UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

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

Defendant.
_____/

1:20-cr-52
Janet T. Neff
U.S. District Judge

FELONY INFORMATION

The United States Attorney charges:

GENERAL ALLEGATIONS

At all times relevant to this Information:

The Medicare Program

1. Medicare is a federally funded program administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency within the United States Department of Health and Human Services. Medicare provides health insurance for, among others, persons aged 65 and older, certain younger people with disabilities, and people with end-stage renal disease. Individuals who receive benefits under Medicare are referred to as Medicare beneficiaries. Medicare is a "health care benefit program," as defined by Title 18, United States Code, Section 24(b).

2. The Medicare Program includes coverage under two primary components, hospital insurance (Part A) and medical insurance (Part B). Part B of the Medicare Program covers the costs of physicians' services and other ancillary services not covered by Part A.

3. Payments under the Medicare Program are often made directly to the provider of the goods or services, rather than to the beneficiary. This direct payment occurs when the provider submits claims to Medicare for payment, either directly or through a billing company.

4. Physicians, clinics, and other health care providers are able to apply for and obtain a Medicare provider number, referred to as a National Provider Identifier ("NPI"). A health care provider who is issued a Medicare provider number is able to file claims with Medicare to obtain reimbursement for services provided to Medicare beneficiaries. A valid Medicare claim must set forth, among other things, the beneficiary's name, the date the service was provided, the cost of the service, and the name and identification number of the physician or health care provider who ordered the service.

5. Medicare claims for Part B are processed and paid by insurance organizations, known as fiscal intermediaries and carriers who contract with CMS to administer their specific part of the Medicare program. Wisconsin Physician Service Insurance Corporation ("WPS") is the local Medicare Administrative Contractor that manages the Part B Medicare services on behalf of CMS.

6. In submitting claims for payment to Medicare, providers must certify that the information on the claim form presents an accurate description of the services rendered and that the services were reasonable and medically necessary for the patient. Medicare reimburses only those services furnished to beneficiaries that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(l)(A). Likewise, Medicare regulations exclude from payment services that are not reasonable and necessary. 42 C.F.R. § 411.15(k)(1).

7. Federal law provides that it is the obligation of the provider of healthcare services to ensure that services provided to Medicare beneficiaries are "provided economically and only

when, and to the extent, medically necessary[,]" and are "[s]upported by evidence of medical necessity." 42 U.S.C. § 1320c-5(a)(1), (3).

The Defendant

8. Women's Health Care Specialists, P.C. ("WHC") is a now-closed obstetrics-gynecology practice located in Kalamazoo. Urological Solutions of Michigan, PLC ("USM") is a now-closed medical company that primarily consisted of traveling nurse practitioners who visited patients in their homes or care facilities to provide treatment for urinary and/or fecal incontinence.

9. SUSAN E. WRIGHT, N.P., J.D. ("SUSAN E. WRIGHT"), a resident of Van Buren County, Michigan, is a nurse practitioner licensed to practice in the state of Michigan. She is also licensed to practice law in the state of Michigan. During all relevant times, SUSAN E. WRIGHT was an employee of WHC and performed some services for USM.

Pelvic Muscle Rehabilitation

10. Pelvic Muscle Rehabilitation ("PMR") is a non-surgical therapy to eliminate or reduce symptoms of pelvic floor disorders, including urinary and/or fecal incontinence.

11. Nurse practitioners employed by USM, along with SUSAN E. WRIGHT on occasion, provided PMR therapy services to Medicare beneficiaries located in assisted-living facilities or the beneficiaries' private homes. Practitioners employed at WHC, including SUSAN E. WRIGHT on occasion, provided PMR services to Medicare patients at WHC's office in Kalamazoo. Practitioners employed at WHC also provided diagnostic anorectal manometry examinations as part of the evaluation of patients' urinary and/or fecal incontinence.

12. PMR therapy services, as provided by WHC and USM practitioners, included multiple components. To perform this therapy, WHC and USM staff utilized equipment

manufactured by The Prometheus Group ("Prometheus"). This equipment included three separate tools. First, a staff member inserted a rectal pressure sensor into the rectum of the patient. A staff member instructed the patient through a series of exercises to strengthen the anal muscle, using the rectal pressure sensor to measure the patient's muscle contractions during the exercises. Second, the staff member inserted a vaginal sensor to provide electrical stimulation and to measure the patient's contraction during the exercises. Third, a staff member placed abdominal patches on the patient's abdomen to ensure the patient was working the pelvic floor muscles during the exercises, and not the abdominal muscles.

CPT Codes and Evaluation and Management Services

13. The American Medical Association assigns and publishes numeric codes, known as the Current Procedural Terminology ("CPT") and Health Care Procedure Common Coding System ("HCPCS") codes. The codes are a systematic listing, or universal language, used to describe the procedures and services performed by health care providers.

14. The procedures and services represented by the CPT and HCPCS codes are health care benefits, items, and services within the meaning of 18 U.S.C. § 24(b). They include codes for physical therapy, office visits, diagnostic testing and evaluation, and other services. Health care providers use CPT and HCPCS codes to describe the services rendered in their claims for reimbursement to health care benefit programs.

15. Health care benefit programs, including Medicare, use these codes to understand and evaluate claims submitted by providers and to decide whether to issue or deny payment. Each health care benefit program establishes a fee or reimbursement level for each service described by a CPT or HCPCS code.

16. Evaluation and management ("E&M") codes (beginning with a "99-" prefix) are used to account for patient visits (such as an initial patient visit), and the appropriate code is dependent on a number of different factors, including the setting and complexity of the visit. For example, CPT code 99336 indicates a "domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: [1] a detailed interval history; [2] a detailed examination; [3] medical decision making of moderate complexity." Am. Medic. Assoc., *CPT Professional Manual* at 29 (2019). Additionally, for 99336, "[u]sually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver." *Id.*

17. Medicare typically rejects coverage of E&M services provided by the same practitioner on the same day as a procedure or other service because the reimbursement for the cost of the E&M is already included in the reimbursable cost of the main service provided. However, Medicare will reimburse an E&M service if the practitioner includes with the E&M code a modifier 25, which represents that the same practitioner or other qualified healthcare professional performed a "significant, separately identifiable evaluation and management service . . . on the same day of the procedure or other service." *Id.* at 791. Billing an E&M code on the same day as a scheduled visit for a procedure or therapy is meant to be the exception. When practitioners use modifier 25 to bill an E&M visit to Medicare, they are certifying to Medicare that the E&M visit performed is significant and separately identifiable from the original service they are providing the beneficiary on that same day.

18. Despite the fact that patients being treated with PMR therapy did not typically require or receive an E&M service that was significant and separately identifiable from the PMR therapy service, USM billed an E&M code with modifier 25 for almost every PMR therapy

session performed by the USM nurse practitioners from late 2011 through 2018. As a result, USM falsely submitted claims for these E&M services for reimbursement to Medicare during this time period.

The Use, Regulation, and Adulteration of Medical Devices

19. The Food and Drug Administration ("FDA") regulates medical devices. The federal Food, Drug, and Cosmetic Act ("FDCA") defines a medical device, in pertinent part, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other condition, or in the cure, treatment, or prevention of a disease, in man or in animals, or intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321(h).

20. Under the FDCA, a device is adulterated if it was prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. 21 U.S.C. § 351(a)(2)(A).

21. The FDCA makes it unlawful to do any act or cause any act to be done with respect to a medical device while the medical device was held for sale after shipment in interstate commerce, if such act results in the device being adulterated. 21 U.S.C. § 331(k). Such conduct is a strict liability misdemeanor. 21 U.S.C. § 333(a)(1).

22. Prometheus is the manufacturer of the Pathway CTS2000 and its components, including the rectal pressure sensors referenced in paragraph 12. On or about February 19, 2003, the FDA cleared the Pathway CTS2000 for introduction into interstate commerce under 510(k) number K023906. The FDA cleared the device as a class II device for the intended use of treating urinary and fecal incontinence and providing neuromuscular reeducation.

23. 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."

24. The FDA-approved Instructions For Use ("IFU") for the rectal pressure sensor warned 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*." The IFU further instructed that the rectal pressure sensor was a "single-user pressure perineometer sensor designed to provide accurate detection and biofeedback of the muscle contraction activity of the pelvic musculature for the purpose of rehabilitation of weak pelvic muscles and/or restoration of neuromuscular control." The IFU directed that the sensor be cleaned with soap and water between any subsequent use on the same patient, and it warned against attempting to "sterilize the sensor by any method." The IFU further warned that the rectal pressure sensor is a "potential bio-hazard" and must be disposed of "in a manner consistent with bio-hazard requirements for your area."

COUNT 1
(Misprision of a Felony)

25. Paragraphs 1 through 24 of this Information are realleged and incorporated by reference.

26. In or about mid – to – late 2018, in Kalamazoo County, in the Western District of Michigan, and elsewhere, the Defendant,

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

having knowledge of the actual commission of a felony cognizable by a court of the United States, to wit, health care fraud, concealed the same by participating in the auditing of USM patient charts and claims, which demonstrated that some patients, including Medicare beneficiaries, only received PMR therapy and no other significant, separately identifiable evaluation and management service, and approving of USM's continued billing of healthcare benefit programs, including Medicare, for some evaluation and management services using Modifier 25 that were not supported by the patient charts. Furthermore, SUSAN E. WRIGHT did not as soon as possible make known the same to some judge or other person in civil or military authority under the United States.

18 U.S.C. § 4

COUNT 2
(Adulteration of Medical Devices)

27. Paragraphs 1 through 24 of this Information are realleged and incorporated by reference.

28. Beginning by at least 2007, and continuing into February 2019, in the Western District of Michigan, the Defendant,

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

adulterated and aided and abetted the adulteration of medical devices.

29. Beginning by at least 2007, and continuing into February 2019, SUSAN E. WRIGHT used, and directed WHC and USM staff to use, the rectal pressure sensor when performing PMR therapy. SUSAN E. WRIGHT 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 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 many different patients.

30. Covering single-user rectal pressure sensors with the finger of a surgical glove, removing the surgical glove after use, storing the rectal pressure sensors between uses with subsequent patients, and reusing the same rectal pressure sensors covered with the finger of a new glove on multiple patients caused the rectal pressure sensors to be held under insanitary conditions whereby they may have been contaminated with filth and rendered injurious to health.

21 U.S.C. § 331(k)
21 U.S.C. § 333(a)(1)
21 U.S.C. § 351(a)(2)(A)

ANDREW BYERLY BIRGE
United States Attorney

Date: 5/4/2020

RAYMOND E. BECKERING III
Assistant United States Attorney