UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

SUSAN E. WRIGHT, N.P., J.D.,

Defendant.
_____/

No. 1:20-cr-52

Hon. Janet T. Neff
U.S. District Judge

PLEA AGREEMENT

This constitutes the plea agreement between the Defendant Susan E. Wright and the United States Attorney's Office for the Western District of Michigan. The terms of the agreement are as follows:

1. Defendant Agrees to Plead Guilty. The Defendant agrees to give up the right to indictment by a grand jury and plead guilty to the felony information charging her with misprision of a felony, in violation of Title 18, United States Code, Section 4, and adulteration of medical devices, in violation of Title 21, United States Code, Sections 331(k) and 333(a)(1).

2. Defendant Understands the Crimes. In order for the Defendant to be guilty of violating Title 18, United States Code, Section 4, the following must be true: (1) a federal felony was committed; (2) the Defendant had knowledge of the commission of that felony; (3) the Defendant failed to notify an authority as soon as possible; an "authority" includes a federal judge or some other federal civil or military authority, such as a federal grand jury, FBI or HHS-OIG agent; and (4) the Defendant did an affirmative act to conceal the crime. In order for the Defendant to be guilty of violating Title 21, United States Code, Sections 331(k) and 333(a)(1),

the following must be true: (1) the relevant products are devices; (2) the Defendant received the devices after shipment in interstate commerce; and (3) in holding the devices for sale, the Defendant adulterated, caused the adulteration, or aided and abetted in the adulteration of the devices.

3. The Defendant Understands the Penalties. The statutory maximum sentence that the Court can impose for a violation of Title 18, United States Code, Section 4, is the following: three years' imprisonment; a one-year period of supervised release; a fine of $250,000.00 or twice the gross gain or loss, whichever is greater; and a mandatory special assessment of $100.00. The statutory maximum sentence that the Court can impose for a violation of Title 21, United States Code, Sections 331(k) and 333(a)(1), is the following: one year of imprisonment; a one-year period of supervised release; a fine of $100,000.00; and a mandatory special assessment of $25.00. The Defendant agrees to pay the special assessments at or before the time of sentencing unless the Defendant affirmatively demonstrates to the Court that she lacks the ability to pay.

4. Supervised Release Defined. Supervised release is a period of time following imprisonment during which the Defendant will be subject to various restrictions and requirements. The Defendant understands that if she violates one or more of the conditions of any supervised release imposed, she may be returned to prison for all or part of the term of supervised release, which could result in the Defendant serving a total term of imprisonment greater than the statutory maximum stated above.

5. Mandatory Restitution (MVRA). The Defendant understands that she will be required to pay full restitution as required by law. The Defendant further understands that the restitution order is not restricted to the amounts alleged in the counts to which the Defendant is

pleading guilty but will include all relevant conduct as determined by the Court.

6. Program Exclusion. The Defendant understands that, upon the Defendant's conviction, pursuant to Title 42, United States Code, Section 1320a-7(a) and (b), the Defendant may be either mandatorily or permissively excluded from participation as a provider in any Federal health care program, as defined in Section 1320a-7b(f).

7. Civil Settlement. This plea agreement is part of a global resolution of the Defendant's criminal culpability related to conduct set forth in paragraph 11(b) below and civil liability related to the "Covered Conduct" as that term is defined in the related civil settlement agreement. Pursuant to 18 U.S.C. § 3664(j)(2)(A), any payments made in the related civil settlement by the Defendant shall be credited towards the criminal restitution ordered in this case.

8. Factual Basis of Guilt. The Defendant and the U.S. Attorney's Office agree and stipulate to the following statement of facts which need not be proven at the time of the plea or sentencing:

Misprision of USM's Fraudulent Billing of Evaluation and Management Services

The Defendant is a nurse practitioner licensed to practice in Michigan. The Defendant is also an attorney licensed to practice law in Michigan. The Defendant's spouse owned and operated Women's Health Care Specialists, P.C. ("WHC") and Urological Solutions of Michigan ("USM"). WHC was a medical office in Kalamazoo, Michigan. USM was a separate medical company that employed nurse practitioners who traveled to provide pelvic muscle rehabilitation therapy ("PMR") in the patients' homes or assisted living facilities. The Defendant was employed at WHC and occasionally assisted USM.

Following several years of audits by Wisconsin Physician Services ("WPS") and an appeal by USM, an Administrative Law Judge ("ALJ") upheld WPS's determination and issued a written decision on May 11, 2011, that USM, utilizing the national provider identifier ("NPI") of the Defendant's spouse, improperly billed PMR therapy services using codes for diagnostic testing, specifically CPT codes 51784 and 91122.

In response to the ALJ determination, USM's practice manager developed a plan

on how to continue to bill for PMR therapy, which included billing for evaluation and management ("E&M") services. On or about September 23, 2011, USM's practice manager drafted a document entitled "PMR Treatment Plan" that proposed billing an E&M code with every PMR therapy. On September 30, 2011, the Defendant emailed her husband asking him to call two of his employees, including USM's practice manager, and indicating, "What they want to know is how you want to bill the PMR's billed for [USM] under the NP's. . . . [USM's practice manager] can bill the way we do at WHCS, but they told you not to bill that way . . . [USM's practice manager] is worried about losing money. He is billing an E&M everytime [sic] . . . he wants your guidance."

Based on her training and education, the Defendant knew that an E&M service billed on the same day as a procedure provided to the same patient must be designated, using billing Modifier 25, as a significant, separately identifiable service from the procedure in order to be payable. In the case of USM, the purported evaluation and management had to be for a significant condition that was separate from the condition for which the patients were receiving PMR therapy.

From late 2011 through 2018, USM's practice manager regularly included a claim to health care benefit plans, including Medicare, for an E&M service for PMR therapy visits performed by USM practitioners. Sometime in 2018, the Defendant was asked to audit some of USM's patient records and billing claims together with other staff. In the course of reviewing the patient charts and claims, the Defendant observed that, for some of the patients, the USM practitioners had simply examined the patients in order to perform PMR therapy and had not otherwise provided a significant, separately identifiable E&M service to support use of Modifier 25. The Defendant informed her spouse and other USM personnel about her concerns; however, when she realized that such claims were still being submitted, she ultimately approved of USM submitting some claims to Medicare that included the improperly coded claims for E&M services, and she did not inform any authorities.

Adulteration of Medical Devices

The Prometheus Group is the manufacturer of the Pathway CTS2000 and its components, including a rectal pressure sensor. On or about February 19, 2003, the FDA cleared the Pathway CTS2000 for introduction into interstate commerce under 510(k) number K023906. FDA cleared the device as a class II device for the intended use of treating urinary and fecal incontinence and providing neuromuscular reeducation. The FDA's 510(k) summary of the Pathway CTS2000's component rectal pressure sensor describes it as a "single-user sensor[]" for insertion into the rectum while using the Pathway CTS2000 "to monitor the muscle activity during contraction and relaxation of the pelvic floor muscles." The FDA-approved IFU for the rectal pressure sensor warned, in bold and italicized font, that the rectal pressure sensor is restricted to use on a single patient: "This sensor is restricted for single person use only. Use by another person is strictly prohibited by Federal Regulations."

Beginning by at least 2007 and continuing into February 2019, upon the training recommendation of persons in the medical device industry, the Defendant used, and directed WHC and USM staff to use, the rectal pressure sensor when performing PMR therapy. The Defendant and the WHC and USM staff reused the single-user rectal pressure sensors on multiple patients. The WHC and USM practitioners covered the rectal pressure sensor with the finger of a surgical glove prior to inserting the rectal pressure sensor into a patient's rectum. Upon withdrawing the rectal pressure sensor at the conclusion of a PMR therapy session from the patient's rectum, the WHC and USM practitioners removed the surgical glove, and covered the rectal pressure sensor with a new glove for use on the next patient. This practice resulted in WHC and USM practitioners reusing the same rectal pressure sensor on different individual patients.

As confirmed by FDA scientists, reusing the single-user rectal pressure sensors on multiple patients, even when covered with the finger of a surgical glove, and storing it between use with subsequent patients also caused the rectal pressure sensors to be held under insanitary conditions whereby they may have been contaminated with filth and rendered injurious to health.

9. Cooperation in Criminal Investigations. The Defendant agrees to fully cooperate with the Food and Drug Administration, Office of Criminal Investigations; the Department of Health and Human Services, Office of Inspector General; the Federal Bureau of Investigation; the U.S. Attorney's Office; and any other law enforcement agency in their investigation of the charges contained in this Information as well as the investigation of crimes over which they have actual or apparent jurisdiction. The Defendant's cooperation will consist of all steps needed to uncover and prosecute such crimes, including, but not limited to, providing investigators with a full, complete and truthful statement concerning the Defendant's knowledge of any and all criminal activity of which she is aware; truthfully answering investigators' questions; meeting with prosecutors before testifying; truthfully testifying before grand juries and in any court proceedings; and providing all relevant tangible evidence in the Defendant's possession or under the Defendant's control, including, but not limited to, objects, documents, and photographs. The Defendant's obligation to cooperate under this paragraph is an affirmative one and includes the

obligation to voluntarily come forward with any and all information which the Defendant should reasonably know will assist in the investigation of other criminal activity. The Defendant will not commit any criminal offense during the course of her cooperation with the United States. The Defendant will submit to polygraph examination(s) upon request. The Defendant's obligation under this paragraph is a continuing one, and shall continue after sentencing until all investigations and prosecutions in which the Defendant's cooperation is deemed relevant by the U.S. Attorney's Office have been completed.

10. Possibility of Sentence Reduction Motions. The U.S. Attorney's Office will decide whether to file a motion for departure or reduction of sentence pursuant to Sentencing Guidelines §5K1.1 and/or Rule 35(b) of the Federal Rules of Criminal Procedure. The Defendant fully understands that such a motion may be made pursuant to law if, and only if, the Defendant fully cooperates with the Government and materially and substantially assists the Government in the investigation or prosecution of others. The determinations of whether the Defendant has provided substantial assistance to the United States, or to designated state or local law enforcement authorities, will be made in the sole discretion of the U.S. Attorney's Office. The Defendant fully understands that this paragraph is not a promise by the Government to file a motion for departure or to reduce a sentence. The Government will consider the benefits already conferred upon the Defendant, including those specified in paragraph 11(b), when deciding whether to file such a motion. Additionally, the Defendant understands that, even if such a motion were filed, the Court has complete discretion to grant or deny the motion. Furthermore, if the Court were to grant the motion, the Court - not the Government - would decide how much of a sentence reduction Defendant receives based upon the nature and extent of Defendant's assistance. The Defendant

acknowledges and agrees that Defendant may not appeal the Court's exercise of its discretion in granting or denying a motion for departure or reduction of sentence, if such a motion is made.

11. The United States Attorney's Office's Agreements.

a. Acceptance of Responsibility. The U.S. Attorney's Office agrees not to oppose the Defendant's request for a two-level reduction of her offense level for acceptance of responsibility under Section 3E1.1(a) of the Sentencing Guidelines. However, the U.S. Attorney's Office reserves the right to object to the Defendant's request if it subsequently learns of conduct by the Defendant that is inconsistent with the criteria set forth in the Commentary to Section 3E1.1. Should the Court grant a two-level reduction as provided herein, the Government will move the Court to grant an additional one-level reduction if the adjusted offense level is 16 or greater pursuant to Section 3E1.1(b).

b. Non-Prosecution Agreement. The U.S. Attorney's Office agrees not to bring additional criminal charges against the Defendant in the Western District of Michigan relating to either the billing of health care services, the preparation of medical records, the providing of services by unqualified practitioners, or the reuse of medical devices at WHC and USM. This promise of non-prosecution shall not include crimes of violence, if any, or criminal tax violations, including conspiracy to commit such violations chargeable under 18 U.S.C. § 371.

12. The Sentencing Guidelines. The Defendant understands that, although the United States Sentencing Guidelines (the "Guidelines") are not mandatory, the Court must consult the Guidelines and take them into account when sentencing the Defendant. The Defendant understands that the Court, with the aid of the presentence report, will determine the facts and calculations relevant to sentencing. The Defendant understands that the Defendant and the

Defendant's attorney will have the opportunity to review the presentence report and to make objections, suggestions, and recommendations concerning the calculation of the Guideline range and the sentence to be imposed. The Defendant further understands that the Court shall make the final determination of the Guideline range that applies in this case and may impose a sentence within, above, or below the Guideline range, subject to the statutory maximum penalties described elsewhere in this Agreement. The Defendant further understands that disagreement with the Guideline range or sentence shall not constitute a basis for withdrawal of her guilty plea.

13. Non-Binding Sentencing Guideline Stipulations. The parties stipulate, pursuant to USSG §6B1.4, and based upon information known to the Government at this time, to the following Sentencing Guideline factors:

a. the fraud loss that the government can establish under USSG §2B1.1(b)(1), relating to the underlying felony offense of health care fraud that is the subject of the misprision offense in Count 1 of the Information and that was reasonably foreseeable to the Defendant as relevant conduct, is more than $250,000 and less than $550,000.00.

b. the underlying felony offense of health care fraud that is the subject of the misprision offense in Count 1 of the Information involved 10 or more victims pursuant to USSG §2B1.1(b)(2)(A);

c. the underlying felony offense of health care fraud that is the subject of the misprision offense in Count 1 of the Information did not involve sophisticated means pursuant to USSG §2B1.1(10);

d. the misprision offense in Count 1 of the Information did not involve the Defendant's abuse of a position of public or private trust or the use of a special skill in a manner

that significantly facilitated the commission or concealment of the offense pursuant to USSG §3B1.3.

The Defendant understands that neither the United States Probation Office nor the Court is bound by any stipulation in this agreement, and that the Court, with the aid of the presentence report, will determine the facts and calculations relevant to sentencing. Both the Defendant and the U.S. Attorney's Office are free to supplement the facts stipulated to in this agreement by supplying relevant information to the United States Probation Office and the Court, and to correct any and all factual misstatements relating to the calculation of the sentence. The Defendant understands that if the Court finds facts or reaches conclusions different from those in any stipulation contained in this agreement, the Defendant cannot, for that reason alone, withdraw her guilty plea. Both parties reserve the right to seek any sentence within the statutory maximum and to argue for any other variances and departures.

14. Waiver of Constitutional Rights. By pleading guilty, the Defendant gives up the right to persist in a plea of not guilty and the right to a speedy and public trial by jury or by the Court. As a result of the Defendant's guilty plea, there will be no trial. At any trial, whether by jury or by the Court, the Defendant would have had the following rights:

a. The right to the assistance of counsel, including, if the Defendant could not afford an attorney, the right to have the Court appoint an attorney to represent the Defendant.

b. The right to be presumed innocent and to have the burden of proof placed on the Government to prove the Defendant guilty beyond a reasonable doubt.

c. The right to confront and cross-examine witnesses against the Defendant.

d. The right, if the Defendant wished, to testify on the Defendant's own behalf and present evidence in opposition to the charges, including the right to call witnesses and to subpoena those witnesses to testify.

e. The right not to be compelled to testify, and, if the Defendant chose not to testify or present evidence, to have that choice not be used against the Defendant.

f. By pleading guilty, the Defendant also gives up any and all rights to pursue in this Court or on appeal any affirmative defenses, Fourth Amendment or Fifth Amendment claims, and other pretrial motions that have been filed or could be filed.

15. Waiver of Other Rights.

a. Waiver. In exchange for the promises made by the government in entering this plea agreement, the Defendant waives all rights to appeal or collaterally attack the Defendant's conviction, sentence, or any other matter relating to this prosecution, except as listed below.

b. Exceptions. The Defendant may appeal or seek collateral relief to raise a claim, if otherwise permitted by law in such a proceeding, on the following grounds:

1. the Defendant's sentence on any count of conviction exceeded the statutory maximum for that count;

2. the Defendant's sentence was based on an unconstitutional factor, such as race, religion, national origin, or gender;

3. the district court incorrectly determined the Sentencing Guidelines range, if the Defendant objected at sentencing on that basis;

4. the guilty plea was involuntary or unknowing;

5. an attorney who represented the Defendant during the course of this

criminal case provided ineffective assistance of counsel.

If the Defendant appeals or seeks collateral relief, the Defendant may not present any issue in the proceeding other than those described in this subparagraph.

c. FOIA Requests and Privacy Rights. The Defendant hereby waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

16. The Court is not a Party to this Agreement. The Defendant understands that the Court is not a party to this agreement and is under no obligation to accept any recommendation by the U.S. Attorney's Office or the parties regarding the sentence to be imposed. The Defendant further understands that, even if the Court ignores such a recommendation or imposes any sentence up to the maximum established by statute, the Defendant cannot, for that reason, withdraw her guilty plea, and she will remain bound to fulfill all her obligations under this agreement. The Defendant understands that no one—not the prosecutor, the Defendant's attorney, or the Court—can make a binding prediction or promise regarding the sentence the Defendant will receive, except that it will be within the statutory maximum.

17. This Agreement is Limited to the Parties. This agreement is limited to the U.S. Attorney's Office for the Western District of Michigan, and cannot bind any other federal, state or local prosecuting, administrative or regulatory authority. This agreement applies only to crimes committed by the Defendant. This agreement does not apply to or preclude any past, present, or future forfeiture or civil actions.

18. Consequences of Breach. If the Defendant breaches any provision of this agreement, whether before or after sentencing, the United States shall have the right to terminate this agreement, or deny any or all benefits to which the Defendant would otherwise be entitled under the terms of this agreement. In the event that the United States elects to terminate this agreement, the agreement shall be considered null and void, and the parties shall return to the same position they were in prior to the execution of this agreement, as though no agreement ever existed. In such an event, the Defendant shall remain liable for prosecution on all original charges, and the United States shall be free to bring such additional charges as the law and facts warrant. The Defendant further agrees to waive and forever give up her right to raise any claim that such a prosecution is time-barred if the prosecution is brought within one (1) year of the breach that gives rise to the termination of this agreement.

19. This is the Complete Agreement. This agreement has been entered into by both sides freely, knowingly, and voluntarily, and it incorporates the complete understanding between the parties. No other promises have been made, nor may any additional agreements, understandings or conditions be entered into unless in a writing signed by all parties or on the record in open court.

ANDREW BYERLY BIRGE
United States Attorney

5/4/2020
Date

RAYMOND E. BECKERING III
Assistant U.S. Attorney

I have read this agreement and carefully discussed every part of it with my attorney. I understand the terms of this agreement, and I voluntarily agree to those terms. My attorney has advised me of my rights, of possible defenses, of the sentencing provisions, and of the consequences of entering into this agreement. No promises or inducements have been made to me other than those contained in this agreement. No one has threatened or forced me in any way to enter into this agreement. Finally, I am satisfied with the representation of my attorney in this matter.

4 May 2020
Date

Susan E. Wright
SUSAN E. WRIGHT
Defendant

I am Susan E. Wright's attorney. I have carefully discussed every part of this agreement with my client. Further, I have fully advised my client of her rights, of possible defenses, of the sentencing provisions, and of the consequences of entering into this agreement. To my knowledge, my client's decision to enter into this agreement is an informed and voluntary one.

May 4, 2020
Date

Charles E. Chamberlain, Jr.
CHARLES E. CHAMBERLAIN, JR.
Attorney for Defendant