

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

UBIOME, INC.,¹

Debtor.

Chapter 11

Case No. 19-____ (____)

**DEBTOR’S MOTION FOR ENTRY OF AN ORDER AUTHORIZING
CERTAIN PROCEDURES TO MAINTAIN THE CONFIDENTIALITY OF
PATIENT INFORMATION AS REQUIRED BY APPLICABLE PRIVACY RULES**

uBiome, Inc., the debtor and debtor in possession in the above-captioned chapter 11 case (the “Debtor”), hereby moves the Court (this “Motion”) for the entry of an order (the “Order”), substantially in the form annexed hereto as Exhibit A, pursuant to sections 105(a), 107, and 521(a)(1) of title 11 of the United States Code (the “Bankruptcy Code”), Rules 1007, 9018, and 9037 of the Federal Rules of Bankruptcy Procedure (the “Bankruptcy Rules”), and Rule 1007-1 of the Local Rules of Bankruptcy Practice and Procedure of the United States Bankruptcy Court for the District of Delaware (the “Local Rules”), authorizing the Debtor to implement certain procedures to maintain the confidentiality of patient information as required by applicable privacy rules. In support of this Motion, the Debtor relies upon and incorporates by reference the *Declaration of Curtis G. Solsvig III in Support of the Debtor’s Chapter 11 Petition and Requests for First Day Relief* (the “First Day Declaration”), which was filed concurrently herewith.² In further support of this Motion, the Debtor respectfully represents as follows:

¹ The Debtor and the last four digits of its taxpayer identification number is: uBiome, Inc. (0019). The Debtor’s headquarters is located at 360 Langton Street, Suite 301, San Francisco, CA 94103.

² Capitalized terms used, but not otherwise defined herein, shall have the meanings given to them in the First Day Declaration.

JURISDICTION

1. The Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 157 and 1334(b), and the *Amended Standing Order of Reference* from the United States District Court for the District of Delaware dated as of February 29, 2012. This is a core proceeding pursuant to 28 U.S.C. § 157(b) and, pursuant to Local Rule 9013-1(f), the Debtor consents to the entry of a final order by the Court in connection with this Motion to the extent that it is later determined that the Court, absent consent of the parties, cannot enter final orders or judgments in connection herewith consistent with Article III of the United States Constitution. Venue is proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409. The statutory predicates for the relief requested herein are sections 105(a), 107, and 521(a)(1) of the Bankruptcy Code, and Bankruptcy Rules 1007, 9018, and 9037.

BACKGROUND

A. General Background

2. On the date hereof (the “Petition Date”), the Debtor commenced a voluntary case (this “Chapter 11 Case”) under chapter 11 of the Bankruptcy Code. Pursuant to sections 1107(a) and 1108 of the Bankruptcy Code, the Debtor is continuing to manage its financial affairs as debtor in possession. No trustee, examiner, or official committee of unsecured creditors has been appointed in this Chapter 11 Case.

3. Additional information regarding the Debtor’s history and business operations, capital structure and primary secured indebtedness, and the events leading up to the commencement of this Chapter 11 Case, can be found in the First Day Declaration.

B. Specific Background

4. As described more fully in the First Day Declaration, using advanced DNA sequencing and utilizing the world’s largest microbiome database, the Debtor has historically

offered a variety of products to patients and consumers to analyze their DNA and microbiomes, including “Explorer,” “SmartGut,” and “SmartJane.” Customers purchase mail-order kits to collect samples, complete a survey, and within a few weeks, the customer receives their results. In 2015, the Debtor received Clinical Laboratory Improvement Amendments certification from the state of California, and, in 2016, received accreditation from the College of American Pathologists. In the ordinary course of business, the Debtor has access to and receives “protected health information” that the Debtor is required to confidentially maintain pursuant to the Health Insurance Portability and Accountability Act of 1996³ and corresponding privacy rules⁴ (“HIPAA”). While the Debtor is no longer processing clinical tests, it has started a claims review process with several insurers regarding potential claim refunds.

RELIEF REQUESTED

5. By this Motion, the Debtor seeks entry of the Order establishing certain procedures to maintain the confidentiality of patient information as required by HIPAA.⁵

THE PROPOSED PRIVACY PROCEDURES

6. The Debtor requests that the Court establish the following procedures (the “Privacy Procedures”) to balance the need to protect patient health information pursuant to HIPAA with the requirement to publicly disclose information regarding this Chapter 11 Case:

- (a) the Debtor shall omit any reference to current or former patients from the matrix of creditors and any certificate of service filed on the docket in this Chapter 11 Case;
- (b) as applicable, the Debtor shall identify current or former patients in the Schedules of Assets and Liabilities (the “Schedules”) and the Statements of

³ 42 Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 42 U.S.C.)

⁴ 45 C.F.R. pts. 160, 164.

⁵ For the avoidance of doubt, the Debtor will continue to manage, protect, and utilize protected information in the ordinary course of its business in accordance with HIPAA. The proposed Privacy Procedures set forth herein only apply to the protection of patient information in this Chapter 11 Case.

Financial Affairs (the “Statements,” and together with the Schedules, the “Schedules and Statements”) solely by a code number, such as “Patient 1,” “Patient 2,” and so forth, and shall make an unredacted copy of the Schedules and Statements available upon request to (i) the Court and to the Office of the United States Trustee for the District of Delaware (the “U.S. Trustee”), (ii) respective counsel to the lenders under the Debtor’s proposed postpetition financing facility, and any statutory committee appointed in this Chapter 11 Case, only after entry into a mutually acceptable non-disclosure agreement that complies with HIPAA’s protected health information requirements, and (iii) any other party-in-interest only after the Court has entered an order, after notice and a hearing, authorizing and directing the Debtor to do so⁶ ((i) through (iii), the “Disclosure Procedures”);

(c) the Debtor or its claims and noticing agent shall maintain a list of all current or former patients (the “Patient List”) that appear on the matrix of creditors or are otherwise served with pleadings, as applicable, and shall make the Patient List, or any portion thereof, available in accordance with the Disclosure Procedures; and

(d) when the Debtor serves any document or pleading upon any person listed on the Patient List, the Debtor shall note in the respective certificate of service that the parties served include persons listed on the Patient List.

BASIS FOR RELIEF

7. It is of paramount importance to the Debtor that protected health information (“PHI”) be maintained during this Chapter 11 Case in accordance with patient expectations and HIPAA. HIPAA imposes stringent standards on health care providers regarding the use and disclosure of patients’ health information and establishes significant penalties for unauthorized use or disclosure of such information. Because the Debtor may qualify as a health care provider which transmits health information electronically, it may qualify as a “covered entity” subject to HIPAA. *See* 42 U.S.C. § 1320d-1(a)(3); 45 C.F.R. §§ 160.103, 164.104(3).

⁶ *See* 45 C.F.R. 164.512(e)(1)(i) (permitting the disclosure of certain information protected by HIPAA pursuant to a Court order, provided that the covered entity discloses only information expressly authorized by such order).

8. Under HIPAA, the Debtor may not disclose, except in limited circumstances, “individually identifiable health information.” *See* 45 C.F.R. § 164.502. HIPAA defines “individually identifiable health information” as

any information, including demographic information collected from an individual, that—

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition 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, and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

42 U.S.C. § 1320d(6); *see* 45 C.F.R. § 160.103 (utilizing same definition).

9. The Debtor could be subjected to significant penalties for the unauthorized disclosure of PHI. *See* 42 U.S.C. §§ 1320d-5 (establishing civil penalties for HIPAA violations), 1320d-6 (establishing criminal penalties for HIPAA violations); and 45 C.F.R. § 160.404 (setting forth the amount of amount of civil penalties for HIPAA violations). Certain penalties can be imposed even if a person “did not know and, by exercising reasonable diligence, would not have known” that a violation occurred. *See* 45 C.F.R. § 160.404(b)(2)(i).

10. The Debtor believes that the requirements to maintain patient confidentiality under HIPAA conflict with the requirements to disclose certain information under the Bankruptcy Code, specifically with regards to a debtor’s obligation to file a list of all creditors under section 521(a)(1)(A) of the Bankruptcy Code, the requirement to file Schedules and Statements under section 521(a)(1)(B) of the Bankruptcy Code, and the requirement to file

applicable certificates or affidavits of service. Therefore, the Debtor respectfully requests that PHI be protected through the proposed Privacy Procedures pursuant to section 107(c) of the Bankruptcy Code, which allows the Court, for cause, to protect an individual if disclosure would create an undue risk of unlawful injury. *See* 11 U.S.C. § 107(c); *see also* Bankruptcy Rule 9018 (allowing a bankruptcy court to protect governmental matters that are made confidential by statute or regulation).

11. The Court may also approve the proposed Privacy Procedures pursuant to section 105(a) of the Bankruptcy Code, which authorizes the a court to “issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title.” 11 U.S.C. § 105(a).

12. The Debtor believes that the relief requested herein appropriately balances the need to maintain confidential patient information under HIPAA with the need for adequate disclosure under the Bankruptcy Code. Given the nature of any information that may reveal even the identity of patients, confidentiality in this context is of paramount importance.

13. Relief similar to that requested in this Motion has been granted in other recent chapter 11 cases in this district which implicated the protection of PHI. *See, e.g., In re Hospital Acquisition LLC*, Case No. 19-10998 (BLS) (Bankr. D. Del. May 8, 2019) (authorizing the implementation of procedures to protect confidential information of current and former patients in compliance with HIPAA); *In re Promise Healthcare Grp., LLC*, Case No. 18-12491 (CSS) (Bankr. D. Del. Nov. 6, 2018) (same); *In re EBH TOPCO, LLC*, Case No. 18-11212 (BLS) (Bankr. Del. May 24, 2018) (same).

WAIVER OF BANKRUPTCY RULES 6004(h)

14. The Debtor also requests that the Court waive the stay imposed by Bankruptcy Rule 6004(h), which provides that “[a]n order authorizing the use, sale, or lease of property other

than cash collateral is stayed until the expiration of 14 days after entry of the order, unless the court orders otherwise.” Fed. R. Bankr. P. 6004(h). As described above, protection of PHI, as requested herein, is necessary for the Debtor to operate its business without interruption and to preserve value for its estate. Accordingly, the Debtor respectfully requests that the Court waive the fourteen-day stay imposed by Bankruptcy Rule 6004(h), as the exigent nature of the relief sought herein justifies immediate relief.

NOTICE

15. The Debtor will provide notice of this Motion to (a) the U.S. Trustee; (b) holders of the thirty (30) largest general unsecured claims against the Debtor; (c) counsel to the DIP Financing Parties; and (d) all parties that have filed a notice of appearance and request for service of papers pursuant to Bankruptcy Rule 2002. Notice of this Motion and any order entered hereon will be served in accordance with Local Rule 9013-1(m). In light of the nature of the relief requested herein, the Debtor respectfully submits that no other or further notice is necessary.

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WHEREFORE, for the reasons set forth herein, the Debtor respectfully requests that the Court (a) enter the Order substantially in the form annexed as **Exhibit A** hereto granting the relief requested herein and (b) grant such other and further relief as the Court may deem just and proper.

Dated: Wilmington, Delaware
September 4, 2019

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Andrew L. Magaziner

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Proposed Counsel to the Debtor and Debtor in Possession

Exhibit A

Proposed Order

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

UBIOME, INC.,¹

Debtor.

Chapter 11

Case No. 19-____ (____)

Ref. Docket No. ____

**ORDER AUTHORIZING CERTAIN PROCEDURES
TO MAINTAIN THE CONFIDENTIALITY OF PATIENT
INFORMATION AS REQUIRED BY APPLICABLE PRIVACY RULES**

Upon the *Debtor's Motion for Entry of an Order Authorizing Certain Procedures to Maintain the Confidentiality of Patient Information as Required by Applicable Privacy Rules* (the "Motion")² filed by the above-captioned debtor and debtor in possession (the "Debtor"); and this Court having found that it has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1334(b) and 157, and the *Amended Standing Order of Reference* from the United States District Court for the District of Delaware dated as of February 29, 2012; and this Court having found that venue of this Chapter 11 Case and the Motion in this district is proper pursuant to 28 U.S.C. §§ 1408 and 1409; and this Court having found that this matter is a core proceeding pursuant to 28 U.S.C. § 157(b); and this Court having found that notice of the Motion has been given as set forth in the Motion and that such notice is adequate and no other or further notice need be given; and this Court having determined that it may enter a final order consistent with Article III of the United States Constitution; and this Court having found and determined that the relief sought in the Motion is in the best interests of the Debtor, its estate, its creditors and all other parties in interest, and that the legal and factual bases set forth in the Motion establish just cause for the relief granted herein; and after due deliberation and sufficient cause appearing therefor,

¹ The Debtor and the last four digits of its taxpayer identification number is: uBiome, Inc. (0019). The Debtor's headquarters is located at 360 Langton Street, Suite 301, San Francisco, CA 94103.

² All capitalized terms not otherwise defined herein are to be given the meanings ascribed to them in the Motion.

IT IS HEREBY ORDERED THAT:

1. The Motion is GRANTED as set forth herein.
2. The following procedures (the “Privacy Procedures”) shall apply in this Chapter

11 Case:

- (a) the Debtor shall omit any reference to current or former patients from the matrix of creditors and any certificate of service filed on the docket in this Chapter 11 Case;
- (b) as applicable, the Debtor shall identify current or former patients in the Schedules of Assets and Liabilities (the “Schedules”) and the Statements of Financial Affairs (the “Statements,” and together with the Schedules, the “Schedules and Statements”) solely by a code number, such as “Patient 1,” “Patient 2,” and so forth, and shall make an unredacted copy of the Schedules and Statements available upon request to (i) the Court and to the Office of the United States Trustee for the District of Delaware (the “U.S. Trustee”), (ii) respective counsel to the lenders under the Debtor’s proposed postpetition financing facility, and any statutory committee appointed in this Chapter 11 Case, only after entry into a mutually acceptable non-disclosure agreement that complies with HIPAA’s protected health information requirements, and (iii) any other party-in-interest only after the Court has entered an order, after notice and a hearing, authorizing and directing the Debtor to do so³ ((i) through (iii), the “Disclosure Procedures”);
- (c) the Debtor or its claims and noticing agent shall maintain a list of all current or former patients (the “Patient List”) that appear on the matrix of creditors or are otherwise served with pleadings, as applicable, and shall make the Patient List, or any portion thereof, available in accordance with the Disclosure Procedures; and
- (d) when the Debtor serves any document or pleading upon any person listed on the Patient List, the Debtor shall note in the respective certificate of service that the parties served include persons listed on the Patient List.

3. The Debtor’s compliance with the foregoing Privacy Procedures shall constitute compliance with section 521 of the Bankruptcy Code, Bankruptcy Rule 1007(a), and Local Rule 1007.

³ See 45 C.F.R. 164.512(e)(1)(i) (permitting the disclosure of certain information protected by HIPAA pursuant to a Court order, provided that the covered entity discloses only information expressly authorized by such order).

4. The Debtor is authorized to take all actions necessary to effectuate the relief granted by this Order in accordance with the Motion.

5. Notwithstanding the possible applicability of Bankruptcy Rules 6004(h), 7062, 9014 or otherwise, this Order shall be immediately effective and enforceable upon its entry.

6. This Court retains jurisdiction with respect to all matters arising from or related to the interpretation or implementation of this Order.

Dated: Wilmington, Delaware
_____, 2019

United States Bankruptcy Judge