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October 30, 2019

Steven T. James
House Clerk
State House Room 145
Boston, MA 02133

Michael D. Hurley
Senate Clerk
State House Room 335
Boston, MA 02133

Dear Mr. Clerk,

Pursuant to Section 158 of Chapter 46 of the Acts of 2015, please find enclosed a status update from the Department of Public Health on the extended-release injectable naltrexone pilot program.

Sincerely,

Monica Bharel, MD, MPH
Commissioner
Department of Public Health

Charles D. Baker
Governor

Karyn Polito
Lieutenant Governor

Marylou Sudders
Secretary

Monica Bharel, MD, MPH
Commissioner

Extended-Release Injectable Naltrexone Pilot Program Status Update

October 2019

Massachusetts Department of Public Health

Legislative Mandate

The following status update is hereby issued pursuant to Section 158 of Chapter 46 of the Acts of 2015:

The department of public health, in consultation with the bureau of substance abuse services, shall create an extended-release injectable naltrexone pilot program for individuals with opioid or alcohol addiction being treated in licensed clinical stabilization service programs. The department of public health shall select locations for the pilot program based on prevalence of need; provided, however, that there shall be not less than 2 program locations selected. Each program shall operate for 2 years and collect outcomes data on an ongoing basis, in a manner described in this section and as determined by the commissioner of public health.

Locations selected by the department for the pilot program shall be granted additional funding, as determined by the department, for staff or other needs associated with prescribing and administering extended-release injectable naltrexone to patients prior to discharge and, as part of discharge planning, connect such patients with community providers prescribing extended-release injectable naltrexone and offering substance abuse counseling.

The department of public health shall collect data in order to gauge the success of the program in effectuating long-term recovery and track trends within the patient population. Such data shall be collected by tracking each individual participant post discharge from the clinical stabilization service program for no less than 1 year in a manner to be determined by the commissioner of public health. Information collected by the department during this time shall include to the extent possible, but shall not be limited to: (i) whether the individual is actively engaged in outpatient or inpatient treatment for a substance use disorder; (ii) whether the individual is using extended-release injectable naltrexone or other medication-assisted therapies; (iii) any barriers to accessing treatment in the community; (iv) any episodes of relapse; (v) any hospitalization related to substance misuse or overdose; and (vi) any record of arrest or incarceration for drug-related offenses since discharging from the clinical stabilization service program.

For the purposes of this section, "clinical stabilization service programs" shall mean 24-hour clinically managed post-detoxification treatment for adults or adolescents, as defined by the department of public health that usually follows acute treatment services for substance abuse; provided, however, that "clinical stabilization service programs" may include intensive education and counseling regarding the nature of addiction and its consequences, relapse prevention, outreach to families and significant others and aftercare planning for individuals beginning to engage in recovery from addiction.

For the duration of the pilot program, the department of public health shall issue a report annually, on or before June 30, to the clerks of the house of representatives and the senate who shall forward the same to the house and senate committees on ways and means, the joint committee on health care financing, the joint committee on mental health and substance abuse, and the joint committee on public health. The report shall include a program progress update and provide outcomes data.

Background

The Bureau of Substance Addiction Services (BSAS) within the Department of Public Health is the Commonwealth's single state authority (SSA) to oversee the provision of substance use and gambling addiction treatment in Massachusetts. BSAS is responsible for licensing substance use and gambling addiction treatment programs, Licensed Alcohol and Drug Counselors (LADC), and certification of addiction prevention programs.

Beyond its regulatory function, BSAS is a vendor of a continuum of addiction services including prevention, intervention, treatment, and recovery support. These services include: licensed treatments such as inpatient detoxification; inpatient post detoxification stabilization; residential rehabilitation; outpatient counseling; and, medication assisted treatment including methadone maintenance and Office Based Opioid Treatment (OBOT). In addition, BSAS funds non-licensed services such as case management for individuals and families and for recovery support.

This report provides a status update for the extended-release injectable naltrexone pilot program for FY2019.

Status Update

Pursuant to Section 158 of Chapter 46 of the Acts of 2015, please find a status update for the extended-release injectable naltrexone pilot program.

The intent of this pilot program is to increase capacity to initiate voluntary clients on extended release injectable naltrexone (ERIN) during their treatment episode at the CSS program and to ensure effective transitioning of these clients to community-based services to continue their medication assisted treatment and support services. BSAS awarded the CSS programs $100,000 each to hire staff and to develop infrastructure for implementing access to and monitoring of ERIN from the time a client is within a CSS program through the transition to a community-based provider upon discharge from CSS. Participating programs will also be responsible for reporting on metrics and outcomes data for clients participating in the ERIN pilot program.

The twelve CSS programs that participated in the ERIN project are below::

- Behavioral Health Network (BHN) - Greenfield
- Behavioral Health Network (BHN) - Springfield
- Community Health Link (CHL) – Worcester
- Dimock – Roxbury
- High Point – Brockton
- High Point- Brockton, Men's Addiction Treatment Center (MATC)
- High Point – Plymouth
- High Point – New Bedford, Women's Addiction Treatment Center (WATC)
- High Point- Jamaica Plain, Shattuck
- Providence Hospital- Holyoke
- Spectrum – Westborough
- Stanley Street Treatment and Resources (SSTAR) Inc. – Fall River

Evaluation Design

The twelve ERIN pilot sites were each asked to enroll 25 participants for the in-person interview component of the evaluation. A total of 196 participants completed baseline (BL) interviews and four-month (4M) and eight-month (8M) follow-up interviews were completed by 110 and 105 participants, respectively.

Each site was asked to enroll 25 participants for in-person interviews. Five of the 12 sites successfully arranged to have 25 participants complete a BL interview. Across the 12 sites, a total of 196 participants completed a BL interview; 110 participants completed a 4M interview; and 105 completed an 8M interview. Outcomes highlighted in this report are based on the 105 participants who completed both a BL and an 8M follow-up interview. Nine of the 12 sites served participants who completed both a BL and an 8M interview, with the number of participants from each site ranging from seven to 19.

Interview participant enrollment varies across sites

The table below shows characteristics of all participants with a BL interview and for those who also completed an 8M interview.

The 8M group's characteristics are described below:

Demographic Characteristics	BL through 8M Group
Age	37
Male	62%
Female	38%
Hispanic/Latino	11%
African-American	8%
Heterosexual	88%
Never Married	67%
Have Children	50%
High School Education or higher	73%
Worked (in the past 90 days) at Baseline	52%
Health Insurance	94%

Collection data Highlights

- Participant's age ranged from 21 to 66 with an average age of 37. More than half of participants are male (62%).
- Most were white (86%), with 8% identifying as African American and 11% identifying as Hispanic/Latino ethnicity.
- Most participants were heterosexual (88%) with 11% identifying as LGBTQ.
- Most (67%) have never been married and are not cohabitating, 22% are separated or divorced, and 12% are married.
- Half have children; of these participants, 42% have children under age 6 and 70% have children ages 6-17.
- Almost everyone had medical coverage; for 91%, this includes publicly-funded coverage (e.g., Medicaid, Medicare, VA).

Age of Onset of Substance Use

Participants were asked two questions to determine age of onset of substance use:

1) Age first used alcohol to intoxication; and

2) Age first used any illegal drug; and two additional questions to determine initiation of opioid use

The median age for first use of alcohol to intoxication was 14 and 15 for first use of any illegal drug. The median first use of opioids for any reason occurred at 18 years (ranging from 9 to 55 years old) and median age at first use of opioids for non-medical reasons was 19 years old.

Participant's Experience with MAT & Extended-Release Injectable Naltrexone (ERIN)

Participants were asked at BL if the ERIN treatment was related to alcohol use, opioid use, or both. For those who participated in this evaluation, 48% of participants said they received ERIN treatment for alcohol use, 42% said they received ERIN treatment for opioid use, and 11% receiving treatment for both alcohol and opioid use.

All participants (100%) received their initial ERIN shot around the time of the BL interview. At follow-up time points (4M and 8M intervals) participants were asked if they were currently receiving medication-assisted treatment (MAT) for their substance use. By 8M, 60% of participants reported that they were still receiving MAT for any substance (this was lower than the sum on MAT for each substance, as some participants report receiving MAT for both alcohol and opioid use). Of those still on MAT at follow-up, most were taking extended-release injectable naltrexone.

The use of MAT remained stable from 4M to 8M for both substances as the percentage of participants on MAT for opioid use did not change over time (34% at 4M, and 31% at 8M). The percentage of participants on MAT for alcohol or other drug use was slightly higher but also remained relatively unchanged (39% at 4M; 36% at 8M).

It is interesting to note that women were more likely to report receiving MAT for opioid use than men: (39% of women report receiving ERIN for opioid use at 8M compared to 27% of men).

Expectations and Barriers

At each time point at the BL, 4M and 8M intervals, participants were asked if they intended to take their next dose of ERIN and to indicate what they perceived to be the main barrier to continuing their ERIN treatment. There was a significant decrease in the percentage of participants reporting that they expect to take their next dose of ERIN between time points.

A decrease in the percentage of participants reported that they expected to take their next dose of ERIN between time points (BL to 4M, 4M to 8M, and BL to 8M). While all participants reported at BL that they

expected to take their next dose of ERIN, only 74% expected to do so at 4M and by 8M only slightly more than half (57%) intended to take their next dose of ERIN.

Just under two-thirds of participants reported no barriers to ERIN treatment at each of the three time points. Transportation and health insurance were the most frequently named barriers at BL, however, the percentage of participants reporting these barriers significantly drop between BL and 4M.

Evaluation Findings at the 4M and 8M Interval

At 4M, 49% of interview participants reported having received an ERIN shot in the past four weeks; this drops slightly to 41% at 8M. At 8M approximately 12% report receiving the initial shot only. Most (88%) reported receiving the second shot and a little more than half (53%) reported receiving at least six shots, which suggests that they had been adhering relatively closely to a monthly injection schedule.

Sub-Group Evaluation Findings

Given the eight-month evaluation period and variability in timing between the first ERIN shot and the baseline interview, participants who received six or more shots during the eight-month period can be considered to have largely received shots on a monthly basis. Substantially more women report having received six or more shots at 8M (74%) than do men (41%).

The breakdown of those receiving monthly ERIN shots are below:

Gender	**Yes**	**No**
Male	41%	59%
Female	74%	26%

Section 35	**Yes**	**No**
Male	55%	45%
Female	51%	49%

Substance	**Yes**	**No**
Opioid or Both		
Male	55%	45%
Female	51%	49%
Alcohol		
Male	54%	46%
Female	51%	49%

Participant Feedback on ERIN

At each time point, participants were asked to respond to items about their perceptions of the efficacy and safety of ERIN treatment, and of its consistency with being drug-free. Overall, participants endorsed a positive opinion/attitude regarding MAT efficacy, safety, and consistency with being drug-free at all time points.

At each time point, participants who had received an ERIN shot in the past month were asked if they experienced side effects from that treatment and, if so, to indicate which side effects they experienced. Approximately 42% reported one or more side effect at BL which drops to 36% at 4M and 31% at 8M; these changes are not significant. Reports of headaches drop continuously over time with the decrease from BL to 8M (both <14%) approaching statistical significance.

Participant Interaction with ERIN Clinician During Time points

At each time point participants were asked how many times they had contact with their ERIN clinician in the past 90 days. At BL, all participants reported having contact at least once with their ERIN clinician in the past 90 days; at 8M, only one-third reported contact in the past 90 days.

At each time point, participants were asked to rate how much help or assistance the ERIN clinician had provided them since they first met. At BL, most participants (87%) rated their ERIN clinician as very helpful (answered “quite a bit” or “extremely”).The percentage who rated ERIN clinicians as very helpful decreases at both the 4M (55%) and 8M (47%) time points. There was also a significant drop in the percentage of participants who report understanding what kind of assistance their ERIN clinician can provide, from 73% at BL to 55% at 8M.

Summary of ERIN Evaluation

Participants reported high satisfaction with all aspects of the ERIN program (services & staff) at all time points. The evaluation showed that 43% of the participants reported no drawbacks to the ERIN program at 4M or 8M, 30% cite drawbacks at both 4M and 8M. The most commonly cited drawbacks at both 4M and 8M are related to the medication itself (e.g., side effects, ineffectiveness, ordering & receiving medication, finding a provider). The lack of aftercare or contact with their ERIN clinician was also noted as drawbacks.

Employment

Participants also reported an increase of employment from BL throughout the 4M and 8M time points (from BL to 4M (17% to 31%) and BL to 8M (17% to 34%). Reports of satisfaction using the Life Satisfaction Index (calculated based on responses to six questions measuring general satisfaction across multiple areas of life) increased significantly on all items from BL to 8M and significantly or nearly significantly on all items from BL to 4M.

Life Satisfaction

Participants also reported an increase of life satisfaction during the length of their time participating in the program. Using the Life Satisfaction Index (calculations based on responses to six questions measuring general satisfaction across multiple areas of life), reports of satisfaction increased significantly on all items from BL to 8M and significantly or nearly significantly on all items from BL to 4M.

Between BL and 8M, the percent reporting satisfaction with: family relationships rises from 51% to 73%; place of residence increases from 50% to 72%; physical intimacy rises from 44% to 64%; one's general level of happiness increases from 41% to 72%; how life is going rises from 23% to 73%; and with school or work rises from 15% to 53%.

Recovery

Participants also reported in increase of a high endorsement of recovery markers during the length of their time participating in the program. Using The Recovery Markers Questionnaire (taken from the Recovery Enhancing Environment (REE) that consists of 22 statements related to functioning and recovery), the percentage agreeing with 75% of recovery markers is high at BL (80%) and rises significantly between both BL and 4M and BL and 8M, reaching 92% at 8M.

Participants' Service Use Patterns Over Time

Treatment Services	Pre-Period	Post Period	% Change
Acute Treatment Services	**146**	**74**	**-49%**
Clinical Stabilization Services	**67**	**64**	**-5%**
Transitional Stabilization Services	**17**	**63**	**271%**
Residential Rehabilitation Services	**25**	**89**	**256%**
Intensive Outpatient	**12**	**11**	**-8%**
Outpatient	**53**	**69**	**30%**
Recovery Support Services	**43**	**75**	**74%**
Opioid Urgent Care Centers	**31**	**31**	**0%**
Other Community-Based Recovery Supports/Case Management	**23**	**53**	**130%**

Notes: Percentages are based on 212 ERIN participants discharged at least 8 months before the end of December 2018. Percent change is reported as the difference between the post-period and pre-period expressed as percentage of the pre-period value.

- The percent of participants receiving acute treatment services decreased over time by 49%.

- Participants utilizing residential treatment services increased from over time by 42%. There were substantial increases at the individual level in Transitional Support Services (271%) and residential rehabilitation (256%). The percent of participants who receive Clinical Stabilization Services decreased slightly (-5%).

- Participants who received intensive outpatient services during the pre-period were low and remained low during the post-period with a decrease of 8%.

- The percent of participants who received outpatient services increased by 30% from the pre- to the post-period.

- Participants who received recovery support services increased by 74%. This change was largely due to the increase in participants receiving "other" community-based recovery support services (130%). The percent who received Opioid Urgent Care services remained the same between the pre- and post-periods.

In closing, ERIN participants reported very high levels of satisfaction with program services. They also felt the program was effective in addressing their substance use disorder. Nearly all the sites experienced significant challenges related to insurance issues and receiving the medication in time/before CSS discharge. Most sites struggled with tracking, retention, follow-up, and reassessments with some sites varying in their infrastructure and capacity to provide ERIN at the CSS level.