AN ANALYSIS OF POINT-OF-CARE TESTING & TREATMENT FOR INFLUENZA, INFLUENZA-LIKE ILLNESS, AND GROUP A STREPTOCOCCUS

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Florida TaxWatch

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Dear Fellow Taxpayer

Point-of-care tests are simple medical tests that can be conducted at or near the point of care. Point-of-care tests bring the test immediately and conveniently to the patient. A common example of a point-of-care test is the home pregnancy test. Point-of-care tests have been developed to diagnose influenza and streptococcus that use methodologies that are so simple to use that the likelihood of an incorrect result is negligible and that pose no reasonable harm to the patient if the test is performed incorrectly.

Point-of-care testing has gained popularity as it provides results quickly, which then permits the physician and medical team to make immediate decisions regarding the proper care of the patient. When used properly, point-of-care testing can lead to more efficient, cost-effective medical treatments and improved quality of medical care.

Legislation has been proposed that would permit pharmacists to diagnose and treat influenza and strep at community pharmacies, using point-of-care tests that have approved by the U.S. Food and Drug Administration. From the patient's perspective, the pharmacist is the most accessible and trusted medical professional. This has the potential to allow better patient experiences, improve the quality of care, and most importantly, encourage patients to take greater control of their medical conditions.

TaxWatch undertakes this independent analysis of point-of-care testing and treatment of influenza and strep at the at the request of Representative Rene Plasencia, the sponsor of the proposed House legislation. TaxWatch is pleased to present this report and its findings and looks forward to engaging policymakers and educators in discussion during the upcoming legislative session and beyond.

Sincerely,

Dominic M. Calabro

Dominic M. Calabro
President & CEO

Introduction

The 2017-18 influenza (flu) season ranks as the deadliest in more than four decades. An estimated 80,000 Americans died of flu and its complications last winter, according to the U.S. Centers for Disease Control and Prevention (CDC). An additional 900,000 or more Americans were hospitalized because of flu.[1] Flu is particularly deadly for pregnant women, children, older adults, and people with chronic conditions.

> *"Across the board, last year was definitely bad."*
>
> —Kristen Nordlund, U.S. Centers for Disease Control & Prevention

Each week in Florida, influenza and influenza-like illness (ILI) kill 23 people aged 65 and older, admit two pregnant women to the Intensive Care Unit, and send more than 1,000 children to the Emergency Department. In children under age five, ILI is responsible for more than 55,000 Emergency Department visits annually and more than $20,000/day ($7 million each year) in lost productivity. In adults aged 65 and older, ILI is responsible for more than 12,500 Emergency Department visits annually.[2]

Streptococcus is a type of bacteria that can cause strep throat (group A) or infections of the blood (type B). The CDC estimates approximately 11,000 to 13,000 cases of invasive group A streptococcus disease[3] occur each year in the United States. Each year between 1,100 and 1,600 people die due to invasive group A streptococcus disease.[4] The CDC does not track non-invasive group A streptococcus infections.

Influenza and streptococcus are diagnosed by a physician, who will conduct a physical exam, looking for signs and symptoms, and possibly ordering a test that detects the presence of viruses. The most commonly used test is called a rapid influenza diagnostics test (RIDT), which looks for substances (antigens) on a swab sample from the back of the nose or throat.

These tests can provide results in about 15 minutes; however, the results may vary greatly and may not always be accurate. Tests can be categorized as "waived" from regulatory oversight if they meet certain requirements established by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) law.[5] CLIA offers waivers if a laboratory test can be performed at "minimal level of complexity and low risk of erroneous results."

Treatment for influenza and influenza-like illness ranges from bed rest and plenty of fluids to prescribed antiviral medications, such as oseltamivir (Tamiflu) or zanamivir (Relenza). If taken soon after noticing symptoms, these drugs may shorten the illness by a day or so and help prevent serious complications.[6]

Streptococcus cannot be diagnosed simply by a visual inspection. A physician may conduct a physical exam, looking for signs and symptoms of streptococcus, supported by one or more of the following tests:

- Rapid antigen test --- using a swab sample from the patient's throat, a rapid antigen test can detect streptococcal bacteria in minutes by looking for substances (antigens) in the throat. If the test is negative but your physician still suspects strep, he or she might do a throat culture.
- Throat culture --- a sterile swab is rubbed over the back of the throat and tonsils to get a sample of the secretions. It's not painful, but it may cause gagging. The sample is then cultured in a laboratory for the presence of bacteria, but results can take as long as two days.[7]

If a patient is diagnosed with streptococcus, the physician will likely prescribe an oral antibiotic to reduce the duration, severity of symptoms, risk of complications, and likelihood that infection will spread to others. Over-the-counter pain relievers may also be used to relieve throat pain and reduce fever.

1 Susan Scutti, "Flu Season Deaths Top 80,000 Last Year, CDC Says," CNN, September 27, 2018, retrieved from www.cnn.com/2018/09/26/health/flu-deaths-2017--2018-cdc-bn/index.html, December 13, 2018.

2 Florida Department of Health, "Florida's State Health Assessment 2017."

3 The CDC does not track non-invasive group A strep infections.

4 U.S. Centers for Disease Control and Prevention, "Group A Streptococcal (GAS) Disease," retrieved from www.cdc.gov/groupastrep/surveillance.html, December 19, 2018.

5 Title 42, Chapter IV, Subchapter G, Part 493, Code of Federal Regulations.

6 Mayo Clinic, "Influenza (flu)," retrieved from www.mayoclinic.org/diseases-conditions/flu/diagnosis-treatment/drc-20351725, December 19, 2018.

7 Mayo Clinic, "Strep Throat," retrieved from www.mayoclinic.org/diseases-conditions/strep-throat/diagnosis-treatment/drc-20350344, December 19, 2018.

Purpose

Florida TaxWatch undertakes this independent analysis at the request of Representative Rene Plasencia (Appendix 1) to examine the benefits of point-of-care testing and treatment on influenza, influenza-like illnesses, and streptococcus at community pharmacies.

Point-of-Care Tests & Treatment

Point-of-care tests are simple medical tests that can be conducted at or near the point of care. Point-of-care tests allow diagnoses to be made in a physician's office, in a hospital, in an ambulance, in a patient's home, or in the field. Point-of-care tests bring the test immediately and conveniently to the patient. A common example of a point-of-care test is the home pregnancy test. Point-of-care testing has gained popularity as it provides results quickly, which then permits the physician and medical team to make immediate decisions regarding the proper care of the patient. When used properly, point-of-care testing can lead to more efficient, cost-effective medical treatments and improved quality of medical care.

Point-of-care testing has provided successful patient diagnoses in the physician's office, an ambulance, the home, the field, or in the hospital. The results of care are timely and allow rapid treatment to the patient. Empowering clinicians such as pharmacists to make decisions at the "point-of-care" has the potential to significantly expand health care delivery and to address the challenges of health disparities. The success of a potential shift from curative medicine, to predictive, personalized, and preemptive medicine could rely on the development of portable diagnostic and monitoring devices for point-of-care testing.[8]

A number of flu tests are available to detect influenza viruses in respiratory specimens. The most common are called "rapid influenza diagnostic tests" (RIDTs). RIDTs work by detecting the parts of the virus (antigens) that stimulate an immune response. These tests can provide results within approximately 10-15 minutes but are not as accurate as other flu tests, such as rapid molecular assays. These tests are simple swab tests and provide an automated reading, usually in the form of a positive (+) or negative (-), much like over-the-counter home pregnancy tests. There are currently eight RIDTs that have been approved by the U.S. Food and Drug Administration (Appendix 2).[9]

Simple, rapid tests for the diagnosis of streptococcus have been available since the 1980s. These "rapid strep tests" (RSTs) can be done at the point of care by swabbing the throat. Based on the results of the RST, the physician or clinician can then decide if antibiotics are needed. The symptoms of viral and bacterial infections may be hard to distinguish; however, only streptococcus can be effectively treated with antibiotics. The prescription of antibiotics will reduce the length and severity of streptococcus, as well as the likelihood of any complications. Like RIDTs, RSTs provide an automated reading, usually in the form of a positive (+) or negative (-),

When the point-of-care test produces a positive result, the dispensing of antiviral therapies (influenza) or antibiotic therapies (streptococcus) is governed by a protocol between the pharmacist and a physician. The protocol establishes criteria and procedures necessary to ensure that individuals who are diagnosed with influenza or streptococcus following diagnostic confirmation using a CLIA-waived tests receive timely and appropriate care.

8 National Institute of Health, "Point of Care Diagnostic Testing," U.S. Department of Health and Human Services, retrieved from https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=112, December 14, 2018.

9 U.S. Centers for Disease Control and Prevention, "Influenza (Flu)," retrieved from www.cdc.gov/flu/about/qa/testing.htm, December 14, 2018.

How well can rapid tests detect influenza and streptococcus?

During an influenza outbreak, a positive rapid flu test is likely to indicate influenza infection. Rapid tests, however, vary in their ability to detect flu viruses, depending on the type of rapid test used the type of flu viruses circulating, and the conditions under which the test is performed. Rapid tests appear to be better at detecting flu in children than adults. This variation in ability to detect viruses can result in some people who are infected with the flu having a negative rapid test result.[10]

The federal Clinical Laboratory Improvement Amendments (CLIA) program establishes quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health.[11] Test systems are characterized as "moderate" or "high complexity" based upon criteria established in CLIA.

"Non-waived testing" is the term used to refer collectively to moderate and high-complexity testing. In contrast, "waived testing" is the term that refers to tests that:

- Employ methodologies that are so simple to use that the likelihood of an incorrect result is negligible;
- Use unprocessed specimens (e.g., nasal swabs); and
- Pose no reasonable risk or harm to the patient if the test is performed incorrectly.[12]

As shown in Appendix 2, six of the eight RIDTs that have been approved by the U.S. Food and Drug Administration are CLIA-waived tests.

Testing during an outbreak of acute respiratory disease can determine if influenza is the cause and to guide prompt implementation of prevention and control measures. During influenza season, testing of selected patients presenting with acute respiratory illnesses compatible with influenza can help establish whether influenza is present in a specific patient population and help health-care providers determine how to use their clinical judgment for diagnosing and treating respiratory illness.

Only 10-15 percent of adults with acute pharyngitis (sore throat) test positive for streptococcus, yet up to 75 percent are prescribed antibiotics. The majority of pharyngitis cases are viral and self-limiting in nature and could be symptomatically treated with over-the-counter products.[13] Viral infections such as colds, flu, and sore throats should not be treated with antibiotics since the overuse and misuse of antibiotics allow the development of antibiotic-resistant bacteria. Antibiotic-resistant are oftentimes more difficult to kill and more expensive to treat. Rapid diagnostic tests for streptococcus can be beneficial in reducing the overuse and misuse of prescribed antibiotics.

10 This situation is called a false negative test result.

11 U.S. Centers for Disease Control and Prevention, "Clinical Laboratory Improvement Amendments (CLIA)," retrieved from https://wwwn.cdc.gov/clia/Regulatory/default.aspx, February 910, 2019.

12 American College of Physicians, "What are CLIA-Waived Tests," retrieved from www.acponline.org/practice-resources/business-resources/laboratory-proficiency-testing-program/clia-waived-testing, February 10, 2019.

13 National Community Pharmacists Association, "Point-of-Care (POC) Testing," retrieved from www.ncpanet.org/innovation-center/diversified-revenue-opportunities/point-of-care-(poc)-testing, February 11, 2019.

Results to Date

A 2016 electronic survey was sent to 379 pharmacists in a division of a large national supermarket chain in western Tennessee, Mississippi, and Arkansas to assess pharmacists' perceptions of point-of-care testing for influenza and streptococcus in a community pharmacy setting. The survey elicited responses from 34 percent (146 of 379) of those surveyed. This study found that 69 percent either agreed or strongly agreed to be willing to perform point-of-care testing in a community pharmacy setting, and 86 percent either agreed or strongly agreed to be willing to recommend appropriate treatment for influenza and streptococcus.[14]

The majority of respondents either agreed (52 percent) or strongly agreed (27 percent) that they possessed the clinical knowledge to treat these infections. In addition, 52 percent agreed and 32 percent strongly agreed that their staff could be trained to assist with these services. Finally, 66 percent acknowledged the presence of barriers to implementing this service.[15]

A 2013 study evaluated patient outcomes associated with a community pharmacy-based, collaborative physician-pharmacist Group A streptococcus management program in 55 chain and independent community pharmacies in Michigan, Minnesota, and Nebraska. Pharmacists screened clinically-stable adult patients who showed signs and symptoms consistent with Group A streptococcus using CentorTM criteria, and performed a physical assessment followed by a rapid antigen detection test for eligible patients. Patients were treated according to a collaborative practice agreement with a licensed prescriber or a physician consult site model. Pharmacists followed up with patients 24-48 hours after the encounter to assess patient status and the need for further intervention.[16]

Of 316 patients screened, 43 (13.6 percent) were excluded and referred for care. Of the 273 remaining patients that were eligible for testing, 48 (17.6 percent) had positive test results and 46 (16.8 percent) received amoxicillin or azithromycin per the collaborative practice agreement. Of those tested, 43.2 percent had no primary care provider and 43.9 percent visited the pharmacy outside of traditional clinic office hours.[17] The researchers concluded that the pharmacists demonstrated ability and capacity to provide care for patients seeking treatment for pharyngitis, and that the number of patients without a primary care provider and seen outside at the pharmacy outside of normal office hours highlights the improved access that community pharmacy-based care offers.

In a related 2013 study, researchers evaluated patient outcomes associated with a community pharmacy-based, collaborative physician-pharmacist influenza-like illness management program in 55 chain and independent community pharmacies in Michigan, Minnesota, and Nebraska. Pharmacists screened adult patients with influenza-like illness symptoms, completed a brief physical assessment, performed a point-of-care rapid influenza diagnostic test (RIDT), and provided appropriate referral or treatment according to a collaborative practice agreement with a licensed prescriber. Pharmacists followed up with patients 24-48 hours after the encounter to assess patient status and the possible need for further intervention.[18]

14 Kelli Dulaney, Kenneth Hoheimer, Cindy Fisher, Lindsey Cardosi, and Mike Wasson. "Exploring Pharmacists' Perceptions Regarding Influenza and Streptococcal Testing Within a Chain Pharmacy," Journal of the American Pharmacists Association, Volume 58, Issue 4, July-August 2018, retrieved from www.japha.org/article/S1544-3191(18)30131-6/fulltext, January 8, 2019.

15 Ibid.

16 Donald G. Klepser, Michael E.Klepser, Allison M. Dering-Anderson, Jaqueline A. Morse, Jaclyn K. Smiith, and Stephanie A. Klepser, "Community Pharmacist-Physician Collaborative Streptococcal Pharyngitis Management Program," Journal of the American Pharmacists Association, Volume 56, Issue 3, May-June 2016, retrieved from www.japha.org/article/S1544-3191(16)00141-2/fulltext, January 9, 2019.

17 Ibid.

18 Michael E.Klepser, Donald G. Klepser, Allison M. Dering-Anderson, Jaqueline A. Morse, Jaclyn K. Smiith, and Stephanie A. Klepser, "Effectiveness of a Pharmacist-Physician Collaborative Program to Manage Influenza-Like Illness," Journal of the American Pharmacists Association, Volume 56, Issue 1, January-February 2016, retrieved from www.japha.org/article/S1544-3191(15)00009-6/fulltext, January 9, 2019.

Of the 121 patients screened, 45 (37 percent) were excluded and referred to their primary care provider or urgent care facility for treatment. Of the 75 patients (62 percent) eligible for participation, 8 (11 percent) had a positive RIDT and were managed according to the collaborative practice agreement, Of the patients tested, 34.6 percent had no primary care physician and 38.7 percent visited the pharmacy outside of normal clinic office hours. Only 3 percent of the patients reported feeling worse at the follow-up.[19]

A sore throat test-and-treat service was introduced in 35 community pharmacies across two localities in England during 2014-15. Trained pharmacy staff assessed patients with sore throat symptoms using the Centor™ scoring system. Patients meeting three or all four of established criteria were offered a throat swab test for streptococcus. Patients with a positive throat swab test were offered antibiotic treatment.[20]

Following screening by pharmacy staff, 40.6 percent (149 of 367) patients were eligible for throat swab testing. Of these, only 24.2 percent (36 of 149) tested positive for Group A streptococci. Antibiotics were supplied to 9.8 percent (36 of 367) of all patients accessing the service. Just under half of patients that were not showing signs of a bacterial infection (60 of 123) would have gone to their general practitioner if the service had not been available. The study concluded that it is feasible to deliver a community-pharmacy-based screening and treatment service using point-of-care testing, and that this type of service has the potential to support the antimicrobial resistance agenda by reducing unnecessary antibiotic use and inappropriate antibiotic consumption.[21]

A 2015 study of the effects and feasibility of pharmacist-directed testing for group-A streptococcus at the point of care analyzed aggregate billing data for 7,050 patients at more than 200 pharmacies in the Canadian provinces of British Columbia, Alberta, and Nova Scotia.

Pharmacists trained in sample collection collected and analyzed throat swabs from patients with symptoms of streptococcus infection using the BD Veritor™ system.[22]

Of the 25.5 percent of the patients who tested positive for group-A streptococcus, antibiotic treatment was initiated the same day in 68.7 percent of the cases. In Alberta, where pharmacists have advanced prescribing authority, same-day treatment was initiated for 73.8 percent of the patients. Researchers concluded that the study highlighted the public's readiness to access point-of-care services in community pharmacies as well as the ability of pharmacists to expedite the management of treatment of patients with group-A streptococcus. Further, pharmacy-based streptococcus testing was shown to facilitate prompt and appropriate access to antibiotic treatment, as was demonstrated in regions with advanced prescribing authority. Researchers noted that the communication of treatment recommendations to the physician remains a barrier.[23]

19 Ibid.

20 Thornley, T., Marshall, G., Howard, P., and Wilson, A.P., "A Feasibility Service Evaluation of Screening and Treatment of Group A Streptococcal Pharyngitis in Community Pharmacies," July 2016, retrieved from www.ncbi.nlm.nih.gov/pubmed/27439523?dopt=Abstract, January 8, 2019.

21 Ibid.

22 John Papastergiou, Chantal Rene Trieu, Deborah Saltmarche, and Artemis Diamantouros, " Community Pharmacist-Directed Point-of-Care Group A Streptococcus Testing: Evaluation of a Canadian Program," Journal of the American Pharmacists Association, Volume 58, Issue 4, July-August 2018, retrieved from www.japha.org/article/S1544-3191(18)30080-3/fulltext, January 8, 2019.

23 Ibid.

Barriers to Implementing Point-of-Care Testing & Treatment

A meta-analysis of 132 studies was undertaken to identify barriers to the implementation of point-of-care testing.[24] Barriers were identified at the following levels:

- Test device level;
- Patient level;
- Provider level; and
- Health system level.

At the test device level, reported barriers were primarily related to diagnostic accuracy (73 percent), followed closely by implementation of barriers such as difficulties in conducting the test (19 percent), with complicated testing protocols as in performing multiple steps, and difficulties in reading the test results or following protocols.

At the patient levels, main barriers identified were:

- A lack of awareness and misconceptions relating to rapid diagnostic testing and point-of-care testing (28 percent), such as patient belief that rapid diagnostic testing and point-of-care testing devices were not accurate;
- Patient time constraints (22 percent) that included the turnaround time it took to perform rapid diagnostic testing and point-of-care testing, including the time to test, counsel, and receive results and linkages;
- Privacy and fear associated with receiving results with rapid diagnostic testing and point-of-care testing (17 percent), such as feeling too overwhelmed to receive a result in a clinic setting or concerns relating to their privacy; and
- Operational errors (9 percent), such as dry mouth, making it difficult for patients to provide a saliva/oral sample, and costs associated with obtaining a confirmatory test.

At the provider level, barriers (13 percent) were predominantly related to challenges in integrating them in their clinical workflow (46 percent). Other challenges were related to time, costs, and attitudes and reluctance of staff to conduct point-of-care tests. For example, clinics were not able to find the time to adequately train staff, or patients were often met with negative attitudes from staff regarding rapid diagnostic testing and point-of-care tests, and clinics did not offer rapid diagnostic tests regularly (33 percent).

A number of studies reported staff reluctance to use rapid diagnostic testing and point-of-care tests, citing reasons such as distrust of their results and apprehension about the reaction of clients to a rapid test result, as well as staff not being aware of rapid diagnostic testing and point-of-care tests availability or not having the time to attend training for them. In summary, a lack of interest, poor investment in training, negative perceptions regarding its benefits, reluctance due to change posed in their workflow, and resultant attitudes impeded their implementation. Other barriers were high costs, preference, and mistrust in accuracy.

At the health system level, reported barriers (18 percent) were predominantly related to integration, including:

- Difficulties integrating the tests within the health care systems (24 percent) or within the hospitals' clinical workflows (38 percent);
- A lack of quality control and assurance of rapid diagnostic testing and point-of-care tests (21 percent); and
- High costs associated with implementing these tests within the existing health care systems (15 percent).

24 Pai, Nitika; Wilkinson, Samantha, Deli-Houssein, Roni, Vijh Rohit, Vadnais, Caroline, Behlim, Tarannum, Steben, Marc, Engel, Nora; Wong, Tom, "Barriers to Implementation of Rapid and Point-of-Care Tests for Human Immunodeficiency Virus Infection: Findings from a Systematic Review (1996–2014)," Point of Care: The Journal of Near-Patient Testing & Technology, Volume 14, Issue 3, September 2015, retrieved from https://journals.lww.com/poctjournal/Fulltext/2015/09000/Barriers_to_Implementation_of_Rapid_and.4.aspx, January 9, 2019.

Point-of-Care Testing & Treatment in Florida

Over the last few years, the scope of practice for pharmacists has expanded to include the administration of vaccines and immunizations, assistance with medication management, as well as the injection of certain medications within an established protocol with a physician. During the 2018 legislative session, HB 431 and its Senate companion SB 524 would authorize pharmacists to test for and treat the flu and strep within the framework of an established written protocol with a physician licensed in this state. To be eligible to provide these services, a pharmacist would be required to meet a number of eligibility criteria, including:

- Acting within the framework of an established written protocol under a supervising physician that, at a minimum specifies the categories of patients the pharmacist is authorized to test for and treat the flu and strep, the supervising physician's instructions for treatment, and a process for reporting and reviewing the pharmacist's actions under the protocol;
- Using a test for which the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) has been waived; and
- Permitting the supervising physician to review the actions taken by the pharmacist in the manner outlined in the protocol.[25]

CS/HB 431 was reported favorably by the House Health Quality Subcommittee but, due to opposition from physicians' associations, died in the Health & Human Services Committee. Critics of the bill expressed concern about taking the authority for diagnosis out of the realm of medicine. A Senate companion bill (SB 524) died in the Health Policy Committee.

HB 111 has been filed for 2019 that would authorize pharmacists to test for and treat the flu and strep within the framework of an established written protocol with a physician licensed in this state. A similar bill (SB 300) has been filed in the Senate.

25 Professional Staff of the House Health Quality Subcommittee, "CS/HB 431 Testing for and Treatment of Influenza and Streptococcus," House of Representatives Staff Analysis, January 18, 2018.

Conclusions & Recommendations

Pharmacists are considered to be the most accessible health care providers. Implementing point-of-care testing and treatment for influenza and streptococcus in community pharmacies is one innovation that has the potential to benefit existing health systems by improving patients' access to care, reducing the costs of care, and by improving the quality of care and patient outcomes.

Studies cited in this report have shown that pharmacists: (1) are willing to perform point-of-care testing in a community pharmacy setting; (2) possess the clinical knowledge to treat influenza and streptococcus; and (3) are willing to recommend appropriate treatment for influenza and streptococcus. It has been demonstrated to be feasible to deliver a community-pharmacy-based screening and treatment service using point-of-care testing, and that this type of service has the potential to support the antimicrobial resistance agenda by reducing unnecessary antibiotic use and inappropriate antibiotic consumption.

These studies have also highlighted the public's readiness to access point-of-care services in community pharmacies, as well as the ability of pharmacists to expedite the management of treatment of patients with influenza and Group-A Streptococcus. Point-of-care testing has been shown to facilitate prompt and appropriate access to antibiotic treatment. Many of the patients tested and treated had no primary care physician and many visited the pharmacy outside of normal clinic office hours.

In addition to improving access, point-of-care testing has the potential to greatly reduce the cost of patient care. In 2017, Floridians made more than 8.9 million Emergency Department visits, at a total cost of more than $54.6 billion. This represents an average cost of $6,136 per Emergency Department visit.[26] The statewide average cost of all low-acuity adult Emergency Department visits in 2017 was $1,428.[27]

26 Floridahealthfinder.gov, "Emergency Department Query Results," retrieved from www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=E, February 14, 2019.

27 Agency for Health Care Administration, "Emergency Department Utilization Report 2017," retrieved from https://fhfstore.blob.core.windows.net/documents/researchers/documents/ED%20Report%202017%20Final.pdf, February 12, 2019.

Low-acuity Emergency Department visits are those involving problems that are self-limited or minor (much like the influenza or streptococcus problems that would be tested and treated at community pharmacies).

In contrast, point-of-care test kits range in cost from $18.00 to $24.50, with an average overall cost of $20.00. In addition to direct cost, testing requires between 15 and 45 minutes to perform, depending on the test used.[28]

The Agency for Health Care Administration reported[29] 250,197 emergency room visits for streptococcus and 83,129 emergency room visits for influenza during fiscal year 2017-18. For every 10 percent that had been tested and treated at a pharmacy instead of at an emergency room, $46.9 million would have been saved.[30]

Finally, these studies have shown that prompt testing and appropriate access to treatment results in positive patient outcomes. Pharmacists are able to see patients within 24-48 hours after the initial testing and treatment to assess patient status and the need for further intervention. A very small percentage of patients reports feeling worse at the follow-up.

These studies have also acknowledged the presence of barriers across all the main levels of the health care system which, although not insurmountable, pose challenges to the successful implementation of point-of-care testing and treatment of influenza and streptococcus. Overcoming these barriers has the potential to expand pharmacy services in community pharmacies, thereby improving access to healthcare, reducing its costs, and improving patient outcomes.

TaxWatch thinks point-of-care testing and treatment of influenza and streptococcus at community pharmacies is worthy of consideration by the Legislature as a way to improve access to healthcare, reduce its costs, and improve patient outcomes. TaxWatch recommends the Legislature more fully evaluate the pros and cons of point-of-care testing and treatment and identify ways to overcome the identified barriers to successful implementation.

28 William J. Hueston, MD and Joseph J. Benich III, "A Cost-Benefit Analysis of Testing for Influenza A in High-Risk Adults," Annals of Family Medicine. February 12, 2019.

29 Response to data request by Florida TaxWatch.

30 33,333 patients (10 percent) X $1,428 (average cost of low-acuity adult emergency department visits) = $47,599,524. 33,333 patients (10 percent) X $20 (cost of point-of-care test) = $666,660. The difference is $46,932,864.

Appendix 1.

Available FDA-Cleared Rapid Influenza Diagnostic Tests (Antigen Detection Only)

These tests provide results in 10-15 minutes and differentiate between influenza A and B				
Manufacturer	**Product**	**Platform/Instrument**	**Approved Specimens[1]**	**CLIA Waived[2]**
Alere	Binax Now Influenza A & B Card 2	Alere Reader	NPS, NS direct	Yes
Becton Dickinson & Co.	BD Veritor™ Flu A + B	BD Veritor Reader	NPS, NS direct	Yes
Quidel Corp.	Sofia® Influenza A + B FIA	Sofia FIA Analyzer	NS, NPS, NPA, NPW direct, NP, NPA, NPW in VTM	Yes
Quidel Corp.	Sofia® Influenza A + B FIA	Sofia 2 FIA Analyzer	NS, NPS, NPA, NPW direct, NP, NPA, NPW in VTM	Yes
Quidel Corp.	QuickVue® Influenza A + B	N/A	NPS, NS direct	Yes
Princeton BioMeditech Corp.	BioSign® Flu A & B LABSCO Advantage Flu A & B LifeSign LLC Status Flu A & B OraSure QuickFlu Rapid A + B Polymedco Poly stat Flu A & B Sekisui Diagnostics OSOM® ULTRA Flu A & B Meridian BioScience ImmunoCard STAT Flu A&B McKesson Consult Diagnostics Influenza A&B	N/A	NS, NPS direct (waived) NPA, NPW (not waived)	Yes
Becton Dickinson & Co.	BD Veritor™ Flu A + B	BD Veritor Reader	NPW, NA, NPS in VTM	No
Remel/Thermo Fisher	XPECT™ Flu A & B	N/A	Nasal wash	No

1. Available FDA cleared tests as of February 7, 2018. List may not include all available test kits approved by the FDA.

   Key:

   FDA = U.S. Food and Drug Administration
   N = nasal
   NP = nasopharyngeal
   A = aspirate
   S = swab
   W = wash
   N/A = RIDT does not use analyzer device
   VTM = viral transport media

2. Approved respiratory specimens according to manufacturer's package insert.

Source: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

Disclaimer: Use of trade names or commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Appendix 2

Representative Rene "Coach P" Plasencia

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October 4th,2018

Mr. Dominic M. Calabro
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Dear Mr. Calabro,

Last year, as Vice Chair of the Health Quality Subcommittee, I sponsored legislation that would have allowed pharmacists to provide point-of-care testing and treatment for Influenza and Strep. The testing and treatment would be provided through a strict protocol with a physician – similar to ones in place now for immunizations. The test for both the Flu and Strep is a simple swab test that is inserted into a device that quickly produces either a positive or negative result. The commonly used test is CLIA waived, (Clinical Laboratory Improvement Amendments) which is defined by the FDA as simple tests with a low risk for an incorrect result. They include: Certain tests listed in the CLIA regulations and tests cleared by the FDA for home use.

According to the Centers for Disease Control and Prevention (CDC), 80,000 people died of Influenza last winter in the U.S. It is acknowledged that diagnosing and treating Influenza within 48 hours of the onset of flu symptoms can shorten the duration and severity of the illness. Sited on the Florida Department of Health website, "the CDC recommends the use of antiviral treatment as soon as possible for all people who are hospitalized, severely ill, or at higher risk for complications with Influenza. A CDC health advisory stresses the importance of rapid and early antiviral treatment and last season even stated clinicians should not wait for laboratory confirmation to administer antivirals to people with suspected Influenza."

According to the Florida Department of Health, Florida's geographic and demographic characteristics make it particularly vulnerable to importation and spread of infectious diseases, including Influenza.

The Florida Department of Health has estimated that an Influenza pandemic could result in Florida of up to 10 million persons infected, with 5 million chronically ill. An estimated 3 million persons may require outpatient care with an additional 71,000 hospitalizations and up to 18,000 deaths. Demands on health care services under these conditions would overwhelm the state's delivery system. Existing medical facilities may be quickly overwhelmed, requiring the use of non-traditional medical settings.

Representative Rene "Coach P" Plasencia

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I respectfully request Florida TaxWatch research the health and economic benefits and potential risks for pharmacists to test and treat for Influenza and Strep, so that we can evaluate whether this legislation will increase healthcare access for Floridians.

Sincerely,

Representative Rene "Coach P" Plasencia

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ABOUT FLORIDA TAXWATCH

As an independent, nonpartisan, nonprofit taxpayer research institute and government watchdog, it is the mission of Florida TaxWatch to provide the citizens of Florida and public officials with high quality, independent research and analysis of issues related to state and local government taxation, expenditures, policies, and programs. Florida TaxWatch works to improve the productivity and accountability of Florida government. Its research recommends productivity enhancements and explains the statewide impact of fiscal and economic policies and practices on citizens and businesses.

Florida TaxWatch is supported by voluntary, tax-deductible donations and private grants, and does not accept government funding. Donations provide a solid, lasting foundation that has enabled Florida TaxWatch to bring about a more effective, responsive government that is accountable to the citizens it serves since 1979.

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The findings in this Report are based on the data and sources referenced. Florida TaxWatch research is conducted with every reasonable attempt to verify the accuracy and reliability of the data, and the calculations and assumptions made herein. Please feel free to contact us if you feel that this paper is factually inaccurate.

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