Response to HHS Statements on Authorizing Licensed Pharmacists to Order and Administer COVID-19 Tests

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American College of Clinical Pharmacy

Society of Infectious Diseases Pharmacists

Infectious Diseases Society of America

The Society for Healthcare Epidemiology of America

The Pediatric Pharmacy Association

On April 8, 2020, Health and Human Services (HHS) published guidance under the Public Readiness and Emergency Preparedness (PREP) Act authorizing licensed pharmacists to order and administer FDA authorized COVID-19 tests, including serology tests, for the duration of the national public-health emergency declared January 31, 2020.

We applaud the leadership of HHS in calling on pharmacists to serve as members of the health care team in this emergency response effort, and for recognizing the central role of America's pharmacies in providing front line services. As we evaluated the guidance currently available from HHS and worked to support the development of best practices, we identified several key issues related to safety, accuracy, and reporting that we believe merit further HHS consideration:

1. **Guidance should be provided on availability/use of personal protective equipment (PPE) and the testing environment for pharmacies conducting POC testing.** The CDC has issued guidance for healthcare workers (HCWs) involved in the collection of respiratory specimens for diagnostic purposes, which would apply to point of care (POC) testing at pharmacies.[1] However, PPE shortages are challenging the U.S. healthcare system in unprecedented ways during this pandemic. In response, the CDC has issued recommendations for PPE equipment optimization.[2] Pharmacies implementing COVID-19 POC testing must consider employee and public safety, and the feasibility of performing testing in the pharmacy environment. To safely conduct optimal POC testing and conserve vital PPE, HHS should consider the following:

    - Drive-through prescription pickup windows operated by most pharmacies are not conducive to proper POC testing and should be avoided.
    - POC testing should be conducted outside the pharmacy itself and in an isolated drive-up setting, such as a pharmacy/supermarket parking lot, to avoid unnecessary viral exposure and allow patients to remain in their cars.
    - Designated pharmacies that meet safety criteria for POC testing should be identified so that PPE can be appropriately allocated to sites where testing will be conducted.
    - Adherence to CDC recommendations for conserving PPE and increasing use of other appropriate barriers should be required until PPE is fully available.
    - Pharmacists must undergo training on the storage, disposal/recycling, and use of PPE, including fit testing prior to using N-95 respirators.

2. **Guidance should be provided regarding test ordering and limitations.**
   Most of the tests that the Food and Drug Administration (FDA) has granted emergency use authorization (EUA) are for use only in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). There are well-documented accounts of false negative tests and the reported sensitivity rates of tests have varied.[3] Sensitivity can be influenced by the testing methodology itself, but also virus quantity in the sample and importantly, the sampling technique used.

   HHS should make available guidelines by which tests should be ordered by pharmacists. Furthermore, only three POC tests are currently authorized in the U.S.[4,5] Each test reports very high sensitivity and specificity, but these evaluations are based on a limited number of samples and internal controls with lack of experience in uncontrolled, community use.[5] The percentage of false negatives or false positives in the community setting is unknown and will be dependent on how widespread the disease is in any given community.

   Given the emergence of new tests on the market, HHS should make available on an ongoing basis information documenting clinical performance and recommending interpretation of currently approved tests.

3. **Guidance should be provided regarding reporting COVID-19 testing results to patients and their providers.** Patients must be advised on the appropriate actions to take if initially mild symptoms worsen (i.e., prompting them to seek emergency department/hospital care). An additional follow-up call or e-mail from the pharmacy several days after a positive result would be valuable, given that patients with COVID-19 can rapidly decompensate after the onset of symptoms.[6]

   HHS should make available to pharmacists guidelines for referring patients to their primary care clinician, including notification of test results, patient symptoms, and any counseling provided to the patient regarding suggested follow up.

4. **COVID-19 testing in the community represents a significant opportunity to characterize the spread of disease. To ensure systematic, ongoing reporting of results in the community, HHS should assure that pharmacies have processes in place to report both positive and negative results to local and state health departments**. Pharmacies should comply with regulatory requirements for testing and HHS should encourage public health departments to establish appropriate mechanisms to receive and record test results from pharmacies.

5. **HHS should only authorize serologic testing at pharmacies that adhere to the safety, testing, and reporting guidelines set forth above. If serologic testing is employed that requires a venous blood draw, training on venipuncture and safe handling/transport of blood samples should also be required.** As POC serologic testing becomes available[7], use of these assays at pharmacies would have an important and quantitatively substantial role in advancing epidemiologic analysis and research by:

   - Characterizing the rate of seropositivity in the community.
   - Identifying any waning in immunity over time.

- Identifying patients with immunity who may be able to donate convalescent serum for therapeutic or research use.
- Assessing response to any future FDA-approved COVID-19 vaccinations or vaccines in development.

We recognize the importance of HHS's leadership in taking steps to expand access to COVID-19 testing while reducing the burden on health care workforce capacity. Provided that the necessary resources can be made available to support and maintain COVID-19 testing by pharmacies, we strongly recommend that HHS pursue the recommendations outlined above.

References:

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