

COUNTY OF



ALLEGHENY

RICH FITZGERALD
COUNTY EXECUTIVE

**Meeting of the Allegheny County Board of Health
March 22, 2023**

1. Call to Order
2. Approval of Minutes for the meeting of January 11, 2023
3. Public Comments on Agenda Items
4. Director's Report
5. New Business Action Items

For Public Comment

- Revisions to Article XXI: Air Pollution Control related to Clean Air Fund and related regulations

For Final Approval

- Revisions to Article II: Syringe Services Programs Approval and Reporting
- Revisions to Article XXIII: Universal Blood Level Testing

6. Public Comment on Non-Agenda Items
7. Adjournment



ALLEGHENY COUNTY HEALTH DEPARTMENT

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Allegheny County Board of Health
January 11, 2023
Minutes

Present: Dr. Lee Harrison, Chairman
Dr. Debra Bogen, Secretary
Anthony Ferraro
Dr. Kotayya Kondaveeti
Caroline Mitchell
Dr. Edie Shapira
Dr. Ellen Stewart
William Youngblood, Vice Chair

Absent: Dr. Donald Burke
Dr. Joylette Portlock

1. Call to Order

Board Chair Lee Harrison welcomed everyone to the Allegheny County Board of Health meeting.

County Executive Rich Fitzgerald, County Manager William McKain and Chief of Staff Jennifer Liptak congratulated the Board of Health and Dr. Debra Bogen on her appointment as PA Secretary of Health. Members of the Board thanked Dr. Bogen for her service.

2. Election of Officers

Edie Shapira moved to nominate Dr. Harrison for Chair and Tony Ferraro seconded the motion.

Action: The board approved the motion unanimously with Dr. Harrison abstaining.

Dr. Shapira moved to nominate William Youngblood as Vice Chair.

Action: The board approved the motion unanimously with Mr. Youngblood abstaining.

3. Approval of Minutes

Dr. Harrison asked for a motion to approve the minutes.

Action: Mr. Youngblood moved and Dr. Shapira seconded the motion to approve the minutes from November 2, 2022. **Members approved the motion unanimously.**

4. Public Comments on Agenda Items

Patrick Dowd reported there were three written comments sent in by email about moving forward with revisions to Article XXI relating to the Clean Air Fund regulations and related regulations.

Patrick Campbell, Daniel Brickman, Matthew Nemeth, Kim Meechum, David Mickel, Mark Jeffrey, Germain Patterson, and Jay Walker spoke on revisions to Article XXI Clean Air Fund Regulations.

5. Director's Report

Director Debra Bogen began her report with National COVID-19 updates. COVID-19 in the last few months has been fairly stable. Hospitalizations have been going up. Dr. Bogen presented a graph with the various variants that are driving the pandemic.

Dr. Bogen proceeded to show our local dashboard from the last few months. The County has had stable levels for quite some time. However, the County has moved into the CDC level of “medium” most likely from the post-holiday season. We continually see deaths from COVID-19. She explained with the “medium” risk people should consider vaccines, exposures and wear a mask indoors.

She gave us an update on vaccine rates in our County. The table is broken down by race and age group and of those both fully vaccinated and the bivalent booster rate. The rates of vaccination increase with age with children still having low vaccination rates. The same holds true for the bivalent booster rates among seniors and children. Disparity by race persists, despite efforts to use trusted messengers and institutions, traveling throughout the county and more.

Dr. Bogen explained the value of a bivalent booster vaccine for protecting senior residents of Allegheny County.

Dr. Bogen turned her attention to syphilis. Cases have been on the rise and from January to October 2022 there have been eleven cases of congenital syphilis. This is completely preventable with screening and appropriate care. The Pennsylvania Department of Health State has shared guidance and recommendations to test for syphilis

Dr. Bogen reviewed notable recent activities, including reports and website updates.

As of January 1, 2023, the new Food Safety regulations are effective.

Air quality in Allegheny County continues to improve. Between 2010-2022, the ACHD has been monitoring the air. The quantity of PM2.5 has decreased 32% at the Liberty monitor since 2010 and our modeling predicts that we would be able to meet the National Air Ambient Quality Standard set by the federal government. At the end of November, the ACHD submitted a Redesignation Request for the Maintenance Plan for PM2.5 to the EPA. She explained that we have room to improve and work to be done.

Dr. Lee Harrison asked if there were any questions. Members asked about vaccines for syphilis. Dr. Bogen explained that there are no vaccines, but we do offer testing at our STI Clinic and work with other clinics across the county to support counseling.

Dr. Bogen introduced Geoff Rabinowitz, Deputy Director, Bureau of Environmental Health.

Mr. Rabinowitz began his Air Quality Program annual update saying that we have made significant progress and the team has done an outstanding job, but there is still more work to be done.

The program consists of four major areas: Monitoring, Planning and Data Analysis, Permitting and Enforcement. There are 60 total FTE positions and 13 current vacancies. The overall budget is about \$6.5 million. The Regulated Entities Portal (REP) which is a data management, facility permitting and compliance software package that is still in development. The portal will help with putting information out publicly and allowing an easy portal for payment and submittals for renewal applications.

The Monitoring program is updating and modernizing its capabilities. The Planning and Data Analysis program just completed the PM2.5 Redesignation Request and Maintenance Plan and is working on new improvement plans. The Permitting program issued seven major (Title V) permits, including USS Clairton and ALCOSAN. The Enforcement program has completed approximately 2,900 inspections and responded to 900 complaints. They have issued 31 enforcement actions with eight resulting in assessed penalties of \$5 million. There are 39 enforcement actions in progress.

Looking ahead, the Air Quality Program plans to:

- Continue sharing information with the public on its regulatory work
- Review the data on the Mon Valley Episodes and consider possible revisions to the rule
- Complete the implementation of the new data system
- Begin evaluating climate resiliency plans
- Improve the fiscal standing of the program

Mr. Rabinowitz explain he has implemented a metric tracking system to understand the work of the program. The goal will be to determine how to improve efficiency and to make sure the costs of the program are properly aligned with the fee structure.

Members of the board asked about the permitting backlog. Geoff answered that we have eighteen months to get through the permitting process and that it would depend on the permit.

Another question was regarding the 2,900 total inspections in 2022. Would there be any data that can be compared to 2021 and then look at it month-to-month every year. Geoff answered it would be possible and that he will get the information to them.

Members of the board asked how much of the fine money had been collected. Mr. Rabinowitz answered that even if a regulated entity appealed an enforcement order, they had to put the fine money in an account, like an escrow account, until the appeal processes was finished.

6. New Business – Action Items For Public Comment

A. Revisions to Article XXI Related to the Clean Air Fund and Related Regulations

Mr. Rabinowitz asked on behalf of the ACHD for permission to take proposed revisions to Article XXI to the public for comment. Mr. Rabinowitz explained that the first portion of the proposed revisions would support the Air Quality Enforcement Program. The second portion of the change would support the Air Quality Program in general as it works to establish long-term sustainable funding for the operations of the program.

The Air Quality Program took this version, which is certainly not the first version, to the Air Quality Advisory Committee in December. The committee unanimously voted not to recommend this to the Board of Health. Mr. Rabinowitz explained that the ACHD feels a sense of urgency about these proposed revisions and wants to have this matter resolved in the first portion of the year. These changes are necessary because of the budget needs of the program.

Mr. Rabinowitz turned to the portion of the revisions related to enforcement. He explained that the minimum cost of an enforcement action would be \$500 and would increase depending on the actual cost to the department, which is not limited to salaries, benefits, supplies and travel. The dollars collected would be deposited in the Air Pollution Control Fund, which is essentially the operating fund for the program. This practice is very common in other jurisdictions both in Pennsylvania and around the country.

Turning to the second portion of the proposed revisions, Mr. Rabinowitz explained that the regulations permit the Air Quality Program to request up to five percent of the prior year fund balance to support normal operating expenses of the program. The proposed revisions would increase that amount to the lesser of 25 percent of the prior year fund balance or \$1.25 million.

The Air Quality Program's budget last year was approximately \$6.5 million. The five percent request returned approximately \$540,000. Because the ACHD experienced shortfalls in other areas of revenue, most notably the EPA 105 grant, the Air Quality Program was not sufficiently

funded in 2022. In prior years, the EPA had said they would fund the program at approximately \$990,000, annually. In the last few years, the EPA funding has fallen well short of that number. As a result, in 2022, the ACHD had to turn to the county government to cover a shortfall of revenue.

Mr. Rabinowitz explained that the ACHD does not want to be in that situation in the future. To that end, he has undertaken a full study of the program, its operations and where efficiencies can be found. In the meantime, it would be important to take these proposed revisions to the public for their comment and consideration.

Board members asked about EPA funding and what might happen were those funds to arrive. Kim Joyce, Deputy Director of Administration, explained that the ACHD would only request Clean Air Fund resources when it was certain there would be insufficient funding for the program.

Board members asked if there was potential that we will have mandated unfunded activities. Ms. Joyce responded, “yes.” The ACHD contract with the EPA requires that the program match the revenue from the EPA, which the program does using its fee revenue.

Board members informed Mr. Rabinowitz that the Air Advisory Board did not want this to go to public comment until there was further information. Mr. Rabinowitz reiterated that the Air Quality Program has met repeatedly with the committee. While they have rejected multiple versions of this document, he and the director remain concerned about the need to properly fund this program. Some board members advocated moving the proposed revisions to the public for comment. Debate followed.

Action: Mr. Ferraro moved not to send the proposed revisions to the public for comment. Caroline Mitchell seconded the motion. Mr. Ferraro, Ms. Mitchell, Mr. Youngblood and Dr. Stewart voted Yes. Dr. Harrison, Dr. Shapira and Dr. Kondaveeti voted No. **The board approved the motion.**

For Final Approval

B. Environmental Health Fund Request for Larvicide

Otis Pitts, Deputy Director of Food, Housing and Public Policy introduced the environmental health request from Vector Control in the Housing and Community Environment Program. He asked for the Board’s approval for the use of fund resources to supplement our supply of mosquito control products for use this spring and summer. This year the program is requesting \$25,950 to compliment the \$45,000 from the State DEP to allow us to purchase 75 cases of mosquito larvicide and catch basis in residential areas around the county and the City of Pittsburgh. Mr. Pitts asked the members if they had any questions, and they did not.

Action: Mr. Ferraro motioned to approve. Mr. Youngblood seconded. **The board approved the motion unanimously.**

C. Environmental Health Fund Request for Publishing Revisions to the International Plumbing Code

Mr. Rabinowitz introduced the request for the Plumbing Program to use the Environmental Health Request fund to request \$17,000. This money would be used for the International Code Council (IPC) to distribute printed copies of the new code to the Health Department and act as the

marketplace for plumbers and business that would need a copy. The new plumbing regulations rules would then be put into a usable rulebook. The contract is for five years for a total of \$17,000.

Action: Mr. Youngblood moved, and Mr. Ferraro seconded. **The board approved the motion passed unanimously.**

7. Public Comments on Non-Agenda Items

Mr. Dowd reported the public submitted no written comments on non-agenda items.

Zachary Barber, Ava Roberts, Angelo Taranto, Christine Graziano, Thaddeus Popovich spoke on Air Quality. Lorraine Starsky, Sally Snyder, and Janet Minnick spoke about COVID.

8. Adjournment

Dr. Harrison adjourned the meeting at approximately 2:50 pm.

For Board of Health review March 22, 2023.

The Air Program is seeking Board approval to submit this regulation revision to public comment.

(The Air Advisory Committee recommended such approval at their March 13, 2023 meeting.)

Proposed

Revisions to

**Allegheny County Health Department
Rules and Regulations
Article XXI, Air Pollution Control**

(Tracking No. 102 – Not A Revision to the State Implementation Plan)

§2109.09, “Allegheny County Clean Air Fund”

and

Related Section

§2109.07 “Penalties, Fines and Interest”

{Document Date: March 15, 2023}

Tracking No. 102
(Not a SIP Change)

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1. **Changes to Article XXI Rules and Regulations:**
 - §2109.07, “Penalties, Fines and Interest”
 - §2109.09, “Allegheny County Clean Air Fund”

2. **Support Document**

3. **Documentation of Public Hearing and Certifications (all “Later”)**
 - Public hearing notice and notice
 - Certification of hearing
 - Summary of comments and responses

1. Proposed Regulation Revision

Deletions are shown with strikethroughs.
Additions are shown in **larger font, bolded, and underlined.**

§2109.06 CIVIL PROCEEDINGS *{Paragraph a.1 amended September 6, 1995, effective October 20, 1995.}*

b. **Penalty Determination.**

1. In determining the amount of the penalty, the Department shall consider: the wilfulness of the violation; the actual and potential harm to the public health, safety, and welfare; the damage to the air, soil, water, and other natural resources of the County and their uses; the economic benefit gained by such person by failing to comply with this Article; the deterrence of future violations; the costs of the Department; the size of the source or facility; the compliance history of the source; the nature, frequency, severity, and duration of the violation; the degree of cooperation in resolving the violation; the speed with which compliance is ultimately achieved; whether or not the violation was voluntarily reported; other factors unique to the owners, operators, or other responsible parties of the source or facility; and other relevant factors.
2. In determining the economic benefit gained by such person, the Department may use the formulas contained in the current Civil Penalty Policy published by the EPA, and/or the regulations promulgated by EPA pursuant to Section 120 of the Clean Air Act, as appropriate.

§2109.07 PENALTIES, FINES, AND INTEREST *{ Subsection b amended September 15, 2021, effective September 25, 2021. **Subsection b amended mm/dd/year, effective mm/dd/year.** }*

- a. **Fees.** A source that fails to pay any fee required under this Article when due shall pay a civil penalty of 50% of the fee amount, plus interest on the fee amount computed in accordance with Paragraph a.4 of §2109.06 of this Article from the date the fee was required to be paid. In addition, the source may have its permit revoked.
- b. **Disposition of Monies Collected.**
 1. All interest received by the County under this Article as a result of fees under Sections 2102.10.h, 2103.40.i, and 2103.41.a.1 of this Article shall be paid into the Allegheny County Air Quality Fund for the major operating permit program.
 2. All interest received by the County under this Article as a result of fees, other than the fees under Sections 2102.10.h, 2103.40.i, and 2103.41.a.1 of this Article, shall be paid into the Allegheny County Air Pollution Control Fund.
 3. All penalties, fines, interest, and other funds received by the County under this Article as a result of consent orders, noncompliance penalties, civil penalty actions, consent decrees, civil penalties, or summary proceedings, other than such funds provided for under paragraph 1 above, shall be paid into the Allegheny County Clean Air Fund; **with the exception of “the costs of the Department” pursuant to §2109.06.b.1. which shall be paid into the Allegheny County Air Pollution Control Fund.**

§2109.08 ALLEGHENY COUNTY AIR POLLUTION CONTROL FUND & AIR QUALITY FUND *{Paragraph c amended July 16, 2009, effective July 26, 2009. Subsection e amended September 15, 2021, effective September 25, 2021.}*

- a. **Purpose.** The purpose of the "Allegheny County Air Pollution Control Fund", a restricted fund established by the Allegheny County Board of Commissioners for the Health Department on August 27, 1992, as of the effective date of this Article, is to receive and disburse all air pollution control fees, related interest, and all other related funds, including but not limited to related administrative charges and reimbursements for costs, in accordance with the Air Pollution Control Act Amendments of 1992, but not funds payable to the Allegheny County Air Quality Fund established under Subsection e below.
- b. **Disposition of Monies Collected.** All funds received by the County under this Article as a result of fees, related interest, and all other related funds, including but not limited to related administrative charges and reimbursements for costs, shall be paid into the special fund known as the Allegheny County Air Pollution Control Fund.
 1. The Funds under this Section shall be administered in accordance with the provisions of the Second Class County Code and other applicable laws. The County Treasurer shall invest monies deposited in the Funds in such manner as not to impair the liquidity of the Funds and shall credit all interest accruing on such monies to the respective Funds.
 2. The Department shall report on the status of the Funds to the Board of Health on an annual basis, or at such other intervals as the Board may require.
 3. Audits of the Funds shall be performed as required by law.
- c. **Disbursements.** Disbursements of monies from the Allegheny County Air Pollution Control Fund shall be utilized solely to cover all reasonable (direct and indirect) costs incurred by the County and required to develop and administer the County's air pollution control program other than those portions of the program required by Title V of the Clean Air Act. No air pollution source, which is subject to the provisions of this Article shall receive monies from the Funds under this Section, or services, equipment, or materials purchased with such monies, to fulfill its obligations under this Article, except for Department facilities supporting the Air Quality Program.
- d. At no time for any purpose shall monies be disbursed or borrowed from the Allegheny County Air Pollution Control Fund, or otherwise distributed or encumbered, except as specifically allowed under this Section.
- e. There is hereby established the "Allegheny County Air Quality Fund" for the major operating permit program which is specifically for the deposit of all fees, and related interest, and only such fees and interest, collected by the County under this article to implement the requirements of Title V of the Clean Air Act, and the disbursement of such funds, and only such funds, solely to cover all of the costs of the County's air pollution control program required by Title V of the Clean Air Act. All funds received by the County under this Article as a result of fees, and related interest, collected from sources that require a major operating permit, and only such funds, shall be paid into the Allegheny County Air Quality Fund for the major operating permit program. Disbursements of monies from the Air Quality Fund for the major operating permit program shall be utilized solely to cover any and all reasonable (direct and indirect) costs required to develop and administer the County's air pollution control program required by Title V of the Clean Air Act, whether such costs are incurred by the County or other State or local agencies that do not issue permits directly but that support permit issuance or administration. At no time for any purpose shall monies be disbursed or borrowed from the Air Quality Fund for the major operating permit program, or otherwise distributed or encumbered, except as specifically allowed under this Section.

§2109.09 ALLEGHENY COUNTY CLEAN AIR FUND *{Paragraphs c & d amended July 16, 2009, effective July 26, 2009. Subsection c & d amended mm/dd/year, effective mm/dd/year.}*

- a. **Purpose.** The purpose of the "Allegheny County Clean Air Fund" is to receive and disburse all penalties, fines, and interest received by the County under this Article as a result of applications, permits, licenses, consent orders, noncompliance penalties, civil penalty actions, consent decrees, civil penalties, or summary proceedings, other than any fees, related interest, and other related funds. The Clean Air Fund is specifically for the disbursement of such funds solely to support activities related to the improvement of air quality within Allegheny County and to support activities which will increase or improve knowledge concerning air pollution, its causes, its effects, and the control thereof.

- b. **Disposition of Monies Collected.** All funds, other than fees, related interest, and other related funds received by the County under this Article shall be paid into the special fund known as the Allegheny County Clean Air Fund.
 1. This Fund shall be administered in accordance with the provisions of the Second Class County Code and other applicable laws. The County Treasurer shall invest monies deposited in the Fund in such manner as not to impair the liquidity of the Fund and shall credit all interest accruing on such monies to the Fund.
 2. The Department shall report on the status of the Fund to the Board of Health on an annual basis, or at such other intervals as the Board may require.
 3. Audits of the Fund shall be performed as required by law.

- c. **Disbursements.**
 1. Disbursements of monies from the Allegheny County Clean Air Fund shall be utilized solely to support the purposes set forth under Subsection a above. Funds may therefore be disbursed for such purposes as, but not limited to:
 - A. The support of research and development of control technologies;
 - B. Health effects studies and surveys concerning air pollution;
 - C. Special purpose monitoring, as defined by the EPA;
 - D. Public education concerning air pollution;
 - E. The acquisition of consulting or other services from persons with special experience and/or expertise;
 - F. The purchase of equipment, materials, or services to supplement the County's air pollution control program; ~~or~~

G. The normal operating costs of the County's Air Quality Program, as described in Paragraph 2, below;
or

H.G. Any other project that is consistent with the purpose of this Section and the mission of the Board of Health.

2. **Disbursements for normal operating costs.**
 - A. **For calendar years 2023 – 2026, an amount, no greater than 25 percent of the balance of the Clean Air Fund on December 31st of the previous calendar year or \$1,250,000, whichever amount is less, may be used to fund the normal operating costs of the County’s Air Quality Program.**
 - B. **After calendar year 2026,** ~~An~~ **an** amount, no greater than five percent of the balance of the Clean Air Fund on December 31st of the previous calendar year, may be used to fund the normal operating costs of the County’s Air Quality Program.
3. No air pollution source, except for Department facilities supporting the Air Quality Program, which are subject ~~t~~**o** the provisions of this Article shall receive monies from this Fund, or services, equipment, or materials purchased with such monies, to fulfill its obligations under this Article.
- d. **Procedures for Disbursement of Funds.** Procedures for disbursement of monies paid into the Clean Air Fund shall be as follows:
 1. The Department shall prepare requests for disbursements.
 2. **In support of a request for disbursement for normal operating costs under Paragraph c.2, the Air Quality Program shall provide a Program budget summary including revenue streams and the operational costs of the Program which the requested funds will go to support.**
 - ~~3.2.~~ The Department shall consult with the Air Pollution Control Advisory Committee regarding the disbursement requests.
 - ~~4.3.~~ The Department shall present requests for disbursements to the Board of Health. The request shall include a summary of the consultation with the Air Pollution Control Advisory Committee.
 - ~~5.4.~~ The Board of Health shall approve or disapprove requests for disbursement made by the Department. Approval of the Air Pollution Control Advisory Committee is not required.

End of Regulation Changes

2. Support Document

Summary of Change

The proposed changes to Article XXI increase the amount that may be drawn annually from the Clean Air Fund for normal operational expenses of the Air Quality Program from 5% of the year-end balance to 25% of the year-end balance or \$1,250,000, whichever is the lesser, during calendar years 2023 to 2026, inclusive, and also specifies that shall deposit the costs to the Department associated with imposing a penalty into the Air Pollution Control Fund.

Impact on PA State Implementation Plan

The following Article XXI sections are being revised:

§2109.07, “Penalties, Fines and Interest

§2109.09, “Allegheny County Clean Air Fund”

None of these sections are in the Allegheny County portion of the Pennsylvania State Implementation Plan, thus this change is **not** a SIP revision.

3. Documentation of Public Hearing and Certifications (all “later”)

Public Hearing Notice
Certification of Hearing
Summary of Comments and Responses

Rules and Regulations

ARTICLE II ~~NEEDLE EXCHANGE~~ **SYRINGE SERVICES** PROGRAMS
APPROVAL AND REPORTING FOR COMMUNICABLE DISEASE
PREVENTION
~~AND PROVIDING DRUG TREATMENT OPPORTUNITIES~~

201. PURPOSES

The Allegheny County Health Department finds the sharing of intravenous injection apparatus **equipment** among ~~injecting drug users~~ **people who inject drugs (PWID)** a threat to public health. Sharing injection apparatus **equipment** is a significant factor in the transmission of infectious diseases, including HIV and Hepatitis B and C. **Syringe services programs are designed to prevent the spread of HIV, Hepatitis B and C, and other bloodborne pathogens by providing clean sterile injection apparatus equipment, and biohazard containers, and other supplies** through a sanctioned needle-exchange program, educating injecting drug users as to the dangers of sharing injection apparatus and continued drug abuse, and providing condoms to prevent sexual transmission of infectious diseases have been shown to reduce the incidence of infectious disease transmission among injecting drug users. Repeated offerings of drug rehabilitation services have also been demonstrated to increase the likelihood that injecting drug users will enter treatment, and through one or more attempts, become drug-free. **They also represent a significant opportunity to connect PWID to appropriate medical care and treatment. Syringe services programs operate under a philosophy of harm reduction, which honors the dignity of those who use drugs or are living with a substance use disorder, reduces the negative consequences of injection drug use, and provides a stigma-free environment for people who inject drugs by providing the care they desire and need. Programs can also act as trusted sources for other harm reduction services, allowing syringe services programs to act as a bridge to initiatives designed to prevent overdoses and overdose deaths as well as to social support services.**

202. STATEMENT OF POLICY

The regulation of ~~needle-exchange~~ **syringe services** programs is necessary to assure that the distribution of **clean-sterile** injection apparatus **equipment** and biohazard containers is carried out in a manner consistent with the goal of preventing infectious disease transmission among ~~injecting drug users~~ **PWID**, and to encourage the provision of the greatest number of ~~treatment and prevention strategies~~ **harm reduction services** possible, with the ultimate goal of reducing the incidence of HIV and Hepatitis B and C among injecting drug users, their sexual partners, and their offspring. Such prevention **services** will promote **improve** the health, safety and welfare of the community.

203. EFFECTIVE DATE

The provisions of this Article will become effective ten days after the enactment date of an ordinance of Allegheny County approving its provisions.

204. DEFINITIONS

The following terms when used in this Article have the meanings indicated in this section, ~~except where the context indicates a clearly different meaning.~~

“Biohazard Containers” shall mean ~~approved~~, limited access, puncture-proof receptacles to be used for the safe storage of used hypodermic needles or sharps waste.

“Board of Health” shall mean the Allegheny County Board of Health.

“Department” shall mean the Allegheny County Health Department.

“Director” shall mean the Director of the Allegheny County Health Department or ~~his or her~~ their authorized representative.

“Emergency Opioid Antagonist” shall mean a drug approved by the United States Food and Drug Administration for the complete or partial reversal of an opioid overdose, including, but not limited to, intramuscular, nasal, and autoinjector formulations.

“Harm Reduction Services” shall mean programs or practices that aim to reduce the negative health and social impacts of substance use. Examples of harm reduction services include but are not limited to: infectious disease screenings; vaccinations; education about overdose prevention; wound care; **emergency opioid antagonist distribution and education; and referrals to health and social services.**

~~“Infectious Disease Screening” or “IDS” shall mean testing blood or other tissue for HIV and Hepatitis B and C, by a Clinical Laboratory Improvement Amendments (CLIA) approved method.~~

~~“Injection Apparatus~~ **Equipment**” shall mean **materials involved in injecting drugs including, but not limited to,** syringes, hypodermic needles, cotton, water, and alcohol wipes.

“Medications for Addiction Treatment” shall mean drugs approved by the United States Food and Drug Administration for the treatment of substance use disorders or the use of such drug, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders and any concomitant conditions associated with it.

“Overdose” shall mean an acute condition, including, but not limited to, physical illness, coma, mania, hysteria, seizure, cardiac arrest, cessation of breathing, or death, which reasonably appears to be the result of consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a layperson would reasonably believe requires medical assistance.

"Program Participant" shall mean any individual receiving services, materials, or referrals from a needle exchange **syringe services** program.

"Program Location" shall mean the specific, **fixed** address at which a Needle Exchange **syringe services** Pprogram provides any materials or services to any Pprogram Pparticipant(s), whether inside a building or at a temporary facility, including, but not limited to, **a building**, tents, outdoor tables, or mobile facilities **vehicles**.

“Key Individuals” shall mean individual(s) with actual authority **and responsibility for** over the day-to-day operations of **the Needle Exchange syringe services** Pprograms **and that serves as the contact for communication with the Department.**

“Needle Exchange **Syringe Services** Program” shall mean a public or private enterprise with the goal of reducing the incidence of infectious disease transmission among, Program Participants, their sexual partners, and their offspring, approved by the Board of Health, through the provision of education on safe practices, counseling opportunities, clean Injection Apparatus, Biohazard Containers, and condoms or other barrier methods of preventing sexually transmitted diseases **a program where unused, sterile hypodermic needles, syringes, and other supplies are distributed and collected for safe disposal. These programs may also provide additional harm reduction services, either through direct access or referral, that are intended to lessen the adverse consequences of drug use and protect public health and safety.**

“Person” shall mean any natural person, corporation, partnership or association.

“Post-exposure Prophylaxis (PEP)” shall mean antiretroviral drugs approved by the United States Food and Drug Administration for the prevention of HIV infection after a possible exposure to HIV.

“Pre-exposure Prophylaxis (PrEP)” shall mean drugs approved by the United States Food and Drug Administration for the prevention of HIV infection in individuals at risk for exposure from sexual activity or injection drug use.

“Secondary Exchange” shall mean a practice through which persons distribute unused injection equipment and other supplies obtained from an approved syringe services program to PWID who are unable to travel to the program location, and who may also collect used hypodermic needles, syringes, and other supplies from PWID for safe disposal.

"Sharps Waste" shall mean used ~~syringes and lancets~~ injection equipment.

"Wound Care" shall mean treatment of the symptoms of skin and soft tissue infections that may result from injection drug use.

205. NEEDLE EXCHANGE SYRINGE SERVICES PROGRAM REQUIREMENTS

205.1 Application and Approval Process

- A. The Department shall, ~~subject to the approval of the Board of Health,~~ devise operating procedures an application process for persons proposing to establish a of Needle Exchange syringe services Pprogram in Allegheny County, Pennsylvania. Applications, including proof of approval of the proposed program location by resolution or ordinance from the municipality in which the program is proposed to operate, are to be submitted to the Department and the Director will present completed applications to the Board of Health for review and final determination of approval. The Board shall not approve or alter any operating procedure without providing written notice of the new procedure(s) to the Allegheny County Council and Chief Executive at least thirty (30) days prior to the Board's vote.
- B. The Board of Health shall review each proposal for a Needle Exchange Program, and upon Following Board of Health approval, the Department shall forward written copies of all materials pertaining to approved proposals applications to the County Chief Executive and County Council, and to the Mayor and Council or, if applicable, Commissioners of each municipality where a Needle Exchange syringe service Pprogram is proposed at least ninety (90) days before the Program proposes to begin operations.
- C. Persons wishing to create and operate Needle Exchange a syringe services Pprogram shall submit to the Board of Health Director a completed application that includes the following information:
- i. ~~w~~Written statements of their intent to promulgate such a program, including a rationale for the necessity for the program;
 - ii. ~~with t~~The names, addresses, and social security numbers position titles, and contact information of ~~K~~key ~~H~~individual(s);
 - iii. Each statement shall include a rationale for the necessity for the program, ~~t~~The intended program location(s), days and hours of operations, and staffing. The description of staffing shall include number of staff, titles of positions, and descriptions of their functions; ~~the proposed method for tracking program users.~~ Any changes in this identifying information or the identity of Key Individuals shall be sent to the Board of Health within thirty days. All Needle Exchange Program shall maintain continuously updated records of the full names, addresses

and telephone numbers of all individuals providing services to or having contact with Program Participants at any Program Location.

- iv. A protocol for the safe and secure disposal of sharps waste and related supplies;**
- v. Proof of approval of the proposed program location by resolution or ordinance from the municipality in which the program is proposed to be located;**
- vi. As applicable, a description of proposed additional harm reduction services to be provided directly by the program; and**
- vii. If known, the names of community organizations the program plans to offer as referrals to participants for additional medical and social services.**

D. No Needle Exchange ~~Program~~ **syringe services** ~~Program~~ shall operate in any location until the address of the ~~Program~~ **Program** ~~Location~~ is specifically approved by **resolution or ordinance from the proposed site's municipality and** the Board of Health and the ~~proposed site's municipality~~ through legislative action. ~~i. Program Locations in operation with the approval of the Allegheny County Health Department as of January 1, 2007~~ **2023** shall not require additional approval by the Department or the municipality in which they are located, although all such Program Locations shall be disclosed to the Mayor, Council, and/or Commissioners of all municipalities in which they are located in writing within ten (10) days of the effective date of this Regulation.

- ~~i. Under no circumstances shall the Department approve any future program location proposed to be within 1,500 feet of any elementary, primary school, secondary school, licensed day care facility, or drug treatment facility, except in the City of Pittsburgh.~~
- ~~ii. The Department shall not approve any temporary facility, including but not limited to tents, outdoor tables, or mobile units, as a Program Location unless such location is first identified by address and in writing by the Needle Exchange Program, and the municipality in which the temporary facility is to be located is notified in writing of the address of the temporary Program Location in accordance with the requirements of Subsection 205.C.~~

205.2 Operations and Services

- A. The Department shall devise application guidance for syringe services programs. The Department shall, at a minimum, make such materials available via print materials and on its website.**

- E. **B.** Needle Exchange Program shall enroll each Program Participant with a unique identifier, and shall not provide services before attempting to elicit the Program Participant's age, gender, self-reported race, zip code, and disease status (HIV, Hepatitis B or C.) **Syringe services programs shall institute a registration process for program participants for the purpose of records or data collection. Such registration shall be voluntary, non-contingent, and non-coercive.**
- C. **Syringe services programs shall maintain the anonymity of all program participants. Information obtained by a syringe services program that might directly or indirectly identify a program participant, including program records, shall be kept confidential.**
- F. Each Needle Exchange encounter shall be documented with the unique identifier and the date and time of the encounter. The person documenting the encounter and all individuals providing materials or services to any Program Participant shall provide his or her initials. Documentation **of registration and encounters with participants** shall be retained by the Needle Exchange **syringe services** Program for at least three (3) years.
- i. — IDUs not known to be infected with HIV, or Hepatitis B or C infections at first screening shall be offered testing at the first visit that is at least six months from the date of first screening.
- ii. — IDUs presenting with one or more symptoms of HIV or Hepatitis B or C shall be informed that they should follow up immediately with their primary care provider or the Department.
- iii. — IDUs shall be counseled on safe sex practices.
- G. Needle Exchange Program shall be primarily for the use of Allegheny County Residents, but non-residents may participate if there are available resources.
- H. — The number of Injection Apparatus and Biohazard Containers dispensed shall be no more than are reasonably necessary for one month's worth of injections at an IDU's first interaction with the Needle Exchange Program.
- D. **Syringe services programs are required to provide the following program components directly to program participants:**
- i. **Provide injection equipment and other supplies at no cost and in quantities sufficient to reasonably ensure that hypodermic needles, syringes, and other supplies are not shared or reused and**

ii. Provide education regarding the proper disposal of sharps waste and other supplies and offer one or more of the following disposal options for used hypodermic needles and syringes:

(a) An onsite hypodermic needle and syringe collection and disposal program that meets applicable state and federal standards;

(b) Furnish, or make available, mail-back biohazard containers authorized by the U.S. Postal Service; or

(c) Furnish, or make available, biohazard containers for use off-site by program participants that meet applicable state and federal standards.

E. Syringe services programs that permit secondary exchange shall make the following materials available for persons to distribute to PWID unable to access the program location:

i. Injection equipment and sharps **biohazard** containers as outlined in § 205.2 D;

ii. Notification of the syringe services program's hours of operation and program location(s); and

iii. Printed materials on availability of infectious disease services and on harm reduction practices, including safer injection practices and the proper disposal of sharps waste.

F. Syringe services programs may directly provide the below infectious disease services. If a syringe services program is unable to provide services directly, the program shall provide referrals to appropriate services or inform program participants of relevant services available through the Department and community organizations. Referrals and direct infectious disease services shall be documented for the purpose of records or data collection and be kept confidential.

i. Testing options for HIV, viral hepatitis, other bloodborne infectious diseases transmitted through injection drug use, sexually transmitted infections, and COVID-19;

ii. Prevention, treatment, and care services for HIV, including PEP and PrEP, viral hepatitis, other bloodborne infectious diseases transmitted through injection drug use, and sexually transmitted infections; and

iii. Vaccinations for hepatitis A, hepatitis B, human papillomavirus (HPV), influenza, pneumococcal, Tdap (tetanus, diphtheria, pertussis), and COVID-19.

I. G. ~~Each IDU shall be offered a referral to drug treatment and counseling services at each Needle Exchange Encounter.~~ Syringe services programs may either directly provide or may provide referrals to the below harm reduction services, where such services are reasonably available in the community. Such ~~referrals~~ Referrals and direct harm reduction services shall be documented for the purpose of records or data collection and be kept confidential with the initials of the person who made the referral and the IDU's response:

i. Emergency opioid antagonist kits and training on overdose prevention, including materials regarding how to recognize an opioid overdose and how an emergency opioid antagonist can help prevent a fatal overdose;

ii. Substance use disorder care, treatment, or recovery services, including, but not limited to, medications for addiction treatment and peer support services, as appropriate;

iii. Mental health services, including peer support services, as appropriate;

iv. Medical treatment services, including provision of antibiotics, wound care, treatment for viral hepatitis, PEP and PrEP, and pre- and post-natal care;

v. Condom distribution and education regarding safer sex practices; and

vi. Assistance with obtaining social services, such as legal services, identification, housing, food, health insurance enrollment, clothing, and transportation services.

205.3 Responsibilities of the Department

A. The Department shall confirm receipt of submitted applications. Programs shall receive notification of incomplete submissions and instructions on submitting needed materials.

B. Upon receipt of a completed application, the Department shall ensure that the Board of Health approval vote is scheduled in a timely manner.

~~I.~~ C. Whenever possible, the Department shall provide infectious disease testing materials as requested by Needle Exchange syringe services ~~P~~programs.

~~K. D.~~ Community laboratory facilities processing Needle Exchange syringe services Pprogram specimens shall report positive infectious disease tests not conducted by the Department shall be reported to the Department within seventy-two (72) hours.

~~L.~~ Department funds shall not be used to support any activity of any Needle Exchange Program without prior approval as required by law.

E. The Department shall ensure that syringe services program reports are submitted annually to the Board of Health.

206. **205.4** Reporting

A. Needle Exchange Syringe services Pprograms shall submit to the Director ~~Semi-annual~~ Annual rReports of the disease status of all enrolled IDUs on or before December 31 and July 1 of each calendar year, in a form to be determined by the Director Board of Health, but which shall include at least:

- i.** ~~€~~The number of encounters;
- ii.** ~~€~~The number of individual participants;
- iii.** ~~€~~The total **quantity** number of injection apparatuses **equipment distributed;** the number of treatment referrals made, the number of infectious disease tests performed.
- iv.** The estimated number of used hypodermic needles and syringes collected by or given to program staff, employees, or volunteers for disposal;
- v.** For programs that distribute emergency opioid antagonists, the quantity distributed;
- vi.** The number of participants who received tests for, or who were referred to services that provide testing for, HIV, viral hepatitis, or other bloodborne infectious diseases;
- vii.** The number of participants who received, or who were referred to services that provide, prevention, treatment, and care services for HIV, including PEP and PrEP, viral hepatitis, other bloodborne infectious diseases transmitted through injection drug use, and sexually transmitted infections; and
- viii.** The number of participants who received, or who were referred to services

that provide, vaccinations for hepatitis A, hepatitis B, human papillomavirus (HPV), influenza, pneumococcal, Tdap (tetanus, diphtheria, pertussis), and COVID-19.

B. If known, programs may also report out on:

- i. Demographic information regarding participants including, but not limited to, age, gender, race, ethnicity, area of residence, types of drugs used, length of drug use, and frequency of injection;
- ii. For programs that permit secondary exchange, an overview of populations served and the municipality or municipalities where secondary distribution has been facilitated;
- iii. The number of participants engaged in, or referred to, substance use disorder treatment services, either through referral or directly provided by the program;
- iv. The number of participants who received, or who were referred to entities that provide, medication for addiction treatment;
- v. The number of participants who received, or who were referred to entities that provide, mental health treatment services;
- vi. The number of participants who received, or who were referred to entities that provide, social services;
- vii. The number of participants who received, or who were referred to entities that provide, health care services, including reproductive health care, treatment for viral hepatitis, PEP, PrEP, and wound care services; and
- viii. The number of participants who received, or who were referred to entities that provide, recovery support services, including peer support services.

2076. VIOLATIONS-NON-COMPLIANCE

- A.** Any Needle Exchange syringe services Pprogram approved by the Board of Health that violates fails to comply with any of the sections contained herein, shall may lose its authorization to continue to operate as a Needle Exchange syringe services Pprogram, subject to the discretion of the Department ~~or upon the repeal of the legislative Program Location approval required under the terms of Subsection 205.D. by the host municipality.~~ In addition to options available in Section 207, aggrieved municipalities in which programs are located may also consult the Department regarding any

limitations, corrective actions, or possible suspensions or terminations of approved syringe services programs.

B. Before any termination, suspension, or limitation of any operations, the Department shall first send written notice of non-compliance to the syringe services program. The written notice shall include the following:

- i. The specific findings of non-compliance;**
- ii. The program location where the non-compliant action(s) took place;**
- iii. The remedial measures, if any, the syringe services program shall take to consider removal of any limitation; and**
- iv. Steps to appeal the decision.**

2087. APPEALS

Any person aggrieved by any action of the Department may file an appeal in accordance with the Allegheny County Health Department Rules and Regulations, Article XI, entitled "Hearings and Appeals."

2098. SEVERABILITY

Should any section, paragraph, sentence, clause or phrase of this Article be declared unconstitutional, null or otherwise invalid for any reason, the remainder of this Article shall not be affected thereby.

Public Comments and Responses for the Proposed Revision of Allegheny County Health
Department Regulation: Article II “Needle Exchange Programs”
Comments received on or before January 20, 2023.

COMMENT	COMMENTER(S)
General	
1. I support the efforts of the Allegheny County Health Department to revise the regulation Article II Needle Exchange Programs and expand access to harm reduction services.	Robert D. Ashford, Alice Bell, Paul Cooley, Molly M. Eggleston, Stuart Neil Fisk
RESPONSE: ACHD appreciates your participation in the public comment process.	
2. The proposed revisions to Article II improve upon the original Article by reducing the use of stigmatizing language and providing more guidance on the process whereby organizations can apply to provide harm reduction services and how to set up operations and reporting.	Aaron Arnold, Alice Bell, Stuart Neil Fisk
RESPONSE: ACHD appreciates your participation in the public comment process.	
3. I recommend that Article II provide legal protections for individuals that, to protect their health, obtain safer use supplies at SSPs.	Alice Bell, Stuart Neil Fisk
RESPONSE: This recommendation is beyond the scope of Article II. SSP operations are currently prohibited under Pennsylvania's Drug Paraphernalia Law. Philadelphia and Allegheny County are the only jurisdictions in Pennsylvania that allow for SSPs and are granted this ability through the use of their public health authority. The ACHD is charged with acting upon that authority by drafting regulations and providing oversight of public health activities within County limits. Advocacy is needed at the state level to amend criminal statutes.	
4. Programs that provide access to health services such as access to medication for opioid use disorder (MOUD), health screenings, and other vital health promotion services, should be encouraged by ACHD and supported through regulations that facilitate expanded locations and services across the many communities in the county desperately in need of them.	Stuart Neil Fisk
RESPONSE: The proposed revisions encourage SSP operators to provide complimentary harm reduction services, either directly or through referral, in Section 205.2 (G). The ACHD believes that the proposed revisions to Article II will allow for the expansion of SSP services in the County and the Department is committed to supporting operators in the administration of a variety of harm reduction services.	

COMMENT	COMMENTER(S)
<p>5. Legalization at the state level for drug testing (such as fentanyl test strips and other drug checking technology) should be expanded in Allegheny County as we have started to see new drugs such as xylazine enter the already toxic illicit drug supply. Effective, real time drug testing programs are an evidence-based intervention that have been instituted and expanded on by Health Departments around the country and should be an integral part of real time public health in our county.</p>	<p>Stuart Neil Fisk</p>
<p>RESPONSE: The ACHD Overdose Prevention program is currently distributing fentanyl test strips to at-risk communities. For more information on these efforts, please contact the ACHD Overdose Prevention program via email at overdoseprevention@alleghenycounty.us or via phone through the ACHD main number 412-687-2243.</p>	
<p>6. State law now allows access to fentanyl test strips from any source by decriminalizing possession and distribution. We should follow this same logic here in Allegheny County with regard to sterile injection equipment and other items that allow people to use drugs more safely. We should allow broad access to items that protect the health of our communities, by simply stating that, in the interest of the public health, all such items shall be legal to possess and distribute without requirement for special organizations, programs or reporting regulations...Why should people not be able to simply purchase syringes at their local drugstore or grocery store, or order them from Amazon, or receive them from any community-based program that chooses to make them available? What purpose does restricting access serve?</p>	<p>Alice Bell</p>
<p>RESPONSE: SSP operations are currently prohibited under Pennsylvania's Drug Paraphernalia Law. Philadelphia and Allegheny County are the only jurisdictions in Pennsylvania that allow for SSPs and are granted this ability through the use of their public health authority. The ACHD is charged with acting upon that authority by drafting regulations and providing oversight of public health activities within County limits. Article II grants access to syringe services while providing guidance and structure that allows for the monitoring and safe distribution of injection equipment in the County.</p>	

COMMENT	COMMENTER(S)
<p>7. We need expanded epidemiological data on not only overdose deaths but other serious but preventable health outcomes such as infectious endocarditis and soft tissue infections related to unsafe injection practices and equipment. This kind of data collection, analysis and public dissemination by a public health department is both appropriate and needed.</p>	<p>Stuart Neil Fisk</p>
<p>RESPONSE: This observation will be shared with the Department's Overdose Surveillance Team.</p>	
<p style="text-align: center;">Section 201 Purposes</p>	
<p>8. Add "and other supplies" after the words "biohazard containers" in the sentence beginning "Syringe services programs are designed to prevent the spread of HIV, Hepatitis B and C, and other bloodborne pathogens by providing..."</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The ACHD finds this comment to have merit and has revised the Article to include this language.</p>	
<p>9. Replace the term "clean" with the term "sterile" in the regulation when in reference to injection equipment.</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The ACHD finds this comment to have merit and has revised the Article to include this language.</p>	
<p style="text-align: center;">Section 202 Statement of Policy</p>	
<p>10. The actual regulation will have the direct opposite effect of encouraging the provision of the greatest number of harm reduction services possible. This is clearly a political compromise. What's the point of lying and pretending it's not?</p>	<p>Corey Davis</p>
<p>RESPONSE: The ACHD believes the proposed revisions are an improvement upon the existing Article II framework that will allow for a greater number of providers to seek authorization.</p>	
<p>11. The proposed revisions fall short of the goals stated in Section 202 and do not do enough to increase access to syringe services.</p>	<p>Aaron Arnold, Alice Bell</p>
<p>RESPONSE: <i>See response to Comment 10.</i></p>	
<p style="text-align: center;">Section 204 Definitions</p>	

COMMENT	COMMENTER(S)
Biohazard Container:	
12. Doubt it matters, but I'd probably remove "limited access" from the definition of Biohazard Container as it's not clear what it means.	Corey Davis
RESPONSE: The ACHD is satisfied with the current definition for "Biohazard Container."	
Harm Reduction Services:	
13. Add the term "emergency" before "opioid antagonist distribution and education."	Aaron Arnold
RESPONSE: The ACHD finds this comment to have merit and has revised the Article to include this language.	
Overdose:	
14. This doesn't really matter either, but "Overdose" really doesn't need to be defined here.	Corey Davis
RESPONSE: The ACHD is satisfied with the inclusion of a definition for the term "Overdose." The term's inclusion compliments the overall goals of the Health Code.	
Program Location:	
15. Not all potential program locations have a postal address. For example, Prevention Point's Hill District site is an intersection with no structures.	Aaron Arnold
RESPONSE: The ACHD recognizes that not all potential program locations will have a postal address; however, a certain level of specificity is required for both the host municipality and the Board of Health to assess and approve a program location.	
16. The definition of program location seems to be saying that SSPs can't have mobile outreach teams and the like, since they don't have a specific, fixed address. Is that the intent?	Corey Davis
RESPONSE: ACHD believes that the proposed revisions authorizing secondary exchange operations will help ensure that programming is made available to hot spot areas in a timely manner.	
17. The definition of program location as a fixed address eliminates the possibility of responding to an outbreak if the municipality does not already have an approved SSP. Our experience has been that the current approval process takes about a year to navigate from start to finish. It is certainly too long to wait if an infectious disease outbreak is detected.	Aaron Arnold
RESPONSE: <i>See response to Comment 16.</i>	
18. The continued need to have a fixed location to be an SSP and before allowing	Robert D. Ashford

COMMENT	COMMENTER(S)
<p>for secondary exchange is a barrier that will continue to limit the positive public health impact such operations could have in the County... While this is somewhat mitigated by the broad definition of secondary exchange, it may prevent all but the largest providers from being able to comply with the application requirements still.</p>	
<p>RESPONSE: In order to provide the appropriate level of oversight of this programming, the ACHD must identify a responsible party to serve as a point of contact and to be accountable for activities provided for in this Article, including secondary exchange.</p>	
<p>19. Requiring a fixed address... limits the ability of potential syringe services providers who work in and across municipalities in Allegheny County to provide services wherever they are doing their work on a particular day and meet people where they are... We ask the board to consider allowing for syringe service provision to be linked to providers, and not only fixed locations.</p>	<p>Aubrey Plesh</p>
<p>RESPONSE: <i>See response to Comment 15.</i></p>	
<p>Syringe Service Program:</p>	
<p>20. This definition may benefit from elaborating on what is included when referencing "other supplies." Leaving it as-is leaves it open to interpretation in good and bad ways. One option is an extensive list including cookers, cottons, ties, alcohol wipes, breakdown powder, FTS, etc. But would that list need to be revised every time a new tool is identified? Another option is to say "other supplies to facilitate safer substance use."</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The ACHD is satisfied with the current definition for "Syringe Services Programs."</p>	
<p>21. This definition obviously leaves out materials for alternate methods of substance use such as smoking, snorting, boofing, etc. It is considered a best-practice to offer these items to 1. Reach and engage people who use substances other than intravenously, 2. Protect against communicable diseases spread by</p>	<p>Aaron Arnold</p>

COMMENT	COMMENTER(S)
<p>non-injection administration of drugs. 3. Make non-injection equipment readily available for those who will choose not to inject when possible to reduce number of injection events.</p>	
<p>RESPONSE: See response to Comment 20.</p>	
<p>22. Revise the definition to read "...supplies are distributed and/or collected for safe disposal."</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The ACHD is satisfied with the current definition of "Syringe Services Programs" and the requirement for operators to both be able to distribute and collect injection equipment. This definition is consistent with requirements as laid out in Section 205.2 (D).</p>	
<p>Sharps Waste:</p>	
<p>23. Replace the terms "syringes and lancets" with "injection equipment."</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The ACHD finds this comment to have merit and has revised the Article to include this language.</p>	
<p style="text-align: center;">Section 205.1 Syringe Services Program Requirements; Application and Approval Process</p>	
<p>24. What is the purpose of the requirement "including a rationale for the necessity for the program"? Isn't this clear in 201 and 202?</p>	<p>Corey Davis</p>
<p>RESPONSE: The quoted language appears in the original Article II. Statements of rationale allow the Board of Health to understand the particular unmet need in a specific community that the proposal is working to address.</p>	
<p>25. Requiring municipal approval in approving proposed program locations poses a major barrier for potential sites and limit the number of SSPs and where they operate.</p>	<p>Aaron Arnold, Robert D. Ashford, Aubrey Plesh</p>
<p>RESPONSE: Municipal engagement and approval will continue to be a vital part of the ACHD's administration of Article II. ACHD believes local officials are best positioned to review and scrutinize SSP proposals and potential unforeseen issues as they relate to zoning, accessibility, and community relations. With the proposed removal of the 1500 foot rule (the current restriction that prevents establishing an SSP outside of Pittsburgh city limits that is within 1500 feet of schools, day care facilities, and drug treatment facilities) the ACHD looks to encourage previously ineligible municipalities to host an SSP site.</p>	
<p>26. We would hope for a route to supersede the localities in circumstances where stigmatization and otherwise political motivations would prevent opening of an SSP where it is desperately needed, including outbreak response SSPs</p>	<p>Robert D. Ashford</p>
<p>RESPONSE: See response to Comment 25.</p>	

COMMENT	COMMENTER(S)
<p>27. How does it possibly make sense that someone in Marshall, or Elizabeth, North Fayette, or Plum who injects drugs must risk their health and that of their communities, because we can't legally mail supplies to them or refer them to any local program or business that chooses to supply them without having to go through a myriad of regulations and requirements?</p>	<p>Alice Bell</p>
<p>RESPONSE: <i>See response to Comment 6.</i></p>	
<p>28. The requirement "The description of staffing shall include number of staff, titles of positions, and descriptions of their functions " seems to assume that SSPs will only be operated by well-resourced entities with paid staff. Why is this required? Resources for harm reduction work like SSPs are extremely limited and the County does not currently fund such services, so it would make sense to assume that the barriers to entry should be as low as possible so that all providers can join.</p>	<p>Aaron Arnold, Corey Davis</p>
<p>RESPONSE: The ACHD believes that these edits represent a more practical standard for collecting staffing information. The proposed revisions remove the requirements for staff addresses, telephone numbers, and social security numbers. This current proposal keeps standards around personnel that speak to an operator's ability to carry out the required provisions of the Article.</p>	
<p>29. What is the purpose of the requirement "Proof of approval of the proposed program location by resolution or ordinance from the municipality in which the program is proposed to be located"? Do municipalities have veto power over other health-promotion activities, or only those involving PWID?</p>	<p>Corey Davis</p>
<p>RESPONSE: <i>See response to Comment 25.</i></p>	
<p style="text-align: center;">Section 205.2 Syringe Services Program Requirements; Operations and Services</p>	
<p>30. Program participant confidentiality protections need to be provided in stronger language. Section 205.2C should make specific calls to HIPAA and 42 CFR Part 2 (if an SSP entity is also a covered entity otherwise). Our recommendation</p>	<p>Robert D. Ashford</p>

COMMENT	COMMENTER(S)
<p>here as confidentiality is cited in several sections is that a section specific to record protection is needed in the revised Article II.</p>	
<p>RESPONSE: The ACHD is satisfied with the proposed confidentiality protections. The proposed revisions expand upon previous confidentiality requirements and align with federal recommendations while allowing for both small and large operators to conduct an SSP. Operators that distribute complimentary harm reduction services, including medical care, in addition to the distribution of injection equipment, continue to be subject to relevant federal and state regulation and licensing requirements, in addition to the provisions of Article II.</p>	
<p>31. Any of these options (205.2 D.ii (a-c)) alone represents a significant cost to the program with no obvious sources of funding. Could the County provide a resource instead of requiring programs have their own?</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The dispensing of biohazard containers as a means of safe disposal of injection equipment is required in the current Article II. The proposed revisions outline and clarify additional options for operators to meet this requirement.</p>	
<p>32. The requirement that "referrals and direct infectious disease services shall be documented for the purpose of records or data collection and be kept confidential is unclear as to what level of documentation would be needed to meet this requirement, or in what situations the referrals would be given. The first visit? Every time? By request? The requirement represents a huge amount of time when we are seeing 100+ individuals in 3 hours.</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The proposed revisions remove the requirement for unique identifiers and other detailed demographic information and instead allows for operators to devise their own participant registration and referral process so long as that process allows for operators to fulfill reporting requirements as outlined in Section 205.4. As all registration shall be voluntary and non-coercive, the tracking of referrals may be performed without directly linking to a participant record and can instead reflect the overall work of the operator to connect participants to needed services.</p>	
<p>33. What is the purpose of Section 205.2 G? It implies that SSPs may only provide these services, and no others. Why would the Department limit the services an SSP can provide?</p> <p>If that's not the intent of this section, what is? Presumably the Department does not</p>	<p>Corey Davis</p>

COMMENT	COMMENTER(S)
<p>intend to and is not authorized to, for example, permit SSPs to provide medical treatment if they're not otherwise authorized and licensed to do so. So what is this section doing?</p>	
<p>RESPONSE: The provisions allowing for complimentary harm reduction services are optional and are included in the proposed revisions to demonstrate endorsement of these practices by the Department as well as to align the regulation with technical guidance from the Centers for Disease Control and the Office of National Drug Control Policy.</p>	
<p>34. This ordinance is intended to regulate SSP. None of these ancillary services needs authorizing in an SSP regulation. (205.2 G.i-vi)</p>	<p>Aaron Arnold</p>
<p>RESPONSE: <i>See response to Comment 33.</i></p>	
<p style="text-align: center;">Section 205.4 Syringe Services Program Requirements; Reporting</p>	
<p>35. From the perspective of an established SSP, it actually seems to increase our burden of reporting by including metrics, which are unrelated to the provision of syringe services. It creates a reporting burden that is unnecessary and could discourage the provision of ancillary services. If programs are doing these things they're going to be documented and reported through mandated means anyway.</p>	<p>Aaron Arnold</p>
<p>RESPONSE: The metrics outlined in section 205.4 (A) are required and reflect the primary services of SSPs through reporting on distribution and disease control measures. The proposed revisions to this section clarify reporting requirements while not deviating from the current reporting metrics of Article II. The metrics outlined in section 205.4 (B) are optional and reflect complimentary harm reduction services. These metrics are proposed as a means for operators to demonstrate the full scope of services that are provided to target communities and are included to align the regulation with technical guidance from the Centers for Disease Control and the Office of National Drug Control Policy.</p>	
<p>36. Requiring expanded data reporting elements, without also providing funding to SSP operators, is an undue burden that is not being fairly compensated by the County through its various funding entities. These requirements should be minimized, or only required if an SSP is otherwise funded directly through County Funds.</p>	<p>Robert D. Ashford</p>
<p>RESPONSE: <i>See response to Comment 35.</i></p>	

COMMENT	COMMENTER(S)
Section 207 Appeals	
<p>37. A non-formal cure process for issues of potential or real non-compliance does not exist in the revised Article II. Organizations who operate SSPs should have the specific right to cure any compliance issues within a specific time period with guaranteed removal of the non-compliance finding within a period of 30 days. Not having a standardized cure period will lead to municipalities potentially punishing otherwise compliant SSPs and forcing them through a lengthy appeals process.</p>	Robert D. Ashford
<p>RESPONSE: The proposed revisions provide that the Department has the sole ability to limit, suspend, or terminate the operations of an approved SSP operator. Municipalities may submit grievances to the Department that are then reviewed before a final determination is made. The proposed revisions also outline responsibilities of the Department to detail to the SSP operator the specific findings of non-compliance and to outline how the operator can come back into compliance. The Department is committed to working closely with SSP operators to maintain or regain compliance with Article II provisions.</p>	
Section 208 Severability	
<p>38. Considering the changing policy and practical landscape that SSPs and other evidence-based harm reduction services are currently in, this section needs a sunset clause to help us prepare for the unknowns of the future.</p>	Aaron Arnold
<p>RESPONSE: The Board of Health and County Council will determine the appropriate effective date for Article II. ACHD will communicate with the regulated community as the effective date approaches.</p>	

Commenter Reference

1. Aaron Arnold, MPH (Executive Director, Prevention Point Pittsburgh)
2. Robert D. Ashford, PhD, MSW (Executive Director, Unity Recovery)
Submitted on behalf of Unity Recovery
3. Alice Bell (Overdose Prevention Project Director, Prevention Point Pittsburgh)
4. Paul Cooley, CRNP
5. Corey Davis
6. Molly M. Eggleston
7. Stuart Neil Fisk RN, MSN CRNP (Center for Inclusion Health, AHN)
8. Aubrey Plesh (Team PSBG, LLC Founder, The Strength in Numbers Project, Inc. Incorporator)

ALLEGHENY COUNTY HEALTH DEPARTMENT

RULES AND REGULATIONS

ARTICLE XXIII. UNIVERSAL BLOOD LEAD LEVEL

TESTING Section 1. AUTHORITY, PURPOSE, AND SCOPE.

Pursuant to the authority granted to the Allegheny County Health Department under the Pennsylvania Local Health Administration Law, 16 P.S. §§ 12010(f) and 12011(c), this regulation has been promulgated to improve the health of the children of Allegheny County. Universal blood lead level testing will facilitate early detection and referral for treatment of ~~lead poisoning~~ **elevated blood lead levels**; will reduce the incidence, impact and cost of ~~lead poisoning~~ **elevated blood lead levels**; will inform parents and guardians of their children's lead exposure; and will enable countywide surveillance of childhood ~~lead poisoning~~ **blood lead levels**. The regulation applies to all residents ~~and schools~~ of Allegheny County.

Section 2. DEFINITIONS.

Blood Lead Level. A measure of lead in the blood, measured in micrograms of lead per deciliter of whole blood ($\mu\text{g}/\text{dL}$).

Child. A natural person under 72 months of age who is a resident of Allegheny County.

Department. Allegheny County Health Department.

Director. The Director of the Allegheny County Health Department.

Elevated Blood Lead Level. A blood sample obtained by venipuncture where the serum blood lead level of a person is equal to or greater than the level defined as elevated by the Centers for Disease Control.

Health Care Practitioner. An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Pennsylvania licensing agency or board.

Record of Blood Lead Level Testing. Any written or electronic document acceptable to the Director showing the date of blood lead level testing, including, but not limited to health care practitioner records, school health records, and other similar documents or history.

Blood Lead Level Testing. A blood sample obtained either by venipuncture or finger stick capillary blood collection ~~from a child not known to be lead poisoned or to have an elevated blood lead level in order to identify the child's risk of lead poisoning or elevated blood lead level~~ **used to measure the amount of lead in the blood calculated in micrograms per deciliter ($\mu\text{g}/\text{dL}$) of lead.**

Section 3. BLOOD LEAD LEVEL TESTING REQUIREMENTS.

- A. *General Rule.* Blood lead level testing shall be performed in accordance with the following:
1. Children shall receive a blood lead level testing in accordance with the following schedule:
 - a. Each child shall be tested between approximately 9 months to 12 months of age and again at approximately 24 months of age.
 - b. All children designated as high risk, as determined by a health care practitioner and based on the child's exposure to lead and any other factors indicating high risk, should receive subsequent blood lead level testing as deemed appropriate by a health care practitioner **and in accordance with Centers for Disease Control guidance.**
 - c. Blood lead level testing may be delayed if the health care practitioner is not able to collect a sufficient blood sample for testing.
 - d. If a child has not had their blood lead level tested between approximately 9 months to 12 months of age and at approximately 24 months of age, then that child shall have their blood lead level tested as soon as possible after 24 months but before 72 months of age or entry into kindergarten, whichever is sooner.
- B. *Testing Methods.* Health care practitioners shall ensure that blood lead level testing is conducted either by venipuncture or by capillary blood sampling in accordance with current best practices. Capillary blood sample testing results of $5\ \mu\text{g}/\text{dL}$ or greater **equal to or greater than the blood lead reference value as established by the Centers for Disease Control (CDC)** shall be confirmed with a venipuncture test.
- C. *Exception.* If the parent or guardian of a child objects on the grounds enumerated in Section 4, below, then the testing required by Subsection A, above, may not be performed.

Section 4. EXCEPTIONS.

- A. *Medical Exemption.* Children need not have a blood lead level testing according to the schedule enumerated in Section 3, above, if a health care practitioner or ~~his/her~~ **their** designee provides a written statement that blood lead level testing may be detrimental to the health of the child. When the health care practitioner determines that blood lead level testing is no longer detrimental to the health of the child, the child should have their blood lead level tested according to Section 3, above.
- B. *Religious Exemption.* Children need not have a blood lead level testing according to the

schedule enumerated in Section 3, above, if the parent, guardian, or emancipated child objects in writing to the blood lead level testing on religious grounds or on the basis of a strong moral or ethical conviction similar to a religious belief.

~~Section 5. RESPONSIBILITIES OF SCHOOLS AND SCHOOL ADMINISTRATORS.~~

~~A. The administrator in charge of every school shall appoint a knowledgeable person to perform the following:~~

~~1. Inform the parent or guardian at registration or prior to registration, if possible, of the requirements of this regulation.~~

~~2. Ascertain the blood lead level testing status of every child prior to admission to kindergarten at the school.~~

~~B. The parent or guardian of a child who has not had their blood lead level tested in accordance with Section 3 (relating to blood lead level testing requirements) shall be informed of the blood lead level testing requirement and advised to go to his/her usual source of care, or to the nearest Allegheny County Health Department location offering blood lead level testing, to obtain a blood lead level test.~~

~~C. Each school shall maintain on file a Record of Blood Lead Level Testing for every child enrolled in kindergarten at the school.~~

~~D. Failure to have or document the blood lead level testing required by Section 3, above, shall not prevent a child's attendance at school.~~

~~Section 6. SCHOOL REPORTING.~~

~~A. Every public, private, parochial or nonpublic school, including intermediate units and special education, cyber and charter schools, in Allegheny County shall, after a child's entry to kindergarten and using forms provided by the Department, report blood lead level testing data to the Department by October 15 of each year.~~

~~B. The school administrator or his/her designee shall forward the blood lead level testing data reports to the Department's Bureau of Assessment, Statistics & Epidemiology, or as otherwise designated by the Department.~~

~~C. The content of the annual blood lead level testing data report shall include, at minimum, the following information:~~

~~1. The identification of the school including the name of the school, the school district, the intermediate unit, and the type of school.~~

~~2. The month, day, and year of report.~~

~~3. The number of children entering kindergarten at the school.~~

- ~~4. The number of children entering kindergarten at the school who have had their blood lead level tested.~~
- ~~5. The number of children entering kindergarten at the school who did not have their blood lead level tested due to medical exemptions.~~
- ~~6. The number of children entering kindergarten at the school who did not have their blood lead level tested due to medical exemptions or exemptions on religious grounds or on the basis of a strong moral or ethical conviction similar to a religious belief.~~
7. Other information as required by the Department.

Section 7 5. RESPONSIBILITES OF THE DEPARTMENT.

- A. The Department will provide the blood lead level testing data reporting forms to schools **shall monitor blood lead level testing data and surveil for elevated blood lead level results among children.**
- B. The Department will monitor school districts for compliance with this regulation and will have access to school blood lead level testing data **shall make educational materials and other relevant services available to eligible families with children found to have elevated blood lead levels.**

Section 8 6. RESPONSIBILITIES OF HEALTH CARE PRACTITIONERS.

- A. Health care practitioners shall perform blood lead level testing on children in accordance with the provisions of this Article.
- B. Health care practitioners shall report the results of blood lead level testing administered in accordance with applicable Pennsylvania law or regulation.

Section 9 7. SEVERABILITY CLAUSE.

The provisions of these Rules and Regulations are severable. Should any section, paragraph, sentence, clause, or phrase of these Rules and Regulations be declared unconstitutional or invalid for any reason, the remainder of said Rules and Regulations shall not be affected thereby.

Section 10 8. EFFECTIVE DATE.

The provisions of these Rules and Regulations shall become effective ~~on January 1, 2018~~ **ten days after the enactment date of an ordinance of Allegheny County approving its provisions.**

Public Comments and Responses for the Proposed Revision of Allegheny County Health
 Department Regulation: Article XXIII “Universal Blood Lead Level Testing”
Comments received on or before January 20, 2023

COMMENT	COMMENTER(S)
General	
1. I support the proposed amendments to Article XXIII.	Dana Donovan
RESPONSE: ACHD appreciates your participation in the public comment process.	
2. Allies for Children applauds the proposed revisions, which aim to reduce administrative burden on schools and families, while still keeping Allegheny County’s children safe from lead exposure. Importantly, these revisions will free up school administrators to focus more directly on the needs of their community in order to help children learn, grow, and thrive.	Jamie Baxter
RESPONSE: ACHD appreciates your participation in the public comment process.	
Section 2	
3. I recommend that the Health Department adopt the 3.5 micrograms per deciliter threshold in every capacity. That includes home investigations for children starting at 3.5 and updating Article VI to define an Elevated Blood Lead Levels as 3.5. These updates would reflect current science and better match Department protocol.	Dana Donovan
RESPONSE: This recommendation is beyond the scope of the Article XXIII update; however, the ACHD Housing and Community Environment Program anticipates public comment during the forthcoming Article VI update.	

Commenter Reference

1. Jamie Baxter (Executive Director, Allies for Children)
Submitted on behalf of Allies for Children
2. Dana Donovan (Women for a Healthy Environment, Lead Safe Allegheny Coalition)