Meeting Agenda – August 9, 2018
SHTF

1. Introductions:

2. Updates:
   a. Harm Reduction from 20,000 feet (local and state initiatives)
   b. SEBHN Pilot Summary: Presentation
   c. Florida Society of Addiction Medicine (FSAM):

3. 2019 Legislation: Discussion
   i. Omnibus SHTF Bill
   ii. Syringe Exchange Expansion

4. FARR
   a. FARR Certification Overview: Presentation
   b. Day/Night-Res. 5 -status

5. Public comments.

6. Closing remarks.
SEFBHN Pilot Summary

- Cultural Probe
- Develop Personas
- Card Sorting
- Customer Interviews
- Listen in on Customer Service Calls
- Field Visits
- User Survey

Run a Usability Test
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item 2b
The pilot began January 2018 with goals, as described in the service agreement, of expanding Medication Assisted Treatment (MAT) Housing options, eliminating barriers to sustained recovery for individuals living with Opioid Use Disorder (OUD), increasing access to Recovery Peer Specialists in order to improve engagement in community-based treatment, recovery support services, mutual aid and meaningful activities including: employment, education, and community service.
Four (4) Recovery Navigational Support (RNS) trainings were conducted, producing seventy-two (72) certificates of completion. Twelve (12) FARR Partners comprising 26 residential locations supporting 451 certified beds were recruited, trained and engaged in utilization of the data collection tool and housing vouchers. Additionally, these Recovery Residences agreed to facilitate delivery of RN to clients residing in their locations. Through ongoing collaboration with FARR, there are now a total of 107 FARR Residences in Palm Beach County (934 certified beds) who admit residents who are enrolled in a MAT protocol.

Since January 1st, 2018 there have been one hundred twenty (120) referrals to the Pilot. The majority of these referrals were initiated in April and May. Of the total individuals referred, sixty-one (61) were enrolled as RNS Clients, 26 are currently pending navigator assignment and 33 were classified as either non-responsive or disqualified for RNS Service. For comparative reporting purposes pending, non-responsive and disqualified referrals are presented throughout this report as a control group labelled "RNS Candidates."

Note: Navigator assignments for ‘pending referrals’ contingent on contract extension.
Criteria

For the purposes of this report, pilot participants were broken into two categories:

- **Clients** - completed REC CAP baseline assessment during Key Working Session 1 (KWS)
- **Candidates** - referrals who were non-responsive and/or disqualified during screening

All data is current as of July 27th, 2018

**REC CAP**: Recovery Capital assessment tool that both informs Recovery Care Planning and measures recovery capital gains over time.

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61 clients
59 candidates
120 total pilot participants
Key Working Session (KWS): structured sessions where client and navigator engage in a defined process to Measure, Plan and Engage (MPE) concrete recovery goals informed by REC CAP Assessment. Typically, eleven (11) KWS are held over six (6) months. **Phase 1 is** comprised of four (4) weekly KWS, followed by **Phase 2** comprised of four (4) bi-weekly KWS and **Phase 3** transitions to three (3) monthly KWS.
Current Status of Enrolled Clients

- Active: 48
- Other Voluntary Discharge: 3
- Other Involuntary Discharge: 1
- Abandoned: 9

Current Status of Candidates

- Non-responsive: 33
- Pending: 26
Housing

Over six thousand safe and sober nights were delivered by FARR Partners during this pilot. 50% of housing vouchers were funded for persons who failed to engage in Recovery Navigational Support (RNS). This can and should be corrected by integrating conditional approval and funding.

Housing stability is clearly enhanced within the RNS Client Group. Average length of stay for RNS Clients is 64.3 days compared to 43.2 days for Candidates, representing a 32.8% enhancement for the RNS Client Group. As we progress forward, it will be of particular interest to determine whether delivery of RNS through term maturity (six months) results in expansion of this differential.

Additional recovery housing data is presented pertaining to compliance with peer community rules and responsibilities, financial commitments, and participation in the peer residential community.

**FARR:** Florida Association of Recovery Residences – state designated credentialing entity and NARR Florida Affiliate
64.3 days
Avg Length of Client Housing

43.2 days
Avg Length of Candidate Housing

6451
Safe & Sober Nights Delivered

Clients Receiving Housing Vouchers

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>49</td>
<td>12</td>
</tr>
<tr>
<td>80.3%</td>
<td>19.7%</td>
</tr>
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</table>

Candidates Receiving Housing Vouchers

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>53</td>
<td>6</td>
</tr>
<tr>
<td>89.8%</td>
<td>10.2%</td>
</tr>
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</table>
Client Peer Community Participation

- Resistant: 1.9% (1 out of 44)
- Requires Monitoring: 33.3% (18 out of 44)
- Reliable: 64.8% (35 out of 44)

Candidate Peer Community Participation

- Resistant: 8.7% (4 out of 46)
- Requires Monitoring: 41.3% (19 out of 46)
- Reliable: 50.0% (23 out of 46)
Employment

At initial screening and intake, 93 individuals reported as being *unemployed*: 47 of these were enrolled as *Clients* and 46 were classified as *Candidates*. As of July 27, 2018, a total of 53 individuals are now employed. Of these, 37 belong to the Client Group and 17 belong to the Candidate Group, resulting in a 37% employment gain for the Client Group compared to only a 7% gain for the Candidate Group. Job satisfaction ratings were consistent across both groups.
### Employment (continued)

#### % Gains in Employment

<table>
<thead>
<tr>
<th></th>
<th>Clients</th>
<th>Candidates</th>
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<tbody>
<tr>
<td>% Gains</td>
<td>37%</td>
<td>7%</td>
</tr>
<tr>
<td></td>
<td>by clients</td>
<td>by candidates</td>
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#### Emploved at Time of Referral

<table>
<thead>
<tr>
<th></th>
<th>Clients</th>
<th>Candidates</th>
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</thead>
<tbody>
<tr>
<td>% Employed</td>
<td>23%</td>
<td>22%</td>
</tr>
<tr>
<td></td>
<td>of clients</td>
<td>of candidates</td>
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</tbody>
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#### Avg Length to Employment

<table>
<thead>
<tr>
<th></th>
<th>Clients</th>
<th>Candidates</th>
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<tbody>
<tr>
<td>Avg Length</td>
<td>27 days</td>
<td>14 days</td>
</tr>
<tr>
<td></td>
<td>for clients</td>
<td>for candidates</td>
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#### % Employed Overall

<table>
<thead>
<tr>
<th></th>
<th>Clients</th>
<th>Candidates</th>
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</thead>
<tbody>
<tr>
<td>% Employed</td>
<td>60%</td>
<td>29%</td>
</tr>
<tr>
<td></td>
<td>of clients</td>
<td>of candidates</td>
</tr>
</tbody>
</table>

#### Avg Job Satisfaction

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
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</thead>
<tbody>
<tr>
<td>Avg Job</td>
<td>3 of 5</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>overall</td>
</tr>
</tbody>
</table>
All measures of engagement, including employment, are enhanced significantly by RNS service delivery. We recently modified service structure to focus on housing and employment goals during KWS 1 and 2. This modification is prompted by an effort to reduce number of days to gainful employment and was introduced during the most recent Navigator Community of Practice (CoP) meeting (July 25, 2018).

While employment is a vital measure of community engagement, other categories positively impact recovery capital. The charts below reflect additional engagement metrics. In September 2018, once a sufficient number of RNS Clients have completed quarterly REC CAP Assessments, we will present correlations between community engagement and growth in recovery capital.

The first set of three charts present comparative data pertaining to engagement in Mutual Aid, Recreational Activities and Community Service for both groups. The RNS Client Group experienced significantly enhanced engagement in every category. The final two charts reflect recovery group service commitments and, for the criminal justice-involved subset, compliance with supervision requirements.
<table>
<thead>
<tr>
<th></th>
<th>Client Mutual Aid Participation</th>
<th>Candidate Mutual Aid Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n = 58</strong></td>
<td>Require Monitoring: 36.2%</td>
<td>Require Monitoring: 35.3%</td>
</tr>
<tr>
<td></td>
<td>Reliable: 63.8%</td>
<td>Reliable: 62.7%</td>
</tr>
<tr>
<td><strong>n = 41</strong></td>
<td>Require Monitoring: 2.0%</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>meetings attended</strong></td>
<td></td>
<td><strong>meetings attended</strong></td>
</tr>
<tr>
<td>by clients</td>
<td></td>
<td>by candidates</td>
</tr>
<tr>
<td>2537</td>
<td></td>
<td>1331</td>
</tr>
</tbody>
</table>
Recreational Engagement

916 activities participated in by clients
351 activities participated in by candidates
Community Service Engagement

395
hours delivered by clients

171
hours delivered by candidates

Client Community Service Participation
n = 35

- Resistant: 25.7% (9)
- Reliable: 42.9% (15)
- Requires Monitoring: 31.4% (11)

Candidate Community Service Participation
n = 29

- Resistant: 31.0% (9)
- Reliable: 17.2% (5)
- Requires Monitoring: 51.7% (15)
Conclusions

1. Due to limited resources, continued eligibility for a Housing Voucher should be conditioned upon both enrollment and active engagement in RNS. Client compliance with the Recovery Care Planning schedule is essential to achieving enhanced outcomes. A data-driven proposal for improvements to screening, orientation and intake procedures will be adopted with approval by SEFBHN.

2. While admission of MAT-enrolled residents no longer presents challenges in Palm Beach County, engaging FARR Certified Recovery Residences in the SEFBHN Pilot as Partners remains problematic. Misinformation concerning requirements, reimbursements and the dollar value of vouchers remain barriers to registration. ROI, in collaboration with FARR and SEFBHN, will prepare and host an on-demand video presentation to educate certified residence operators regarding the housing voucher program.

3. Having held four (4) Navigator Trainings in support of the Pilot, we have determined a) recovery capital history, theory and science (Day One) be formatted as on-demand e-learning content and that b) the ‘mechanics’ of Measure, Plan and Engage (Day Two), focus on Key Working Session structure and engage registrants in hands-on, interactive exercises.
4. All stakeholders have validated usability of the data collection tool. Navigators, supervisors, clients, family members and network administrative staff concur that the framework and user interface readily support assessment, recovery care planning and data collection. However; the Pilot has also revealed a need to invest in certain modifications. Among them is retooling to allow Navigators to collect client engagement data during KWS (currently maintained by Partners). Additionally, certain enhancements pertaining to the monitoring of engagement in structured session and community integration will be undertaken. This will result in revision to our current practice of reimbursing Partners for intake and monthly data maintenance. Screening, orientation and intake responsibilities will transfer to dedicated administrative staff and monthly data maintenance will transfer to Navigators.

5. Another lesson learned is the need to staff Navigators, on a full or part-time basis, as employees with scheduled service hours. While ROI will continue to maintain independent contractors, in order to ensure response time commitments, we must employ individuals who do not have full-time positions elsewhere and “moonlight” as Recovery Navigators.
Thank you.
PALM BEACH COUNTY SOBER HOMES TASK FORCE PROPOSED

LEGISLATION

An act relating to substance abuse services; amending s. 394.4572, F.S.;
authorizing the Department of Health and the Agency for Health Care
Administration to grant exemptions from disqualification for service provider
personnel to work solely in certain treatment programs and facilities; amending s.
397.311, F.S.; defining the term "peer specialist"; amending s. 397.4073, F.S.;
revising provisions relating to background checks and exemptions from
disqualification for certain service provider personnel; requiring the Department of
Children and Families to grant or deny an exemption from disqualification within a
certain timeframe; authorizing an applicant for an exemption to work under the
supervision of certain persons for a specified period of time while his or her
application is pending; authorizing certain persons to be exempted from
disqualification from employment; authorizing the department to grant exemptions
from disqualification for service provider personnel to work solely in certain
treatment programs and facilities; creating s. 397.417, F.S.; providing
qualifications for
certification as a peer specialist; requiring the department to develop and
implement a training program for individuals seeking certification as peer
specialists; authorizing the department to designate certain credentialing entities to
certify peer specialists; providing requirements for individuals providing certain
recovery support services as peer specialists; amending s. 397.487, F.S.; revising
legislative findings relating to voluntary certification of recovery residences;
requiring recovery residences to comply with specified Florida Fire Prevention
Code provisions; revising background screening requirements for owners,
directors, and chief financial officers of recovery residences; amending s.
397.4873, F.S.; providing exceptions to limitations on referrals by recovery
residences to licensed service providers; providing additional conditions for an
exception to limitations on referrals by licensed service providers to their wholly
owned subsidiaries; prohibiting recovery residences and specified affiliated
individuals from receiving pecuniary benefits from licensed service providers for
certain referrals; providing penalties; amending s. 435.07, F.S.; authorizing certain
persons to be exempted from disqualification from employment; amending ss.
212.055, 397.416, and 440.102, F.S.; conforming cross-references; providing an
effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 394.4572, Florida Statutes, is amended to read:

394.4572 Screening of mental health personnel.—

(2)(a) The department or the Agency for Health Care Administration may
grant exemptions from disqualification as provided in chapter 435.

(b) The department or the Agency for Health Care Administration, as
applicable, may grant exemptions from disqualification for service provider
personnel to work solely in mental health treatment programs or facilities or
in programs or facilities that treat co-occurring substance use and mental
health disorders.

Section 2. Subsections (30) through (49) of section 397.311, Florida Statutes, are
renumbered as subsections (31) through (51), respectively, and subsection (37) is
amended and a new subsection (30) is added to that section to read:

397.311 Definitions.—As used in this chapter, except part VIII, the term:

(30) "Peer specialist" means a person who has been in recovery from a substance
use disorder or mental illness for at least 2 years who uses his or her personal
experience to deliver services in behavioral health settings to support others in
their recovery, or a person who has experience as a family member or a caregiver of a person with a substance use disorder or mental illness. The term does not include a person who is a qualified professional or otherwise certified under chapter 394 or 397.

(37) “Recovery Residence” means a residential dwelling unit, including community housing as established by the department by rule, or other form of group housing, that is offered or advertised through any means, including oral, written, electronic, or printed means, by any person or entity as a residence that provides a peer-supported, alcohol free, and drug free living environment.

Section 3. Paragraphs (a), (f), and (g) of subsection (1) and subsection (4) of section 397.4073, Florida Statutes, are amended to read:

397.4073 Background checks of service provider personnel.
— (1) PERSONNEL BACKGROUND CHECKS; REQUIREMENTS AND EXCEPTIONS.—

(a) For all individuals screened on or after July 1, 2018, background checks shall apply as follows:

1. All owners, directors, chief financial officers, and clinical supervisors of service providers are subject to level 2 background screening as provided under chapter 435. Such screening shall also include background screening as provided in s. 408.809. Inmate substance abuse programs operated directly or under contract with the Department of Corrections are exempt from this requirement.

2. All service provider personnel who have direct contact with children receiving services or with adults who are developmentally disabled receiving services are subject to level 2 background screening as provided under chapter 435. Such screening shall also include background screening as provided in s. 408.809.

3. All peer specialists who have direct contact with Individuals receiving services are subject to level 2 background screening as provided under chapter 435. Such screening
shall also include background screening as provided in s. 408.809 (f) Service provider personnel who request an exemption from disqualification must submit the request within 30 days after being notified of the disqualification. The department shall grant or deny the exemption from disqualification within 60 days after receipt of a complete application.

(g) If 5 years or more have elapsed since the applicant for the exemption completed or was lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the most recent disqualifying offense, such applicant service provider personnel may work with adults with substance use disorders under the supervision of persons who meet all personnel requirements of this chapter for up to 90 days after being notified of the disqualification or until the department a qualified professional licensed under chapter 490 or chapter 491 or a master's level certified addictions professional until the agency makes a final determination regarding the request for an exemption from disqualification, whichever is earlier.

(h)(g) The department may not issue a regular license to any service provider that fails to provide proof that background screening information has been submitted in accordance with chapter 435.

(4) EXEMPTIONS FROM DISQUALIFICATION.—

(a) The department may grant to any service provider personnel an exemption from disqualification as provided in s. 435.07.

(b) Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of individuals with substance use disorders, for service providers which treat adolescents 13 years of age and older, service provider personnel whose background checks indicate crimes under s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(e), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related criminal attempt, solicitation, or conspiracy. 
under s. 777.04, may be exempted from disqualification from employment pursuant to this paragraph.

(c) The department may grant exemptions from disqualification for service provider personnel to work solely in substance abuse treatment programs or facilities or in programs or facilities that treat co-occurring substance use and mental health disorders. The department may further limit such grant exemptions from disqualification which would limit service provider personnel to working with adults in substance abuse treatment facilities.—

387.4075 Unlawful activities relating to personnel; penalties.

Section 4 5. Section 397.417, Florida Statutes, is created to read.

397.417 Behavioral health peer specialists.—

(1) An individual is eligible for certification as a peer specialist if he or she has been in recovery from a substance-use disorder or mental illness for at least 2 years or if he or she has experience as a family member or caregiver of a person with a substance-use disorder or mental illness.

(2) The department shall develop and implement a training program for individuals seeking certification as peer specialists. The department may designate one or more credentialing entities that have met nationally recognized standards for developing and administering professional certification programs to certify peer specialists.

(3) An individual providing department-funded recovery support services as a peer specialist shall be certified pursuant to subsection (2). However, an individual who is not certified may provide recovery support services as a peer specialist for up to
1 year if he or she is working toward certification and is supervised by a qualified professional or by a certified peer specialist with supervisory training who has at least 3 years of full-time experience as a peer specialist at a licensed behavioral health organization.

mental health or substance use disorders or co-occurring disorders under the supervision of persons who meet all personnel requirements of this chapter for up to 90 days after being notified of the disqualification or until the department a qualified professional licensed under chapter 490 or chapter 491 or a master’s level certified addictions professional until the agency makes a final determination regarding the request for an exemption from disqualification, whichever is earlier.

(h) The department may not issue a regular license to any service provider that fails to provide proof that background screening information has been submitted in accordance with chapter 435.

(4) EXEMPTIONS FROM DISQUALIFICATION.—

(a) The department may grant to any service provider personnel an exemption from disqualification as provided in s. 435.07.

(b) Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of individuals with substance use disorders, for service providers which treat adolescents 13 years of age and older, service provider personnel whose background checks indicate crimes under s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(c), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related criminal attempt, solicitation, or conspiracy under s. 777.04, may be exempted from disqualification from employment pursuant to this paragraph.
(c) The department may grant exemptions from disqualification for service provider personnel to work solely in substance abuse treatment programs or facilities or in programs or facilities that treat co-occurring substance use and mental health disorders. The department may further limit such grant exemptions from disqualification which would limit service provider personnel to working with adults in substance abuse treatment facilities.

(d) When evaluating a peer specialist’s application for exemption from disqualification, the department shall consider:

1. The need for peer specialists to provide support services and the shortage of professionals and paraprofessionals to provide behavioral health services.

2. That peer specialists may have criminal histories resulting from substance use disorders or mental illnesses that prevent them from meeting background screening requirements.

3. That peer specialists provide effective mental health and substance abuse treatment support services because they share common life experiences with the persons they assist and promote a sense of community among those in recovery.

4. That research has shown that peer support facilitates recovery and reduces health care costs.

Section 4. Section 397.417, Florida Statutes, is created to read:

397.417 Behavioral health peer specialists.—

(1) An individual is eligible for certification as a peer specialist if he or she has been in recovery from a substance use disorder or mental illness for at least 2 years or if he or she has experience as a family member or caregiver of a person with a substance use disorder or mental illness.
(2) The department shall develop and implement a training program for individuals seeking certification as peer specialists. The department may designate one or more credentialing entities that have met nationally recognized standards for developing and administering professional certification programs to certify peer specialists. The credentialing entity shall develop and implement a training program for individuals seeking certification as peer specialists.

(3) An individual providing department-funded recovery support services as a peer specialist shall be certified pursuant to subsection (2). However, an individual who is not certified may provide recovery support services as a peer specialist for up to 1 year if he or she is working toward certification and is supervised by a qualified professional or by a certified peer specialist with supervisory training who has at least 3 years of full-time experience as a peer specialist at a licensed behavioral health organization.

(4) Any person required to be certified under this section, and not exempt pursuant to subsection (3), who provides recovery services as a peer specialist commits a misdemeanor of the first degree.

Section 5. Section 397.4075, Florida Statutes, is amended to read:

**It is a Felony misdemeanor of the third first degree**, punishable as provided in s. 775.082 or s. 775.083, for any person willfully, knowingly, or intentionally to:

(1) Inaccurately disclose by false statement, misrepresentation, impersonation, or other fraudulent means, or fail to disclose as part of an application for licensure or in any application for voluntary or paid employment, any fact which is material in making a determination as to the person’s qualifications to be an owner, a director, a volunteer, or other personnel or a service provider;

(2) Operate or attempt to operate as a service provider with personnel who are in noncompliance with the minimum standards contained in this chapter; or
(3) Use or release any criminal or juvenile information obtained under this chapter for any purpose other than background checks of personnel for employment.

Section 6. Subsection (1), paragraph (m) of subsection (3), and subsection (6) of section 397.487, Florida Statutes, are amended to read:

397.487 Voluntary certification of recovery residences.—

(1) The Legislature finds that a person suffering from addiction has a higher success rate of achieving long-lasting sobriety when given the opportunity to build a stronger foundation by living in a recovery residence while receiving treatment or after completing treatment. The Legislature further finds that this state and its subdivisions have a legitimate state interest in protecting these persons, who represent a vulnerable consumer population in need of adequate housing. It is the intent of the Legislature to protect persons who reside in a recovery residence.

(3) A credentialing entity shall require the recovery residence to submit the following documents with the completed application and fee:

(m) Proof of satisfactory fire, safety, and health inspections. A recovery residence must comply with the provisions of the Florida Fire Prevention Code which apply to one-family and two-family dwellings, public lodging establishments, or rooming houses, or other housing facilities, as applicable. The State Fire Marshall shall, in cooperation with the department, establish and enforce minimum fire safety standards, which standards must be included in the rules adopted by the department.

(6) All owners, directors, and chief financial officers of an applicant recovery residence are subject to level 2 background screening as provided under chapter 435 and s. 408.809. A recovery residence is ineligible for certification, and a credentialing entity shall deny a recovery residence's application, if any owner, director, or chief
financial officer has been found guilty of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in s. 408.809(4) or s. 435.04(2) unless the department has issued an exemption under s. 397.4073 or s. 397.4872. In accordance with s. 435.04, the department shall notify the credentialing agency of an owner's, director's, or chief financial officer's eligibility based on the results of his or her background screening.

Section 7. Section 397.4873, Florida Statutes, is amended to read:

397.4873 Referrals to or from recovery residences; prohibitions; penalties.—

(1) A service provider licensed under this part may not make a referral of a prospective, current, or discharged patient to, or accept a referral of such a patient from, a recovery residence unless:

(a) the recovery residence holds a valid certificate of compliance as provided in s. 397.487 and is actively managed by a certified recovery residence administrator as provided in s. 397.4871, or

(b) the recovery residence, as part of a licensable community housing component established by rule, is required by the department to adopt and maintain national standards consistent with those standards enumerated in s. 397.487.

(2) Subsection (1) does not apply to:

(a) A licensed service provider under contract with a managing entity as defined in s. 394.9082.

(b) Referrals by a recovery residence to a licensed service provider when the recovery residence or its owners, directors, operators, or employees do not benefit, directly or indirectly, from the referral.

(c) Referrals made before January 1, 2019 July 1, 2018, by a licensed service provider to that licensed service provider's wholly owned subsidiary, provided that applications and associated fees are submitted by July 1, 2018.
(3) A recovery residence or its owners, directors, operators, employees, or volunteers may not receive a pecuniary benefit, directly or indirectly, from a licensed service provider for a referral made pursuant to subsection (1) or subsection (2).

(4) For purposes of this section, a licensed service provider or recovery residence shall be considered to have made a referral if the provider or recovery residence has informed a patient by any means about the name, address, or other details of a recovery residence or licensed service provider, or informed a licensed service provider or a recovery residence of any identifying details about a patient.

(5) A licensed service provider shall maintain records of referrals to or from recovery residences as may be prescribed by the department in rule.

(6) After June 30, 2019, a licensed service provider violating this section shall be subject to an administrative fine of $1,000 per occurrence. Repeat violations of this section may subject a provider to license suspension or revocation pursuant to s. 397.415.

(7) Nothing in this section requires a licensed service provider to refer a patient to or to accept a referral of a patient from a recovery residence.

Section 78. Subsection (2) of section 435.07, Florida Statutes, is amended to read:

435.07 Exemptions from disqualification.—Unless otherwise provided by law, the provisions of this section apply to exemptions from disqualification for disqualifying offenses revealed pursuant to background screenings required under this chapter, regardless of whether those disqualifying offenses are listed in this chapter or other laws.

(2) Persons employed, or applicants for employment, by treatment providers who treat adolescents 13 years of age and older who are disqualified from employment solely because of crimes under s. 796.07(2)(e), s. 810.02(4), s.
812.014(2)(c), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related criminal attempt, solicitation, or conspiracy under s. 777.04, may be exempted from disqualification from employment pursuant to this chapter without application of the waiting period in subparagraph (1)(a)1.

Section 8 9. Paragraph (e) of subsection (5) of section 212.055, Florida Statutes, is amended to read:

212.055 Discretionary sales surtaxes; legislative intent; authorization and use of proceeds.—It is the legislative intent that any authorization for imposition of a discretionary sales surtax shall be published in the Florida Statutes as a subsection of this section, irrespective of the duration of the levy. Each enactment shall specify the types of counties authorized to levy; the rate or rates which may be imposed; the maximum length of time the surtax may be imposed, if any; the procedure which must be followed to secure voter approval, if required; the purpose for which the proceeds may be expended; and such other requirements as the Legislature may provide. Taxable transactions and administrative procedures shall be as provided in s. 212.054.

(5) COUNTY PUBLIC HOSPITAL SURTAX.—Any county as defined in s. 125.011(1) may levy the surtax authorized in this subsection pursuant to an ordinance either approved by extraordinary vote of the county commission or conditioned to take effect only upon approval by a majority vote of the electors of the county voting in a referendum. In a county as defined in s. 125.011(1), for the purposes of this subsection, "county public general hospital" means a general hospital as defined in s. 395.002 which is owned, operated, maintained, or governed by the county or its agency, authority, or public health trust.

(e) A governing board, agency, or authority shall be chartered by the county commission upon this act becoming law. The governing board, agency, or authority shall adopt and implement a health care plan for indigent health care
services. The governing board, agency, or authority shall consist of no more than seven and no fewer than five members appointed by the county commission. The members of the governing board, agency, or authority shall be at least 18 years of age and residents of the county. No member may be employed by or affiliated with a health care provider or the public health trust, agency, or authority responsible for the county public general hospital. The following community organizations shall each appoint a representative to a nominating committee: the South Florida Hospital and Healthcare Association, the Miami-Dade County Public Health Trust, the Dade County Medical Association, the Miami-Dade County Homeless Trust, and the Mayor of Miami-Dade County. This committee shall nominate between 10 and 14 county citizens for the governing board, agency, or authority. The slate shall be presented to the county commission and the county commission shall confirm the top five to seven nominees, depending on the size of the governing board. Until such time as the governing board, agency, or authority is created, the funds provided for in subparagraph (d)2. shall be placed in a restricted account set aside from other county funds and not disbursed by the county for any other purpose.

(1) The plan shall divide the county into a minimum of four and maximum of six service areas, with no more than one participant hospital per service area. The county public general hospital shall be designated as the provider for one of the service areas. Services shall be provided through participants' primary acute care facilities.

(2) The plan and subsequent amendments to it shall fund a defined range of health care services for both indigent persons and the medically poor, including primary care, preventive care, hospital emergency room care, and hospital care necessary to stabilize the patient. For the purposes of this section, "stabilization" means stabilization as defined in s. 397.311(46), s. 397.311(45).
Where consistent with these objectives, the plan may include services rendered by physicians, clinics, community hospitals, and alternative delivery sites, as well as at least one regional referral hospital per service area. The plan shall provide that agreements negotiated between the governing board, agency, or authority and providers shall recognize hospitals that render a disproportionate share of indigent care, provide other incentives to promote the delivery of charity care to draw down federal funds where appropriate, and require cost containment, including, but not limited to, case management. From the funds specified in subparagraphs (d)1. and 2. For indigent health care services, service providers shall receive reimbursement at a Medicaid rate to be determined by the governing board, agency, or authority created pursuant to this paragraph for the initial emergency room visit, and a per-member per-month fee or capitation for those members enrolled in their service area, as compensation for the services rendered following the initial emergency visit. Except for provisions of emergency services, upon determination of eligibility, enrollment shall be deemed to have occurred at the time services were rendered. The provisions for specific reimbursement of emergency services shall be repealed on July 1, 2001, unless otherwise reenacted by the Legislature. The capitation amount or rate shall be determined before program implementation by an independent actuarial consultant. In no event shall such reimbursement rates exceed the Medicaid rate. The plan must also provide that any hospitals owned and operated by government entities on or after the effective date of this act must, as a condition of receiving funds under this subsection, afford public access equal to that provided under s. 286.011 as to any meeting of the governing board, agency, or authority the subject of which is budgeting resources for the retention of charity care, as that term is defined in the rules of the Agency for Health Care Administration. The plan shall also include innovative health care
programs that provide cost-effective alternatives to traditional methods of
service and delivery funding.

3. The plan’s benefits shall be made available to all county residents currently
eligible to receive health care services as indigents or medically poor as defined in
paragraph (4)(d).

4. Eligible residents who participate in the health care plan shall receive coverage
for a period of 12 months or the period extending from the time of enrollment to
the end of the current fiscal year, per enrollment period, whichever is less.

5. At the end of each fiscal year, the governing board, agency, or authority
shall prepare an audit that reviews the budget of the plan, delivery of
services, and quality of services, and makes recommendations to increase
the plan's efficiency. The audit shall take into account participant hospital
satisfaction with the plan and assess the amount of poststabilization
patient transfers requested, and accepted or denied, by the county public
general hospital.

Section 9 10. Section 397.416, Florida Statutes, is amended to read:

397.416 Substance abuse treatment services; qualified professional.—
Notwithstanding any other provision of law, a person who was certified through a
certification process recognized by the former Department of Health and
Rehabilitative Services before January 1, 1995, may perform the duties of a qualified
professional with respect to substance abuse treatment services as defined in this
chapter, and need not meet the certification requirements contained in s. 397.311(35) s. 397.311(34).

Section 10 11. Paragraphs (d) and (g) of subsection (1) of section 440.102, Florida
Statutes, are amended to read:
440.102 Drug-free workplace program requirements.—

The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(1) DEFINITIONS.—Except where the context otherwise requires, as used in this act:

(d) "Drug rehabilitation program" means a service provider, established pursuant to s. 397.311(44) s. 397.311(43), that provides confidential, timely, and expert identification, assessment, and resolution of employee drug abuse.

(g) "Employee assistance program" means an established program capable of providing expert assessment of employee personal concerns; confidential and timely identification services with regard to employee drug abuse; referrals of employees for appropriate diagnosis, treatment, and assistance; and followup services for employees who participate in the program or require monitoring after returning to work. If, in addition to the above activities, an employee assistance program provides diagnostic and treatment services, these services shall in all cases be provided by service providers pursuant to s. 397.311(44) s. 397.311(43).

Section 44 12. This act shall take effect July 1, 2019.
381.0038: Education; sterile needle and syringe exchange pilot program

(4) The University of Miami and its affiliates may establish single sterile needle and syringe exchange pilot programs. The Pilot programs may operate at a fixed location or through a mobile health unit. The pilot programs shall offer the free exchange of clean, unused needles and hypodermic syringes for used needles and hypodermic syringes as a means to prevent the transmission of HIV, AIDS, viral hepatitis, or other blood-borne diseases among intravenous drug users and their sexual partners and offspring.

(e) County or municipal funds may be used to operate these pilot programs. The pilot programs may be funded through grants and donations from private resources and funds.

(f) The pilot programs shall expire July 1, 2021.
FARR Certification Overview

FARR 2018
Step 1 & 2 – Application & Payment

- Organizational Information
- Owners, Managers, Staff Contact
- Locations
- Certification & Compliance Agreement
Step 3 – Level II Backgrounds per 397.487

- Owners
- Directors
- CFO
- CRRA’s

FCB
Step 4 – Documentation Review

- 4 Domains = 37 NARR Standards
- 169 “as evidenced by” Sub- Standards
- 37 Ethical Codes
- 8 Additional Requirements required by 397.487 not covered by NARR Standards
- 52 STANDARD Compliance Documentation Requirements
- 450 STANDARD Documentation Review Questions
- 165 STANDARD Onsite Assessment Questions
- 9 Special Assessment Domains
### Example 4 – Medication Storage & Usage Protocol

<table>
<thead>
<tr>
<th>Question</th>
<th>Compliant</th>
<th>Non-Compliant</th>
<th>NP/NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the procedure include where medications are to be stored, with a minimum an &quot;out of sight&quot; policy? (both prescribed as well as OTC)</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does procedure include how residents can access their medications? (if held by staff) (both prescribed as well as OTC)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does procedure include an observation protocol as opposed to an administration protocol? (if held by staff)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does procedure include documentation of observation? (if held by staff)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does policy include a complete list of prohibited medications? (both prescribed as well as OTC)</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is procedure inclusive of all levels of care operated by the provider? (if multiple levels exist)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Documentation Review

#### Example – Medication Storage & Usage Protocol

<table>
<thead>
<tr>
<th>Question</th>
<th>Compliance</th>
<th>Non-Compliance</th>
<th>NP/NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the procedure make sense for the type of structure, level of care, staffing plan, and priority population served?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the procedure include what happens to resident medications in the event of a relapse, discharge, and/or AMA.</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is the procedure staff directed instead of resident directed?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
## Documentation Review

### Example – Medication Storage & Usage Consent

<table>
<thead>
<tr>
<th>Question</th>
<th>Compliant</th>
<th>Non-Compliant</th>
<th>NP/NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the policy include a safe storage requirement that at minimum includes an &quot;out of sight&quot; policy?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy include the process for reporting and having new medications (prescribed and OTC) approved by management?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy include how residents can access their medications if staff held?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does the policy include what happens to medications if the resident is discharged/transfered/or abandons property?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy include capturing resident consent?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is the policy inclusive of all levels of care operated by the provider? (if multiple levels exist)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does the policy make sense for the type of structure, level of care, staffing plan, and priority population served?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
### Example 4 – Medication Storage & Usage Policy & Procedure

2. All medications prescribed to a client will be documented in the resident file.
3. Lock boxes will be available for residents to store and secure their medication and/or any medication supplies, such as syringes.

<table>
<thead>
<tr>
<th>Per Medication Storage &amp; Usage:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Your protocol states residents are responsible for handling and storage of medications but that staff administers medications. Are you stating that residents have to track down staff in order to take meds?</td>
</tr>
<tr>
<td>• Please provide licenses/credentials maintained by BHTs that would allow them to administer medications.</td>
</tr>
<tr>
<td>• Please include how OTC meds are approved and handled.</td>
</tr>
<tr>
<td>• Please include a list of prohibited medications.</td>
</tr>
<tr>
<td>• Please clarify, you are applying for Level II certification but employ BHTs and medical staff? Are residents enrolled in a clinical program?</td>
</tr>
<tr>
<td>• Policy states there is no onsite storage. Are you stating medications must be stored offsite?</td>
</tr>
</tbody>
</table>

Medication Storage and Usage protocol lists terminology and staff associated with a clinical program. Procedure states residents are to hold/store their medications but then states medications are administered by staff and logged on MORS in KIPU.
Step 5 – Onsite Assessment

- Pre-Screening
- Orientation
- Administration
- Staff Knowledge
- Property
- Resident Interview
Step 6 – Ongoing Compliance

- FARR Staff Trainings
- Annual Renewals
- Audits
397.410 Licensure Requirements; minimum standards; rules.

  (5) (a) On or before the first day services are provided to a client, a licensee must inform the client and his or her immediate family or representative, if appropriate, of the right to report:

  1. Complaints. The statewide toll-free telephone number for reporting complaints to the department must be provided to clients in a manner that is clearly legible and must include the words: “To report a complaint regarding the services you receive, please call toll-free (phone number).”

  2. Abusive, neglectful, or exploitative practices. The statewide toll-free telephone number for the central abuse hotline must be provided to clients in a manner that is clearly legible and must include the words: “To report abuse, neglect, or exploitation, please call toll-free (phone number).”

  3. Insurance fraud. An agency-written description of insurance fraud and the statewide toll-free telephone number for the central fraud hotline must be provided to clients in a manner that is clearly legible and must include the words:
“To report suspected insurance fraud, please call
toll-free (phone number).”

The agency shall publish a minimum of a 90-day
advance notice of a change in the toll-free
telephone numbers.

(b) Each licensee shall establish appropriate
policies and procedures for providing such notice
to clients.

(6) Providers licensed pursuant to this
chapter shall display a sign in a conspicuous
location within the facility readily visible to all
patients indicating that, pursuant to s. 626.9892,
the Department of Financial Services may pay
rewards of up to $25,000 to persons providing
information leading to the arrest and conviction of
persons committing crimes investigated by the
Division of Investigative and Forensic Services
arising from violations of s. 440.105, s. 624.15,
s. 626.9541, s. 626.989, or s. 817.234. An
authorized employee of the Division of
Investigative and Forensic Services may make
unannounced inspections of a facility licensed
under this part a facility shall allow full and
complete access to the premises to such authorized
employee of the division who makes an inspection to
determine compliance with this subsection.
397.487 Voluntary certification of recovery residences.

(3) A credentialing entity shall require the recovery residence to submit the following documents with the completed application and fee:

(a) A policy and procedures manual containing:

1. Job descriptions for all staff positions.

2. Drug-testing procedures and requirements for all persons who are expected to, or whose responsibilities may require him or her to, provide personal care or services to or have direct contact with clients or have access to client funds, personal property, or living areas.

(11) The State Fire Marshal shall, in cooperation with the department and the credentialing entities approved by the department, establish and enforce minimum firesafety standards for recovery residences, which standards must be included in the rules adopted by the Department of Financial Services, Division of State Fire Marshal. The use of a structure as a recovery residence, standing alone, shall not be deemed a conversion of use requiring heightened life safety standards including but not limited to fire sprinkler protection.
(12) The credentialing entity shall develop a poster to be publicly displayed in a conspicuous location in a recovery residence containing the names, addresses, and telephone numbers for the credentialing entity’s abuse hotline, the department’s abuse hotline, the Advocacy Center for Persons with Disabilities, the Florida Statewide Advocacy Council, and the local police department, with a clear description of the assistance to be expected from each.
633.206 Uniform firesafety standards— The Legislature hereby determines that to protect the public health, safety, and welfare it is necessary to provide for firesafety standards governing the construction and utilization of certain buildings and structures. The Legislature further determines that certain buildings or structures, due to their specialized use or to the special characteristics of the person utilizing or occupying these buildings or structures, should be subject to firesafety standards reflecting these special needs as may be appropriate.

(1) The department shall establish uniform firesafety standards that apply to:

(a) All new, existing, and proposed state-owned and state-leased buildings.

(b) All new, existing, and proposed hospitals, nursing homes, assisted living facilities, adult family-care homes, recovery residences, correctional facilities, public schools, transient public lodging establishments, public food service establishments, elevators, migrant labor camps, mobile home parks, lodging parks, recreational vehicle parks, recreational camps, residential and nonresidential child care facilities, facilities for the developmentally disabled, motion picture
and television special effects productions, tunnels, and self-service gasoline stations, of which standards the State Fire Marshal is the final administrative interpreting authority.
200 a Day Now Dying of Overdose. Chris Christie’s New Jersey Had Nation’s Second Worst Hike in Deaths

By ROGER PARLOFF|June 15, 2018

Quick Takeaway

- Latest CDC data show 72,855 dying of drug overdose in the 12 months ending Nov. 2017.
- 49,466 died of overdoses involving an opioid during that period.
- New Jersey showed a 33 percent hike in drug overdose death—the nation's second worst.

According to the CDC’s latest statistics, about 200 Americans are now dying each day from drug overdoses—the first time the numbers have breached that benchmark. About 136 of the 200, or 68 percent, are dying of opioid overdoses.

The agency’s provisional data show that 72,855 people likely died of drug overdose during the 12-month period ending November 30, 2017—a rise of 13.2 percent over the previous 12-month period, ending November 30, 2016. The agency reports that 49,466 of those deaths involved at least one opioid.

The most commonly detected drugs in fatal overdose victims during this period were synthetic opioids—mainly illicit fentanyl and its chemical variations—which were found in 40 percent of all overdose victims and in 59 percent of all opioid-related deaths.

Fentanyl is 30 to 50 times more powerful than heroin, and some of its variations, or analogs, are stronger still. Fentanyl is often now laced into heroin or other drugs, without the user’s knowledge. Even those who seek out fentanyl may not be able to survive its unexpected strength, especially if they are relapsing after period of abstinence, and have lost their tolerance to opioids.

At least another 15,279 deaths during this period—21 percent of all drug deaths and 31 percent of all opioid fatalities—involved common prescription drugs, like hydrocodone and oxycodone. Though some people think the prescription opioid problem is subsiding, this figure still represents a 3 percent increase year-over-year. (The CDC’s categories are not mutually exclusive, and many overdose victims have multiple drugs in their system.)

The most recent finalized overdose death numbers from the Centers for Disease Control and Prevention are for calendar year 2016. They showed 63,632 deaths, of which 42,249 involved an opioid. The finalized figures for 2017 won’t be ready until December.
Last August, however, the CDC began releasing, after a six-month lag, monthly updates of provisional overdose death data relating to rolling 12-month periods. This data is incomplete and, therefore, “subject to change.” The “predicted” numbers described in this article are a mix of both hard data—69,948 reported deaths for the 12 months ending November 30, for instance—plus statistical adjustments reflecting past experience with the data still outstanding or under investigation.

The state with the most severe hike in overdose death rates, according to these numbers, was Nebraska, which experienced a 35.7 percent increase. But that jump may reflect, at least in part, that Nebraska had the country’s lowest overdose death rate to start with—just 6.4 per 100,000 people in 2016, compared to a national average of 19.8. (The worst statewide rate that year was West Virginia’s, at 52 per 100,000.) A spokesperson at the Nebraska Department of Health and Human Services did not respond to calls and an email seeking comment.

More troubling is the case of New Jersey, which endured the country’s second worst overdose fatality hike—a 33 percent year-over-year increase for the period ending November 30. (For the 12-month spans ending September 31 and October 31, New Jersey owned the nation’s worst increases, at 50 percent and 42 percent, respectively.)

New Jersey’s numbers are striking because few American political figures have been as associated with the fight against drugs as New Jersey’s then-governor, Chris Christie, who last year chaired the President’s Commission on Combating Drug Addiction and the Opioid Crisis. (Christie was succeeded as governor by Phil Murphy on January 16.) While campaigning for the presidency in November 2015, Christie revealed—in speeches whose videos later went viral—how he had been personally touched by the epidemic. He recounted how an admired law school classmate fatally overdosed on Percocet (oxycodone plus acetaminophen) and vodka. His administration later spent $42.6 million on television commercials, in which Christie himself appeared, urging residents to seek help for addiction.

Christie did not respond to inquiries left with his spokesperson.

Four experts interviewed by Opioid Watch identify the rising influx of fentanyl into the New Jersey as the key factor in the increase, rather than any glaring failure on Christie’s or New Jersey’s part.

Lewis Nelson, chair of the medical toxicology division at the Rutgers New Jersey Medical School, observes in an interview that fentanyl can be flown, shipped, or mailed into the state in many ways, including the Port of Newark and the Newark, New York, and Philadelphia airports.

“We’re so close to the source,” he says, “the purity is greater, so the concentration is higher”—i.e., more dangerous. “The further you go down the chain of distribution, the more it gets diluted.”

Frank Greenagel, Jr., who headed a New Jersey task force on heroin and opiate use in 2014, also focused on fentanyl, but with a slight twist. He says the recent numbers may reflect that fentanyl was actually a little slower to reach New Jersey than in some other northeastern states—and now
it’s finally catching up with a vengeance. “Now the wave is cresting,” says Greenagel, an adjunct professor at the Rutgers School of Social Work.

New Jersey has severe pockets of poverty that have had heroin problems for years, especially in Camden, Newark, and Paterson, and where fentanyl is now elevating death rates.

“I do think that deep down he did care,” Nelson said of former Gov. Christie. “But the problem he cared about was prescription opioid-related death, which is a middle-class problem. The population really dying at a much higher rate is the illicit users.”

The neighboring states of Delaware and Pennsylvania experienced the third and fourth worst overdose fatality hikes in the country: 29.4 percent and 27 percent, respectively, with Pennsylvania being tied with Indiana.

Eight states showed reductions in overdose death, though most of them—like Wyoming, which had the largest drop, at 26.3 percent—had relatively low statewide death rates to start with. The only hard-hit, northeastern state to show a reduction was Rhode Island, with a 4 percent drop. (We’ve written about some reasons why.) The other states with decreasing death rates were Utah, Minnesota, North Dakota, Idaho, Kansas, and Mississippi.

The CDC’s data for the latest 12-month period are summarized below.

<table>
<thead>
<tr>
<th>Drug Present</th>
<th># of ODs</th>
<th>% opioid ODs</th>
<th>% drug ODs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Drug</td>
<td>72,855</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Any Opioid</td>
<td>49,466</td>
<td>100%</td>
<td>68%</td>
</tr>
<tr>
<td>Synthetic opioid (e.g., illicit fentanyl)</td>
<td>29,293</td>
<td>59%</td>
<td>40%</td>
</tr>
<tr>
<td>Heroin (an opioid)</td>
<td>16,240</td>
<td>33%</td>
<td>22%</td>
</tr>
<tr>
<td>Natural or Semi-Synthetic opioid (e.g. oxycodone, hydrocodone, etc.)</td>
<td>15,279</td>
<td>31%</td>
<td>21%</td>
</tr>
<tr>
<td>Cocaine</td>
<td>14,263</td>
<td>100%</td>
<td>20%</td>
</tr>
<tr>
<td>Psychostimulant (e.g., meth)</td>
<td>10,643</td>
<td>100%</td>
<td>15%</td>
</tr>
<tr>
<td>Methadone (an opioid)</td>
<td>3,299</td>
<td>7%</td>
<td>5%</td>
</tr>
</tbody>
</table>
As opioid crisis fuels patient-brokering fraud, Congress urged to act

By Susannah Luthi | July 24, 2018

A representative of the addiction treatment industry on Tuesday urged a key House panel to consider policies to crack down on patient-brokering—a complicated, fraudulent practice stemming from the opioid epidemic that insurance companies have been navigating for the past few years.

Patient-brokering has become prevalent enough that Marvin Ventrell, executive director of the National Association of Addiction Treatment Providers, told the House Energy and Commerce oversight subcommittee that his organization adopted ethics rules in late 2017 to ban any of its members from taking part.

"First and foremost [in the new ethics rules] is patient brokering: under no circumstances should a provider buy or sell leads," Vantrell said. "It is now prohibited by our code."

The issue has nabbed headlines for months now. It involves a third party, often a treatment center that may not meet adequate care standards, paying a recruiter to fraudulently enroll an addicted patient in a flexible Obamacare individual market plan offering out-of-state coverage. Then the patient heads out to a treatment center, likely in a desirable locale like Florida, Southern California or Arizona, that may or may not offer adequate care. If the fraud is discovered and can be proven to the CMS, the agency rescinds coverage and the patient is expelled from the treatment center.
Ventrell blamed the widespread nature of the fraud on lack of clarity within current law. "The law has been confusing and sometimes nonexistent, state by state," he told lawmakers. "I would support a federal law. There needs to be a federal law in that regard."

It is unclear how much money the fraud has cost insurers. Industry representatives who spoke with Modern Healthcare shied away from quantifying how many of these fraud cases they have seen over the past few years and declined to say whether that number is ticking up or down. But one consultant who works with insurance companies on the issue said claims filed for these fraudulent plans can rise upwards of $100,000.

In June, the Justice Department arrested addiction treatment center operators who had filed more than $106 million in fraudulent insurance claims related to the scheme.

But insurers concede that a legislative push would be complicated because patient-brokering schemes span different states' regulatory and licensing issues while also touching on the CMS' overarching role in managing the federally facilitated marketplace for some states' Obamacare exchanges.

First, the states have explicit authority to license treatment facilities. So Kim Holland, who focuses on state issues for Blue Cross and Blue Shield Association, said she plans to focus lobbying efforts on strict licensing standards when state legislative sessions resume early next year.

"It's the state's responsibility to license facilities," she told Modern Healthcare "It's state legislatures that create the opportunities, so where we want to focus attention is to help states with more robust licensing and oversight for any substance use disorder facility."

The role Obamacare individual market plans play in the fraud add another layer of complexity. For one thing, third parties are allowed to pay for part or all of an enrollee's premiums — a practice that facilitates patient-brokering. For another, the CMS manages many state Obamacare markets and is ultimately responsible for rescinding or preempting the fraudulent enrollments in those states.

Rachel Jones, a financial investigations official with Pittsburgh-based Highmark Blue Cross and Blue Shield, said that although body brokering has been happening for years there are still few controls in place to catch fraudulent enrollments before the plans have been approved unless the body broker is a repeat offender who has already been flagged.
try to capture likely fraudulent addresses as soon as possible. But that takes time: it involves finding the person who is supposedly signing up for an exchange plan and seeking proofs of identity after a fraudulent broker has used a false address.

"A lot of times when we try to reach out we don't hear back," Jones said. "It's hard to track down the people at the time of enrollment."

Once Highmark concludes that a plan is fraudulent, the company then has to prove it to the CMS so that the plan can be rescinded. Before the CMS can remove a person from the insurer's rolls, Highmark must fully document the fraud and hand over supporting documents that essentially audit the request.

Jones declined to give a typical time frame for how long this rescission can take, but said the cases her division is working on "aren't necessarily present day." A consultant who works extensively with plans on the issue said the process can drag on for months. Michael Adelberg, a former CMS official who now works as a consultant with the Washington firm Faegre Baker Daniels, said the "common appraisal from the qualified health plans is that this process is not yet very efficient or transparent."

Patient brokering has become a major rallying point for insurers. For Tuesday's hearing, America's Health Insurance Plans (AHIP) submitted a statement for the record that reiterated the industry push for policy to deal what the group calls a "serious, potentially widespread issue that needs to be addressed with serious solutions."

"These fraudulent, abusive practices not only put patients' lives in grave danger, but they also make it more difficult for people to afford their coverage and care," AHIP said. "These practices raise overall health system costs and increase premiums for everyone, not just those who are sent to 'sober homes.'"

Some states are discussing policies that could mitigate the practice. California's legislature, whose legislative session runs through August, is currently considering a measure to curb third-party payments.

The bill, introduced by State Sen. Connie Leyva (D), would limit use of third-party payments specifically for substance use treatment facilities and dialysis clinics. The measure faces a hefty lobbying battle with the dialysis industry, where third-party...
"If facilities have financial gain in getting the patient insured, they shouldn't be the person paying the premiums, and it is through that some of the third-party payments that we're seeing people encouraged and enticed into facilities," Holland said.

But, she noted, the issue of patient brokering is complicated, particularly because it falls within the overarching crisis of widespread opioid use, and there is no easy answer.

"It's an imperfect system that we're working to remedy," Holland said.

Tags: Enforcement & Compliance, Government, Insurance, Opioid abuse, Providers

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Susannah Luthi covers health policy and politics in Congress for Modern Healthcare. Most recently, Luthi covered health reform and the Affordable Care Act exchanges for Inside Health Policy. She returned to journalism from a stint abroad exporting vanilla in Polynesia. She has a bachelor’s degree in Classics and journalism from Hillsdale College in Michigan and a master’s in professional writing from the University of Southern California.
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§8.12 Federal opioid treatment standards.

(a) General. OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) Administrative and organizational structure. An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid use disorder which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) Continuous quality improvement. (1) An OTP must maintenance quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current “Diversion Control Plan” or “DCP” as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) Staff credentials. Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.
(e) **Patient admission criteria**—(1) **Maintenance treatment.** An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) **Maintenance treatment for persons under age 18.** A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) **Maintenance treatment admission exceptions.** If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) **Detoxification treatment.** An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) **Required services**—(1) **General.** OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) **Initial medical examination services.** OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) **Special services for pregnant patients.** OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific
services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) Recordkeeping and patient confidentiality. (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid use disorder. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program
physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) Medication administration, dispensing, and use. (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid use disorder. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid use disorder:

(i) Methadone;

(ii) Levomethadyl acetate (LAAM); and

(iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid use disorder.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose,
frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) Unsupervised or “take-home” use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, e.g., drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(iii) of this section.

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are two doses per week.
(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP’s name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.)).

(j) Interim maintenance treatment. (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of §8.11(g).
(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or “take-home” use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

GLOBAL OPIOID EPIDEMIC: DOOMED TO FAIL WITHOUT GENETICALLY BASED PRECISION ADDICTION MEDICINE (PAM™): LESSONS LEARNED FROM AMERICA

Kenneth Blum*,1,2,3,4,5,6,7,8,9,10, Edward J. Modestino11, Marjorie C. Gondré-Lewis12, Jennifer Neary8, David Siwicki6, Mary Hauser4, Debmalya Barh7, Bruce Steinberg11, and Rajendra D. Badgaiyan13

1Department of Psychiatry, University of Florida & McKnight Brain Institute, College of Florida, Gainesville, FL, USA
2Department of Psychiatry, Human Integrated Services Unit University of Vermont Center for Clinical & Translational Science, College of Medicine, Burlington, VT, USA
3Department of Clinical Neurology, Path Research Foundation, NY, NY, USA
4Dominion Diagnostics, LLC, North Kingstown, RI, USA
5Department of Psychiatry, Wright State University, Boonshoft School of Medicine, Dayton, OH USA
6Division of Genetic Testing, Geneus Health LLC, San Antonio, Texas, USA
7Center for Genomics and Applied Gene Technology, Institute of Integrative Omics and Applied Biotechnology (IIOAB), Nonakuri, Purba Medinipur, West Bengal, India
8Institute of Psychology, Eötvös Loránd University Budapest, Hungary
9Department of Psychiatry, University of Southern California, Keck School of Medicine, Los Angeles, CA, USA
10Division of Neuroscience Based Addiction Research and Therapy, The Shores Treatment & Recovery Center, Port t. Lucie, FL, USA
11Department of Psychology, Curry College, Milton, MA, USA
12Departments of Anatomy, Psychiatry & Behavioral Sciences, Howard University, Washington, DC, USA

*Corresponding author: drd2gene@gmail.com, Tel.: +1 352-392-6680, Fax: +1 352-392-8217.

CONFLICT OF INTEREST
Kenneth Blum, PhD owns stock in RDSS LLC, Synaptamine, INC, Igene LLC, Geneus Health, LLC, and RestoreGen, LLC. Synaptamine is the exclusive distributor worldwide of patents related to Reward Deficiency Syndrome (RDS). Dr. Blum is the Chief Scientific Advisor for Dominion Diagnostics. Blum, Modestino, Steinberg, Neary, Gondré-Lewis, Barh, Badgaiyan, Siwicki, and Hauser are on the Scientific Advisory Board of Geneus Health, LLC. There are no other competing interests to declare.

FINANCIAL DISCLOSURE
Drs Kenneth Blum PhD and Marjorie C. Gondré-Lewis are recipients of R41 MD012318/MD/NIMHD NIH HHS/United States and MGL is the recipient of R01 AA021262/NIAAA NIH HHS/United States. Rajendra D. Badgaiyan is supported by the National Institutes of Health grants www.ncbi.nlm.nih.gov/1R01NS073884.
Abstract

It is a reality that globally opioid deaths have soared for men and women of all social, economic status and age from heroin and fentanyl overdoses. Specifically, in the United States, deaths from narcotic overdoses have reached alarming metrics since 2010. In fact, the Fentanyl rise is driven by drug dealers who sell it as heroin or who use it to lace cocaine or to make illegal counterfeit prescription opioids. The President’s Commission on the crisis has linked the death toll as equivalent to “September 11th every three weeks.” In fact, The U.S. Centre for Disease Control (CDC) released data showing that opioid-related overdoses were up 15% in the first three quarters of 2016 compared to 2015. Various governmental organizations including NIDA, are actively seeking solutions. However, we argue that unless the scientific community embraces genetic addiction risk coupled with potential precision or personalized medicine to induce “dopamine homeostasis” it will fail. We now have evidence that a ten-gene and eleven single nucleotide polymorphism (SNP) panel predicts Addiction Severity Index (ASI) for both alcohol and drugs of abuse (e.g., Opioids). In a large multi-addiction centre study involving seven diverse treatment programs, the genetic addiction risk score (GARS™) was shown to have a predictive relationship with ASI–MV derived alcohol (≥ seven alleles), and other drugs (≥4 alleles) severity risk scores. In a number of neuroimaging studies, we also display that in both animal (bench) and abstinent Chinese severe heroin-dependent patients (bedside), BOLD dopamine activation across the brain reward circuitry revealed increases in resting state functional connectivity as well volume connectivity. It is also known that published nutrigenomic (coupling gene polymorphisms with altered KB220z) studies reveal improved clinical outcomes related to obesity.

Keywords

addiction; dependence; Genetic Addiction Risk Score™; heroin; opioid epidemic

INTRODUCTION

Drug, alcohol and other addiction rehabilitation in the United States was a $35 billion business in 2015. There are over 14,500 treatment facilities and growing. A total of 2.5 million patients received treatment, but much more need it and many facilities are at capacity. Additionally, insurance coverage for rehabilitation is limited. As a result, most of the bill is paid by government/state agencies or out of pocket by the patients. High-end establishments have emerged for the higher income population, and new nooks are developing in areas such as: problem gamblers, sex addiction, nicotine addiction and Internet addiction. Facilities are also diversifying into treating people with anxiety disorders, eating disorders, and posttraumatic stress.

Addiction concerns

Often, the greatest fear for a parent is that their children might become addicted to drugs and/or alcohol. According to a survey by Parent.co, which included 1500 participants, fear
of drug and alcohol addiction vastly outweighed concerns about terrorism, economic collapse, crime, and war. Most Americans have first-hand experience with someone struggling with addictions.

- 44% of Americans know someone with a history of painkiller addiction, CNBC reports.
- 20% claimed it was one of their family members.
- 24.6 million Americans abused drugs.
- This is equivalent to 9.4% of the U.S. population (up from 8.3% in 2002).
- Essentially, this is equivalent to the population of Texas.

**Nationwide American trends**

Annual surveys conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) reveal that drug abuse is increasing in America. The participants in the National Survey on Drug Use and Health, those who are 12 years and older, provided critical commentary on the use and abuse of various substances. This included information for different periods, such as weekly, monthly, and even lifetime use of alcohol and drugs.

According to the 2013 survey results:

- 23.5 million U.S. citizens are addicted to alcohol and drugs.
- Marijuana accounts for the majority of this increase as 19.8 million Americans disclosed to using it in 2013. This is an increase from 14.5 million in 2007.
- Marijuana, after alcohol, accounts for the increased rates of dependence (4.2 million in clinical trials for treatment of abuse)
- 1.9 million people fulfilled the criteria for dependence on painkillers and 855k met the criteria for cocaine.
- Methamphetamine use and abuse increased to 595k in 2013 (up from 353k in 2010).
- Cocaine, however, is currently trending downwards, from 2.4 million reported uses from 2002 to 2007, down to 1.4 million uses in 2013.

**Emerging trends in opiate addiction**

The nature of heroin addiction in the America has transformed over recent decades. Relocating from urban areas to the more suburban, from lower incomes to that of more affluent neighbourhoods, the portrait of a heroin addict progressed from poor, urban, black and male users and transformed to predominantly Caucasian addicts of whom half are females.

According to Dr. Theodore Cicero (Washington University in St Louis), first-time users of heroin tend to be in their mid-20s. In decades past, first-time users tended to be around age 16. Between 2007 and 2013, heroin use has increased dramatically, from 370,000 to 680,000 users [1].
Similar to illicit substance abuse, the patterns observed in the market for prescription
painkillers like oxycodone addiction have skyrocketed in recent years. In the 1990s, there
was an increase in the accessibility of prescription painkillers. This culminated in a crest of
addiction, which surpassed the combined use of illicit substances (i.e., LSD,
methamphetamines, ecstasy, and cocaine). In 2012, the mortality was 16 thousand deaths
due to painkillers and thus, clinicians, regulatory agencies, government and other
professionals have been working to counter the excessive use of prescription painkillers. For
example, oxycodone is now being produced so that it cannot be easily crushed to allow for
dissolving for injection or even snorting [2].

Foreign illicit drug markets are responding to the increased demand for heroin in the U.S.
Mexico is the main supplier of heroin to the U.S., as it is cheaper than sources from
Columbia or Asia. The legalization of marijuana in the U.S., has resulted in a significant
decrease in demand from illegal foreign sources. This market was quickly replaced by
opium and opium compounds from Mexico. Additionally, user preferences for brown heroin,
which is more readily snorted and smoked, surpassing the use of injectable drugs which are
more widely used and potentially less fatal, is well known on the street [3]. However, the
Opiate/opioid epidemic is a world-wide problem, with European, Middle Eastern and Asian
countries reporting significant uptick in overdoses and overdose deaths. The reasons for this
is not easily explained.

Addiction and overdose

In 2016, the NY Times noted that the U.S. had seen significantly increased overdoses
leading to death, from heroin and prescription medications. Overdose mortality rates are
comparable to those caused by HIV in the 1980s- 1990s. Unlike HIV mortality, overdose-
related deaths are not localized to just cities but everywhere. Specific regions and states have
been experiencing the impact of opiate overdoses more acutely than others. Based on
information from the Centre for Disease Control (CDC) [4], the Southwest regional U.S. and
Appalachia (specifically in West Virginia) tend to be the most affected. In the Appalachia
region, overdose mortality is primarily due to prescription painkillers often prescribed to
blue-collar workers, initially to treat chronic pain resulting from job-related injuries. Due to
laws put in place to prevent abuse of such prescription medications, many have turned to
illicit substances like heroin for relief. Subsequently, this has led to addiction.

With inadequate resources available to provide services and addiction-related treatment, the
increases overdose mortality has soared. State by state discrepancies in access to treatment
and expenditures for such treatment also is becoming more apparent. For example, in New
Hampshire (N.H.), an overdose of opiates, mostly connected to fentanyl, caused 326 deaths
in 2014 [5]. N.H. allocated less funding per capita than all other states (excluding Texas) in
providing the desperately needed treatment services. In New Mexico, heroin overdose deaths
has persisted since the 1990s, where it is often considered akin to a hereditary disease.
According to Jennifer Weiss-Burke, the executive director of the non-profit organization,
Healing Addiction in Our Community, heroin addiction is seemingly passed down through
generations.
Furthermore, Ms. Weiss-Burke has noticed that the younger generations are often more difficult to treat. In fact, some are unwilling to get sober. These individuals vacillate between treatment centers and jail. This chronic situation is due to staying within the same environment, surrounded by the very same people. Almost more trouble is the rise of fentanyl abuse, for which a greater amount of Naloxone is necessary to resuscitate overdose victims versus that of a heroin overdose. Naloxone is also used to reverse other opioid drug overdoses, and it is not specific to fentanyl [6].

**Combating prescription medications and illicit heroin use in the US**

In March 2016, President Obama enunciated a multifaceted plan to enhance resources and treatment facilities and provided greater access to naloxone. The Obama administration appealed for $1.1 billion in the hopes of funding new measures aimed at reducing continued opioid overdose mortality. President Obama emphasized that the profile of heroin addiction has transmogrified with a socioeconomic shift and altered public opinions: specifically, heroin addiction is no longer an affliction of the urban poor nor due to presumed moral ineptitude, but rather affects every day folk - sons and daughters, aunts and uncles, and even grandparents residing in suburbia.

The FDA has increased warnings on immediate-release opioid prescription medications to warn patients about abuse, potential overdose, and complications. Previously, in 2013, the FDA relabelled thirty-four brands of extended-release medications. This latest change includes the relabelling of 288 medications. New CDC guidelines attempt to restrict the prescribing of opioids to cases in which no other option exists. Thus, these new warnings labels and guidelines will remain integral in combating opioid dependency and addiction [7].

**Understanding the role of genetic testing in addiction medicine**

Over 100 million Americans with addictive personalities have a genetic predisposition for addiction, which is called the Reward Deficiency Syndrome (RDS) [8–20]. They have a lower utilization level of the pleasure chemicals in the brain called neurotransmitters, known as “neurotransmitter deficits,” than those with normal counts. This puts them at a disadvantage and makes them prone to accidents, aberrant cravings, and drug-seeking behaviours, which overburdens the health care delivery system as a whole.

The etiology of drug addiction is highly complex. The primary consideration is how the patient is to be treated. These individuals are prescribed behavioral or psychiatric modification instead of being treated for the underlying medical condition. Drug addicts are relatively easy to detoxify with careful professional oversight and management [21]. However, to prevent drug relapse and the intense psychological cravings are another matter. Most drug-seeking behaviours originate in the dopaminergic centres of the mesolimbic brain.

These pathways are responsible for the feelings of pleasure and a sense of well-being. Any deficits or decrease in the dopaminergic system will lead to a loss of pleasure and eventually lead to drug-seeking or high-risk behaviours [22]. Our laboratory now documented, and it is widely known and accepted, that there is a genetic relationship between RDS and the dopaminergic system. The RDS is based on deficits in the ‘brain reward cascade’ and
originates primarily from a relatively common genetic deficiency in the dopamine D2 receptors and other genes. A genetically-dependent decline in the number of receptors for neurotransmitters will lessen or attenuate the neurological reward/pleasure signal to the affected target organs, known as “dopamine resistance.” The dopamine resistance creates a lower sense of well-being. DNA gene testing can identify these individuals who carry the affected Reward Deficiency Genes [23].

Can we predict risk using genetic testing?

Various alleles in the P450 system are currently utilized in pain medicine clinics to evaluate metabolic concerns to help identify high and low metabolizers.

Genetic Addiction Risk Score™

Molecular genetic or DNA testing is critical for examining the genetic link of aberrant behaviours to specific individual. Blum’s laboratory proposed [24] that disturbances along the brain reward cascade may be due to gene variations (polymorphisms) and/or environment (epigenetics) resulting in aberrant-addictive behaviours or Reward Deficiency Syndrome (RDS). In spite of a global genome-wide search to divulge candidate or specific genes, or even clusters of genes, it is well-known that many attempts have either not replicated or have been inconclusive. However, Palmer et al. [25] recently showed that between 25–36% of the genetic variance in vulnerability to substance dependence/abuse might be attributable to relatively common single-nucleotide polymorphisms (SNPs). Additionally, the additive effect of common SNPs may be shared across comorbid drug dependency/addiction. Finally, recent evidence has revealed that specific candidate gene variants account for risk prediction.

Adopting a Bayesian approach, earlier studies from Blum’s laboratory divulged a Positive Predictive Value (PPV) of 74% specifically for the DRD2 A1 variant associated with a lower amount of D2 receptors. A newborn with this polymorphism is at substantially higher risk of becoming addicted to either drug, food, or aberrant behaviours at some point in his/her future [26, 27]. Since this finding in 1990 by Blum and Noble of the association of the DRD2 A1 variant and severe alcoholism, various laboratories and research centres across the globe, including those associated with or funded by NIDA and NIAAA, not only have confirmed this finding [9], but have extended the magnitude of candidate genes and second messengers located in the reward circuitry of the brain [28].

Examples include Moeller et al. [29], who suggested drug-cues substantially contribute to relapse. Neurogenetic results have revealed the DAT1R 9R-allele as a vulnerability allele for potential relapse, especially during early abstinence (e.g., detoxification) in treatment. The DAT1 9 allele impacts the fast acting reuptake-transport of dopamine sequestered from the synapse leading to a hypodopaminergic trait.

It seems shrewd to utilize genetic testing to reveal reward circuitry gene polymorphisms, especially those related to dopaminergic pathways, as well as the opioid receptors, with the intention of improving treatment outcome. It is imperative to understand the interaction of reward circuitry’s involvement in buprenorphine treatment effects and their respective
genotypes to provide a novel framework to augment a patient’s clinical experience and benefits during opioid replacement therapy [30].

Our laboratory is developing a genetic risk score that represents a panel of known reward genes and associated risk polymorphisms providing the genetic risk for addiction and other behaviours including medical monitoring and clinical outcome response.

Pharmacogenomics – Precision addiction medicine (PAM™)

Blum and Kozlowski have published on the “Brain Reward Cascade” (BRC) [31]. This concept served as a blueprint for how neurotransmitters interact in the reward system of the brain. Also, it has been firmly established that reward-related genes that regulate chemical messengers mediate the quantity of dopamine released into the reward circuit and in other regions of the brain. Moreover, it is well established that resting-state functional connectivity integrity is essential for healthy homeostatic functioning. Zhang et al. [32] recently revealed that in heroin addicts there was a significant reduction of connectivity between the rostral anterior cingulate (rACC) and the dorsal anterior cingulate cortex (dACC), as well as reduced connectivity between the dACC and subcallosal (sACC). These findings of variations in the functional connectivity within three sub regions of the ACC within heroin addicts has implied that these sub regions, together with crucial other brain areas (such as the putamen, dorsal striatum, orbital frontal cortex, dorsal striatum, cerebellum, amygdala, etc.) may play essential aspects in heroin addiction. More recently, in Blum’s laboratory, and along with Zhang’s group [33] in abstinent heroin addicts showed that KB220Z™ (Pro-Dopamine Regulator) a complex dopamine agonist, induced a significant increase in MRI BOLD activation within the caudate-accumbens-dopaminergic pathways compared to placebo following one-hour acute administration. Additionally, KB220Z™ also reduced resting-state activity in the cerebellum of abstinent heroin addicts in recovery. In the second tier of this pilot study, all ten abstinent heroin-dependent subjects, three brain regions of interest (ROIs) were observed to be significantly activated in resting state by KB220Z™ contrasted with placebo (p < 0.05). This increased functional connectivity was observed in a presumed network which encompassed the dACC, posterior cingulate, nucleus accumbens, medial frontal gyrus, occipital cortical areas, and cerebellum.

SUMMARY

The development of a polymorphic gene panel [34–43] has enabled customized (personalized) anti-obesity compounds [44] and now could provide personalized induction of “dopamine homeostasis.” This serves as the basis of futuristic personalized addiction medicine utilizing the Genetic Addiction Risk Score (GARS).

Acknowledgments

The authors acknowledge the editorial work of Margaret A. Madigan.

References


## HIGHLIGHTS

- The opioid-addiction epidemic is a plague to modern society.
- Genetic Addiction Risk Score (GARS™), paired with potential precision or personalized medicine (i.e., nutrigenomics) to induce “dopamine homeostasis” is essential in treating addiction.
- The compounds KB220Z/KB220ZBR/KB220PAM™ (Pro-Dopamine Regulators) are complexes with known dopamine agonistic qualities that successfully mediates “dopamine homeostasis”.

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*Precis Med (Bangalore). Author manuscript; available in PMC 2018 January 23.*
July 27, 2018

Greetings,

Recently, two issues have generated Department policy questions. The first focuses on the use of telemedicine while the second focuses on the term “partial hospitalization.” We would like to clear up any misunderstanding about best practices, legal, and policies relevant to these issues.

Telemmedicine

The first issue relates to inquiries about whether the use of telemedicine is acceptable in programs licensed, certified, or designated by the Department. The Florida Administrative Code defines “Telemedicine” as:

the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof.

This definition is consistent for both licensed physicians (6488-9.0141, F.A.C.) and licensed osteopathic physicians, (64815-14.0081, F.A.C.) and is found in the specific sections of rule entitled “Standards for Telemedicine Practice.”

These rules provide additional directives on the standard of care required, the fitness of the equipment being used for the telemedicine sessions, the prescribing of drugs, and the obligations of the physician and ancillary health care personnel to perform at the standard of care. The rules referenced above specifically state “Telemedicine equipment and technology must be able to provide, at a minimum, the same information to the physician and physician assistant which will enable them to meet or exceed the prevailing standard of care for the practice of medicine.”

In addition, the Medicaid Program reimburses for services provided using telemedicine. The rule on telemedicine is found in Chapter 59G-1.057 F.A.C., and states that “Florida Medicaid reimburses for telemedicine services using interactive telecommunications equipment that includes, at a minimum audio and video equipment permitting two-way, real time, interactive communication between a recipient and a practitioner.” The rule authorizes any licensed practitioner within their scope of practice to perform a covered service for an eligible patient.

Lastly, a reference to telemedicine is found in s.394.453, F.S., the first substantive section of the Baker Act describing legislative intent. The section reads in part, “the Legislature finds that the use of telemedicine for patient evaluation, case management, and ongoing care will improve management of patient care and reduce costs of transportation.”

1317 Winwood Boulevard, Tallahassee, Florida 32399-0700

Mission: Work in Partnership with Local Communities to Protect the Vulnerable, Promote Strong and Economically Self-Sufficient Families, and Advance Personal and Family Recovery and Resiliency
The use of telemedicine for the purposes of evaluation, diagnosis, or treatment is permissible, as long as provider staff are performing services within their scope of practice and the standard of care provided is equal to what would be provided if the individual was receiving services on-site. It is your organization's responsibility to ensure telemedicine services are consistent with the standard of care provided in your agency and only qualified staff operating under clearly stated policies and protocols are delivering services.

As a reference, we encourage you to review the following resources:

The Florida Administrative Code:

- Section 64B8 – 9.0141 – Board of Medicine - Standards of Practice for Medical Doctors – Standards for Telemedicine Practice
- Section B15-14.0081 - Board of Osteopathic Medicine – Standards for Telemedicine Practice
- Section 59G-1.057 – General Medicaid - Telemedicine.
- http://www.americantelemed.org/main/about/telehealth-faqs-

Partial Hospitalization

We have observed the consistent use of the term “partial hospitalization” in our conversation with license applicants, articles about Florida’s substance abuse industry, and in conversations with outside organizations (e.g., insurance carriers and other state government agencies). This term is used as an alternate name for DCF’s licensed Day or Night Treatment with Community Housing and other forms of non-residential treatment.

To be clear, the Office of Substance Abuse and Mental Health does not license or designate partial hospitalization programs. When the 1993 Florida Legislature enacted Chapter 93-39, Laws of Florida, existing chapters 396 (Relating to Alcoholism) and 397 (Treatment and Rehabilitation of Drug Dependents) were combined into a new Chapter 397, the "Hal S. Marchman Alcohol and Other Drug Services Act of 1993." The Act defined a licensed service provider as a:

- Public agency under this chapter
- Private for-profit or not-for-profit agency under this chapter
- Physician licensed under chapter 458 or chapter 459, or
- Any other private practitioner licensed under this chapter, or
- Hospital licensed under chapter 395

These identified licensed service providers could offer services through one or more licensable service components, which did not include partial hospitalization. The previous reference to “partial hospitalization” which had appeared as one of the included services was also struck from Chapter 397, F.S. by this act.

The Substance Abuse and Mental Health Program Office is committed to the continued development of a system of care that is individual-centered and provides services and supports to meet the needs of
those individuals in their communities. As part of this commitment, we will correct any misidentification of our licensed services with those we interact with and encourage you to do the same.

If you have any questions regarding this letter, please contact Mr. Chris Weller at (850) 717-4286 or at Chris.Weller@myflfamilies.com.

Thank you again for the work you do.

Respectfully,

[Signature]

Ute Gazioch
Director of Substance Abuse and Mental Health

cc: John N. Bryant, Assistant Secretary for Substance Abuse and Mental Health
Regional Substance Abuse and Mental Health Directors
1. Introductions:

2. Updates:
   a. Harm Reduction from 20,000 feet (local and state initiatives)
   b. SEBHN Pilot Summary: Presentation
   c. Florida Society of Addiction Medicine (FSAM):

3. 2019 Legislation: Discussion
   i. Omnibus SHTF Bill
   ii. Syringe Exchange Expansion

4. FARR
   a. FARR Certification Overview: Presentation
   b. Day/Night-Res. 5 -status

5. Public comments.

6. Closing remarks.
SEFBHN Pilot Summary

- Cultural Probe
- Develop Personas
- Card Sorting
- Customer Interviews
- Listen in on Customer Service Calls
- Field Visits
- User Survey

Run a Usability Test
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Overview

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Engagement

Conclusions
Pilot Background & Description

The pilot began January 2018 with goals, as described in the service agreement, of expanding Medication Assisted Treatment (MAT) Housing options, eliminating barriers to sustained recovery for individuals living with Opioid Use Disorder (OUD), increasing access to Recovery Peer Specialists in order to improve engagement in community-based treatment, recovery support services, mutual aid and meaningful activities including: employment, education, and community service.
Summary

Four (4) Recovery Navigational Support (RNS) trainings were conducted, producing seventy-two (72) certificates of completion. Twelve (12) FARR Partners comprising 26 residential locations supporting 451 certified beds were recruited, trained and engaged in utilization of the data collection tool and housing vouchers. Additionally; these Recovery Residences agreed to facilitate delivery of RN) to clients residing in their locations. Through ongoing collaboration with FARR, there are now a total of 107 FARR Residences in Palm Beach County (934 certified beds) who admit residents who are enrolled in a MAT protocol. Since January 1st, 2018 there have been one hundred twenty (120) referrals to the Pilot. The majority of these referrals were initiated in April and May. Of the total individuals referred, sixty-one (61) were enrolled as RNS Clients, 26 are currently pending navigator assignment and 33 were classified as either non-responsive or disqualified for RNS Service. For comparative reporting purposes pending, non-responsive and disqualified referrals are presented throughout this report as a control group labelled “RNS Candidates”.

Note: Navigator assignments for ‘pending referrals’ contingent on contract extension.
Criteria

For the purposes of this report, pilot participants were broken into two categories:

- **Clients** - completed REC CAP baseline assessment during Key Working Session (KWS)
- **Candidates** - referrals who were non-responsive and/or disqualified during screening

All data is current as of July 27th, 2018

**REC CAP:** Recovery Capital assessment tool that both informs Recovery Care Planning and measures recovery capital gains over time.
**Overview (continued)**

Item 2b

<table>
<thead>
<tr>
<th>Overview</th>
<th>Days</th>
<th>Avg Length of Client Involvement</th>
<th>Avg Length of Candidate Involvement</th>
<th>Key Working Sessions</th>
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</thead>
<tbody>
<tr>
<td>Overview</td>
<td>87.9</td>
<td>49.6</td>
<td>247</td>
<td></td>
</tr>
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</table>

**Key Working Session (KWS):** structured sessions where client and navigator engage in a defined process to Measure, Plan and Engage (MPE) concrete recovery goals informed by REC CAP Assessment. Typically, eleven (11) KWS are held over six (6) months. **Phase 1 is** comprised of four (4) weekly KWS, followed by **Phase 2** comprised of four (4) bi-weekly KWS and **Phase 3** transitions to three (3) monthly KWS.
Overview (continued)

**Current Status of Enrolled Clients**

<table>
<thead>
<tr>
<th>Network Status</th>
<th>Count of Network Status</th>
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<tr>
<td>Active</td>
<td>48</td>
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<tr>
<td>Other Voluntary Discharge</td>
<td>3</td>
</tr>
<tr>
<td>Other Involuntary Discharge</td>
<td>1</td>
</tr>
<tr>
<td>Abandoned</td>
<td>9</td>
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</tbody>
</table>

**Current Status of Candidates**

<table>
<thead>
<tr>
<th>Network Status</th>
<th>Count of Network Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-responsive</td>
<td>33</td>
</tr>
<tr>
<td>Pending</td>
<td>26</td>
</tr>
</tbody>
</table>
Over six thousand safe and sober nights were delivered by FARR Partners during this pilot. 50% of housing vouchers were funded for persons who failed to engage in Recovery Navigational Support (RNS). This can and should be corrected by integrating conditional approval and funding.

Housing stability is clearly enhanced within the RNS Client Group. Average length of stay for RNS Clients is 64.3 days compared to 43.2 days for Candidates, representing a 32.8% enhancement for the RNS Client Group. As we progress forward, it will be of particular interest to determine whether delivery of RNS through term maturity (six months) results in expansion of this differential.

Additional recovery housing data is presented pertaining to compliance with peer community rules and responsibilities, financial commitments, and participation in the peer residential community.

**FARR**: Florida Association of Recovery Residences – state designated credentialing entity and NARR Florida Affiliate
Housing (continued)

64.3 days
Avg Length of Client Housing

43.2 days
Avg Length of Candidate Housing

6451
Safe & Sober Nights Delivered

Clients Receiving Housing Vouchers

Yes 80.3%

No 19.7%

12

Candidates Receiving Housing Vouchers

Yes 89.8%

No 10.2%

53

6
Client Rules & Responsibilities Compliance
n = 57
- Resistant: 3.6%
- Requires Monitoring: 38.0%
- Reliable: 58.4%

Client Financial Commitment Compliance
n = 35
- Resistant: 2.9%
- Requires Monitoring: 31.4%
- Reliable: 65.7%

Candidate Rules & Responsibilities Compliance
n = 50
- Resistant: 6.9%
- Requires Monitoring: 40.0%
- Reliable: 54.0%

Candidate Financial Commitment Compliance
n = 35
- Resistant: 5.7%
- Requires Monitoring: 46.7%
- Reliable: 48.6%
**Client Peer Community Participation**

- **n = 44**
- Resistant: 1 (1.9%)
- Requires Monitoring: 35 (83.3%)
- Reliable: 35 (64.8%)

**Candidate Peer Community Participation**

- **n = 46**
- Resistant: 4 (8.7%)
- Requires Monitoring: 19 (41.3%)
- Reliable: 23 (50.0%)
Employment

At initial screening and intake, 93 individuals reported as being *unemployed*: 47 of these were enrolled as *Clients* and 46 were classified as *Candidates*. As of July 27, 2018, a total of 53 individuals are now employed. Of these, 37 belong to the Client Group and 17 belong to the Candidate Group, resulting in a 37% employment gain for the Client Group compared to only a 7% gain for the Candidate Group. Job satisfaction ratings were consistent across both groups.
### Employment (continued)

<table>
<thead>
<tr>
<th>Employed at Time of Referral</th>
<th>% Gains in Employment</th>
<th>% Employed Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>23% of clients</td>
<td>37% by clients</td>
<td>60% of clients</td>
</tr>
<tr>
<td>22% of candidates</td>
<td>7% by candidates</td>
<td>29% of candidates</td>
</tr>
</tbody>
</table>

**Avg Length to Employment**

- **27 days** for clients
- **14 days** for candidates

**Avg Job Satisfaction**

- 3 of 5 overall
All measures of engagement, including employment, are enhanced significantly by RNS service delivery. We recently modified service structure to focus on housing and employment goals during KWS 1 and 2. This modification is prompted by an effort to reduce number of days to gainful employment and was introduced during the most recent Navigator Community of Practice (CoP) meeting (July 25, 2018).

While employment is a vital measure of community engagement, other categories positively impact recovery capital. The charts below reflect additional engagement metrics. In September 2018, once a sufficient number of RNS Clients have completed quarterly REC CAP Assessments, we will present correlations between community engagement and growth in recovery capital.

The first set of three charts present comparative data pertaining to engagement in Mutual Aid, Recreational Activities and Community Service for both groups. The RNS Client Group experienced significantly enhanced engagement in every category. The final two charts reflect recovery group service commitments and, for the criminal justice-involved subset, compliance with supervision requirements.
Mutual Aid Engagement

2537 meetings attended by clients

1331 meetings attended by candidates

Client Mutual Aid Participation
n = 58

- Requires Monitoring: 21 (36.2%)
- Reliable: 37 (63.8%)

Candidate Mutual Aid Participation
n = 41

- Resistant: 1 (2.0%)
- Requires Monitoring: 18 (35.3%)
- Reliable: 32 (62.7%)
Engagement Comparison (continued)

Recreational Engagement

<table>
<thead>
<tr>
<th>Activities Participated In</th>
<th>Clients</th>
<th>Candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>916</td>
<td>351</td>
</tr>
</tbody>
</table>

Client Recreational Participation
- n = 37
- Resistant: 10.8%
- Requires Monitoring: 27.0%
- Reliable: 62.2%

Candidate Recreational Participation
- n = 32
- Resistant: 18.8%
- Requires Monitoring: 34.4%
- Reliable: 46.9%
Community Service Engagement

<table>
<thead>
<tr>
<th></th>
<th>Hours Delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clients</td>
<td>395</td>
</tr>
<tr>
<td>Candidates</td>
<td>171</td>
</tr>
</tbody>
</table>

Client Community Service Participation
n = 35

- Resistant: 25.7%
- Requires Monitoring: 31.4%
- Reliable: 42.9%

Candidate Community Service Participation
n = 29

- Resistant: 31.0%
- Requires Monitoring: 51.7%
- Reliable: 17.2%
Engagement Comparison (continued)

**Client Group Service Commitment Compliance**

- Total: 36
- Resistant: 11 (11.1%)
- Requires Monitoring: 11 (30.6%)
- Reliable: 21 (58.3%)

**Candidate Group Service Commitment Compliance**

- Total: 35
- Resistant: 6 (17.1%)
- Requires Monitoring: 18 (51.4%)
- Reliable: 11 (31.4%)

**Client Community Supervision Compliance**

- Total: 6
- Reliable: 58.3%

**Candidate Community Supervision Compliance**

- Total: 7
- Requires Monitoring: 6 (85.7%)
Conclusions

1. Due to limited resources, continued eligibility for a Housing Voucher should be conditioned upon both enrollment and active engagement in RNS. Client compliance with the Recovery Care Planning schedule is essential to achieving enhanced outcomes. A data-driven proposal for improvements to screening, orientation and intake procedures will be adopted with approval by SEFBHN.

2. While admission of MAT-enrolled residents no longer presents challenges in Palm Beach County, engaging FARR Certified Recovery Residences in the SEFBHN Pilot as Partners remains problematic. Misinformation concerning requirements, reimbursements and the dollar value of vouchers remain barriers to registration. ROI, in collaboration with FARR and SEFBHN, will prepare and host an on-demand video presentation to educate certified residence operators regarding the housing voucher program.

3. Having held four (4) Navigator Trainings in support of the Pilot, we have determined a) recovery capital history, theory and science (Day One) be formatted as on-demand e-learning content and that b) the ‘mechanics’ of Measure, Plan and Engage (Day Two), focus on Key Working Session structure and engage registrants in hands-on, interactive exercises.
4. All stakeholders have validated usability of the data collection tool. Navigators, supervisors, clients, family members and network administrative staff concur that the framework and user interface readily support assessment, recovery care planning and data collection. However, the Pilot has also revealed a need to invest in certain modifications. Among them is retooling to allow Navigators to collect client engagement data during KWS (currently maintained by Partners). Additionally, certain enhancements pertaining to the monitoring of engagement in structured session and community integration will be undertaken. This will result in revision to our current practice of reimbursing Partners for intake and monthly data maintenance. Screening, orientation and intake responsibilities will transfer to dedicated administrative staff and monthly data maintenance will transfer to Navigators.

5. Another lesson learned is the need to staff Navigators, on a full or part-time basis, as employees with scheduled service hours. While ROI will continue to maintain independent contractors, in order to ensure response time commitments, we must employ individuals who do not have full-time positions elsewhere and “moonlight” as Recovery Navigators.

Conclusions (continued)
Thank you.
PALM BEACH COUNTY SOBER HOMES TASK FORCE PROPOSED

LEGISLATION

An act relating to substance abuse services; amending s. 394.4572, F.S.; authorizing the Department of Health and the Agency for Health Care Administration to grant exemptions from disqualification for service provider personnel to work solely in certain treatment programs and facilities; amending s. 397.311, F.S.; defining the term "peer specialist"; amending s. 397.4073, F.S.; revising provisions relating to background checks and exemptions from disqualification for certain service provider personnel; requiring the Department of Children and Families to grant or deny an exemption from disqualification within a certain timeframe; authorizing an applicant for an exemption to work under the supervision of certain persons for a specified period of time while his or her application is pending; authorizing certain persons to be exempted from disqualification from employment; authorizing the department to grant exemptions from disqualification for service provider personnel to work solely in certain treatment programs and facilities; creating s. 397.417, F.S.; providing qualifications for certification as a peer specialist; requiring the department to develop and implement a training program for individuals seeking certification as peer specialists; authorizing the department to designate certain credentialing entities to certify peer specialists; providing requirements for individuals providing certain recovery support services as peer specialists; amending s. 397.487, F.S.; revising legislative findings relating to voluntary certification of recovery residences; requiring recovery residences to comply with specified Florida Fire Prevention Code provisions; revising background screening requirements for owners, directors, and chief financial officers of recovery residences; amending s.
397.4873, F.S.; providing exceptions to limitations on referrals by recovery
residences to licensed service providers; providing additional conditions for an
exception to limitations on referrals by licensed service providers to their wholly
owned subsidiaries; prohibiting recovery residences and specified affiliated
individuals from receiving pecuniary benefits from licensed service providers for
certain referrals; providing penalties; amending s. 435.07, F.S.; authorizing certain
persons to be exempted from disqualification from employment; amending ss.
212.055, 397.416, and 440.102, F.S.; conforming cross-references; providing an
effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 394.4572, Florida Statutes, is amended to read:

394.4572 Screening of mental health personnel.—
(2)(a) The department or the Agency for Health Care Administration may
grant exemptions from disqualification as provided in chapter 435.
(b) The department or the Agency for Health Care Administration, as
applicable, may grant exemptions from disqualification for service provider
personnel to work solely in mental health treatment programs or facilities or
in programs or facilities that treat co-occurring substance use and mental
health disorders.

Section 2. Subsections (30) through (49) of section 397.311, Florida Statutes, are
renumbered as subsections (31) through (51), respectively, and subsection (37) is
amended and a new subsection (30) is added to that section to read:

397.311 Definitions.—As used in this chapter, except part VIII, the term:
(30) "Peer specialist" means a person who has been in recovery from a substance
use disorder or mental illness for at least 2 years who uses his or her personal
experience to deliver services in behavioral health settings to support others in
their recovery, or a person who has experience as a family member or a caregiver of a person with a substance use disorder or mental illness. The term does not include a person who is a qualified professional or otherwise certified under chapter 394 or 397.

(37) “Recovery Residence” means a residential dwelling unit, including community housing as established by the department by rule, or other form of group housing, that is offered or advertised through any means, including oral, written, electronic, or printed means, by any person or entity as a residence that provides a peer-supported, alcohol free, and drug free living environment.

Section 3. Paragraphs (a), (f), and (g) of subsection (1) and subsection (4) of section 397.4073, Florida Statutes, are amended to read:

397.4073 Background checks of service provider personnel.
— (1) PERSONNEL BACKGROUND CHECKS; REQUIREMENTS AND EXCEPTIONS.—

(a) For all individuals screened on or after July 1, 2018, background checks shall apply as follows:

1. All owners, directors, chief financial officers, and clinical supervisors of service providers are subject to level 2 background screening as provided under chapter 435. Such screening shall also include background screening as provided in s. 408.809. Inmate substance abuse programs operated directly or under contract with the Department of Corrections are exempt from this requirement.

2. All service provider personnel who have direct contact with children receiving services or with adults who are developmentally disabled receiving services are subject to level 2 background screening as provided under chapter 435. Such screening shall also include background screening as provided in s. 408.809.

3. All peer specialists who have direct contact with Individuals receiving services are subject to level 2 background screening as provided under chapter 435. Such screening
shall also include background screening as provided in s. 408.809 (f) Service provider personnel who request an exemption from disqualification must submit the request within 30 days after being notified of the disqualification. The department shall grant or deny the exemption from disqualification within 60 days after receipt of a complete application.

(g) If 5 years or more have elapsed since the applicant for the exemption completed or was lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the most recent disqualifying offense, such applicant service provider personnel may work with adults with substance use disorders under the supervision of persons who meet all personnel requirements of this chapter for up to 90 days after being notified of the disqualification or until the department a qualified professional licensed under chapter 490 or chapter 491 or a master's level certified addictions professional until the agency makes a final determination regarding the request for an exemption from disqualification, whichever is earlier.

(h)(g) The department may not issue a regular license to any service provider that fails to provide proof that background screening information has been submitted in accordance with chapter 435.

(4) EXEMPTIONS FROM DISQUALIFICATION.—

(a) The department may grant to any service provider personnel an exemption from disqualification as provided in s. 435.07.

(b) Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of individuals with substance use disorders, for service providers which treat adolescents 13 years of age and older, service provider personnel whose background checks indicate crimes under s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(e), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related criminal attempt, solicitation, or conspiracy
under s. 777.04, may be exempted from disqualification from employment pursuant to this paragraph.

(c) The department may grant exemptions from disqualification for service provider personnel to work solely in substance abuse treatment programs or facilities or in programs or facilities that treat co-occurring substance use and mental health disorders. The department may further limit such grant exemptions from disqualification which would limit service provider personnel to working with adults in substance abuse treatment facilities.

387.4075 Unlawful activities relating to personnel; penalties.
Section 4. Section 397.417, Florida Statutes, is created to read.

397.417 Behavioral health peer specialists.—
(1) An individual is eligible for certification as a peer specialist if he or she has been in recovery from a substance-use disorder or mental illness for at least 2 years or if he or she has experience as a family member or caregiver of a person with a substance-use disorder or mental illness.

(2) The department shall develop and implement a training program for individuals seeking certification as peer specialists. The department may designate one or more credentialing entities that have met nationally recognized standards for developing and administering professional certification programs to certify peer specialists.

(3) An individual providing department-funded recovery support services as a peer specialist shall be certified pursuant to subsection (2). However, an individual who is not certified may provide recovery support services as a peer specialist for up to
1 year if he or she is working toward certification and is supervised by a qualified professional or by a certified peer specialist with supervisory training who has at least 3 years of full-time experience as a peer specialist at a licensed behavioral health organization.

mental health or substance use disorders or co-occurring disorders under the supervision of persons who meet all personnel requirements of this chapter for up to 90 days after being notified of the disqualification or until the department a qualified professional licensed under chapter 490 or chapter 491 or a master’s level certified addictions professional until the agency makes a final determination regarding the request for an exemption from disqualification, whichever is earlier.

(h) The department may not issue a regular license to any service provider that fails to provide proof that background screening information has been submitted in accordance with chapter 435.

(4) EXEMPTIONS FROM DISQUALIFICATION.—

(a) The department may grant to any service provider personnel an exemption from disqualification as provided in s. 435.07.

(b) Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of individuals with substance use disorders, for service providers which treat adolescents 13 years of age and older, service provider personnel whose background checks indicate crimes under s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(c), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related criminal attempt, solicitation, or conspiracy under s. 777.04, may be exempted from disqualification from employment pursuant to this paragraph.
(c) The department may grant exemptions from disqualification for service provider personnel to work solely in substance abuse treatment programs or facilities or in programs or facilities that treat co-occurring substance use and mental health disorders. The department may further limit such grant exemptions from disqualification which would limit service provider personnel to working with adults in substance abuse treatment facilities.

(d) When evaluating a peer specialist’s application for exemption from disqualification, the department shall consider:

1. The need for peer specialists to provide support services and the shortage of professionals and paraprofessionals to provide behavioral health services.

2. That peer specialists may have criminal histories resulting from substance use disorders or mental illnesses that prevent them from meeting background screening requirements.

3. That peer specialists provide effective mental health and substance abuse treatment support services because they share common life experiences with the persons they assist and promote a sense of community among those in recovery.

4. That research has shown that peer support facilitates recovery and reduces health care costs.

Section 4. Section 397.417, Florida Statutes, is created to read:

397.417 Behavioral health peer specialists.—

(1) An individual is eligible for certification as a peer specialist if he or she has been in recovery from a substance use disorder or mental illness for at least 2 years or if he or she has experience as a family member or caregiver of a person with a substance use disorder or mental illness.
(2) The department shall develop and implement a training program for individuals seeking certification as peer specialists. The department may shall designate one or more credentialing entities that have met nationally recognized standards for developing and administering professional certification programs to certify peer specialists. The credentialing entity shall develop and implement a training program for individuals seeking certification as peer specialists.

(3) An individual providing department-funded recovery support services as a peer specialist shall be certified pursuant to subsection (2). However, an individual who is not certified may provide recovery support services as a peer specialist for up to 1 year if he or she is working toward certification and is supervised by a qualified professional or by a certified peer specialist with supervisory training who has at least 3 years of full-time experience as a peer specialist at a licensed behavioral health organization.

(4) any person required to be certified under this section, and not exempt pursuant to subsection (3), who provides recovery services as a peer specialist commits a misdemeanor of the first degree.

Section 5. Section 397.4075, Florida Statutes, is amended to read:

It is a Felony misdemeanor of the third first degree, punishable as provided in s. 775.082 or s. 775.083, for any person willfully, knowingly, or intentionally to:

(1) Inaccurately disclose by false statement, misrepresentation, impersonation, or other fraudulent means, or fail to disclose as part of an application for licensure or in any application for voluntary or paid employment, any fact which is material in making a determination as to the person’s qualifications to be an owner, a director, a volunteer, or other personnel or a service provider;

(2) Operate or attempt to operate as a service provider with personnel who are in noncompliance with the minimum standards contained in this chapter; or
(3) Use or release any criminal or juvenile information obtained under this chapter for any purpose other than background checks of personnel for employment.

Section 6. Subsection (1), paragraph (m) of subsection (3), and subsection (6) of section 397.487, Florida Statutes, are amended to read:

397.487 Voluntary certification of recovery residences.—

(1) The Legislature finds that a person suffering from addiction has a higher success rate of achieving long-lasting sobriety when given the opportunity to build a stronger foundation by living in a recovery residence while receiving treatment or after completing treatment. The Legislature further finds that this state and its subdivisions have a legitimate state interest in protecting these persons, who represent a vulnerable consumer population in need of adequate housing. It is the intent of the Legislature to protect persons who reside in a recovery residence.

(3) A credentialing entity shall require the recovery residence to submit the following documents with the completed application and fee:

(m) Proof of satisfactory fire, safety, and health inspections. A recovery residence must comply with the provisions of the Florida Fire Prevention Code which apply to one-family and two-family dwellings, public lodging establishments, or rooming houses, or other housing facilities, as applicable. The State Fire Marshall shall, in cooperation with the department, establish and enforce minimum fire safety standards, which standards must be included in the rules adopted by the department.

(6) All owners, directors, and chief financial officers of an applicant recovery residence are subject to level 2 background screening as provided under chapter 435 and s. 408.809. A recovery residence is ineligible for certification, and a credentialing entity shall deny a recovery residence's application, if any owner, director, or chief
financial officer has been found guilty of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in s. 408.809(4) or s. 435.04(2) unless the department has issued an exemption under s. 397.4073 or s. 397.4872. In accordance with s. 435.04, the department shall notify the credentialing agency of an owner's, director's, or chief financial officer's eligibility based on the results of his or her background screening.

Section 7. Section 397.4873, Florida Statutes, is amended to read:

397.4873 Referrals to or from recovery residences; prohibitions; penalties.—

(1) A service provider licensed under this part may not make a referral of a prospective, current, or discharged patient to, or accept a referral of such a patient from, a recovery residence unless:

(a) the recovery residence holds a valid certificate of compliance as provided in s. 397.487 and is actively managed by a certified recovery residence administrator as provided in s. 397.4871, or

(b) the recovery residence, as part of a licensable community housing component established by rule, is required by the department to adopt and maintain national standards consistent with those standards enumerated in s. 397.487.

(2) Subsection (1) does not apply to:

(a) A licensed service provider under contract with a managing entity as defined in s. 394.9082.

(b) Referrals by a recovery residence to a licensed service provider when the recovery residence or its owners, directors, operators, or employees do not benefit, directly or indirectly, from the referral.

(c) Referrals made before January 1, 2019 July 1, 2018, by a licensed service provider to that licensed service provider's wholly owned subsidiary, provided that applications and associated fees are submitted by July 1, 2018.
(3) A recovery residence or its owners, directors, operators, employees, or volunteers may not receive a pecuniary benefit, directly or indirectly, from a licensed service provider for a referral made pursuant to subsection (1) or subsection (2).

(4) (3) For purposes of this section, a licensed service provider or recovery residence shall be considered to have made a referral if the provider or recovery residence has informed a patient by any means about the name, address, or other details of a recovery residence or licensed service provider, or informed a licensed service provider or a recovery residence of any identifying details about a patient.

(5) (4) A licensed service provider shall maintain records of referrals to or from recovery residences as may be prescribed by the department in rule.

(6) (5) After June 30, 2019, a licensed service provider violating this section shall be subject to an administrative fine of $1,000 per occurrence. Repeat violations of this section may subject a provider to license suspension or revocation pursuant to s. 397.415.

(7) (6) Nothing in this section requires a licensed service provider to refer a patient to or to accept a referral of a patient from a recovery residence.

Section 7. Subsection (2) of section 435.07, Florida Statutes, is amended to read:

435.07 Exemptions from disqualification.—Unless otherwise provided by law, the provisions of this section apply to exemptions from disqualification for disqualifying offenses revealed pursuant to background screenings required under this chapter, regardless of whether those disqualifying offenses are listed in this chapter or other laws.

(2) Persons employed, or applicants for employment, by treatment providers who treat adolescents 13 years of age and older who are disqualified from employment solely because of crimes under s. 796.07(2)(e), s. 810.02(4), s.
812.014(2)(c), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related criminal attempt, solicitation, or conspiracy under s. 777.04, may be exempted from disqualification from employment pursuant to this chapter without application of the waiting period in subparagraph (1)(a)1.

Section 8 9. Paragraph (e) of subsection (5) of section 212.055, Florida Statutes, is amended to read:

212.055 Discretionary sales surtaxes; legislative intent; authorization and use of proceeds.—It is the legislative intent that any authorization for imposition of a discretionary sales surtax shall be published in the Florida Statutes as a subsection of this section, irrespective of the duration of the levy. Each enactment shall specify the types of counties authorized to levy; the rate or rates which may be imposed; the maximum length of time the surtax may be imposed, if any; the procedure which must be followed to secure voter approval, if required; the purpose for which the proceeds may be expended; and such other requirements as the Legislature may provide. Taxable transactions and administrative procedures shall be as provided in s. 212.054.

(5) COUNTY PUBLIC HOSPITAL SURTAX.—Any county as defined in s. 125.011(1) may levy the surtax authorized in this subsection pursuant to an ordinance either approved by extraordinary vote of the county commission or conditioned to take effect only upon approval by a majority vote of the electors of the county voting in a referendum. In a county as defined in s. 125.011(1), for the purposes of this subsection, "county public general hospital" means a general hospital as defined in s. 395.002 which is owned, operated, maintained, or governed by the county or its agency, authority, or public health trust.

(e) A governing board, agency, or authority shall be chartered by the county commission upon this act becoming law. The governing board, agency, or authority shall adopt and implement a health care plan for indigent health care
services. The governing board, agency, or authority shall consist of no more than seven and no fewer than five members appointed by the county commission. The members of the governing board, agency, or authority shall be at least 18 years of age and residents of the county. No member may be employed by or affiliated with a health care provider or the public health trust, agency, or authority responsible for the county public general hospital. The following community organizations shall each appoint a representative to a nominating committee: the South Florida Hospital and Healthcare Association, the Miami-Dade County Public Health Trust, the Dade County Medical Association, the Miami-Dade County Homeless Trust, and the Mayor of Miami-Dade County. This committee shall nominate between 10 and 14 county citizens for the governing board, agency, or authority. The slate shall be presented to the county commission and the county commission shall confirm the top five to seven nominees, depending on the size of the governing board. Until such time as the governing board, agency, or authority is created, the funds provided for in subparagraph (d)2. shall be placed in a restricted account set aside from other county funds and not disbursed by the county for any other purpose.

1) The plan shall divide the county into a minimum of four and maximum of six service areas, with no more than one participant hospital per service area. The county public general hospital shall be designated as the provider for one of the service areas. Services shall be provided through participants' primary acute care facilities.

2) The plan and subsequent amendments to it shall fund a defined range of health care services for both indigent persons and the medically poor, including primary care, preventive care, hospital emergency room care, and hospital care necessary to stabilize the patient. For the purposes of this section, "stabilization" means stabilization as defined in s. 397.311(46).
Where consistent with these objectives, the plan may include services rendered by physicians, clinics, community hospitals, and alternative delivery sites, as well as at least one regional referral hospital per service area. The plan shall provide that agreements negotiated between the governing board, agency, or authority and providers shall recognize hospitals that render a disproportionate share of indigent care, provide other incentives to promote the delivery of charity care to draw down federal funds where appropriate, and require cost containment, including, but not limited to, case management. From the funds specified in subparagraphs (d)1. and 2. For indigent health care services, service providers shall receive reimbursement at a Medicaid rate to be determined by the governing board, agency, or authority created pursuant to this paragraph for the initial emergency room visit, and a per-member per-month fee or capitation for those members enrolled in their service area, as compensation for the services rendered following the initial emergency visit. Except for provisions of emergency services, upon determination of eligibility, enrollment shall be deemed to have occurred at the time services were rendered. The provisions for specific reimbursement of emergency services shall be repealed on July 1, 2001, unless otherwise reenacted by the Legislature. The capitation amount or rate shall be determined before program implementation by an independent actuarial consultant. In no event shall such reimbursement rates exceed the Medicaid rate. The plan must also provide that any hospitals owned and operated by government entities on or after the effective date of this act must, as a condition of receiving funds under this subsection, afford public access equal to that provided under s. 286.011 as to any meeting of the governing board, agency, or authority the subject of which is budgeting resources for the retention of charity care, as that term is defined in the rules of the Agency for Health Care Administration. The plan shall also include innovative health care
programs that provide cost-effective alternatives to traditional methods of service and delivery funding.

3. The plan’s benefits shall be made available to all county residents currently eligible to receive health care services as indigents or medically poor as defined in paragraph (4)(d).

4. Eligible residents who participate in the health care plan shall receive coverage for a period of 12 months or the period extending from the time of enrollment to the end of the current fiscal year, per enrollment period, whichever is less.

5. At the end of each fiscal year, the governing board, agency, or authority shall prepare an audit that reviews the budget of the plan, delivery of services, and quality of services, and makes recommendations to increase the plan's efficiency. The audit shall take into account participant hospital satisfaction with the plan and assess the amount of poststabilization patient transfers requested, and accepted or denied, by the county public general hospital.

Section 9 10. Section 397.416, Florida Statutes, is amended to read:

397.416 Substance abuse treatment services; qualified professional.— Notwithstanding any other provision of law, a person who was certified through a certification process recognized by the former Department of Health and Rehabilitative Services before January 1, 1995, may perform the duties of a qualified professional with respect to substance abuse treatment services as defined in this chapter, and need not meet the certification requirements contained in s. 397.311(35) s. 397.311(34).

Section 11. Paragraphs (d) and (g) of subsection (1) of section 440.102, Florida Statutes, are amended to read:
440.102 Drug-free workplace program requirements.—

The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(1) DEFINITIONS.—Except where the context otherwise requires, as used in this act:

(d) "Drug rehabilitation program" means a service provider, established pursuant to s. 397.311(44) s. 397.311(43), that provides confidential, timely, and expert identification, assessment, and resolution of employee drug abuse.

(g) "Employee assistance program" means an established program capable of providing expert assessment of employee personal concerns; confidential and timely identification services with regard to employee drug abuse; referrals of employees for appropriate diagnosis, treatment, and assistance; and followup services for employees who participate in the program or require monitoring after returning to work. If, in addition to the above activities, an employee assistance program provides diagnostic and treatment services, these services shall in all cases be provided by service providers pursuant to s. 397.311(44) s. 397.311(43).

Section 12. This act shall take effect July 1, 2019.
381.0038: Education; sterile needle and syringe exchange pilot program

(4) The University of Miami and its affiliates may establish single sterile needle and syringe exchange pilot programs. The pilot programs may operate at a fixed location or through a mobile health unit. The pilot programs shall offer the free exchange of clean, unused needles and hypodermic syringes for used needles and hypodermic syringes as a means to prevent the transmission of HIV, AIDS, viral hepatitis, or other blood-borne diseases among intravenous drug users and their sexual partners and offspring.

(e) County or municipal funds may be used to operate these pilot programs. The pilot programs may be funded through grants and donations from private resources and funds.

(f) The pilot programs shall expire July 1, 2021.
FARR Certification Overview

FARR 2018
Step 1 & 2 – Application & Payment

- Organizational Information
- Owners, Managers, Staff Contact
- Locations
- Certification & Compliance Agreement
Step 3 – Level II Backgrounds per 397.487

- Owners
- Directors
- CFO
- CRRA’s

FCB
Step 4 – Documentation Review

- 4 Domains = 37 NARR Standards
- 169 “as evidenced by” Sub-Standards
- 37 Ethical Codes
- 8 Additional Requirements required by 397.487 not covered by NARR Standards
- 52 STANDARD Compliance Documentation Requirements
- 450 STANDARD Documentation Review Questions
- 165 STANDARD Onsite Assessment Questions
- 9 Special Assessment Domains
### Example 4 – Medication Storage & Usage Protocol

<table>
<thead>
<tr>
<th>Question</th>
<th>Compliant</th>
<th>Non-Compliant</th>
<th>NP/NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the procedure include where medications are to be stored, with a minimum an &quot;out of sight&quot; policy? (both prescribed as well as OTC)</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does procedure include how residents can access their medications? (if held by staff) (both prescribed as well as OTC)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does procedure include an observation protocol as opposed to an administration protocol? (if held by staff)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does procedure include documentation of observation? (if held by staff)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Does policy include a complete list of prohibited medications? (both prescribed as well as OTC)</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is procedure inclusive of all levels of care operated by the provider? (if multiple levels exist)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Example – Medication Storage & Usage Protocol

<table>
<thead>
<tr>
<th>Question</th>
<th>Compliant</th>
<th>Non-Compliant</th>
<th>NP/NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the procedure make sense for the type of structure, level of care, staffing plan, and priority population served?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the procedure include what happens to resident medications in the event of a relapse, discharge, and/or AMA.</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is the procedure staff directed instead of resident directed?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
### Example – Medication Storage & Usage **Consent**

<table>
<thead>
<tr>
<th>Question</th>
<th>Compliant</th>
<th>Non-Compliant</th>
<th>NP/NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the policy include a safe storage requirement that at minimum includes an &quot;out of sight&quot; policy?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy include the process for reporting and having new medications (prescribed and OTC) approved by management?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy include how residents can access their medications if staff held?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy include what happens to medications if the resident is discharged/ transferred/or abandons property?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy include capturing resident consent?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is the policy inclusive of all levels of care operated by the provider? (if multiple levels exist)</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the policy make sense for the type of structure, level of care, staffing plan, and priority population served?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Example 4 – Medication Storage & Usage Policy & Procedure

2. All medications prescribed to a client will be documented in the resident file.
3. Lock boxes will be available for residents to store and secure their medication and/or any medication supplies, such as syringes.

Per Medication Storage & Usage:
• Your protocol states residents are responsible for handling and storage of medications but that staff administers medications. Are you stating that residents have to track down staff in order to take meds?
• Please provide licenses/credentials maintained by BHTs that would allow them to administer medications.
• Please include how OTC meds are approved and handled.
• Please include a list of prohibited medications.
• Please clarify, you are applying for Level II certification but employ BHTs and medical staff? Are residents enrolled in a clinical program?
• Policy states there is no onsite storage. Are you stating medications must be stored offsite?

Medication Storage and Usage protocol lists terminology and staff associated with a clinical program. Procedure states residents are to hold/store their medications but then states medications are administered by staff and logged on MORS in KIPU.
Step 5 – Onsite Assessment

- Pre-Screening
- Orientation
- Administration
- Staff Knowledge
- Property
- Resident Interview
Step 6 – Ongoing Compliance

- FARR Staff Trainings
- Annual Renewals
- Audits
397.410 Licensure Requirements; minimum standards;

rules.-

(5) (a) On or before the first day services are provided to a client, a licensee must inform the client and his or her immediate family or representative, if appropriate, of the right to report:

1. Complaints. The statewide toll-free telephone number for reporting complaints to the department must be provided to clients in a manner that is clearly legible and must include the words: “To report a complaint regarding the services you receive, please call toll-free (phone number).”

2. Abusive, neglectful, or exploitative practices. The statewide toll-free telephone number for the central abuse hotline must be provided to clients in a manner that is clearly legible and must include the words: “To report abuse, neglect, or exploitation, please call toll-free (phone number).”

3. Insurance fraud. An agency-written description of insurance fraud and the statewide toll-free telephone number for the central fraud hotline must be provided to clients in a manner that is clearly legible and must include the words:
“To report suspected insurance fraud, please call toll-free (phone number).”

The agency shall publish a minimum of a 90-day advance notice of a change in the toll-free telephone numbers.

(b) Each licensee shall establish appropriate policies and procedures for providing such notice to clients.

(6) Providers licensed pursuant to this chapter shall display a sign in a conspicuous location within the facility readily visible to all patients indicating that, pursuant to s. 626.9892, the Department of Financial Services may pay rewards of up to $25,000 to persons providing information leading to the arrest and conviction of persons committing crimes investigated by the Division of Investigative and Forensic Services arising from violations of s. 440.105, s. 624.15, s. 626.9541, s. 626.989, or s. 817.234. An authorized employee of the Division of Investigative and Forensic Services may make unannounced inspections of a facility licensed under this part a facility shall allow full and complete access to the premises to such authorized employee of the division who makes an inspection to determine compliance with this subsection.

CODING: Words stricken are deletions; words underlined are additions.
397.487 Voluntary certification of recovery residences.

(3) A credentialing entity shall require the recovery residence to submit the following documents with the completed application and fee:

(a) A policy and procedures manual containing:

1. Job descriptions for all staff positions.

2. Drug-testing procedures and requirements for all persons who are expected to, or whose responsibilities may require him or her to, provide personal care or services to or have direct contact with clients or have access to client funds, personal property, or living areas.

(11) The State Fire Marshal shall, in cooperation with the department and the credentialing entities approved by the department, establish and enforce minimum firesafety standards for recovery residences, which standards must be included in the rules adopted by the Department of Financial Services, Division of State Fire Marshal. The use of a structure as a recovery residence, standing alone, shall not be deemed a conversion of use requiring heightened life safety standards including but not limited to fire sprinkler protection.
(12) The credentialing entity shall develop a poster to be publicly displayed in a conspicuous location in a recovery residence containing the names, addresses, and telephone numbers for the credentialing entity’s abuse hotline, the department’s abuse hotline, the Advocacy Center for Persons with Disabilities, the Florida Statewide Advocacy Council, and the local police department, with a clear description of the assistance to be expected from each.
633.206 Uniform firesafety standards— The Legislature hereby determines that to protect the public health, safety, and welfare it is necessary to provide for firesafety standards governing the construction and utilization of certain buildings and structures. The Legislature further determines that certain buildings or structures, due to their specialized use or to the special characteristics of the person utilizing or occupying these buildings or structures, should be subject to firesafety standards reflecting these special needs as may be appropriate.

(1) The department shall establish uniform firesafety standards that apply to:

(a) All new, existing, and proposed state-owned and state-leased buildings.

(b) All new, existing, and proposed hospitals, nursing homes, assisted living facilities, adult family-care homes, recovery residences, correctional facilities, public schools, transient public lodging establishments, public food service establishments, elevators, migrant labor camps, mobile home parks, lodging parks, recreational vehicle parks, recreational camps, residential and nonresidential child care facilities, facilities for the developmentally disabled, motion picture...
27 and television special effects productions, 
28 tunnels, and self-service gasoline stations, of 
29 which standards the State Fire Marshal is the final 
30 administrative interpreting authority.
200 a Day Now Dying of Overdose. Chris Christie’s New Jersey Had Nation’s Second Worst Hike in Deaths

By ROGER PARLOFF|June 15, 2018

Quick Takeaway

- Latest CDC data show 72,855 dying of drug overdose in the 12 months ending Nov. 2017.
- 49,466 died of overdoses involving an opioid during that period.
- New Jersey showed a 33 percent hike in drug overdose death—the nation's second worst.

According to the CDC’s latest statistics, about 200 Americans are now dying each day from drug overdoses—the first time the numbers have breached that benchmark. About 136 of the 200, or 68 percent, are dying of opioid overdoses.

The agency’s provisional data show that 72,855 people likely died of drug overdose during the 12-month period ending November 30, 2017—a rise of 13.2 percent over the previous 12-month period, ending November 30, 2016. The agency reports that 49,466 of those deaths involved at least one opioid.

The most commonly detected drugs in fatal overdose victims during this period were synthetic opioids—mainly illicit fentanyl and its chemical variations—which were found in 40 percent of all overdose victims and in 59 percent of all opioid-related deaths.

Fentanyl is 30 to 50 times more powerful than heroin, and some of its variations, or analogs, are stronger still. Fentanyl is often now laced into heroin or other drugs, without the user’s knowledge. Even those who seek out fentanyl may not be able to survive its unexpected strength, especially if they are relapsing after period of abstinence, and have lost their tolerance to opioids.

At least another 15,279 deaths during this period—21 percent of all drug deaths and 31 percent of all opioid fatalities—involved common prescription drugs, like hydrocodone and oxycodone. Though some people think the prescription opioid problem is subsiding, this figure still represents a 3 percent increase year-over-year. (The CDC’s categories are not mutually exclusive, and many overdose victims have multiple drugs in their system.)

The most recent finalized overdose death numbers from the Centers for Disease Control and Prevention are for calendar year 2016. They showed 63,632 deaths, of which 42,249 involved an opioid. The finalized figures for 2017 won’t be ready until December.
Last August, however, the CDC began releasing, after a six-month lag, monthly updates of provisional overdose death data relating to rolling 12-month periods. This data is incomplete and, therefore, “subject to change.” The “predicted” numbers described in this article are a mix of both hard data—69,948 reported deaths for the 12 months ending November 30, for instance—plus statistical adjustments reflecting past experience with the data still outstanding or under investigation.

The state with the most severe hike in overdose death rates, according to these numbers, was Nebraska, which experienced a 35.7 percent increase. But that jump may reflect, at least in part, that Nebraska had the country’s lowest overdose death rate to start with—just 6.4 per 100,000 people in 2016, compared to a national average of 19.8. (The worst statewide rate that year was West Virginia’s, at 52 per 100,000.) A spokesperson at the Nebraska Department of Health and Human Services did not respond to calls and an email seeking comment.

More troubling is the case of New Jersey, which endured the country’s second worst overdose fatality hike—a 33 percent year-over-year increase for the period ending November 30. (For the 12-month spans ending September 31 and October 31, New Jersey owned the nation’s worst increases, at 50 percent and 42 percent, respectively.)

New Jersey’s numbers are striking because few American political figures have been as associated with the fight against drugs as New Jersey’s then-governor, Chris Christie, who last year chaired the President’s Commission on Combating Drug Addiction and the Opioid Crisis. (Christie was succeeded as governor by Phil Murphy on January 16.) While campaigning for the presidency in November 2015, Christie revealed—in speeches whose videos later went viral—how he had been personally touched by the epidemic. He recounted how an admired law school classmate fatally overdosed on Percocet (oxycodone plus acetaminophen) and vodka. His administration later spent $42.6 million on television commercials, in which Christie himself appeared, urging residents to seek help for addiction.

Christie did not respond to inquiries left with his spokesperson.

Four experts interviewed by Opioid Watch identify the rising influx of fentanyl into the New Jersey as the key factor in the increase, rather than any glaring failure on Christie’s or New Jersey’s part.

Lewis Nelson, chair of the medical toxicology division at the Rutgers New Jersey Medical School, observes in an interview that fentanyl can be flown, shipped, or mailed into the state in many ways, including the Port of Newark and the Newark, New York, and Philadelphia airports.

“We’re so close to the source,” he says, “the purity is greater, so the concentration is higher”—i.e., more dangerous. “The further you go down the chain of distribution, the more it gets diluted.”

Frank Greenagel, Jr., who headed a New Jersey task force on heroin and opiate use in 2014, also focused on fentanyl, but with a slight twist. He says the recent numbers may reflect that fentanyl was actually a little slower to reach New Jersey than in some other northeastern states—and now
it’s finally catching up with a vengeance. “Now the wave is cresting,” says Greenagel, an adjunct professor at the Rutgers School of Social Work.

New Jersey has severe pockets of poverty that have had heroin problems for years, especially in Camden, Newark, and Paterson, and where fentanyl is now elevating death rates.

“I do think that deep down he did care,” Nelson said of former Gov. Christie. “But the problem he cared about was prescription opioid-related death, which is a middle-class problem. The population really dying at a much higher rate is the illicit users.”

The neighboring states of Delaware and Pennsylvania experienced the third and fourth worst overdose fatality hikes in the country: 29.4 percent and 27 percent, respectively, with Pennsylvania being tied with Indiana.

Eight states showed reductions in overdose death, though most of them—like Wyoming, which had the largest drop, at 26.3 percent—had relatively low statewide death rates to start with. The only hard-hit, northeastern state to show a reduction was Rhode Island, with a 4 percent drop. (We’ve written about some reasons why.) The other states with decreasing death rates were Utah, Minnesota, North Dakota, Idaho, Kansas, and Mississippi.

The CDC’s data for the latest 12-month period are summarized below.

<table>
<thead>
<tr>
<th>Drug Present</th>
<th># of ODs</th>
<th>% opioid ODs</th>
<th>% drug ODs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Drug</td>
<td>72,855</td>
<td>—</td>
<td>100%</td>
</tr>
<tr>
<td>Any Opioid</td>
<td>49,466</td>
<td>100%</td>
<td>68%</td>
</tr>
<tr>
<td>Synthetic opioid (e.g., illicit fentanyl)</td>
<td>29,293</td>
<td>59%</td>
<td>40%</td>
</tr>
<tr>
<td>Heroin (an opioid)</td>
<td>16,240</td>
<td>33%</td>
<td>22%</td>
</tr>
<tr>
<td>Natural or Semi-Synthetic opioid (e.g. oxycodone, hydrocodone, etc.)</td>
<td>15,279</td>
<td>31%</td>
<td>21%</td>
</tr>
<tr>
<td>Cocaine</td>
<td>14,263</td>
<td>—</td>
<td>20%</td>
</tr>
<tr>
<td>Psychostimulant (e.g., meth)</td>
<td>10,643</td>
<td>—</td>
<td>15%</td>
</tr>
<tr>
<td>Methadone (an opioid)</td>
<td>3,299</td>
<td>7%</td>
<td>5%</td>
</tr>
</tbody>
</table>
A representative of the addiction treatment industry on Tuesday urged a key House panel to consider policies to crack down on patient-brokering—a complicated, fraudulent practice stemming from the opioid epidemic that insurance companies have been navigating for the past few years.

Patient-brokering has become prevalent enough that Marvin Ventrell, executive director of the National Association of Addiction Treatment Providers, told the House Energy and Commerce oversight subcommittee that his organization adopted ethics rules in late 2017 to ban any of its members from taking part.

"First and foremost [in the new ethics rules] is patient brokering: under no circumstances should a provider buy or sell leads," Vantrell said. "It is now prohibited by our code."

The issue has nabbed headlines for months now. It involves a third party, often a treatment center that may not meet adequate care standards, paying a recruiter to fraudulently enroll an addicted patient in a flexible Obamacare individual market plan offering out-of-state coverage. Then the patient heads out to a treatment center, likely in a desirable locale like Florida, Southern California or Arizona, that may or may not offer adequate care. If the fraud is discovered and can be proven to the CMS, the agency rescinds coverage and the patient is expelled from the treatment center.
Ventrell blamed the widespread nature of the fraud on lack of clarity within current law. "The law has been confusing and sometimes nonexistent, state by state," he told lawmakers. "I would support a federal law. There needs to be a federal law in that regard."

It is unclear how much money the fraud has cost insurers. Industry representatives who spoke with Modern Healthcare shied away from quantifying how many of these fraud cases they have seen over the past few years and declined to say whether that number is ticking up or down. But one consultant who works with insurance companies on the issue said claims filed for these fraudulent plans can rise upwards of $100,000.

In June, the Justice Department arrested addiction treatment center operators who had filed more than $106 million in fraudulent insurance claims related to the scheme.

But insurers concede that a legislative push would be complicated because patient-brokering schemes span different states' regulatory and licensing issues while also touching on the CMS' overarching role in managing the federally facilitated marketplace for some states' Obamacare exchanges.

First, the states have explicit authority to license treatment facilities. So Kim Holland, who focuses on state issues for Blue Cross and Blue Shield Association, said she plans to focus lobbying efforts on strict licensing standards when state legislative sessions resume early next year.

"It's the state's responsibility to license facilities," she told Modern Healthcare "It's state legislatures that create the opportunities, so where we want to focus attention is to help states with more robust licensing and oversight for any substance use disorder facility."

The role Obamacare individual market plans play in the fraud add another layer of complexity. For one thing, third parties are allowed to pay for part or all of an enrollee's premiums — a practice that facilitates patient-brokering. For another, the CMS manages many state Obamacare markets and is ultimately responsible for rescinding or preempting the fraudulent enrollments in those states.

Rachel Jones, a financial investigations official with Pittsburgh-based Highmark Blue Cross and Blue Shield, said that although body brokering has been happening for years there are still few controls in place to catch fraudulent enrollments before the plans have been approved unless the body broker is a repeat offender who has already been flagged.
Jones said the CMS is trying to tighten up-front verification of applicants during the special enrollment periods. This is when the fraudulent brokers are more likely to strike citing a major life change like a permanent move, and then setting up a false address that may lead to a vacant lot or a house listed for sale. Highmark also hired a vendor to try to capture likely fraudulent addresses as soon as possible. But that takes time: it involves finding the person who is supposedly signing up for an exchange plan and seeking proofs of identity after a fraudulent broker has used a false address.

"A lot of times when we try to reach out we don't hear back," Jones said. "It's hard to track down the people at the time of enrollment."

Once Highmark concludes that a plan is fraudulent, the company then has to prove it to the CMS so that the plan can be rescinded. Before the CMS can remove a person from the insurer's rolls, Highmark must fully document the fraud and hand over supporting documents that essentially audit the request.

Jones declined to give a typical time frame for how long this rescission can take, but said the cases her division is working on "aren't necessarily present day." A consultant who works extensively with plans on the issue said the process can drag on for months. Michael Adelberg, a former CMS official who now works as a consultant with the Washington firm Faegre Baker Daniels, said the "common appraisal from the qualified health plans is that this process is not yet very efficient or transparent."

Patient brokering has become a major rallying point for insurers. For Tuesday's hearing, America's Health Insurance Plans (AHIP) submitted a statement for the record that reiterated the industry push for policy to deal what the group calls a "serious, potentially widespread issue that needs to be addressed with serious solutions."

"These fraudulent, abusive practices not only put patients' lives in grave danger, but they also make it more difficult for people to afford their coverage and care," AHIP said. "These practices raise overall health system costs and increase premiums for everyone, not just those who are sent to 'sober homes.'"

Some states are discussing policies that could mitigate the practice. California's legislature, whose legislative session runs through August, is currently considering a measure to curb third-party payments.

The bill, introduced by State Sen. Connie Leyva (D), would limit use of third-party payments specifically for substance use treatment facilities and dialysis clinics. The measure faces a hefty lobbying battle with the dialysis industry, where third-party
"If facilities have financial gain in getting the patient insured, they shouldn't be the person paying the premiums, and it is through that some of the third-party payments that we're seeing people encouraged and enticed into facilities," Holland said.

But, she noted, the issue of patient brokering is complicated, particularly because it falls within the overarching crisis of widespread opioid use, and there is no easy answer.

"It's an imperfect system that we're working to remedy," Holland said.

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Susannah Luthi
Susannah Luthi covers health policy and politics in Congress for Modern Healthcare. Most recently, Luthi covered health reform and the Affordable Care Act exchanges for Inside Health Policy. She returned to journalism from a stint abroad exporting vanilla in Polynesia. She has a bachelor’s degree in Classics and journalism from Hillsdale College in Michigan and a master’s in professional writing from the University of Southern California.
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§8.12 Federal opioid treatment standards.

(a) General. OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) Administrative and organizational structure. An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid use disorder which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) Continuous quality improvement. (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current “Diversion Control Plan” or “DCP” as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) Staff credentials. Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.
(e) **Patient admission criteria**—(1) **Maintenance treatment.** An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) **Maintenance treatment for persons under age 18.** A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) **Maintenance treatment admission exceptions.** If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) **Detoxification treatment.** An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) **Required services**—(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) **Initial medical examination services.** OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) **Special services for pregnant patients.** OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific
services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) Recordkeeping and patient confidentiality. (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid use disorder. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program
physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) Medication administration, dispensing, and use. (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid use disorder. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid use disorder:

(i) Methadone;

(ii) Levomethadyl acetate (LAAM); and

(iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid use disorder.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose,
frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) Unsupervised or “take-home” use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, e.g., drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(iii) of this section.

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are two doses per week.
(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.)).

(j) Interim maintenance treatment. (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of §8.11(g).
(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or “take-home” use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

GLOBAL OPIOID EPIDEMIC: DOOMED TO FAIL WITHOUT GENETICALLY BASED PRECISION ADDICTION MEDICINE (PAM™): LESSONS LEARNED FROM AMERICA

Kenneth Blum*,1,2,3,4,5,6,7,8,9,10, Edward J. Modestino11, Marjorie C. Gondré-Lewis12, Jennifer Neary6, David Siwicki6, Mary Hauser4, Debmalya Barh7, Bruce Steinberg11, and Rajendra D. Badgaiyan13

1Department of Psychiatry, University of Florida & McKnight Brain Institute, College of Florida, Gainesville, FL, USA
2Department of Psychiatry, Human Integrated Services Unit University of Vermont Center for Clinical & Translational Science, College of Medicine, Burlington, VT, USA
3Department of Clinical Neurology, Path Research Foundation, NY, NY, USA
4Dominion Diagnostics, LLC, North Kingstown, RI, USA
5Department of Psychiatry, Wright State University, Boonshoft School of Medicine, Dayton, OH USA
6Division of Genetic Testing, Geneus Health LLC, San Antonio, Texas, USA
7Center for Genomics and Applied Gene Technology, Institute of Integrative Omics and Applied Biotechnology (IIOAB), Nonakuri, Purba Medinipur, West Bengal, India
8Institute of Psychology, Eötvös Loránd University Budapest, Hungary
9Department of Psychiatry, University of Southern California, Keck School of Medicine, Los Angeles, CA, USA
10Division of Neuroscience Based Addiction Research and Therapy, The Shores Treatment & Recovery Center, Port t. Lucie, FL, USA
11Department of Psychology, Curry College, Milton, MA, USA
12Departments of Anatomy, Psychiatry & Behavioral Sciences, Howard University, Washington, DC, USA

*Corresponding author: drd2gene@gmail.com, Tel.: +1 352-392-6680, Fax: +1 352-392-8217.

CONFLICT OF INTEREST
Kenneth Blum, PhD owns stock in RDSS LLC, Synaptamine, INC, Igene LLC, Geneus Health, LLC, and RestoreGen, LLC. Synaptamine is the exclusive distributor worldwide of patents related to Reward Deficiency Syndrome (RDS). Dr. Blum is the Chief Scientific Advisor for Dominion Diagnostics. Blum, Modestino, Steinberg, Neary, Gondre-Lewis, Barh, Badgaiyan, Siwicki, and Hauser are on the Scientific Advisory Board of Geneus Health, LLC. There are no other competing interests to declare.

FINANCIAL DISCLOSURE
Drs Kenneth Blum PhD and Marjorie C. Gondré-Lewis are recipients of R41 MD012318/MD/NIMHD NIH HHS/United States and MGL is the recipient of R01 AA021262/NIAAA NIH HHS/United States. Rajendra D. Badgaiyan is supported by the National Institutes of Health grants www.ncbi.nlm.nih.gov/1R01NS073884.
Abstract

It is a reality that globally opioid deaths have soared for men and women of all social, economic status and age from heroin and fentanyl overdoses. Specifically, in the United States, deaths from narcotic overdoses have reached alarming metrics since 2010. In fact, the Fentanyl rise is driven by drug dealers who sell it as heroin or who use it to lace cocaine or to make illegal counterfeit prescription opioids. The President’s Commission on the crisis has linked the death toll as equivalent to “September 11th every three weeks.” In fact, The U.S. Centre for Disease Control (CDC) released data showing that opioid-related overdoses were up 15% in the first three quarters of 2016 compared to 2015. Various governmental organizations including NIDA, are actively seeking solutions. However, we argue that unless the scientific community embraces genetic addiction risk coupled with potential precision or personalized medicine to induce “dopamine homeostasis” it will fail. We now have evidence that a ten-gene and eleven single nucleotide polymorphism (SNP) panel predicts Addiction Severity Index (ASI) for both alcohol and drugs of abuse (e.g., Opioids). In a large multi-addiction centre study involving seven diverse treatment programs, the genetic addiction risk score (GARS™) was shown to have a predictive relationship with ASI–MV derived alcohol (≥ seven alleles), and other drugs (≥ 4 alleles) severity risk scores. In a number of neuroimaging studies, we also display that in both animal (bench) and abstinent Chinese severe heroin-dependent patients (bedside), BOLD dopamine activation across the brain reward circuitry revealed increases in resting state functional connectivity as well volume connectivity. It is also known that published nutrigenomic (coupling gene polymorphisms with altered KB220z) studies reveal improved clinical outcomes related to obesity.

Keywords
addiction; dependence; Genetic Addiction Risk Score™; heroin; opioid epidemic

INTRODUCTION

Drug, alcohol and other addiction rehabilitation in the United States was a $35 billion business in 2015. There are over 14,500 treatment facilities and growing. A total of 2.5 million patients received treatment, but much more need it and many facilities are at capacity. Additionally, insurance coverage for rehabilitation is limited. As a result, most of the bill is paid by government/state agencies or out of pocket by the patients. High-end establishments have emerged for the higher income population, and new nooks are developing in areas such as: problem gamblers, sex addiction, nicotine addiction and Internet addiction. Facilities are also diversifying into treating people with anxiety disorders, eating disorders, and posttraumatic stress.

Addiction concerns

Often, the greatest fear for a parent is that their children might become addicted to drugs and/or alcohol. According to a survey by Parent.co, which included 1500 participants, fear...
of drug and alcohol addiction vastly outweighed concerns about terrorism, economic
collapse, crime, and war. Most Americans have first-hand experience with someone
struggling with addictions.

- 44% of Americans know someone with a history of painkiller addiction, CNBC
  reports.
- 20% claimed it was one of their family members.
- 24.6 million Americans abused drugs.
- This is equivalent to 9.4% of the U.S. population (up from 8.3% in 2002).
- Essentially, this is equivalent to the population of Texas.

Nationwide American trends

Annual surveys conducted by the Substance Abuse and Mental Health Services
Administration (SAMHSA) reveal that drug abuse is increasing in America. The participants
in the National Survey on Drug Use and Health, those who are 12 years and older, provided
critical commentary on the use and abuse of various substances. This included information
for different periods, such as weekly, monthly, and even lifetime use of alcohol and drugs.

According to the 2013 survey results:

- 23.5 million U.S. citizens are addicted to alcohol and drugs.
- Marijuana accounts for the majority of this increase as 19.8 million Americans
disclosed to using it in 2013. This is an increase from 14.5 million in 2007.
- Marijuana, after alcohol, accounts for the increased rates of dependence (4.2
  million in clinical trials for treatment of abuse)
- 1.9 million people fulfilled the criteria for dependence on painkillers and 855k
  met the criteria for cocaine.
- Methamphetamine use and abuse increased to 595k in 2013 (up from 353k in
  2010).
- Cocaine, however, is currently trending downwards, from 2.4 million reported
  uses from 2002 to 2007, down to 1.4 million uses in 2013.

Emerging trends in opiate addiction

The nature of heroin addiction in the America has transformed over recent decades.
Relocating from urban areas to the more suburban, from lower incomes to that of more
affluent neighbourhoods, the portrait of a heroin addict progressed from poor, urban, black
and male users and transformed to predominantly Caucasian addicts of whom half are
females.

According to Dr. Theodore Cicero (Washington University in St Louis), first-time users of
heroin tend to be in their mid-20s. In decades past, first-time users tended to be around age
16. Between 2007 and 2013, heroin use has increased dramatically, from 370,000 to 680,000
users [1].
Similar to illicit substance abuse, the patterns observed in the market for prescription painkillers like oxycodone addiction have skyrocketed in recent years. In the 1990s, there was an increase in the accessibility of prescription painkillers. This culminated in a crest of addiction, which surpassed the combined use of illicit substances (i.e., LSD, methamphetamines, ecstasy, and cocaine). In 2012, the mortality was 16 thousand deaths due to painkillers and thus, clinicians, regulatory agencies, government and other professionals have been working to counter the excessive use of prescription painkillers. For example, oxycodone is now being produced so that it cannot be easily crushed to allow for dissolving for injection or even snorting [2].

Foreign illicit drug markets are responding to the increased demand for heroin in the U.S. Mexico is the main supplier of heroin to the U.S., as it is cheaper than sources from Columbia or Asia. The legalization of marijuana in the U.S., has resulted in a significant decrease in demand from illegal foreign sources. This market was quickly replaced by opium and opium compounds from Mexico. Additionally, user preferences for brown heroin, which is more readily snorted and smoked, surpassing the use of injectable drugs which are more widely used and potentially less fatal, is well known on the street [3]. However, the Opiate/opioid epidemic is a world-wide problem, with European, Middle Eastern and Asian countries reporting significant uptick in overdoses and overdose deaths. The reasons for this is not easily explained.

Addiction and overdose

In 2016, the NY Times noted that the U.S. had seen significantly increased overdoses leading to death, from heroin and prescription medications. Overdose mortality rates are comparable to those caused by HIV in the 1980s-1990s. Unlike HIV mortality, overdose-related deaths are not localized to just cities but everywhere. Specific regions and states have been experiencing the impact of opiate overdoses more acutely than others. Based on information from the Centre for Disease Control (CDC) [4], the Southwest regional U.S. and Appalachia (specifically in West Virginia) tend to be the most affected. In the Appalachia region, overdose mortality is primarily due to prescription painkillers often prescribed to blue-collar workers, initially to treat chronic pain resulting from job-related injuries. Due to laws put in place to prevent abuse of such prescription medications, many have turned to illicit substances like heroin for relief. Subsequently, this has led to addiction.

With inadequate resources available to provide services and addiction-related treatment, the increases overdose mortality has soared. State by state discrepancies in access to treatment and expenditures for such treatment also is becoming more apparent. For example, in New Hampshire (N.H.), an overdose of opiates, mostly connected to fentanyl, caused 326 deaths in 2014 [5]. N.H. allocated less funding per capita than all other states (excluding Texas) in providing the desperately needed treatment services. In New Mexico, heroin overdose deaths has persisted since the 1990s, where it is often considered akin to a hereditary disease. According to Jennifer Weiss-Burke, the executive director of the non-profit organization, Healing Addiction in Our Community, heroin addiction is seemingly passed down through generations.
Furthermore, Ms. Weiss-Burke has noticed that the younger generations are often more difficult to treat. In fact, some are unwilling to get sober. These individuals vacillate between treatment centers and jail. This chronic situation is due to staying within the same environment, surrounded by the very same people. Almost more trouble is the rise of fentanyl abuse, for which a greater amount of Naloxone is necessary to resuscitate overdose victims versus that of a heroin overdose. Naloxone is also used to reverse other opioid drug overdoses, and it is not specific to fentanyl [6].

**Combating prescription medications and illicit heroin use in the US**

In March 2016, President Obama enunciated a multifaceted plan to enhance resources and treatment facilities and provided greater access to naloxone. The Obama administration appealed for $1.1 billion in the hopes of funding new measures aimed at reducing continued opioid overdose mortality. President Obama emphasized that the profile of heroin addiction has transmogrified with a socioeconomic shift and altered public opinions: specifically, heroin addiction is no longer an affliction of the urban poor nor due to presumed moral ineptitude, but rather affects every day folk - sons and daughters, aunts and uncles, and even grandparents residing in suburbia.

The FDA has increased warnings on immediate-release opioid prescription medications to warn patients about abuse, potential overdose, and complications. Previously, in 2013, the FDA relabelled thirty-four brands of extended-release medications. This latest change includes the relabelling of 288 medications. New CDC guidelines attempt to restrict the prescribing of opioids to cases in which no other option exists. Thus, these new warnings labels and guidelines will remain integral in combating opioid dependency and addiction [7].

**Understanding the role of genetic testing in addiction medicine**

Over 100 million Americans with addictive personalities have a genetic predisposition for addiction, which is called the Reward Deficiency Syndrome (RDS) [8–20]. They have a lower utilization level of the pleasure chemicals in the brain called neurotransmitters, known as “neurotransmitter deficits,” than those with normal counts. This puts them at a disadvantage and makes them prone to accidents, aberrant cravings, and drug-seeking behaviours, which overburdens the health care delivery system as a whole.

The etiology of drug addiction is highly complex. The primary consideration is how the patient is to be treated. These individuals are prescribed behavioral or psychiatric modification instead of being treated for the underlying medical condition. Drug addicts are relatively easy to detoxify with careful professional oversight and management [21]. However, to prevent drug relapse and the intense psychological cravings are another matter. Most drug-seeking behaviours originate in the dopaminergic centres of the mesolimbic brain.

These pathways are responsible for the feelings of pleasure and a sense of well-being. Any deficits or decrease in the dopaminergic system will lead to a loss of pleasure and eventually lead to drug-seeking or high-risk behaviours [22]. Our laboratory now documented, and it is widely known and accepted, that there is a genetic relationship between RDS and the dopaminergic system. The RDS is based on deficits in the ‘brain reward cascade’ and
originates primarily from a relatively common genetic deficiency in the dopamine D2 receptors and other genes. A genetically-dependent decline in the number of receptors for neurotransmitters will lessen or attenuate the neurological reward/pleasure signal to the affected target organs, known as “dopamine resistance.” The dopamine resistance creates a lower sense of well-being. DNA gene testing can identify these individuals who carry the affected Reward Deficiency Genes [23].

Can we predict risk using genetic testing?

Various alleles in the P450 system are currently utilized in pain medicine clinics to evaluate metabolic concerns to help identify high and low metabolizers.

Genetic Addiction Risk Score™

Molecular genetic or DNA testing is critical for examining the genetic link of aberrant behaviours to specific individual. Blum’s laboratory proposed [24] that disturbances along the brain reward cascade may be due to gene variations (polymorphisms) and/or environment (epigenetics) resulting in aberrant-addictive behaviours or Reward Deficiency Syndrome (RDS). In spite of a global genome-wide search to divulge candidate or specific genes, or even clusters of genes, it is well-known that many attempts have either not replicated or have been inconclusive. However, Palmer et al. [25] recently showed that between 25–36% of the genetic variance in vulnerability to substance dependence/abuse might be attributable to relatively common single-nucleotide polymorphisms (SNPs). Additionally, the additive effect of common SNPs may be shared across comorbid drug dependency/addiction. Finally, recent evidence has revealed that specific candidate gene variants account for risk prediction.

Adopting a Bayesian approach, earlier studies from Blum’s laboratory divulged a Positive Predictive Value (PPV) of 74% specifically for the DRD2 A1 variant associated with a lower amount of D2 receptors. A newborn with this polymorphism is at substantially higher risk of becoming addicted to either drug, food, or aberrant behaviours at some point in his/her future [26, 27]. Since this finding in 1990 by Blum and Noble of the association of the DRD2 A1 variant and severe alcoholism, various laboratories and research centres across the globe, including those associated with or funded by NIDA and NIAAA, not only have confirmed this finding [9], but have extended the magnitude of candidate genes and second messengers located in the reward circuitry of the brain [28].

Examples include Moeller et al. [29], who suggested drug-cues substantially contribute to relapse. Neurogenetic results have revealed the DAT1 9R-allele as a vulnerability allele for potential relapse, especially during early abstinence (e.g., detoxification) in treatment. The DAT1 9 allele impacts the fast acting reuptake-transport of dopamine sequestered from the synapse leading to a hypodopaminergic trait.

It seems shrewd to utilize genetic testing to reveal reward circuitry gene polymorphisms, especially those related to dopaminergic pathways, as well as the opioid receptors, with the intention of improving treatment outcome. It is imperative to understand the interaction of reward circuitry’s involvement in buprenorphine treatment effects and their respective
genotypes to provide a novel framework to augment a patient’s clinical experience and benefits during opioid replacement therapy [30].

Our laboratory is developing a genetic risk score that represents a panel of known reward genes and associated risk polymorphisms providing the genetic risk for addiction and other behaviours including medical monitoring and clinical outcome response.

**Pharmacogenomics – Precision addiction medicine (PAM™)**

Blum and Kozlowski have published on the “Brain Reward Cascade” (BRC) [31]. This concept served as a blueprint for how neurotransmitters interact in the reward system of the brain. Also, it has been firmly established that reward-related genes that regulate chemical messengers mediate the quantity of dopamine released into the reward circuit and in other regions of the brain. Moreover, it is well established that resting-state functional connectivity integrity is essential for healthy homeostatic functioning. Zhang et al. [32] recently revealed that in heroin addicts there was a significant reduction of connectivity between the rostral anterior cingulate (rACC) and the dorsal anterior cingulate cortex (dACC), as well as reduced connectivity between the dACC and subcallosal (sACC). These findings of variations in the functional connectivity within three sub regions of the ACC within heroin addicts has implied that these sub regions, together with crucial other brain areas (such as the putamen, dorsal striatum, orbital frontal cortex, dorsal striatum, cerebellum, amygdala, etc.) may play essential aspects in heroin addiction. More recently, in Blum’s laboratory, and along with Zhang’s group [33] in abstinent heroin addicts showed that KB220Z™ (Pro-Dopamine Regulator) a complex dopamine agonist, induced a significant increase in MRI BOLD activation within the caudate-accumbens-dopaminergic pathways compared to placebo following one-hour acute administration. Additionally, KB220Z™ also reduced resting-state activity in the cerebellum of abstinent heroin addicts in recovery. In the second tier of this pilot study, all ten abstinent heroin-dependent subjects, three brain regions of interest (ROIs) were observed to be significantly activated in resting state by KB220Z™ contrasted with placebo (p < 0.05). This increased functional connectivity was observed in a presumed network which encompassed the dACC, posterior cingulate, nucleus accumbens, medial frontal gyrus, occipital cortical areas, and cerebellum.

**SUMMARY**

The development of a polymorphic gene panel [34–43] has enabled customized (personalized) anti-obesity compounds [44] and now could provide personalized induction of “dopamine homeostasis.” This serves as the basis of futuristic personalized addiction medicine utilizing the Genetic Addiction Risk Score (GARS).

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**References**


### HIGHLIGHTS

- The opioid-addiction epidemic is a plague to modern society.
- Genetic Addiction Risk Score (GARS™), paired with potential precision or personalized medicine (i.e., nutrigenomics) to induce “dopamine homeostasis” is essential in treating addiction.
- The compounds KB220Z/KB220ZBR/KB220PAM™ (Pro-Dopamine Regulators) are complexes with known dopamine agonistic qualities that successfully mediates “dopamine homeostasis”.

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