UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION **MDL No. 1:13-md-2428-DPW**

This Document Relates to:

All Cases

CASE MANAGEMENT ORDER NO. 3
(Mechanism for Expedited Disclosure by Defendants of Plaintiffs' Medical Records and Extension of Date for Service of Plaintiff Fact Sheets)

THIS MATTER, having been submitted to the Court on agreement of the parties and for good cause shown, **IT IS HEREBY ORDERED,** that the deadlines for the completion of Plaintiff and Defendant Fact Sheets as set forth in Case Management Order No. 2 (Initial Scheduling Order) are amended as follows:

I. PRE-LITIGATION MEDICAL RECORD REQUESTS

1. In any case currently pending in this MDL where the injury/death is alleged to have been the result of treatment at a Fresenius Medical Care North America ("FMCNA") dialysis clinic, and a HIPAA compliant request (including legal proof of authority under applicable state law) for the patient's dialysis clinic medical chart was made prior to the filing of the complaint, and that request remains outstanding as of the date of this Order, counsel for Plaintiff shall by November 27, 2013, provide a designated representative of the law firm of Bradley Arant Boult Cummings with:

(a) a completed *CMO-3 Plaintiff Case Information Form* ("CIF") (Exhibit A);

(b) a copy of the pre-litigation request;

(c) a completed and executed HIPAA Authorization for the Release of Healthcare Records ("*HIPAA Authorization*") signed by the injured party or decedent's next of

kin, or the proposed representative of the decedent's estate in the form attached to this Order as Exhibit B; and

(d) any relevant, non-privileged medical records of the injured party/decedent in Plaintiff's possession or, in the absence of any such records, an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit C.

The foregoing shall be provided both by electronic and U.S. mail to:

GranuFloPlaintiffCaseInformation@babc.com

and

Darrell Tucker, Esq.
Bradley Arant Boult Cummings, LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203-2119

2. No later than forty-five (45) days following receipt of the materials identified in paragraph 1(a)-(d) above, FMCNA shall either:

(a) produce to the individual Plaintiff's attorney the Plaintiff's clinic medical chart[1] in its possession, custody and control, or,

[1]As used herein, the term "clinic medical chart" means all HIPAA protected medical information as defined in 45 C.F.R. § 164.501, whether in paper or electronic form that is maintained by the dialysis facility. The parties are still in the process of addressing Plaintiffs' request for patient data which may be in Defendants' possession, custody and control that may not be part of a traditional clinic medical chart or record related to the Plaintiff but that may be housed in Defendant's "Data Warehouse" database, or any other database containing data relating to the Plaintiff ("additional HIPAA Plaintiff Information"). The parties shall meet and confer within 20 days from the entry of this order to conduct an "over the shoulder" review of the Data Warehouse for a limited number of plaintiffs' counsel and any other agreed upon review of this type of data possessed by Defendants, in order to then either reach agreement or present to the Court competing versions of a discovery request as to this topic (including the nature, scope and timing of same), to be filed prior to the next scheduled Status Conference for consideration by the Court at that time. Plaintiffs continue to reserve the right to seek discovery of additional patient data from the defendants' databases as requested during the course of pretrial discovery.

(b) provide an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit D, provided, however, that to the extent FMCNA is unable to provide the full clinic medical chart within forty-five (45) days, the parties may extend the deadline for production by mutual agreement or upon motion by FMCNA.

3. Within forty-five (45) days following receipt of either the clinic medical chart or *Affidavit of Completion and No Records Statement* referred to in paragraph 2, the Plaintiff shall serve a completed *Plaintiff Fact Sheet* on the designated representative of Bradley Arant Boult Cummings as set forth in paragraph 1 above.

4. Within sixty (60) days following receipt of the Plaintiff Fact Sheet, FMCNA shall serve a completed Defendant Fact Sheet on Plaintiff's counsel.

II. POST-LITIGATION MEDICAL RECORD REQUESTS

5. In any case currently pending in this MDL where the injury/death is alleged to have been the result of treatment at an FMCNA dialysis clinic and counsel for Plaintiff did not request the patient's clinic medical chart prior to the filing of the complaint, counsel for Plaintiff shall, within five (5) days of the date of this order, provide the designated representative of the law firm of Bradley Arant Boult Cummings with:

(a) a completed *CMO-3 Plaintiff Case Information Form* ("CIF") (Exhibit A); and,

(b) a completed and executed HIPAA Authorization for the Release of Healthcare Records ("*HIPAA Authorization*") signed by the injured party or decedent's next of kin, or the proposed representative of the decedent's estate in the form attached to this Order as Exhibit B; and,

(c) any relevant, non-privileged medical records of the injured party/decedent in Plaintiff's possession or, in the absence of any such records, an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit C.

6. No later than ninety (90) days following receipt of the materials identified in paragraph 5(a)-(c) above, FMCNA shall either:

(a) produce to the individual Plaintiff's attorney the Plaintiff's clinic medical chart for the facility identified in the CIF, or,

(b) provide an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit D,

provided, however, that if the number of clinic medical chart requests received by FMCNA pursuant to paragraph 5 of this Order exceeds one hundred (100), the parties may extend the deadline for production by mutual agreement or upon motion by FMCNA.

7. Within thirty (30) days following receipt of either the clinic medical chart or *Affidavit of Completion and No Records Statement* referred to in paragraph 5, the Plaintiff shall serve a completed *Plaintiff Fact Sheet* on the designated representative of Bradley Arant Boult Cummings as set forth in paragraph 1 above.

8. Within sixty (60) days following receipt of the Plaintiff Fact Sheet, FMCNA shall serve a completed Defendant Fact Sheet on Plaintiff's counsel.

III. NEWLY FILED, REMOVED OR TRANSFERRED CASES

9. For cases that are not currently pending in this MDL as of the date of the entry of this Order, the deadline for the completion of *Plaintiff Fact Sheets* set forth in paragraph 4(d) of *Case Management Order No. 2 (Initial Scheduling Order)* may be extended in accordance with paragraphs 5 through 8 of this CMO in a case alleging injury/death resulting from treatment at a

FMCNA dialysis clinic if, prior to the existing deadline for serving the *Plaintiff Fact Sheet*, that Plaintiff provides the representative of Bradley Arant Boult Cummings identified in paragraph 1 above with the information and documents set forth in paragraphs 5 (a)-(c) above.

V. FURTHER PROCEEDINGS

10. All other provisions of *Case Management Order No. 2* remain in full force and effect.

11. This Order may be modified in the interests of justice, expedience, or judicial economy on the Court's own motion or a motion by the parties for good cause shown.

IT IS SO ORDERED.

BY THE COURT:

Douglas P. Woodlock
United States District Judge

November 6, 2013

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 1:13-MD-2428-DPW**

EXHIBIT A

Case Information Form

I. CASE INFORMATION

Caption: _____ Date Filed: _____

Docket No. (Including Court):

_____

Plaintiff's Attorney and Contact Information, Including Telephone Number:

_____

_____

_____

II. PLAINTIFF'S INFORMATION

Full Name of Patient: _____

Last Address: _____

Date of Birth: _____

Patient's FMS Medical Record Number, also known as the Patient Identification Number:

_____

If unknown, please provide the following information:

a. Patient's Medicare Identification Number, if known: _____

b. Last four digits of Patient's Social Security Number: _____

Name and address of FMS dialysis facility where Patient received last dialysis treatment prior to injury / death: _____

_____

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

Patient Name:	Date of Birth:	Social Security Number:
Patient Address:		

I, or my authorized representative, request that health information regarding my care and treatment be released as set forth on this form.

In accordance with the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. 164.508, I understand that:

1. This authorization may include disclosure of information relating to **alcohol and drug abuse, mental health treatment,** except psychotherapy notes, and **confidential HIV related information,** only if I place my initials on the appropriate line in Item 11(a). In the event the health information described below include any of these types of information, and I initial the line on the box in Item 11(a), I specifically authorize release of such information to the person(s) indicated in Item 10.

2. If I am authorizing the release of HIV-related, alcohol or drug treatment, or mental health treatment information, the recipient is prohibited from redisclosing such information without my authorization unless permitted to do so under federal or state law. I understand that I have a right to request a list of people who may receive or use my HIV-related information without authorization.

3. I have the right to revoke this authorization at any time by writing to the health care provider listed below. I understand that I may revoke this authorization except to the extent that action has already been taken based on this authorization.

4. I understand that signing this authorization is voluntary. My treatment, payment, enrollment in a health plan, or eligibility for benefits will not be conditioned upon my authorization of this disclosure. **Any photostatic copy of this document shall have the same authority as the original, and may be substituted in its place.**

5. Information disclosed under this authorization might be redisclosed by the recipient, and this redisclosure may no longer be protected by federal or state law, except as noted in Item 2.

6. This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).

7. This authorization shall be valid through December 31, 2016.or the conclusion of my case, whichever occurs first; unless it is revoked as provided in Item 3, and shall remain in full force and effect until such expiration, and further authorizes the Provider to release to the Recipient any additional records created or obtained by the Provider after the date hereof. **The records requester has agreed to pay reasonable charges made by the Provider to supply copies of such records.**

8. This authorization specifically does **NOT** authorize the release of original documents and materials, including tissue slides, tissue blocks and tissue samples.

9. Name and address of health provider or entity to release this information:	
10. Name and address of entity(ies) to whom this information will be mailed or sent:	Name and address of entity as designee to whom this information will be mailed or sent:

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

11(a). Specific information to be released:

☑ Medical Records and patient data (See CMO - ___ in MDL No. 2428)

☑ Entire Medical Record, including, but not limited to, patient histories, office notes (except psychotherapy notes, biopsy/pathology specimens and/or materials, and autopsy materials), diagnoses, analyses, progress reports, laboratory reports, test results, x-rays, radiology reports, radiology films or scans (in any form), referrals, consults, billing records, correspondence, prescription records, autopsy reports, pathology reports, death certificates, consents for treatment, insurance records, and records sent to you by other health care providers.

☐ Other: _____

_____

Include: (*Indicate by initialing)*

_____**Alcohol/Drug Treatment**

_____**Mental Health Information**

_____ **HIV-Related Information**

Authorization to Discuss Health Information

11(b) ☐ By initialing here _____ I authorize _____

Name of individual health care provider

to discuss my health information with my attorney, or a governmental agency listed here:

_____

(Attorney/Firm Name or Governmental Agency Name)

*****This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).**

12. Reason for release of information:	13. Date or event on which this authorization will expire:
☐ At request of individual ☑ Other: **Litigation**	**December 31, 2016 or at the conclusion of the case, whichever occurs first.**
14. If not the patient, name of person signing form:	15. Authority to sign on behalf of patient:

All items on this form have been completed and my questions about this form have been answered. In addition, I have been provided a copy of the form.

_____ Date: _____

Signature of patient or authorized representative

ACKNOWLEDGMENT

The undersigned, as the record requester named in the above medical authorization, hereby declares under penalty of perjury, pursuant to 28 U.S.C. Section 1746, that the attorney to the patient named in the foregoing medical authorization has been given notice that the authorization will be used to request records from the person or entity to whom it is addressed, and the attorney has been given five (5) days advance notice and has been afforded an opportunity to object to the request and any objections have been resolved. The attorney for the patient named in the foregoing medical authorization has also been afforded an opportunity to order copies of the records from the undersigned requestor at a reasonable cost.

_____

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

Patient Name:	Date of Birth:	Social Security Number:
Patient Address:		

I, or my authorized representative, request that health information regarding my care and treatment be released as set forth on this form.

In accordance with the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. 164.508, I understand that:

1. This authorization includes disclosure of all mental health or other confidential records relating to my emotional or other psychiatric/psychological condition for the purpose of review and evaluation in connection with a legal claim. I expressly request that all covered entities under HIPAA identified in Item 9, below, disclose full and complete protected medical information spanning the time period of the beginning of my treatment to the present, including the following:

   All mental health, psychiatric, and psychological records, notes, and evaluations, including inpatient, outpatient and emergency room treatment, all clinical charts, reports, order sheets, progress notes, nurse's notes, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, marriage or family counseling records, records received by other physicians, pharmacy and prescription record, billing records and records of billing to third party payers and payment or denial of benefits.

2. This authorization includes information relating to **alcohol and drug abuse** and **confidential HIV related information,** only if I place my initials on the appropriate line in Item 11(a). In the event the health information described below include any of these types of information, and I initial the line on the box in Item 11(a), I specifically authorize release of such information to the person(s) indicated in Item 10. If I am authorizing the release of HIV-related, alcohol or drug treatment, the recipient is prohibited from redisclosing such information without my authorization unless permitted to do so under federal or state law. I understand that I have a right to request a list of people who may receive or use my HIV-related information without authorization.
3. I have the right to revoke this authorization at any time by writing to the health care provider listed in Item 9, below. I understand that I may revoke this authorization except to the extent that action has already been taken based on this authorization. I also understand and intend this authorization to be continuing in nature. If information responsive to this authorization is created, learned or discovered at any time in the future, either by you or another party, you must produce such information to the party indicated below in 11(b).
4. I understand that signing this authorization is voluntary. My treatment, payment, enrollment in a health plan, or eligibility for benefits will not be conditioned upon my authorization of this disclosure.
5. **Any photostatic copy of this document shall have the same authority as the original, and may be substituted in its place.**
6. Information disclosed under this authorization might be redisclosed by the recipient, and this redisclosure may no longer be protected by federal or state law, except as noted in Item 2.
7. This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).
8. This authorization shall be valid through December 31, 2016. or the conclusion of my case, whichever occurs first; unless it is revoked as provided in Item 3, and shall remain in full force and effect until such expiration, and further authorizes the Provider to release to the Recipient any additional records created or obtained by the Provider after the date hereof. **The records requester has agreed to pay reasonable charges made by the Provider to supply copies of such records.**

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

9. Name and address of health provider or entity to release this information:

10. Name and address of entity(ies) to whom this information will be mailed or sent:

Name and address of entity as designee to whom this information will be mailed or sent:

11(a). Specific information to be released:

☑ Medical Records from (insert date) _____ to (insert date) _____.

☑ Entire Medical Record, including, but not limited to, all mental health, psychiatric, and psychological records, notes, and evaluations, including inpatient, outpatient and emergency room treatment, all clinical charts, reports, order sheets, progress notes, nurse's notes, clinic records, treatment plans, admission records, discharge summaries, requests for and reports of consultations, documents, correspondence, test results, statements, questionnaires/histories, marriage or family counseling records, records received by other physicians, pharmacy and prescription record, billing records and records of billing to third party payers and payment or denial of benefits.

☐ Other: _____
_____

Include: (*Indicate by initialing)*
_____ **Alcohol/Drug Treatment**
_____ **HIV-Related Information**

Authorization to Discuss Health Information

11(b) ☐ By initialing here _____ I authorize _____
Name of individual health care provider
to discuss my mental heath information with my attorney, or a governmental agency listed here:

_____
(Attorney/Firm Name or Governmental Agency Name)

*****This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).**

12. Reason for release of information:
☐ At request of individual
☑ Other: **Litigation**

13. Date or event on which this authorization will expire:
December 31, 2016 or at the conclusion of the case, whichever occurs first.

14. If not the patient, name of person signing form:

15. Authority to sign on behalf of patient:

All items on this form have been completed and my questions about this form have been answered. In addition, I have been provided a copy of the form.

_____ Date: _____
Signature of patient or authorized representative

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

ACKNOWLEDGMENT

The undersigned, as the record requester named in the above medical authorization, hereby declares under penalty of perjury, pursuant to 28 U.S.C. Section 1746, that the attorney to the patient named in the foregoing medical authorization has been given notice that the authorization will be used to request records from the person or entity to whom it is addressed, and the attorney has been given five (5) days advance notice and has been afforded an opportunity to object to the request and any objections have been resolved. The attorney for the patient named in the foregoing medical authorization has also been afforded an opportunity to order copies of the records from the undersigned requestor at a reasonable cost.

_____

Exhibit "C"

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	**MDL No. 1:13-md-2428-DPW**
This Document Relates to:	
[INSERT NAME AND COURT TERM AND NUMBER OF INDIVIDUAL CASE]	

AFFIDAVIT OF COMPLETION AND/OR NO RECORDS STATEMENT
(Medical Records in Plaintiff's Possession and Authorizations)

1. I, [INSERT ATTORNEY] am counsel for Plaintiff [insert Plaintiff's name and, if in representative capacity, name of injured/decedent] in the above-captioned matter

2. I am familiar with the discovery obligations set forth in CMO-2 and CMO-3 relating to the production of relevant, non-privileged medical records in Plaintiffs' possession and authorizations for additional records of a plaintiff or claimant.

3. I make this Affidavit after a reasonable inquiry of a diligent check for medical and other records of the Plaintiff in the Plaintiffs' possession and counsel's possession as of the date of this Affidavit and hereby attest that, to the best of my knowledge, information, and belief: (1) all relevant, non-privileged medical records in Plaintiffs' or Plaintiff's Counsel's possession as of the date of this Affidavit have been produced to counsel for Defendants; or (2) if no such records have been produced by the date of this Affidavit, no such records are in the possession of either the Plaintiff or counsel for the Plaintiff.

4. I hereby attest that completed authorizations for additional records of the plaintiff or claimant have been produced to counsel for the Defendants on this date.

I declare under the penalty of perjury that the forgoing is true and correct.

_____

[Insert]

Exhibit "D"

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	**MDL No. 1:13-md-2428-DPW**
This Document Relates to:	
[INSERT NAME AND COURT TERM AND NUMBER OF INDIVIDUAL CASE]	

AFFIDAVIT OF COMPLETION AND NO RECORDS STATEMENT

1. I, [INSERT ATTORNEY PERFORMING/SUPERVISING SEARCH], am counsel for defendants FRESENIUS USA, INC, FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA (hereinafter "North American Defendants") in the Granuflo MDL.

2. Pursuant to Case Management Order No. 3 (Mechanism for Expedited Disclosure of Plaintiffs' Medical Records), I have made a diligent check and I have sufficient knowledge of the processes conducted to comply with the discovery obligations set forth in CMO-3 entered by this Court.

3. I make this Affidavit after a reasonable inquiry of a diligent check for medical and other records of the Plaintiff in the above-referenced case as is required under Rule 26 of the Code of Civil Procedure and CMO-3, and hereby attest that to the best of my knowledge, information, and belief that no responsive documents or data were located and/or identified by Defendants' personnel and/or any third party. If responsive documents or data are identified and

/or located then the PEC will be promptly advised and a prompt production will be made to the Plaintiffs' counsel in the above-captioned case.

I declare under the penalty of perjury that the forgoing is true and correct.

_____

[Insert]