

## Executive Summary

- Representatives from the Baltimore City Health Department Sexual Health Clinics, University of Maryland, Johns Hopkins University, and Johns Hopkins Homecare Group have identified a need for expanded access to injectable antibiotics. Authorizing pharmacists to administer injectable therapies for the treatment of gonorrhea and syphilis in Maryland would address this need. This is based on CDC recommendations for the treatment of sexually transmitted infections (STI) during COVID-19-related interruptions of STD clinical services:
  - [Providing Non-Vaccine Injectables](#)
  - “STD clinics may need to find alternate ways to deliver non-vaccine injectables such as ceftriaxone and benzathine penicillin G. Where allowed, clinics may want to consider referring STD patients to pharmacists for the delivery of these injectables.”
- There have been dramatic changes in access to healthcare and clinical practice during the COVID-19 pandemic in the US. Although Maryland has begun implementing phased reopening, health care capacity is extremely limited and likely to remain so for quite some time, especially in jurisdictions with ongoing high numbers of COVID-19 cases. Currently, many public health and private healthcare facilities remain closed to in-person visits. As clinical services open back up, many practice sites will be short-staffed due to school and day-care closures. Limited staff capacity and on-going social distancing needs will result in significant delays in addressing the back-log of patients needing in-person care. Providers will continue to perform visits using telemedicine and prioritize in-person care for patients with urgent needs for many months to come. Maryland’s local health departments, vital safety net providers for some of the state’s most vulnerable residents, are severely impacted by the pandemic, according to monthly assessments of health departments’ STI clinical capacity. Staff in local health department STI and Family Planning programs, which provide STI testing and treatment, report being deployed full-time or part-time for COVID-19 response efforts.
- Mirroring national trends over the past five years, Maryland has experienced increases in reportable STIs, with sustained high rates of curable STIs such as chlamydia, gonorrhea, and syphilis. Rates of maternal and congenital syphilis have also increased in recent years. Furthermore, parts of Maryland have ongoing, high rates of HIV transmission.
- The introduction of social distancing, suspension of non-essential services and travel, have dramatically decreased clinical services that ordinarily provide diagnosis and treatment of STIs in Maryland. This creates an urgent need to address sexual health services, including presumptive STI treatment, in Maryland in order to treat patients who are unable to obtain treatment from their health care providers, and prevent increases in STIs including HIV. Since the presence of an STI significantly increases the likelihood of HIV transmission and acquisition, STI prevention is a critical part of HIV prevention.

Many first line STI treatments (i.e. preferred due to evidence supporting greater efficacy), as recommended by the CDC in the current [2015 STD Treatment Recommendations](#), require healthcare administered injection therapy. Utilizing non first line oral therapy increases the likelihood of gonorrhea and syphilis treatment failures and fosters the development of multi-drug resistant gonorrhea.

- Pharmacists are well positioned and trained to safely expand access to healthcare administered injection therapies, including IM antibiotic therapies. However, Maryland law does not allow pharmacists to administer injection therapy beyond immunizations and self-injectable medications.

## Statement of need for pharmacy administration of injectable antibiotics 1-14-2021

- As of 2019, 29 states allow pharmacists to administer non-vaccine injectables without restrictions (<https://naspa.us/wp-content/uploads/2017/07/Pharmacists-Authority-to-Administer-Medications.pdf>). This allows increased access and convenience for patients to receive their life saving therapies and the flexibility to come to the pharmacy for their scheduled dose(s) without an appointment. Pharmacies are also prepared to track and monitor missed doses and follow up with patients that have missed or are overdue for treatment. These benefits would not only improve access but also improve adherence to injectable therapies.
- Pharmacist training includes curriculum with extensive education regarding proper preparation and administration of all medications. All Accreditation Council for Pharmacy Education (ACPE) accredited colleges also prepare pharmacists to be able to administer all available immunizations which include intramuscular, subcutaneous, and intranasal administration. Pharmacists providing immunizations in Maryland are already basic life support (BLS) certified and prepared to monitor and treat anaphylactic or other serious reactions to immunizations.
- Under the Code of Maryland Regulations (COMAR) [10.34.32](#), pharmacists administering vaccines are required to create and follow a written protocol which includes assessment of precautions and contraindications, assessment of dose and route, process for handling adverse reactions, and process for documentation and informing prescriber of administration. Similar procedures could be created to allow pharmacists to effectively and safely provide access to additional injection therapies.
- Signatures of support for this position from public health specialists, infectious disease specialists, and primary care providers and pharmacists from the University of Maryland Medical System, Johns Hopkins University (School of Medicine, and JH Medicine), and Johns Hopkins Home Care Group can be found starting on page 6.

### Background

There have been dramatic changes in access to healthcare and clinical practice during the COVID-19 pandemic in the US. Maryland, like many other parts of the country has been affected by the pandemic with estimates of greater than 43,000 cases, 1,300 current hospitalizations, and 2,000 deaths as of May 2020 (<https://coronavirus.maryland.gov/>). Because of the introduction of social distancing, suspension of non-essential services, and non-essential travel, clinical services that ordinarily provide diagnosis and treatment of sexually transmitted infections (STI) in Maryland have dramatically decreased. In Baltimore City for example, the two public sexual health clinics, which typically provide STI-related care for 50-60 patients per day Mon-Fri, have been closed to walk-in appointments since 16 March 2020. Although the Governor has begun releasing a phased plan to reopen business and healthcare facilities, in-person operations of outpatient clinics will not return to “normal” for many months to come. Future second and subsequent waves of infection, which may include long-term redeployment of clinical staff to COVID-19 responses, have the potential to delay return to full operational capacity for months or even years. Clinics, and primary care practices will continue to perform most visits using telemedicine and prioritize in-person care for patients that require more emergent or acute illness requiring physical examination.

Many health care providers are attempting to provide STI diagnoses and prescribing treatment using telemedicine. In this scenario a clinician will discuss symptoms with a patient over the phone or video and prescribe therapy as indicated. The clinician will then send a prescription, based on likely STI(s), to a pharmacy that is convenient to the patient. The patient will then go to the pharmacy to collect that oral medication. In the case of gonorrhea and syphilis, providers are resorting to oral medications, instead of preferred injectable therapy, due to reduced access to injectable antibiotics.

## Statement of need for pharmacy administration of injectable antibiotics 1-14-2021

At present, pharmacists in Maryland are unable to administer injectable therapies to patients, aside from vaccinations and products considered self-injectable by patients. Importantly, the Centers for Disease Control and Prevention recommended first line therapies for STIs (specifically gonorrhea and syphilis) involve the administration of an injectable antibiotic. With limitations in travel currently in place due to COVID-19, access to injectable antibiotics for STI infections is limited, leading to increased prescriptions of non-standard oral medications for STI treatment. This results in a prescribed treatment that may be suboptimal. In the case of suspected syphilis, for example, a patient would typically receive an injection of long-acting penicillin in the clinic. This is administered by a healthcare professional and there is no doubt that the full dose has been delivered. In contrast, if a person were to be sent to a pharmacy for treatment, they would be asked to take an oral medication twice a day for up to 28 days. Given the twice-daily schedule and long duration, it is possible, that a significant proportion of those patients would miss doses or fail to complete the antibiotic course, leading to under-treatment or treatment failure. This may be a particular issue in certain vulnerable groups such as the homeless and those with substance use disorders.

Maryland has sustained high rates incidences of bacterial (ie., curable) STIs such as chlamydia, gonorrhea, and syphilis. Rates of maternal and congenital syphilis have also increased in recent years. According to the Sexually Transmitted Infections in Maryland, 2019 Snapshot (<https://phpa.health.maryland.gov/OIDPCS/CSTIP/CSTIPDocuments/2019%20Snapshot%20Report%20-%20Maryland%20STI%2010%20Year%20Trends.pdf>)

- Chlamydia

In 2019, the chlamydia rate per 100,000 population was 625.2, an increase of 6.6 percent compared to 2018

Cases have been increasing consistently since 2012 with an overall increase of 44 percent over the past 10 years

- Gonorrhea

In 2019, the gonorrhea rate per 100,000 population was 191.9, an increase of 12.7 percent compared to 2018

Cases in 2019 were over 56 percent higher than they were 10 years ago

- Syphilis

868 cases of Primary and Secondary (P&S) syphilis, the most infectious stages of infection, were reported to the Maryland Department of Health in 2019, an 18 percent increase from 2018

From 2010 to 2019, the rate of P&S syphilis infections increased from 5.7 cases per 100,000 to 14.4, a 153 percent increase overall

Furthermore, parts of Maryland are experiencing ongoing, high rates of HIV transmission. (<https://phpa.health.maryland.gov/OIDEOR/CHSE/SiteAssets/Pages/statistics/Maryland-HIV-Fact-Sheet-2019.pdf>).

STIs have many and diverse health consequences. Some of these are immediate and apparent; other complications may occur months or even years after the initial infection; including fetal death and disability

(syphilis); chronic pelvic pain and female infertility (chlamydia and gonorrhea); loss of vision, heart disease and dementia (syphilis). As well as the direct effects of STIs on the individual and the State's healthcare economy, there are very serious indirect effects. One of the most important consequences of untreated or improperly treated STIs is the risk of HIV acquisition and transmission. Therefore, parts of Maryland, with high rates of HIV and other STIs have the potential to see further increases in HIV infections.

### **Urgent state of STI treatment during COVID-19**

The full extent of any problem associated with limited treatment of STI will likely not be fully realized until more usual STI services have been reestablished. However, there are steps that can be taken now to safeguard the present and future sexual and reproductive health of Maryland's populations.

As a health care community providing essential treatment and preventive strategies for mitigation of the effects of STIs, we urgently need additional strategies that complement in-clinic activities, which are currently restricted. Aside from the limitations imposed by COVID-19, many patients, including those in rural areas and those without access to transportation, are at a distance from their nearest clinic. Pharmacists are ideally placed to step in to improve the sexual health of the population. They could administer an antimicrobial listed in the CDC's treatment guidelines to an individual with a prescription from an authorized prescriber. Such an expansion in the role of the pharmacist could dramatically expand the options open to patients, decrease time to treatment, decrease onward transmission of infection, improve antimicrobial stewardship, prevent emergence of resistant organisms, and help prevent complications of STIs.

### **Public health significance of under or partially treated STIs**

In addition to the numerous healthcare-related concerns outlined above, there are further, critical considerations when considering the inability of patients to access gold standard therapy for STIs. There are issues of access and equity where the more vulnerable members of society may be disadvantaged in terms of their ability to access the best, in this case injectable, therapies. While pharmacist -delivered injectable antibiotics is not a panacea and will not be acceptable or preferable to some patients, it does expand access and increase choice. In that sense pharmacist-delivered therapy will add to the arsenal of available options for patients and providers.

Gonorrhea has developed resistance to the last class of antibiotics used to treat the infection. Multi-drug resistant gonorrhea is a global threat to public health and requires vigilance of state public health laboratories and public and private clinicians nationwide. (<https://www.ncbi.nlm.nih.gov/pubmed/28746372>). The current treatment regimen recommended by the CDC involves a combined treatment with an injectable combined with an oral antibiotic. Gonorrhea infection can affect the genitals, rectum, eyes, and pharynx (throat). In the throat, the infection is eradicated effectively with this combined injection and oral therapy. However, an alternative oral-only regimen - which presently is all that can be provided in pharmacies in Maryland - is associated with significant treatment failure at the pharyngeal site. This failure is due, in part, to the pharmacokinetic properties of the oral drug cefixime in the pharynx; resulting in poor drug penetration at this site (<https://www.ncbi.nlm.nih.gov/pubmed/29624558>).

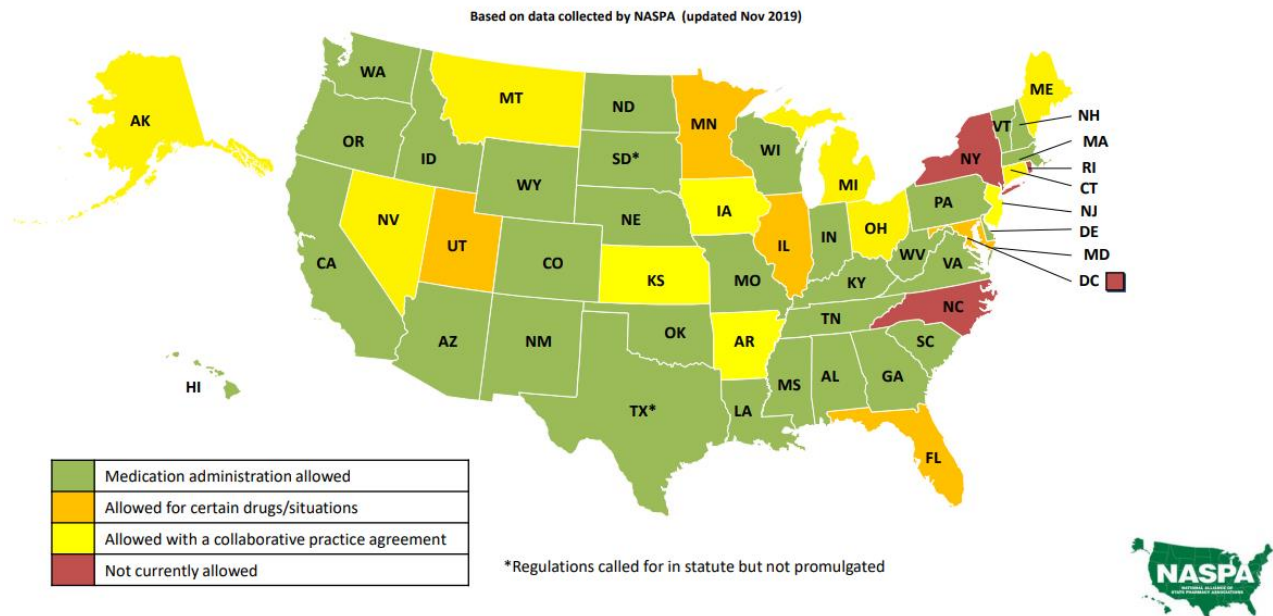
Apart from the risk of clinical failure and onward transmission of gonorrhea, good antimicrobial stewardship practices are compromised using an inappropriate therapy. There are data from Baltimore City demonstrating that antibiotic resistance in gonorrhea is common (<https://www.ncbi.nlm.nih.gov/pubmed/30126088>); particularly worrisome is the 2.1% prevalence of high level azithromycin resistance as azithromycin is a first-line drug used to treat gonorrhea (Figure 1).

### Pharmacy Administration and Safety

Pharmacists are well positioned and trained to safely expand access to healthcare administered injection therapies, including IM antibiotic therapies. Pharmacists have been able to expand access to immunizations in Maryland and across the country safely and effectively for many years. Pharmacist training includes curriculum with extensive education regarding proper preparation and administration of all medications. All Accreditation Council for Pharmacy Education (ACPE) accredited colleges also prepare pharmacists to be able to administer all available immunizations which include intramuscular, subcutaneous, and intranasal administration. Pharmacists providing immunizations in Maryland are already basic life support (BLS) certified and prepared to monitor and treat anaphylactic or other serious reactions to immunizations. Under the Code of Maryland Regulations (COMAR) 10.34.32 pharmacists administering vaccines are required to create and follow a written protocol which includes assessment of precautions and contraindications, assessment of dose and route, process for handling adverse reactions, and process for documentation and informing prescriber of administration. Similar procedures could be created to allow pharmacists to effectively and safely provide access to additional injection therapies.

Maryland is not unique in the need to utilize pharmacists to expand access to nonvaccine injectable medications. As of 2019, 29 states allow pharmacists to administer nonvaccine injectables without restrictions (<https://naspa.us/>). Pharmacist administered injections offers patients increased access and convenience to their life saving therapy and allows patients flexibility to come for their scheduled dose without an appointment. Pharmacies are also prepared to track and monitor missed doses to follow up with patients that have missed or are overdue for their dose(s). These benefits not only improve access but also likely improve adherence to injectable therapy.

### Pharmacist Authority to Administer Medications



<https://naspa.us/wp-content/uploads/2017/07/Pharmacists-Authority-to-Administer-Medications.pdf>

### **Intramuscular injectable antimicrobial therapy**

The CDC's STD treatment guidelines inform first line and alternative therapy choices for STI treatment. The preferred therapies for gonorrhea and syphilis are intramuscular injections whose efficacy is not equivalent when administered by other routes (oral, etc). The CDC-preferred injectable therapies including ceftriaxone, benzathine penicillin, procaine penicillin, gentamicin, and cefoxitin are routinely provided in outpatient office settings and could be administered in pharmacy settings.

### **Pharmacists are important members of a multidisciplinary therapeutic team**

Pharmacists undergo extensive training regarding medication safety and administration. As an important member of a medical team, pharmacists already support clinicians (including physicians, nurse practitioners, and physician assistants) with immunization, medication interaction assessment, and patient counseling.

Signed:

**Anne Rompalo, MD, ScM**

Professor of Medicine

Johns Hopkins Medicine

[arompalo@jhmi.edu](mailto:arompalo@jhmi.edu)

**Barbara Wilgus, MSN, CRNP**

Nurse Practitioner Johns Hopkins Medicine,

Project administrator, STD/HIV Prevention Training Center at Johns Hopkins

[bwegwei1@jhmi.edu](mailto:bwegwei1@jhmi.edu)

**Denise Fu, PharmD**

Clinical Programs Manager, Johns Hopkins Outpatient Pharmacy

[dfu5@jhmi.edu](mailto:dfu5@jhmi.edu)

**Elizabeth Gilliams, MD, MS**

Medical Director for STD services, Sexual Health Clinics

Baltimore City Health Department

Clinical Associate, Division of Infectious Diseases

Johns Hopkins Medicine

[Elizabeth.gilliams@baltimorecity.gov](mailto:Elizabeth.gilliams@baltimorecity.gov)

**Gregory Taylor, MD**

Associate Professor of Family and Community Medicine

University of Maryland Medical System

[GTaylor@som.umaryland.edu](mailto:GTaylor@som.umaryland.edu)

**Jeanne C. Keruly, MS, CRNP**

Assistant Professor of Medicine, Investigator, HIV Clinical Cohort

Johns Hopkins University School of Medicine

[jkeruly@jhmi.edu](mailto:jkeruly@jhmi.edu)

**John Gerwig, PA-C**

Physician Assistant Manager

Johns Hopkins University School of Medicine

[jgerwig@jhmi.edu](mailto:jgerwig@jhmi.edu)

**Joyce Leitch Jones, M.D., M.S.**

Assistant Professor of Medicine

Johns Hopkins University School of Medicine

[jjone154@jhmi.edu](mailto:jjone154@jhmi.edu)

**Mark Sulkowski, MD, FAASLD, FIDSA**

Professor of Medicine

Chief, Division of Infectious Diseases Johns Hopkins Bayview

Associate Dean, Office of Capital Region Research

Johns Hopkins University School of Medicine

[msulkowski@jhmi.edu](mailto:msulkowski@jhmi.edu)

**Mary Regan, RN, PhD**

Associate Professor, Organizational Systems and Adult Health

Statement of need for pharmacy administration of injectable antibiotics 1-14-2021

University of Maryland School of Nursing

[regan@umaryland.edu](mailto:regan@umaryland.edu)

**Matthew Hamill, MBChB, PhD**

Clinical Chief for STD services, Sexual Health Clinics

Baltimore City Health Department

Assistant Professor of Medicine Johns Hopkins Medicine

[mhamill6@jhu.edu](mailto:mhamill6@jhu.edu)

**Matthew Lengel, PharmD, MS, BCACP**

Clinical Pharmacy Manager, Johns Hopkins Outpatient Pharmacy

[mlengel1@jhmi.edu](mailto:mlengel1@jhmi.edu)

**Paul G. Auwaerter, MD**

Sherrilyn and Ken Fisher Professor of Medicine

Clinical Director, Division of Infectious Diseases

Johns Hopkins University School of Medicine

[pauwaert@jhmi.edu](mailto:pauwaert@jhmi.edu)

**Richard D. Moore, MD, MHS**

Professor, Medicine

Johns Hopkins University School of Medicine

[rdmoore@jhmi.edu](mailto:rdmoore@jhmi.edu)

**Sherilyn Brinkley, MSN, CRNP**

Program Manager of Clinical Services and Research for the Viral Hepatitis Center

[sbrinkle@jhmi.edu](mailto:sbrinkle@jhmi.edu)

**Sheila Goldscheider, R.N., M.S.**

Nurse Manager, John G. Bartlett Specialty Practice



[sgoldsc1@jhmi.edu](mailto:sgoldsc1@jhmi.edu)

**Typhanye Vielka Dyer, MPH, PhD**

Assistant Professor, Epidemiology and Biostatistics

University of Maryland School of Public Health

[typhanye@umd.edu](mailto:typhanye@umd.edu)

**Yukari C. Manabe, MD**

Medical Director, John G. Bartlett Specialty Practice

Johns Hopkins Medicine, School of Medicine, Division of Infectious Diseases

[ymanabe@jhmi.edu](mailto:ymanabe@jhmi.edu)