ATTACHMENT D

106 Irving Street, NW
Physicians Office Building
Suite 4700, North Tower
Washington, DC 20010-2975
202-877-7479 PHONE
202-877-7414 FAX
MedStarWashington.org

06-05-2019

Women's and Infants' Services

MedStar Washington Hospital Center

June 5, 2019

Hi Gregory,

Thank you for speaking with me on the phone. As I mentioned, I did file an on-line complaint yesterday, through the website ambulatory surgical center--> file a complaint.

Here is what we spoke of and I wrote in that report.

Patient BW, DOB 2/7/97 presented to Capital Women's Services at 6323 Georgia Ave, NW 20011 on Monday 6/3/19 for termination of pregnancy at 9 wks. She complained of excessive pain, was told everything was all done and to take ibuprofen. She presented to Medstar Washington Hospital Center ER that night with pain. She was evaluated in the morning of 6/4 and found to have swollen loop of bowel in her vagina. Ultrasound revealed she still had viable 9 wk pregnancy in the uterus. She was taken to the OR where she had surgery, 15 cm of bowel resected, and her abortion was completed. She is recovering well today (6/5) though still hospitalized.

On 4/13/19, another pt presented after having an abortion at 14-15 weeks with 30 cm of small bowel hanging out of her vagina. She was taken to the OR and had lengthy resection of her bowel.

Within the past 12-18 months there are at least 2 other cases that have presented to WHC for serious complications. Unfortunately at this moment I do not have their names and date of service, but could find at least 1 of their information. That women called herself an ambulance at 2am to be taken to hospital after she became certain they were not able to complete her case at the clinic. In the OR she was found to have fetal parts in the abdomen and likely a perforation of the vagina.

While I understand that complications happen with any procedures, the severity and frequency of these complications is disturbing. This has prompted me to reach out to the department of health. By report, the patients have only mentioned nurse practitioners in their care, no physician.

I believe that women need to have access to safe and legal abortions. I fear that this center may not be meeting those standards.

Thank you for your time and consideration of these complaints.

Parn Lotke

202-877-7415

Knowledge and Compassion

Focused on You

Capital Women's Services

June 17, 2019

Ms. Sharon Williams Lewis, DHA, RN-BC, CPM Senior Deputy Director
Health Regulation and Licensing Administration
899 North Capital Street, Second Floor
Washington, D.C. 20002
(202) 478-5746

Re: Capital Women's Services

Dear Ms. Lewis:

United Health Group, LLC d/b/a Capital Women's Services (Capital) is in receipt of the subpoena that you issued to us Thursday, June 13, 2019. The purpose of this letter is partially to respond to your subpoena, partially to present Capital Women's Services to you and your Administration, and partially to discuss the patient whose chart you subpoenaed.

Who Are We and What Do We Do?

Capital Women's Services is a private medical practice owned by Dr. Myron Rose, MD, FACOG. We provide outpatient gynecology and family planning services. The large majority of our patient encounters (about 80%) are non-surgical services and only about 20% of our services are surgical. We also provide first, second, and (rarely) third trimester abortion services. The large majority of our abortion services are first trimester cases and are done either non-surgically or by vacuum aspiration. The early second trimester procedures are done by D&E, and the few late-second trimester cases are done either in a non-surgical induction manner or using hybrid techniques. The third trimester cases are very rare, and they are indicated cases. These cases are all done non-surgically, using a combination of digoxin to induce intra-fetal demise, laminaria and medication to induce a natural delivery. The large majority are for fetal anomalies, with a few cases for maternal health indications. Most come by referral from genetic counselors and other providers.

Dr. Myron Rose, MD, FACOG

Capital Women's Services is a private medical practice owned by Dr. Myron Rose. Dr. Rose is a Board-Certified Ob/Gyn, a former Assistant Professor of Obstetrics & Gynecology at George Washington University, and a founding member of the National Abortion Federation. He has more than 40 years' experience as an Ob/Gyn and as a provider of abortion services. He serves as Capital's Medical Director and our CLIA Lab Director. He also occasionally sees patients as a provider.

Dr. Elizabeth Swallow, M.D.

Dr. Swallow is a previously Board-Certified Ob/Gyn with many years of experience as an Ob/Gyn and an abortion provider. She provides medical care for our patients.

Khalilah Jefferson, DNP, MSN, almost CNM

Khalilah Jefferson is a Women's Health Nurse Practitioner who holds a Doctorate Degree as a Nurse Practitioner, specializing in Women's Health. In addition, she is enrolled in a Certified Nurse Midwife training program, and has almost finished that training. She provides clinical care to Capital's patients.

Cathy Chapman, CNP, MSN

Cathy Chapman is a licensed certified Nurse Practitioner who provides gyn care and only early first-trimester nonsurgical and aspiration abortion care for Capital.

Legal Compliance

Because you are from the Health Regulation and Licensing Administration, we wanted you to know that before opening this medical practice, in an effort to comply with your rules and regulations, we asked our attorneys to please review your regulations and rules in an effort to ensure that we were in compliance. In particular, we reviewed the question of whether or not we needed to be licensed as an ambulatory surgical facility and whether or not we needed a Certificate of Need. Our attorneys concluded that because we were a private medical practice whose primary service is not surgery, therefore, under both the current and the proposed regulations, we were not required to become a licensed surgical center. This was also consistent with the recent Supreme Court case Whole Women's Health vs Hellerstedt which concluded that requiring abortion providers to be licensed as a surgical center provided "little or no henefit" to the patients and was therefore, unconstitutional. Indeed, as shown in the attached information, the large majority of our patient encounters are not for surgical services. Likewise, the lawyers concluded that we were not required to obtain a CON, because we are a private medical practice.

Nevertheless, despite our view that we are not legally required to obtain licensure, we are willing to fully cooperate with your administration as part of our mutual goal of ensuring best practices and patient safety. Indeed, last year one of your investigators, Emilia Moran, visited our office and made several informal suggestions for improvement, and we have implemented all of them. In addition, we are cooperating fully with this current investigation. And if your administration has any further suggestions for how we can improve, we are all ears. We thank you for your time and we welcome your input, which we will take very seriously.

To further demonstrate that we take seriously and look closely at your regulations and attempting to comply, as best we can, I will comment upon DC 7-161, which requires the reporting of an "adverse event". We are not planning to report any of the three patients you

subpoenaed to your administration as "adverse events". First of all, your administration already is fully aware of the patients and don't need a report from us. But more importantly, we don't know for a fact that any of them meet the definition of "adverse event" as defined in the regulation:

suffered no injury. Her first procedure was failed, perhaps because she was so early. But her second procedure was uneventful.

was the case of a 1st trimester procedure done under local anesthesia. NP Chapman said that she encountered difficulty during the procedure, and so she stopped and asked the patient, who was stable, to return the next morning to see Dr Swallow, who was a more

experienced provider. What happened after that, we don't know for sure.

requested a procedure at 23 weeks by Dr. Swallow. The procedure seemed to be going uneventfully. The fetus was delivered vaginally without complication. However, when she went to deliver the placenta, the uterus inverted and was attached to the placenta. Because the placenta failed to detach, Dr. Swallow said that she was worried that this might be a case of an invasive placenta, such as a placenta accreta or placenta percreta. Such placentas are known to cause serious hemorrhage. Because the patient was stable and not bleeding, Dr. Swallow felt that the safest course of action for the patient was not to touch the placenta/uterus complex – lest she precipitate bleeding. Rather, Dr. Swallow felt that this patient needed to be transferred to a hospital. Certainly, an inverted uterus has the potential to become a serious complication – as does placenta accreta. However, we do not know for a fact that this was an accreta, and many times the uterus can be reverted back to normal state with no serious injury to the patient. So, it is possible that suffered no serious injury. We do not know what ultimately happened to the patient after she was transferred to the hospital, so therefore, we are not planning to report her as an adverse event.

Response to the Subpoena

On Thursday, June 13, 2019 we were served with the attached Subpoena for a list of documents. We were asked to provide all of these documents on the following Monday. In other words, we were provided with only <u>one business day</u> to find, assemble, copy and produce all of these documents, in-between taking care of patients. We feel that giving us one business day is an unreasonable time-frame and we will not be able to produce all of these documents today. However, we have been making great efforts to comply with the subpoena and we are producing for you what we can today. We will respond point-by-point to the 12 items listed in the subpoena:

1. You requested the medical record for the patient. It is enclosed.

To save you time and for your convenience, I will provide a summary of a scare. It is enclosed.

To save you time and for your convenience, I will provide a summary of a scare. It is enclosed.

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and signed, our "Supplemental Informed Consent for Very Early Abortion" form which warned her that she was at increased risk of missed abortion and that this risk would be reduced if she waited a few weeks to terminate her pregnancy. She also signed that "I understand that is why it is imperative that I return to the offices of United Health Group, I.I. for my follow-up examination no more than two weeks from the date of my abortion procedure". And the form concluded that "I am willing to accept the additional risks associated with very early abortion procedures because of my desire to obtain an abortion as soon as possible". The procedure was performed uneventfully by NP Chapman with the patient conscious and using only local anesthesia. Following the procedure, the patient wanted to leave early and so the patient signed out Against Medical Advice. When the tissue was examined after the procedure, it was noted that 23 grams of tissue was obtained. However, NP Chapman was not sure that the procedure had been completed. So, NP Chapman asked to bring the patient back to the procedure room so that we perform an ultrasound and examine her. However, the patient had already left the office AMA. In addition, the patient also failed to return for her two-week follow-up visit. Eventually, after waiting for more than two months, on May 15, 2019, the patient finally returned to the practice. At that time, wrote that she "loved the compassionate care, respect and way you treated me, - but am very concerned that I am still pregnant..." Indeed, ultrasound confirmed a 16-week intrauterine pregnancy consistent with a continued pregnancy. Because NP Chapman does not perform any 2rd trimester procedures (or even late 1st trimester procedures), care was transferred to Dr. Elizabeth Swallow. Dr. Swallow examined and inserted laminaria into her cervix and administered Misoprostol, Ibuprofen, Rhogam, and Doxycycline. After waiting for several hours to allow her cervix to soften and dilate, Dr. Swallow performed the procedure without incident. Examination of the products of conception, and repeat ultrasound examination confirmed that the procedure was successful. Because the patient was returning home to Louisiana and would not be seeing us for ongoing care, she was asked to return to the practice the next day for a check-up examination by Dr. Swallow. The patient did return on May 16, 2019, and underwent another ultrasound exam and a pelvic examination by Dr. Swallow, both of which confirmed that the termination was successful and that the patient was doing well. At her request, we sent a copy of the patient's medical record to her physician in Louisiana, for follow-up and ongoing medical care.

2. You requested 6 months' worth of individual patient sign-in sheets. This request is difficult to complete in only one business day. Also, while we desire to cooperate with your investigation, we also have to balance this against our other duty to protect our patient's confidentiality. Certainly, if your administration is concerned about the care and treatment of a single particular patient, especially one who had a complication, then we have been very forthcoming with providing full medical records. This request, however, asks for sign-in sheets for thousands of patients, many of whom live in DC, and some of whom may even work for your agency, and 99.9% of whom have no medical complication or problem at all. Even to reveal their identities is somewhat of a violation of their confidentiality, for no clear medical benefit to them. For that reason, if you insist on obtaining these sheets, our plan

would be to redact individual patient names and leave only patient initials. These patient initials would still permit you to request further information if you want to focus on a particular patient, without us violating the confidentiality of thousands of women. We hope that you would find that acceptable. However, that would also create a lot of work for us and it would take some time to complete.

However, in a further spirit of cooperation, we may have found another solution. I have enclosed with this letter copies of portions of the "Daily Session Forms" for each day during the time that you subpoenaed. You did not subpoena these forms, but these forms will give you a broad picture of what kinds of services were rendered on a day-by-day and provider-by-provider basis. Our thought was that perhaps these forms will give you the information that you seek, without the need to violate thousands of women's confidentiality. Please let us know if this is acceptable.

Incidentally, it is worth noting that these Daily Session Forms reveal that during the 6 month period of time that you specified, only about 25% of our patient visits were for surgical services, and about 75% of our patient visits were NOT for surgical services.

- 3. You requested a document entitled "staffing sheet and emergency coverage". Please be advised that we don't have any such document with this title.
- 4. You requested transfer agreements. These will be provided at a later date.
- 5. You asked for "copy of liability coverage". Enclosed please find a copy of two medical malpractice insurance policies for our providers in the amount of \$1,000,000/\$3,000,000.
- 6. You asked for "Preventive Maintenance Agreement/Logs". Please see enclosed. All of our equipment undergoes regular maintenance and, at least annually, all of the equipment gets a PM check-up by a certified bio-medical technician.
- 7. You asked for "*Policy and Procedure Manual(s)*". Enclosed please find one of our P&P Manuals.
- 8. You asked "procedure for sterilization of equipment". Some of the information regarding our sterilization procedures is contained in the attached Policy and Procedure Manual.
- 9. You asked for "Waste Disposal Agreements". Please see enclosed
- 10. You asked for "Contract for all service agreements (i.e. medical gages, narcotics/medications/anesthesia)". We were unclear what you meant. We especially did not understand your reference to "gages". Did you mean "Gauges?"

or "Gases?" We do not have any contracts for servicing our medical gauges, but we do have a contract for supplying oxygen which will be provided at a later date.

- 11. You asked for "Invoices for all medications and biologicals from December 1, 2018 to present". We were unclear what you meant. We do not receive individual invoices for individual medications and we do not know what you mean when you say "biologicals". Please kindly clarify.
- 12. You asked for "employment contracts" for three of our providers. None of our providers are employees and therefore we do not have the specific documents you have subpoenaed. Nevertheless, because they are all Independent Contractors, we do have "Independent Contractor Agreements" with these providers. In a spirit of cooperation, we have redacted financial information and enclosed these three Independent Contractor Agreements with this letter.

I wish to thank you for taking the time to visit and inspect our private medial practice. If your team has any specific suggestions or recommendations for us, we would welcome your feedback.

Finally, if you have any additional questions or concerns, or if you desire any further information or documents, please do not hesitate to contact me.

Sincerely yours,

United Health Group, LLC