

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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VIA EMAIL

June 1, 2016

Ms. Jocelyn Samuels, Director
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHS Bldg.
Washington, D.C. 20201

Dear Director Samuels:

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the business practices of businesses who procure and resell fetal tissue.

The Panel's investigation uncovered a series of business contracts between StemExpress,¹ a tissue procurement business ("TPB"), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

These contracts produced a regime of cooperation between StemExpress and each clinic. In particular: (1) the day before scheduled abortions, StemExpress received a fax from a clinic with information about the abortions scheduled for the next day; (2) StemExpress employees were granted access to the medical files of individual patients; (3) The clinic's medical employees (doctors and nurses) directed the StemExpress employees to particular patients who were "good candidates" for fetal tissue donations; (4) the StemExpress employees had access to the "patient terminal" inside the abortion clinic; and (5) the StemExpress employees were permitted by the abortion clinic to interview the patients about personal information, including their dates of birth.

¹ StemExpress and Stem-Ex are the same company.

In particular, the Panel's investigation has uncovered information indicating that StemExpress and Planned Parenthood Mar Monte ("PPMM"), Planned Parenthood Shasta Pacific ("PPSP") and Family Planning Specialists Medical Group ("FPS") (hereinafter "the abortion clinics") committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rule from about 2010 to 2015. **These violations occurred when the abortion clinics disclosed patients' individually identifiable health information to StemExpress to facilitate the TPB'S efforts to procure human fetal tissue for resale.** This complaint is against each of these entities, and we request a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services.

In addition to this letter, we are submitting a referral to the HHS Office for Human Research Protections indicating that StemExpress violated 45 CFR 46 by using invalid consent forms and failing to have valid Institutional Review Board ("IRB") approval.²

I. BACKGROUND

The abortion clinics are "covered entities" under HIPAA, while StemExpress is not.³ StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."⁴

From about 2010 to 2015, the abortion clinics permitted StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain *individually identifiable health information*, or *protected health information* ("PHI") about their patients; interact with patients; and seek and obtain patient consent for tissue donation.⁵ StemExpress embedded tissue procurement technicians inside the abortion clinics whose **work sequence** followed a daily routine:

1. A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue.⁶
2. The abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.⁷

² See Attachment A.

³ See 45 CFR Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) See also OCR Privacy Brief, Summary of the HIPAA Privacy Rule, available at <http://www.hhs.gov/sites/default/files/privacysummary.pdf> (last visited May 5, 2016) (used as reference throughout this complaint).

⁴ Stemexpress, About Us, available at <http://stemexpress.com/about/> (last visited Apr. 29, 2016).

⁵ See Attachment B: Clinic Procedures & Policies.

⁶ See Attachment C: Researcher Procurement Record.

⁷ See Attachment D: Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.

3. The day the abortion procedures were scheduled, StemExpress posted the order on a website “task board” (order page) to be accessed by their procurement technician or communicated the order to the tissue technician via email.⁸
4. The StemExpress procurement technician informed the clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic provided the medical files, including PHI, for the patients with abortions scheduled for that day.⁹
5. The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. The procurement technician was also permitted to interview patients and obtain their PHI.¹⁰
6. StemExpress procurement technicians were paid an hourly wage and a per tissue “bonus” for each item they procured from the order page.¹¹
7. StemExpress paid the abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for sale to the researcher.¹²

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients’ PHI. Instead, the abortion clinics shared patients’ PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.¹³

II. THE HIPAA PRIVACY RULE

The HIPAA privacy rule (“Privacy Rule”) protects all *individually identifiable health information* held or transmitted by a covered entity or its business associate, and calls this information *protected health information* (“PHI”).¹⁴ PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security Number), and includes demographic data relating to: an individual’s past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.¹⁵

⁸ See Attachment E: Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Attachment F: Navigating The Task Board.

⁹ See Attachment G: StemExpress Emails.

¹⁰ See Attachment B, *supra*: Clinic Procedures and Policies and Attachment H: Consenting Patients.

¹¹ See Attachment I: Procurement Technician Compensation Policy for Tissue and Blood Procurement.

¹² See Attachment J: StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439.

¹³ See Attachment K: Standard Operating Procedure.

¹⁴ 45 C.F.R. § 160.103.

¹⁵ 45 C.F.R. § 160.103.

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,¹⁶ or as the individual or their representative authorizes in writing (see discussion below). HHS may impose civil money penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses, and any person who knowingly obtains, PHI in violation of the Privacy Rule can face criminal fines or imprisonment.¹⁷

III. THE CONTRACTS BETWEEN STEMEXPRESS AND THE ABORTION CLINICS

Particular language, contained within the four corners of the written contracts between StemExpress and the abortion clinics raises serious concerns that the parties violated the Privacy Rule.

The written contracts between StemExpress and the abortion clinics contain the following language:

[a]ny information obtained from [the abortion clinics] patients' charts shall be privileged, and [Stem-Ex / StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex / StemExpress] will not receive any information concerning identity of donors **except as necessary to obtain patients' consent** for use of POCs and maternal bloods (emphasis added).¹⁸

This admission, on the face of the contracts, that the abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI **prior to obtaining patients' consent to donate fetal tissue or patients' authorization to view their PHI.**

IV. VIOLATIONS OF THE HIPAA PRIVACY RULE BY STEMEXPRESS AND THE ABORTION CLINICS

This complaint argues that the agreements between StemExpress and the abortion clinics, on their face and in practice, are fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" **cannot trump a law prohibiting the abortion clinics from permitting these disclosures in the first place.** As discussed below, the abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (A) The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were

¹⁶ 45 C.F.R. §164.502(a).

¹⁷ Pub. L. 104-191; 42 U.S.C. §§ 1320d-5 – 1320d-6.

¹⁸ See Attachments L, M, and N.

neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (B) The consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (C) The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (D) StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A. The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research.

The disclosures of PHI that the abortion clinics made to StemExpress are neither required¹⁹ nor permitted²⁰ by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.²¹ **Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers.**

1. Cadaveric organ, eye or tissue transplantation

Importantly, the disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act," 42 U.S.C. 274e(c)(1), the abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. **Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for research, which is not covered by the cadaveric organ, eye or tissue exception.**²²

2. Research

Further, the disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board ("IRB") for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.²³

3. Violations Preceding "Consent"

¹⁹ 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).

²⁰ See 45 C.F.R. § 164.502(a)(1).

²¹ See 45 C.F.R. § 164.506(c).

²² See 45 C.F.R. § 164.512(h).

²³ 45 C.F.R. § 164.512(i).

Because StemExpress employees actually sought consent for tissue donation from patients, the abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past and present medical treatment, and more. **Each time that an abortion clinic employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.**

No evidence suggests the abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set²⁴ regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the abortion clinics to StemExpress were inarguably direct and intentional—not incidental.²⁵ StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. The consent for fetal tissue donation obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI.

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule.

The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.²⁶ Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.²⁷

Neither the consent form provided by StemExpress ("SE form") nor the consent form provided by Planned Parenthood ("PP form") to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.²⁸ The statement in the SE form that a patient's "health information will be protected at all times" is ironic given that StemExpress's possession of the patient's PHI already placed the abortion clinics and StemExpress in violation of the HIPAA privacy rule.

²⁴ See 45 C.F.R. § 164.514(e).

²⁵ See 45 C.F.R. §§ 164.502(a)(1)(iii).

²⁶ 45 C.F.R. § 164.508.

²⁷ 45 C.F.R. § 164.508(c).

²⁸ See Attachments O: StemExpress Consent Form and P: Planned Parenthood Consent Form.

The SE form also stated that “[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier.”²⁹

Like the privacy provision in the contracts between Stem Express and the abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The SE form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The SE form did not state who will disclose or use the patient’s PHI. It also did not state when the patient’s authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The PP form, purportedly used to obtain patient consent for human fetal tissue donation at PPMM and PPSP,³⁰ was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient’s PHI to researchers or others; or the patient’s right to revoke her authorization in writing.

C. The disclosures of patients’ PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants.

The abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the “minimum necessary” PHI to facilitate the procurement of human fetal tissue from aborted infants.³¹ StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients’ consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by the abortion clinics.

As addressed above, the abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue that would later be sold by StemExpress to researchers at a huge mark-up.

D. StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity’s workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting,

²⁹ Attachment O, *supra*.

³⁰ Attachment P, *supra*.

³¹ 45 C.F.R. §§ 164.502(b) and 164.514(d).

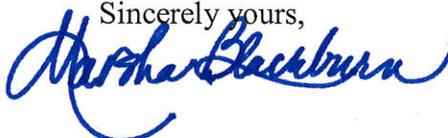
consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.³²

Clearly, StemExpress did not perform one of these services for the abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the abortion clinics' patients.

CONCLUSION

We appreciate your swift attention to the serious and systematic violations of the HIPAA privacy rule committed by StemExpress, Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, and Family Planning Specialists Medical Group. If you have any questions about this request, please contact Mary Harned, Investigative Counsel at (202) 480-7160, or by email at Mary.Harned@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

³² 45 C.F.R. § 160.103.