Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CEDARS-SINAI MEDICAL CENTER: AUDIT OF MEDICARE PAYMENTS FOR BARIATRIC SURGERIES

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Amy J. Frontz
Deputy Inspector General
for Audit Services

October 2020
A-09-18-03010

Office of Inspector General

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Report in Brief
Date: October 2020
Report No. A-09-18-03010

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Cedars-Sinai Medical Center: Audit of Medicare Payments for Bariatric Surgeries

Why OIG Did This Audit

Medicare paid hospitals $372 million for bariatric surgeries provided to Medicare beneficiaries in calendar years 2015 and 2016. Bariatric surgery helps those with morbid obesity to lose weight by making changes to their digestive system. Although OIG has not conducted an audit in this area, the Centers for Medicare & Medicaid Services' (CMS's) study of certain bariatric surgery procedure codes found that 98 percent of improper payments lacked sufficient documentation to support the procedures. After analyzing Medicare claim data for bariatric surgery claims with dates of service from January 2015 through December 2016 (audit period), we selected for audit Cedars-Sinai Medical Center (Cedars-Sinai), located in Los Angeles, California.

Our objective was to determine whether Cedars-Sinai complied with Medicare requirements and the Medicare contractor's local coverage determinations (LCDs) and local coverage article (LCA) when billing for bariatric surgeries.

How OIG Did This Audit

Our audit covered $1.3 million in Medicare payments to Cedars-Sinai for 62 bariatric surgery claims. We reviewed the beneficiaries' medical records to determine whether the claims met Medicare requirements and the specifications in Noridian Healthcare Solutions, LLC's (Noridian's) LCDs and LCA for bariatric surgery. An independent medical review contractor reviewed the medical records for 23 claims.

What OIG Found

Cedars-Sinai did not fully comply with Medicare requirements and the Medicare contractor's LCDs and LCA when billing for bariatric surgeries. For 37 of the 62 claims we reviewed, Cedars-Sinai complied with Medicare requirements and the specifications in Noridian's LCDs and LCA for documenting previously unsuccessful medical treatment for obesity. However, for the remaining 25 claims, Cedars-Sinai did not comply with Noridian's specifications. Specifically, Cedars-Sinai did not provide adequate documentation of the beneficiaries' multidisciplinary medical evaluations or participation in a weight management program. Cedars-Sinai did not comply with the specifications in the LCDs for 12 claims, with payments totaling $154,074, and did not comply with the specifications in the LCA for 13 claims, with payments totaling $175,199. As of the publication of this report, these payments include claims outside of the 4-year reopening period.

What OIG Recommends and Cedars-Sinai Comments

We recommend that Cedars-Sinai: (1) refund to Medicare the portion of the $154,074 in overpayments for bariatric surgery claims that did not comply with the specifications in the LCDs and that are within the 4-year reopening period; (2) based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; (3) work with Noridian to take action deemed necessary by CMS or Noridian, or both, regarding $175,199 in payments for bariatric surgery claims with dates of service on or after the effective date of the LCA; (4) update its patient checklist to include all of Noridian's specifications for billing bariatric surgeries; and (5) obtain supporting medical record documentation from other providers, such as primary care physicians, mental health providers, or dietitians, before performing any future bariatric surgeries.

Cedars-Sinai partially agreed with our first and third recommendations and agreed with our second, fourth, and fifth recommendations. Regarding our first and third recommendations, Cedars-Sinai disagreed with our finding for one claim that did not comply with the specifications in the applicable LCD and our findings for two claims that did not comply with the specifications in the LCA. Cedars-Sinai provided information on actions that it had taken or planned to take to address our recommendations.

We maintain that our findings and recommendations remain valid. For all 25 noncompliant claims (including the 3 claims for which Cedars-Sinai disagreed with our findings), either OIG or the independent medical review contractor found that the information in the beneficiaries' medical records did not support the eligibility specifications for bariatric surgery.

The full report can be found at https://oig.hhs.gov/oas/reports/region9/91803010.asp.

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INTRODUCTION

WHY WE DID THIS AUDIT

Medicare paid hospitals approximately $372 million for inpatient and outpatient bariatric surgeries provided to Medicare beneficiaries nationwide in calendar years 2015 and 2016. Bariatric surgery helps those with morbid obesity to lose weight by making changes to their digestive system, such as reducing the size of the stomach with a gastric band. Although the Office of Inspector General (OIG) has not conducted an audit in this area, the Centers for Medicare & Medicaid Services' (CMS's) Comprehensive Error Rate Testing program's special study[1] of certain procedure codes for bariatric surgical procedures found that approximately 98 percent of improper payments lacked sufficient documentation to support the procedures.

After analyzing Medicare claim data for bariatric surgery claims with dates of service from January 1, 2015, through December 31, 2016 (audit period), we selected for audit Cedars-Sinai Medical Center (Cedars-Sinai), located in Los Angeles, California. Our analysis indicated that Cedars-Sinai was among the top 10 hospitals nationwide based on Medicare payments for bariatric surgeries and was the hospital that had the highest average Medicare payment for those surgeries in California.

OBJECTIVE

Our objective was to determine whether Cedars-Sinai complied with Medicare requirements and the Medicare contractor's local coverage determinations (LCDs) and local coverage article (LCA) when billing for bariatric surgeries.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the program. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services.

CMS contracts with Medicare administrative contractors (MACs) to, among other things, process and pay claims and conduct reviews and audits for a defined geographic area, or jurisdiction. During our audit period, Noridian Healthcare Solutions, LLC (Noridian), was the MAC that processed and paid Cedars-Sinai's Medicare claims.

[1] CMS Medicare Learning Network's *Medicare Quarterly Provider Compliance Newsletter: Guidance to Address Billing Errors*, volume 4, issue 4, July 2014.

Medicare Payment Requirements

Medicare Part A pays inpatient hospital costs at predetermined rates for patient discharges. The rates vary according to the Medicare Severity Diagnosis-Related Group (MS-DRG) to which a beneficiary's stay is assigned. The MS-DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs (e.g., the costs for multiple medical procedures) associated with the beneficiary's stay. Medicare Part B pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification.

To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Social Security Act (the Act) § 1862(a)(1)(A)). In addition, payment must not be made to any provider of services without information necessary to determine the amount due the provider (the Act § 1815(a)). The provider must furnish to the MAC sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

Bariatric Surgery

Bariatric surgery is a procedure that helps beneficiaries with morbid obesity[2] to lose weight by making changes to their digestive system. There are two types of bariatric surgical procedures: restrictive procedures restrict the amount of food the stomach can hold, and malabsorptive procedures divert food from the stomach to a lower part of the digestive tract, resulting in less absorption of nutrients. Surgery can combine both types of procedures.

Medicare Coverage of Bariatric Surgery

Medicare Parts A and B cover approved inpatient and outpatient bariatric surgery procedures that are performed to treat comorbid (i.e., present at the same time) health conditions associated with morbid obesity, such as cardiac and respiratory diseases, diabetes, and hypertension. Treatments for obesity alone are not covered.[3]

According to Medicare's "National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity," Medicare will cover certain specified bariatric surgery procedures if a beneficiary meets all of the following three eligibility requirements:

[2] Morbid obesity is "a serious health condition that can interfere with basic physical functions, such as breathing or walking. Those who are morbidly obese are at greater risk for illnesses, including diabetes, high blood pressure, sleep apnea, gastroesophageal reflux disease, gallstones, osteoarthritis, heart disease, and cancer." Available at https://www.urmc.rochester.edu/highland/bariatric-surgery-center/questions/morbid-obesity.aspx. Accessed on April 30, 2020.

[3] CMS's *Medicare National Coverage Determinations Manual,* Pub. No. 100-03, chapter 1, part 2, § 100.1(C).

- has a body mass index (BMI) greater than or equal to 35,[4]
- has at least one comorbidity related to obesity, and
- has previously been unsuccessful with medical treatment for obesity.[5]

In addition, the NCD gives MACs the discretion to cover standalone laparoscopic sleeve gastrectomy (LSG)[6] within their respective jurisdictions when all three of these eligibility requirements are met.[7] According to Noridian's LCDs and LCA in effect during our audit period, Noridian covers LSG procedures in its jurisdictions.[8]

Medicare Contractor Specifications for Documenting Previously Unsuccessful Medical Treatment for Obesity in a Beneficiary's Medical Record

Noridian issued LCDs and an LCA listing specifications for demonstrating that a beneficiary has met the NCD requirement of having been previously unsuccessful with medical treatment for obesity. According to LCDs effective from January 1, 2015, through April 30, 2016, for LSG procedures[9] and an LCA effective beginning on May 1, 2016, for LSG procedures and all other bariatric surgeries covered under the NCD,[10] two of those specifications are:

- a thorough multidisciplinary evaluation and
- active participation in a weight management program.

[4] BMI is a person's weight in kilograms divided by the square of height in meters. A high BMI can indicate a high body-fat level.

[5] CMS's *Medicare National Coverage Determinations Manual*, chapter 1, part 2, § 100.1.

[6] This bariatric procedure is performed by vertically removing approximately 70 to 80 percent of the stomach. The substantially reduced stomach decreases the amount of food that can fit in the stomach. As a result, a beneficiary feels full after eating a small meal.

[7] CMS's *Medicare National Coverage Determinations Manual,* chapter 1, part 2, § 100.1(D). In addition, the NCD gives MACs the discretion to cover any other bariatric surgery procedures that are not specifically identified in an NCD as covered or noncovered when all three of these eligibility requirements are met.

[8] An LCD is a decision by a MAC whether to cover a particular item or service on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCA provides billing and coding guidance on a subject that also may have an associated LCD.

[9] LCDs L33362 and L34238 provided additional coverage specifications for LSG procedures. LCD L33362 was effective January 1 through September 30, 2015. LCD L34238 was effective October 1, 2015, through April 30, 2016. LCD L34238 was retired and included in LCA A53026, effective May 1, 2016.

[10] LCA A53026, effective May 1, 2016, provides additional coverage specifications for all bariatric surgeries, including LSG procedures.

Thorough Multidisciplinary Evaluation

According to Noridian's LCDs and LCA, a thorough multidisciplinary evaluation must have been performed within the previous 6 months and must include all of the following:

- an evaluation of the beneficiary by the bariatric surgeon who recommends surgical treatment, including a description of the proposed procedure or procedures;
- a separate medical evaluation from a physician other than a surgeon that includes both a recommendation for bariatric surgery and a medical clearance for the surgery;
- a clearance for bariatric surgery by a mental health provider, including a statement regarding motivation and ability to follow postsurgical requirements; and
- a nutritional evaluation by a physician or registered dietitian.

Active Participation in a Weight Management Program

According to Noridian's LCDs and LCA, active participation in a weight management program must include participation within the 12 months before bariatric surgery in a weight management program that is supervised by a physician or other health care professionals for a minimum of 4 consecutive months. In addition, the program must include monthly documentation of the beneficiary's weight and BMI, current dietary regimen, and physical activity (e.g., exercise program).

Cedars-Sinai Medical Center

Cedars-Sinai is an acute-care hospital located in Los Angeles, California. Medicare paid Cedars-Sinai $1.3 million for inpatient and outpatient bariatric surgeries performed during our audit period.

Medicare Requirements for Providers To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.[11]

[11] The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.[12]

HOW WE CONDUCTED THIS AUDIT

Our audit covered approximately $1.3 million in Medicare payments to Cedars-Sinai for 62 bariatric surgery claims[13] with dates of service during our audit period.[14] The 62 claims consisted of 59 inpatient claims and 3 outpatient claims. We reviewed all 62 claims.

For each of the 62 bariatric surgery claims, we reviewed supporting medical record documentation provided by Cedars-Sinai to determine whether the beneficiaries' medical records met Medicare requirements and the specifications in Noridian's LCDs and LCA for documenting previously unsuccessful medical treatment for obesity. We provided to an independent medical review contractor copies of the medical records for 23 claims that we determined did not have adequate supporting documentation and that included other medical procedures[15] performed with the bariatric surgeries to determine whether the surgeries complied with Medicare requirements and the specifications in Noridian's LCDs and LCA and whether the other procedures were medically necessary.[16] Of the 23 claims, 11 claims had a date of service when Noridian's LCDs were effective, and 12 claims had a date of service when Noridian's LCA was effective.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[12] 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*—Part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

[13] We limited our audit to claims that included at least one of the bariatric surgery procedure codes covered by the MAC.

[14] Medicare paid a total of $1,340,731 ($1,319,320 for inpatient and $21,411 for outpatient bariatric surgery claims).

[15] During the same bariatric operation, a surgeon may perform other, unrelated procedures, such as repair of a hernia or excision of a liver. These procedures may not have been medically necessary. Some bariatric claims included other procedures that were performed on a different date, either before the bariatric surgery (e.g., lab testing) or after the bariatric surgery (e.g., providing pain medication).

[16] We obtained a determination on the medical necessity of the other procedures on each of the 23 bariatric surgery claims to determine how much, if any, of the total amount that Medicare paid for each claim was unallowable.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

Cedars-Sinai did not fully comply with Medicare requirements and the Medicare contractor's LCDs and LCA when billing for bariatric surgeries. For 37 of the 62 claims we reviewed, Cedars-Sinai complied with Medicare requirements and the specifications in Noridian's LCDs and LCA for documenting previously unsuccessful medical treatment for obesity.[17] However, for the remaining 25 inpatient claims,[18] Cedars-Sinai did not comply with Noridian's specifications. Specifically, Cedars-Sinai did not provide adequate documentation of the multidisciplinary medical evaluations of the beneficiaries or the beneficiaries' participation in a weight management program.

Cedars-Sinai did not comply with the specifications in the LCDs for 12 claims, with payments totaling $154,074, and did not comply with the specifications in the LCA for 13 claims, with payments totaling $175,199. As of the publication of this report, these payments include claims outside of the 4-year reopening period.[19] Appendix B contains details on the 25 claims that did not comply with either Noridian's LCDs or LCA.

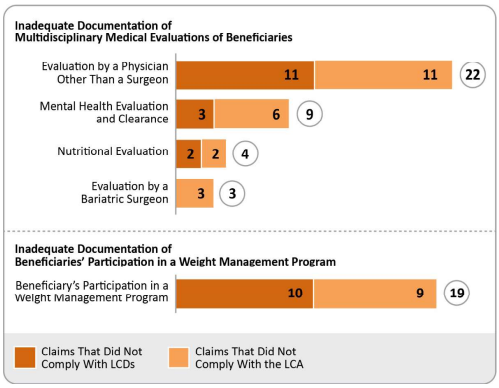
The figure on the following page shows the type and number of documentation-related deficiencies for the 25 claims. The total number of deficiencies exceeds 25 because 23 claims contained more than 1 deficiency.

[17] Of the 37 claims, 34 were inpatient claims and 3 were outpatient claims.

[18] Of these 25 claims, 1 claim did not include other procedures, and 1 claim had other procedures that were related to the bariatric surgery and did not require a determination of medical necessity (e.g., postoperative pain management). Therefore, we had the independent medical review contractor review only 23 claims for medical necessity. The contractor determined that the other procedures on all 23 claims were not medically necessary inpatient procedures; therefore, the entire claim payment amount was used to determine the amount on the claim that did not comply with Noridian's LCDs or LCA.

[19] See 42 CFR § 405.980(b)(2) (permitting a contractor to reopen an initial determination within 4 years for good cause) and 42 CFR § 405.980(c)(2) (permitting a provider to request that a contractor reopen within 4 years for good cause). Notwithstanding, a provider may request that a contractor reopen an initial determination for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period (42 CFR § 405.980(c)(4)).

Figure: Cedars-Sinai's Documentation-Related Deficiencies for Bariatric Surgery Claims



These deficiencies occurred because Cedars-Sinai: (1) used an incomplete patient checklist[20] to ensure compliance with Medicare requirements and the specifications in Noridian's LCDs and LCA for bariatric surgery and (2) did not always obtain medical records from other providers to assure itself that the Medicare requirements and the specifications in the LCDs and LCA were met.

CEDARS-SINAI DID NOT PROVIDE ADEQUATE DOCUMENTATION OF MULTIDISCIPLINARY MEDICAL EVALUATIONS OF BENEFICIARIES

Cedars-Sinai did not provide adequate documentation of multidisciplinary medical evaluations of beneficiaries. Specifically, the claims did not comply with the specifications in Noridian's LCDs or LCA because the following were not adequately documented: (1) evaluation by a physician other than a surgeon (22 claims), (2) mental health evaluation and clearance (9 claims), (3) nutritional evaluation (4 claims), and (4) evaluation by a bariatric surgeon (3 claims).

[20] Cedars-Sinai's "Bariatric Surgery: Preliminary Patient Checklist." The checklist included consultations, tests and procedures, and supervised diets that a beneficiary must have completed before Cedars-Sinai would perform bariatric surgery on the beneficiary. However, the checklist lacked specific Medicare requirements and the specifications in Noridian's LCDs and LCA.

Evaluation by a Physician Other Than a Surgeon Was Not Adequately Documented

A beneficiary's medical record must include documentation of a separate medical evaluation from a physician other than a surgeon within 6 months before the bariatric surgery. In addition, the documentation must include both a recommendation for bariatric surgery and a medical clearance for the proposed bariatric surgery (LCDs L33362 and L34238; LCA A53026).

Physician's Recommendation and Medical Clearance for Bariatric Surgery

According to Noridian, a "recommendation means that the patient will likely benefit from and is a suitable candidate for the surgery based on current clinical guidelines, while a medical clearance means that the patient appears to be mentally and physically capable to withstand the surgery and the postoperative requirements."

Of 22 claims,[21] 11 claims did not comply with the specifications in the LCDs and 11 claims did not comply with the specifications in the LCA because the evaluation by a physician other than a surgeon was not adequately documented. Specifically, the beneficiary medical records did not include documentation to support that: (1) the beneficiary received a separate medical evaluation from a physician other than a surgeon (2 claims), (2) a physician recommended the beneficiary for bariatric surgery (19 claims), or (3) the physician provided a medical clearance for the beneficiary for the proposed bariatric surgery (4 claims).

Example of Evaluation by a Physician Without a Recommendation and Medical Clearance for Bariatric Surgery

Medicare paid Cedars-Sinai $12,098 for a bariatric surgery performed on February 12, 2016. The beneficiary's medical record included four evaluations by a physician other than a surgeon (in April 2015, May 2015, August 2015, and February 2016). Two of these evaluations were performed within 6 months before the bariatric surgery; however, the evaluations did not include a recommendation and medical clearance for the bariatric surgery. For example, when the beneficiary was seen by an internal medicine physician in February 2016 for a preoperative examination and an annual wellness screening, the physician reviewed the beneficiary's medications, allergies, and health history and ordered lab tests; however, the physician did not recommend or clear the beneficiary for the bariatric surgery.

[21] The total number of deficiencies exceeds 22 because 3 claims contained more than 1 deficiency.

Mental Health Evaluation and Clearance Were Not Adequately Documented

A beneficiary's medical record must include documentation of a mental health provider's evaluation and clearance of the beneficiary within 6 months before the bariatric surgery is performed. In addition, the mental health provider's clearance must include a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements (LCDs L33362 and L34238; LCA A53026).

Patient's Motivation and Ability To Adhere to Postsurgical Regimen Are Important

According to the American Society for Metabolic and Bariatric Surgery (ASMBS) guidelines: "It is important for patients to understand that the outcome of surgery is variable and strongly dependent upon consistent implementation of the recommended lifestyle changes. They should also be able to verbalize an understanding of the need to be an active participant in one's own care and a commitment to adhere to the postsurgical regimen." ("Recommendations for the presurgical psychosocial evaluation of bariatric surgery patients," Feb. 2016.)

Of nine claims, three claims did not comply with the specifications in the LCDs and six claims did not comply with the specifications in the LCA because documentation of a mental health provider's evaluation of the beneficiary and clearance for bariatric surgery were inadequate. Specifically, the beneficiary medical records did not include documentation to support that: (1) the beneficiary received a mental health evaluation (two claims), (2) the evaluation was performed within 6 months before the bariatric surgery (six claims), and (3) the mental health clearance included a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements (one claim).

Example of a Mental Health Evaluation That Was More Than 6 Months Before Surgery

Medicare paid Cedars-Sinai $12,098 for a bariatric surgery performed on May 9, 2016. The only documentation of a mental health evaluation and clearance included in the beneficiary's medical record was a letter from a licensed clinical social worker dated January 7, 2015. The letter included a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements. However, the mental health evaluation and clearance was performed 16 months before the bariatric surgery.

Nutritional Evaluation Was Not Adequately Documented

A beneficiary's medical record must include documentation of a nutritional evaluation by a physician or registered dietitian within 6 months before bariatric surgery is performed (LCDs L33362 and L34238; LCA A53026).

Nutritional Evaluation Is Vital for Success of Bariatric Surgery

According to ASMBS guidelines: "Nutrition assessment and dietary management in surgical weight loss have been shown to be an important correlate with success. A comprehensive nutrition assessment should be conducted preoperatively . . . to identify the patient's nutritional and educational needs. It is essential to determine any preexisting nutritional deficiencies, develop appropriate dietary interventions for correction, and create a plan for postoperative dietary intake that will enhance the likelihood of success." ("ASMBS Allied Health Nutritional Guidelines for the Surgical Weight Loss Patient," March 2008.)

Of four claims, two claims did not comply with the specifications in the LCDs and two claims did not comply with the specifications in the LCA because documentation of a nutritional evaluation by a physician or registered dietitian was inadequate. Specifically, the beneficiary medical records did not include documentation to support that the beneficiary received a nutritional evaluation (one claim) or that the nutritional evaluation was performed within 6 months before the bariatric surgery was performed (three claims).

Evaluation by a Bariatric Surgeon Was Not Adequately Documented

A beneficiary's medical record must include documentation of an evaluation of the beneficiary by a bariatric surgeon who recommends surgical treatment. The evaluation must be performed within 6 months before the bariatric surgery is performed and include a description of the proposed procedures (LCDs L33362 and L34238; LCA A53026).

Three claims included documentation of an evaluation by a bariatric surgeon with a description of the proposed procedures; however, the claims did not comply with the specifications in the LCA because the beneficiary medical records showed that the evaluation was not performed within 6 months before the bariatric surgery.

CEDARS-SINAI DID NOT PROVIDE ADEQUATE DOCUMENTATION OF BENEFICIARIES' PARTICIPATION IN A WEIGHT MANAGEMENT PROGRAM

A beneficiary's medical record must include evidence of the beneficiary's active participation within the last 12 months before the bariatric surgery was performed in a weight management program that was supervised by a physician or other health care professionals for a minimum of 4 consecutive months. This monthly documentation must include all of the following data elements: the beneficiary's weight, BMI, current dietary regimen, and physical activity data (LCDs L33362 and L34238; LCA A53026).

Monitoring Food Intake Is Essential for Successful Weight Loss and Maintenance

According to the peer-reviewed psychology journal *Psychology Research and Behavior Management:* "Obtaining an objective behavioral sample of eating behavior is a critical component of the presurgical evaluation . . . . A simple method is to gather a 24-hour food recall during the clinical interview . . . . Regular monitoring of food intake and weight has been associated with long-term weight maintenance in behavioral weight-management programs." ("Preoperative psychological assessment of patients seeking weight-loss surgery: identifying challenges and solutions," *Psychology Research and Behavior Management,* vol. 8, Nov. 2015.)

Of 19 claims, 10 claims did not comply with the specifications in the LCDs and 9 claims did not comply with the specifications in the LCA because the beneficiary medical records did not include documentation of the beneficiary's weight, BMI, current dietary regimen, or physical activity for 4 consecutive months within the 12 months before the bariatric surgery was performed.

Example of Missing Documentation for Participation in a Weight Management Program

Medicare paid Cedars-Sinai $12,020 for a bariatric surgery performed on December 8, 2016. The only documentation related to participation in a weight management program included in the medical record was a physician's short note dated September 29, 2016, stating that the beneficiary had successfully completed 12 nutritional classes. The note did not indicate whether the beneficiary had participated in the weight management program for 4 consecutive months or whether the nutritional classes were held within 12 months before the bariatric surgery. The note also did not include any information on the beneficiary's weight, BMI, dietary regimen, or physical activity.

Example of Weight Management Consultations That Were More Than 12 Months Before Surgery and Were Nonconsecutive

Medicare paid Cedars-Sinai $12,020 for a bariatric surgery performed on November 2, 2016. The medical documentation included five records (May and June 2015 and March, May, and June 2016) related to the beneficiary's participation in a weight management program. However, the first two weight management consultations in May and June 2015 were performed more than 12 months before the bariatric surgery. In addition, the records for June 2015, March 2016, and May 2016 were nonconsecutive.

CAUSE AND EFFECT OF IMPROPER BILLING OF BARIATRIC SURGERY CLAIMS

Cedars-Sinai did not have adequate documentation for 25 claims because it used an incomplete patient checklist[22] and did not always obtain sufficient documentation from other providers to assure itself that the beneficiaries' medical records met Medicare requirements and the specifications in Noridian's LCDs and LCA for bariatric surgery. As a result, Cedars-Sinai did not comply with the specifications in the LCDs for 12 claims, with payments totaling $154,074, and did not comply with the specifications in the LCA for 13 claims, with payments totaling $175,199.

Incomplete Patient Checklist

The multidisciplinary medical evaluations were not adequately documented because the patient checklist did not specify that the evaluations must be performed within 6 months before the bariatric surgery and did not list the information to be included in the evaluations. For example, for the evaluation by a physician other than a surgeon, the patient checklist listed "Cardiologist's Clearance" and "Pulmonologist's Clearance." However, the patient checklist did not specify that the evaluation by the cardiologist or pulmonologist (a physician other than a bariatric surgeon) must include both a recommendation for bariatric surgery and a medical clearance for the proposed bariatric surgery. In addition, for the mental health evaluation and clearance, the patient checklist stated "Assessment & Clearance by CSMC Psychologist (must see dietitian before psychology visit)" but did not list the information to be included in the evaluations (e.g., a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements).

The beneficiaries' participation in a weight management program was not adequately documented because the patient checklist listed only "Supervised Diet – 4 months (i.e. Medicare)" and did not include all of the specifications in Noridian's LCDs and LCA for documenting a beneficiary's weight, BMI, current dietary regimen, and physical activity for 4 consecutive months within the 12 months before the bariatric surgery was performed.

[22] See footnote 20.

Sufficient Documentation Not Always Obtained From Other Providers

The beneficiaries' multidisciplinary medical evaluations and participation in a weight management program were not adequately documented because Cedars-Sinai did not always obtain all supporting medical record documentation from other providers (e.g., weight management program documentation from a physician or dietitian, documentation of a recommendation and clearance from a physician other than a surgeon, or documentation of an evaluation and clearance by a mental health provider).

RECOMMENDATIONS

We recommend that Cedars-Sinai Medical Center:

- refund to the Medicare program the portion of the $154,074 in overpayments for bariatric surgery claims that did not comply with the specifications in the LCDs and that are within the 4-year reopening period;[23]
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation;
- work with Noridian to take action deemed necessary by CMS or Noridian, or both, regarding $175,199 in payments for bariatric surgery claims with dates of service on or after the effective date of the LCA;[24]
- update its patient checklist to include all of Noridian's specifications for billing bariatric surgeries; and
- obtain supporting medical record documentation from other providers, such as primary care physicians, mental health providers, or dietitians, before performing any future bariatric surgeries.

[23] OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal.

[24] Generally, section 1871(a)(2) of the Act requires CMS to use notice-and-comment rulemaking to establish or change a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits. In *Azar v. Allina,* 139 S. Ct. 1804 (2019), the Supreme Court vacated a policy change announced on CMS's website because it violated section 1871(a)(2). We express no opinion on the enforceability of the LCA under section 1871(a)(2).

CEDARS-SINAI COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Cedars-Sinai partially agreed with our first and third recommendations and agreed with our second, fourth, and fifth recommendations:

- Regarding our first recommendation, Cedars-Sinai agreed to refund the overpayments for bariatric surgery claims but disagreed that 1 claim (of the 12 claims in our findings) did not comply with the specifications in the applicable LCD.
- Regarding our third recommendation, Cedars-Sinai agreed to work with Noridian to take action deemed necessary by CMS or Noridian, or both, regarding the payments for bariatric surgery claims with dates of service on or after the effective date of the LCA. However, Cedars-Sinai disagreed that 2 claims (of the 13 claims in our findings) did not comply with the specifications in the LCA.
- Regarding our second, fourth, and fifth recommendations, Cedars-Sinai provided information on actions that it had taken or planned to take to address these recommendations. Regarding our second recommendation, Cedars-Sinai stated that it would identify, report, and return any overpayments in accordance with the 60-day rule. Regarding our fourth recommendation, Cedars-Sinai stated that, among other actions, it has implemented a checklist to ensure that Medicare requirements are met before scheduling bariatric surgery. Regarding our fifth recommendation, Cedars-Sinai stated that it had implemented appropriate controls to ensure that all supporting medical record documentation verifies that all requirements are met, including obtaining medical record documentation from other providers before scheduling bariatric surgery.

Cedars-Sinai's comments are included in their entirety as Appendix C.

After reviewing Cedars-Sinai's comments, we maintain that our findings and recommendations remain valid. For all 25 claims that did not comply with the specifications in the LCDs or the LCA (including the 3 claims for which Cedars-Sinai disagreed with our findings), either OIG or the independent medical review contractor found that the information in the beneficiaries' medical records did not support the eligibility specifications for bariatric surgery.[25]

ONE CLAIM THAT DID NOT COMPLY WITH THE LOCAL COVERAGE DETERMINATION

Cedars-Sinai Comments

Cedars-Sinai disagreed with our finding related to claim number 10 (see Appendix B, Table 1) that did not comply with the specifications in LCD L34238. Cedars-Sinai stated that

[25] The independent medical review contractor provided a determination for 23 claims. After the medical review was completed, Cedars-Sinai did not provide any additional medical record documentation.

documentation provided to OIG reflected that the beneficiary was assessed by physicians other than the surgeon and was cleared for bariatric surgery based on the preoperative evaluation by the internal medicine physician on February 2, 2016, and the followup assessment by the anesthesiologist on the morning of the surgery. In addition, Cedars-Sinai provided specific comments on certain documents in the beneficiary's medical records, covering specific dates in the period from April 2015 through February 12, 2016.

Office of Inspector General Response

We maintain that claim number 10 did not comply with the specifications in the LCD because the medical records did not include documentation to support that within the previous 6 months the beneficiary had received a separate medical evaluation from a physician other than a surgeon that included both a recommendation and a medical clearance for bariatric surgery:

- The evaluations in April and May 2015 did not explicitly recommend the beneficiary for bariatric surgery; instead, the physicians recommended weight-loss medication and exercise. In addition, the evaluations were performed more than 6 months before the bariatric surgery.
- The evaluation on August 17, 2015, stated "discussed bariatric surgery" but did not specifically include a recommendation for bariatric surgery.
- The evaluation on August 19, 2015, was not performed by a physician other than a surgeon.
- The evaluation on February 2, 2016, did not include a recommendation or medical clearance for bariatric surgery. It simply stated that labs were drawn and a chest x-ray was ordered, and it provided instructions to stop certain medications before surgery.
- The assessment on February 12, 2016, the morning of the bariatric surgery, did not specifically include both a recommendation and a medical clearance for the surgery. The evaluation stated: "Assessment Plan: Based upon a chart review of pertinent history, a review of pertinent lab results and the above assessment: ASA 3 Anesthesia Type: General."

TWO CLAIMS THAT DID NOT COMPLY WITH THE LOCAL COVERAGE ARTICLE

Cedars-Sinai Comments

Cedars-Sinai disagreed with our findings related to claim numbers 6 and 13 (see Appendix B, Table 2) that did not comply with the specifications in LCA A53026. For each claim, Cedars-Sinai stated that the documentation provided to OIG reflected that the beneficiary was assessed by physicians other than the surgeon and was evaluated by a mental health professional and a registered dietitian. Cedars-Sinai provided specific comments on certain documents in the

beneficiaries' medical records, covering specific dates in the periods from July 23, 2015, through October 17, 2016, for claim number 6 and November 4, 2015, through July 27, 2016, for claim number 13.

Office of Inspector General Response

We maintain that the two claims did not comply with the specifications in the LCA because the medical records did not include documentation to support that within the previous 6 months each of the beneficiaries received: (1) a separate medical evaluation from a physician other than a surgeon that included a recommendation for bariatric surgery and (2) a clearance for bariatric surgery by a mental health provider.

Specifically, for claim number 6, we maintain the following:

- The evaluations on July 23, 2015, and September 3, 2015, were performed more than 6 months before the bariatric surgery. In addition, the evaluation on September 3, 2015, was not performed by a physician other than a surgeon.
- The evaluations by physicians other than the surgeon on June 6 and October 17, 2016, were performed within 6 months before the bariatric surgery and provided a medical clearance for the surgery. However, these evaluations did not specifically include a recommendation for the bariatric surgery.
- The mental health evaluation on October 8, 2015, was performed more than 1 year before the bariatric surgery. The clearance on May 25, 2016, was provided by a registered dietitian, not by a mental health provider.

Specifically, for claim number 13, we maintain the following:

- The evaluations on November 4 and 9, 2015, were performed more than 6 months before the bariatric surgery. In addition, the evaluation on November 9, 2015, was performed by a nurse practitioner from the bariatric surgeon's office, not by a physician other than a surgeon.
- The evaluation by the cardiologist on February 3, 2016, did not specifically include a recommendation or medical clearance for the bariatric surgery.
- The evaluation by a physician other than a surgeon on July 27, 2016, included a medical clearance for the bariatric surgery but did not specifically include a recommendation for the surgery.
- The mental health evaluation on January 6, 2016, was performed more than 6 months before the bariatric surgery. The clearance on March 14, 2016, was provided by a registered dietitian, not by a mental health provider.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $1,340,731 in Medicare payments to Cedars-Sinai for 62 bariatric surgery claims with dates of service from January 1, 2015, through December 31, 2016. The 62 claims consisted of 59 inpatient claims (totaling $1,319,320) and 3 outpatient claims (totaling $21,411). We reviewed all 62 claims.

For each of the 62 bariatric surgery claims, we reviewed supporting medical documentation provided by Cedars-Sinai to determine whether the beneficiaries' medical records met Medicare requirements and the specifications in Noridian's LCDs and LCA for documenting previously unsuccessful medical treatment for obesity. We provided to an independent medical review contractor copies of the medical records for 23 bariatric surgery claims that we determined did not have adequate supporting documentation and that included other medical procedures performed with or separately from the bariatric surgeries to determine whether the surgeries complied with Medicare requirements and the specifications in Noridian's LCDs and LCA and whether the other procedures were medically necessary.[26] Of the 23 claims, 11 claims had a date of service when Noridian's LCDs were effective, and 12 claims had a date of service when Noridian's LCA was effective.

We did not review Cedars-Sinai's overall internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective.

We conducted our audit from February 2018 to July 2020, which included fieldwork performed at Cedars-Sinai, located in Los Angeles, California.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials to gain an understanding of Medicare billing requirements for bariatric surgery and to identify any oversight and existing reviews of bariatric surgery claims;
- interviewed Noridian officials to obtain an understanding of the MAC's claim processing, system edits, and eligibility specifications for bariatric surgeries;

[26] See footnotes 15, 16, and 18.

- used CMS's National Claims History (NCH) file to identify 62 Medicare Part A and Part B inpatient and outpatient bariatric surgery claims with dates of service during our audit period for which Cedars-Sinai received payments;[27]
- interviewed Cedars-Sinai officials to obtain an understanding of Cedars-Sinai's policies and procedures for documenting beneficiaries' previously unsuccessful medical treatment for obesity;
- reviewed data from CMS's Common Working File for the selected claims to determine whether the claims had been canceled or adjusted;
- reviewed billing and medical record documentation provided by Cedars-Sinai for 62 claims to determine whether the identified claims met Medicare requirements and the specifications in Noridian's LCDs and LCA;
- provided to an independent medical review contractor the medical records for 23 bariatric surgery claims that we determined did not have adequate supporting documentation (11 claims related to LCD specifications and 12 claims related to LCA specifications) and that included other medical procedures performed with the bariatric surgeries;[28]
- reviewed the independent medical review contractor's results and determined how much, if any, of the total amount Medicare paid for each bariatric surgery claim was unallowable;
- discussed the results of our audit with Cedars-Sinai officials; and
- shared the results of our audit with CMS.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[27] Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file, but we did not assess the completeness of the file.

[28] The independent medical review contractor determined whether: (1) the claims complied with Medicare requirements and the specifications in Noridian's LCDs and LCA and (2) the other procedures included on the claims were medically necessary.

APPENDIX B: DETAILS ON 25 CLAIMS THAT DID NOT COMPLY WITH NORIDIAN'S LOCAL COVERAGE DETERMINATIONS OR LOCAL COVERAGE ARTICLE

Table 1: Twelve Claims That Did Not Comply With Local Coverage Determination Specifications

Claim Number	Not Adequately Documented					Amount That Did Not Comply With LCDs
	Evaluation by Physician Other Than Surgeon	Participation in Weight Management Program	Mental Health Evaluation	Nutritional Evaluation	Evaluation by Bariatric Surgeon	
1		X				$12,189
2	X	X				12,075
3	X		X			12,156
4	X	X				12,156
5	X	X	X	X		12,096
6	X	X				12,096
7	X	X	X	X		15,749
8	X	X				14,658
9	X	X				12,189
10	X					12,098
11	X	X				14,514
12	X	X				12,098
	11	**10**	**3**	**2**	**0**	**$154,074**

Table 2: Thirteen Claims That Did Not Comply With Local Coverage Article Specifications

Claim Number	Not Adequately Documented					Amount That Did Not Comply With LCA
	Evaluation by Physician Other Than Surgeon	Participation in Weight Management Program	Mental Health Evaluation	Nutritional Evaluation	Evaluation by Bariatric Surgeon	
1	X	X				$13,953
2	X	X	X	X		12,020
3		X	X		X	12,098
4		X	X	X		12,020
5	X	X				12,098
6	X		X			12,020
7	X		X		X	13,282
8	X	X				14,515
9	X	X				13,361
10	X	X				12,020
11	X				X	12,098
12	X	X				12,098
13	X		X			23,616
	11	**9**	**6**	**2**	**3**	**$175,199**

APPENDIX C: CEDARS-SINAI COMMENTS

Cedars Sinai

August 27, 2020

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Reference: Draft Report No: A-09-18-03010

Dear Ms. Ahlstrand:

This letter is in response to the recent Office of Inspector General (OIG) report entitled "*Cedars-Sinai Medical Center: Audit of Medicare Payments for Bariatric Surgeries.*" Cedars-Sinai appreciates the work performed by OIG and the opportunity to review and comment on the draft report. Please contact me if you have any questions.

Sincerely,

[Gretchen Case]

Gretchen Case, MPH, CPC
Executive Director, Compliance & Revenue Integrity
Cedars-Sinai
6500 Wilshire Blvd, Suite 2400
Los Angeles, CA 90048

Enclosure

Cedars Sinai

Attachment

Cedars-Sinai Medical Center Response to: The Office of the Inspector General's report entitled, *Cedars-Sinai Medical Center: Audit of Medicare Payments for Bariatric Surgeries* (A-09-18-03010)

Finding 1: Cedars-Sinai did not comply with specifications in the LCDs for 12 claims, with payments totaling $154,074.

Recommendation 1: Refund to Medicare the portion of the $154,074 in overpayments for bariatric surgery claims that did not comply with the specifications in the LCDs and that are within the 4-year reopening period.

Response: Cedars-Sinai partially agrees with the recommendation. Cedars-Sinai agrees to refund the overpayments for the bariatric surgery claims. Of the 12 claims, we have 1 claim that we disagree with.

Nonconcurrence with Claim No. 10 in Table 1 of Appendix B.

Issue: Inadequate Evaluation by a Physician Other than a Surgeon
Documentation provided to the OIG reflects that the beneficiary was assessed by physicians other than the Surgeon and cleared for surgery based on the pre-operative evaluation by the internal medicine physician on February 2, 2016 and the follow up assessment by the anesthesiologist on the morning of surgery.

- April of 2015 – Beneficiary was seen by a cardiologist during an episode of acute hospital-based care and notes reflect obesity and the need for weight loss. and the recommendation for pharmaceutical weight loss medication.
- May of 2015 – Beneficiary was seen by an internal medicine physician for follow up care. The note documents that the beneficiary had not been taking weight loss medication as prescribed and further recommendations provided for the need for regular exercise and weight loss.
- August 17, 2015 – Beneficiary was seen again by the internal medicine physician. Documentation reflects that the beneficiary was again counseled on the need for weight loss and exercise and that bariatric surgery was discussed.
- August 19, 2015 - Beneficiary was seen for a consultation with a bariatric surgeon and bariatric surgery was recommended.
- February 2, 2016 - After completing all requirements for bariatric surgery, the beneficiary was evaluated for a pre-operative evaluation by the same internal medicine physician who had referred him to the bariatric surgeon with a plan for pre-operative laboratory work to be

Cedars Sinai

done, chest x-ray to be completed, and for the beneficiary to stop taking aspirin and Eliquis in preparation for the planned surgery date.

- February 12, 2016 – Beneficiary was evaluated by an anesthesiologist who reviewed all laboratory results and other pre-procedure testing. After repeating two lab values that were of concern and found to be within normal limits, the beneficiary was cleared for surgery by the anesthesiologist.

Finding 2: OIG believes that this audit report constitutes credible information of potential overpayments.

Recommendation 2: Based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

Response: Cedars-Sinai agrees with the recommendation and will identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments.

Finding 3: Cedars-Sinai did not comply with specifications in the LCA for 13 claims, with payments totaling $175,199.

Recommendation 3: Work with Noridian to take action deemed necessary by CMS or Noridian, or both, regarding $175,199 in payments for bariatric surgery claims with dates of service on or after the effective date of the LCA.

Response: Cedars-Sinai partially agrees with the recommendation. Cedars-Sinai agrees to work with Noridian to take action deemed necessary by CMS or Noridian, or both, regarding payments for bariatric surgery claims with dates of service on or after the effective date of the LCA. Of the 13 claims, Cedars-Sinai disagrees with 2 claims.

Nonconcurrence with Claim No. 6 in Table 2 of Appendix B.

Issue #1: Inadequate Evaluation by a Physician Other than a Surgeon
Documentation provided to the OIG reflects that the beneficiary was assessed by physicians other than the Surgeon.

- July 23, 2015 - Beneficiary was initially seen as a new patient by a cardiologist who, at that time, identified obesity as a current problem and made a referral to a surgical weight loss physician for evaluation.
- September 3, 2015 - Beneficiary was subsequently seen by a bariatric surgeon whose notes reflect the name of beneficiary's

cardiologist as the referring physician and that the referral was for evaluation of surgical weight loss

- June 6, 2016 (4 months prior to surgery) – Beneficiary was seen by the cardiologist and the note reflects that the beneficiary was being considered for bariatric surgery and that based upon testing and evaluations already performed, no additional cardiology clearance would be required prior to bariatric surgery
- October 17, 2016 - The beneficiary was evaluated by an Internal Medicine physician and cleared for surgery

Issue #2: Inadequate Evaluation by a Mental Health Provider

Documentation provided to the OIG reflects that the beneficiary was evaluated by a mental health professional and registered dietician.

- Beneficiary was evaluated by a mental health provider on October 8, 2015. The documentation reflects that the beneficiary had researched the procedure, understood potential risks and benefits of surgery, and demonstrated sufficient emotional and cognitive skills required to handle the challenges associated with a successful weight loss regimen. In addition, the note states that the beneficiary is an appropriate candidate for weight reduction surgery and no further psychological consultation is needed at this time. However, despite the mental health clearance it was identified by the registered dietician from the initial evaluation on October 8, 2015 that the beneficiary had significant diet/lifestyle changes to make prior to being considered for bariatric surgery, including smoking cessation and decreasing alcohol (beer) consumption.
- The beneficiary continued to be followed by a registered dietician for on-going evaluation and counseling through May of 2016. Once the registered dietician noted on May 25, 2016 that the beneficiary had stopped smoking in March and had resolved alcohol (beer) consumption, the beneficiary was cleared for bariatric surgery.

Nonconcurrence with Claim No. 13 in Table 2 of Appendix B.

Issue #1: Inadequate Evaluation by a Physician Other than a Surgeon

Documentation provided to the OIG reflects that the beneficiary (at time of initial evaluation) had a history of severe dilated cardiomyopathy secondary to hypertension versus morbid obesity was being considered for evaluation for heart transplantation. Documentation provided to the OIG reflects that the beneficiary was assessed by physicians other than the Surgeon.

- November 4, 2015 – Beneficiary was seen by the cardiologist in the advanced heart disease clinic. Documentation reflects that the beneficiary was referred to the surgical weight loss program at Cedars Sinai Medical Center and had an appointment for November 9, 2015 for evaluation by a weight loss surgeon. This note further reflects that the beneficiary was urged by the cardiologist to

comply and present for this evaluation and attend the required weight loss visits so he may qualify for bariatric surgery.

- November 9, 2015 - Beneficiary was evaluated by a nurse practitioner and the initial consult note reflects that the beneficiary was referred for medical versus surgical weight loss. After the initial evaluation, the beneficiary was enrolled into the bariatric surgical weight loss program.
- February 3, 2016 - Beneficiary was seen for follow up in the cardiomyopathy clinic by the cardiologist and the documentation reflects that the beneficiary was undergoing evaluation for bariatric surgery. In addition, the note states that the cardiologist was pleased to see the beneficiary's engagement in care and instructed the beneficiary to continue participation in the cardiac rehabilitation program and weight loss program.
- July 27, 2016 - The beneficiary was seen by the cardiologist prior to surgery. Beneficiary was found to be optimized from a cardiac standpoint and was an acceptable risk for laparoscopic gastric sleeve surgery.

Issue #2: Inadequate Evaluation by a Mental Health Provider

Documentation provided to the OIG reflects that the beneficiary was evaluated by a mental health professional and registered dietician.

- January 6, 2016 - Beneficiary was evaluated by a mental health provider. The documentation reflects that the beneficiary appeared to be an appropriate candidate for weight reduction surgery and was knowledgeable about the potential risks and benefits of the proposed surgery. Documentation also supports that the beneficiary demonstrated sufficient emotional and cognitive skills required to manage the challenges associated with a safe weight loss regimen and that the beneficiary was cleared regarding his psychological consultation and required no further psychological consultation. However, despite the mental health clearance, it had been documented by the registered dietician on the initial evaluation on December 1. 2015 that while the beneficiary had no psychosocial issues identified there were significant diet/lifestyle changes to make prior to being considered for bariatric surgery, including undesirable food choices and lack of physical activity. The beneficiary was not cleared for bariatric surgery at that time and continued to be followed by a registered dietician for ongoing evaluation and counseling through March of 2016.
- On March 14, 2016, the registered dietician documented that the beneficiary had made substantial progress in making food choices, had clear goals for physical activity and was cleared for bariatric surgery.

Finding 4: Cedars-Sinai used an incomplete checklist to ensure compliance with Medicare requirements and the specifications in Noridian's LCDs and LCA for bariatric surgery.

Recommendation 4: Cedars-Sinai should update its patient checklist to include all of Noridian's specifications for billing bariatric surgeries.

Response: Cedars-Sinai agrees with the recommendation.

- Cedars-Sinai has developed an internal review process, checklist, (CSMC Medicare Bariatric Surgery Scheduling Policy) that documents that medical necessity is met prior to surgery.
- Cedars-Sinai has implemented a checklist to ensure Medicare requirements are met prior to scheduling surgery (Checklist for Medicare Requirements for Bariatric Surgery 2019).
- Cedars-Sinai will re-review all Medicare FFS bariatric surgery accounts to ensure all requirements are met prior to billing (Medicare patients undergoing Bariatric surgery at Cedars-Sinai surgery Scheduling Workflow).

Finding 5: Cedars-Sinai did not always obtain medical records from other providers to assure itself that the Medicare requirements and the specifications in the LCDs and LCA were met.

Recommendation 5: Cedars-Sinai should obtain supporting medical record documentation from other providers, such as primary care physicians, mental health providers, or dieticians, before performing any future bariatric surgeries.

Response: Cedars-Sinai agrees with the recommendation and has implemented appropriate controls to ensure all supporting medical record documentation verifies all requirements are met.

- Cedars-Sinai has implemented a Medical Necessity Evaluation Policy and Process (CSMC Medicare Bariatric Surgery Scheduling Policy), which includes obtaining medical record documentation from other providers, that must be completed before a bariatric surgery for Medicare FFS patient is scheduled.
- Cedars-Sinai has developed a workflow (Medicare patients undergoing Bariatric surgery at Cedars-Sinai surgery Scheduling Workflow) that requires outside physician offices to send Cedars-Sinai a completed checklist of Medicare guidelines prior to scheduling a surgery.
- Cedars-Sinai distributed the Medical Necessity Evaluation Policy and Process (CSMC Medicare Bariatric Surgery Scheduling Policy) (Medicare FFS Bariatric Surgery for Morbid Obesity Process Improvement Overview) and provided education to physicians and staff involved with the evaluation and scheduling of bariatric

surgery, including: central schedulers, all bariatric surgeons, private physician office schedulers, dieticians, and psychologists.

- Cedars-Sinai has implemented a requirement for an attestation form from a physician other than the surgeon, preferably the beneficiary's primary care physician. The form is an attestation that the physician is recommending bariatric surgery and providing medical clearance for the proposed bariatric surgery (Bariatric Medicare Letter to Private Medical Doctor for signature).