

September 14, 2022

The Honorable Kathleen Hochul
Governor of New York State
Executive Chamber
New York State Capitol Building
Albany, NY 12224

RE: A.3040-B/S.4870-B Chapter Amendment Request

Dear Governor Hochul,

As a Coalition, we are writing to request your consideration of chapter amendments to A.3040-B (McDonald)/S.4870-B (Breslin), which authorizes pharmacists to administer long-acting injectable (LAI) medications for the treatment of mental health conditions and substance use disorders (SUD). Our Coalition strongly supported the original bill, A.3040/S.4870-A, and we are incredibly grateful to Assemblymember McDonald and Senator Breslin for their leadership on this issue and for pushing the legislation forward this session.

However, we have significant concerns with several of the amendments that were included in A.3040-B/S.4870-B which was ultimately passed by the Legislature. Specifically, the bill in its current form limits injection sites to deltoid only and prohibits pharmacists from administering the initial dose of an LAI. We believe these amendments severely limit the intent of the original legislation and negatively impact patient access to care.

We are respectfully requesting your consideration and support for chapter amendments that remove these limitations and provide more meaningful and equitable access to LAI medications. Additionally, we have included some additional background on this issue which we thought would be helpful in your review and consideration of this legislation.

Expanded Access

This legislation, as originally drafted, would have significantly expanded individual's available options for accessing LAI treatments. Providing increased access through local pharmacies to these critical treatments will help to improve patient choice and continuity of care and reduce the stigma of accessing such treatments. Moreover, this legislation, with our suggested changes, would rectify additional barriers that have emerged during the COVID-19 pandemic, and as a result of the expansion of telehealth in New York State.

Access to medications and psychosocial support services are important components of care for persons in the treatment of mental health conditions and substance use disorders.^{1,2,3} There is currently a significant public health need for increased access to behavioral health services, including the use of LAIs for mental health conditions and substance use disorders. However,

¹ FDA. *Information about Medication-Assisted Treatment*. <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat>

² SAMHSA. *Medication for the Treatment of Alcohol Use Disorder: A Brief Guide*. 2015
<https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4907.pdf>

³ APA. *Practice Guideline for the Treatment of Schizophrenia*. Page 52. <https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines>

limiting to oral forms of these medications can create challenges. For instance, about half of individuals diagnosed with schizophrenia do not take their medications as prescribed.^{4,5,6,7,8,9} In a retrospective data analysis, patients who remained in the program for 6 months or more and received their LAI antipsychotic medication in an alternate setting, such as a pharmacy, were 4.16 times more likely to take medication as prescribed than those who did not use alternative care centers for their medication injections.¹⁰

The enactment of this legislation would improve continuity of care even further, as the pharmacist is required to maintain communication with the patient's prescriber throughout the medication administration process. For example, the bill provides that the pharmacist must report the administration of the LAI medication to the patient's licensed prescriber to ensure the patient received their medication. The pharmacy is also able to put into place additional policies and procedures for communicating with the patient and the health care provider, and institute other coordination services.

Pharmacists Ability to Administer LAIs

New York is the only state that has not authorized pharmacists to administer long-acting injectable medications. Moreover, none of the other states have placed limitations on pharmacists' ability to administer by injection site, and only one state has limited the pharmacists' scope to maintenance-only injections. This is because pharmacists are highly skilled in administering injections in the deltoid, gluteal, abdominal, and thigh areas, as well as in the rest of the body, and are well-versed in the adverse side effects of such medications. Under New York law, there is no injection site restriction for intramuscularly administered vaccines. In fact, New York pharmacists are currently administering gluteal injections of the medication Evushield for the treatment of COVID-19 under PREP Act authority. Further, gluteal vaccinations are at times given to patients with small deltoids because of the available muscle mass. ***Our coalition urges you to remove these unnecessary statutory limitations and provide more meaningful and equitable access to LAI medications.***

Expanded Patient Choice

Meeting patients where they are is a critical element of successful recovery, especially in this unprecedented pandemic. Allowing pharmacists to administer LAIs greatly increases treatment points for patients, due to high accessibility of community pharmacies in comparison to treatment providers. Pharmacies can be much closer to a patient's home and have more convenient hours of operation, which is essential for patients in underserved and rural communities, patients with transportation issues, and patients who cannot access their

⁴ The clinical treatment of schizophrenia with antipsychotic medication. SR Hirsch, TRE Barnes - Schizophrenia, 1995 - Blackwell Science: Oxford.

⁵ Dolder CR, Lacro JP, Dunn LB, Jeste DV. Antipsychotic medication adherence: is there a difference between typical and atypical agents? Am J Psychiatry 2002;159:103-8.

⁶ Olfson M, Mechanic D, Hansell S, Boyer CA, Walkup J, Weiden PJ: Predicting medication noncompliance after hospital discharge among patients with schizophrenia. **Psychiatr Serv** 2000; 51:216-222.

⁷ Velligan DI, Lam F, Ereshefsky L, Miller AL. Psychopharmacology: perspectives on medication adherence and atypical antipsychotic medications, *Psychiatr Serv*, 2003, vol. 54 (pg. 665-667).

⁸ Gilmer TP, Dolder CR, Lacro JP, et al: Adherence to treatment with antipsychotic medication and health care costs among Medicaid beneficiaries with schizophrenia. **American Journal of Psychiatry** 161:692-699, 2004.

⁹ Velligan, D. I., Diamond, P. M., Lopez, J., Castillo, D. A., Maples, N. J., Lam, F., et al. (2007a). Cognitive adaptation training improves adherence to medication and functional outcome in schizophrenia. *Schizophrenia Bulletin*, 33(2), 608.

¹⁰ Joshi K, Benson C, Fastenau J, Lapne K. The impact of Janssen Connect injection centers on adherence to an atypical long-acting injectable antipsychotic among patients with schizophrenia enrolled in a support program. Paper presented at: 27th Annual U.S. Psychiatric and Mental Health Congress Conference and Exhibition. September 20-23, 2014; Orlando, FL.

treatment provider during their normal hours of operation due to employment, educational, or family care commitments.

Amended Bill Perpetuates Mental Health Stigma

Stigma is a devastating reality for individuals living with mental health conditions and substance use disorder. The legislation as originally drafted seeks to decrease the stigma patients experience by allowing them to access their medication like most New York State residents do every single day - in the pharmacy. Limiting injection sites and opportunities would only perpetuate the stigma.

Furthermore, we feel that the language added in A.3040-B/S.4870-B which limited the pharmacists' scope to deltoid only injections would not only create a two-tiered system of care in New York, but would also stigmatize patients who receive their medications gluteally or via any other location strictly authorized by the FDA, or based on the patient's preference or body type. These types of administration limitations would perpetuate the devastating barriers patients encounter and it would compound the stigma they already face in accessing their medications. ***We are respectfully requesting your consideration and support of a chapter amendment to remove the language that limits injection sites to the deltoid muscle.***

Legislation Does Not Work as Intended

Despite the legislative intent of A.3040-B/S.4870-B to allow for "the injection of medication into the deltoid muscle for the treatment of mental health and substance use disorder," none of the currently FDA approved LAI medications for the treatment of SUD can be administered via the deltoid muscle.^{11,12} As we stated above, in order for this legislation to be operational as originally intended to allow pharmacists to administer LAI for the treatment of mental health and SUD, the deltoid limitation must be removed.

Opportunities to Learn from Other States

Given that NYS is the last state to allow pharmacists to administer LAI medications, there are opportunities to learn from other states and to work to improve access more fully. It is important to note that Massachusetts is the only state that has prohibited the initial dose of mental health and substance use disorder LAI medications by pharmacists and, unfortunately, there is plenty of anecdotal evidence to highlight how this has proven to be a significant barrier to access. There are many patients who would benefit tremendously from an LAI, but many psychiatrists are simply unwilling to prescribe them because they do not provide injections in their offices. Further, with the expansion of the use of telehealth, there has been an even greater deleterious effect on in-office injection opportunities due to the reduction of on-site services.

Because of these barriers, alternative settings of care for those patients currently receiving LAIs, as well as those who may be appropriate to begin LAIs, need to be created. Allowing pharmacists to administer initial doses of these important medications would go a long way in resolving this substantial barrier to treatment. Moreover, 48 other states have moved forward with authorizing the first dose to be administered by the pharmacist and we have yet to hear of an example where patient safety wasn't maintained. Lastly, while patient safety protocols are clearly embedded into the language of the original bill, the unintended consequences of

¹¹ <https://www.sublocade.com/Content/pdf/prescribing-information.pdf>

¹² <https://www.vivitrol.com/content/pdfs/prescribing-information.pdf>

prohibiting first dose will do much more harm to patients who would otherwise have been able to benefit from an LAI. ***We are respectfully requesting your consideration and support for a chapter amendment to remove the limitation that pharmacists cannot provide the initial dose of such LAI medications.***

As your administration well knows, recovery for patients with mental health conditions and substance use disorder is critically dependent on ease of access to treatments and services. The guiding principle of this legislation, as originally drafted, was to improve access, patient choice, and reduce stigma. By limiting injection sites and pharmacist's administration of an initial dose, A.3040-B/S.4870-B allows outside biases to dictate care, rather than what the prescriber and patient determine would be the best and most appropriate treatment. The specific medication and where and when it is administered should be an informed decision made only by the patient and their healthcare team in collaboration with a pharmacist. We appreciate everything your administration has done in furtherance of supporting the needs of these patients, and hope that you will support these proposed chapter amendments as they are essential to effectively addressing access issues, providing parity, and eliminating unnecessary barriers to mental health and SUD treatments.

We thank you for your consideration and ask for your support of these critical chapter amendments to A.3040-B/S.4870-B.

Sincerely,

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