TO: Health Centers

FROM: Colleen Meiman

Director of Regulatory Affairs

National Association of Community Health Centers

DATE: July 2017

**RE:** Sample Policy and Procedure on Syringe Services Program

NACHC is pleased to provide the attached sample Policy and Procedure (P&P) regarding Syringe Services Programs (SSPs).

The Consolidated Appropriations Act of 2016 prohibits the use of federal funds (grant funding) to purchase sterile needles or syringes for the purpose of hypodermic injection of any illegal drug. However, health centers may be permitted to use federal funds for other elements of SSPs, provided that (among other requirements):

- the CDC has determined that their area is experiencing -- or is at risk for -- a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and
- the health center has received HRSA approval.

This sample P&P can be tailored to meet the needs of health centers in any of the following situations:

- The health center does not operate a SSP, but requires staff to receive training about and certify their compliance with Federal rules around syringes
- The health center operates an SSP under its Section 330 scope of project
- The health center operates an SSP outside of its Section 330 scope of project.

#### Which health centers should have a P&P on Syringe Services Programs?

- Health centers that operate, or plan to establish and operate, a SSP should definitely tailor and adopt this sample P& P, regardless of whether the SSP is operated under or outside of their Section 330 scope of project.
- For health centers that do not operate a SSP, or intend to establish one, we nonetheless recommend that applicable staff receive training regarding the prohibition on using federal funds (including grant funds) to purchase sterile needles or syringes for the purpose of hypodermic injection of any illegal drug. This P&P can easily be tailored to reflect this arrangement.

**Legal Notices:** When adapting this sample P&P for your health center, please note:

• The Authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The sample documents offer general guidance based on federal law

and regulations and do not necessarily apply to all health centers under all facts and circumstances. Further, these materials do not replace, and are not a substitute for, legal advice from qualified legal counsel.

• This sample Policy and Procedure was drafted to conform with relevant federal laws, regulations, and guidance effective as of December 1, 2016. Health centers that seek to adapt and adopt this sample Policy and Procedure to align with the health center's particular operations are advised to seek legal advice from qualified legal counsel to ensure that the Policy and Procedure reflects current requirements, both from a federal and state level.

When preparing your Health Center's P&P: Using the following sample as a guide, health centers should tailor the procedures to reflect their own structure and operations, as well as any relevant requirements in their state. When revising the sample, please pay particular attention to those footnotes that begin with "Authors' Note", as they contain information that is important for tailoring this P&P. In particular:

- Choose the appropriate policy statement for Section III.B: This section contains three sample policy statements -- all of which are labelled "B" -- to address each of the three situations outlined above (no SSP, SSP under 330 program, SSP outside 330 program.) It is important to choose one of these three statements (to reflect your health center's policy) and delete the others.
- **Determine which staff this P&P should apply to:** This sample P&P, as drafted, may not be applicable to all health center staff and volunteers. Accordingly, a health center may wish to modify the description of who must comply with the P&P, and sign the certification set forth in Exhibit A. For example, a health center may wish to modify the phrase "All Health Center employees, contractors, and volunteers" to state "All Health Center employees, contractors, and volunteers who provide clinical services and non-clinical support services ..."
- Decide whether to require the Certification in Exhibit A: It is not mandatory to require applicable staff and volunteers to sign the certification in Exhibit A; however, it is encouraged, as such certifications would serve as useful documentation of the health center's efforts to comply. A health center that opts to require its staff to sign this certification should also extend that requirement to its volunteers.
- **Delete the "Authors' notes" in footnotes:** As the footnotes that start with "Authors' note" contain information to assist in tailoring this sample to your health center's unique structure and operations, they should be deleted before the P&P is finalized. All other footnotes should remain in the final P&P.

Please contact Colleen Meiman at <u>cmeiman@nachc.org</u> or 202-296-0158 if you have questions about this P&P.

# Sample Policy and Procedure<sup>1</sup>: Syringe Services Program<sup>2</sup>

### I. Purpose of Policy and Procedure

[Health Center Name] ("Health Center") is committed to high standards and compliance with all applicable federal, state, and local laws and regulations.<sup>3</sup>

The purpose of the Syringe Services Program Policy and Procedure is to provide safeguards to ensure Health Center's compliance with laws and regulations that apply to Syringe Services Programs (SSPs) established and operated by health centers that receive federal grant funds under Section 330 of the Public Health Service Act ("Section 330") through the U.S. Department of Health and Human Services ("HHS").

The term "syringe services programs" includes provision of sterile needles, syringes and other drug preparation equipment and disposal services, as well as some or all of the following services: comprehensive sexual and injection risk reduction counselling; human immunodeficiency virus ("HIV"), viral hepatitis, other sexually transmitted diseases ("STDs") and tuberculosis ("TB") screening; provision of naloxone to reverse opioid overdoses; referral and linkage to HIV, viral hepatitis, other STDs and TB prevention care and treatment services, referral and linkage to hepatitis A virus ("HAV") and hepatitis B virus ("HBV") vaccination, as well as referral to integrated and coordinated substance use disorder, mental health services, physical health care, social services, and recovery support services.

<sup>&</sup>lt;sup>1</sup> Author's note: The Authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The sample documents offer general guidance based on federal law and regulations and do not necessarily apply to all health centers under all facts and circumstances. Further, these materials do not replace, and are not a substitute for, legal advice from qualified legal counsel.

<sup>&</sup>lt;sup>2</sup> Authors' note: Health centers that to do not operate, and do not intend to establish and operate, a syringe services program may opt not to adopt this sample Policy and Procedure. Notwithstanding, even if a health center does not operate, or intend to establish and operate, a syringe services program, we nonetheless recommend that applicable staff receive training regarding the prohibition on using federal funds to purchase sterile needles or syringes for the purpose of hypodermic injection of any illegal drug, as set forth under Section III. A below.

<sup>&</sup>lt;sup>3</sup> Authors' note: This sample Policy and Procedure was drafted to conform with relevant federal laws, regulations, and guidance effective as of December 1, 2016. Health centers that seek to adapt and adopt this sample Policy and Procedure to align with the health center's particular operations are advised to seek legal advice from qualified legal counsel to ensure that the Policy and Procedure reflects current requirements, both from a federal and state level.

<sup>&</sup>lt;sup>4</sup> <u>Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016.</u>

### **II.** Policy that ensures compliance with the Consolidated Appropriations Act

# **A.** The Consolidated Appropriations Act

Health Center will assure compliance with the Consolidated Appropriations Act, which includes a statutory provision that prohibits the use of federal funds<sup>5</sup> to purchase sterile needles or syringes for hypodermic injection of any illegal drugs.<sup>6</sup> The Consolidated Appropriations Act prohibition does not extend to the use of federal funds for other elements of SSPs based on evidence of a demonstrated need (i.e., experiencing, or at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use) by the state or local health department and in consultation with the Centers for Disease Control and Prevention ("CDC").<sup>7</sup>

**Note:** Health centers must choose only one of the following three policy statements labelled "B", and delete the other.

### **B.** Prohibition on participation in Syringe Services Programs

Participation in any SSP is strictly prohibited at Health Center. This prohibition applies to all Health Center employees, contractors, and volunteers, and to all Health Center facilities and equipment.<sup>8</sup>



### B. Providing SSP Services Within the Section 330 Program

In accordance with the above, if Health Center seeks to use Section 330 grant funds to operate a new SSP or expand an existing SSP as a component of its Section 330-supported health center program, Health Center will take the necessary and required steps to obtain prior approval from the Health Resources and Services Administration ("HRSA").

<sup>&</sup>lt;sup>5</sup> Section 330 grantees must use program income in accordance with Section 330(e)(5)(D) (42 U.S.C. § 254b(e)(5)(D)) which provides that program income "shall be used as permitted under [Section 330], and may be used for such other purposes as are not specifically prohibited under [Section 330] if such use furthers the objectives of the project." HHS will likely interpret the purchase of sterile needles or syringes for hypodermic injection of any illegal drug as being "specifically prohibited" under Section 330 and thus an impermissible use of Section 330 grant-related program income.

<sup>&</sup>lt;sup>6</sup> Consolidated Appropriations Act, 2016, Pub. L. No. 114-113 § 520, 129 STAT. 2242, 2652 (2015).

<sup>&</sup>lt;sup>7</sup> <u>Centers for Disease Control and Prevention Program Guidance for Implementing Certain Components of Syringe Services Programs, 2016.</u>

<sup>&</sup>lt;sup>8</sup> Authors' note: Health centers that prohibit participation in SSPs should delete Subsections C, D, and E under Section III, Procedure.

<sup>&</sup>lt;sup>9</sup> Authors' note: According to the <u>Health Resources and Services Administration-Specific Implementation</u> <u>Guidance to Support Certain Components of Syringe Services Programs, 2016</u>, beginning in FY 2017 and thereafter, HRSA funding opportunity announcements ("FOAs") will identify whether the programs

In addition, in establishing and operating a SSP as a component of its Section 330-supported health center program, Health Center will assure compliance with:

- (a) the applicable terms and conditions incorporated or referenced in its Section 330 grant award;
- (b) applicable state and local laws and regulations; and
- (c) other requirements related to such programs or services. 10



### B. Providing SSP Services Outside of the Section 330 Program<sup>11</sup>

If Health Center establishes and operates a syringe services program outside the scope of its Section 330 program, Health Center will not use Section 330 grant funds to pay for such out-of-scope program or associated overhead costs. Health Center will ensure that the revenue from such out-of-scope activities is segregated from the Section 330 program and that the direct and indirect costs associated with these out-of-scope activities are appropriately allocated consistent with applicable grants management rules, set forth in 45 C.F.R. Part 75. Health Center will ensure that it maintains documentation of such segregation and allocation.

### III. Procedures<sup>12</sup>

# A. Syringe Services Program Training. 13

All applicable Health Center employees, contractors, and volunteers<sup>14</sup> will be trained on the requirements relevant to syringe services programs, including the prohibition on using federal funds to purchase sterile needles or syringes for the purpose of hypodermic injection of any illegal

funded under the FOA or contract will permit support of syringe services programs, including criteria for eligibility and any budgetary or programmatic requirements.

<sup>&</sup>lt;sup>10</sup> Health Resources and Services Administration-Specific Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016.

<sup>&</sup>lt;sup>11</sup> Authors' note: Health centers that operate a SSP outside of their Section 330 scope of project should delete Subsection C under Section III, Procedure.

<sup>&</sup>lt;sup>12</sup> Authors' note: Using this following sample as a guide, health centers should tailor the procedures to reflect their own structures and operations.

<sup>&</sup>lt;sup>13</sup> Authors' note: While not required, we generally recommend incorporating the requirements applicable to syringe services programs into staff training. As noted elsewhere, health centers are advised to modify the text of the Policy and Procedure to specify which applicable staff must receive the training.

<sup>&</sup>lt;sup>14</sup> Author's note: A health center may wish to modify the description of who must comply with this Policy and Procedure and sign the certification in Exhibit A. For example, a health center may wish to modify the phrase "Applicable Health Center employees, contractors, and volunteers" to state "Health Center employees, contractors and volunteers who furnish services through Health Center's syringe services programs..."

drug. Health Center shall maintain records indicating the completion of such training in each applicable personnel file.

### B. Certification of Compliance by Employees, Contractors, and Volunteers

All applicable Health Center employees, contractors, and volunteers are required to comply with this Syringe Services Program Policy and Procedure by signing and returning the certification included in this document as Exhibit A.<sup>15</sup>

# C. Obtaining Prior HRSA Approval and Complying with HRSA Requirements 16

In accordance with the <u>Health Resources and Services Administration-Specific Implementation</u> <u>Guidance to Support Certain Components of Syringe Services Programs, 2016</u>, if Health Center seeks to use new or existing Section 330 grant funds to support a SSP, Health Center will first obtain the following documents:

- 1. the CDC notification to the applicable state, local, territorial, or tribal health department that the evidence submitted by the health department is sufficient to demonstrate that the jurisdiction is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use; and
- 2. a certification in the form of a letter signed by the Health Officer from the state, local, territorial, or tribal health department that such program is operating in accordance with applicable law.

Health Center will contact its HRSA Project Officer to discuss its interest in using Section 330 funds for a syringe services program. Health Center will also electronically submit the required documentation described above. If Health Center wishes to reallocate existing Section 330 funding to support a syringe services program, it will follow standard procedures established for the awarded Section 330 grant.

Following submission of required documentation and HRSA approval, funds may be reallocated starting in the Fiscal Year (FY) for which the HRSA approval was granted, and such reallocation may continue in future FYs unless otherwise indicated.

The HRSA Project Officer will instruct the Health Center of any additional requirements to use Section 330 funds for a SSP under the Section 330 scope of project. Health Center will comply with such additional requirements.

NACHC Sample P&P on Prohibition on Syringe Service Programs, July 2017

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<sup>&</sup>lt;sup>15</sup> Author's note: It is not mandatory to require applicable staff and volunteers to sign the certification in Exhibit A; however, it is encouraged, as such certifications would serve as useful documentation of the health center's efforts to comply.

<sup>&</sup>lt;sup>16</sup> Author's note: Subsection II.C should be included in the P&P only by those Health Centers that operate a SSP under their Section 330 scope of project.

## D. Cooperation from Local Law Enforcement<sup>17</sup>

Health Center will coordinate with and work toward obtaining cooperation from local law enforcement officials when implementing a syringe services program.

# E. Operating Syringe Services Programs<sup>18</sup>

Health Center recognizes that syringe services programs, as they are implemented, should be a part of a comprehensive service program<sup>19</sup> that includes, as appropriate:

- a. Provision of sterile needles, syringes and other drug preparation equipment (purchased with non-federal funds) and disposal services;
- b. Education and counseling to reduce sexual, injection and overdose risks;
- c. Provision of condoms to reduce risk of sexual transmission of viral hepatitis, HIV or other STDs;
- d. HIV, viral hepatitis, STD and TB screening;
- e. Provision of naloxone to reverse opioid overdoses;
- f. Referral and linkage to HIV, viral hepatitis, STD and TB prevention, treatment and care services, including antiretroviral therapy for hepatitis C virus (HCV)and HIV, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother-to-child transmission and partner services;
- g. Referral and linkage to hepatitis A virus (HAV) and hepatitis B virus (HBV) vaccination;
- h. Referral and linkage to and provision of substance use disorder treatment (including

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<sup>&</sup>lt;sup>17</sup> Authors' note: The recommendation to consult with law enforcement is set forth in the "<u>Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016</u>." This Subsection should be maintained by health centers that operate a SSP, either under or outside of their 330 scope of project, and should be deleted by health centers that do not operate a SSP.

<sup>&</sup>lt;sup>18</sup> Authors' note: The recommendations regarding a "comprehensive service program" are set forth in the "<u>Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016</u>." This Subsection should be maintained by health centers that operate a SSP, either under or outside of their 330 scope of project, and should be deleted by health centers that do not operate a SSP.

<sup>&</sup>lt;sup>19</sup> CDC. (2012) <u>Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases</u>, and <u>Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services</u>. MMWR; 61(RR05):1-40.

medication-assisted treatment for opioid use disorder which combines drug therapy (e.g., methadone, buprenorphine, or naltrexone) with counseling and behavioral therapy); and

i. Referral to medical care, mental health services, and other support services.

In addition, Health Center will ensure that syringe services programs supported with federal funds provide referral and linkage to HIV, viral hepatitis, and substance use disorder prevention, care and treatment services, as appropriate. Health Center will also coordinate and collaborate with other local agencies, organizations, and providers involved in comprehensive prevention programs for persons who inject drugs to minimize duplication of effort.

# F. Reviewing and Updating the SSP Policy and Procedure<sup>20</sup>

The Syringe Services Program Policy and Procedure shall be reviewed periodically and updated consistent with requirements established by the Board of Directors, Health Center's senior management, federal and state law and regulations, and applicable accrediting and review organizations.

## **Responsible Parties:**

Signature	Date
CEO	
Signature	Date
Board Chairperson	

<sup>&</sup>lt;sup>20</sup> This Subsection should be retained by all health centers who adopt this P&P.

#### EXHIBIT A<sup>21</sup>

# CERTIFICATION OF COMMITMENT TO COMPLY WITH SYRINGE SERVICES POLICY AND PROCEDURE

I hereby acknowledge and certify that I have received and reviewed a copy of the Health Center Syringe Services Program Policy and Procedure and I understand that it represents a mandatory policy of Health Center.

By signing this form below, I agree to abide by the Syringe Services Program Policy and Procedure during the term of my employment, contract, or agency or while otherwise authorized to serve on Health Center's behalf. In addition, I acknowledge that I have a duty to report any suspected or known violation of the Syringe Services Program Policy and Procedure to my supervisor or through the normal chain of command. I acknowledge that I may also report the information directly to the Compliance Officer or any other member of senior management.

Please return this completed, signed Certification of Commitment to the Compliance Officer.

Date
Signature

Printed Name

Title/Position

<sup>&</sup>lt;sup>21</sup> Authors' note: Requiring applicable staff to sign this certification is not mandatory, but such certifications would serve as useful documentation of the health center's efforts to comply. A health center that opts to require its staff to sign this certification should also extend that requirement to its volunteers.