WMG

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:21-CR-259-D

UNITED STATES OF AMERICA	)	
	)	
v.	)	SUPERSEDING INDICTMENT
	)	
ANITA LOUISE JACKSON	)	

The grand jury charges as follows:

I. INTRODUCTION

1. During times material to this Superseding Indictment ANITA LOUISE JACKSON ("Jackson") was a licensed North Carolina physician who operated an Ear, Nose, and Throat (ENT) practice in Rockingham, Lumberton, and other locations within the Eastern District of North Carolina. The name of the practice was Greater Carolina Ear, Nose, & Throat, P.A. (GCENT). Jackson was a registered Medicare provider who utilized provider number 2243423B and National Provider Identifier (NPI) 1346286010. GCENT conducted business through Medicare provider number 2243423A and NPI 1821179037.

2. Between 2014 and the end of 2018 Jackson, through GCENT, billed Medicare more than $46 Million for allegedly rendering more than 1,200 incidents of "balloon sinuplasty" services to more than 700 patients. GCENT received more than $5.4 Million for the services. During portions of this same time period, JACKSON

was the top-paid provider of balloon sinuplasty services in the United States, despite the location of her practice outside of a major metropolitan area. JACKSON profited substantially from these billings to the Medicare program.

3. To generate and retain these substantial profits, however, JACKSON engaged in a series of crimes, frauds, and other acts that abused the trust of both the Medicare program, and her patients. Specifically:

(a) **Re-use of "single use" of balloon sinuplasty devices**. JACKSON re-used balloon sinuplasty devices on her patients, even though the devices were marketed and sold to JACKSON, for further consumption by her patients, as sterile, "single use" devices. The devices specified herein, which routinely contacted blood, phlegm, pus, and mucous secretions when inserted into the sinuses, were not approved or cleared by the United States Food and Drug Administration (FDA) to be reprocessed or reused. JACKSON was fully informed that the devices were strictly single-use devices, and that the devices were not intended to be reprocessed or sterilized. Nevertheless, across the relevant time period, JACKSON purchased no more than 30 of these devices. She reused the devices as a routine business practice, sometimes inserting the same device into more than one patient on the same business day. JACKSON failed to inform her patients that she was reusing the devices, and instead, represented on "Pre-Op Instruction for Sinus Spa" forms that the devices were sterile. JACKSON netted hundreds of thousands of dollars in profits by engaging in this practice.

(b) **Illegal payment of remuneration by routinely failing to charge**

and collect patient coinsurance obligations. JACKSON routinely concealed from her Medicare patients the true amount that they were obligated to pay for the balloon sinuplasty services that JACKSON was billing to Medicare in their names. Characterizing these services as a "Sinus Spa," JACKSON and her subordinates routinely led patients to believe they owed either nothing, or only a small copayment of up to $50. In fact, patients were obligated to pay hundreds – in some instances thousands – of dollars for the services. To induce the receipt of these services, JACKSON deceived and failed to inform the patients of their obligations, failed to collect the patient copayments, and ultimately caused the patient obligations to be written off without making genuine efforts to collect. By engaging in this practice, Jackson caused Medicare to pay all, or nearly all, of her balloon sinuplasty charges for her Medicare-only patients, when Medicare was, in fact, only obligated to pay 80 percent of such charges. JACKSON profited from this scheme because it enabled her to reap millions in balloon sinuplasty payments from Medicare which might not otherwise have been incurred had the true patient obligations been disclosed.

(c) **Billing Medicare based upon Missing, Cloned, or Templated Medical Records**. In an abuse of the Medicare program's trust, JACKSON billed Medicare for millions in balloon sinuplasty services without creating and maintaining, at the time of each alleged service, a genuine office visit record and operative report supporting the performance of the billed service, and the medical need for each billed service. In some instances, JACKSON maintained no operative report at all to justify her billings. In other instances, JACKSON created and

maintained a "carbon copy" operative report, which was often blank, or missing JACKSON's signature and date. Even where copied operative reports did exist, they alleged virtually identical actions and services, without documenting what occurred during each individual procedure. The medical record did not objectively identify why, for each individual patient, there was a genuine medical need to conduct balloon sinuplasty on each of the particular sinuses identified and allegedly treated. Likewise, instead of maintaining a true electronic medical record pertaining to each patient's balloon sinuplasty, JACKSON created a template record to bill Medicare. Medicare paid JACKSON millions in balloon sinuplasty services in good faith, and on the assumption, that JACKSON was keeping and maintaining genuine medical records, as opposed to cloned and copied records. JACKSON's creation of cloned and template records thwarted Medicare's ability to assess, after the fact, the medical necessity of the services, and the level of the services that JACKSON allegedly rendered to specific patients on specific dates of service. JACKSON profited from this practice because, under Medicare's prospective payment system, she was able tobill and reap millions in balloon sinuplasty services without Medicare learning of the scheme.

(d) **Fabricating Medical Records to Thwart Medicare Audits.** Even after prospectively paying a provider for alleged medical services, Medicare retains the right to conduct post-payment audits of a provider's records to determine whether payments were warranted. If the provider's medical records do not support the nature and extent of the billed services, Medicare can recoup from the provider all

amounts that are not properly supported. When Medicare attempted to conduct audits of JACKSON's medical records, JACKSON and her subordinates engaged in a scheme to fabricate, backdate, and forge records to deceive the auditors. By deceiving Medicare auditors with fraudulent records, JACKSON attempted to prevent, and in some instances did prevent, auditors from recouping substantial Medicare proceeds from JACKSON.

II. BACKGROUND

A. THE MEDICARE PROGRAM, COPAYMENTS, AND AUDITS

4. Medicare is a federal health insurance program administered by the Centers for Medicare and Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. Medicare helps pay for reasonable and medically necessary medical services for people aged 65 and older and some persons under 65 who are disabled. A qualified individual who receives Medicare benefits is referred to as a beneficiary. Individuals who accept Medicare benefits agree that their records may be reviewed by the Medicare Program and Medicare fraud investigators to determine whether services were rendered as billed.

5. Medicare is divided into Part A (hospital insurance), Part B (medical insurance), Part C (optional Medicare-approved private health insurance), and Part D (prescription drug coverage). Under Medicare Part B, payment is made to the providers of outpatient services. Such providers include physicians, therapists, ambulance providers, and numerous other healthcare providers. Medicare beneficiaries pay a monthly premium for Part B coverage and all services are

generally subject to a 20 percent coinsurance and an annual deductible, payable by the Medicare beneficiary or secondary insurance, if applicable.

6. A "copayment" or "coinsurance" is the portion of the cost of an item or service which the Medicare beneficiary must pay. Medicare Part B copayments are20 percent of the reasonable charge for the item or service. The routine waiver of Medicare deductibles and copayments by providers is unlawful because it results in false claims, violations of the Medicare Antikickback Statute, and excessive utilization of items and services paid for by Medicare. Medicare is generally only obligated to pay 80 percent of covered items of services. When a provider routinely and intentionally fails to charge and collect the patient coinsurance and copayment amounts owed, this causes Medicare to pay up to 100 percent of the actual charge, rather than the required 80 percent. Additionally, when patients are not directed to make payment of their coinsurance obligations, they are less likely to question amounts billed to Medicare in their names, and are more likely to request and receive services that might not otherwise be payable. The waiver of coinsurance and deductible amounts (or any part thereof), is considered "remuneration," and is illegal when offered or paid to induce a patient to purchase any good, service or item payable under a federal health care benefit program.

7. For services provided in an office setting, the Medicare Part B payment to the provider includes reimbursement for the cost of supplies, equipment, and staff utilized while providing services.

8. CMS awards geographic jurisdictions to private healthcare insurers

known as Medicare Administrative Contractors (MAC), who are responsible for processing Medicare claims, making and accounting for payments for Medicare claims, enrolling providers in the Medicare program, reviewing medical records for selected claims, and other functions related to the administration of the Medicare program. CMS contracted with Palmetto GBA (Palmetto) as the MAC to process and pay Medicare Part B claims in the State of North Carolina. CMS also contracted with AdvanceMed, as a Zone Program Integrity Contractor ("ZPIC") for Medicare. ZPICs are responsible for, among other things, investigating fraud, waste, and abusein the Medicare program.

9. To determine the correct payment, all claims submitted for reimbursement to Medicare Part B must be completed accurately and reflect the correct Healthcare Common Procedure Coding System (HCPCS) codes. These codes that describe the services that were provided during the encounter with the beneficiary. Medicare Part B reimburses the physician for each covered service based on the payment rate from the applicable fee schedule. Certain billing modifiers can be appended to a HCPCS that have the effect of increasing reimbursement for the service, such as those that indicate the procedures were performed bi-laterally and/or required more work than is typically necessary for the procedure.

10. Normally, a provider's reimbursement for approved Medicare claims is paid to the provider or his/her assignee by the MAC by either check or direct deposit. However, if the provider has a liability to the Medicare program, such as historical

claims that were already paid but later determined by CMS or its contractors to have been paid improperly, then the reimbursement for a provider's current claims will be applied toward the liability until it is fully satisfied.

11. Providers are only allowed to bill for services that they perform. Reimbursement for services is paid to the provider by Medicare without the provider having to produce proof that the services were performed. At the time of enrollment, however, Medicare providers agree to retain for inspection all medical records relating to billed services.

12. From time to time, Medicare carries out provider audits to determine whether billed services were actually performed, and whether the documentation created and maintained by the provider at the time services were allegedly delivered supported that the billed service was medically necessary for the patient.

13. During a Medicare audit, providers are required to produce the records that were created and maintained by the provider in the ordinary course for the billed services under review by the auditors. In the event that no medical record exists to support a billed service under review, Medicare auditors will direct the provider to repay the Medicare program the funds in what is known as a "recoupment." Likewise, if the provider possesses records concerning a billed service under audit, but those records do not objectively support the nature and extent of the billed services, and the medical necessity for such services, audits may also direct arecoupment from the provider. Medicare may also impose other sanctions in the event that billed services are not supported by the provider's medical records.

14. Under no circumstances were providers authorized to create, fabricate, or backdate records requested under Medicare audits.

B. BALLOON SINUPLASTY

15. Balloon sinuplasty is a procedure used for the treatment of chronic sinusitis (sinus infection). During the procedure, a deflated balloon is inserted alonga guide wire through the patient's nose and into the sinus opening(s) where it is inflated to reshape the sinus passageway(s) and increase airflow and drainage. Theprocedure can be performed on each of three sinuses and on both sides of the face in one session.

16. The HCPCS codes for balloon sinuplasty are 31295, 31296, or 31297 when the procedure is performed on the maxillary, frontal, or sphenoid sinus, respectively, and 31298 when the procedure is performed on both the frontal and sphenoid sinuses. These codes can be submitted on a claim individually or in combination when the procedure is performed on multiple sinuses.

C. THE USE, REGULATION, AND ADULTERATION OF MEDICAL DEVICES

17. The United States 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)(1).

18. Under the FDCA, a device is adulterated if, among other things, it was prepared, packaged, 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).

19. 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). If such conduct is committed with intent to defraud or mislead, it is a felony. 21 U.S.C. § 333(a)(2).

COUNT 1

20. Introductory paragraphs 1 through 19, and 44 through 49, are realleged and incorporated as though fully set forth in this Count.

A. The Entellus XprESS Multi-Sinus Dilation Tool

21. During times material to this Indictment, the Entellus XprESS Multi-Sinus Dilation Tool (the "Entellus XprESS") was a medical device manufactured by Entellus Medical outside of the state of North Carolina.

22. In 2010, Entellus Medical submitted a premarket notification to the FDA, commonly known as a 510(k) premarket notification, in which it sought FDA clearance to market and sell the Entellus XprESS in interstate commerce as a sterile,

single-use device, for consumption by patients suffering from such conditions as chronic sinusitis. As such, the Entellus XprESS was designed to perform balloon sinuplasty.

23. The Entellus XprESS was intended to remodel or recreate the sinus outflow tract via trans-nasal balloon dilation. The device combined the features of a curved suction tip and a frontal ostium seeker, with the tissue expansion effect of balloon dilation. Since the distal end of the device was re-shapable, the device could be modified or bent to reach multiple sinus openings on the same patient. The device also came with an Inflation Device and an Infusion Line.

24. By first bending the tip of the Entellus XprESS to reach the desired sinus, a trained physician could insert the device into the obstructed sinus opening and expand the balloon tip on the device. The expansion of the balloon created micro-fractures in the sinus openings, such that sinus openings were widened,allowing for increased airflow and drainage.

25. During the performance of balloon sinuplasty, the Entellus XprESS regularly made contact with blood, mucus, pus, and other bodily fluids of patients suffering from sinus infections and other ailments. The device could come into contact with infected, ruptured, and bleeding tissues, in addition to obstructed sinus openings. The expansion of the balloon on the device, resulting in micro-fracturing of the sinus openings, also had the potential to cause bleeding and the release of bodily fluids; all of which could contact the device during balloon sinuplasty.

26. In addition to the expandable balloon, the Entellus XprESS had a hollow

interior cavity which ran from the end of the device all the way to the tip. This hollow interior allowed for the physician to run a light source, or alternatively suction, through the center of the device to an opening at the flexible tip. The devicealso had a mechanical, telescoping slide feature which allowed the balloon to be advanced or retracted into the sinus openings.

27. While each of the foregoing features of the Entellus XprESS provided advantages during treatment, they also created areas of the device that could collect blood, mucus, and other filth, and which could not be adequately reached for manual scrubbing and cleaning. Moreover, since the device was made of plastic, it could not be subjected to high temperature sterilization procedures.

28. For these and other reasons, when Entellus Medical submitted its 510k premarket notification for the Entellus XprESS to the FDA for clearance to market in commerce, it did so only as a single-use device. Entellus was required to demonstrate that its sterilization procedures were adequate to ensure human safety during the first and only use of the device by the patient. Since the device was never designed or intended to be re-used, the FDA was neither asked to, nor did it, review any proposed methods of cleansing and reprocessing of the device for use on more than one patient, or any data supporting such reprocessing methods.

29. The instructions for use of the Entellus XprESS, which were also submitted to the FDA as part of the 510(k) process, directly warned physicians that the device could only be used once, and that the device could not be cleaned and reprocessed. For example, under the heading "WARNINGS" the instructions stated:

a. The Entellus XprESS "is provided sterile and for single use only."

b. "Do not use breached or damaged packages, since the sterility … of the device may be compromised."

c. "This XprESS device is provided sterile. Do not re-sterilize because device integrity may be compromised."

d. "This XprESS device, inflation device and other accessories are intended for single procedure use only. Do not attempt to reuse or re-sterilize because the integrity of the XprESS devices may be compromised."

e. "Do not clean the XprESS device with anti-microbial agents as the compatibility of the XprESS device with these agents has not been tested."

30. In the "System Preparations" section of the Entellus XprESS instructions, the physician is advised to first "remove the Inflation Device and the Infusion Line from the sterile package." The physician is also advised to "Remove the XprESS device from its sterile package."

31. In the "Operation" instructions, the physician is advised:

a. Following completion of sinus dilation to "Clean up the ostium site by cutting or removing flaps of tissue, fragments of exposed bone, or any other bone and mucosa that may obstruct or otherwise prevent re-establishment of ventilation and drainage of the sinus."

b. "After completing the entire procedure, dispose of XprESS device, infusion line, guidewire if used, Inflation Device, and all waste product

according to appropriate environmental health safety guidelines."

32. In the "How Supplied" section of the Entellus XprESS instructions, the physician is advised:

a. "The contents of the XprESS Multi-Sinus Dilation Tool are provided sterile and are intended for single-use only."

b. "Do not re-sterilize and/or re-use, as it may result in compromised device performance and risk improper sterilization and cross-contamination."

33. The "Limited Warranty" section of the Entellus XprESS instructions advised physicians that use of the device in violation of the instructions was not warranted by the manufacturer. Specifically, the warranty advised that "This limited warranty does not extend to any abuse or misuse of the XprESS Multi-SinusDilation Tool … failure to follow any instructions or specifications provided with theXprESS Multi-Sinus Dilation Tool (including, without limitation, any re-use, re- processing, or re-sterilization … not in accordance with such instructions or specifications), in each case, whether caused or carried out by Customer or by any third party."

B. Device Adulteration

34. Beginning at a time unknown, but no later than January of 2014, and continuing to November of 2018, in the Eastern District of North Carolina and elsewhere, the defendant, ANITA LOUISE JACKSON, with intent to defraud and mislead, did or caused to be done the following acts with respect to medical devices, specifically, the Entellus XprESS, while the medical devices were held for sale after

shipment in interstate commerce, that resulted in the medical devices being adulterated. 21 U.S.C. § 351(a)(2)(A).

35. In 2012, Jackson began to purchase and use the Entellus XprESS device to perform balloon sinuplasty services through GCENT in the Eastern District of North Carolina and elsewhere. Just between 2014 and December of 2018, Jackson billed Medicare alone for more than 1,200 incidents of balloon sinuplasty services to more than 700 patients, using the Entellus XprESS. GCENT received more than $5.4 Million for the services.

36. Jackson, however, did not purchase and hold in inventory a new Entellus XprESS device for each patient and procedure. Instead, by no later than January of 2014, in direct violation of express warnings and precautions, Jackson re-used the Entellus XprESS devices on hundreds of patients. During the period between January 2014 and December of 2018, Jackson purchased no more than 30 Entellus XprESS devices.

37. Jackson directly profited from the practice of re-using the Entellus XprESS devices. At a cost of around $1,000 per device, Jackson saved more than a million dollars by re-using the devices, rather than purchasing and delivering new and sterile devices to each patient.

38. Jackson defrauded and misled her clients with respect to the reuse of the Entellus XprESS devices. Despite owing a medical duty to her patients, Jackson concealed from them the fact that she was re-using the Entellus XprESS devices in violation of the FDA cleared manufacturer instructions. Moreover, Jackson's pre-

operative instruction sheets misrepresented to patients that the procedure would be performed with a sterile balloon, when, in fact, the re-used Entellus XprESS devices were not sterile. Likewise, Jackson's staff, who assisted with the device use and re-use, did not inform patients of such improper practices.

39. To carry out the re-use, Jackson utilized her staff, who had no specialized training in microbiology or the reprocessing of medical devices. Under Jackson's supervision, staff engaged in certain processes between re-uses of the Entellus XprESS. In sum, to attempt to clean the Entellus XprESS devices between uses, Jackson's staff scrubbed the outside of the device with soap and tap water in a sink near the procedure chair. No specialized tools were used to attempt to clean or scrub the interior, hollow portions, and unreachable crevices of the device. No attempts were made to open or disassemble the device. Similar procedures were carried out for the Inflation Device accessory. After a tap water rinse, the devices were placed into cleaning agents for several minutes. After soaking in the cleaning agents, the devices were placed on a non-sterile "chuck pad" on a table near the procedure chair to dry. In some instances, multiple devices would be left to dry in this non-sterile environment, while Jackson saw patients in the nearby procedure chair. After drying multiple Entellus XprESS devices, and Inflation Devices, all were placed in a drawer under the procedure chair, or nearby. Despite the foregoingprocedures, the Entellus XprESS devices were not sterile at the time that they werere-used on subsequent patients. Staff carried out these procedures under Jackson's supervision.

40. In some instances, due to the low number of re-used Entellus XprESS devices Jackson had on hand, Jackson would use the same device on different patients during the same business day after engaging in the attempted cleaning procedures described in the preceding paragraph.

41. From time to time, Jackson's layperson staff would notify Jackson that, upon visual inspection, the Entellus XprESS devices should no longer be used. The staff based these conclusions upon, among other things, the fact that the plastic of the device had become discolored with age and use, or that the balloon slide mechanism was no longer sliding properly. Staff had no way to inspect the interior portions of the device to even conduct a lay-person examination for buildup of filth. Despite being advised by staff that a device should no longer be used, Jackson did not immediately purchase and use new, sterile, Entellus XprESS devices for all following procedures. Likewise, staff did not resign or inform law enforcement, licensing officials, or public health authorities regarding Jackson's reuse of the devices, but rather continued to assist Jackson with the re-use of the Entellus XprESS devices.

42. By engaging in foregoing, in violation of the FDA-cleared manufacturer instructions, Jackson, with intent to defraud and mislead, caused the Entellus XprESS devices to be held under insanitary conditions, whereby they may have been contaminated with filth and rendered injurious to health, while held for sale after shipment in interstate commerce.

All in violation of Title 21, United States Code, Sections 331(k), 333(a)(1), 333(a)(2), and 351(a)(2)(A).

COUNTS 2 - 11

43. Introductory paragraphs 1 through 19 are realleged and incorporated as though fully set forth in these Counts.

44. Jackson was aware that Medicare generally only paid 80 percent of her allowable charges for balloon sinuplasty services, and that the remaining 20 percent was considered the obligation of the patient, whether through secondary insurance or out of pocket expense. The patients that are the subject the Counts in this section did not possess secondary insurance and, as such, were obligated to pay the full 20 percent of Jackson's allowable charges for balloon sinuplasty.

45. Depending upon the number of sinuses treated and billed to Medicare, the total cost of balloon sinuplasty typically amounted to several thousand dollars. As such, Jackson's patient coinsurance obligations typically amounted to several hundred dollars or, in some instances, more than a thousand dollars.

46. Rather than fully advising her patients of the nature and extent of their coinsurance obligations, Jackson actively deceived patients regarding their responsibilities. Despite representing on routine office documents that "All co-pays and deductibles are due the day of treatment," Jackson did not bill and collect all coinsurance sums owed on the day of treatment. Instead, Jackson and her staff caused patients to assign their Medicare benefits to GCENT, whose staff later billed Medicare as though all coinsurance sums had been collected from the patients on the date of the alleged balloon sinuplasty services. Jackson also mislead patients as to

the amount they owed for the balloon sinuplasty services that Jackson billed in their names, typically charging patients a copayment of only $50. Jackson caused this to occur by charging Medicare for several balloon sinuplasty procedures, but by manipulating patient billing software to make it appear that a smaller number of balloon sinuplasty procedures had been performed. Even with respect to the small co-insurance sums billed to patients, such sums were rarely collected. The non-collection of coinsurance, and the act of removing charges from patient bills to make it appear that the amount owed was only a small sum, was carried out by Jackson and Jackson's staff, at Jackson's instruction. For some patients, these actions not only influenced the purchase on the original date of service but also future purchases of sinuplasty services.

47. Jackson did not inform Medicare that she was engaging in the foregoing practices. Instead, she continued to bill Medicare as though such sums were being charged and collected.

48. The foregoing practices did not occur as the result of an individualized assessment of each patient's financial need or ability to pay, but rather, as a standard business practice for Medicare patients who lacked secondary insurance. Likewise, Jackson engaged in no substantial efforts to collect the true patient coinsurance obligations.

49. In total, between August of 2011 and November of 2018, Jackson caused more than half of one million dollars in Medicare patient obligations to go uncharged, written off, and uncollected. Despite this fact, Jackson reaped the full financial

benefit of all such balloon sinuplasty charges billed to Medicare for these same patients.

50. For each count listed in the following table, between the approximate dates listed for each count, in the Eastern District of North Carolina and elsewhere, the defendant, ANITA LOUISE JACKSON, did knowingly and willfully pay, and cause to be paid remuneration, to wit, the value of uncollected patient coinsurance obligations, directly and indirectly, in cash and in kind, to the person listed in each row of the table below, to induce said person to purchase balloon sinuplasty services, a good, item, and service for which payment may be made in whole or in part under Medicare, a Federal Health Care Program:

COUNT	DATES	PATIENT	JACKSON CHARGES	ALLOWED CHARGES	CO-INSURANCE DUE FROM PATIENT	REMUNERATION (UNCOLLECTED CO-INSURANCE)	AMOUNT PATIENT PAID
2	2/27/2018 to 3/21/2018	E.M.	$17,900	$6,623.61	$1,471.12	$1,421.12	$50
3	1/29/2018 to 3/9/2018	D.M.	$17,900	$6,623.61	$1,597.27	$1,547.27	$0
4	1/8/2018 to 2/9/2018	G.G.	$23,270	$5,500.13	$1,174.77	$1,124.77	$0
5	11/7/2017 to 11/30/2017	E.S.	$17,900	$5,073.40	$1,014.69	$964.69	$0
6	10/16/2017 to 10/31/2017	W.L.	$23,270	$7,354.76	$1,528.96	$1,478.96	$0
7	10/2/2017 to 10/18/2017	J.S.	$17,900	$5,073.40	$1,014.69	$964.69	$50
8	8/28/2017	J.S.	$23,270	$7,354.76	$1,470.95	$1,420.95	$0

	to 9/13/2017						
9	6/8/2017 to 7/7/2017	G.G.	$17,900	$5,073.40	$1,014.69	$964.69	$50
10	5/18/2017 to 7/31/2017	D.B.	$17,900	$5,073.40	$1,014.69	$1,014.69	$0
11	1/24/2017 to 2/20/2017	C.W.	$23,270	$7,354.76	$1,327.16	$1,277.16	$50

Each row of the foregoing table constituting a separate violation of violation of Title 42, United States Code, Section 1320a-7b(b)(2)(B) and Title 18, United States Code, Section 2.

COUNTS 12 - 14

51. Introductory paragraphs 1 through 19 are realleged and incorporated as though fully set forth in these Counts.

A. 2016 ADVANCEMED AUDIT

52. In 2016, AdvanceMed, a Medicare program integrity contractor, conducted an analysis of GCENT's Medicare billings for balloon sinuplasty services. This analysis is referred to herein as the "2016 AdvanceMed Audit." AdvanceMed conducted the audit because Jackson was an outlier in comparison to her peers for services related to endoscopic sinus surgery. As a part of the medical review, AdvanceMed conducted an on-site visit to GCENT's office in Lumberton, North Carolina.

53. AdvanceMed reviewed GCENT's medical records that purported to justify Jackson's billings for 20 balloon sinuplasty claims. In June of 2016,

AdvanceMed informed Jackson that 100 percent of the services billed failed to meet Medicare documentation requirements for medical necessity. AdvanceMed's letter to Jackson stated, among other things, that "[t]he Operative Report in every single claim was cloned, word for word, beneficiary to beneficiary." As such, AdvanceMed found that Medicare had overpaid Jackson $31,035.26 for only those claims reviewed during the 2016 AdvanceMed Audit.

B. 2017 PALMETTO AUDIT

55. Based upon the results of the 2016 AdvanceMed Audit, Palmetto, GCENT's MAC, initiated its own audit of GCENT's balloon sinuplasty billings. This audit began on or about April 5, 2017 and is referred to herein as the "2017 Palmetto Audit." As is customary for such audits, Palmetto directed GCENT to turn over for inspection medical records on file that purported to support and justify balloon sinuplasty billings on 36 claims.

56. Instead of supplying a true and accurate copy of GCENT's medical records relating to the audited claims at the time the audit was initiated, Jackson and employees of GCENT altered existing documentation and created new documentation in support of the billed claims. Jackson then caused these new and altered records to be produced to Palmetto in response to the audit.

57. In particular, at the outset of the audit most patient files contained only template records and boilerplate language that was insufficient, standing alone, to justify billed claims. Jackson altered the existing operative reports to include additional details about particular beneficiaries and procedures. She then caused these modified records to SAC

be supplied to Palmetto, as though they had existed at the time the audit was initiated. Jackson also withheld from Palmetto existing records in the patient file.

58. Palmetto received and relied upon the aforementioned false and fabricated records in evaluating GCENT's claims for payment for the balloon sinuplasty services. Even after the audit, Jackson logged into the patient's electronic medical record and made various modifications in support of an appeal of the 2017 Palmetto Audit.

C. 2018 ADVANCEMED AUDIT

59. On or about January 8, 2018, Medicare, by and through AdvanceMed, its ZPIC, initiated an audit of GCENT's billings for various balloon sinuplasty services. This audit is referred to herein as the "2018 AdvanceMed Audit." As is customary for such audits, AdvanceMed directed GCENT to turn over for inspection the medical records on file that purported to support and justify certain GCENT billings. In total, AdvanceMed requested documentation pertaining to 30 claims relating to $169,087.29 in payments for balloon sinuplasty services.

60. Instead of supplying a true and accurate copy of GCENT's medical records relating to the audited claims at the time the audit was initiated, JACKSON and employees of GCENT altered existing documentation and created new documentation in support of the billed claims. JACKSON then caused these new and altered records to be produced to AdvanceMed in response to the audit.

61. In particular, at the outset of the audit most patient files contained only

template records and boilerplate language that was insufficient, standing alone, to justify billed claims. JACKSON logged into the patient's electronic medical record and made various modifications to enable the claims to pass the audit. JACKSON supplied these modified records to AdvanceMed as though they had existed at the time the audit was initiated.

62. AdvanceMed received and relied upon the aforementioned false and fabricated records in evaluating GCENT's claims for payment for the balloon sinuplasty services.

D. 2018 PALMETTO AUDIT

63. On or about June 7, 2018, Medicare, by and through Palmetto, its MAC, initiated an audit of GCENT's billings for various balloon sinuplasty services. This audit is referred to herein as the "2018 Palmetto Audit." As is customary for such audits, Palmetto directed GCENT to turn over for inspection the medical records on file that purported to support and justify certain GCENT billings. In total, Palmetto requested documentation pertaining to 27 claims relating to $123,181.15 in payments for balloon sinuplasty services.

64. Instead of supplying a true and accurate copy of GCENT's medical records relating to the audited claims at the time the audit was initiated, JACKSON and employees of GCENT altered existing documentation and created new documentation in support of the billed claims. JACKSON then caused these new and altered records to be produced to Palmetto in response to the audit.

65. In particular, at the outset of the audit most patient files contained only

template records and boilerplate language that was insufficient, standing alone, to justify billed claims. JACKSON logged into the patient's electronic medical record and made various modifications to enable the claims to pass the audit. JACKSON supplied these modified records to Palmetto as though they had existed at the time the audit was initiated.

66. Additionally, various patient encounter forms maintained in the file were not signed by the patient prior to the time of the audit. JACKSON, and GCENT staff acting at her direction, acquired patient signatures after the fact and backdated them to appear as though they had been in the patient file prior to the audit. Likewise, JACKSON directed one staff member, who was a notary, to notarize various patient signatures as though they had been signed on the date of thepatient encounter when, in fact, the signatures were added during the audit. JACKSON also supplied these documents to Palmetto in response to the auditors demands.

67. Palmetto received and relied upon the aforementioned false and fabricated records in evaluating GCENT's claims for payment for the balloon sinuplasty services.

* * *

68. For each count listed in the table below, between the approximate dates listed for each count, in the Eastern District of North Carolina and elsewhere, the defendant, ANITA LOUISE JACKSON, knowingly and willfully made and used materially false writings and documents, to wit, patient medical records, knowing the same to contain materially false, fictitious, and fraudulent statements and

entries including, but not limited to, backdated and altered entries that did not exist in the medical record prior to the time of the Medicare Audit identified in each row of the tablebelow, in connection with the delivery of and payment for health care benefits, items, and services, to wit, alleged balloon sinuplasty services, paid for by, and involving Medicare, a health care benefit program as defined in 18 U.S.C. § 24(b):

COUNT	DATE	MEDICARE AUDIT
12	4/5/2017 through 11/30/2017	2017 Palmetto Audit
13	1/8/2018 through 1/23/2018	2018 AdvanceMed Audit
14	2/2/2018 through 7/13/2018	2018 Palmetto Audit

Each row of the foregoing table constituting a separate violation of Title 18, United States Code, Sections 1035(a)(2) and 2.

COUNTS 15 - 16

69. Introductory paragraphs 1 through 19, and 51 through 68, are realleged and incorporated as though fully set forth in these Counts.

70. For each count listed in the table below, between the approximate dates listed for each count, in the Eastern District of North Carolina, the defendant, ANITA LOUISE JACKSON, aiding and abetting others, did knowingly transfer, possess, and use, without lawful authority, the Means of Identification described in each row of the table below, during and in relation to the felony violation enumerated in 18 U.S.C. § 1028A(c), to wit, False Statements Relating to Health Care Matters, in violation of Title 18, United States Code, Section 1035, knowing that said means of identification

belonged to another actual person:

COUNT	DATE	MEANS OF IDENTIFICATION USED
15	2/2/2018 through 7/13/2018	The name and forged signature of a patient with initials L.J. on a backdated declaration
16	2/2/2018 through 7/13/2018	The name and forged signature of a patient with initials W.F. on a backdated declaration

Each row of the foregoing table constituting a separate violation of Title 18, United States Code, Sections 1028A(a)(1) and 2.

COUNTS 17 - 19

THE SCHEME TO DEFRAUD

71. Introductory paragraphs 1 through 19, and 51 through 68, are realleged and incorporated as though fully set forth in these Counts.

72. Between 2014 and 2018, Jackson created and caused to be created template and cloned medical records for her balloon sinuplasty patients. While limited handwritten notations were made on records from time to time, the operative reports and electronic medical records pertaining to alleged balloon sinuplasty services were largely duplicated and copied from one patient to the next.

73. As such, Jackson was aware, at the outset of the 2017 Palmetto Audit, the 2018 AdvanceMed Audit, and the 2018 Palmetto Audit, that she did not possess customized medical records for the balloon sinuplasty services she had already billed that would be sufficient to withstand the scrutiny of Medicare auditors. Jackson was also aware that, lacking such records, Medicare auditors could recoup funds paid to her for such balloon sinuplasty services.

74. Therefore, in response to each of the aforementioned Medicare audits, Jackson engaged in a scheme to deceive Medicare auditors regarding the existence and content of the medical records that actually existed for each of the audited patient files. Specifically, Jackson created, and caused others to create, false and fictitious medical records and reports including, but not limited to, patient encounter notes and operative reports.

75. Jackson then caused said records to be delivered to the respective Medicare auditors via mail and private carriers as though they were genuine medical records that existed prior to the audits.

76. Additionally, after being directed to repay Medicare more than $1.7 Million in conjunction with the 2017 Palmetto Audit, Jackson appealed the decision. In preparation for such appeal filings, Jackson supplied what she represented were genuine medical records for the audit patients, to a fellow ENT practitioner in Georgia with initials K.D. Jackson sought to have K.D. swear under oath that Jackson's billings to Medicare were supported by the medical records supplied to him. But in fact, the records supplied to K.D. were not genuine. Instead, the operative reports and office sinuplasty encounter records, were manufactured by Jackson after the fact to aid in her efforts to thwart the audit. Jackson never informed K.D. that the records had been created and altered after the fact. As such, K.D. relied upon Jackson's representations regarding the authenticity of the medical records, and wrongfully executed a declaration supporting Jackson's efforts to overturn the 2017 Palmetto Audit. K.D.'s declaration was even supplied to a Medicare administrative

law judge in support of Jackson's appeals, which remain pending as of the time of this Indictment.

77. Therefore, between April 5, 2017 and the date of this Indictment, in the Eastern District of North Carolina and elsewhere, the Defendant, ANITA LOUISE JACKSON, with the intent to defraud, devised and attempted to devise, and willfully participated in, with knowledge of its fraudulent nature, the above-described scheme and artifice to defraud and obtain, and to retain, money by materially false and fraudulent pretenses, representations, and promises.

78. For each count listed in the table below, on the approximate dates listed for each count, in the Eastern District of North Carolina and elsewhere, the defendant, ANITA LOUISE JACKSON, for the purpose of executing and attempting to execute the above-described scheme and artifice to defraud and deprive, knowingly caused to be delivered by mail and private and commercial interstate carrier, according to the direction thereon, the matter listed in each row of the table below:

COUNT	DATE OF MAILING	MAIL MATTER
17	1/22/2018	FedEx Express Package containing alleged medical records, sent from the Eastern District of North Carolina to AdvanceMed in Virginia
18	3/13/2018	US Postal Service Express Mail Package containing alleged medical records, sent from the Eastern District

		of North Carolina to K.D. in Georgia
19	7/12/2018	FedEx Express Package containing alleged Medical records, sent from the Eastern District of North Carolina to Palmetto in Georgia

Each row of the foregoing table constituting a separate violation of violation of Title 18, United States Code, Sections 1341, 1349, and 2.

COUNT 20

THE CONSPIRACY

79. Beginning at a time unknown, but no later than January of 2014, and continuing to a time unknown, but no earlier than December 31, 2018, within the Eastern District of North Carolina and elsewhere, defendant ANITA LOUISE JACKSON, and others known to the grand jury, did knowingly combine, conspire, confederate, and agree with each other and others known and unknown to the grand jury, to commit offenses against the United States, to wit:

(1) To, with intent to defraud and mislead, do and cause to be done acts to medical devices, while said devices were held for sale after shipment in interstate commerce, that resulted in the medical devices being adulterated, in violation of Title 21, United States Code, Sections 331(k), 333(a)(2), and 351(a)(2)(A) (Adulteration of Medical Devices)

(2) To knowingly and willfully pay and cause to be paid remuneration, in cash and in kind, to induce patients to arrange for, purchase, and order

balloon sinuplasty services, a good, item, and service for which payment may be made in whole or in part under Medicare, a Federal Health Care Program, in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(B) (Illegal Remunerations);

(3) To knowingly and willfully make and use materially false writings and documents, knowing the same to contain materially false, fictitious, and fraudulent statements and entries in connection with the delivery of and payment for health care benefits, items, and services, paid for by, and involving Medicare, a health care benefit program as defined in 18 U.S.C. § 24(b), in violation of Title 18, United States Code, Section 1035(a)(2) (Making and Using False Health Care Documents); and

(4) To, with the intent to defraud, devise a scheme and artifice to defraud and obtain, and to retain, money by materially false and fraudulent pretenses, representations, and promises; and for the purpose of executing and attempting to execute the scheme and artifice to defraud and deprive, to knowingly cause a matter to be delivered by mail and private and commercial interstate carrier, according to the direction thereon, in violation of Title 18, United States Code, Section 1341 (Mail Fraud).

PURPOSE OF THE CONSPIRACY

80. The purpose of the conspiracy was financial gain and security for the conspirators, derived from billings to Medicare for balloon sinuplasty services.

MANNER AND MEANS

81. Paragraphs 1 through 78 are realleged and incorporated into this Count.

OVERT ACTS

82. In furtherance of the conspiracy, and to effect the objects thereof, there were committed in the Eastern District of North Carolina and elsewhere various overt acts, including, but not limited to, the following:

For Device Adulteration

A. Presenting documents to patients reflecting that the device to be used was sterile.

B. Inserting an Entellus XprESS devise into the sinus of at least one patient, that had previously been used on another patient.

C. Washing at least one Entellus XprESS device in tap water and soap.

D. Placing at least one Entellus XprESS device on a "chuck pad" to dry.

E. Placing at least one Entellus XprESS device into a drawer for future use on other patients.

For Illegal Remunerations

A. Supplying documentation to at least one patient representing that the full amount of their Medicare coinsurance amounts was payable in conjunction with the receipt of balloon sinuplasty services.

B. For at least one patient, manipulating billing software to remove Medicare patient charges for balloon sinuplasty to generate a patient bill reflecting a lower patient obligation that what was, in fact, owed.

C. Presenting a false patient bill to at least one Medicare patient.

For Making/Using False Healthcare Documents and Mail Fraud

A. Altering at least one patient medical record for balloon sinuplasty services that was directed to be produced in conjunction with a Medicare audit.

B. Altering at least one patient operative report for balloon sinuplasty services that was directed to be produced in conjunction with a Medicare audit.

C. Obtaining at least one patient signature on a document that was directed to be produced in conjunction with a Medicare audit.

D. Forging or altering at least one patient signature on a document that was directed to be produced in conjunction with a Medicare audit.

E. Depositing and sending through an interstate mail carrier, a fabricated or altered document that was directed to be produced in conjunction with a Medicare audit.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE NOTICE

Notice is hereby given that all right, title and interest in the property described herein is subject to forfeiture.

Upon conviction of any Federal health care offense as defined in 18 U.S.C. § 24(a), the defendant shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the said offense. Counts 1 through 16 and 20 are Federal Health Care Offenses.

The forfeitable property includes, but is not limited to, the following:

Forfeiture Money Judgment:

a) A sum of money representing the gross proceeds of the offense(s) charged herein against ANITA LOUISE JACKSON, in the amount of at least $5,400,000.

If any of the above-described forfeitable property, as a result of any act or omission of a defendant: cannot be located upon the exercise of due diligence; has been transferred or sold to, or deposited with, a third party; has been placed beyond the jurisdiction of the court; has been substantially diminished in value; or has been commingled with other property which cannot be divided without difficulty;

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it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of said defendant up to the value of the forfeitable property described above.

A TRUE BILL

Foreperson

Date: 1-4-2022

REDACTED VERSION

Pursuant to the E-Government Act and the federal rules, the unredacted version of this document has been filed under seal.

MICHAEL F. EASLEY, JR
United States Attorney

BY: WILLIAM M. GILMORE
Assistant United States Attorney