consider implementing infection control procedures for serving or dispensing prescriptions to patients. These procedures include exploring options to serve patients via drive-thru, curbside pick-up, or delivery rather than in the pharmacy itself. If a pharmacy is allowing the public to enter, the pharmacy should consider limiting the number of people who can be in the pharmacy.

One way to lower the number of people in the pharmacy is to create targeted procedures for more “at-risk” patients including older adults (60+), pregnant women, and individuals with chronic health conditions. This may be accomplished with signs directing these patients to drive-thru, curb-side delivery, mail delivery, or “senior hours,” etc.

Social Distancing of Patients

If patients are allowed to enter the pharmacy, then the pharmacy should create procedures to ensure proper “social distancing” of the patients. These may include placing signs encouraging social distancing, spacing of chairs in the waiting area at least six feet apart, and marking on the floor where patients should stand in line to ensure proper distancing from each other. If space allows, the pharmacy should place a barrier table or clear shower curtain in front of the pharmacy counter to ensure at least six feet separation between staff and patients.

Automated Dispensing Machines

Many states are seeing an increase in Automated Dispensing Machines (“ADMs”) by pharmacies. However, most states do not allow the placement of an ADM in an establishment properly registered as a pharmacy. Some states have relaxed the rule of the placement of an ADM and when and how it may be used, (e.g., Texas), but others have not (e.g., New York).

Before expanding the use of an ADM, the pharmacy should check with its State Board of Pharmacy to determine whether the state has relaxed its standards.

Alternate Staffing Models

Many pharmacies are running two separate shifts rather than overlapping shifts throughout the day. For example, Shift A may operate the pharmacy from 7am to 2pm and Shift B will operate the pharmacy from 2pm to 9pm. Both shifts are responsible for a complete cleaning of work surfaces at both the beginning and end of each shift to avoid contamination issues.

Identify Reserves

The pharmacy should contact pharmacists in its area who would be willing to work to prevent an emergency closing. The pharmacy should contact its State Board of Pharmacy for a list of pharmacists and technicians looking for hours. The pharmacy can also contact local schools of pharmacy to solicit student help.

Communications

The pharmacy should update its phone recording in order to inform patients of the pharmacy's COVID-19 procedures. The pharmacy should ask patients to like the pharmacy's Facebook page to receive updates. The pharmacy should also frequently update its website in order to inform patients.

Role of Personal Protective Equipment ("PPE")

The first line of defense for every business includes hand washing, alcohol-based hand rub, visual signs and alerts, and physical barriers between personnel and patients. If possible, pharmacy employees should wear gloves; the better practice would be to also wear face masks. Environmental decontamination (i.e., cleaning) is vital. If PPE is available, then it should be given to (i) staff and (ii) patients suspected of infection. If PPE is not available, the pharmacy should document attempts to obtain it.

THIS ARTICLE DOES NOT CONSTITUTE LEGAL ADVICE. THIS ARTICLE WAS PREPARED ON A SPECIFIC DATE. THE LAW MAY HAVE CHANGED SINCE THIS ARTICLE WAS WRITTEN. BEFORE ACTING ON THE ISSUES DISCUSSED IN THIS ARTICLE, IT IS IMPORTANT THAT THE READER OBTAIN ADVICE FROM A HEALTH CARE ATTORNEY.

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