UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

ROGER D. BEYER, M.D.,

Defendant.
_____/

1:20-cr-64
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 Practitioner 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 within Michigan.

CPT Codes

6. 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.

7. 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.

8. 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.

9. CPT code 51784 is used to code for "Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique." *Am. Medic. Assoc.*, CPT Code 51784 (2010). CPT code 91122 is used to code for "anorectal manometry." *Am. Medic. Assoc.*, CPT Code 91122 (2010). Both CPT code 51784 and CPT code 91122 are used to code for diagnostic testing services and represent tests performed by practitioners to diagnose fecal or urinary incontinence.

The Defendant

10. ROGER D. BEYER, M.D. ("ROGER D. BEYER"), a resident of Van Buren County, Michigan, is an obstetrics and gynecology physician licensed to practice in the state of Michigan. ROGER D. BEYER is the owner, operator, president, and director of Women's Health Care Specialists, P.C. ("WHC"). He is also the owner, operator, and sole member of Urological Solutions of Michigan, PLC ("USM"). WHC is a now-closed obstetrics-gynecology practice located in Kalamazoo. 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.

Pelvic Muscle Rehabilitation

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

12. Nurse practitioners employed by USM provided PMR therapy services to Medicare beneficiaries located in assisted-living facilities or the beneficiaries' private homes. Practitioners employed at WHC, including ROGER D. BEYER, 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.

13. 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.

USM's Audit History with WPS and The Administrative Law Judge's Decision

14. In order to receive reimbursement from Medicare for services rendered by the medical practitioners at USM, USM was required to correctly identify the service or procedure performed by using the appropriate CPT codes. Payment of USM's claims by Medicare

depended on the service or procedure as reflected in the CPT codes submitted on the claim forms.

15. After an audit conducted in 2008 and 2009, WPS found that USM improperly billed CPT codes 91122 and 51784 as part of PMR therapy billed under ROGER D. BEYER's NPI. Specifically, WPS found that "Electromyography (EMG) and Anorectal Manometry are diagnostic services."

16. ROGER D. BEYER disputed WPS's determination and argued, inter alia, that anal manometry and electromyography are important "monitoring tools" in PMR therapy.

17. In a November 2009 letter, WPS rejected ROGER D. BEYER's arguments, stating, "Electromyography and Anorectal Manometry are considered to be diagnostic services. . . . Subsequent EMG sessions and frequent Anorectal Manometry services are not required to monitor the patient's progress. Therefore, subsequent Electromyography Studies and Anorectal Manometry services have been determined to be Not Medically Necessary services."

18. In October 2010, WPS reopened its audit and found that—despite the November 2009 letter—USM continued to bill the two diagnostic codes improperly for subsequent PMR therapy services. In December 2010, WPS wrote USM again, stating, "Subsequent Electromyography Studies and Anorectal Manometry services have been determined as Not Medically Necessary services. Electromyography (EMG) Studies and Anorectal Manometry are diagnostic services. . . . Therefore, subsequent EMG sessions and Anorectal Manometry services are not required to monitor the patient's progress."

19. As part of the dispute with ROGER D. BEYER and USM, WPS noted that the documentation submitted by ROGER D. BEYER and reviewed by WPS "states that these procedures were carried out as part of 'pelvic muscle rehab treatments' and were not being done

to determine a diagnosis." As such, WPS concluded that the claims at issue did "not support necessity under Medicare rules and regulations and [were] therefore not payable." WPS also noted that the documentation "appear[ed] to suggest that these services are being performed as part of a biofeedback session for pelvic muscle rehabilitation."

20. ROGER D. BEYER and USM again appealed the determination made by WPS in these audits and, in February 2011, the dispute was brought before an Administrative Law Judge ("ALJ") with the Office of Medicare Hearings and Appeals in Cleveland, Ohio. ROGER D. BEYER attended this hearing with counsel. At the hearing, ROGER D. BEYER and USM's counsel contended that WPS was wrong in its determination that USM's use of EMG and anorectal manometry diagnostic codes were medically unnecessary for ongoing PMR therapy. ROGER D. BEYER asserted that WPS's contention that these codes were diagnostic showed that they "d[o] not understand."

21. On May 11, 2011, the ALJ issued a decision finding that USM was not conducting diagnostic tests on the dates of the PMR therapy reviewed, and that "code 51784 and code 91122 should not have been used to bill the services performed." The ALJ further held that, under Medicare's coding requirements, these diagnostic codes are not appropriate for coding PMR therapy.

22. The ALJ sent the decision to USM and USM's counsel. Further, USM's general manager also separately forwarded a copy of the ALJ decision directly to ROGER D. BEYER. Although the ALJ decision upheld WPS's determination that the use of the two CPT diagnostic codes was improper for PMR therapy, USM continued billing PMR therapy under the NPI of ROGER D. BEYER and utilizing CPT codes 51784 and 91122 in the several months following the ALJ decision.

23. On July 27, 2011, WPS sent letter informing USM that it would remain on a Provider Audit List, and that WPS intended to monitor ROGER D. BEYER's USM claims on a prepayment basis for CPT codes 51784 and 91122, effective August 10, 2011. Consequently, WPS put USM on notice that ROGER D. BEYER's USM claims submitted to Medicare for the two diagnostic codes would not be paid until WPS conducted a review of the underlying patient records to determine whether the services were actual diagnostic testing or merely more PMR therapy. USM's general manager forwarded a copy of this July 27, 2011 prepayment review letter to ROGER D. BEYER.

The Use, Regulation, and Adulteration of Medical Devices

24. 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).

25. 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).

26. 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).

27. Laborie is the manufacturer of the T-DOC Air-Charged Anorectal Manometry Catheter ("ARM Catheter"). On or about June 5, 1997, Laborie cleared the ARM Catheter for introduction into interstate commerce under 510(k) number K963064. The FDA cleared the ARM Catheter as a class II device for the intended use of quantifying ano-rectal pressures. The ARM Catheter, which is connected to a urodynamic machine, is inserted through the rectum and utilizes multiple pressure-sensing air balloons to assess internal pressures. The ARM Catheter is a single-use, disposable device.

28. The ARM Catheter's outer package stated that the catheter is "disposable," and warns: "Do not re-use." The FDA-approved instructions for use ("IFU") explained that the ARM Catheter is "a disposable pressure catheter." The IFU directed the practitioner, after use of the ARM Catheter, to "[d]ispose of catheter according to hospital protocol and local environmental regulations."

29. Prometheus is the manufacturer of the Pathway CTS2000 and its components, including the rectal pressure sensors referenced in paragraph 14. 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.

30. 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."

31. The FDA-approved 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
(Conspiracy to Commit Health Care Fraud)

32. Paragraphs 1 through 31 of this Information are realleged and incorporated by reference.

33. Beginning in or about May 2011 and continuing to in or about March 2015, in Kalamazoo County, in the Western District of Michigan, and elsewhere, the Defendant,

ROGER D. BEYER, M.D.,

combined, conspired, and confederated and agreed with other persons to knowingly and willingly execute a scheme and artifice to defraud a health care benefit program affecting interstate commerce, that is, Medicare.

Purpose of the Conspiracy

34. It was the purpose of the conspiracy that USM collect increased reimbursement through the submission of false and fraudulent Medicare claims, specifically the improper billing of PMR therapy utilizing more lucrative diagnostic codes that WPS specifically directed USM not to submit for PMR therapy.

Manner and Means of the Conspiracy

35. From in or about August 2011 through in or about March 2015, the Defendant and others directed USM nurse practitioners to perform PMR therapy services on Medicare beneficiaries.

36. During this same time period, the Defendant and others caused USM and WHC employees to bill Medicare for PMR therapy services using CPT codes 51784 and 91122, which WPS and the ALJ determined represented diagnostic testing that was not medically necessary for ongoing PMR therapy services.

37. In order to continue billing these more lucrative diagnostic codes for USM's PMR therapy services, and to avoid scrutiny by WPS's audits, the Defendant and others caused USM and WHC employees to submit claims for reimbursement to Medicare for USM's PMR therapy services under the NPIs of the USM nurse practitioners and not under ROGER D. BEYER's NPI.

Acts in Furtherance of the Conspiracy

38. On May 20, 2011, PERSON A emailed ROGER D. BEYER a PMR therapy financial analysis for USM. This analysis included a plan to alternate the use of CPT codes 51784 and 91122 for PMR therapy under the NPIs of USM's nurse practitioners.

39. On August 18, 2011, at 8:21 a.m., one of ROGER D. BEYER's employees emailed PERSON A, copying ROGER D. BEYER, stating, in part, "Dr. Beyer wants [USM] to be billing NP's [sic] as soon as possible. . . . In any case, can you get with [USM's biller] and figure out the game plan (coding changes, etc) to implement this and of course keep Dr. Beyer in the loop." At 1:33 p.m. that same day, PERSON A emailed multiple USM employees to set up a conference call to "review switching to the new [USM] billing."

40. On August 23, 2011, PERSON A emailed ROGER D. BEYER a copy of WPS's July 27, 2011 prepayment review letter that directed USM not to use CPT codes 51784 and 91122 to bill Medicare for PMR therapy and informed USM that ROGER D. BEYER's claims for these two CPT codes would be under prepayment review. In his email, PERSON A wrote, "We need to talk about a plan for these audits as well as these pre-payment audits." ROGER D. BEYER responded to this email, saying "Let me know what you want to do. The sooner we change our billing approach to [the one] we talked about the better. I don't know why you

haven't changed the billing sequence like you said you were going to. The NP charges have to be done ASAP also. If we don't get this done, it is going to bite us (you and me) in the ass."

41. On August 25, 2011, PERSON A emailed USM employees, including ROGER D. BEYER, that USM was going to test bill PMR therapy under the USM nurse practitioners' NPIs. He further indicated that "[t]he second thing we are testing is if the new billing plan we are using will go through. Right now they are doing a pre-payment audit on the 91122 and the 51784. What we need to know [is] if we only bill one, will that trigger a prepayment review. . . . We need to monitor the claims we are putting through on both the NPs and Dr Beyer to see if the NP claims are going through and if they are being flagged for prepayment review."

42. On or about September 23, 2011, PERSON A drafted a document entitled "PMR Treatment Plan." This plan proposed that USM bill CPT codes 51784 and 91122 one at a time, for alternating PMR therapy sessions, and also added additional services. These additional services included billing an evaluation and management (E&M) code with every PMR therapy session, as well as a pelvic ultrasound code with every other PMR therapy session.

43. On September 30, 2011, PERSON B emailed ROGER D. BEYER, asking him to call two of his employees, including PERSON A, and indicating, "What they want to know is how you want to bill the PMR's billed for [USM] under the NP's. . . . [PERSON A] can bill the way we do at WHCS, but they told you [ROGER D. BEYER] not to bill that way . . . [PERSON A] is worried about losing money. He is billing an E&M everytime . . . he wants your guidance."

44. On or around October 2, 2011, PERSON A drafted a document entitled "PMR Analysis 10-2-11." This document included USM's "Old Way" of billing, which included billing the two diagnostic codes under ROGER D. BEYER's NPI. It then proposed two options,

one of which alternated the two diagnostic codes between PMR therapy sessions under the nurse practitioners' NPIs.

45. In or around the fall of 2011, at the direction of ROGER D. BEYER and PERSON A, USM "test" billed the plan that alternated the use of the diagnostic codes for PMR therapy under the NPIs of the USM nurse practitioners.

46. In a letter dated November 16, 2011, WPS wrote USM and ROGER D. BEYER informing them of the initial results of the prepayment audit for services billed by USM under ROGER D. BEYER's NPI utilizing CPT codes 51784 and 91122 from August 11, 2011 through September 30, 2011. The letter informed USM and ROGER D. BEYER that all thirty services reviewed were denied. Significantly, WPS's audit did not include a review of services billed under the NPIs of the USM nurse practitioners and, therefore, did not uncover and reject USM's test billing that alternated the two diagnostic codes.

47. In or around January 2015, ROGER D. BEYER and PERSON A learned that WPS intended to publish a local coverage determination. This proposed policy indicated that, because CPT codes 51784 and 91122 represent diagnostic tests, Medicare would expect to see these diagnostic tests billed only once before a course of treatment and, in rare occasions, after a course of treatment has been completed. On January 22, 2015, PERSON A wrote an email to USM personnel, including ROGER D. BEYER, discussing USM's continued billing of PMR therapy using the two diagnostic codes. PERSON A wrote: "As we all know from experience, they [WPS] target by individual provider and then by people who bill that code significantly more than others. They may look for the top 10 or 20 providers. That is why billing under the NPs is important. It spreads it around. I feel (I hope?) that if they aren't enforcing this in some automated way that we will continue to fly under the radar due to our small size."

18 U.S.C. § 1347
18 U.S.C. § 1349

COUNT 2
(Adulteration of Medical Devices)

48. Paragraphs 1 through 31 of this Information are realleged and incorporated by reference.

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

ROGER D. BEYER, M.D.,

adulterated and aided and abetted the adulteration of medical devices.

50. Beginning by at least 2015, ROGER D. BEYER directed WHC staff to use the single-use, disposable ARM Catheters as part of an initial diagnostic examination of patients presenting with urinary or fecal incontinence. ROGER D. BEYER further directed WHC staff to reuse the disposable ARM Catheters on multiple patients. During the diagnostic test, WHC staff placed a condom over the top portion of ARM Catheter prior to inserting the ARM Catheter into a patient's rectum. At the end of the diagnostic test, WHC staff withdrew the ARM Catheter from the patient's rectum, removed and discarded the condom, and left the ARM Catheter attached to the urodynamic machine for use with the next patient.

51. Beginning by at least 2007, and continuing into February 2019, ROGER D. BEYER directed WHC and USM staff to use the rectal pressure sensor when performing PMR therapy. 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 many different patients.

52. Covering the single-use ARM Catheters with a condom, removing the condom after use, storing the used ARM Catheters still attached to the urodynamic machine between patients, and reusing the same ARM Catheters covered with a new condom on multiple patients caused the ARM Catheters to be held under insanitary conditions whereby they may have been contaminated with filth and rendered injurious to health. Additionally, Michigan law prohibits health care providers from knowingly reusing single-use medical devices. MCL § 333.20153.

53. 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)

United States Attorney

Date:

RAYMOND E. BECKERING III
Assistant United States Attorney