Probuphine® REMS Program
Healthcare Provider Who Performs Probuphine Surgical Procedures
Recertification Form

(for completion by healthcare providers who will **insert** or **remove** Probuphine. Please fax to 609-423-0965)

Probuphine may only be inserted by healthcare providers who are certified in the Probuphine REMS Program to perform these procedures. Patients having Probuphine removed must be monitored to ensure that removal is performed by a healthcare provider who is certified to insert. In addition, Probuphine is only available from healthcare providers who are certified in the Probuphine REMS Program to prescribe Probuphine.
Annual recertification is required to maintain your certification to insert Probuphine. Based upon your healthcare provider background and the number of insertion/removal procedures you have completed; your recertification requirements are outlined below:

Probuphine® REMS Recertification Training Requirements[1]

I have current operating privileges at hospitals or out-patient surgical centers: (Select the "yes" or "no" Column below that Applies)		
If YES ↓	**If NO ↓**	
	Number of Probuphine procedures in the past 12 months (Select the Row that applies)	
I must review the ***Probuphine REMS Program Surgical Procedures Recertification Video*** found on the Probuphine REMS website **every year.**	**≥10** Performed 10 or more successful[2] procedures (comprised of at least five insertions and five removals) →	I must review the ***Probuphine REMS Program Surgical Procedures Recertification Video*** found on the Probuphine REMS website **every year.** I understand that I should keep documentation of all successfully completed procedures on the ***Probuphine REMS Program Procedure Record for Recertification*** or another record of my choosing - which must be provided to the Probuphine REMS Program if I am audited.
	<10 Performed less than 10 successful[2] procedures (comprised of at least five implantations and five removals) →	I must (annually): • attend a ***Probuphine REMS Program Live Training: Lecture and Practicum*** session • successfully complete the ***Probuphine REMS Program Knowledge Assessment*** test • meet the ***Probuphine REMS Program Criteria for Procedural Competency***

Your Training Requirements can be found at the intersection of the row and column you select below based upon your personal experience

[1] Denotes the minimal requirements. Healthcare Providers should utilize the tools provided for recertification as needed to ensure proper insertion/ removal of Probuphine is conducted in accordance with the Probuphine REMS Program.

[2] "Successful" implantation and removal procedures exclude attempted procedures that require assistance of other surgical specialties for completion. Removal procedures assisted by imaging studies prior to completion can be included, provided that the Healthcare Provider successfully removes all implants identified by imaging without involving additional surgical consultants.

To maintain your certification to insert Probuphine, you must attest that you have completed the following requirements:

Healthcare Providers Who Perform Probuphine Surgical Procedures Recertification Agreement

By signing this form, I attest that:

I meet one of the following recertification requirements (please select):

- ☐ I am a HCP with operating privileges at hospitals or out-patient surgical centers and I have reviewed the ***Probuphine REMS Program Surgical Procedures Recertification Video*** within the past 12 months of my last Probuphine REMS certification.
- ☐ I am a HCP with no operating privileges at hospitals or out-patient surgical centers. I have performed 10 or more successful* procedures (comprised of at least five insertions and five removals) during the past 12 months and I have reviewed the ***Probuphine REMS Program Surgical Procedures Recertification Video***.
- ☐ I am a HCP with no operating privileges at hospitals or out-patient surgical centers. I have performed less than 10 successful* procedures (comprised of at least five insertions and five removals) during the past 12 months and have repeated and successfully completed the ***Probuphine REMS Program Live Training: Lecture and Practicum*** on

  _____ (insert date).

I further attest to the following:

1. I understand that Probuphine is only available through healthcare providers who are certified by the Probuphine REMS Program and that I must comply with the program requirements to insert/remove Probuphine.
2. I have reviewed and understand the ***Probuphine Prescribing Information*** and the ***Probuphine Instructions for Use***.
3. I understand the risks of migration, protrusion, expulsion, and nerve damage associated with insertion/removal of Probuphine and the risks of accidental overdose, misuse, and abuse associated with Probuphine.
4. I understand the safe administration of Probuphine, including the proper insertion and removal techniques, as well as appropriate wound care.
5. I will provide each patient with a copy of the ***Probuphine Medication Guide*** prior to each insertion procedure and counsel each patient about:
   a. The risks associated with the insertion and removal of Probuphine,
   b. The risks of accidental overdose, misuse and abuse if an implant comes out or protrudes from the skin
   c. The importance of appropriate wound care.

6. I will document patient counseling in the ***Probuphine REMS Program Insertion/Removal Log*** or by using another method or system (e.g. electronic health record) specific to my medical practice.
7. I will perform the insertion and removal procedures in a healthcare setting in which a prescriber certified in the Probuphine REMS Program is also practicing.
8. I will ensure that this healthcare setting has appropriate equipment to perform the insertion and removal procedures described in the ***Probuphine Instructions for Use***.
9. I will document the insertion and removal of Probuphine including the date, serial number, number of implants inserted/removed, serial number, name of individual performing the procedure, and location of implants for individual patients on the ***Probuphine REMS Program Insertion/Removal Log*** or by using another method or system (e.g. electronic health record) specific to the prescriber's medical practice.
10. The removed implant contains a significant amount of residual buprenorphine. I will dispose of Probuphine implants in compliance with facility procedure for a Schedule III drug product and per applicable local, state and federal regulations governing the disposal of pharmaceutical bio-hazardous waste.
11. I will not transfer Probuphine outside the healthcare setting to anyone who is not certified as a Healthcare Provider Who Prescribes in the Probuphine REMS Program.
12. I understand that I will need to recertify in the Probuphine REMS Program annually.
13. I understand that the Probuphine REMS Program may contact me via phone, mail, or email to survey me on the REMS Program requirements.
14. I understand that personnel from the Probuphine REMS Program may contact me via phone, mail, or email to gather or to provide information related to the Probuphine REMS Program.
15. I will comply with requests to be audited by Braeburn Pharmaceuticals to ensure all recertification requirements are being followed for the Probuphine REMS Program, and appropriate documentation is available upon request.
16. I will report any adverse events associated with the insertion/removal of Probuphine and the risks of accidental overdose, misuse and abuse to Braeburn Pharmaceuticals at 1-844-859-6341.

Healthcare Provider Signature | Date

Print Name **NPI #**

Please print the following information clearly and legibly in order to more easily process your enrollment in the Probuphine REMS Program.

First Name: _____

Last Name: _____

Practice Name: _____

Street Address: _____

City: State: Zip:

Are you a: MD ☐ DO ☐ PA ☐ NP ☐ Other - Please specify: _____

Clinical Specialty: Addiction Medicine ☐ Family Medicine ☐ Internal Medicine ☐ Psychiatry ☐ Other _____

Telephone #:	Fax #:
E-mail:	Confirm E-mail:

Preferred Method of Communication (please select one): ☐ Fax ☐ Email

For more information, please contact the *Probuphine REMS Program* at 1-866-397-8939 or online at *www.ProbuphineREMS.com*.