

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS  
GRANUFLO/NATURALTE DIALYSATE  
PRODUCTS LIABILITY LITIGATION

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MDL NO. 1:13-MD-2428-DPW

*THIS DOCUMENT RELATES TO ALL  
CASES*

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CASE MANAGEMENT ORDER NO. [ ]

**(Protective Order Regarding Inadvertently or Mistakenly Produced Protected Health Information)**

**I. SCOPE OF ORDER**

1. This Protective Order incorporates by reference Case Management Order No. 5 (Protective Order of Confidentiality), Document 413.

2. This Protective Order applies all to Discovery Material produced or disclosed in this Litigation, whether produced or disclosed prior or subsequent to the entry of this Protective Order.

**II. DEFINITIONS**

3. Protected Health Information. “Protected Health Information” is defined herein as “individually identifiable health information...that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium.” 45 C.F.R. § 160.103. Individually identifiable health information (“IIHI”) as used herein shall mean any information about the past, present or future physical or mental health or condition, or treatment, of an individual, the provision of health care to an individual, or the past, present or

future payment for the provision of health care to an individual. To the extent that the materials described above include IIHI of a relative or other person (other than the patient), such information also shall be considered IIHI.

4. Party. “Party” means any of the parties in this Litigation, including employees, agents, officers and directors of such parties. “Parties” means all of the parties in this Litigation.

5. Discovery Material. “Discovery Material” means all non-public information, documents, medical records, or tangible things, responses to discovery requests, deposition testimony or transcripts, including exhibits thereto, and any other similar materials, or portions thereof.

6. Receiving Party. “Receiving Party” means a Party to this Litigation, and all employees, agents and directors of the Party that receive Discovery Material from a Producing Party.

7. Producing Party. “Producing Party” means a Party to this Litigation, and all directors, employees and agents of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party.

8. This Litigation. “This Litigation” means all cases currently pending in the above-captioned multidistrict litigation and all related actions that have been filed in, transferred or removed to this Court and assigned thereto.

**III. INADVERTENT OR MISTAKEN PRODUCTION OF PROTECTED HEALTH INFORMATION – CLAWBACK PROCEDURES**

9. In view of the large volume of Discovery Material produced in this Litigation, the Court recognizes that Discovery Material may inadvertently include Protected Health Information that should have been withheld in whole or in part on the basis of an absolute or qualified privilege or other legal protection from disclosure, including but not limited to the

protections afforded Protected Health Information under the Health Insurance Portability and Accountability Act (“HIPAA”) and various state and federal laws and regulations (“PHI Privilege”).

10. Inadvertent or mistaken production of Protected Health Information shall not constitute a waiver of any objection or applicable privilege or legal protection, including without limitation any PHI Privilege, either as to the specific information disclosed or as to any other information relating thereto or of the same or related subject matter. No action taken or not taken in accordance with this CMO nor failure to object to such action shall be construed as a waiver of any claim or defense in this Litigation.

11. In the event the Producing Party discovers it has inadvertently or mistakenly produced Protected Health Information, the Producing Party shall, within thirty (30) calendar days of the discovery of the inadvertent or mistaken disclosure, notify the Receiving Party in writing of the inadvertent or mistaken disclosure. The Producing Party may, in the notice, request a “clawback” of the inadvertently or mistakenly disclosed Protected Health Information. Except as set forth in paragraph 12 below, the Party receiving such clawback notice shall immediately and diligently act to retrieve any inadvertently or mistakenly produced protected health information, and all copies, including any loaded onto any litigation support databases, and return them to the Producing Party or destroy them as agreed between the Parties. All notes or other work product of the Receiving Party reflecting the contents of such materials shall be destroyed and not used.

12. If, upon receipt of such clawback notice set forth in paragraph 11, the Receiving Party challenges the designation of Protected Health Information, the Receiving Party shall notify the Producing Party of the challenge, in writing, within 10 days following receipt of the

clawback notice. Upon receipt of a challenge to the designation of Protected Health Information, the Producing Party may, within 14 days, move the Court to resolve the challenge to the Protected Health Information. Pending the resolution of such motion, the Receiving Party may retain possession of the inadvertently or mistakenly disclosed Protected Health Information as well as any notes or other work product of the Receiving Party reflecting the contents of such materials but shall segregate and not use such information or materials pending resolution of the motion, except as part of any briefing on the motion to the Court. The parties may, in support of their positions, submit the inadvertently produced information to the Court in a sealed envelope that shall be clearly marked:

“THIS ENVELOPE CONTAINS DOCUMENTS MARKED AS CONFIDENTIAL THAT ARE THEREFORE COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER AND LOCAL RULE 7.2. THE CONFIDENTIAL CONTENTS OF THIS ENVELOPE MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT.”

If the Producing Party’s motion is allowed, the Receiving Party shall promptly comply with paragraph 11 above and no use shall be made of such inadvertently or mistakenly produced Protected Health Information during depositions or at trial, nor shall the information be disclosed to anyone who was not given access to it prior to the request to return or destroy it unless otherwise ordered by the Court.

13. In the event the Receiving Party discovers Protected Health Information in Discovery Material that identifies any individual other than a named plaintiff, the Receiving Party shall as soon as practicable within thirty (30) calendar days of the discovery of the Protected Health Information, notify the Producing Party in writing of the Protected Health Information, specifically indicating the Discovery Material in question, so that the Producing

Party can determine whether an inadvertent or mistaken disclosure has occurred. After receiving notice from the Receiving Party, the Producing Party then has thirty (30) calendar days to determine whether an inadvertent or mistaken disclosure has in fact occurred, and if so, to notify the Receiving Party in writing of the inadvertent or mistaken disclosure and invoke the procedures relating to “clawback” of such Discovery Material as set forth in paragraph 11 herein. Nothing herein obligates the Receiving Party affirmatively to review Discovery Material specifically for Protected Health Information; this paragraph is intended only to require the Receiving Party to notify the Producing Party in instances where the Receiving Party plainly identified Protected Health Information in Discovery Material.

14. Once the Receiving Party has returned or destroyed the inadvertently or mistakenly disclosed Protected Health Information, the Producing Party then has an additional thirty (30) calendar days to produce Discovery Material that has been redacted to omit the inadvertently or mistakenly disclosed Protected Health Information.

15. The Parties hereby confirm the continued applicability of any and all protective orders in this Litigation including but not limited to protective orders governing the disclosure of Protected Health Information in this Litigation.

**IT IS SO ORDERED.**

**BY THE COURT:**



Douglas P. Woodlock  
United States District Judge

Dated: *June 19, 2014*