Central Registry Frequently Asked Questions

Under the new regulation at 105 CMR 160.000, all Opioid Treatment Programs (OTPs) will be required to participate in a Central Registry database. The database will be operated by Lighthouse, which provides the same service to several other states. The Registry database will serve as both an electronic verification system and will include a disaster assistance module to ensure the uninterrupted delivery of medication in cases of emergency. The Central Registry will also allow for more efficient communication between BSAS and OTPs, as well as for more expedited data collection and reporting.

1. **What is the timeline for implementation of the Central Registry?**
   a. **Can implementation be extended in recognition of the significant time that it takes for provider organizations to sync reporting systems (often months)?**
   b. **Can questions be resolved prior to implementation expectations, because it is difficult to speak to clients about how data will be utilized before firm answers are received?**

Providers will be given 90 days to implement the Massachusetts Central Registry once the regulations are promulgated. BSAS encourages providers to begin implementing parts of the process they are comfortable with now. The expectation is that on the 91st day post-promulgation, all necessary preparation for the implementation of the Central Registry will be completed, (e.g., signed patient consents, training/onboarding of staff, etc.) and the full function of operations must be started. Through the process of working with Lighthouse towards implementation, many of the questions related to how data is used will be answered. If, after good faith efforts to comply with this timeframe have been made, a licensed OTP may request additional time through a regulatory waiver pursuant to 105 CMR 164.023 which the Department will review in the normal course.

2. **Will BSAS be receiving patient identifying information? This would depart from the data they currently receive through their data collection system.**

BSAS will receive patient identifying information from the Central Registry system. In the initial awarding of the contract, a Qualified Service Organization Agreement (QSOA) was signed between the Department and Lighthouse which includes stringent safeguards for all patient information. Additionally, the proposed Business Associate Agreement (BAA) / QSOA between providers and Lighthouse similarly includes requirements to protect all patient information in accordance with all applicable privacy laws.

3. **Who is responsible for ensuring security of data and who is responsible in the event of a data breach?**

Regarding the Central Registry database, Lighthouse is responsible for protecting all data collected by The Central Registry. The data is housed in a Tier 3 professional data center and is monitored 24/7 for intrusion attempts. All patient identifying information is encrypted at rest and in transit. The security protocols in place meet and exceed HIPAA, 42 CFR Part 2 and PHI security standards. With regard to site access, each clinic will determine staff access to their site. State rules cover the maintenance of protected data.

4. **Who sees what information?**
    a. **Are there different types of information requests?**
    b. **When an OTP enters a request, what will the provider see?**
    c. **Will law enforcement have access to data? Emergency Departments? Hospitals? DCF/Child Welfare? RMV? If so, under what circumstances?**

Each site has access to the data of its site and controls user access and can never see data collected about patients at another treatment facility. Specifically identified BSAS staff have access to data collected by all sites. No other entity will have the ability to access any data collected by The Central Registry unless consent is given and/or disclosure falls under an exemption of 42 CFR Part 2.

5. **Are there different types of information requests?**

Yes – the following types of information will be collected:
- Patient identifying information to perform dual enrollment verifications
- Supplemental information as defined by BSAS that helps classify patients, such as race and ethnicity
- Emergency contact information to ensure emergency notifications to patients in the event of disasters or clinic closures
- Medication information to allow patients to receive appropriate doses should their home clinic be forced to temporarily close for an emergency

6. **When an OTP enters a request, what will the provider see?**

A provider will enter 5 fields of information to identify a patient, including first name, last name, last four digits of SSN, gender, and birth date. The Central Registry will then search all sites in the Massachusetts Central Registry to determine if the new patient is in treatment. The provider will see one of 4 enrollment status responses including; New patient, Existing patient that has not been enrolled for treatment in the last 60 days, a patient who was discharged from an OTP in the last 60 days and the patient is currently enrolled in another OTP.

7. **How will data be handled for clients in bordering states?**

A system generated dual enrollment verification fax will be sent to treatment facilities in neighboring states with each new patient admission. If a bordering state participates in the Lighthouse system, that OTP will only have access to the patient's dosing information during a disaster as part of the disaster module. Currently New York is the only regional state which utilizes Light House.

8. **How will programs without EHRs be impacted by the Central Registry requirements?**

There are two places where providers that don't have an EHR will be impacted. The first will be on the initial setup of The Central Registry. Providers with an EHR will be able to create a file of all existing active patients and that file will be used to create all the patients for the site. A provider that does not have an EHR and does not have the ability to generate an Excel spreadsheet of their active patients will have to manually enter each patient into The Central Registry. The second place where providers that don't have an EHR will be impacted is on the maintenance of emergency dosing information. Providers that have an EHR that is compatible with The Central Registry will generate a file of dose changes on a

daily or weekly basis and upload the file. Providers that have no EHR will have to manually enter dose changes into The Central Registry on a weekly basis. In other states, this weekly maintenance is typically under an hour.

9. **How will the Registry interact with dosing computers, if at all?**

EHRs that are compatible with The Central Registry will generate a file that contains information about how to dose a patient each day for the following week. Depending on the EHR, the file will either be automatically uploaded to The Central Registry by the EHR, or clinic staff will have to log in to The Central Registry and click on the Upload process to manually upload the medication file. The Central Registry will use this information to tell another provider the dosage and medication for the presenting patient in the event that a patient's home site is forced to close for any reason.

10. **Who is responsible for "automating" data entry?**

Electronic/Automated Entry: Medication values in the Central Registry will be updated on a weekly basis, as a minimum standard. With a connection between the clinic EHR and our system, we receive updates on a daily basis, and thus this relieves clinic staff from updating the Central Registry. In current versions of Tower, Smart, Methasoft, and the most recent Netsmart application, this electronic connection is already built. The clinic simply has to validate that the patient identifying information matches between the two systems. To get this started, the clinic requests their vendor to automate the dosing data transfer.

Manual Entry: Clinics on the older version of virtually every clinic software platform including Samms will download a file from their clinic system and upload this file to the Central Registry. This typically takes the clinic staff 2-4 minutes a week to complete. In rare cases where there is no clinical EHR, the Lighthouse manual update process can be used. The time involved depends on the number of patients.

11. **Will there be any additional technology required for providers to comply?**

Other than a computer and an internet connection, there is no additional hardware or software required.

12. **What information will be required to be submitted to the Registry? How will BSAS ensure that providers utilize the Central Registry and all data collection requests?**

The revised patient consent form details the information that is required to be submitted to the Central Registry.

The Central Registry focuses on patient safety during emergencies. A patient photo is used for verification of identity if they are forced to dose at another OTP. A patient may not have identification in their possession, and by consenting to have their photo stored in the Central Registry they are making it easier to obtain emergency dosing. However, a patient may still seek emergency treatment without agreeing to store their photo. A patient may decline to provide their photographic image and still participate in the Central Registry.

BSAS can generate compliance reports from the Lighthouse Central Registry System. Additionally, through licensing inspections, BSAS will review Central Registry implementation and use.

13. **What happens when client does not provide consent?**

OTPs may not deny a patient access to treatment should the patient refuse enrollment in the Central Registry System; however BSAS hopes that all OTPs will encourage, through clinical conversations, participation in the Central Registry System by explaining all of the benefits of participation. These clinical conversations must be documented in the patient record.
All OTPs must create policies and procedures should a patient refuse consent to participate in the Central Registry System. OTPs must develop policies that ensure that the OTP tracks patients that choose not to participate in the Central Registry System. The OTP must issue protocols for dual enrollment verification, disaster response, and communication for those patients who will not receive the benefit of the Central Registry System disaster management response.

OTPs must document in each patient record that a patient did or did not consent to participate in the Central Registry System. If a patient refuses consent, the documentation must include evidence of orienting the patient on how to receive disaster response information and updates.

14. **Will BSAS/DPH cover additional costs related to implementing the Central Registry System, including the following?**
    a. **Implementation (weeks-months) for providers to sync reporting systems and fee for EHR to complete uploads to Lighthouse/automation of data entry**
    b. **Legal review costs**
    c. **Staff data input**

While BSAS cannot provide a blanket guarantee to cover all costs associated with implementation, BSAS is committed to ensuring that all reasonable costs within the framework as currently outlined and discussed will be covered.