Grayken Center for Addiction
Training & Technical Assistance

Boston Medical Center

INJECTABLE BUPRENORPHINE IMPLEMENTATION GUIDE

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The Massachusetts Nurse Care Manager Model of Office Based Addiction Treatment: Injectable Buprenorphine Implementation Guide was prepared by Vanessa L. Loukas, MSN, NP-C, CARN-AP; Andrea M. Jodat, DNP, FNP-BC, CARN-AP; and Colleen T. LaBelle, MSN, RN-BC, CARN. We would also like to acknowledge the efforts of Victoria Rust, BS and Alexa Wilder, MPH in the editing of this document.

Disclaimer

Boston Medical Center (BMC) Grayken Center for Addiction Training and Technical Assistance (TTA) is pleased to share its Injectable Buprenorphine Implementation Guide. Although Boston Medical Center has attempted to confirm the accuracy of the information contained in these documents, this information is not a substitute for informed medical decision making by an appropriate, licensed provider. Clinicians must confirm the appropriateness of all treatment that they provide to a patient and are responsible for the health care decisions they make when caring for patients. If clinicians believe that any information included in these guidelines should be revised or clarified, please contact Boston Medical Center at 617-414-7453.

The contents of these guidelines do not necessarily represent the official views of the Bureau of Substance Addiction Services (BSAS), the Massachusetts Department of Public Health, and the Substance Abuse and Mental Health Administration (SAMHSA); nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

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A GUIDE TO IMPLEMENTING INJECTABLE BUPRENORPHINE

This document is a guide for implementing injectable buprenorphine treatment in the healthcare setting in compliance with the current rules and regulations set by the Drug Enforcement Administration (DEA) and Food and Drug Administration's (FDA) medication-specific Risk Evaluation and Mitigation Strategies (REMS) requirements. Sites must adhere to both federal and state regulations related to medication logging procedures, ordering, receiving, tracking, administering, and disposal of injectable buprenorphine. Organization-specific policies often include administration procedures, documentation, and patient tracking. This guide outlines the key components for implementing injectable buprenorphine treatment, including relevant definitions, regulating agencies, education and training resources, and associated tools to assist in regulation compliance while providing quality patient care.

- Due to the potential for regulation changes and availability of new formulations of injectable buprenorphine, sites should periodically review federal and state regulations to ensure practices, including proper disposal of medications, adhere to current recommendations and regulations.
- **Buprenorphine** is a Schedule III medication. Formulas approved under the DATA 2000 for treatment of opioid use disorder (OUD) require handling and security in compliance with federal and state regulations, in addition to organization and site-specific policies. Due to the risk for overdose or serious health complications associated with misuse or improper use of injectable buprenorphine, the DEA and FDA regulate handling and administration of this medication (SAMHSA, 2022). This medication should always be managed by the health care team and not in the hands of patients/public due to safety risks.
- The **Drug Enforcement Administration (DEA)** enforces laws and regulations for controlled substances, including those pertaining to buprenorphine-containing products approved by the FDA for the treatment of OUD.
- **Buprenorphine Prescribers** must have an unencumbered license, a current DEA registration that includes Schedule III authority, and permitted by applicable state law can prescribe buprenorphine (SAMHSA, 2023b).
- The **Food and Drug Administration (FDA)** implemented the **Risk Evaluation Mitigation Strategies (REMS)** program for buprenorphine-containing products, including injectable buprenorphine, to mitigate the risk of accidental overdose and misuse. Organizations using the buy-and-bill method to obtain injectable buprenorphine and specialty pharmacies dispensing injectable buprenorphine must apply for REMS certification and follow the associated regulations (FDA, 2023).
- The two pathways for ordering injectable buprenorphine are **buy-and-bill** and **specialty pharmacy.**

- Organizations using the **buy-and-bill system** purchase injectable buprenorphine in bulk directly from a **network specialty pharmacy** and coordinate bulk delivery to their site. This method requires the organization to be REMS certified. It allows the organization to have injectable buprenorphine on hand, but also requires the organization to assume the cost of the medication up front and the liability of uncovered medication. When the medication is administered to a patient, the organization then submits a claim to that patient's insurance for reimbursement. This is billed as a *medical benefit* and may not show up on the state prescription drug monitoring program (PDMP) website (state dependent).
- Organizations using the **specialty pharmacy system** order injectable buprenorphine by sending a prescription for a specific patient to a REMS-certified specialty pharmacy for delivery to the address listed on the prescriber's DEA license. If a prescriber belongs to an organization with multiple sites or works at multiple organizations, they must have a separate DEA number for each address in which are they are prescribing. The organization is not required to be REMS certified when using this pathway. The patient's insurance carrier determines which specialty pharmacy can be used so organizations often coordinate with multiple specialty pharmacies. The specialty pharmacy bills the patient's insurance directly. This is billed as a *pharmacy benefit* and therefore will show up on the state PDMP website.

TABLE 1: IMPLEMENTING INJECTABLE BUPRENORPHINE: ADMINISTRATIVE REQUIREMENTS

IMPLEMENTING INJECTABLE BUPRENORPHINE: ADMINISTRATIVE REQUIREMENTS

DEA Licensing & Prescribing ☐ DEA license for Schedule III substances for each site ☐ Organizational policies adherent to DEA, state, and location regulations for handling buprenorphine	▪ Each site within an organization handling controlled substances is required to have a separate DEA license for handling Schedule III medications. ▪ Organizations applying for a DEA license or revising their current DEA license must adhere to DEA security requirements, which may include a site assessment or submitting facility blueprint. ▪ The DEA may present to an organization for an unannounced site visit to ensure adherence to regulations for receiving, storing, tracking, administering, security and disposing of buprenorphine. ▪ Buprenorphine prescribers must be unencumbered with an active DEA license. Injectable buprenorphine will be delivered to the address listed on the prescriber's DEA license. Prescribers should have a distinct DEA license for each site in which they are prescribing injectable buprenorphine.	DEA: Registration, Renewals, and Revisions (Drug Enforcement Administration, 2022) Code of Federal Regulations: Title 21 - Chapter II - Part 1301 - Security Requirements (National Archives and Records Administration, 2023a)
Medication Storage & Tracking ☐ Secured, double-locked storage system ☐ *Refrigerator for storage if required by manufacturer.* ☐ Medication log	▪ Tracking and handling of buprenorphine should be performed by a licensed healthcare provider (MD, DO, NP, PA, RN, LPN, pharmacist). ▪ Organizations must follow DEA regulations for storing buprenorphine in a double-locked system in addition to following manufacturer storage guidelines. ▪ If refrigeration is indicated by the manufacturer, a designated pharmaceutical grade refrigerator is preferred, and temperature monitoring should be documented. Refer to manufacturer for product specific temperature and storage guidelines. ▪ Best practice is for medication logs to be signed by two licensed providers following institutional, state and federal policies. Ensure you are following the standards of care for your organization and licensing requirements of the facility. Accurate and timely accounts of controlled substances protect healthcare workers and the public. Reconciling a discrepancy are easier when counts are more frequent and involve another professional.	DEA: Buprenorphine Q&A (Drug Enforcement Administration, n.d.-a) SAMHSA: Provider Support Services (SAMHSA, 2023a)
Medical Records ☐ Record storage adherent to DEA and state regulations ☐ *Adherence to 42 CFR regulations*	▪ Maintenance of medical records for two years in adherence with DEA guidelines, or longer based on state regulations. Electronic medical records meet criteria. ▪ Electronic prescribing required by CMS and others for Schedule III-V medications. ▪ 42 CFR Part 2 regulations provide an additional layer of protection within the medical record and release of information for patients seeking treatment for substance use disorder.	Code of Federal Regulations: Title 21 - Chapter II - Part 1304 - Records and Reports of Registrants

		(National Archives and Records Administration, 2023c) Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule (SAMHSA, 2020)
Delivery Method: Buy-and-Bill ☐ Policies adherent to REMS certification and DEA	▪ Organizations using buy-and-bill must be REMS certified and use a network specialty pharmacy. ▪ Medication is purchased in bulk directly from a network specialty distributor, and then patient's insurance is billed (as a medical benefit) only after administration of the medication.	FDA: Information on REMS for Sublocade (FDA, 2023) Sublocade Risk Evaluation and Mitigation Strategy (REMS) (INDIVIOR, n.d.)
Delivery Method: Specialty Pharmacy ☐ Policies adherent to DEA regulations	▪ Organizations using a specialty pharmacy do not need to be REMS certified. ▪ Medication is ordered for a specific patient through a specialty pharmacy (determined by insurance carrier) and billed as a pharmacy benefit at the time it is ordered. Specialty pharmacies will not accept medication returns after distributed to an organization. Medication that is patient-specific can only to stored onsite for 14 days, after which it needs to be disposed of following your organizations protocol/polices.	DEA: Buprenorphine Q&A (Drug Enforcement Administration, n.d.-a)
Organization Policies & Education ☐ Development of organization specific policies and procedures for workflows related to injectable buprenorphine ☐ Training for involved members of the healthcare team ☐ Assessing nursing competency	▪ Organization specific policies, procedures and workflows related to initiating injectable buprenorphine on-site that are in accordance with DEA and, if indicated, REM certification requirements. Policies and workflows may include controlled substance storage and inventory, coordination with pharmacy, patient tracking and monitoring, and maintaining records. ▪ Training members of the healthcare team, particularly nurses and providers, is an important part of this process to ensure safe and appropriate use of injectable buprenorphine, in addition to ensuring federal and organization specific policies are followed. Education topics may include patient selection, medication administration, patient education, missed appointments, laboratory testing, and adverse medication effects. ▪ Assessing nursing competency for ability to safely and effectively administer buprenorphine may be indicated in addition to education.	BMC Grayken Center for Addiction TTA Clinical Guidelines – Subsections on Injectable Buprenorphine (Wason et al., 2021a) BMC Grayken Center for Addiction TTA Nursing Competencies – See Assessment (starts on p. 29) and Skills Checklists (starts on p. 44) (Wason et al., 2021b)

TABLE 2: EXAMPLE OF INJECTABLE BUPRENORPHINE MEDICATION LOG

INJECTABLE BUPRENORPHINE MEDICATION LOG							
Patient Name **DOB** **MRN**	**Dose**	**Lot #**	**Exp. Date**	**Received from pharmacy** *Signatures & Date*	**Removed from refrigerator or medication box** *Signatures & Date*	**Returned to refrigerator or medication box** *(If med not administered)* *Signatures & Date*	**Removed from refrigerator or medication box** *Signatures & Date*
				1. 2.	1. 2.	1. 2.	1. 2.
				1. 2.	1. 2.	1. 2.	1. 2.
				1. 2.	1. 2.	1. 2.	1. 2.
				1. 2.	1. 2.	1. 2.	1. 2.

TABLE 3: EXAMPLE OF DISPOSAL OF BUPRENORPHINE LOG

DISPOSAL OF BUPRENORPHINE LOG							
Patient Name **DOB** **MRN**	**Dose**	**Lot #**	**Exp. Date**	**Reason for Disposal (expired, unwanted, damaged, etc.)**	**Method of Disposal: Destruction or Reverse Distribution**	**Destruction**	**Reverse Distribution**
						☐ Method and date of destruction: ☐ Signatures of 2 licensed employees who witness the destruction: 1. 2. ☐ Document in patient's chart ☐ DEA Form 41 completed	☐ Name of reverse distributor used and date: ☐ Signatures of 2 licensed employees who witness the reverse distribution: 1. 2. ☐ Document in patient's chart
						☐ Method and date of destruction: ☐ Signatures of 2 licensed employees who witness the destruction: 1. 2. ☐ Document in patient's chart ☐ DEA Form 41 completed	☐ Name of reverse distributor used and date: ☐ Signatures of 2 licensed employees who witness reverse distribution: 1. 2. ☐ Document in patient's chart

FIGURE 1: BOSTON MEDICAL CENTER'S GRAYKEN CENTER FOR ADDICTION TRAINING & TECHNICAL ASSISTANCE RESOURCES

Injectable Buprenorphine Training and Resources

Grayken Center for Addiction Training & Technical Assistance
Boston Medical Center

Injectable Buprenorphine Resources
https://www.addictiontraining.org/resources/?category=11

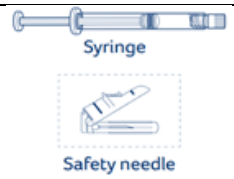
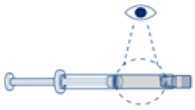
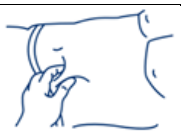
- Clinical Guidelines
- Patient Consent for Treatment
- Injectable Buprenorphine Video – demonstration of procedures for administering injectable buprenorphine in the clinic setting
- Administration Checklist
- Patient Medication Guide

Injectable Buprenorphine Trainings – Filter Category by "Injectable Buprenorphine" and any scheduled trainings will appear.
https://www.addictiontraining.org/training/register/

Nursing Competencies – See the Assessment Document and the Skills Checklist
https://www.addictiontraining.org/resources/?category=13

FIGURE 2: GUIDE FOR PREPARING AND ADMINISTERING SUBLOCADE

PREPARING AND ADMINISTERING SUBLOCADE

1. Getting Ready Ensure medication has been ordered by prescriber and that dosage is correct. Remove medication from fridge at least 15 minutes prior to administration to allow medication to reach room temperature. Do not remove from the carton until ready to administer. Remove the foil pouch and safety needle from the carton. Open the pouch and remove the syringe.	
2. Check the Liquid Clarity Check that the medication does not contain contaminants or particles. Sublocade ranges in color from colorless to yellow to amber.	
3. Attach the Safety Needle Remove the cap from the syringe and the safety needle supplied in the carton from its sterile package. Gently twist the needle clockwise until it is tight and firmly attached.	
4. Prepare the Abdominal Injection Site Choose an injection site on the abdomen with adequate subcutaneous tissue that is free of skin conditions (e.g. nodules, lesions, excessive pigment). It is recommended that patient is in supine position. Clean injection site with an alcohol swab. Rotate injection sites with each administration.	
5. Remove Excess Air from Syringe Hold the syringe upright for several seconds to allow air bubbles to rise. Remove needle cover and slowly depress the plunger to push out the excess air from the syringe.	
6. Pinch the Injection Site Pinch the skin around injection area. Be sure to pinch enough skin to accommodate the size of the needle. Lift adipose tissue from underlying muscle to prevent accidental intramuscular injection.	
7. Inject the Medication Insert needle at a 45-degree angle fully into the abdominal subcutaneous tissue. Use a slow, steady push to inject the medication. Continue pushing until all of the medication is given. Total volume: 0.5 mL for 100 mg and 1.5 mL for 300 mg. *Sublocade is for subcutaneous injection only.*	
8. Withdraw the Needle Withdraw needle at the same angle used for insertion and release the pinched skin. Do not rub the injection area after injection. There may be a small amount of blood or fluid at the injection site; wipe with a cotton ball or gauze before applying gauze pad or bandage using minimal pressure.	
9. Lock the Needle Guard and Discard the Syringe Lock needle guard into place by pushing it against a hard surface such as a table. Dispose of syringe components in a secure sharps disposal container. After administration, syringes should be properly disposed, per facility procedure for a Schedule III drug, and per applicable federal, state, and local regulations.	
10. Instruct the Patient Advise the patient the lump on their abdomen will decrease in size over time. Instruct the patient not to rub or massage the injection site and to be aware of the placement of any belts or clothing waistbands. Educate the patient about signs of injection site reaction and when follow-up would be needed.	

Adapted from FDA Sublocade Prescribing Information, 2017

DISPOSAL OF LONG-ACTING INJECTABLE BUPRENORPHINE

Reverse Distribution

Injectable buprenorphine that is expired, damaged, or unwanted must be reverse distributed or destroyed and disposed of following DEA rules and regulations (Title 21 CRF Part 1330). The method of delivery of injectable buprenorphine (buy-and-bill vs specialty pharmacy) and organization-specific policies and procedures may influence the chosen method for managing unused controlled substances following state and federal regulations (Drug Enforcement Administration, n.d.-c).

Reverse distribution of controlled substances can be facilitated through a DEA-registered reverse distributor or through the medication manufacturer (typically only offered with the buy-and-bill pathway). For assistance in finding a DEA-registered reverse distributor, you may contact your Local DEA Diversion Field Office.

The DEA regulations for destroying and disposing or "wasting" Schedule III medications require the process must render the controlled substance "non-retrievable," meaning the substance is permanently changed to an unusable state. Mixing controlled substances with undesirable items (i.e. kitty litter or coffee grounds) or flushing down a toilet or sink **do not** meet the DEA non-retrievable standards. Once a substance is properly destroyed and becomes non-retrievable, it is no longer subject to the DEA's regulations because it cannot be misused or diverted for illicit use as it would be ineffective (National Archives and Records Administration, 2023d).

Methods for Rendering a Substance "Non-Retrievable"

The two DEA-approved methods for rendering a substance destroyed and non-retrievable are **incineration** and **chemical digestion.** Due to the cost and logistical complications of incineration, this method is typically reserved for hazardous waste material through smaller practices and organizations. Chemical digestion involves putting the controlled substance in a cartridge, pouch, or bottle that contains a chemical (e.g. carbon, bentonite clay, calcium hypochlorite) that deactivates, neutralizes, or breaks down the medication rendering the ingredients inert.

The DEA and the Environmental Protective Agency (EPA) have not endorsed a specific chemical digestion product (Healthcare Environmental Resource Center, 2022). Industry best practice is to use a specially designed pharmaceutical receptacle that renders the controlled substance non-retrievable and partnering with a waste management vendor to remove and process or incinerate the waste containers. There are a variety of chemical digestion systems on the market that meet the DEA standards for rendering controlled substance medication in pill and/or liquid form non-retrievable. An organization-specific policy for destroying and disposing of irretrievable long-acting injectable buprenorphine should be implemented to ensure safety and adherence to DEA guidelines.

Documentation and Record Keeping

The DEA requires organizations maintain a record of controlled substances, including injectable buprenorphine, that are destroyed using DEA Form 41 (Appendix A). Additionally, the regulations state that record of the medication is "complete and accurate and include the name and signatures of the two licensed employees who witnessed the destruction" (National Archives and Records Administration, 2023b). The DEA reinforces the importance of two employees witnessing the medication destruction and disposal in addition to appropriate documentation, including signatures (Drug Enforcement Administration, n.d.-b).

You are not required to submit this form to DEA, unless requested to do so. This form must be kept for at least two years, along with associated controlled substance log, or longer if required by state law. Best practice is to standardize documentation of destruction and disposal of injectable buprenorphine.

OMB APPROVAL NO. 1117-0007 Expiration Date 1/31/2024

U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION

REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED

FORM DEA-41

A. REGISTRANT INFORMATION

Registered Name: Your Health Center/Facility Name		DEA Registration Number: Health Center/Facility DEA #
Registered Address: 100 Main Street		
City: Any Town	State: MA	Zip Code: 12345
Telephone Number: 123-456-7890		Contact Name: Your site's designated DEA contact person

B. ITEM DESTROYED

1. Inventory

	National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
Examples	***16590-598-60***	***N/A***	***Kadian***	***60mg***	***Capsules***	***60***	***2***	***0***	***120 Capsules***
	0555-0767-02	***N/A***	***Adderall***	***5mg***	***Tablet***	***100***	***0***	***83***	***83 Tablets***
	9050	***B02120312***	***Codeine***	***N/A***	***Bulk***	***1.25 kg***	***N/A***	***N/A***	***1.25 kg***
1.									
2.									
3.									
4.									
5.									
6.									
7.									

2. Collected Substances

	Returned Mail-Back Package	Sealed Inner Liner	Unique Identification Number	Size of Sealed Inner Liner	Quantity of Packages(s)/Liner(s) Destroyed
Examples	***X***		***MBP1106, MBP1108 - MBP1110, MBP112***	***N/A***	***5***
		X	***CRL1007 - CRL1027***	***15 gallon***	***21***
		X	***CRL1201***	***5 gallon***	***1***
1.					
2.					
3.					
4.					
5.					
6.					
7.					

Form DEA-41 *See instructions on reverse (page 2) of form.*

C. METHOD OF DESTRUCTION

Date of Destruction:	Method of Destruction:	
Location or Business Name:		
Address:		
City:	State:	Zip Code:

D. WITNESSES

I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.

Printed name of first authorized employee witness:	Signature of first witness:	Date:
Printed name of second authorized employee witness:	Signature of second witness:	Date:

E. INSTRUCTIONS

1. Section A. REGISTRANT INFORMATION: The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
2. Section B. (1) Inventory: This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).
3. Section B. (2) Collected Substances: This part shall be used by registrants destroying controlled substances obtained through an authorized collection activity in accordance with 21 U.S.C. 822(g). In each row, indicate whether registrant is destroying a mail-back package or an inner liner. If destroying a mail-back package, enter each unique identification number separated by a comma and/or as a list in a sequential range and total quantity of packages being destroyed. If destroying an inner liner, enter each unique identification number separated by a comma and/or as a list in a sequential range based on the size of the liners destroyed and the total quantity of inner liners being destroyed. In the case of mail-back packages or inner liners received from a law enforcement agency which do not have a unique identification number or clearly marked size, include the name of the law enforcement agency and, if known, the size of the inner liner or package. DO NOT OPEN ANY MAIL-BACK PACKAGE OR INNER LINER; AN INVENTORY OF THE CONTENTS OF THE PACKAGES OR LINERS IS PROHIBITED BY LAW AND IS NOT REQUIRED BY THIS FORM.
4. If additional space is needed for items destroyed in Section B, attach to this form additional page(s) containing the requested information for each controlled substance destroyed.
5. Section C. METHOD OF DESTRUCTION: Provide the date, location, and method of destruction. The method of destruction must render the controlled substance to a state of non-retrievable and meet all applicable destruction requirements.
6. Section D. WITNESSES: Two authorized employees must declare by signature, under penalty of perjury, that such employees personally witnessed the destruction of the controlled substances listed in Section B in the manner described in Section C.
7. You are not required to submit this form to DEA, unless requested to do so. This form must be kept as a record of destruction and be available by the registrant for at least two years in accordance with 21 U.S.C. 827.

Paperwork Reduction Act Statement: The information collected on this form is necessary for DEA registrants to record controlled substances destroyed in accordance with the Controlled Substances Act (CSA). The records that DEA registrants maintain in accordance with the CSA must be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827. DEA estimates that it will take approximately 30 minutes to complete this form, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The completion of this form by DEA registrants that destroy controlled substances is mandatory in accordance with 21 U.S.C. 827. Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Comments regarding this information collection, including suggestions for reducing the burden estimate, should be directed to the Drug Enforcement Administration, DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

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