# PROBUPHINE® REMS Program
# Healthcare Provider Dual Enrollment Form

(for completion by healthcare providers who will **prescribe**, **insert**, and **remove** Probuphine)

Probuphine is only available from prescribers who are certified in the *Probuphine REMS Program* to prescribe Probuphine and may only be inserted or removed by healthcare providers who are certified in the *Probuphine REMS Program* to insert or remove Probuphine.

To become certified in the *Probuphine REMS Program* as a healthcare provider who may prescribe, insert, and remove Probuphine **in a dual role**, you must:

1. Successfully complete the *Probuphine REMS* training requirements which include:

    *a. Probuphine REMS Program Didactic Training*

    *b. Probuphine REMS Program Knowledge Assessment*

    *c. Probuphine REMS Program Live Practicum Training*

    *d. Probuphine REMS Program Criteria for Procedural Competency*

2. Complete and submit the *Probuphine REMS Program Healthcare Provider Dual Enrollment Form*

## Attestations for Healthcare Providers Who Prescribe, Insert, and Remove

By signing this form, I attest that:

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 prescribe, insert, and remove Probuphine.
2. I have reviewed and understand the *Probuphine Prescribing Information*, the *Probuphine Instructions for Use*, and successfully completed the *Probuphine REMS Program Live Didactic and Practicum Training*, the *Probuphine REMS Program Knowledge Assessment;* and meet the *Probuphine REMS Program Criteria for Procedural Competency.*
3. I understand the risks of migration, protrusion, expulsion, and nerve damage associated with improper insertion/removal of Probuphine and the risks of accidental overdose, misuse, and abuse associated with Probuphine.
4. I understand appropriate patient selection for 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 using the *Probuphine REMS Program Patient Counseling Tool,* counsel each patient about:
    a. The risks of improper insertion and removal of Probuphine,
    b. The risks of accidental overdose, misuse and abuse, and
    c. Appropriate wound care
6. I will document patient counseling on 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 order Probuphine only from a wholesaler/distributor that is enrolled in the Probuphine REMS program.
8. I will not transfer Probuphine to anyone not certified in the *Probuphine REMS Program.*

9. I will perform the insertion and removal procedures in a clinical setting with appropriate equipment to perform the insertion and removal procedures as described in the *Probuphine Instructions for Use*
10. I will document the insertion and removal of Probuphine including the date, number of rods inserted/removed, name of individual performing the procedure, and location of rods 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 my medical practice; and I will maintain such documentation of insertion and removal of Probuphine in each patient's medical record.
11. I will dispose of Probuphine implants in keeping with local, state and federal regulations governing the disposal of pharmaceutical bio-hazardous waste.
12. I understand that the *Probuphine REMS Program* may contact me via phone, mail, or email to survey me on the effectiveness of the REMS Program requirements.
13. I understand that I may request personnel from the *Probuphine REMS* to observe my first Probuphine insertion and removal.
14. I agree personnel from the *Probuphine REMS Program* may contact me to gather information or resolve discrepancies or to provide other information related to the Probuphine REMS Program.
15. I will report any adverse events associated with the improper insertion/removal of Probuphine and the risks of accidental overdose, misuse and abuse to Braeburn Pharmaceuticals at 1-844-859-6341.

Prescriber Signature _____ Date _____

**Print Name** _____ **NPI #** _____ **DEA#** _____

First Name: _____

Last Name: _____

Practice Name: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Are you a: MD ☐ DO ☐

Clinical Specialty: Addicition 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 1-844-859-6341 or online at *ProbuphineREMS.com*.**