

KATHY HOCHUL Governor MARY T. BASSETT, M.D., M.P.H. Acting Commissioner KRISTIN M. PROUD Acting Executive Deputy Commissioner

Date

December 13, 2021

DAL: Subject:

DAL #21-25 Class 3a Controlled Substance License Requirements

Dear Adult Care Facility Operators and Administrators:

The purpose of this correspondence is to remind adult care facilities of the basic requirements for Class 3a controlled substance licensure. A "Class 3A Institutional Dispenser, Limited" license is only available to an adult care facility ("ACF") with a certification for an additional service or services as specified on its operating certificate, and subject to the provisions of Title 18 of New York Codes, Rules and Regulations ("18 NYCRR") Part 487, 488 or 490. Such license is required before an ACF may take possession of a resident's prescribed controlled substance or may assist the resident with administration of a controlled substance medication.

An ACF must have a valid operating certificate issued by the New York State Department of Health ("Department") under an applicable regulatory subset. ACFs whose operating certificate is pending approval or was revoked or surrendered are ineligible for a Class 3a Institutional Dispenser, Limited license. An ACF with a valid operating certificate must determine if it is permitted within its regulatory confines to provide health-related services as defined in Public Health Law §2801(4)(b), and if so, the ACF must confirm that it indeed will provide such services and how, as detailed via policy and procedure available upon request of the Department of Health or its agents. ACFs must determine if they intend to take temporary possession of a resident's prescribed controlled substances pursuant to a prescription from an authorized prescriber, to be filled by a registered pharmacy. If the ACF will be taking temporary possession of a resident's prescribed controlled substances, then the ACF must determine which type of licensed healthcare provider, whose scope of practice allows for the administration of controlled substances, will administer, oversee the administration to, or oversee the resident's self-administration of the controlled substance medication.

The eligibility of certain ACFs, including Enriched Housing Programs, for a Class 3a license is as follows, with the applicable regulations for reference:

Enriched Housing Programs under 18 NYCRR §488.7, without additional certification, do <u>not</u> have the authority to retain an end user's prescribed controlled substance and are not entitled to a Class 3A license.

Adult Homes under 18 NYCRR §487.7, may retain an end-user's prescribed controlled substance and obtain a Class 3A license.

Enriched Housing Programs certified as **Assisted Living Residences (ALR)** may retain an end-user's prescribed controlled substance and obtain a Class 3A license. 18 NYCRR §1001.10(I), referring back to §487.7.

Enriched Housing Programs certified as **Enhanced Assisted Living Residences (EALR)** may retain an end-user's-controlled substance and obtain a Class 3A license. 18 NYCRR §1001.10(m) referring back to Assisted Living Residences.

Enriched Housing Programs certified as **Special Needs Assisted Living Residences (SNALR)** may retain an end-user's prescribed controlled substance and obtain a Class 3A license. 18 NYCRR §1001.10(n) referring back to Assisted Living Residences.

An ACF that believes it meets the above criteria may apply to the Department's Bureau of Narcotic Enforcement for Class 3a licensure prior to assuming possession of or administering any resident's prescribed controlled substances and must maintain such licensure so long as the ACF retains possession of or administers controlled substances. Controlled substance licensure is detailed online at: <u>https://health.ny.gov/professionals/narcotic/licensing_and_certification/</u>.

ACFs that are deemed ineligible for Class 3a licensure should develop policies and procedures to assist residents with individual safe retention, storage, and disposal practices of their controlled substances with careful consideration of diversion potential. These policies should include information on safe storage and proper disposal of discontinued controlled substances which may include, but not be limited to, disposal at an approved medication receptacle at their local pharmacy. ACFs must ensure that the storage of a resident's controlled substance allows the resident direct individual access to the resident's own controlled substance without also giving the resident access to the controlled substances of other residents, and vice-versa.

The Department strongly encourages ACF administrators and operators to review applicable resident services regulations at 18 NYCRR §§ 487.7, 488.7, and 490.7 to self -assess the ACF's eligibility for Class 3a licensure before applying. ACFs found to possess a resident's controlled substance without a current controlled substance license, are subject to enforcement action as appropriate.

Thank you for your consideration and cooperation. Questions regarding this correspondence should be referred as follows:

Class 3a licensure, eligibility, status: <u>bnelicensing@health.ny.gov;</u> ACF policy, surveillance: <u>acfinfo@health.ny.gov;</u> ACF licensure status: <u>acfcon@health.ny.gov</u>.

Sincerely,

Joshua Vinciguerra, Director Bureau of Narcotic Enforcement New York State Department of Health

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