

Exhibit 8



March 27, 2020

VIA FEDEX - OVERNIGHT

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
Office of Counsel to the Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Cohen Building, Room 5527
Washington D.C. 20201

**Re: USC Care Medical Group, Inc.'s Voluntary Disclosure Regarding
Federal Healthcare Program Physician Claims For Intraoperative
Neurophysiological Monitoring Services**

Dear Ms. Gillin:

This office represents USC Care Medical Group, Inc. ("USC Care"), the medical faculty practice plan of the University of Southern California ("USC"), a California non-profit public benefit corporation, doing business as Keck Medicine of USC ("Keck Medicine of USC") concerning the matters addressed in this letter. We are writing on behalf of USC Care pursuant to the Office of Inspector General's ("OIG") Provider Self-Disclosure Protocol (April 17, 2013) ("OIG-SDP") to disclose a matter that USC Care has identified with respect to its federal healthcare program claims for Intraoperative Neurophysiological Monitoring ("IONM") professional physician services. We are also requesting acceptance of USC Care into the OIG's Voluntary Self-Disclosure Program with respect to this matter.

USC CARE'S VOLUNTARY DISCLOSURE

I. DESCRIPTION OF MATTER BEING DISCLOSED

Between approximately January 1, 2014 and July 1, 2019, USC Care incorrectly submitted approximately 2,457 claims by USC Care physicians for intraoperative neurophysiological monitoring services ("IONM Services") which were performed remotely in a manner that was not compliant with the requirements of HCPCS Code G0453 and CPT Code 95941. As a result, USC Care was overpaid approximately **\$168,628** by federal health care programs, consisting of Medicare, TRICARE, Medi-Cal (and out of state Medicaid), and California Children's Services, for these services. These codes require "real time" monitoring of patients during surgery. These IONM overpayments fall into two categories.

First, USC Care incorrectly billed IONM physician services provided during otolaryngology ("ENT") surgeries because the monitors in the ENT operating rooms lacked the

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 2

required technical capability to transmit the nervous system data in real time to the IONM physicians so that they could continuously monitor the patients' nervous system during such surgeries from their remote monitoring location (known as "the Control Room"). Since HCPCS Code G0453 and CPT Code 95941 both require such a real time data connection as a condition of payment, USC Care's IONM claims for these ENT surgeries were incorrect because no remote continuous monitoring was performed. This category involves approximately 307 claims for which USC Care was overpaid **\$89,223.19** by federal healthcare programs.

Second, USC Care also submitted incorrect claims for IONM physician services that were provided by a fellow on Mondays and Thursdays, but were billed by two IONM physicians who were not physically present in the Control Room to supervise the fellow or monitor the surgeries because they were taking an "academic research" day. Since the CMS-1500 claim forms required the provider of services to be accurately identified, USC Care's IONM claims were incorrect because the two IONM physicians identified as providers did not perform or supervise the billed monitoring services. This category involves approximately 1,575 claims to federal healthcare programs for which USC Care was overpaid **\$79,404.98**.

As further detailed below, USC Care's internal investigation and self-assessment has concluded that these incorrect IONM claims were caused by Andres A. Gonzalez, M.D., the IONM Program Chief, who supervised the staffing, medical oversight, and billing of the IONM program. For reasons that are not clear, Dr. Gonzales mistakenly concluded that HCPCS Code G0453 and CPT Code 95941 could be billed for ENT surgeries even if physicians were not monitoring the cases in "real time" because the proximity of the Control Room to operating rooms allowed the IONM physicians to immediately go to those rooms if there was an emergency during a surgery. Dr. Gonzalez was also responsible for scheduling his and another IONM physician's academic research days. He erroneously advised the IONM physicians that they could bill fellow's services as their own even though they were not physically present because the IONM physicians were remotely available to supervise the fellow upon request.

As a result of Dr. Gonzalez's handling of the IONM billing in these cases, his employment contract will not be renewed and his employment will end in June 2020. USC Care revised the IONM Program's policies and procedures to make clear that remote monitoring cannot be billed without a real-time data connection between the operating room and the Control Room. USC Care also clarified and re-educated the IONM physicians that a fellow's monitoring services cannot be billed by IONM physicians unless the physicians are physically present in the Control Room to supervise the fellow and the proper modifier is included in their billing information. Based on this remediation, USC Care is confident that these billing errors will not be repeated given their unusual and unique cause.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 3

While USC Care is in the process of refunding overpayments to federal health care programs for these IONM claims, and this process is now largely complete, this disclosure is being made in an abundance of caution because USC Care has concluded that these claims may potentially have violated the False Claims Act, 31 U.S.C. §§ 3729 - 3733 (“FCA”).

II. BASIC INFORMATION

A. Identification Of Disclosing Entity

In accordance with the OIG-SDP, USC Care provides the following “basic information” as part of its voluntary disclosure:

USC Care is a California non-profit public benefit corporation and the medical faculty practice plan for physicians who provide services to patients of Keck Medicine of USC, a multi-disciplinary university-based system of hospitals and outpatient facilities, including Keck Hospital of USC.¹

USC Care is located at 1520 San Pablo Street, Los Angeles, California 90033.

The name and address of USC Care’s designated legal representatives for purposes of this voluntary disclosure are:

Mark Hardiman
Jonathan Radke
Nelson Hardiman LLP
1100 Glendon Avenue, 14th Floor
Los Angeles, CA 90024
Tel: (310) 203-2800
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jradke@nelsonhardiman.com

B. Type Of Health Care Provider and Federal Programs Implicated

USC Care is a medical faculty practice group and is enrolled in the Medicare program as a physician practice organization. The group’s Medicare provider number is W18762, its Medi-

¹ USC is the sole corporate member of USC Care. As the faculty practice plan, USC Care has a contractual relationship with Keck Medicine of USC that allows USC’s faculty physicians to provide medical services at USC’s hospitals, as well as other hospitals not owned by USC, through USC Care.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 4

Cal provider number is GR0100430, and its NPI is 1902846306. The group's tax identification number is 95-4540991.

The federal health care programs implicated in this matter are Medicare, Medi-Cal/Medicaid, TRICARE, and California Children's Services (the "Federal Programs"). The federal government contractors involved are Noridian Healthcare Solutions LLC ("Noridian"), the Medicare Administrative Contractor ("MAC") for Jurisdiction E, and Health Net Federal Services, which administers the TRICARE program for the Western Region. California's Medi-Cal and Children's Services programs are administered through the California Department of Healthcare Services.

C. Pending Government Inquiry

On November 1, 2018, Keck Medicine of USC received an Investigative Subpoena for Documents (the "Subpoena") from the California Department of Insurance ("CDI"), a copy of which is enclosed as Exhibit A.² The CDI Subpoena requested communications, including "chat logs," between USC Care physicians who provided IONM professional services billed to commercial insurance companies in connection with CDI's investigation of whether Keck Hospital of USC and USC Care engaged in "billing for services not rendered" and "upcoding" in violation of California's Insurance Frauds Prevention Act, California Insurance Code § 1871.7. Keck Medicine of USC has produced documents in response to this state agency subpoena.

USC Care has not received any notice from any federal health care program or agency that Keck Medicine of USC is under investigation for IONM claims to any such program. However, in 2019, CDI requested and received Keck Medicine of USC's consent to share the documents produced in response to the CDI Subpoena with the U.S. Department of Justice, indicating that this agency may be investigating the IONM claims to federal health care programs.

III. USC CARE'S INVESTIGATION REPORT

Since 2006, Keck Medicine of USC's Intraoperative Neurophysiological Monitoring Program (the "IONM Program") has provided all aspects of surgical neurophysiology in order to reduce the risk of damaging the nervous system during surgery. IONM services involve, among other things, recording and assessing electrical potentials from the nervous system during surgical operations, allowing providers to detect deficits before they become permanent injuries following an operation. At Keck Medicine of USC, the IONM Program consists of

² The exhibits to this voluntary disclosure letter can be found on the enclosed thumb drive.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 5

intraoperative monitoring, brain mapping and brain implants, and provides services to approximately 1,800 patients annually through Keck Hospital of USC.

A. IONM Program And Physicians

Keck Medicine of USC's IONM Program is part of the Department of Neurology. During the relevant time period of 2014 through 2019, IONM Program attending physicians included Andres A. Gonzalez, M.D., the IONM Program Chief, Parastou Shilian, D.O., and Justin A. Cheongsiatmoy, M.D. In addition, between 2016 and 2019, the IONM Program also had two fellows – Dr. Jonathan Chen (July 2016 – June 2017) and Dr. John Parker (July 2017 – June 2019) – who provided IONM services.

A 1997 graduate of the Colombian School of Medicine, Dr. Gonzalez completed a research fellowship at Harvard University and a clinical fellowship at UCLA in neurophysiology before joining the USC faculty in 2006. Apart from being Chief of the IONM Program, he is also co-director of the Neurology Residency Program and an Assistant Professor of Neurology.

Dr. Shilian graduated from the Western University of Health Sciences College of Osteopathic Medicine of the Pacific in 2008 and is board certified in neurology and clinical neurophysiology. Following her neurology residency at LAC/USC Medical Center, she completed fellowships in clinical neurophysiology and intraoperative neurophysiological monitoring at USC. She joined the IONM Program in 2014. She is also an Assistant Professor of Neurology.

Dr. Cheongsiatmoy is a 2010 graduate of the David Geffen School of Medicine at UCLA and was credentialed as a billing physician for IONM services at USC on or about July 1, 2016. According to Dr. Gonzalez, Dr. Cheongsiatmoy was hired to expand the IONM Program and to provide additional IONM services for the program whose volume had grown too large for two physicians to handle.

Drs. Gonzalez, Shilian and Cheongsiatmoy provided and billed their IONM professional services through USC Care, the faculty practice plan.

B. IONM Services

The IONM Program's three attending physicians (Gonzalez, Shilian, and Cheongsiatmoy) and fellow typically monitored surgeries from a single room (the "Control Room") located one floor below the operating rooms in Keck Hospital of USC.

During the surgeries, the IONM Program physicians, including the fellow, monitored cases simultaneously on multiple monitors in the Control Room, with the fellow being

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 6

supervised by the physicians who were present that day. This process allowed the IONM physicians to collectively work together to make quick decisions in potentially life threatening situations with dramatic consequences, such as paralysis or death. In addition, if an IONM clinical issue arose during a surgery that required an IONM physician to focus on that specific case, this team approach ensured seamless monitoring and continuity of care because the other physicians were available to continue monitoring the other cases.

Except for Otolaryngology (“ENT”) surgery cases, the IONM software could be accessed remotely through nearly any device, including iPhones, iPads, and computers. Although monitoring could be performed at a location outside of Keck Hospital of USC, the general practice was for each physician to monitor and supervise the cases from the Control Room in the hospital during regular business hours. It was rare that an IONM physician monitored a case inside the operating room because the IONM Program allowed the IONM physicians to remotely monitor the multiple surgeries typically scheduled each day during overlapping time periods from the Control Room.

The IONM Program was very busy and often had numerous surgeries scheduled on the same day. According to Dr. Gonzalez, this presented significant staffing challenges for the IONM Program when monitoring was ordered for numerous overlapping surgeries because there were only four IONM physicians, including the fellow. In particular, the Medicare billing code for IONM services (HCPCS code G0453) requires exclusive monitoring of the surgery and does not permit a physician to bill monitoring for overlapping surgeries. Since Medicare beneficiaries made up a significant portion (30 to 50 percent) of the IONM cases, Medicare IONM services were often not billed because although monitored simultaneously with other surgeries (which is permissible and within the standard of care for payors other than Medicare), an IONM physician was not always available to exclusively monitor each Medicare IONM surgery.

C. Monitoring Of ENT Surgeries

Generally, the IONM equipment allowed for remote monitoring of all surgeries with one exception. ENT surgeries could not be remotely monitored because the IONM equipment that was used lacked that technical capability and could not provide a remote monitoring connection to the Control Room or to the monitoring physicians’ mobile devices. As a result, the IONM physicians did not monitor the ENT surgeries with a real time connection.

Rather, for ENT surgeries, IONM services were monitored by the ENT surgeons and IONM technicians³ inside the operating rooms. If needed, these surgeons and technicians

³ All of the IONM technicians were certified in Neurophysiological Intraoperative Monitoring or supervised by a licensed technician.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 7

communicated with the IONM physicians in the Control Room by text or phone call. In some cases, the technician would text or email a screen shot of the data to the IONM physician for review. For example, if the ENT surgeon stimulated a nerve, either accidentally or intentionally, the technician could measure and communicate the monitoring response via phone, text or email to the IONM physician in the Control Room who could review the data and discuss the response with the surgeon using the same methods. In addition, because the Control Room was near the operating rooms, an IONM physician was available to go to the operating room in an emergency or if requested to do so by the ENT surgeon or IONM technician. But to be clear, the IONM physicians did not have a “real time” connection to the ENT surgeries as required by Medicare rules. As a result, these services should not have been billed.

According to Dr. Gonzalez, although initially the IONM team tried to always have a physician in the operating room during an ENT surgery, the volume of surgery cases at Keck Hospital of USC ultimately did not allow for operating room monitoring of any case, including ENT cases. Nevertheless, Dr. Gonzalez incorrectly believed that the IONM physicians could bill for the ENT surgeries because they were “continuously involved with the case,” “responsible if anything happens” and immediately available in the nearby vicinity to respond.

D. IONM Physician “Academic Research” Days

As IONM Program Chief, Dr. Gonzalez set the weekly schedule of the IONM team for monitoring. As a general matter, all three IONM physicians and the fellow were present at Keck Hospital of USC providing monitoring services on Tuesdays, Wednesdays and Fridays. Only Drs. Gonzalez and Shilian worked on call over the weekends. On Mondays, Dr. Gonzalez took an “academic research” day and was not present in the Control Room. On Thursdays, Dr. Shilian was not present in the Control Room because this was her academic research day. These two physicians began taking academic research days in 2016 when the IONM Program brought on fellows.

Although Drs. Gonzalez and Shilian were not physically present or monitoring cases in the Control Room on their academic research days, they were immediately available for consultation via their mobile devices. In addition, the fellow was directly supervised by the attending physicians who were present on Mondays or Thursdays. As a result, Drs. Gonzalez and Shilian would only login to monitor a case remotely on their academic research day if requested by the fellow or one of the other physicians present in the Control Room.

The following chart depicts the precise weekly schedule of all IONM physicians:

Day	Physicians Present in IONM Control Room	Physicians Not Present in IONM Control Room
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Susan Gillin
 Chief of the Administrative & Civil Remedies Branch
 March 27, 2020
 Page 8

Monday	Dr. Cheongsiatmoy Dr. Shilian Fellow	Dr. Gonzalez took an academic research day and was generally not at the hospital but was available for consultation when needed and could remotely monitor on his mobile devices.
Tuesday	Dr. Cheongsiatmoy Dr. Gonzalez Dr. Shilian Fellow	
Wednesday	Dr. Cheongsiatmoy Dr. Gonzalez Dr. Shilian Fellow	
Thursday	Dr. Cheongsiatmoy Dr. Gonzalez Fellow	Dr. Shilian took an academic research day and was generally not present at the hospital but was available for consultation when needed and could remotely monitor on her mobile devices.
Friday	Dr. Cheongsiatmoy Dr. Gonzalez Dr. Shilian Fellow	
Saturday	Dr. Gonzalez (on call) Dr. Shilian (on call)	Dr. Cheongsiatmoy Fellow
Sunday	Dr. Gonzalez (on call) Dr. Shilian (on call)	Dr. Cheongsiatmoy Fellow

On each day of the business week (Monday through Friday), the three attending physicians would bill for IONM services, with one of the physicians assigned as the primary biller for that day, including services provided by the fellow.⁴ This billing division remained the

⁴ As an example of billing division between the IONM physicians, if there were ten total cases in a day, seven of which were private insurance cases, and three of which were Medicare cases (with two that overlapped in terms of timing), one physician (the person acting as the primary

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 9

same on Mondays and Thursdays even though either Dr. Gonzalez or Dr. Shilian was not present in the Control Room to supervise the fellow and provide continuous monitoring because they were taking an academic research day. As a result, certain Monday and Thursday claims for monitoring identified Dr. Gonzalez or Dr. Shilian as the rendering physician even though the services were provided by the fellow and supervised by other physicians in the Control Room.

Dr. Gonzalez believed that he and Dr. Shilian could bill for the monitoring of cases performed by the fellow on their academic research days because the fellow was supervised by at least one attending physician who was physically present on those days in the Control Room. In addition, Dr. Gonzalez and Dr. Shilian were still immediately available for consultation on their academic research days.

E. IONM Coding

The Medicare program covers IONM services as part of the physician fee schedule. *See* 77 Fed. Reg. 68892, 69069 (Nov. 16, 2012). Prior to 2013, Medicare paid for remote monitoring billed under American Medical Association's ("AMA") Current Procedural Terminology ("CPT") Code 95920, which was used for both in-person and remote monitoring. 78 Fed. Reg. 74230, 74305 (Dec. 10, 2013). However, in 2013, the CPT Editorial Panel deleted CPT Code 95920 and replaced it with two new codes, CPT Code 95940 for continuous intraoperative monitoring inside the operating room, and CPT Code 95941 for continuous remote intraoperative monitoring from outside the operating room. *Id.* Given these changes, Medicare created HCPCS Code G0453 to be used instead of CPT Code 95941 for remote monitoring, while maintaining its adoption of CPT Code 95940 for in-person monitoring.

Thus, since 2013, three time-based codes have been used for IONM services, distinguished primarily by payor, location of services, and type of monitoring service performed:

- HCPCS Code G0453 (Medicare and TRICARE): Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient), each 15 minutes.

billor for that day) would bill for the seven private pay cases, one physician would bill for the two Medicare cases that did not overlap, and one physician would bill for the last Medicare case. USC Care generally did not permit a fellow to bill for services. *See* USC Care, *Billing for Fellows Participating in Private Practice*, Standard B-407 (12/01/1997), available at <https://ooc.usc.edu/healthcare-compliance/usc-care-medical-group-compliance-standards/b-407-billing-fellows-participating-private-practice/>.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 10

- CPT Code 95941 (Medicaid and California Children's Services): Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour.
- CPT Code 95940 (Medicare, TRICARE, Medicaid and California Children's Services): Continuous intraoperative neurophysiology monitoring in the operating room, one-on-one monitoring requiring personal attendance, each 15 minutes.

HCPCS code G0453 allows continuous remote monitoring for Medicare and TRICARE patients, but specifically requires that "attention [be] directed exclusively to one patient." That is, code G0453 can be billed "only for undivided attention by the monitoring physician to a single beneficiary, not for monitoring of multiple beneficiaries simultaneously." 78 Fed. Reg. at 74305.⁵

CPT code 95941 similarly applies to continuous "real time" monitoring of Medicaid and California Children's Services surgeries, in which the "monitoring professional must be solely dedicated to performing the intraoperative neurophysiologic monitoring and must be available to intervene at all times during the service as necessary, for the reported time period(s)." *See* 2014 AMA CPT Coding Manual, pg. 403. However, in contrast to HCPCS code G0453, CPT code 95941 permits physician monitoring of "one or more simultaneous cases" so long as the physician has the immediate ability to transfer cases to another physician if one of the cases requires the physician's intervention. *Id.*

CPT code 95940 applies to Medicare, Medicaid, TRICARE and California Children's Services and requires exclusive and continuous monitoring by a physician inside the operating room. 2014 AMA CPT Manual, pg. 403. The physician must be physically present inside the operating room and providing one-on-one patient monitoring. *Id.* Thus, no other cases may be monitored during the same time period. *Id.*

According to Dr. Gonzalez, the IONM Program used primarily two of these time-based codes for their services: G0453 for Medicare and TRICARE cases and 95941 for all other cases, including Medi-Cal patients. CPT code 95940, which requires exclusive and continuous

⁵ Although CMS noted that some commenters opposed this Medicare one-on-one physician monitoring model, CMS decided that this requirement "precludes inaccurate payment in cases where multiple patients are being monitored simultaneously" and also prevents physicians from billing for "more than 60 minutes of work during a 60 minute time frame." 78 Fed. Reg. at 74305.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 11

monitoring by a physician inside the operating room, was rarely, if ever, used by the IONM group because their practice was premised on remote monitoring.

In addition, the IONM physicians also billed CPT base codes with a 26 modifier for the professional component (i.e., interpretation and report) of the type of neurophysiologic monitoring performed, including, most commonly, an electromyography (“EMG”),⁶ motor evoked potentials (“MEP”),⁷ or short-latency somatosensory evoked potentials (“SSEP”) study.⁸

F. USC Care Billing Of IONM Physician Professional Services

The only IONM claims to Federal Programs were submitted by USC Care for the IONM physicians’ professional services.⁹ Each IONM Program physician was responsible for providing supporting records and determining the appropriate codes for the professional service, including those applicable to Medicare and private payors. In addition, the IONM Program was responsible for ensuring that the billing complied with coverage conditions, including the Medicare prohibition on simultaneous monitoring of multiple beneficiaries.

IV. REASONS WHY USC CARE BELIEVES A VIOLATION OF THE FEDERAL FALSE CLAIMS ACT MAY HAVE OCCURRED

Under the FCA, the essential elements of civil liability for presenting false claims are (1) a false or fraudulent claim, (2) which was presented, or caused to be presented, by a person to the United States for payment or approval, (3) with knowledge that the claim was false. *See* 31 U.S.C. § 3729(a)(1)(A); *U.S. v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001). To satisfy the “knowledge” requirement, there must be evidence that the person (1) had actual knowledge of the information; (2) acted in deliberate ignorance of the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b). No proof of specific intent to defraud is required to establish knowledge under the FCA. *Id.*

⁶ CPT code 95860, 95861, 95863, 95864, 95865, or 95870.

⁷ CPT code 95929, 95930, or 95939.

⁸ CPT code 95925, 95926, or 95938.

⁹ Under Medicare, Keck Hospital of USC is reimbursed for the technical component (“TC”) of the CPT base codes through the Medicare Severity-Diagnosis Related Group (“MS-DRG”) assigned to the surgery patient’s hospital stay. Medicare does not permit Keck Hospital of USC to separately bill the TC of HCPCS code G0453. The hospital also does not bill the technical component of CPT Code 95941 to Medi-Cal or any other Federal Program.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 12

A. USC Care's Claims For IONM Services That Were Not Provided During ENT Surgeries

Based on USC Care's review of applicable coverage rules, it has concluded that its claims for IONM professional physician services during ENT surgeries should not have been billed to Federal Programs because the IONM physicians did not continuously monitor the ENT surgeries. In particular, because the software used by the ENT surgeons did not allow for a remote "real time" connection, the IONM physicians were unable to continuously monitor ENT surgeries, which were instead monitored by the ENT surgeons and the IONM technicians who relayed information to the IONM Program physicians via text messages and/or telephone calls. Although the IONM physicians were located in the Control Room, continuously involved in each ENT case, and immediately available to discuss the cases in person if necessary, they were not "continuously" monitoring by way of an electronic "real time" connection the ENT cases that were billed to Federal Programs within the meaning of either HCPCS Code G0453 or CPT Code 95941. For the same reasons, USC Care does not believe that the IONM physicians could properly bill for the professional component of the monitoring modality used (e.g., EMG, SSEP or MEP) in ENT surgery cases.

USC Care does not believe that Dr. Gonzalez had a specific intent to defraud Federal Programs. First, Dr. Gonzalez was entirely candid during USC Care's internal investigation and brought the issue of IONM billing for ENT surgeries to USC Care's attention. Second, Dr. Gonzalez appeared to have a genuine (albeit mistaken) belief that the IONM Program could bill remote monitoring without a "real-time" data connection because the Control Room was located "nearby" in the same building as the operating rooms.¹⁰ Third, Dr. Gonzalez sought to ensure

¹⁰ Dr. Gonzalez's belief was based on the fact that both HCPCS code G0453 and CPT code 95941 require "continuous" monitoring, but neither the AMA nor Medicare define the coding terms "remote" and "nearby" as they relate to the standards for supervision. Because the term "nearby" is described separately from the term "remote," Dr. Gonzalez believed that the term "nearby" refers to the direct supervision model that some providers used prior to 2013 in accordance with CPT code 95920. Under that model, continuous monitoring could arguably include a provider who was in the vicinity and available to respond. However, USC Care found no controlling authority to support this interpretation as it relates to HCPCS code G0453 and CPT code 95941. Given that the services also require a "real time connection" and a professional who is performing the monitoring, USC Care concluded that the proper interpretation is that the terms "remote" or "nearby" simply refer to the proximity of the location where the "continuous" monitoring takes place in relation to the operating rooms. That is, monitoring that is performed outside of the operating rooms can be "nearby" in Keck Hospital of USC or be "remote" if off site. This interpretation was confirmed by USC billing consultants and Marc Nuwer, M.D., the

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 13

that the IONM Program physicians were actively involved in monitoring of ENT surgeries despite the lack of a remote data connection by requiring the IONM technicians to provide periodic updates to the IONM physicians who were immediately available to consult via mobile devices if any clinical issues came up. In Dr. Gonzalez's view, this process was essentially equivalent to a "real time" connection, particularly as it related to patient safety issues. Finally, Dr. Gonzalez enforced HCPCS code G0453's requirement of exclusive monitoring for Medicare surgery cases when such compliance resulted in the IONM physicians' provision of substantial monitoring services that were free and could not be billed. His enforcement of Medicare billing rules under these circumstances appears inconsistent with an intent to defraud the program.

Nevertheless, USC Care believes that Dr. Gonzalez's enforcement of the "continuous" remote monitoring billing requirements (including the existence of a real-time remote connection) for all other surgeries could arguably support a finding that he acted in reckless disregard of whether the IONM Program's billing of HCPCS code G0453 and CPT code 95941 for monitoring of ENT surgeries was correct. The fact that Dr. Gonzalez initially tried to always have an IONM Program physician in the operating room during ENT surgeries, but had insufficient physicians to permit such operating room monitoring, also indicates that he was not sure that his justification for billing IONM Program monitoring services for these surgeries was correct.

B. USC Care's Claims For IONM Services That Were Not Provided By The Billing Physicians On Their Academic Research Days

USC Care has also concluded that its IONM claims for Drs. Gonzalez's and Shilian's professional physician services on their "academic research" days should not have been billed to Federal Programs because these physicians did not personally provide such services. Specifically, Drs. Gonzalez and Shilian each took an academic research day on Mondays and Thursdays, respectively, and were not present in the Control Room to supervise the fellow who performed the monitoring services. The two physicians then incorrectly billed monitoring services on their academic research days without indicating that they were supervising the fellow and not personally providing the "continuous" monitoring services being billed under their provider numbers.

Again, USC Care does not believe that Dr. Gonzalez, who was responsible as Chief of the IONM Program for the decision to bill his and Dr. Shilian's IONM professional monitoring

Director of the Clinical Neurophysiology Program at UCLA, who was contacted after Dr. Gonzalez identified him as a local IONM expert on this issue.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 14

services on their academic research days, had a specific intent to defraud Federal Programs. In particular, the billed monitoring services were in fact provided by the fellow, who was supervised by the other attending physicians who were present in the Control Room on Mondays and Thursdays. In addition, Dr. Gonzalez appeared to sincerely believe, although mistakenly, that he and Dr. Shilian could bill for the fellow's monitoring services under their general supervision (i.e., while not physically present in the Control Room, they were immediately available to remotely consult with the fellow by mobile devices).¹¹

However, USC Care has concluded that Dr. Gonzalez's incorrect authorization of billing by Dr. Shilian and himself on their academic research days could again potentially support a finding that he was acting in reckless disregard of applicable billing rules. In particular, Dr. Gonzalez arguably should have known that the billing of IONM services on their academic research days could not be justified as remote supervision of the fellow when other attending physicians were in the Control Room to supervise on the days that he and Dr. Shilian were physically absent.

V. USC CARE'S RESPONSE TO ITS INCORRECT BILLING OF IONM PROFESSIONAL PHYSICIAN SERVICES

In August 2018, USC Care opened an investigation of the IONM Program's billing practices after Dr. Cheongsiatmoy, the newest IONM Program physician at the time,¹² complained to both Dr. Gonzalez and Helena Chui, M.D., the Chair of the Department of Neurology, that the program was engaged in "fraud," including billing for monitoring services not performed.¹³

¹¹ Medicare does allow a teaching physician to bill for services furnished by a fellow when the supervising physician is present during the "critical" or "key" portions of the service. *See* 42 C.F.R. §§ 415.170, 415.172; Medicare Claims Processing Manual, Publication 100-04, Chapter 12, Section 100. However, Dr. Gonzalez's and Dr. Shilian's claims on their academic research days did not include the required "GC modifier" and they were not present in the Control Room to personally supervise any aspect of the fellow's monitoring services. Instead, actual supervision of the fellow on their academic research days was provided by other attending physicians.

¹² According to Dr. Gonzalez, Dr. Cheongsiatmoy's two-year income guarantee ended in June 2018 and his subsequent request to be paid the same amount as Dr. Gonzalez and Dr. Shilian under USC's faculty plan was denied.

¹³ Nelson Hardiman, LLP was retained to assist the investigation after Keck Medicine received the CDI Subpoena (described above) in November 2018.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 15

A. The Internal Investigation

As part of USC Care's investigation, interviews were conducted of Dr. Gonzalez, Dr. Shilian, Dr. Chui, and Grace Barba, the manager of USC Care's billing department. In addition, USC Care interviewed Lynn Chu, a billing and compliance expert employed by Compliance Concepts, Inc., an outside consultant that had conducted prior audits and training sessions for the IONM Program physicians. USC Care also spoke with Dr. Nuwer, the Director of UCLA's Clinical Neurophysiology Program, about the proper interpretation of HCPCS code G0453 and CPT code 95941.¹⁴

In addition, USC Care reviewed the IONM Program's policies and procedures, the IONM Program physicians' documentation of monitoring services (including billing information), and examples of USC Care claims for IONM professional physician services.

As detailed above, USC Care's investigation found that its claims for IONM professional physician services should not have been submitted for (a) ENT surgeries because no continuous remote monitoring was provided and (b) Dr. Gonzalez's and Dr. Shilian's services on academic research days when they did not perform the services nor supervise the performing fellow. USC Care found that Dr. Cheongsiatmoy's other allegations about inadequate documentation and improper group billing by the IONM Program were not substantiated.

B. USC Care's Remediation Of Its IONM Billing Errors

Based on its investigation findings of billing errors, USC Care identified (a) all claims submitted by USC Care between January 1, 2014 and July 1, 2019 to Medicare and any other Federal Program for IONM professional physician services (HCPCS code G0453 and CPT code 95941) of ENT surgeries, as well as for the professional component of the monitoring modality used (e.g., EMG, SSEP or MEP) for such surgeries, and (b) all claims submitted by USC Care between 2016 and August 2018 to Medicare and any other Federal Program for IONM services by Drs. Gonzalez and Shilian on their academic research days.

¹⁴ A list of witnesses and their contact information is attached as Appendix A. Please note that these witnesses may be contacted through the University's outside legal counsel, Mark Hardiman and Jonathan Radke.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 16

USC Care then directed that any USC Care overpayments received from Medicare and other Federal Programs for these two categories of incorrect claims be refunded.¹⁵ USC Care's refund of these overpayments included all Federal Program, secondary payer and patient payments. The overpayment and refund amounts are further detailed in the next section regarding USC Care's estimate of damages in this matter. This refund process is ongoing but has largely been completed.

USC Care also instituted a bill hold and prohibited IONM physicians from billing IONM physician services unless real time monitoring was provided with the appropriate monitor. Likewise, the IONM physicians were directed not to bill for fellow services unless they are physically present in the Control Room to supervise the fellow and the proper modifier is included in their billing information. The IONM Program's policies and procedures have been revised to reflect these new directives.¹⁶ In addition, IONM physicians were provided mandatory training regarding IONM billing requirements in March 2019 by Compliance Concepts, Inc., the outside billing consultant that had conducted prior audits and training sessions for the IONM physicians.

Finally, USC Care has informed Dr. Gonzalez that his employment contract as a USC physician and faculty member will not be renewed when it expires in June 2020 based on USC Care's assessment that he was the individual primarily responsible for USC Care's substantial billing errors and overpayments because he incorrectly authorized the IONM physician claims for ENT surgeries and academic research days as Chief of the IONM Program. USC Care has not disciplined Dr. Shilian based on its conclusion that she followed Dr. Gonzalez's directions and accepted his billing justifications in good faith given his position as the IONM Program Chief and his role as her mentor, including during her fellowship with the program.

VI. USC CARE'S ESTIMATE OF DAMAGES RESULTING FROM ITS INCORRECT IONM CLAIMS

Between January 1, 2014 and July 1, 2019, USC Care submitted 307 claims to Federal Programs for IONM monitoring of ENT surgeries when there was no real time remote connection that allowed these cases to be continuously monitored by the IONM physicians at

¹⁵ USC Care has also refunded overpayments made by commercial insurers on IONM claims involving ENT surgeries.

¹⁶ See USC Care, *Documentation and Coding Guidelines for Intraoperative Neurophysiology Monitoring (IONM)*, Standard DC-326 (10/01/2019), available at <https://ooc.usc.edu/healthcare-compliance/usc-care-medical-group-compliance-standards/documentation-and-coding-guidelines-for-ionm/>.

Susan Gillin
 Chief of the Administrative & Civil Remedies Branch
 March 27, 2020
 Page 17

Keck Hospital of USC. Based on these USC Care claims, USC Care's estimate of single damages relating to the monitoring of ENT surgeries is **\$89,223.19**. These overpayments and resulting refunds are broken out by Federal Program as follows:

Federal Program	Overpayment & Refund
Medicare Part B (Noridian)	\$ 65,897.73
Gold Coast Health Plan	\$ 8,261.91
Department of Health Care Services MS-1101	\$ 4,795.62
TRICARE	\$ 2,618.10
Kern Health Systems	\$ 1,985.86
Anthem Blue Cross Medi-Cal	\$ 1,458.35
WPS Tricare for Life	\$ 631.91
Southland San Gabriel Valley Me Medi-Cal	\$ 348.84
La Care Healthcare	\$ 303.45
Omnicare Medical Group Medi-Cal HMO	\$ 301.87
Healthnet Medi-Cal	\$ 283.68
Dept Of Public Health & Social Services	\$ 283.20
Pacific IPA Pipa Medi-Cal	\$ 264.45
Medicaid Out of State Health Plans of Nevada	\$ 223.20
United Healthcare Medicare Advantage PPO	\$ 209.98
Caremore Medicare Advantage	\$ 177.80
Altamed Health Services Medi-Cal	\$ 168.78
Anthem Blue Cross Medicare Advantage PPO	\$ 144.95
Prospect Medical Systems Medi-Cal HMO	\$ 138.95
Lakeside Medical Group Medi-Cal	\$ 127.96
Global Care Medical Group Medi-Cal HMO	\$ 84.41
California Health & Wellness	\$ 75.41
Exceptional Care Medi-Cal HMO	\$ 64.31
Healthcare La Medi-Cal HMO	\$ 64.31
South Atlantic Medical Group Medi-Cal HMO	\$ 64.31
Aetna Medicare Advantage PPO	\$ 55.79
Altamed Health Services Medicare Advantage	\$ 51.04
Easy Choice Health Plan Medicare Advantage	\$ 44.76
CalOptima Medi-Cal	\$ 37.63
Accountable Healthcare IPA	\$ 28.71

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 18

Federal Program	Overpayment & Refund
Medicare Secondary	\$ 25.92
Total:	\$89,223.19

USC Care is still identifying whether Federal Programs were payors for 114 claims totaling \$11,611.79 submitted to 13 plans¹⁷ which require a manual review of the underlying claim documentation to determine whether the payor was a Federal Program versus a commercial plan.

On June 30, 2018, USC Care submitted approximately 1,575 claims to Medicare that identified Dr. Gonzalez or Dr. Shilian as the rendering provider of IONM services provided on Mondays and Thursdays when neither physician was present at the hospital and supervising the IONM fellow who monitored the surgeries. USC Care's estimate of single damages to the Medicare program relating to these services is **\$79,404.98**.¹⁸ USC Care is still in the process of identifying any overpayments from other Federal Programs relating to this category of claims.

USC Care expects to supplement this disclosure with the additional information described above regarding any additional Federal Program overpayments in the next few weeks, although they expect that the amount of any such overpayments will be low.

Spreadsheets detailing the IONM claim overpayment amounts for ENT surgeries and the refunds that have been processed are enclosed as Exhibits B and C, respectively.¹⁹ Similar spreadsheets detailing the Medicare overpayments and refunds for IONM academic research days are enclosed as Exhibits D and E, respectively.

¹⁷ The 13 payors being checked manually are Preferred IPA, Health Plans of Nevada, HealthCare LA IPA, Coastal Communities IPA, Axminster Medical Group, Choice Care Network, Santa Barbara Medical Foundation, Torrance Hospital IPA, LA Care Health Plan – Direct Referrals, Physician's Healthways IPA, Coventry Health Care, Non Contract Medical Group IPA, and DHS Managed Care systems.

¹⁸ This overpayment amount includes reimbursement received for Dr. Gonzalez's Monday claims (\$44,566) and Dr. Shillian's Thursday claims (\$34,839) for IONM monitoring services.

¹⁹ Note that Exhibit C reflects total refunds of \$84,815.41 for monitoring of ENT surgeries which is lower than Exhibit B's total overpayment amount of \$89,223.19 for this category of claims. The difference of \$4,407.78. consists of refunds that were previously made on the IONM claims for miscellaneous reasons unrelated to the billing issue regarding ENT surgeries being disclosed.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 19

VII. USC CARE'S SELF-ASSESSMENT

USC Care is subject to a robust compliance program as a part of the Keck Medicine of USC health system.²⁰ While USC Care's incorrect IONM claims relating to ENT surgeries and academic research days were not discovered by the regular audits of the IONM physicians' billings and their supporting documentation, USC Care's root cause analysis indicates that this was not due to compliance program weaknesses, but because the billing errors were largely the result of Dr. Gonzalez's mistaken direction of the IONM Program and, by their unique nature, were unlikely to be detected by the Compliance Program's standard and industry-accepted compliance monitoring tools.

A. Keck Medicine of USC's Compliance Program

The foundation for Keck Medicine of USC's Compliance Program is the Department of Health and Human Services, Office of the Inspector General's (OIG) Model Compliance Program Guidance for Hospitals (February 1998) and its additional supplemental guidance (January 2005). Based on this guidance, USC's Compliance Program has a compliance plan based on the following elements:

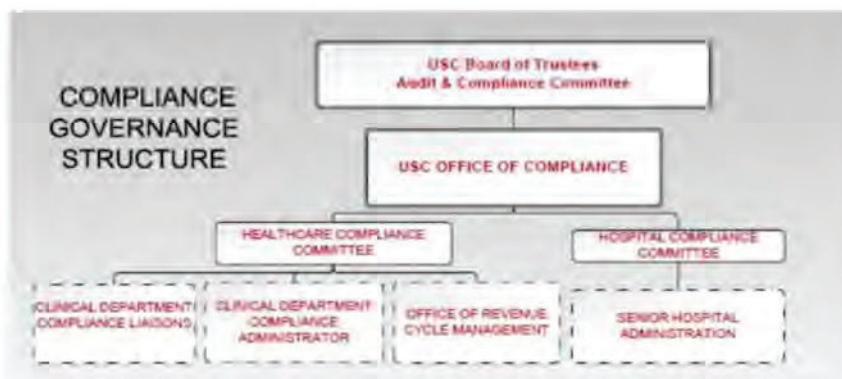
- Commitment and support from executive leaders;
- Institutional policies, standards and expectations;
- Education and outreach efforts to ensure that workforce members understand their roles and responsibilities;
- Monitoring and auditing activities to ensure the effectiveness of internal controls;
- On- going assessments and proactive responses to emerging risks and regulatory developments;
- Safe mechanisms for reporting compliance concerns, including a Help Hotline that supports anonymous reporting;
- Timely investigations of reported concerns and protection of complainants from retaliation;
- Appropriate sanctions and corrective actions to address non- compliance when it occurs;
- Process improvement projects as needed to enhance compliance efforts; and

²⁰ As noted earlier in this letter, Keck Medicine of USC is a multi-disciplinary university-based system of hospitals and outpatient facilities, including Keck Hospital of USC and USC Care.

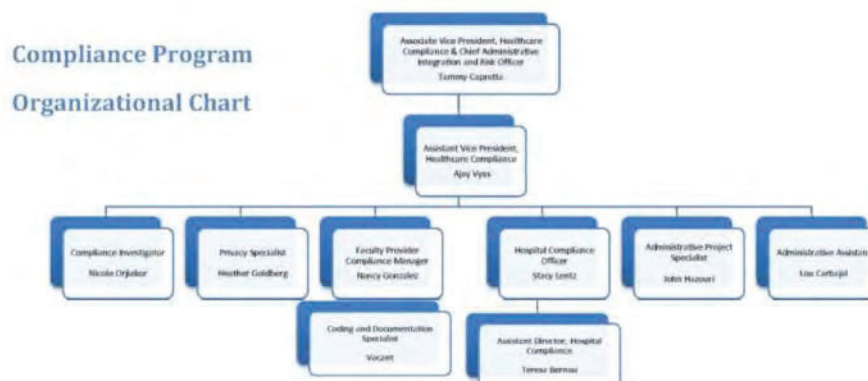
Susan Gillin
 Chief of the Administrative & Civil Remedies Branch
 March 27, 2020
 Page 20

- Evaluations of program effectiveness and annual reporting.²¹

Oversight for the Compliance Program is provided through a governance structure which flows from senior Keck Medicine of USC leadership and each clinical department up through two compliance committees, the USC Office of Compliance and to the Audit & Compliance Committee of the USC Board of Trustees:



Day- to- day responsibilities for the Compliance Program rest with the Associate Senior Vice President, Compliance, USC Office of Compliance, through Keck Medicine of USC's Chief Administrative Integration and Risk Officer to the Deputy Healthcare Compliance Officer and staff:



²¹ A full description of USC's Compliance and Ethics Program is available at: <http://ooc.usc.edu/sites/ooc.usc.edu/files/pdfs/USC-Compliance-Plan.pdf>.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 21

With respect to USC Care, the Compliance Program also has a specific Faculty Provider Compliance Program, the cornerstones of which are (a) an Office of Compliance monitoring program, guided by Keck Medicine of USC's data analytics²² and government- identified risk areas, which conducts regular reviews of USC Care established physicians' procedural and diagnosis code assignments, medical record supporting documentation and code abstractions every other year prior to their re- credentialing date, as well as focused reviews of provider risk areas; (b) education of USC Care physicians, including a mandatory compliance orientation for all new physicians regarding use of CMS guidelines for documentation, coding and billing, as well as mandatory annual compliance refresher training, online compliance modules for physicians that need to be completed annually and at the time of recredentialing, and yearly compliance education for each University department; and (c) structured reporting of USC Care physician monitoring results, key initiatives, new policies or revisions, and compliance workplan items to Keck Medicine of USC's Quarterly Healthcare Compliance Committee (consisting of the physician liaison and administrator for each department) and at the department- specific physician liaison meetings.²³

The Office of Compliance shares the monitoring results with the specific USC Care physician and his or her department representative. USC Care physicians who do not successfully complete a monitoring round are subject to education requirements and a re- audit. USC Care Physicians who fail three rounds of monitoring are placed on concurrent review status with a compliance bill hold in the centralized billing system. Supplemental monitoring is also

²² Since 2014, Keck Medicine of USC has used REVEAL/md, a predictive analytic software that quickly identifies audit risk exposure for physicians' coding based on the physician's specialty and CMS's national billing averages and mimics the same statistical methodology used by auditors to compare each physician against known risk indicators. Monthly billing activity for USC Care is uploaded into REVEAL/md which then provides a monthly snapshot of physicians, E/M codes, modifier usage and departments or specialties that may potentially pose an audit risk based on CMS's national billing averages.

²³ The department- specific physician liaison meetings are also held on a quarterly basis and include the USC Care physician liaison for the department, the department administrator, the Office of Revenue Cycle Management director, the coding director, the billing manager, the faculty provider compliance manager and a coding/documentation specialist from the Office of Compliance. There is a standing agenda for these meetings consisting of credit balances, missing charges, monitoring results with required charge corrections and/or refunds, Medicare denials for coding and compliance reasons, and any other topics relating to the department.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 22

conducted for established USC Care physicians who fail their first round of monitoring or who are identified as needing such monitoring by the Office of Compliance.²⁴

B. USC Care's Root Cause Analysis Of Its Incorrect IONM Billing

USC Care's root cause analysis indicates that the primary cause of its incorrect IONM claims relating to ENT surgeries and academic research days was Dr. Gonzalez's mistaken direction of the IONM Program with respect to these billings. As Program Chief, he directed that IONM monitoring be billed for ENT surgeries and that claims be submitted under his and Dr. Shilian's provider numbers on academic research days that he scheduled after Dr. Parker was hired as a fellow. He also incorrectly assured other IONM physicians, most notably Dr. Shilian, that his misinterpretations of the IONM billing rules were correct. While he appeared to genuinely believe that billing remote monitoring for ENT surgeries without a remote data connection was permissible because IONM physicians were nearby and that he and Dr. Shilian could bill for a fellow's monitoring services on their academic research days as supervising physicians, these justifications were incorrect interpretations of the applicable billing codes. In addition, his rationalizations were undermined by the IONM Program's use of remote data connections to monitor all other surgeries and by other physicians being present in the Control Room to supervise the fellow on the academic research days. In USC Care's view, Dr. Gonzalez's mistakes were a serious misjudgment and reflected a leadership failure on the critical compliance issue of correct billing.

Secondarily, USC Care believes that Dr. Gonzalez's judgment was likely clouded by the IONM Program's heavy utilization, including the frequent monitoring of Medicare surgeries which could not be billed by the IONM physicians because of HCPCS code G0453's prohibition on simultaneous monitoring of multiple Medicare cases. However, if Dr. Gonzalez had a concern that the IONM Program was overburdened, he should have requested more resources. In USC Care's view, the fact that the IONM Program was very busy does not reasonably explain or excuse Dr. Gonzalez's ill advised billing decisions.

Unfortunately, the unique nature of these billing errors also made them unlikely to be detected by the USC Compliance Office's regular monitoring of billing by USC Care physicians, including IONM Program physicians. With respect to ENT surgeries, the lack of a real time data connection on the monitors being used by the physicians was not reflected on the claims or

²⁴ More detailed information about Keck Medicine of USC's Compliance Program can be found in the Office of Compliance's "Healthcare Compliance Executive Program Summary" and "Faculty Provider Compliance Program Overview," enclosed as Exhibits F and G, respectively.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 23

IONM physician documentation of the monitoring services, which relied significantly on the monitoring technician's report of the data produced by the monitor but not actually transmitted to the Control Room. Similarly, without knowledge of the academic research days, the Compliance Office's monitoring of claims submitted under Dr. Gonzalez's or Dr. Shillian's provider numbers, including the review of supporting documentation, did not reveal that they were not present in the Control Room to supervise the fellow's services. For example, during the relevant time period, Compliance Concepts, Inc., a University compliance consultant, conducted regular reviews of IONM Program billing and documentation, but did not discover either billing error. Instead, USC Care first learned that the ENT surgery monitors had no real time data connection when Dr. Gonzalez candidly brought up the issue during its investigation and likewise only discovered the billing on academic research days when Dr. Cheongsiatmoy complained about the practice. Neither of these billing errors are of a type that would be identified by accepted compliance monitoring tools, including regular reviews of claims and supporting documentation. As a result, USC Care does not believe that discovery of its incorrect IONM claims was delayed by any weaknesses in Keck Medicine of USC's otherwise comprehensive and robust compliance monitoring program.

Finally, USC Care does not believe that these unique and somewhat unusual IONM billing errors are systemic or likely to be repeated in the future. In particular, USC Care has eliminated both of the incorrect billing practices relating to ENT surgeries and academic research days. In addition, as previously noted, USC Care has informed Dr. Gonzalez that his faculty appointment will not be renewed when it expires in June 2020²⁵ because of its loss of confidence in his leadership as a result of the significant billing errors that he expressly authorized and which resulted in unacceptable overpayments by Medicare and other Federal Programs.²⁶ With his departure, USC Care is confident that the same or similar billing errors are unlikely to occur.

VIII. CERTIFICATION AND SETTLEMENT AUTHORITY

²⁵ The four-month delay before Dr. Gonzalez departs is necessary for USC Care to find a new and qualified physician to replace him as Chief of the IONM Program without disrupting the continuity of the program's high quality and critical remote monitoring services for Keck Medicine of USC's surgery patients.

²⁶ Holding Dr. Gonzalez accountable is consistent with Keck Medicine of USC's Compliance Program which emphasizes holding leaders and managers responsible for understanding and adhering to relevant policies and procedures, seeking clarification when questions arise, and effectively monitoring compliance within their respective areas of oversight.

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 24

A certification by Thomas Jackiewicz, Senior Vice President and Chief Executive Officer for Keck Medicine of USC, concerning the truthfulness of the information contained in this voluntary disclosure letter, investigation report, and self-assessment, is attached at the end of this letter. Mr. Jackiewicz is also authorized to enter into a settlement agreement on behalf of USC Care.

IX. CONCLUSION

Based on the foregoing, USC Care requests that it be accepted in the OIG's voluntary disclosure program with respect to its incorrect IONM claims because it is committed to complying with all applicable laws and regulations, and cooperating with the government to refund any federal healthcare program overpayments that it may have received.

We look forward to working with the OIG to complete this voluntary disclosure process in a comprehensive and satisfactory manner.

Should you have any questions or require additional information, please call Mark Hardiman or Jonathan Radke at (310) 203-2800 or email them at mhardiman@nelsonhardiman.com and jradke@nelsonhardiman.com.

Sincerely,

NELSON HARDIMAN, LLP

M.S. Hardiman

By: Mark Hardiman

Enclosure - Thumb Drive

Susan Gillin
Chief of the Administrative & Civil Remedies Branch
March 27, 2020
Page 25

CERTIFICATION

On behalf of USC Care Medical Group, Inc., I hereby certify that, to the best of my knowledge, the foregoing voluntary disclosure letter, investigation report, and self-assessment contains truthful information and is based on a good faith effort to bring the matter to the government's attention for the purpose of resolving any potential liabilities to the government.

Thomas Jackiewicz
Thomas Jackiewicz (Mar 27, 2020)

Thomas Jackiewicz
Chief Executive Officer, Keck Medicine of USC
Senior Vice President, USC