WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Health TITLE-SERIES: 64-105

RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No

RULE NAME: 64-105 Harm Reduction Programs

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 16-1-4, 16-3-1, 16-3C-8

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

STATUTORY AUTHORITY
The Secretary of the Department of Health and Human Resources shall propose rules for legislative approval in accordance with W. Va. Code §29A-3-1 et seq. to implement the all of the provisions of W. Va. Code § 16-1-4, 16-3-1, 16-3C-8. The Department of Health and Human Resources is empowered to enact each provision of W. Va. Code of State Rules 64-105 by the authority specifically found in W. Va. Code § 16-1-4, 16-3-1, 16-3C-8.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/27/2017

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/27/2017

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

NA

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

Brief Summary of Rule: This legislative rule is intended to establish a certification process for harm reduction programs (herein referred to as Harm Reduction Programs or HRPs). HRPs provide services intended to lessen the adverse consequences of drug use and protect public health. This rule series will provide a mechanism for the certification of harm reduction programs to reduce drug-related harm while enhancing individual, family, and community wellness, primarily through the provision of appropriate and competent services to injection drug users. The goal of harm reduction programs include:
Reducing the transmission of blood borne infections, including hepatitis & HIV, to limit the frequency of physical injury from abscesses & vein damage, and to minimize other diseases such as endocarditic & septicemia;
Educating participants on ways to reduce the potential for harm associated with substance use and other related activities;
Facilitating access to other health-related services including traditional preventive and primary medical care, as well as alternative healthcare resources;
Acting as a conduit for referring participants to additional substance use treatment programs when requested;
Referring participants to behavioral health and other social services such as housing, counseling services, benefit programs, and other supportive services and
Supporting participants within the parameters of providing professional services.
To be certified as a Harm Reduction Program by the Bureau, an applicant must:
Provide an injection drug user with the information and the means to protect himself or herself, his or her partner, and his or her family from exposure to blood-borne disease through access to education, sterile injection equipment, voluntary testing for blood-borne diseases, and counseling;
Provide referrals to drug abuse treatment;
Encourage usage of medical care and mental health services as well as social welfare and health promotion;
Provide safety protocols and classes for the proper handling and disposal of injection materials;
Plan and implement the clean syringe exchange program with the clear objective of reducing the transmission of blood-borne diseases within a specific geographic area;
Develop a timeline for the proposed program and for the development of policies and procedures;
If the applicant is not a local health department, have the written approval of the local health department whose service area includes the location of the proposed HRP; and
Have a written statement from the county commission for the county in which the HRP is to be located, and the municipality, if the HRP will operate in a municipality, that the county and municipality has approved the operation of the harm reduction program.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Statement of Circumstances: Drug use and misuse continue to create public health challenges in West Virginia, leading to overdose deaths, HIV and hepatitis C infections, and other chronic health conditions. Public health approaches such as harm reduction programs, offer effective evidence-based responses to substance use disorder. Harm reduction is a public health philosophy and intervention that seeks to reduce the harms associated with drug use and ineffective drug policies. Harm reduction programs use accurate, fact-based drug education, drug-related illness and injury prevention, and effective drug treatment for problematic substance use.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

This legislative rule establishes a certification process for harm reduction programs (herein referred to as Harm Reduction Programs or HRPs). HRPs provide services intended to lessen the adverse consequences of drug use and protect public health, also known as harm reduction programs. This rule series is intended to provide a mechanism for the certification of harm reduction programs to reduce drug-related harm while enhancing individual, family, and community wellness, primarily through the provision of appropriate and competent services to injection drug users.

The requirements of the rule can be handled with existing budgeted resources, as discussed below. Revenues will not be affected.

B. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

This legislative rule establishes a certification process for harm reduction programs (herein referred to as Harm Reduction Programs or HRPs). HRPs provide services intended to lessen the adverse consequences of drug use and protect public health, also known as harm reduction programs. This rule series is intended to provide a mechanism for the certification of harm reduction programs to reduce drug-related harm while enhancing individual, family, and community wellness, primarily through the provision of appropriate and competent services to injection drug users.

The requirements of the rule can be handled with existing budgeted resources, as discussed below. Revenues will not be affected.

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2017 Increase/Decrease (use "-")	2018 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost		83,957.00	83,957.00
Personal Services		77,107.00	77,107.00
Current Expenses		5,350.00	5,350.00
Repairs and Alterations			
Assets			
Other		1,500.00	1,500.00
	0		0

2. Estimated Total Revenues				

D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

Personnel expenses are based on the salary for hiring a Syringe Services Program (SSP) Coordinator and includes fringe and indirect expenses. Syringe services programs are one component of a spectrum of HRP strategies. Current expenses include in-state travel, estimated at 10,000 miles per year, for the SSP Coordinator to conduct site visits to applicants and to monitor certified SSPs. "Other" includes a laptop computer and cell phone for use by the SSP Coordinator. Personnel and current expenses are expected to remain stable with minimal increase from year to year.

Half of the funding for the SSP Coordinator will come from federal funding through an optional component of the Centers for Disease Control and Prevention "Strengthening Surveillance in Jurisdictions at High Incidence for Hepatitis C and Hepatitis B Virus Infections (CDC-RFA-PS17-1703). The additional 0.5 FTE and other expenses will be funded through the CDC HIV Prevention grant. No additional state funding is being requested.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH

SERIES 105
HARM REDUCTION PROGRAMS

§64-105-1. General.

1.1 *Scope*. This legislative rule establishes rules for certifying harm reduction programs (herein referred to as "Harm Reduction Programs" or "HRPs") that provide services intended to lessen the adverse consequences of drug use and protect public health that must be approved and certified by the Commissioner.

1.2. *Authority. W. Va. Code* §§16-1-4 & 16-3-1, 16-3C-8.

1.3. *Filing Date.*

1.4. *Effective Date.*

1.5 *Sunset Provision*. This rule shall terminate and have no further force or effect upon the expiration of 5 years from its effective date.

1.6. *Applicability.* This rule series applies to an person or entity that desires to offer harm reduction services in the state.

1.7. *Purpose*. This rule series is intended to provide a mechanism for the certification of harm reduction programs to reduce drug-related harm while enhancing individual, family, and community wellness, primarily through the provision of appropriate and competent services to injection drug users. The goal of harm reduction programs include:

1.7.a. Reducing the transmission of bloodborne infections, including hepatitis & HIV, to limit the frequency of physical injury from abscesses & vein damage, and to minimize other diseases such as endocarditis & septicemia;

1.7.b. Educating participants on ways to reduce the potential for harm associated with substance use and other related activities;

1.7.c. Facilitating access to other health-related services including traditional preventive and primary medical care, as well as alternative healthcare resources;

1.7.d. Acting as a conduit for referring participants to additional substance use treatment programs when requested;

1.7.e. Referring participants to behavioral health and other social services such as housing, counseling services, benefit programs, and other supportive services; and

1.7.f. Supporting participants within the parameters of providing professional services.

§64-105-2. Definitions

The following definitions used in these rules shall have the meaning:

2.1. "AIDS" means acquired immune deficiency syndrome.

2.2. "Administrator" means a person having the authority and responsibility for the operation of the HRP and serves as the contact for communication with the harm reduction program with the Bureau.

2.3 "Applicant" means the entity applying for authorization under this rule series, and includes the individual who signs the application for certification of the HRP.

2.4 "Bloodborne pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus, hepatitis C virus and human immunodeficiency virus (HIV).

2.6. "Bureau" means the West Virginia Bureau for Public Health.

2.7. "Certification" means Bureau authorization of an HRP to operate for up to 2 years.

2.8. "Core services" means the primary activities an entity undertakes in order to serve its clients.

2.9. "Fixed site" means a building or single location, not a mobile site, where harm reduction services are provided on a regular basis.

2.10. "Harm Reduction Program" or "HRP" means a program that provides services intended to lessen the adverse consequences of drug use and protect public health.

2.11. "HIV" means the etiologic virus of AIDS or Human Immunodeficiency Virus.

2.12. "Injection drug user" means a person who uses a syringe to self-administer drugs.

2.13. "Local Health Department" means a health department operated by a local board of health created, established and maintained pursuant to *W.Va. Code* §§ 16-2-1 *et seq.*

2.14. "Local Law Enforcement Official" means the individual designated by the sheriff or police chief in the jurisdiction in which the HRP operates who has authority to receive communications from state and local public health agencies.

2.15. "Location" means a site within the service area of a local health department. A location can be a fixed or mobile site.

2.16. "Mobile site" means a location where harm reduction is conducted using a vehicle such as a van, or by foot in a location that is not a fixed indoor setting.

2.17. "Needlestick Injury" means a penetrating wound from a needle that may result in exposure to blood.

2.18 "Needlestick Injury Protocol" means policies and procedures to prevent needlestick injury to HRP staff, including volunteers, and to HRP participants, and that outline both immediate and subsequent remedial and prophylactic actions to take in the event of a needlestick injury.

2.19. “Needs Statement” means a document that provides the rationale for the request for certification in the location specified and uses data and other objective sources to document the need. In preparing the “needs statement” the applicant shall consult with interested stakeholders concerning the establishment of the clean syringe exchange program. Interested stakeholders shall include, but need not be limited to, local law enforcement agencies, the local health department if the applicant is not a local health department, prosecuting attorneys, substance abuse treatment providers, persons in recovery, nonprofit organizations, hepatitis C and HIV advocacy organizations, and members of the community. The “needs statement” must include, the following:

2.19.a. The scope of the problem being addressed and the population the program would serve;

2.19.b. Concerns of the law enforcement community;

2.19.c. Statistics on HIV infection and/or viral hepatitis among injection drug users in the service area of a local health department;

2.19.d. The presence of injection drug users in the location; and

2.19.e. The presence or absence of other harm reduction services in the service area of the local health department.

2.20. “Participant” means a person who uses harm reduction services, a client of the HRP.

2.21. “Participant Confidentiality Protocols” means written protocols that strictly limit the disclosure of participant identification information.

2.22. “Program” means an HRP.

2.23. “Protocols” means written guidelines that define the limits and extent of practice of the staff of an HRP.

2.24 “Public Comment Period” means a 30-day period, commencing from the date the applicant posts information about an application is published in a newspaper paper of general circulation in the service area of the local health department that includes the HRP location, and posted on its website, if applicable, during which the public may file with the local health department comments on an application for HRP certification. However, a local health department that is operating a HRP as of the effective date of this rule series is exempt from the requirement that it publish information about an application in a newspaper paper of general circulation in the service area of the local health department, and its website, if applicable.

2.25. “Service Area” means the territorial jurisdiction of the local board of health;

2.26. “Sharps Waste” means used needles, syringes and lancets.

2.27. “Site” means the location(s) where Harm Reduction services are offered to participants.

2.28. “Staff” means anyone who provides Harm Reduction services on behalf of a program.

2.29. “Syringe” means both the needle and syringe used to inject fluids into the body.

2.30 “Viral hepatitis” means any of the forms of hepatitis caused by a virus, including hepatitis B (HBV) virus and hepatitis C virus (HCV).

§64-105-3. Harm Reduction Program Certification Process.

3.1. An applicant desiring state authorization to operate an HRP must file an application for certification with the Bureau, through its website or by mail on a form approved by the Commissioner.

3.2 Each application must contain the following information:

3.2.a. The name under which it will be providing harm reduction services and the date the application is submitted;

3.2.b. The full name, title, email address and telephone number of the individual designated by the applicant as the administrator of the HRP;

3.2.c. A description of the applicant organization's mission and core services, including a list of services the applicant currently provides to injection drug users. Services may be offered directly or by referral. These are:

3.2.c.1. Drug abuse treatment services;

3.2.c.2. HIV or hepatitis screening;

3.2.c.3. Hepatitis A and Hepatitis B vaccination;

3.2.c.4. Screening for sexually transmitted diseases;

3.2.c.5. Behavioral health services; and

3.2.c.6. Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms;

3.2.d. A needs statement that includes information about the presence or absence of other harm reduction services in the proposed location;

3.2.e. A description of the proposed harm reduction services, the anticipated number of participants to be served each year and the estimated number of syringes to be dispensed and collected each year. HRP services include:

3.2.e.1. Providing needles and syringe exchange services for all of its participants;

3.2.e.2. Providing HIV and viral hepatitis prevention education services for all of its participants; and

3.2.e.3. Providing for the safe recovery and disposal of used syringes and sharps waste from all of its participants;

3.2.f. A description of the service delivery mode(s) to be employed, whether fixed or mobile site, including:

3.2.f.1. The number of locations at which harm reduction services will be provided; and

3.2.f.2. A description of the location(s) where harm reduction services will be provided that includes the full physical address (street number, street name, city and zip code) and county of the fixed or mobile site location(s);

3.2.g. A description of additional services that will accompany harm reduction, such as overdose prevention supplies and education;

3.2.h. The HRP hours of operation in the location(s) and staffing. The description of hours of operation must include the specific days the HRP is open, opening and closing times, and frequency of harm reduction services. The description of staffing must include number of staff, titles of positions and descriptions of duties;

3.2.i. A paragraph, not to exceed 150 words that will be published in a newspaper of general circulation in the service area of the local health department that contains the HRP location, and posted on the applicant's website, if applicable, that summarizes the proposed program and includes the name of the applicant organization, the name of the HRP, location(s), hours of service, the types of services to be delivered, and the date upon which comments must be received. A local health department that is operating a HRP as of the effective date of this rule series is exempt from the requirement that it publish information about its application in a newspaper paper of general circulation in the service area of the local health department, and post it on its website, if applicable;

3.2.j. A copy of the following plans that guide the HRP's operations:

3.2.j.1. A syringe dispensing plan as described in subsection 7.1.;

3.2.j.2. A syringe collection and sharps disposal plan as described in subsection 7.2.;

3.2.j.3. A service delivery plan as described in subsection 7.3.;

3.2.j.4. A staff training plan as described in subsection 7.4.;

3.2.j.5. A data collection and program evaluation plan as described in subsection 7.5.; and

3.2.j.6. A community relations plan as described in subsection 7.6.;

3.2.k. A budget for the program which includes at a minimum projected income and costs for personnel, outside services, and operating expenses, including but not limited to rent, utilities, equipment, materials including syringes and disposal containers, transportation, insurance, training, meetings, syringe disposal services, and indirect costs; and

3.2.l. If the applicant is not a local health department, the written approval from the local health department whose service area includes the location of the proposed HRP;

3.2.m. A written statement from the county commission for the county in which the HRP is to be located that the county has not prohibited the operation of a harm reduction program by ordinance.

3.2.n. A signed statement attesting to truthfulness of the information contained in the application and the applicant's compliance with state laws, rules, and local ordinances.

3.3. If the applicant is required to publish information about an application, the public may submit comments about an application during the 30-day public comment period, which commences on the date information about the application is published in a newspaper paper of general circulation in the service area of the local health department that includes the location of the HRP.

3.4. The Bureau, after consultation with the local health officer and local law enforcement leadership, shall issue a final decision to certify or not to certify within 30 business days after the close of the 30-day public comment period. The certification is valid for no more than two years, subject to renewal.

3.4.a. In considering whether approve or disapprove an application, the Commissioner shall consider the applicant's ability to:

3.4.a.1. Provide an injection drug user with the information and the means to protect himself or herself, his or her partner, and his or her family from exposure to blood-borne disease through access to education, sterile injection equipment, voluntary testing for blood-borne diseases, and counseling;

3.4.a.2. Provide referrals to facilitate entry into drug abuse treatment, including opioid substitution therapy;

3.4.a.3. Encourage usage of medical care and mental health services as well as social welfare and health promotion;

3.4.a.4. Provide safety protocols and classes for the proper handling and disposal of injection materials;

3.4.a.5. Plan and implement the clean syringe exchange program with the clear objective of reducing the transmission of blood-borne diseases within a specific geographic area;

3.4.a.6. Develop a timeline for the proposed program and for the development of policies and procedures;

3.4.b. The Commissioner will not approve a application unless it contains both:

3.4.b.1. If the applicant is not a local health department, the written approval from the local health department whose service area includes the location of the proposed HRP;

3.4.b.2. A written statement from the county commission for the county in which the HRP is to be located that the county has not prohibited the operation of a harm reduction program by ordinance.

§64-105-4. Renewal of HRP Certification.

4.1. A certification is valid for no more than two years and may be renewed by the Bureau by request.

4.2. At least 30 days prior to the end of the two-year certification period, the HRP administrator may communicate to the Bureau by mail or email to request renewal of certification for an additional two years.

4.3. The Bureau will consult with the local health officer and local law enforcement leadership regarding reauthorization requests. The Bureau has 30 business days to review and respond to the applicant's request for renewal of the certification.

§64-105-5. Denial of Certification Renewal or Revocation of HRP Certification

An HRP certification will be revoked and an application for renewal of certification may be denied by the Bureau if the applicant or the HRP violates the provisions of this rules series.

§64-105-6. Process to Request Review Following Denial or Revocation.

Any person aggrieved by the Bureau's decision to deny, revoke or refuse to renew a certification, or by the Bureau's deemed denial resulting from the Bureau's failure to respond to the applicant's request for renewal within 30 business days, may request a hearing.

6.1. A request for a hearing must be made in writing within 30 days of the date that the Bureau's notification of denial or revocation is issued, or after the date of the Bureau's deemed denial, if applicable.

6.2. The request for hearing must be made in writing to the address found on the Bureau website and must clearly state the reasons for the request.

6.3. Hearings will be conducted pursuant to 64 CSR 1.

§64-105-7 Operational Requirements for Certified HRPs.

A certified HRP must include program participant input into the program design, implementation and evaluation. Program design, implementation, and evaluation must be guided by the following plans:

7.1. A syringe dispensing plan that:

7.1.a. Is designed to provide new, sterile syringes to meet the needs of participants in accordance with the recommendations made by the U.S. Public Health Service, published by the Centers for Disease Control and Prevention, to support the use of a new, sterile syringe for each injection; and

7.1.b. Tracks the number of syringes dispensed.

7.2. A syringe collection and sharps waste disposal plan that:

7.2.a. Is designed to maximize return of used syringes without increasing risk of needlestick injury to staff or program participants;

7.2.b. Tracks number of syringes returned in a manner that eliminates direct handling of sharps waste and does not interfere with service provision;

7.2.c. Includes a needlestick injury protocol and a plan for ensuring staff and participant familiarity with the protocol;

7.2.d. Includes sharps waste disposal education that ensures staff and participants are familiar with state law regulating proper disposal of home-generated sharps waste; and

7.2.e. Includes a plan and budget for sharps waste disposal, or an explanation if no cost is associated with sharps waste disposal.

7.3. A service delivery plan that includes:

7.3.a. Needles and syringe exchange services for all of its participants;

7.3.b. HIV and viral hepatitis prevention education services for all of its participants;

7.3.c. The safe recovery and disposal of used syringes and sharps waste from all of its participants;

7.3.d. HIV or hepatitis screening;

7.3.e. Hepatitis A and hepatitis B vaccination;

7.3.f. Screening for sexually transmitted infections;

7.3.g. Education and supplies for safer sex practices; and

7.3.h. Participant confidentiality protocol.

7.4. A staff training plan that includes:

7.4.a. Mandatory staff training on the following topics:

7.4.a.1. Orientation to the applicant's services and eligibility requirements for the program;

7.4.a.2. Overview of harm reduction philosophy and the harm reduction model used by the program;

7.4.a.3. The applicant's approved policies and procedures that cover syringe exchange transactions, handling disposal of infectious waste, and needlestick prevention management;

7.4.a.4. Procedures that ensure secure storage, handling and disposal of syringes in accordance with State law and rules;

7.4.a.5. Procedures for making referrals, including primary care, detox and drug treatment, HIV counseling and testing, prenatal care, tuberculosis and Hepatitis A, B and C screening and treatment, screening and treatment for sexually transmitted infections, and other HIV support and social services;

7.4.a.6. Hierarchy of risks associated with sexual and drug-using behaviors and risk reduction practices for those behaviors;

7.4.a.7. Education and demonstration of safer injection practices, including techniques for disinfecting injection equipment, rotation of injection sites and the use of alcohol pads to disinfect injection sites; and

7.4.a.8. Education and demonstration of Naloxone administration;

7.4.a.9. Cultural diversity including sensitivity to race/ethnicity, age, gender and gender identity, sexual orientation, literacy, socio-economic status and employment status.

7.4.b. Training logs and attendance sheets for all trainings provided to HRP staff. The training log must include the name of the training and trainer, date, location and agenda/topics covered. The attendance sheet must record the names of all staff who received the training, date and agenda/topics. A copy of the attendance sheet or a certificate of completion must be maintained in the personnel/training record for each HRP staff member.

7.5. A data collection and program evaluation plan that:

7.5.a. Incorporates evaluation data into program design; and

7.5.b. Uses the Bureau designated data reporting method to collect the data elements which includes:

7.5.b.1. The total number of persons served;

7.5.b.2. The total number of syringes and needles dispensed, collected and disposed of; and

7.5.b.3. The total numbers and types of referrals made to drug treatment and other services.

7.6. A community relations plan that:

7.6.a. Records adverse incidents and positive interactions between local law enforcement and HRP staff, volunteers or participants in their role as program participants;

7.6.b. Documents concerns and positive feedback expressed by program participants, community members, neighborhood associations and/or local law enforcement officials; and

7.6.c. Documents steps the program has taken to address any reasonable concerns.

§64-105-8. Compliance with State Laws, Regulations and Local Ordinances.

The program and its staff shall operate and furnish services in compliance with all applicable state laws, rules and local ordinances.

§64-105-9. Reporting Requirements for Certified HRPs.

HRPs certified pursuant to this rules series must return a report to the Bureau, postmarked or delivered by email by the anniversary date of certification each and every year of the program's operation under the Bureau's certification. The report must include:

9.1. The data elements listed in subsection 7.5.; and

9.2. A report on the events recorded under the community relations plan, contained in subsection 7.6.