IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

UNITED STATES OF AMERICA and
STATE OF FLORIDA
ex rel. Jael Cancel,

Plaintiffs,

Case No. 6:14-cv-512-Orl-28TBS

v.

CENTRAL MEDICAL SYSTEMS, LLC,
and ALAN T. HARLEY,

Defendants.
_____/

UNITED STATES OF AMERICA'S
COMPLAINT IN INTERVENTION

The United States of America brings this action against Central Medical Systems, LLC (CMSI[1]) and Alan T. Harley (collectively, Defendants) under the False Claims Act (FCA), 31 U.S.C. § 3729-33, and the common law to recover damages from false claims that CMSI and Harley presented to the Medicare program. Harley is the managing member of and operates CMSI. Defendants' false claims arise from fraudulent billing practices that led to the submission of false claims during the period from at least in or about February 2009 through at least in or about June 2015, including claims for payment for surgical dressings and other items that were for a higher paying code than is allowed—that is, upcoded—and claims for items not provided to patients, specifically by billing for greater quantities of items than were provided to patients. By knowingly presenting these false

[1] Defendant Central Medical Systems, LLC previously operated as Central Medical Systems, Inc. and is commonly referred to by its owner, employees, and affiliates as CMSI.

claims for payment, Defendants violated the FCA, were paid by mistake, and were unjustly enriched.

I. Nature of the Action

1. The United States brings this action to recover treble damages and civil penalties under the FCA and the common law theories of payment by mistake and unjust enrichment.

2. During the period from at least in or about February 2009 through at least in or about June 2015 (the Relevant Time Period), Defendants knowingly presented, or knowingly caused to be presented, false and fraudulent claims to the United States for payment and approval from the Medicare program. Defendants also knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims. These false claims and false statements resulted in payment to Defendants of reimbursement that would not have been paid but for Defendants' misconduct.

II. Jurisdiction and Venue

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

4. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because the acts committed by Defendants in violation of the FCA occurred in the Middle District of Florida, and because Defendants reside and transact business in the Middle District of Florida.

5. Venue is proper in the Middle District of Florida under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Defendants reside and transact business in this District.

III. Parties

6. The United States brings this action on behalf of the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, 42 U.S.C. §§ 1395 et seq. (Medicare).

7. Plaintiff-Relator Jael Cancel was employed by CMSI between July of 2005 and September of 2017. From 2010 through 2017 she served as CMSI's office manager.

8. In or about March of 2014, Cancel filed an action alleging violations of the FCA on behalf of herself, the United States, and the State of Florida pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

9. On January 18, 2018, the United States noticed its decision to intervene in part in Cancel's action.

10. Defendant CMSI is a limited liability corporation, located at 1221 E Broadway St. 1011, Oviedo, Florida. CMSI provides surgical dressings, durable medical equipment (DME), or other Medicare reimbursable items to patients.

11. Defendant Alan Trent Harley is the managing member and owner of CMSI. Since in or about May of 2008 Harley has been operating CMSI. Harley resides in Seminole County, FL.

12. CMSI participates in the Medicare program and submits claims for reimbursement from the Medicare trust fund.

IV. The False Claims Act

13. The FCA provides for the award of treble damages and civil penalties for, among other things, knowingly presenting or causing the presentment of false or fraudulent claims to the United States for payment or approval. 31 U.S.C. § 3729(a)(1)(A).

14. The FCA provides, in pertinent part, that a person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; . . .
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (20 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729 (internal footnote omitted).[2]

15. For purposes of the False Claims Act, the terms "knowing" and "knowingly":

> (A) mean that a person, with respect to information –
>
> > (i) has actual knowledge of the information;
> > (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> > (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

[2] The FCA was amended pursuant to Public Law 111-21, 123 Stat. 1617 (2009), the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. Given the nature of the claims at issue in this case, section 3729(a)(1) of the prior statute, and section 3729(a)(1)(a) of the revised statute are both applicable here. Section 3729(a)(1) applies to conduct that occurred before FERA's enactment, and section 3729(a)(1)(A) applies to conduct after FERA's enactment. Section 3729(a)(1)(B) is applicable to all claims in this case by virtue of Section 4(f) of FERA, which makes the new changes to that provision applicable to all claims for payment pending on or after June 7, 2008.

16. The FCA provides that a person is liable to the United States Government for three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of $5,500 to $11,000 per violation.[3] 31 U.S.C. § 3729(a)(1).

V. The Medicare Program

17. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services and items. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. See 42 U.S.C. §§ 426-426A, 1395o. HHS is the agency responsible for administering and supervising the Medicare program, which it does through CMS, an agency of HHS. The Medicare program has several components, including Part B.

18. Eligible persons may enroll in Part B of the Medicare program, which covers benefits including surgical dressings and other items required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician. 42 U.S.C. §§ 1395k(a)(2)(B), 1395x(s)(5); 42 C.F.R. § 410.36(a)(1).

19. To assist in the administration of Medicare Part B, CMS awards contracts for administration of Medicare fee-for-service claims, including claims for surgical dressings durable medical equipment, and other items, to Medicaid Administrative Contractors (MACs). MACs contact with the Government to receive, adjudicate, and pay fee-for-service claims on behalf of the Medicare program.

[3] For conduct that occurred after November 2, 2015, civil penalties under the False Claims Act are to be assessed at the inflation-adjusted amount set forth in 28 C.F.R. § 85.5.

20. In 2012, CMS announced that CGS Administrators, LLC (CGS) was awarded the contract for the administration of Medicare fee-for-service claims for surgical dressings, durable medical equipment, and other items in the region that includes Florida.

21. The original contract for the region was awarded in September 2006 to CIGNA Government Services, which was later renamed CGS when the company was purchased by Blue Cross and Blue Shield of South Carolina.

22. As a provider under the Medicare program, CMSI was required to submit health insurance claims form "CMS 1500" for paper claims or "837P" for electronic claims to MACs such as CGS. In submitting its claims for payment, CMSI certified that: (1) the information on its CMS 1500 forms or 837P submissions was true, accurate, and complete; and (2) the claims complied with all Medicare laws, regulations, and program instructions for payment.

23. To identify the items, services, or equipment provided to Medicare beneficiaries, participating entities like CMSI use standardized codes found in the Healthcare Common Procedure Coding System (HCPCS). The HCPCS lists the identifying codes along with descriptions of the service, supply, or equipment that correspond with each code.

VI. Defendants' Fraudulent Conduct

24. According to its website, CMSI provides "advanced wound care products that are conveniently shipped directly to patients in their homes." www.cmsiwoundcare.com.

25. Since at least February 2009, CMSI, through Harley, has been submitting inflated billing for surgical dressing, DME, or other healthcare items that include upcoded

wound care supplies or wound care supplies that were not provided to patients in order to receive inflated and ineligible payments from the United States.

26. In interviews with the United States, multiple then-current and former employees of CMSI stated that Harley is the only person who submits billing on behalf of CMSI. This conduct includes submitting claims to Medicare for reimbursement. Harley submits billing in the evenings or on weekends when minimal personnel (if anyone) remain in the office.

27. Relator Cancel stated that Harley has a standing order that no billing is to be finalized until he approves it. Harley is the only person allowed to submit billing.

28. Relator Cancel stated that Harley routinely upcoded items to a larger size or more expensive product than was actually shipped to receive higher reimbursement from Medicare.

29. Another former employee confirmed that Harley routinely would bill for different, more expensive items than what was shipped to patients.

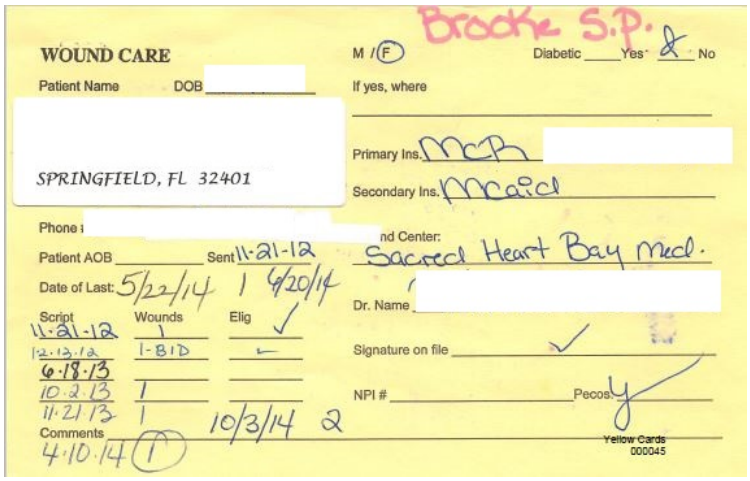
30. Harley would routinely manipulate item quantities to make it appear that larger quantities of items were sent to patients than the quantities that actually were sent, thus causing CMSI to bill Medicare for wound care supplies that never were provided to patients.

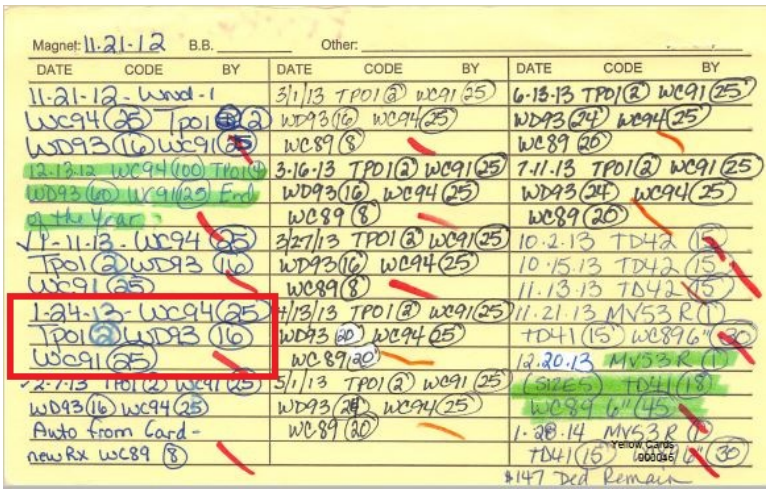
31. Proof that CMSI, through Harley, regularly engaged in upcoding and regularly billed Medicare for wound care supplies that were not provided to patients can be found in CMSI's own business records, as well as in Medicare claims records.

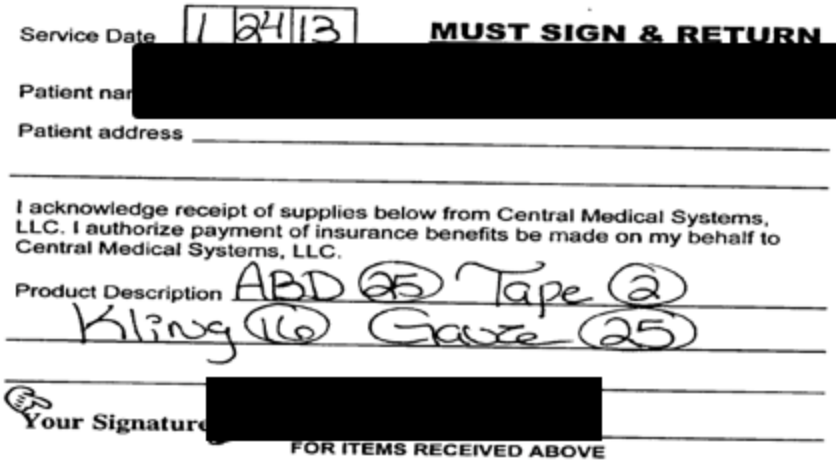
32. From at least as early as February 2009 until some point in 2015, CMSI used a paper-based system for keeping track of the wound care supplies it shipped to patients.

Specifically, when an order of supplies was to be sent to a patient, CMSI created two cards—a yellow card and a white card—recording the supplies sent. On the yellow card, which CMSI retained for billing purposes, CMSI recorded (a) the patient's name, (b) the date, (c) a list of CMSI-specific alphanumeric codes representing each type of item sent, and (d) numbers indicating the quantity of each type of item sent. CMSI recorded multiple shipments on the back of a patient's yellow card. On the white card, which CMSI sent to the patient along with the supplies, CMSI included the same information but instead used more familiar terms (e.g., "tape", "gauze") instead of CMSI's alphanumeric codes to identify each type of item sent. Patients were then asked to sign the white card in order to acknowledge receipt of the supplies listed on the white card. Patients also were asked to return the signed white card to CMSI. As a result of this system, CMSI's business records should include a substantial number of white cards indicating, and confirmed with a patient signature, the types and quantities of wound care supplies sent to the patient on a particular date.

33. A redacted example of a yellow card, followed by a redacted example of a white card, for supplies sent to a patient on January 24, 2013, are shown below:






Service Date 1/24/13 MUST SIGN & RETURN

Patient nar [redacted]

Patient address _____

I acknowledge receipt of supplies below from Central Medical Systems, LLC. I authorize payment of insurance benefits be made on my behalf to Central Medical Systems, LLC.

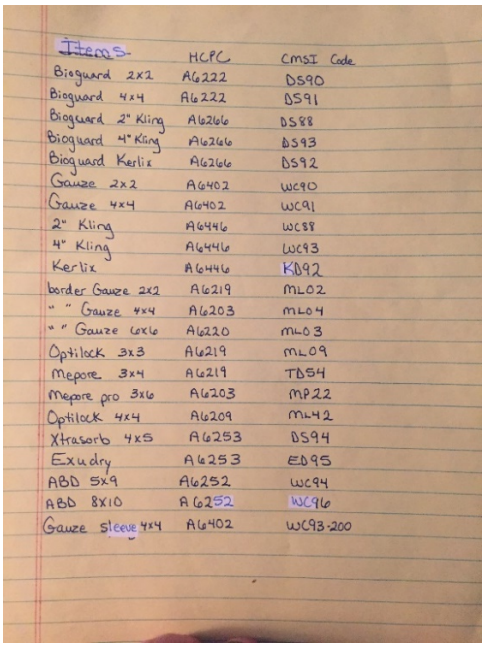
Product Description ABD (25) Tape (2)
Kling (16) Gauze (25)

Your Signatur [redacted]

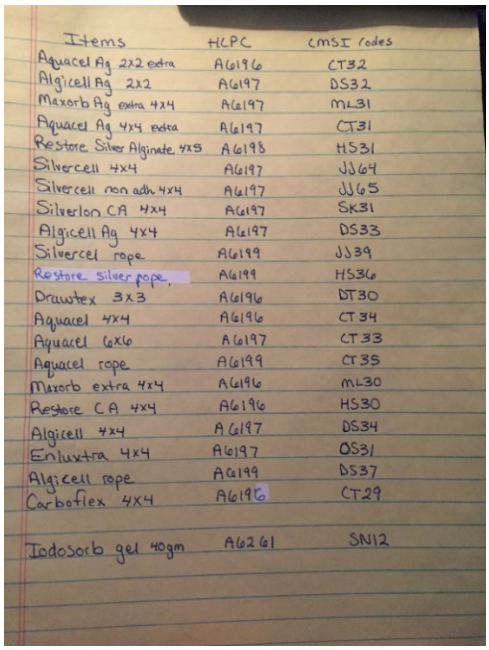
FOR ITEMS RECEIVED ABOVE

34. During this same period, CMSI used an electronic billing system. After a shipment of supplies was sent to a patient, a CMSI employee would enter the information from the shipment's yellow card into this electronic billing system. To do so, the employee would reference the card itself, as well as an internal item list that listed CMSI's internal alphanumeric codes and indicated which HCPCS code (or "HCPCS") would be billed for each alphanumeric code used on the yellow card. An exemplar page of the internal item list is shown below, followed by an employee's handwritten "quick reference" sheets:

Category	CMSI CODE	CMSI HCPC	Not	Default items in yellow	SIZE	Description	COMPANY	Item #	HCPC
Color Coordina	CMSI	CMSI	In Stock	Default Items	Inches	Item Information			CODE
				FOAM					
Antimicrobial	N/A		NIS	Kendall Copa AMD Foam	1" Disc	4mm Hole (Fenestrated)	Covidien	55511AMD	A6209
Antimicrobial	N/A		NIS	Kendall Copa AMD Foam	1" Disc	7mm Hole (Fenestrated)	Covidien	55512AMD	A6209
Antimicrobial	WD12	A6209		Algidex AG	2x2		Deroyal	46-ag22	A6209
Antimicrobial	N/A	N/A	NIS	Kendall Copa AMD Foam	2x2		Covidien	55522AMD	N/A
Antimicrobial	N/A	A6209	NIS	Aquacel Ag Foam Dressing non Adh	2x2	Foam Dressing non Adh	Convatec	420639	A6209
Antimicrobial	N/A	N/A	NIS	Polymem Wic Silver Cavity Filler	3x3		Ferris MFG Corp	1333	A6215
Antimicrobial	N/A	N/A	NIS	Kendall Copa AMD Foam	3x3	(Fenestrated)	Covidien	55535AMD	N/A
Antimicrobial	N/A	N/A	NIS	Mediplus SuperFoam AG	3x4	Tri-layer	MediPurpose	MP7510PSFAG	A6209
Antimicrobial	WD13	A6210	NIS	Algidex AG	4x4		DeRoyal	46-AG44	A6209
Antimicrobial	GW40	A6210	NIS	RTD Foam Pad	4x4		GWM	72040414	A6210
Antimicrobial	CP11 or CP40	A6210		Biatain AG	4x4		Coloplast	9622	A6209
Antimicrobial	TD43	A6209		Mepilex AG	4x4	w/ silver --- f/ ricky 12.00	Molynlycke	287100	A6209
Antimicrobial	HS40	A6209		Restore	4x4		Hollister	509345	A6209
Antimicrobial	ML47	A6209	YES	Optifoam AG	4x4		Medline	MSC9614	A6209
Antimicrobial	N/A	N/A	NIS	Kendall Copa AMD Foam	4x4		Covidien	55544AMD	A6209
Antimicrobial	N/A	A6209	NIS	Aquacel Foam	4x4	Foam Dressing non Adh	Convatec	420642	A6209
Antimicrobial	N/A	N/A	NIS	Mediplus SuperFoam AG	4x4	Tri-layer	MediPurpose	MP1010PSFAG	A6209
Antimicrobial	FR41		NIS	Polymem Silver	4.25x4.25	Non-Adherent	Ferris MFG Corp	1044	A6210
Antimicrobial	N/A	N/A	NIS	Mepilex AG	4x5		Molynlycke	287090	A6210
Antimicrobial	SN52	A6210		Acticoat Absorbant	4x5		S/N	20381	A6210
Antimicrobial	AF40	A6210	NIS	Ultra Silver Foam	4x5	Was Also Known as (AFM AG)	Milliken	3000051018	A6210
Antimicrobial	N/A	N/A	NIS	Mediplus SuperFoam AG	4x5	Heel	MediPurpose	MP1013PSFAG	A6210
Antimicrobial	N/A	N/A	NIS	Kendall Copa AMD Foam	4x8		Covidien	55548AMD	A6210
Antimicrobial	TD57	A6211	NIS	Mepilex AG	4x8		Molynlycke	287200	A6210
Antimicrobial	N/A	N/A	NIS	Polymem Silver	4.25x12.5		Ferris MFG Corp	1124	A6210
Antimicrobial	N/A	N/A	NIS	Kendall Copa AMD Foam	6x6		Covidien	55566AMD	A6210
Antimicrobial	N/A	N/A	NIS	Mepilex AG	6x6		Molynlycke	287300	A6210
Antimicrobial	N/A	N/A	NIS	Mediplus SuperFoam AG	6x6	Tri-layer	MediPurpose	MP1515PSFAG	A6210
Antimicrobial	N/A	N/A	NIS	Polymem Silver	6.5x7.5		Ferris MFG Corp	1077	A6210
Antimicrobial	HS42	A6210	NIS	Restore	6x8		Hollister	509346	A6210
Antimicrobial	TD59	A6211	NIS	Mepilex AG	8x8		Molynlycke	287400	A6211
Antimicrobial	N/A	N/A	NIS	Kendall Copa AMD Foam	8x8		Covidien	55588AMD	A6211



Items	HCPC	CMSI Code
Bioguard 2x2	A6222	DS90
Bioguard 4x4	A6222	DS91
Bioguard 2" Kling	A6266	DS88
Bioguard 4" Kling	A6266	DS93
Bioguard Kerlix	A6266	DS92
Gauze 2x2	A6402	WC90
Gauze 4x4	A6402	WC91
2" Kling	A6446	WC88
4" Kling	A6446	WC93
Kerlix	A6446	KD92
border Gauze 2x2	A6219	ML02
" " Gauze 4x4	A6203	ML04
" " Gauze 6x6	A6220	ML03
Optilock 3x3	A6219	ML09
Mepore 3x4	A6219	TD54
Mepore pro 3x6	A6203	MP22
Optilock 4x4	A6209	ML42
Xtrasorb 4x5	A6253	DS94
Exudry	A6253	ED95
ABD 5x9	A6252	WC94
ABD 8x10	A6252	WC96
Gauze sleeve 4x4	A6402	WC93-200



Items	HCPC	CMSI Codes
Aquacel Ag 2x2 extra	A6196	CT32
Algicell Ag 2x2	A6197	DS32
Maxorb Ag extra 4x4	A6197	ML31
Aquacel Ag 4x4 extra	A6197	CT31
Restore Silver Alginate 4x5	A6198	HS31
Silvercell 4x4	A6197	JJ64
Silvercell non adh 4x4	A6197	JJ65
Silverlon CA 4x4	A6197	SK31
Algicell Ag 4x4	A6197	DS33
Silvercel rope	A6199	JJ39
Restore Silver pope	A6199	HS36
Drawtex 3x3	A6196	DT30
Aquacel 4x4	A6196	CT34
Aquacel 6x6	A6197	CT33
Aquacel rope	A6199	CT35
Maxorb extra 4x4	A6196	ML30
Restore CA 4x4	A6196	HS30
Algicell 4x4	A6197	DS34
Enluxtra 4x4	A6197	OS31
Algicell rope	A6199	DS37
Carboflex 4x4	A6196	CT29
Iodosorb gel 40gm	A6261	SN12

35. Although some of the HCPCS codes listed on the internal item list were the appropriate ones for the items listed, others of the HCPCS codes listed on the internal item list were not appropriate. For example, CMSI's internal item list identified HCPCS code A6211 as the appropriate HCPCS code for the item with the internal CMSI Code TD58. Internal CMSI Code TD58 corresponds to a 6-inch by 8-inch foam dressing called Mepilex® Border 6x8:

CMSI CODE	CMSI HCPC	STOCK	Default items	SIZE	COMPANY	Item #	HCPC
CMSI	CMSI	IN HOUSE	Default Items				CODE
TD58	A6211	NIS	Mepilex Border	6x8	Molnlycke	295600	A6211

According to the manufacturer's information, this foam dressing should not be billed using HCPCS code A6211 (for which Medicare paid $32.60 per unit in July 2015), as CMSI's internal item list indicated, but instead should be billed using either HCPCS codes A6212 (which paid $10.77 in July 2015) or A6213 (which is an excluded code that is billed incident to physician services and would result in $0.00 reimbursement to CMSI if billed correctly).

36. After a CMSI employee had entered the yellow card information into the electronic billing system, but before a claim was submitted to Medicare for the supplies referenced on that yellow card, Harley would routinely modify the information in the electronic billing system. Specifically, Harley would routinely change the item code or the HCPCS code associated with items that had previously been entered by an employee based on the yellow card information, which would result in a higher reimbursement from Medicare. Harley also would routinely change the quantities associated with certain items to replace the quantity entered by the employee based on the yellow card information with a larger quantity that would result in higher reimbursement from Medicare. Claims submitted to Medicare reflected the changed information entered by Harley, rather than the original yellow card information entered by the CMSI employee.

37. In approximately 2015, CMSI ceased using the yellow card and white card system and switched to an electronic system with printed packing slips. According to Relator Cancel, this did not stop Harley from manipulating CMSI's Medicare billing, however.

38. Harley also issued "standing orders" that would result in upcoding. For example, when employees received a prescription for 4x4 gauze pads, there was a "standing order" issued by Harley that the employees were to send Bioguard® antimicrobial gauze sponges rather than traditional gauze pads because Bioguard® gauze sponges were reimbursed by Medicare at a higher rate.

39. According to several former CMSI employees, Harley's conduct as described above was routine and pervasive during the Relevant Time Period.

40. For example, one former employee said Harley was "notorious" for upcharging when he billed. She observed that, when she reviewed previous billing to confirm payment information for refills, the items billed by Harley did not match the items written on the prescription, yellow card, or white card.

41. Another former employee stated that, in 2015, she picked up extra duties to earn overtime pay. This included inputting information from yellow cards into CMSI's billing system. This employee personally observed Harley changing billing in CMSI's computer system.

42. CMSI also ordered fewer items than it billed to Medicare. For instance, between January 2009 and December 2014, CMSI purchased less than 17,000 units of HCPCS A6210 from suppliers; from January 2009 to July of 2014, CMSI billed Medicare for over 77,000 units of HCPCS A6210. Similarly, between January 2009 and July 2014, CMSI purchased less than 90,000 units of HCPCS A6253; from January 2009 to July of 2014, CMSI billed Medicare for over 167,000 units of HCPCS A6253.

A. Example #1

43. One HCPCS code Harley routinely upcoded before submitting claims to Medicare was A6252. HCPCS code A6252 corresponds to specialty absorptive dressings with a pad size more than 16 square inches but less than or equal to 48 square inches. When CMSI sent specialty absorptive dressings to patients that met this description, Harley would routinely upcode the claim to HCPCS code A6253, which corresponds to specialty absorptive dressings with a pad size greater than 48 square inches.

44. One example of this conduct occurred regarding a shipment of supplies sent to Patient J in January 2013. According to the yellow card and white card memorializing

this shipment (shown in paragraph 33 above), the shipment included, among other things, 25 "ABD"s (or sterile abdominal pads) that had the internal CMSI code WC94:

45. According to CMSI's internal item list, internal CMSI code WC94 corresponds to 5-inch by 9-inch abdominal gauze pads. Such pads have an area of 45 square inches.

46. According to the handwritten "quick reference" sheet in paragraph 33, the HCPCS code corresponding to item number WC94 (5-inch by 9-inch abdominal gauze pad) was A6252. In this instance, CMSI's internal reference appears to be correct, as a 45-square-inch abdominal gauze pad appears to fall within the description of an item for which HCPCS code A6252 should be billed.

47. When billing Medicare for this shipment to Patient J, however, Harley upcoded the claim to falsely indicate that larger (and more expensive) abdominal gauze pads were sent to Patient J. Specifically, Harley billed Medicare for these pads using HCPCS code A6253. The relevant Medicare claims data are shown below:

BENE LAST NAME	BENE FIRST NAME	FROM DATE	THRU DATE	Principal DIAG	DIAG 1	PROC CODE	UNITS SUBMITTED	UNITS ALLOWED	AMOUNT SUBMITTED	PROVIDER PAID AMT	Claim Receipt Date	PAID DATE
[redacted]		1/24/2013	1/24/2013	70719	70719	A6253	25	25	$249.25	$137.20	2/26/2013	3/1/2013

48. The knowing submission of this upcoded claim to Medicare resulted in the submission of a fraudulent claim to the United States for $249.25—as well as the making of a false record or statement material to a fraudulent claim—and increased payment from Medicare to CMSI.

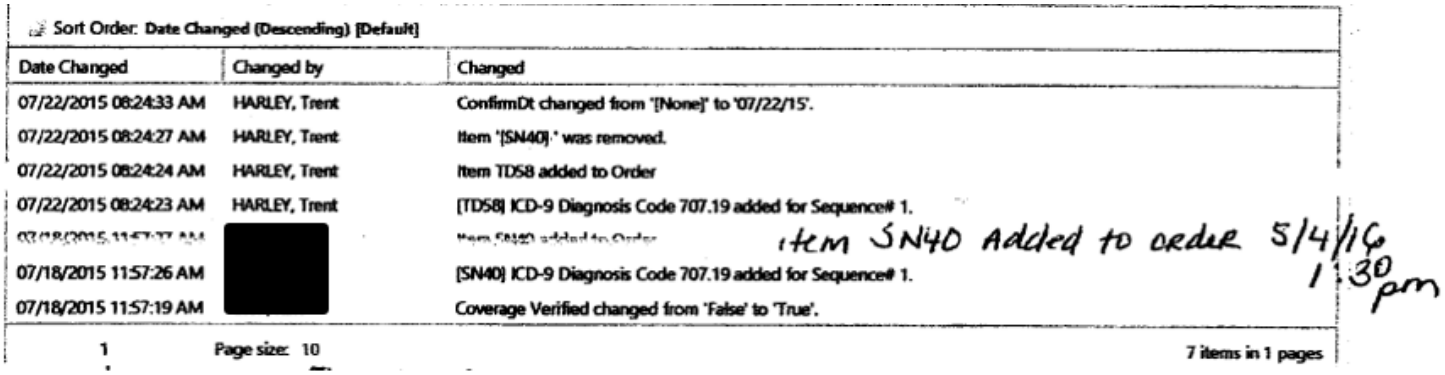
B. Example #2

49. Another way Harley routinely caused the upcoding of CMSI's claims to Medicare was by manipulating CMSI's electronic billing system to indicate that different items were sent to patients than the items that were, in fact, sent.

50. For example, in July 2015, CMSI apparently sent foam would dressings to a patient, which correspond to CMSI Code SN40. Accordingly, an entry stating, "Item SN40 added to order" was entered into CMSI's electronic billing system on July 18, 2015, by a CMSI employee.

51. A few days later, on the morning of July 22, 2018, Harley manipulated the information in CMSI's electronic billing system to add item TD58 to the order and remove item SN40 from the order. According to CMSI's internal item list, TD58 corresponds to a 6-inch by 8-inch foam dressing called Mepilex® Border 6x8.

52. The following screen shot shows this manipulation by Harley:



Sort Order: Date Changed (Descending) [Default]

Date Changed	Changed by	Changed
07/22/2015 08:24:33 AM	HARLEY, Trent	ConfirmDt changed from '[None]' to '07/22/15'.
07/22/2015 08:24:27 AM	HARLEY, Trent	Item '[SN40]' was removed.
07/22/2015 08:24:24 AM	HARLEY, Trent	Item TD58 added to Order
07/22/2015 08:24:23 AM	HARLEY, Trent	[TD58] ICD-9 Diagnosis Code 707.19 added for Sequence# 1.
[redacted]	[redacted]	[redacted]
07/18/2015 11:57:26 AM	[redacted]	[SN40] ICD-9 Diagnosis Code 707.19 added for Sequence# 1.
07/18/2015 11:57:19 AM	[redacted]	Coverage Verified changed from 'False' to 'True'.

1 Page size: 10 7 items in 1 pages

Item SN40 Added to order 5/4/16 1:30 pm

53. According to CMSI's internal tracking sheet, the item with CMSI Code SN40 was to be billed using HCPCS code A6212 and the item with CMSI Code TD58 was to be billed using HCPCS code A6211. In July 2015, Medicare paid $10.77 per unit for HCPCS code A6212 and $32.60 for HCPCS code A6211.

54. Thus, by replacing item SN40 (which CMSI would bill using HCPCS code A6212) with item TD58 (which CMSI would bill using HCPCS code A6211) in CMSI's electronic billing system, Harley more than tripled the reimbursement CMSI claimed for this item in this shipment.

C. Example #3 and Example #4

55. In addition to upcoding, as described above, Harley also manipulated CMSI's Medicare billings by representing to Medicare that CMSI sent patients a larger quantity of a particular item on a particular date than the quantity actually prescribed or sent (or both).

56. For example, one former employee recalled orders for rolled gauze, with a HCPCS code of A6266. The largest quantity of rolled gauze CMSI sent to patients was 150 units; however, on multiple occasions, this witness observed between 400 and 600 units of gauze being billed for reimbursement. This witness stated Harley made this billing change.

57. Relator Cancel also stated that she observed Mr. Harley's fraudulent billing in this manner. Specifically, in September 2016, a customer service representative approached Relator Cancel with a question about a prescription for 30 Aquacel™ pads that was entered by Mr. Harley in the computer system. Although the prescription called for only 30 Aquacel™ pads, the payment request Harley submitted requested reimbursement for 90 Aquacel™ pads.

58. Relator Cancel stated she observed this type of fraudulent billing throughout her employment at CMSI, up to the time she left her employment in September of 2017.

D. Routine Upcoding of Other Orders

59. Example #1 and Example #2 above (and the additional examples listed in the chart in paragraph 70 below) are just a handful of examples of the upcoded claims CMSI, as a result of Harley's conduct, submitted to Medicare.

60. For instance, CMSI consistently upcoded orders for which different HCPCS codes were appropriate to the following, more financially lucrative, HCPCS codes:

a. A6197 – Alginate or other fiber gelling dressing, wound cover, sterile, pad size 16 square inches or less, each dressing;

b. A6210 – Foam dressing, wound cover, sterile, pad size more than 16 inches but less than or equal to 48 square inches, without adhesive border, each dressing;

c. A6253 – Specialty absorptive dressing, wound cover, sterile, pad size more than 48 square inches, without adhesive border, each dressing.

61. Upon information and belief, CMSI also upcoded A6223 (Gauze, more than 16" but less than 48") to A6224 (Gauze, more than 48"). The reimbursement rate for A6224 is approximately 30% higher than A6223.

62. As noted above, CMSI's internal item list itself also led to upcoding because some of the entries on the list identified an improper HCPCS code for the corresponding item. As a result, employees would unknowingly enter upcoded items into CMSI's billing system and CMSI, in turn, would submit those upcoded claims to Medicare.

63. For example, the item with CMSI Code FR40 was described on CMSI's internal item list as "Polymem 4x4" (Manufacturer's item number 5044). The tracking sheet stated that this item was to be billed using HCPCS code A6210, as shown below:

CMSI CODE	CMSI HCPC	Not	Default items in yellow	SIZE
CMSI	CMSI	In	Default Items	
FR40	A6210	NIS	Polymem	4x4

Item #	HCPC
	CODE
5044	A6210

However, according to the manufacturer of this product, Ferris Manufacturing Company, part number 5044 should be billed using HCPCS code A6209, not A6210.

64. The current payment for HCPCS code A6209 is $8.41. The current payment for HCPCS code A6210 is $22.42. As a result, by instructing employees to use an internal item list that incorrectly stated FR40 was billable as HCPCS code A6210 instead of A6209, CMSI ensured each claim for PolyMem® 4x4 (CMSI Code FR40) would be increased by approximately 166%.

65. Upon information and belief, CMSI also consistently upcoded orders to other more financially lucrative HCPCS codes beyond those specifically identified in this complaint.

E. Routine Quantity Increases in Other Orders

66. In addition, Example #3 and Example #4 above (and the additional examples listed in the chart in paragraph 70, below) are just a handful of examples of the claims CMSI, as a result of Harley's conduct, submitted to Medicare for which the quantity of items actually prescribed or sent to patients was less than the quantity of items for which CMSI claimed reimbursement from Medicare.

67. For example, upon information and belief, CMSI billed HCPCS code A6407 (packing strips), which are sold in a 1 yard lengths, up to five units per package; however, CMSI would consistently bill this as if ten units were sent to the patient, instead of one package of five units.

68. Upon information and belief, CMSI also billed for items not provided by billing HCPCS code A6199. Items under this code come in three units per item; CMSI billed this as if it sent five units to patients.

F. Additional Specific Examples

69. As detailed above, the Defendants' business involved providing surgical dressings, durable medical equipment, and other healthcare items to patients with prescriptions. The Defendants upcoded their claims for these products. That is, they routinely billed Medicare for dressings or items that were more expensive than what was actually provided to the patient. The Defendants also increased the quantity of their claims. That is, they routinely billed Medicare for more dressings or items than were actually provided to the patient. This resulted in increased payment to Defendants.

70. Listed below are additional examples of specific false claims, with identifying information removed to protect patient privacy, that Defendants presented and caused to be presented to the United States.

Date of Service	Beneficiary	HCPCS Code Billed by Defendants	Correct HCPCS Code	Amount Paid	Description
5/26/09	Patient A	A6210	A6213	$401.66	Upcoded
6/4/09	Patient B	A6210	A6213	$167.36	Upcoded
11/29/10	Patient C	A6210	A6197	$502.08	Upcoded
7/26/11	Patient D	A6197	A6196	$689.60	Upcoded
8/8/11	Patient E	A6197, 90 units	A6196, 50 units provided to patient	$1,241.28	Upcoded, Changed Quantity
8/30/11	Patient F	A6253	A6254	$106.4	Upcoded
11/15/11	Patient G	A6210	A6209	$66.88	Upcoded
3/22/12	Patient H	A6253	A6402	$544.80	Upcoded
10/23/12	Patient I	A6210	A6213	$17.12	Upcoded
1/24/13	Patient J	A6253	A6252	$137.20	Upcoded
8/30/13	Patient K	A6253, 100 units	A6253, 60 units sent to patient	$537.82	Increased Quantity, Upcoded
6/10/13	Patient L	A6210, 40 billed.	A6211, 4 units sent to patient	$676.44	Increased Quantity
6/10/13	Patient M	A6253	A6252	$53.78	Upcoded
8/30/13	Patient N	A6253	A6252	$107.56	Upcoded
10/18/13	Patient O	A6197, 30 units	A6196, 15 units A6197, 15 units	$418.42	Upcoded
12/30/13	Patient P	A6210	A6209	$169.11	Upcoded
12/30/13	Patient Q	A6210, 10 units	A6209, 20 units	$169.11	Upcoded, Changed Quantity

Date of Service	Beneficiary	HCPCS Code Billed by Defendants	Correct HCPCS Code	Amount Paid	Description
2/12/14	Patient R	A6253	A6252	$651.97	Upcoded
7/23/14	Patient S	A6197	A6196	$211.33	Upcoded
10/24/14	Patient T	A6253	A6403	$271.66	Upcoded

G. Harley's Firing of Employees Who Refused to Attest to the Lack of Billing Practice Violations at CMSI

71. In or about November of 2015, after receiving an HHS Office of Inspector General subpoena for medical records related to the investigation that preceded the filing of this complaint, CMSI representatives asked employees if they knew of any improper billing. After that request, CMSI provided employees with a sworn statement and asked them to sign it. The statement included this language:

> I do not have any knowledge of any violations, past or present, of state or federal laws relating to billing practices, maintenance of patient records, or improper disclosure of patient information that occurred or is occurring at Central Medical Systems, LLC.

72. Two employees refused to the sign the statement because they knew of fraudulent billing.

73. CMSI fired both employees.

74. According to one of the employees, she was told she was fired because she did not sign the statement.

75. Relator Cancel recalls that both employees were fired for refusing to sign the statement.

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1) and (a)(1)(A))

76. The United States realleges and incorporates by this reference all preceding paragraphs of this complaint as if fully set forth herein.

77. This is a claim for treble damages and civil penalties of $11,000 for each violation of the False Claims Act, 31 U.S.C. §§ 3729-33, as amended.

78. From in or about February 2009 through in or about June 2015, through the acts described above, Defendants and their agents and employees knowingly presented, and caused to be presented, false and fraudulent claims for payment and approval to the United States, in violation of 31 U.S.C. § 3729(a)(1) and (a)(1)(A).

79. The claims for payment presented by the Defendants and their agents and employees include, but are not limited to:

a. Claims for payment for surgical dressings, items, or equipment at a higher rate than cost of the equipment actually provided.

b. Claims for payment for surgical dressings, items, or equipment that were not provided.

80. Defendants presented, and caused to be presented, these false claims with actual knowledge of their falsity, or with deliberate ignorance or reckless disregard of the truth or falsity of the claims.

81. Because of Defendants' conduct set forth in this count, the United States suffered actual damages in an amount to be determined, and therefore is entitled to treble damages under the FCA, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

SECOND CAUSE OF ACTION
(False Claims Act: Making and Using False Records and Statements to Get False Claims Paid)
(31 U.S.C. § 3729(a)(1)(B) and (a)(2))

82. The United States realleges and incorporates by this reference all preceding paragraphs of this complaint as if fully set forth herein.

83. As more fully alleged in the above paragraphs, Defendants knowingly made and used, and caused to be made and used, false records and statements, including forms CMS 1500 and 837P, to get false and fraudulent claims paid by the United States for surgical dressings, items, or equipment that were not provided or were improperly upcoded and therefore ineligible for payment.

84. As more fully alleged in the above paragraphs, Defendants made and used these false records and statements, and caused these false records and statements to be made and used, during the Relevant Time Period, and for which they sought and received reimbursement from Medicare

85. By virtue of the false records and statements that Defendants made and used, and caused to be made and used, the United States suffered damages and therefore is entitled to treble damages under the FCA, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

THIRD CAUSE OF ACTION
(Payment by Mistake)

86. The United States realleges and incorporates by this reference all preceding paragraphs of this complaint as if fully set forth herein.

87. This is a claim for the recovery of monies paid by the United States to Defendants as a result of mistaken understandings of fact.

88. The false claims that Defendants presented to the United States constituted misrepresentations of material facts in that they misrepresented whether surgical dressings, items, or equipment were in fact provided to patients and misrepresented the dressings, items, or equipment provided to patients.

89. The United States, acting in reasonable reliance on the accuracy and truthfulness of the information contained in the claims, paid Defendants certain sums of money to which they were not entitled and are thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

FOURTH CAUSE OF ACTION
(Unjust Enrichment)

90. The United States realleges and incorporates by this reference all preceding paragraphs of this complaint as if fully set forth herein.

91. This is a claim for the recovery of monies by which Defendants have been unjustly enriched.

92. By obtaining government funds to which they were not entitled, Defendants were unjustly enriched, and are liable to account for and pay for such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants as follows:

93. On the First Cause of Action under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

94. On the Second Cause of Action under the False Claims Act, for the amount of the United States damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

95. On the Third Cause of Action for payment by mistake, for the damages sustained or amounts by which Defendants were paid by mistake or by which Defendants retained illegally obtained monies, or all three, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

96. On the Fourth Cause of Action for unjust enrichment, for the damages sustained or amounts by which Defendants were unjustly enriched or by which Defendants retained illegally obtained monies, or all three, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

Maria Chapa Lopez
United States Attorney

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Certificate of Service

I hereby certify that on March 23, 2018, I electronically filed the foregoing United States' Complaint in Intervention with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all registered CM/ECF users.

/s/Jeremy Bloor
Jeremy R. Bloor