Dear Healthcare Provider:

Prescription drug diversion is a significant challenge facing everyday clinical practice. For healthcare providers who treat patients with a history of opioid dependency, taking the necessary steps to establish diversion control measures has taken on even greater importance of late.

Given the urgent need for diversion control, BioDelivery Sciences (BDSI) has developed a Buprenorphine Diversion Control Plan Toolkit, which is designed to help you implement an office-based plan to mitigate the diversion and misuse of opioids, which includes buprenorphine. This toolkit is composed of 3 primary sections:

1) Patient Assessment Materials for both the office staff and patient
2) Office Materials recommended to establish a diversion control plan
3) Additional Literature on diversion control

Collectively, these materials are intended to help your office integrate a plan that will not only track all existing pharmaceutical prescriptions, but will also help build a practitioner-patient relationship that optimizes the treatment of opioid dependency.

As you may know, the limit of opioid-dependent patients who can be prescribed treatment with buprenorphine has recently been expanded, provided healthcare providers meet several qualifications, including adherence to a diversion control plan. Public comments to the proposed rule, as well as scientific publications, highlight the need to prescribe at the lowest effective dose of buprenorphine at the smallest quantity in appropriate patients.

This resource is a tool designed to help you develop a Diversion Control Plan for your office. Healthcare providers must attest to the fact that they have created and maintained a diversion control plan, when they apply and are approved to treat patients at a higher limit. However, healthcare providers are not required to submit this plan to the Substance Abuse and Mental Health Services Administration (SAMHSA)^1.

The American Society of Addiction Medicine (ASAM) has provided information on “Office Based Opioid Use Disorders” which can be found in the additional resources section of this toolkit. ASAM’s manual policy and procedure highlight effective approaches that may be used to discuss and establish ways to prevent and monitor the misuse and diversion of buprenorphine. Many of the procedures listed to prevent, monitor and respond to diversion are included as information, forms and literature in this toolkit.

The enclosed Patient Assessment Materials will assist your office in evaluating the patient, developing an appropriate treatment plan, and ensuring that the patient understands the treatment process:

- **Your First Doctor’s Appointment**: Provides the patient with appropriate expectations and guidelines to help him/her prepare for the initial office visit.

- **Important Information About Your Treatment**: Provides the patient with a description of the initial examination and outlines each stage of treatment.

- **Understanding Opioid Addiction and Treatment**: Provides the patient with an explanation of what opioid addiction is, whom it affects, and what to expect during treatment.

- **Patient Treatment Agreement**: Outlines the terms to which the patient will be held accountable during treatment so that he/she may achieve the desired outcome.

- **Clinical Opiate Withdrawal Scale (COWS)**: To be used by the staff in measuring the patient’s degree of opioid withdrawal.

- **Substance Dependence Assessment, Intake History, and Physical Examination Forms**: To be used by the staff in recording the patient’s substance abuse and medical history, and physical examination results.

- **Patient Log**: Assists the office in tracking all current patients who are being treated for opioid dependence with buprenorphine/naloxone.

- **Proof of Counseling**: The patient must get the counselor’s signature after each session and provide the completed form to the healthcare provider.

The kit also contains the following Office Materials that are useful for any office-based diversion control plan:

- **Elements to Consider When Developing a Diversion Control Plan**: Provides healthcare providers and their office staff with a detailed list to assist with the mitigation of diverting opioids.

- **Prescription Log**: Assists the office in tracking all active prescriptions.

- **Records to Be Maintained**: A copy of important records that must be presented to the Drug Enforcement Agency (DEA) upon their request, including current DEA registration, state narcotics license, and state medical license.

- **Tutorial and Certificate of Completion**: Please visit www.BDSIDiversionToolkit.com or use the QR code below to review an online tutorial and print a certificate of completion to maintain as part of your office’s Diversion Control Plan.
Lastly, the kit includes some **Additional Literature** that may be helpful in continuing to educate your office staff on the importance of preventing the abuse and misuse of opioids:

- **American Society of Addiction Medicine (ASAM)/Federal Guidelines on Diversion**: Diversion Guidelines developed by ASAM and the Federal Government are provided, as well as requirements that practitioners must meet in order to increase the number of patients they may treat with buprenorphine from 100 to 275.

- **American Society of Addiction Medicine. Office-Based Opioid Use Disorder Policy and Procedure Manual**: This document highlights effective approaches recommended to aid in preventing, monitoring and responding to diversion.

- **Poster Presented at the 2016 International Conference on Opioids, Boston, Massachusetts, June 6, 2016: Reduced Buprenorphine/Naloxone Prescriptions Dispensed in a State Medicaid Population Following Formulary Conversion from Suboxone® to BUNAVAIL®: Implications for Potential Diversion**: This poster summarizes the results of a study looking at the implications of potential diversion with reduced prescriptions.

- **How to Dispose of Unused Medicines**: This article reviews proper techniques for disposing of unused medicines.

- **How to Prepare for a Visit from the Drug Enforcement Agency (DEA) Regarding Buprenorphine Prescribing**: This article summarizes the steps that should be taken for your office to prepare for a visit from the DEA.

- **American Society of Addiction Medicine. Summary: Major Components of the HHS Final Rule**: This document summarizes the HHS final ruling on the increase to treat up to 275 patients.

- **Department of Health and Human Services. Medication Assisted Treatment for Opioid Use Disorders: Final Rule**: This document provides commentary and responses from HHS on this ruling.

BDSI has developed an informational website where healthcare providers and their staff can download and print additional copies of the Diversion Plan Toolkit components. In addition, a tutorial on each of these components, with an explanation of the importance of having a Diversion Plan, can be found on this website. After viewing the tutorial, staff members can print a certificate of completion indicating that they have reviewed and have been trained on the various Diversion Plan components listed here. Please visit [www.BDSIDiversionToolkit.com](http://www.BDSIDiversionToolkit.com) or scan the QR code below to access the Toolkit components and complete the online tutorial.

If you have any questions about the components of the kit and how they can be used to help implement a diversion control plan in your practice, please contact your BDSI sales representative. We hope that you, your staff, and your patients find this kit of value in your treatment of patients with opioid dependence.

BDSI makes no guarantee that these are all the components necessary for a Diversion Plan that will be considered compliant with the promulgated regulations. BDSI is providing these materials for your reference and use in creating your own Diversion Plan.