

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS  
GRANUFLO/NATURALYTE DIALYSATE  
PRODUCTS LIABILITY LITIGATION,

This Document Relates To:

ALL CASES

MDL No. 1:13-md-02428-DPW

**CASE MANAGEMENT ORDER No. 16**  
**(Rules and Procedures Relating to the Authorization for Release of**  
**Protected Health Information Relating to Claimants)**

**THIS MATTER**, having been submitted to the Court on agreement of the parties and for good cause shown, **IT IS HEREBY ORDERED** as follows:

1. *The basis for this Order.* On February 17, 2016 the parties reported that they have reached a settlement in principle of all claims related to this litigation. In order to facilitate the timely and efficient processing of the settlement, each claimant's treatment records must be reviewed to verify product identification and any other medical information related to his or her claim. Third-party healthcare providers have custody of these records in many cases, and the MDL Plaintiffs Executive Committee has indicated that certain healthcare providers have refused to release information protected under the Health Insurance Portability and Accountability Act ("HIPAA") unless specific forms prepared by the particular entity are used or, in the case of a deceased claimant, only where a duly appointed personal representative has authorized said filing. These requirements will cause delay in the exchange of relevant information and will unnecessarily prolong the settlement process. In order to facilitate the timely settlement of this litigation, the PEC has prepared the HIPAA-compliant authorization

form attached as Exhibit A. The purpose of this order is to provide for a simple, uniform, and cost-effective process for the collection of records necessary for a determination of compensable claims in this and related litigations. Accordingly, this Order is issued pursuant to the Court's authority to direct and control the coordinated discovery in this litigation pursuant to 28 U.S.C. § 1407, Fed.R.Civ.P. 16, Fed.R.Civ.P. 26(b), and the All Writs Act, 28 U.S.C. § 1651.

**2. *Claimants Affected By This Order.*** This Order applies to all claims for personal injury brought by plaintiffs in connection with use of GranuFlo and/or NaturaLyte, whether pending before this Court under MDL 2428, in the consolidated Massachusetts state court litigation, MICV-2013-03400-O, in other state courts including but not limited to cases pending in St. Louis, Missouri, New York, New York, California and other states, as well as cases pending in the District Court of the Navajo Nation, Judicial District of Dzil Yijiin, Arizona, DY-CV-10-2014, and the San Carlos Apache Trial Court in and for the San Carlos Apache Reservation, No. CV.2014-0017.

**3. *Duty to Accept Court-Approved Authorization to Release Medical Records.*** The Authorization Form attached to this Order is HIPAA compliant and has been approved for use in all claims affected by this Order. Accordingly:

- (a) All physicians, healthcare providers, any federal, state, and/or local government agencies, or any other entity asked to produce records relating to a claimant (all referred to as "Entities") shall accept the Authorization Form as valid for all claims affected by this Order;
- (b) Entities may not request or insist upon different forms or terms different from the Authorization Forms;

- (c) When signed by a claimant or claimant's personal representative in claims affected by this Order, the Authorization Form shall be relied upon by all Entities to authorize the release of all records, including all medical and psychiatric records;
- (d) No facility-specific or different form shall be necessary for production of any records relating to a current or former patient;
- (e) A photocopy or .pdf image of the Authorization Form shall be accepted;
- (f) No original signatures shall be required on the Authorization Form for production of any records relating to a current or former patient;
- (g) Any Authorization Form dated after the entry of this Case Management Order, shall be effective for production of any records relating to a current or former patient and no differently dated Authorization shall be necessary or requested by the Entities;
- (h) Entities may not impose any waiting period for the production of records; and
- (i) Entities may not condition the release of requested records upon the payment of unreasonable "processing" or "handling" fees.

4. ***Deceased Claimants.*** In many cases, claimants in this litigation are deceased. Requiring the probate of a deceased claimant's estate for the sole purpose of executing a HIPAA authorization is inefficient, costly, and unnecessarily taxes the resources of the probate courts. Due to the difficulties the parties are experiencing in obtaining pertinent medical records on behalf of those clients who are deceased, the Court finds it necessary for the efficient procurement of those records to have specific rules pertaining to claims involving deceased claimants or potential claimants. For the sole and limited purpose of obtaining records associated with a claim covered by this Order, Plaintiff's counsel is considered the "personal representative" of an estate he/she represents and may sign the

Court-Approved Authorization to obtain records. All Entities are hereby Ordered to accept an Authorization for a deceased plaintiff signed by Plaintiff's counsel.

**SO ORDERED** this 10<sup>th</sup> day of March, 2016.

  
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DOUGLAS P. WOODLOCK, J.