| # | Rule Section | By Whom? | Summary of Comments | Response to Comment |
|---|---|---|---|---|
| 1 | 3.1. | Dan Lauffer, President & CEO Thomas Health | General licensure provisions.<br><br>Will there be separate licensures for a facility that wishes to provide services in both fixed and mobile locations? What about a mobile unit that moves to various locations as the need evolves, i.e. new clusters or hotspots of infectious diseases are identified and need to be addressed in an expedient manner? | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |
| 2 | 3.1.2., 3.1.3., 3.1.5., 3.1.6. | A. Toni Young, Community Education Group<br><br>Catherine C. Slemp, MD, MPH<br><br>Dan Lauffer, President & CEO Thomas Health | Licensed locations.<br><br>A license for each individual address and site eliminates the ability of a Harm Reduction Program (HRP) to utilize a mobile unit, as authorized in 16-64-7(c).<br><br>Does this requirement mean that, if an HRP utilizes mobile unit, each individual place at which this mobile unit stops, in the present or in the future, must obtain a separate license, obtain individual approvals from County Commissions and municipal governing bodies for each individual stop, and pay $250 to be licensed for each stop?<br><br>Does every mobile cancer screening or dental services van have to secure an individual license to provide mobile services in each location they stop? If this is not the case, nor should it be the case for the mobile provision of harm reduction services.<br><br>The rules need to better support mobile program delivery, a highly effective, efficient, ad evidence-based program model. Requiring a separate license and licensure fee per service location and a 30-day advance notification of a location change (3.1.2., 3.1.3., and 3.1.6.) markedly impedes the ability | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |

| # | Rule Section | By Whom? | Summary of Comments | Response to Comment |
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| | | | to offer mobile programs. Mobile services are referenced in and should still be made equally if not more viable under the enacted code, especially given West Virginia's rural nature and limited public transportation infrastructure. In addition, per site program licensure presents an undue cost and administrative burden on programs (fixed and mobile) and thus a deterrent to program delivery.<br><br>In urgent situations, greater program flexibility is needed so that service delivery can quickly be adapted, and emergent issues rapidly addressed. The standard process outlined, especially sections 3.1.2., 3.1.3., and 3.1.6. (single site per license, 30-day pre-notification of location change, etc.) does not allow programs the needed flexibility to address urgent situations. Patterns of drug use and their adverse consequences can shift location quickly and rarely give 30-day notice. | |
| 3 | 3.1.7. | Dan Lauffer, President & CEO Thomas Health | Periodic licensure.<br><br>What does the "periodic licensure survey during the course of the annual licensing term" consist of? | The Department has reviewed this comment. Existing provisions in the rule address this issue, therefore, no changes were made. |
| 4 | 3.1.8., 3.1.9. | A. Toni Young, Community Education Group | Entry into a location operating without a license.<br><br>Provision 3.1.8. grants the Director or his/her designee the authority to enter the premises of "...any practice, office, or facility" irrespective of the time of day or the presence of facility staff. There appear to be no restrictions related to hours of operation, notice of intent to enter, or the ability to require justification for entry.<br><br>Additionally, provision 3.1.8. raises significant concerns that this authority may apply to private residences, as well. Should this be the case, what accountability exists for OHFLAC and the Director?<br><br>It appears that 3.1.8. places significant levels of discretion into the hands of the Director, giving broad authority to inspect | The Department has reviewed this comment. Existing provisions in the rule address this issue, therefore, no changes were made. |

| # | Rule Section | By Whom? | Summary of Comments | Response to Comment |
|---|---|---|---|---|
| | | | virtually *any* business or facility, regardless of whether said premises fall under the purview of OHFLAC. | |
| 5 | 3.1.9. | Rich Sutphin, Executive Director, WVRHA | Owner defined.<br><br>Recommendation to delete or define 'owner'. It does not appear in the statute or in the rule. Existing SSPs are operated by local health departments and by free clinics. It is anticipated that any new SSPs seeking certification will also be operated by not-for-profit entities – *i.e.* Federally Qualified Health Centers (FQHCs), not-for-profit hospitals, et cetera as this is not a revenue generating activity. These types of entities are not owned but governed by community boards. If the agency elects to retain the term 'owner' the WVRHA recommends defining this term in the rule. | The Department has reviewed this comment. Existing provisions in the rule address this issue, therefore, no changes were made. |
| 6 | 3.2.1.a., 3.2.1.b. | A. Toni Young, Community Education Group | Harm reduction services.<br><br>§16-64-3. Program requirements specifically state that:<br>" (a) To be approved for a license, a syringe services program shall be part of a harm reduction program which offers or refers an individual to the following services which shall be documented in the application:"<br>Provisions 3.2.1.a. and 3.2.1.b. specifically do not mention that those services can be referred. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |
| 7 | 5.2. | Rich Sutphin, Executive Director, WVRHA | Program administrator.<br><br>WVRHA recommends OHFLAC consider allowing specialized continuing education training as a substitute for experience for section 5.2.1.a. (persons with an associate degree) and 5.2.1.b. (persons with a bachelor's degree). For example, an organization may have a registered nurse with a bachelor's degree, but not the requisite experience. Permitting a professional with this credential to substitute a required number of specialized continuing education credits in lieu of years of experience will expand the number of qualified individuals who can administer an SSP. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |
| 8 | 6.1.2. | A. Toni Young, Community | Harm reduction services. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |

| # | Rule Section | By Whom? | Summary of Comments | Response to Comment |
|---|---|---|---|---|
| | | Education Group | Provision 6.1.2. implies that all SSPs will offer all harm reduction services, specifically leaving out the legal requirement under §16-64-3(a) that those services may be referred and not directly provided by the SSP. Under that legal requirement, SSPs *do not* require space and equipment to offer services that they do not directly provide. | |
| 9 | 6.4. | Dan Lauffer, President & CEO Thomas Health | Policies and procedures.<br><br>Support 6.4. on page 9 that "All syringe services programs must comply with its own policies and procedures." | The Department has reviewed this comment. This comment is general in nature and offers no specific areas for amendment. |
| 10 | 6.5. | Dan Lauffer, President & CEO Thomas Health | Minor children.<br><br>If a patient comes in under the influence and/or picking up syringes and it is known they are actively using while caring for their children, where does this line fall for us to make a mandated report to CPS? This is difficult when working on trying to establish trust if the participant believes or knows we will report them to CPS. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |
| 11 | 6.5.2., 6.5.3. | A. Toni Young, Community Education Group | Minor children.<br><br>6.5.3. is both unreasonable and places an undue burden on participants in SSPs. One of the primary concerns facing any patient when attempting to access healthcare services is whether there is sufficient care for any minor children. In response to this, several healthcare providers in West Virginia offer staffed areas where children may be left in the care of a responsible adult while patients are seen. This includes West Virginia Health Right's primary healthcare facility. To specifically prevent providers from offering short-term childcare creates an undue barrier to accessing care and services. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |
| 12 | 9.1.2. | Dan Lauffer, President & CEO Thomas Health | West Virginia identification.<br><br>Provide examples of acceptable forms of West Virginia identification. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |

| # | Rule Section | By Whom? | Summary of Comments | Response to Comment |
|---|---|---|---|---|
| 13 | 9.1.2. | Dan Lauffer, President & CEO Thomas Health | West Virginia identification.<br><br>Support but encourage flexibility regarding the policy a program develops that will show permanent or temporary residency in West Virginia. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. Licensed providers must create a policy to address this issue. |
| 14 | 9.2.3. | Rich Sutphin, Executive Director, WVRHA | Enrollment information.<br><br>WVRHA recommends deleting 9.2.3. items a-i. This information collection is not required by the statute and goes beyond the provisions of the statute. | The Department has reviewed this comment. Existing provisions in the rule address this issue, therefore, no changes were made. |
| 15 | 9.3.1., 9.4.1. | A. Toni Young, Community Education Group | Harm reduction and syringe services.<br><br>Both provisions 9.3. and 9.4. completely omit the legal requirements set forth under §16-64-3(a) that the SSPs and HRPs may refer clients to these services. As written, these rules *require* that every provider offer every service. | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |
| 16 | 9.4.2. | Dan Lauffer, President & CEO Thomas Health | Syringe unique to program.<br><br>Support but encourage flexibility in the manner a program chooses to address this issue. | The Department has reviewed this comment, and no changes were made. Licensed providers may create a policy to address this issue. |
| 17 | 9.4.3. | Dan Lauffer, President & CEO Thomas Health | Weighing returned needles.<br><br>Explain methodology for weighing syringes as an acceptable alternative to counting to ensure 1:1 exchange. | The Department has reviewed this comment, and no changes were made. Licensed providers may create a policy to address this issue. |
| 18 | 9.4.3. | Dan Lauffer, President & CEO Thomas Health | Syringe unique to program.<br><br>Can returned needles to a SSP that are not the "uniquely" identified needle to that particular SSP be counted for the 1:1 exchange? | The Department has reviewed this comment, and no changes were made. Licensed providers may create a policy to address this issue. |
| 19 | 9.4.3. | Dan Lauffer, President & CEO Thomas Health | Syringe exchange model.<br><br>This restriction does not afford clarity or flexibility to determine whether the "goal" is met. Will there be flexibility afforded to programs to develop policies to meet this requirement? | The Department has reviewed this comment, and no changes were made. Licensed providers may create a policy to address this issue. |

| # | Rule Section | By Whom? | Summary of Comments | Response to Comment |
|---|---|---|---|---|
| 20 | 9.5. | Dan Lauffer, President & CEO Thomas Health | Syringe disposal.<br><br>Provide examples of other SSP syringe disposal plans for needles found in the community. Is there a time frame for when the public reports to when these must be collected and disposed of? | The Department has reviewed this comment, and no changes were made. Licensed providers may create a policy to address this issue. |
| 21 | 10.3.3. | A. Toni Young, Community Education Group | Incidents and adverse events.<br><br>Provisions 10.3.3.a. and 10.3.3.b. are both unclear as to whether the incidences or adverse events described in the provisions are limited to whether they occur on-site at an HRP/SSP.<br><br>Does this mean that SSPs must create incident reports for every client who attempts or completes suicide, whether or not those attempts or completions occur on their premises? If a client dies by suicide at their private residence, must every SSP from which that client receives services complete an incident report and then follow up on all the steps laid out in 10.3.5.?<br><br>Does this mean that SSPs must create incident reports for every client who dies in a vehicle collision, regardless of where those collisions may occur? | The Department has reviewed this comment and finds clarification is needed; therefore, changes were made. |
| 22 | 13.1.2. c. | Dan Lauffer, President & CEO Thomas Health | County commission.<br><br>Guidelines need to be developed that require County Commissions and/or Municipalities to have valid proof of impropriety on the part of a program to rescind a license. The whims of the political atmosphere in a community should not be the sole determining factor that a program should be closed. | The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute. |
| 23 | General | Dan Lauffer, President & CEO Thomas Health | General.<br><br>Would participant transport be permitted? | The Department has reviewed this comment. This comment is general in nature and offers no specific areas for amendment. Licensed providers may create a policy to address this issue. |

Robertson, April L. <april.l.robertson@wv.gov>

# Response to Title Series 69-17, §16-64

1 message

**A. Toni Young** <tyoung@communityeducationgroup.org> Fri, Aug 13, 2021 at 11:10 AM
To: "April.L.Robertson@wv.gov" <April.L.Robertson@wv.gov>
Cc: "A. Toni Young" <tyoung@communityeducationgroup.org>, Marcus Hopkins <mhopkins@communityeducationgroup.org>, Lee Storrow <lstorrow@communityeducationgroup.org>, Hilary Viens <hviens@communityeducationgroup.org>

Ms. Robertson:

Please find attached the Community Education Group's public comment on Title Series 69-17, §16-64. I hope that these comments and recommendations are helpful in the process of finalizing these rules.

If you have any additional questions, please feel free to reach out to us.

Sincerely,

A. Toni Young

Schedule a meeting with A. Toni Young: https://doodle.com/bp/1690553306/atoniyoung

Community Education Group

RURAL HEALTH SERVICE PROVIDERS NETWORK

A. Toni Young
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We will be adding you to our Newsletter mailing list.
You have the ability to opt out, but we hope you will stay with us.

**Response to Syringe Services Program Licensure.pdf**
185K

Community Education Group

**Response to Syringe Services Program Licensure**
**§16-64-7(c)**
**§69-17**

To Whom It May Concern:

Please find below Community Education Group (CEG)'s response to the proposed Syringe Services Program Licensure rule, title series §69-17, and statute authority §16-64-7(c).

While reviewing the proposed rules, we have identified the following sections that are areas of concern. These sections are followed by our concerns and reasoning.

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*§69-17-3. Licensure.:*

*3.1. General Licensure Provisions.*

*3.1.2. A license is valid only for the location and persons named and described in application.*

*3.1.3. Each syringe services program shall be license separately, regardless of whether the program is operated under the same business name or management as another syringe program.*

*3.1.5. If the ownership of a syringe services program changes, the new owner shall notify the Secretary within 10 days and immediately apply for a new license. The new owner's application for a license has the effect of a valid license for three months from the date the application is received by the Director.*

*3.1.6. The syringe services program shall notify the Director in writing 30 days prior to a change in the name or location of the program and submit an application form for a license amendment.*

Concerns:

Provision 3.1.2., 3.1.3., 3.1.5., and 3.1.6. seem to indicate that each individual location where a Syringe Services Program (SSP) operates must obtain a separate license for each individual address. This, in effect, eliminates the ability of a Harm Reduction Program (HRP) to utilize a mobile unit, as authorized in **16-64-7(c)**.

Does this requirement mean that, if an HRP utilizes a mobile unit, each individual place at which this mobile unit stops, in the present or in the future, must obtain a separate license, obtain individual approvals from County Commissions and municipal governing bodies for each individual stop, and pay $250 to be licensed for each stop?

RURAL HEALTH

If so, this creates an undue burden that no other providers of mobile healthcare services face in the state of West Virginia. Does every mobile cancer screening or dental services van have to secure an individual license to provide mobile services in each location they stop? If this is not the case, nor should it be the case for the mobile provision of harm reduction services.

Additionally, if a county or municipality has numerous locations where syringe services are needed (e.g., multiple homeless encampments, multiple areas with a high incidence of drug overdoses and overdose deaths), mobile units *must* have the flexibility to go where the services are needed. Those locations may change, as Persons Who Use Drugs (PWUDs) relocate or migrate based upon a variety of factors, including municipal destruction of encampments, seasonal weather events, and/or natural disasters. Mobile units *must* have the ability to adapt and go where services are most needed in order to effective respond to the needs of their clients.

Recommended Revision:

The Community Education Group recommends that these provisions be modified to include language that allows for HRPs who intend to provide syringe services via mobile unit be required to apply for only one license and that that mobile unit and the services it provides receive/seek county-wide approval by the County Commission and municipality-wide approval by municipal governments.

This would allow SSP mobile units the ability to move to where their services are needed, rather than being forced to reapply with every new stop or secure multiple licenses in order to allow them to provide services at every new stop.

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*3.1.8. The Director or his or her designee may enter the premises of any practice, office, or facility if the Director has reasonable belief that it is being operated and maintained as a syringe services program without a license*

*3.1.9. If the owner or operator, or program administrator of a licensed syringe services program or of any other unlicensed practice, office, or facility while the Director has reasonable belief that it is being operated as a syringe services program refuses entry pursuant to this rule, the Director shall petition the Circuit Court of Kanawha County for an inspection warrant.*

Concerns:

Prima facie, it appears that provision 3.1.8. grants the Director or his/her designee the authority to enter the premises of "...any practice, office, or facility" irrespective of the time of day or the presence of facility staff. There appear to be no restrictions related to hours of operation, notice of intent to enter, or the ability to require justification for entry.

Additionally, provision 3.1.8. raises significant concerns that this authority may apply to private residences, as well. Should this be the case, what accountability exists for OHFLAC and the Director?

It appears that 3.1.8. places significant levels of discretion into the hands of the Director, giving broad authority to inspect virtually *any* business or facility, regardless of whether or not said premises fall under the purview of OHFLAC.

Recommendations:

3.1.8. should place an immediate requirement that an inspection warrant be necessary for any entry into a facility under suspicion of what amounts to a criminal offense. If operating an unlicensed SSP *is* a criminal offense, the Director should not have the ability to initiate an on-site investigation of simply any facility without first obtaining a warrant.

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*3.2. Initial License*

> *3.2.1a. Any existing syringe services program, as of the effective date of W. Va. Code §16-64-1, et seq., which offers the full array of harm reduction services may continue operation and shall have until January 1, 2022, to come into compliance with the provisions of W. Va. Code §§16-64-1, et seq., and this rule and apply for licensure.*
>
> *3.2.1b. Any existing syringe services program, as of the effective date of W. Va. Code §15-54-1, et seq., which does not offer the full array of harm reduction services must cease and desist from offering all syringe services and operating as a syringe services program. These syringe services programs may continue in operation for the sole purpose of referring current participants to other syringe services programs.*

Concerns:

§16-64-3. Program requirements. specifically states that:

" (a) To be approved for a license, a syringe services program shall be part of a harm reduction program **which offers or refers** an individual to the following services which shall be documented in the application:"

Provisions 3.2.1.a. and 3.2.1.b. specifically do not mention that those services can be referred.

Recommendation:

3.2.1.a. should be updated to read:

*Any existing syringe services program, as of the effective date of W. Va. Code §16-64-1, et seq., which offers* **OR REFERS FOR** *the full array of harm reduction services may continue operation and shall have until January 1, 2022, to come into compliance with the provisions of W. Va. Code §§16-64-1, et seq., and this rule and apply for licensure*

3.2.1.b. should be updated to read:

*Any existing syringe services program, as of the effective date of W. Va. Code §15-54-1, et seq., which does not offer* **OR MAKE REFERENCES FOR** *the full array of harm reduction services must cease and desist from offering all syringe services and operating as a syringe services program. These syringe services programs may continue in operation for the sole purpose of referring current participants to other syringe services programs.*

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*§69-17-6. Service Environment and Operations*

*6.1. Each syringe services program shall have*

*6.1.2. Sufficient space and adequate equipment for the provision of all services specified in the syringe services program's description of harm reduction services offered pursuant to W.Va. Code §16-64-3.*

Concerns:

Provision 6.1.2. implies that all SSPs will offer all harm reduction services, specifically leaving out the legal requirement under §16-64-3(a) that those services may be referred and not directly provided by the SSP. Under that legal requirement, SSPs *do not* require space and equipment to offer services that they do not directly provide.

Recommendation:

6.1.2. should be updated to read:

*6.1.2. Sufficient space and adequate equipment for the provision of* OR REFERRAL TO *all services specified in the syringe services program's description of harm reduction services offered pursuant to W.Va. Code §16-64-3.*

This will allow SSPs, particularly mobile units and those located in smaller physical locations to refer clients to services without having to expend funds on unnecessary space and equipment.

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*6.5 Participants Accompanied by Minor Children*

*6.5.2. If another adult is not with the minor child, a syringe exchange shall not occur and other injection equipment may not be distributed. The other adult may be any other adult that accompanies the participant*

*6.5.3. Program staff members, contracted individuals, or volunteers shall at no time be responsible for a participant's minor child*

Concerns:

First and foremost, 6.5.3. is both unreasonable and places an undue burden on participants in SSPs. One of the primary concerns facing any patient when attempting to access healthcare services is whether or not there is sufficient care for any minor children. In response to this, several healthcare providers in West Virginia offer staffed areas where children may be left in the care of a responsible adult while patients are seen. This includes West Virginia Health Right's primary healthcare facility. To specifically prevent providers from offering short-term childcare creates an undue barrier to accessing care and services.

Recommendations:

6.5.2. should be amended to include any adult that accompanies the participant or any adult(s) specifically designated for the purpose of watching minor children while services are provided.

6.5.3. should be stricken.

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*§69-17-9.Provision of Services*

*9.3. Harm Reduction Services*

*9.3.1. A syringe services program shall be part of a harm reduction program and offer the harm reduction services described herein. A syringe services program shall not offer syringe services only.*

*9.4. Syringes Services.*

*9.4.1. Each visit at the syringe services program shall include an offer of harm reduction services from a qualified, licensed provider.*

Concerns:

Both provisions 9.3 and 9.4 completely omit the legal requirements set forth under §16-64-3(a) that SSPs and HRPs may refer clients to these services. As written, these rules *require* that every provider offer every service.

Recommendations:

9.3.1. should be amended to read:

*A syringe services program shall be part of a harm reduction program which offers* **or refers an individual to** *the harm reduction services described herein.*

9.4.1. should be amended to read:

*Each visit at the syringe services program shall include an offer of* **or a referral to** *harm reduction services from a qualified, licensed provider.*

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*§69-17-10. Reports and Records.*

*10.3 Incident Reporting and Adverse Events*

*10.3.3. Incidents or adverse events may include:*

*10.3.3.a. Completed participant suicide and suicide attempts*

*10.3.3.b. Participant death or serious injury due to trauma, suicide, or unusual circumstances*

*10.3.5. The syringe services program shall ensure in the event of an incident or adverse event that:*

*10.3.5.a. The incidence or adverse event is fully documented and appropriately reported to the correct state agencies as necessary;*

*10.3.5.b. There is prompt investigation and review of the situation surrounding the incident or adverse event;*

*10.3.5.c. Timely and appropriate corrective action is taken; and*

*10.3.5.d. Ongoing monitoring of any corrective action takes place until effectiveness of the action is established;*

*10.3.6. Within seven days of an incident or adverse event, the program shall file a report with the Director consisting of the following:*

*10.3.5.a. The action or actions implemented to prevent the reoccurrence of the incident or adverse event;*

*10.3.5.b. The time frames for the action or actions to be implemented;*

*10.3.5.c. The person or persons designated to implement and monitor the actions or actions; and*

*10.3.6.d. The strategies for the measurements of effectiveness to be established.*

Concerns:

Provisions 10.3.3.a. and 10.3.3.b. are both unclear as to whether or not the incidences or adverse events described in the provisions are limited to whether or not they occur on-site at an HRP/SSP.

Does this mean that SSPs must create incident reports for every client who attempts or completes suicide, whether or not those attempts or completions occur on their premises? If a client dies by suicide at their private residence, must every SSP from which that client receives services complete an incident report and then follow up on all of the steps laid out in 10.3.5.?

Does this mean that SSPs must create incident reports for every client who dies in a vehicle collision, regardless of where those collisions may occur?

If so, this places an undue burden of reporting and time expenditure on staff that is not faced by virtually any other healthcare provider in West Virginia.

Recommendations:

Both 10.3.3.a. and 10.3.3.b. should be amended to include the language "...that occur on-site"

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Thank you for taking the time to read our concerns related to §69.17. We hope that these concerns and recommendations prove helpful as these rules are finalized.

Sincerely,

A. Toni Young
tyoung@communityeducationgroup.org
(202) 465-1590
Founder & Executive Director
Community Education Group

Robertson, April L <april.l.robertson@wv.gov>

## Comments Regarding Syringe Service Program Legislative Rule

2 messages

**Johns, Linda** <linda.johns@thomashealth.org>
To: "april.l.robertson@wv.gov" <april.l.robertson@wv.gov>
Cc: "Lauffer, Dan" <dan.lauffer@thomashealth.org>

Mon, Aug 16, 2021 at 1:41 PM

Here are my comments/request for clarification:

1. Explain methodology for weighing syringes as an acceptable alternative to counting to ensure 1:1 exchange.

2. Provide examples of acceptable forms of West Virginia identification.

3. What does the "periodic licensure survey during the course of the annual licensing term" consist of?

4. Will there be separate licensures for a facility that wishes to provide services in both fixed and mobile locations? What about a mobile unit that moves to various locations as the need evolves, i.e. new clusters or hotspots of infectious diseases are identified and need to be addressed in an expedient manner?

5. Can returned needles to a SSP that are not the "uniquely" identified needle to that particular SSP be counted for the 1:1 exchange?

6. Provide examples of other SSP syringe disposal plans for needles found in the community. Is there a time frame for when the public reports to when these must be collected and disposed of?

Section 6.5 Participants Accompanied by Minor Children – this section references bringing children when picking up syringes

If a patient comes in under the influence and/or picking up syringes and we know they are actively using while caring for their children. Where does this line fall for us to make a mandated report to CPS? This is also difficult when working on trying to establish trust if they population believes or knows we will report them to CPS.

This was also an argument when everything was occurring as complaints were made children were present while syringes were being provided and there were no interventions or services for this.

I did wonder 1 element that I did not see in these rules. Would participant transport be permitted? Not that we would offer that but it could assist with access if multiple locations are not permitted without a full licensing requirement for a location.

Title 69 CSR 17 Legislative Rule Comments:

1/Section 3: Do not support 3.1.3 – A valid program should be afforded the right to add additional locations based on the ability to provide access to participants. Believe that 3.1.6 should suffice for adding a new location based on need. If HIV spread occurs, flexibility needs to be allowed to address outbreaks as they occur.

2/Another comment/question on 3.1.3 – for additional locations, would approval be needed by County Commission and/or Municipality for each new site? See #1 above regarding recognition of HIV outbreak locations associated with IV drug use.

3/Support 6.4 on page 9 that "All syringe services programs must comply with its own policies and procedures";

4/9.1.2 on page 13 - Valid ID – Support but **encourage flexibility** regarding the policy a program develops that will show permanent or temporary residency in West Virginia;

5/9.4.2 on page 14 – Unique Syringe – support but **encourage flexibility** in the manner a program chooses to address this issue;

6/9.4.3 on pages 14 and 15 – Goal 1 to 1 exchange model – I believe this restriction does not afford clarity or flexibility in order to determine whether the "goal" is met. Will there be flexibility afforded to programs to develop policies to meet this requirement?

7/13.1.2.c. page 19 – Guidelines need to be developed that require County Commissions and/or Municipalities to have valid proof of impropriety on the part of a program in order to rescind a license. The whims of the political atmosphere in

a community should not be the sole determining factor that a program should be closed.

Encourage the above revisions in Title 69 Rules.

Thank you so much.

Dan Lauffer

President & CEO

Thomas Health

Linda Johns

Executive Secretary

Administration

ThomasHealth

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Robertson, April L. <april.l.robertson@wv.gov>

# SSP Rule Public Comments

1 message

cathy.slemp@att.net <cathy.slemp@att.net> Mon, Aug 16, 2021 at 3:52 PM
To: April.l.robertson@wv.gov

Dear April.

I do hope this finds you well and wish you all the best.

Attached are comments related to the OHFLAC rule on syringe service programs. I appreciate everyone's efforts on this issue.

Sincerely,

Cathy

Catherine C. Slemp, MD, MPH

304-654-0026

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SSP Rule Comments - Cathy Slemp 8-16-21.pdf
222K

Catherine C. Slemp, MD, MPH

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August 14, 2021

April L. Robertson
One Davis Square, Suite 100 East,
Charleston, WV 25301
April.L.Robertson@wv.gov

**RE: Comments on 69CSR17 LEGISLATIVE RULE, SYRINGE SERVICES PROGRAM LICENSURE**

Dear April:

First, my sincere thanks and gratitude to you and the many others at WVDHHR working to advance our efforts against the COVID-19 pandemic. I know first-hand both how stressful and how rewarding such work can be, and I so appreciate your and others' commitment, passion, and hard work on this.

I write today to provide public comment on another critical topic I have continued to follow and to support use of sound public health and societal policy in -- our substance use epidemic. While I cannot in good faith or with public health knowledge and experience support most of SB334 passed during the 2021 legislative session, I do appreciate the fact that DHHR must implement the law as written and is working to best do so via the required rule-making process. I greatly appreciate that OHFLAC has worked closely with program staff and with field operators to understand the work of these programs and to minimize the law's potential negative effects on the health and safety of both those who would utilize syringe service programs and the public more broadly. In many challenging areas, OHFLAC has created needed flexibility where possible. This is much appreciated and will make a difference in allowing at least some programs to continue operations.

As you know, for many reasons the availability of syringe services pre-pandemic was insufficient. The mental health and economic toll of the COVID 19 pandemic now makes the need for well-run SSPs even greater as well as service delivery more challenging. How OHFLAC implements the law affects the sustainability of existing and the likelihood of new evidence based, community-supported programs where critically needed. These services are critical to addressing rising HIV, hepatitis and other infectious disease outbreaks, reining in high health care facility and broader community costs from substance use's secondary consequences, and to linking more West Virginians into recovery and off of drugs. I cannot emphasize enough the importance of doing everything possible within the law's constraints to maximize effective, efficient, evidence-based service delivery.

I am particularly concerned about two areas of the emergency rule that unintentionally limit services beyond the constraints the law already imposes.

1) **In urgent situations, greater program flexibility is needed so that service delivery can quickly be adapted and emergent issues rapidly addressed.** The standard process outlined, especially sections 3.1.2, 3.1.3, and 3.1.6 (single site per license, 30-day pre-notification of location change, etc.) does not allow programs the needed flexibility to address urgent situations. Patterns of drug use and their adverse consequences can shift location quickly and rarely give 30-days notice. Examples where rapid shifts

(added services, new locations) may be needed include newly identified infectious disease or overdose clusters in a community, documented high risk population movement (e.g., homeless population dispersal / displacement) or a sudden change in service accessibility (bus line closure, building fire, etc.).

**I would strongly encourage WVDHHR to allow for an expedited or emergency process to rapidly or presumptively approve a new location/site/application under urgent circumstances such as those outlined above so programs can flexibly and appropriately respond to emergent or urgent public health issues or newly identified spread of communicable diseases.**

2) **The rules need to better support mobile program delivery, a highly effective, efficient, and evidence-based program model. Requiring a separate license and licensure fee per service location and a 30-day advance notification of a location change (3.1.2, 3.1.3, and 3.1.6) markedly impedes the ability to offer mobile programs.** Mobile services are referenced in and should still be made equally if not more viable under the enacted code, especially given West Virginia's rural nature and limited public transportation infrastructure. **In addition, per site program licensure presents an undue cost and administrative burden on programs (fixed and mobile) and thus a deterrent to program delivery.** While likely well intentioned, these two licensure provisions undermine the effectiveness, availability, and cost savings that SSPs can offer, including cost savings to DHHR, hospitals, and society more broadly.

The requirement that each service delivery site be licensed as a separate program does not seem to be required by the law – the law defines a "program" (SSP, HRP) by the services offered, not a specific locale, and references both fixed and mobile sites. In addition, in *§16-63-4(b)(3) Procedure for revocation or limitation of the syringe services programs*, the law notes that OHFLAC should reference the site location that the limitation applies to, implying more than one location per program may exist.

OHFLAC is certainly long-experienced at licensing health care services. If the per site license requirement is to parallel licensure of SSPs with that of MAT or other more traditional health care system services, I would note that SSP services are very different from these and deserve a different approach. No prescriptions are written or complex medical procedures performed through syringe service provision. In addition, SSPs are designed to and are most effective because they reach out to and build a first, trusting relationship with high-risk individuals where they are -- typically outside of the traditional health care system. Persons at highest risk have repeatedly been shown to not trust or come to traditional health care settings for valid reasons and to be mobile.

I do recognize there is a cost of implementing this program licensure for OHFLAC and I suspect little to no additional funding was provided to DHHR for this service. Program revenue generation through licensure fees has likely been an important and appropriate component of OHFLACs sustainability model and is appropriate for most traditional services being licensed. Although the cost here is relatively low, it is important to note, that SSPs typically have little to no revenue generating potential (in fact SB334 prohibits future Medicaid payment for such) and are typically run by non-profit entities. Thus, separate licenses per site are an undue administrative and fiscal burden that again discourages program availability or expansion and decreases both effectiveness and efficiency. A reduction in quality services in turn increases costs to other DHHR programs in BMS, BPH, BHHF, etc., due to increasing infectious diseases, decreased linkages to recovery, etc. -- far greater costs than the cost of program licensure implementation and certainly more than the additional revenue the one site per program licensing approach will generate. I strongly encourage DHHR to identify other sources to support such.

**Potential alternatives to the one site per program requirement include the following: For mobile programs, OHFLAC could define the mobile unit itself as the service location (as long as services remain within the approving jurisdiction and service delivery site logs are maintained and reported). An alternative approach could allow a set number of routine stops to be listed under a single mobile**

**program licensure application with some flexibility granted as to exact location and service time for practicality purposes.**

**For fixed sites operating under a single described program model, OHFLAC could reaspmably allow for multiple pre-defined service delivery locations within the supporting jurisdiction.** If necessary for licensure program practicality purposes, OHFLAC could limit the number of pre-defined service locales under a single license to a reasonable number (3? 5?). Alternatively, the program could offer a markedly reduced fee and simplified application process for satellite sites operating under a single program / delivery structure.

In sum, I thank you again for the work you and others have done to implement licensure of these programs, allowing for at least some continued service provision. I strongly encourage you to address the two remaining issues above, mostly through revisions to sections 3.1.2, 3.1.3, and 3.1.6 so that mobile programs, a proven and utilized model in the state, can operate more effectively and efficiently and so that programs, both fixed and mobile, have the flexibility needed to address emergent and urgent public health situations. Thank you for your sincere consideration of both.

My best to all,

Catherine C. Slemp

Catherine C. Slemp, MD, MPH
Principal Consultant, Catherine C. Slemp, LLC, and
Former Commissioner and State Health Officer
WV Bureau for Public Health

Robertson, April L <april.l.robertson@wv.gov>

# Comments on Syringe Services Program Licensure (69CSR17)

1 message

rich@wvrha.org <rich@wvrha.org> Mon, Aug 16, 2021 at 3:57 PM
To: april.l.robertson@wv.gov

Hello, Ms. Robertson,

Please find attached letter outlining WVRHA's comments on the emergency rules governing Syringe Services Program Licensure (69CSR17).

Thank you for the opportunity to provide comments. WVRHA appreciates your consideration of our input.

Sincerely,

Rich Sutphin (he, him, his)

Executive Director

West Virginia Rural Health Association

PO Box 908,

Barboursville, WV 25504

cell:304-435-7491

West Virginia Rural Health Association

**WVRHA Comments on 69CSR17.pdf**
3511K

August 16, 2021

***via email to:*** april.l.robertson@wv.gov
April L. Robertson
General Counsel
Department of Health and Human Resources
One Davis Square
Suite 100 East
Charleston, West Virginia 25301

Dear Ms. Robertson:

The West Virginia Rural Health Association offers the following comments on the emergency rules governing the Syringe Services Program Licensure (69CSR17).

**Section 3.1.9 – WVRHA recommends using defined and consistent terms for SSP Operation and Administration**

3.1.9. If the owner or person in charge of a licensed syringe services program or of any other unlicensed practice, office, or facility which the Director has reasonable belief that it is being operated as a syringe services program refuses entry pursuant to this rule, the Director shall petition the Circuit Court of Kanawha County for an inspection warrant.

*Recommend deleting or defining* 'owner' this does not appear in the statute and does not appear in the rule. In addition, of the existing certified syringe services programs (SSPs) none are owned – they are operated by local health departments and by free clinics. It is anticipated that any new SSPs seeking certification will also be operated by not-for-profit entities – *i.e.*, Federally Qualified Health Centers (FQHCs), not-for-profit hospitals, et cetera as this is not a revenue generating activity. These types of entities are not owned but governed by community boards.

If the agency elects to retain the term 'owner' the WVRHA recommends defining this term in the rule.

**Section 5.2- WVRHA recommends allowing specialized continuing education as a substitute for experience for certain categories**

5.2. Program Administrator.

5.2.1. The administrator of a syringe services program shall have at a minimum one of the following:

5.2.1.a. An associate degree in an appropriate area of study and a minimum of three years of experience in the fields of substance use disorders, behavioral health, health care administration, peer recovery programs, or harm reduction;

5.2.1.b. A bachelor's degree in an appropriate area of study and a minimum of two years of experience in the fields of substance use disorders, behavioral health, health care administration, peer recovery programs, or harm reduction

*WVRHA recommends OHFLAC consider allowing specialized continuing education training as a substitute for experience for sections 5.2.1a (persons with an associate degree) and 5.2.1b (persons with a bachelor's degree).* For example, an organization may have a registered nurse with a bachelor's degree, but not the requisite experience. Permitting a professional with this credential to substitute a required number of specialized continuing education credits in lieu of years of experience will expand the number of qualified individuals who can administer an SSP.

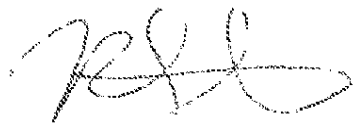
Section 9.2.3 - WVRHA Recommends Deleting Information Requested During Enrollment as it exceeds the scope of the statute and may violate 4 CFR Part 2

9.2.3 Information to be requested during enrollment into the syringe services program includes, at a minimum: *items a-i*

*WVHRA recommends deleting 9.2.3 items a-i.* This information collection is not required by the statute and goes beyond the provisions of the statute. Existing certified syringe services providers perform intake and maintain medical records for participants.

Again, thank you for the opportunity to provide comments. WVRHA appreciates your consideration of our input. If you have any questions, please contact me at rich@wvrha.org and 304-435-7491.

Sincerely,



Rich Sutphin
Executive Director