UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

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

This Document Applies to All Cases

CASE MANAGEMENT ORDER NO. 13 COLLECTION OF RECORDS

Pursuant to the Court's authority to direct and control the coordinated discovery in this multi-district litigation under 28 U.S.C. § 1407, Rules 16, 26(b), and 45 of the Federal Rules of Civil Procedure, the Court's inherent authority, and by agreement of the parties, the Court **ORDERS** as follows:

I. Definitions

I.A. Plaintiff

Any person with an action pending in this MDL as of the entry of this Order; any person who files an action in this MDL on or after the date of this Order; any person who files an action that is transferred to this MDL on or after the date of this Order; and any person listed on Schedule A (ECF No. 150-1).

I.B. Entity/Entities

Any facility or individual in possession of medical, disability, and/or other records documenting the care or treatment of a Plaintiff that has received an executed authorization to produce records, including but not limited to: healthcare providers, medical facilities, dental practices, pharmacies, prescription benefit managers,

Case: 1:24-md-03092-JPC Doc #: 194 Filed: 02/13/25 2 of 5. PageID #: 5291

insurance providers, and medication-assisted-treatment programs, or any employee thereof responsible for an Entity's records.

II. Basis

The Court finds that the timely and complete production of medical and other records documenting a Plaintiff's care and treatment is necessary to the efficient conduct of these proceedings. Any lack of cooperation by medical providers and/or records custodians in timely providing records as requested or authorized by a Plaintiff runs the risk of delaying, obstructing, or frustating this MDL's progress.

III. Applicability

The Court sets the following terms and procedures regarding the production of a Plaintiff's medical or other records as authorized by a Plaintiff in this litigation according to this Order. This stipulated Order is entered to efficiently and timely obtain proof of Suboxone Film use, dental records, and other necessary records in support of management of this complex litigation, including but not limited to the Census Protocol set forth in Case Management Order No. 12 (ECF No. 158) and any subsequent orders.

IV. Production of Records as Authorized by a Plaintiff

Upon receipt of an executed authorization to produce records on behalf of a Plaintiff, the below terms apply to any Entity in possession of medical records and/or other records documenting that Plaintiff's care or treatment:

IV.A. Plaintiff's Signature

Entities must accept a Plaintiff's ink or electronic signature on authorizations to release records. Entities cannot refuse to accept electronically signed authorizations (by DocuSign or similar program to secure electronic signature).

IV.B. Authorizations and Additional Documentation

IV.B.1. Entities may not require proprietary/entity-specific authorizations for release of records and must unconditionally accept any one the following executed authorizations provided: (1) the Medical, Dental, and Pharmacy/MAT Authorization attached to this Order as Exhibit A, (2) the Court-approved Medical, Dental, and Pharmacy/MAT Authorization entered in Case Management Order No. 12 (ECF No. 158-2),or (3) any Medical, Dental, and Pharmacy/MAT Authorization provided by the Plaintiff's counsel either executed before the date of this Order or delivered to the Entity before the Plaintiff filed his or her case in this MDL (including requests delivered to the Entity before the date of this Order).

IV.B.2. Entities may not require additional documentation beyond a Plaintiff's executed authorization, such as a copy of Plaintiff's identification, before producing records. Counsel for the Plaintiff is responsible for verifying that the individual executing the authorization is the Plaintiff.

IV.C. Deadline to Provide Records

Upon receipt of one of the above-listed Plaintiff executed medical authorizations and a copy of this Order, an Entity must produce such records to requesting counsel or its designee listed in the authorization **within 30 days**.

3

IV.D. Procedural Protections (Fed. R. Civ. P. 45)

An Entity receiving an authorization under Paragraph IV.B of this Order will treat the request as a subpoena under Rule 45 of the Federal Rules of Civil Procedure issued in the district where the Entity is located. A copy of Rule 45 is appended to this Order. It is presumed that the parties are aware that records of a Plaintiff's care and treatment will be requested from a Plaintiff's providers. Therefore, a requesting party does not need to provide notice under Rule 45(a)(4) to the non-requesting party or parties.

V. Failure to Comply

Failure to comply with any of the terms of this Order will result in an Order to Show Cause why the Entity should not be held in contempt or subjected to sanctions under Rule 37(b)(2)(A) for failure to comply with a discovery order. Any Plaintiff's counsel that needs to alert the Court to lack of compliance with this Order shall notify Plaintiff's' Liaison Counsel by email (alyson@hsglawgroup.com), providing the name of the Plaintiff, the name of the Entity, and the date of the request. The parties will alert the Court to any non-compliance issues with their joint agendas to the regularly scheduled case-management conferences. At the earliest possible date, the Court will set a hearing at which a representative of the Entity that does not timely comply with this Order will be required to appear personally before the Court to explain the Entity's failure to obey this Order.

VI. Order Remains in Force

This Order shall remain in force and effect until modified, superseded, or terminated by consent of the Parties or by Order of the Court. The Court retains jurisdiction after termination of this action to enforce this Order and to make such amendments, modifications, deletions, and additions to this Order as the Court may deem appropriate.

VII. Modifying Order

Nothing in this Order shall be construed to prohibit the Parties from agreeing to modify any provision of this Order or seeking relief from the Court. Nor shall anything in this Order or any Party's compliance with it be construed as a waiver of any Party's rights under applicable law.

SO ORDERED.

Dated: February 13, 2024

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

Case: 1:24-md-03092-JPC Doc #: 194-1 Filed: 02/13/25 1 of 2. PageID #: 5295

EXHIBIT A to CMO 13

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:

[X] 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 xrays, panorexes, 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: ______ 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 C.F.R. § 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)

United States Code Annotated Federal Rules of Civil Procedure for the United States District Courts (Refs & Annos) Title VI. Trials

Federal Rules of Civil Procedure Rule 45

Rule 45. Subpoena

Currentness

(a) In General.

(1) Form and Contents.

(A) Requirements--In General. Every subpoena must:

(i) state the court from which it issued;

(ii) state the title of the action and its civil-action number;

(iii) command each person to whom it is directed to do the following at a specified time and place: attend and testify; produce designated documents, electronically stored information, or tangible things in that person's possession, custody, or control; or permit the inspection of premises; and

(iv) set out the text of Rule 45(d) and (e).

(B) *Command to Attend a Deposition--Notice of the Recording Method.* A subpoena commanding attendance at a deposition must state the method for recording the testimony.

(C) Combining or Separating a Command to Produce or to Permit Inspection; Specifying the Form for Electronically Stored Information. A command to produce documents, electronically stored information, or tangible things or to permit the inspection of premises may be included in a subpoena commanding attendance at a deposition, hearing, or trial, or may be set out in a separate subpoena. A subpoena may specify the form or forms in which electronically stored information is to be produced.

(D) *Command to Produce; Included Obligations.* A command in a subpoena to produce documents, electronically stored information, or tangible things requires the responding person to permit inspection, copying, testing, or sampling of the materials.

(2) Issuing Court. A subpoena must issue from the court where the action is pending.

(3) *Issued by Whom.* The clerk must issue a subpoena, signed but otherwise in blank, to a party who requests it. That party must complete it before service. An attorney also may issue and sign a subpoena if the attorney is authorized to practice in the issuing court.

(4) *Notice to Other Parties Before Service.* If the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then before it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party.

(b) Service.

(1) By Whom and How; Tendering Fees. Any person who is at least 18 years old and not a party may serve a subpoena. Serving a subpoena requires delivering a copy to the named person and, if the subpoena requires that person's attendance, tendering the fees for 1 day's attendance and the mileage allowed by law. Fees and mileage need not be tendered when the subpoena issues on behalf of the United States or any of its officers or agencies.

(2) Service in the United States. A subpoena may be served at any place within the United States.

(3) *Service in a Foreign Country*. 28 U.S.C. § 1783 governs issuing and serving a subpoend directed to a United States national or resident who is in a foreign country.

(4) *Proof of Service.* Proving service, when necessary, requires filing with the issuing court a statement showing the date and manner of service and the names of the persons served. The statement must be certified by the server.

(c) Place of Compliance.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

- (i) is a party or a party's officer; or
- (ii) is commanded to attend a trial and would not incur substantial expense.
- (2) For Other Discovery. A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction--which may include lost earnings and reasonable attorney's fees--on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) *Appearance Not Required*. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises--or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) *When Required*. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative*. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) *Producing Documents or Electronically Stored Information*. These procedures apply to producing documents or electronically stored information:

(A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoend does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery

from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(f) Transferring a Subpoena-Related Motion. When the court where compliance is required did not issue the subpoena, it may transfer a motion under this rule to the issuing court if the person subject to the subpoena consents or if the court finds exceptional circumstances. Then, if the attorney for a person subject to a subpoena is authorized to practice in the court where the motion was made, the attorney may file papers and appear on the motion as an officer of the issuing court. To enforce its order, the issuing court may transfer the order to the court where the motion was made.

(g) Contempt. The court for the district where compliance is required--and also, after a motion is transferred, the issuing court-may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

CREDIT(S)

(Amended December 27, 1946, effective March 19, 1948; December 29, 1948, effective October 20, 1949; March 30, 1970, effective July 1, 1970; April 29, 1980, effective August 1, 1980; April 29, 1985, effective August 1, 1985; March 2, 1987, effective August 1, 1987; April 30, 1991, effective December 1, 1991; April 25, 2005, effective December 1, 2005; April 12, 2006, effective December 1, 2006; April 30, 2007, effective December 1, 2007; April 16, 2013, effective December 1, 2013.)

<Amendments received through April 1, 2024>

Rule 45. Subpoena, FRCP Rule 45 Doc #: 194-2 Filed: 02/13/25 6 of 6. PageID #: 5302

Footnotes

1 So in original. Probably should be "subparagraph (c)(2)(B)".

Fed. Rules Civ. Proc. Rule 45, 28 U.S.C.A., FRCP Rule 45 Including Amendments Received Through 2-1-2025

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