

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE SUBOXONE)	Case No. 1:24-md-3092
(BUPRENORPHINE/NALOXONE))	
FILM PRODUCTS LIABILITY)	MDL No. 3092
LITIGATION)	
)	Judge J. Philip Calabrese
This Document Applies to All Cases)	
)	

**CASE MANAGEMENT ORDER NO. 12
CENSUS PROTOCOL**

I. Scope of Order

In furtherance of the effective and efficient management of this complex litigation, this Case Management Order governs the guidelines and procedures for establishing and implementing a Census Protocol.

II. Approval of Census Form and Record Authorizations

The Court approves the Census Form attached as Exhibit 1 and the Medical, Dental, and Pharmacy/MAT Authorizations attached as Exhibit 2. The obligation to complete the Census Form and Authorizations, and to provide records establishing proof of use of brand-name Suboxone Film and proof of injury, applies to (1) Plaintiffs with individually filed complaints pending as of October 7, 2024; and (2) the individuals listed on Schedule A and its supplements (ECF No. 150-1). This Case Management Order refers to both groups, collectively, as “Plaintiffs.” Plaintiffs filing on or after October 7, 2024 will be subject to future orders.

II.A. Establishing a Crosslink Account

Service of the Census Form and accompanying documents shall be accomplished via the Rubris Crosslink system. The PLC and defense counsel will work together to include appropriate instructions accompanying the Census Form, which will be visible to the Crosslink user as a “mouseover” wherein the instructions appear when the mouse hovers over the “Instruction” graphic symbol of an encircled ‘i.’(i). Each Plaintiff’s counsel and Defendants’ counsel must establish a Crosslink account. The Crosslink application can be accessed at <https://crosslink.rubris.com>. To request access to Crosslink, counsel must send an email to CrosslinkSupport@Rubris.com and provide the law firm, name, and email address for each individual requiring access to the application. At least one attorney or firm representative must be specified as the account administrator for the law firm and should be identified in the request. Please use the following email subject: Request for Access to Suboxone Film Census. Inquiries for establishing a Crosslink account should be directed to CrosslinkSupport@Rubris.com.

Pro se Plaintiffs must establish a Crosslink account by sending an email to the same address and will serve as their own account administrator. If a *pro se* Plaintiff lacks access to the technology to complete this process, the *pro se* Plaintiff should email Liaison Counsel Alyson Beridon (alyson@hsglawgroup.com) to facilitate access.

II.B. Rubris to Maintain Secure Database

Rubris shall maintain a secure, confidential, and searchable database available to the PLC and defense counsel for all records that a Plaintiff’s counsel serves on defense counsel and all records Defendants upload to Rubris. How each

party accesses or uses the data and the database shall be strictly confidential and not disclosed in any manner by Rubris. All documents and information uploaded to the Rubris Crosslink database shall be deemed “Confidential” and subject to CMO No. 5 regardless of the presence or absence of any formal confidentiality designation.

II.C. Dual Representation of Plaintiffs

To ensure that the responsible counsel are linked with a Plaintiff’s entry in Crosslink for subsequent submission of Census data, within 10 days of the date of this Order, the PLC will ensure that Rubris analyzes the data in Schedule A and filed cases to identify potential instances of dual representation of Schedule A Plaintiffs and/or Plaintiffs with filed cases by multiple firms. When a potential dual representation is identified, Rubris will notify counsel through the Rubris Crosslink system.

Once a dual representation is identified in Crosslink and notification is transmitted, Plaintiff’s counsel will have 21 days to resolve the potential dual representation and indicate in the Crosslink system either (1) which firm will be responsible for that Plaintiff in Crosslink moving forward or (2) confirm that the potential dual representation identified is actually two distinct Plaintiffs.

Both firms involved in a dual-representation situation must respond to the notification. If counsel confirm that there is a dual representation and their responses match regarding which firm will have responsibility for that Plaintiff in Crosslink, the Plaintiff will be assigned to the firm indicated. If counsel confirm that there is no dual representation and the identified potential dual representation is actually separate Plaintiffs, then separate entries will remain in Crosslink for each

Plaintiff. The dual-representation task will remain open and no documents may be submitted for that Plaintiff until the dual-representation is resolved.

Any subsequent dual representations that are identified as additional information is entered regarding Plaintiffs will be resolved on the same timeline and in the same manner once identified in Crosslink and notification is transmitted.

II.D. Determining Whether to Remove Schedule A Plaintiffs

The Court entered CMO No. 4 to give potential Plaintiffs additional time to investigate their claims with the understanding and expectation that not all Schedule A Plaintiffs would remain in this litigation. To streamline these proceedings based on the investigation conducted to date, the Court directs that counsel for each Schedule A Plaintiff indicate through the Crosslink system whether that Plaintiff should (1) remain on Schedule A (for Plaintiffs for whom product-identification and proof of subsequent dental injury has been secured or for whom records requests to secure product-identification and/or proof of subsequent injury remain in progress) or (2) should be removed from Schedule A with that Plaintiff's consent.

Following the completion of the process described in Paragraph II.C regarding dual representations, the PLC will ensure that Crosslink pushes a task to counsel for each Schedule A Plaintiff to indicate whether that Plaintiff should remain on or be removed from Schedule A. Counsel will have 30 days to respond to the question. This task is to provide Defendants with a preliminary count of the cases that Plaintiffs' counsel have vetted and determined will not proceed and will not prejudice any Schedule A Plaintiff; any Schedule A Plaintiff whose counsel does not respond to this

question shall remain on Schedule A. Within two business days of the conclusion of the 30-day period, the PLC shall provide a list to the Court and Counsel for Defendants of the Schedule A Plaintiffs whose claims should be dismissed without prejudice.

The task to indicate that a Schedule A Plaintiff should be removed from Schedule A shall remain open following the completion of the initial 30-day period described above. At any time, counsel can indicate that a Plaintiff should be removed from Schedule A. In advance of future status conferences, the PLC will provide updates to the Court and counsel for Defendants listing any Schedule A Plaintiffs who are eligible for dismissal.

II.E. Documents for Plaintiffs to Submit and Related Deadlines

Plaintiffs shall complete and serve the Census Form attached as Exhibit 1. Contemporaneous with serving the Census Form, Plaintiffs will also provide executed authorizations for medical, dental, and pharmacy/MAT records attached as Exhibit 2. The Census Form and authorizations may be executed via DocuSign, provided that the DocuSign signature is effectuated via an actual written (as opposed to typed) electronic signature that will be accepted by the facility in question and will be HIPAA-compliant. Plaintiffs will bear the entirety of any cost associated with the use of DocuSign for these documents. Also contemporaneous with serving the Census Form and executed authorizations, Plaintiffs will be required to upload records establishing (1) proof of use of brand-name Suboxone Film, and (2) proof of dental injury post-dating the use of Suboxone Film.

The Court orders that Census Forms and accompanying materials be served on a rolling basis, and the Court will ascertain the status of the completion of census forms at the regularly scheduled Court conferences. Service of Census Forms and accompanying documents must be completed no later than 270 days from the entry of this Order, subject to the deficiency process described in Paragraph II.G.

II.F. Documents for Defendants to Submit to Crosslink

If a Defendant secures records using an authorization provided by a Plaintiff, that Defendant shall upload via Crosslink copies or electronic files of all of that Plaintiff's records that come into the Defendant's possession via the authorization. A Plaintiff will not be charged for any records a Defendant elects to collect, and Defendants will not be charged for any records a Plaintiff elects to collect.

II.G. Deficiency Process

In the event a Defendant asserts that a Census Form, the executed authorizations, or the accompanying records are incomplete or inadequate, that Defendant may serve a deficiency notice specifying the claimed deficiencies to that specific Plaintiff's counsel. Service of said deficiency notice shall be accomplished via Crosslink (or provided directly to the Plaintiff if proceeding *pro se*) within 60 days of receipt of the material(s) claimed to be deficient. If a Plaintiff supplements the Census Form, authorization, or records required to be produced, the 60-day period shall restart as to the supplemented portion(s) but will not restart as to portions unchanged from prior submissions, unless supplemental information makes information previously provided deficient.

The Plaintiff shall have 30 days from the date of the notice to correct the deficiency. If Defendant asserts that the deficiency at issue is not corrected by this time, defense counsel shall request a meet and confer, which must take place within 14 days from the date the request is made. Any disputes not resolved after meeting and conferring may be placed on the agenda for the next conference with the Court. Plaintiffs who cannot substantiate injury or product identification within the applicable deadline will be dismissed with prejudice. Plaintiffs who do not timely complete and serve the Census Form, authorizations, or proof of product use and injury due to transience or similar reasons will be dismissed without prejudice. The Court will periodically issue notices of upcoming dismissals for Plaintiffs who fail to meet their obligations under this Order. To the extent a Plaintiff experiences difficulty securing records from a provider, the Plaintiff should promptly notify Plaintiffs' Liaison Counsel to bring the issue to the Court's attention for assistance.

Counsel for all parties shall exercise good faith in all aspects of this deficiency process and must act with diligence to meet the deadlines in this Order.

II.H. Sharing of Crosslink Costs

The cost of the Rubris Crosslink system for Paragraph II.E (Census Form and related documents) will be shared by the parties. Upon service of the Census Form to Defendants, the serving Plaintiff will be charged \$17 and Defendants will be charged \$17. There will be no cost associated with amendments to the Census Form and related records or to upload any subsequent documents ordered by the Court to be submitted by a Plaintiff who uploads a Census Form. There will be no charge for

submission of any Deficiency Notice as provided for in Paragraph II.G or for uploading records as provided for in Paragraph II.F.

The cost of the Rubris Crosslink system for Paragraph II.D will be paid by Plaintiffs. Upon indication by a Plaintiff's counsel in Crosslink that a Plaintiff should be removed from Schedule A, that Plaintiff will be charged an administrative fee of \$10.

II.I. Dismissal of Plaintiffs for Non-Compliance with This Protocol

Any Plaintiff who does not timely comply with the deadlines detailed in this Order for submission of documents in Paragraph II.E *and* to whom Defendants have issued a timely deficiency notice under Paragraph II.G will be eligible to have their actions dismissed in accordance with the Court's October 8, 2024 Minutes and Order (ECF No. 154) 330 days from the date of this Order (September 30, 2025).

Within two business days after that date, the PLC will provide Defendants a list of the Plaintiffs whose claims are eligible for dismissal. Within five business days, Defendants shall confirm their agreement with or objection to the list. If the parties agree on the list, Defendants shall submit it to the Court to effectuate the dismissals in accordance with the Court's October 8, 2024 Minutes and Order (ECF No. 154). If the parties disagree on the list despite good-faith efforts to agree, Defendants shall submit a list of agreed dismissals and disputed dismissals to the Court. The Court will effectuate the dismissals of the Plaintiffs on the agreed list in accordance with the terms of this Order and will address the disputed dismissals at the next case management conference.

SO ORDERED.

Dated: November 4, 2024

A handwritten signature in black ink, appearing to read "J. Calabrese", written in a cursive style.

J. Philip Calabrese
United States District Judge
Northern District of Ohio

SUBOXONE FILM CENSUS FORM

I. CASE INFORMATION

- A. Filed Case: (Yes/No)
 - 1. Caption:
 - 2. Docket number:
- B. Name, email, and phone number of attorney with whom Defendants' Counsel should correspond regarding Census Form/records
- C. If you do not have a lawyer and are suing on your own behalf, please check here __

II. PLAINTIFF INFORMATION

- A. Full name:
- B. Date of birth:
- C. Current Address:
- D. Social Security number:
- E. Gender: Male Female Non-Binary
- F. Loss-of-consortium claim (Yes/No) [If Yes, spouse's name]:
- G. Is the injured party deceased? (Yes/No) [If Yes, name and contact information of estate representative]:

III. PRODUCT USE AND DURATION

- A. When were you first prescribed Suboxone Film (month/year)?
- B. When did you first use Suboxone Film (month/year)?
- C. Have you ever taken (check one of the following three boxes):
 - 1. Brand-name Suboxone Film
 - 2. Generic version of Suboxone Film
 - 3. Both
- D. How long did you take brand-name Suboxone Film? (list total number of months)
- E. Did you take Suboxone Film or a generic version of Suboxone Film after July 2022? (Y/N)

IV. INJURIES

- A. Have you experienced any dental injuries that you claim were caused in whole or in part by Suboxone Film? (Yes/No).

[The remaining fields in IV will not appear for anyone who answers "No" to IV.A]

- B. Are you claiming that your only injury is a cavity or cavities? (Y/N)
- C. Have you experienced a fractured, broken, or cracked tooth, which has not been extracted, that you claim was caused by Suboxone Film? (Y/N). If yes, indicate # of teeth fractured, broken, or cracked).
- D. Have you lost or had any teeth extracted as a result of using Suboxone film: Y/N. If yes, indicate # of teeth lost/extracted.
- E. Have you experienced any other significant dental injuries not identified in IV(B)-(D)?
- F. Has a dental professional or any other medical professional ever treated your injuries caused by Suboxone film? Y/N
- G. Have you had any of your lost/extracted teeth replaced? Y/N

V. DAMAGES

- A. Check the box beside each type of damages you seek:
 - Emotional distress
 - Psychiatric injury
 - Medical/dental expenses
 - Lost wages
 - Other [Provide Description]

VI. HEALTHCARE PROVIDERS

- A. Please provide the name and address of:
 1. Healthcare provider(s) who prescribed Suboxone Film;
 2. Dental professional(s) who treated you for claimed injuries; and
 3. Pharmacies or MAT Clinic where you picked up Suboxone Film.

VII. RECORDS ESTABLISHING PROOF OF USE AND PROOF OF INJURY AND AUTHORIZATIONS

Plaintiff will provide:

- A. Documents establishing product identification/proof of use of brand-name Suboxone Film;
- B. Documents establishing proof of subsequent dental injury, if any; and
- C. Executed authorizations for dental records and x-rays, medical records, and pharmacy dispensing records (attached).

VIII. DECLARATION

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the information provided in this Census Form is true and correct to the best of my knowledge and recollection.

**AUTHORIZATION FOR DISCLOSURE OF
MEDICAL/DENTAL INFORMATION**

SECTION I. PATIENT DATA

1. **NAME** (*last, first, middle initial*): _____
2. **ALIAS/MAIDEN NAME:** _____
3. **DATE OF BIRTH:** _____
4. **SOCIAL SECURITY NUMBER:** _____
5. **ADDRESS:** _____

SECTION II. FACILITY INFORMATION

1. **NAME/ADDRESS:** _____
2. **DATE BEGIN (5 years prior to initial Suboxone prescription date):**

3. **DATE END:** _____
4. **INFORMATION TO BE DISCLOSED:**

Dental and Medical Records (including all dental and medical records, physician's records, notes, reports and orders, hospital records, admission records, emergency room records, surgeon's records, pathology/cytology reports, physicals and histories, laboratory reports, operating room records, discharge summaries, progress notes, patient intake forms, consultations, disability records, prescriptions, nurses' notes, birth certificate and other vital statistic records, communicable disease testing and treatment records, correspondence (inclusive of any and all electronic communications (i.e. text messages or electronic mail), patient intake forms and health history forms, telephone logs, telephone messages, prescription records, medication records, orders for medications, social worker's records, insurance records, any medical consent(s), statements of account, itemized bills, invoices and any other papers relating to any examination, diagnosis, treatment, periods of hospitalization, or stays of confinement, or documents containing information regarding amendment of protected health information (PHI) in the medical records. Copies of all x-rays, CT scans, MRI films, photographs, and any other radiological, nuclear medicine, radiation therapy reports, including, but not limited to dental x-rays, panorex, or other dental or digital imaging.

I authorize the above-named individual or organization to disclose the above-named patient's health information, as described below, to the following recipients or any of their representatives: Bowman and Brooke LLP and/or its agent _____.

I understand that the information in the patient's health records authorized above may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, or treatment for alcohol or drug abuse.

This authorization shall remain in full force and effect until it expires three years from the date set forth below.

PHOTOCOPIES OF THIS RELEASE ARE VALID.

ELECTRONICALLY SIGNED COPIES OF THIS RELEASE ARE VALID.

I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing by sending or presenting my written revocation to the Privacy Contact of the healthcare provider named above. I understand that the revocation of this authorization will not apply to the extent that the healthcare provider has taken action in reliance thereon.

I understand that authorizing the disclosure of this healthcare information is voluntary. I can refuse to sign this authorization. I understand that I may inspect or copy the information to be used or disclosed, as provided in 45 CFR § 164.524.

I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure of the patient's health information by the recipient, resulting in the health information no longer being protected by federal or state confidentiality rules.

Signature: _____ **Date:** _____
(Patient and/or Legal Representative)