

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE OVERPAID  
MORE THAN \$636 MILLION  
FOR NEUROSTIMULATOR  
IMPLANTATION SURGERIES**

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October 2021  
A-01-18-00500

# *Office of Inspector General*

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## Report in Brief

Date: October 2021

Report No. A-01-18-00500

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



### Why OIG Did This Audit

The Centers for Medicare & Medicaid Services' (CMS's) analysis of past Medicare claims data has identified vulnerabilities in the Medicare payment process that allow billing for neurostimulator implantation surgeries that violate Medicare coverage requirements. Claims for spinal neurostimulator implantation surgeries, involving either the insertion or replacement of neurostimulators, increased by nearly 175 percent between 2007 and 2018, according to CMS. CMS directed a supplemental medical review contractor to conduct postpayment medical reviews of Medicare Part B spinal neurostimulator implantation surgeries. Those reviews found payment error rates as high as 72 percent.

Our objective was to determine whether health care providers complied with Medicare requirements when they billed for neurostimulator implantation surgeries.

### How OIG Did This Audit

Our audit covered \$1.4 billion in Medicare payments to providers for 58,213 beneficiaries who had at least one neurostimulator implantation surgery during calendar years 2016 and 2017. We identified beneficiaries as having a neurostimulator implantation surgery if a Medicare claim was submitted with Healthcare Common Procedure Coding System codes 61885, 61886, or 63685. We reviewed a stratified random sample of 106 beneficiaries associated with 124 Medicare claims with payments totaling \$3.4 million. These claims were submitted by 102 providers.

## Medicare Overpaid \$636 Million for Neurostimulator Implantation Surgeries

### What OIG Found

More than 40 percent of the health care providers covered by our audit did not comply with Medicare requirements when they billed for neurostimulator implantation surgeries. We determined that medical records for 48 of the sampled beneficiaries (associated with 46 providers) did not contain support that providers met Medicare requirements. On the basis of our sample results, we estimated that during calendar years 2016 and 2017 providers received \$636 million in unallowable Medicare payments associated with neurostimulator implantation surgeries and beneficiaries paid \$54 million in related unnecessary copays and deductibles. These unallowable payments occurred because providers did not include sufficient documentation in the medical records to support that Medicare coverage requirements were met. Furthermore, claims for neurostimulator implantation surgeries did not require prior authorization and are not subject to prepayment review. During our audit, CMS published a final rule that requires prior authorizations for implanted spinal neurostimulators; however, this rule does not include claims for Parkinson's disease or seizure disorders.

### What OIG Recommends and CMS Comments

We recommend that CMS instruct the Medicare contractors to: (1) recover the portion of the \$1,205,654 in identified Medicare potential overpayments for the 54 incorrectly billed claims that are within the 4-year reopening period; (2) instruct the 46 providers identified with the incorrectly billed claims to refund \$115,206 in coinsurance amounts that have been collected from the 48 sampled beneficiaries for claims within the 4-year reopening period; (3) determine which of the remaining 58,107 claims in our sampling frame were incorrectly billed, recover Medicare overpayments that are within the 4-year reopening period, and instruct the providers to refund beneficiary coinsurance amounts; and (4) notify the providers with potential overpayments estimated at \$636,498,547, so they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule. We also recommend that CMS: (1) conduct provider outreach and education regarding the Medicare coverage requirements for neurostimulator implantation surgeries and (2) require prior authorization for neurostimulator implantation surgeries for Parkinson's disease and seizure disorders.

In written comments on our draft report, CMS concurred with our recommendations and provided details about the actions it has taken or plans to take.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

The Centers for Medicare & Medicaid Services' (CMS's) analysis of past Medicare claims data has identified vulnerabilities in the Medicare payment process that allow billing for neurostimulator implantation surgeries that violate Medicare coverage requirements. Claims for spinal neurostimulator implantation surgeries, involving either the insertion or replacement of neurostimulators, increased by nearly 175 percent between 2007 and 2018, according to CMS. CMS researched possible causes for the increased volume of these procedures that would indicate the services are increasingly necessary, but CMS did not find any plausible reason for the increase in services and concluded that a financial motivation was the most likely cause for the increase.<sup>1</sup> CMS directed a supplemental medical review contractor to conduct postpayment medical reviews of Medicare Part B spinal neurostimulator implantation surgeries.<sup>2</sup> Those reviews found payment error rates as high as 72 percent.

### OBJECTIVE

Our objective was to determine whether health care providers complied with Medicare requirements when they billed for neurostimulator implantation surgeries.<sup>3</sup>

### BACKGROUND

#### The Medicare Program

Medicare provides health insurance for people aged 65 years and older, people with disabilities, and people with permanent kidney disease. 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 is responsible for administering the Medicare program. CMS contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals, conduct reviews and audits, and safeguard against fraud and abuse. CMS is responsible for providing Medicare contractor oversight, such as facilitating contractor compliance with current regulations, ensuring Medicare contractors' compliance with CMS operating instructions, and providing ongoing feedback and guidance to Medicare contractors regarding the Medicare

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<sup>1</sup> 85 Fed. Reg. 48772, 49028–29 (Aug. 12, 2020).

<sup>2</sup> Supplemental Medical Review Contractor Project Y3P167.

<sup>3</sup> For this audit, we use the term provider to refer to both providers and suppliers as defined by 42 CFR § 400.202 to include hospitals and ambulatory surgery centers.

program. Medicare contractors must establish and maintain efficient and effective internal controls.<sup>4</sup>

Section 1833(e) of the Social Security Act states: “No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

## **Neurostimulators**

A neurostimulator is a battery-powered electronic device enclosed in a small metal container that is surgically implanted under a patient’s skin and connected to wires called leads. The neurostimulator sends low levels of electrical energy through the leads to nerve fibers. The term “neurostimulator” refers to a general category of implantable devices that includes spinal cord, deep brain, and vagus nerve stimulator (VNS) devices. The Food and Drug Administration (FDA) initially approved neurostimulators to stimulate the spinal cord for treatment of chronic pain. Rapid technological changes in spinal cord stimulation; deep brain stimulation for the treatment of Parkinson’s disease, essential tremor, dystonia, and obsessive-compulsive disorder; and vagus nerve stimulation for seizures and epilepsy have extended the neurostimulator’s potential benefits to a wider range of services and people. When FDA approved these devices, the manufacturers claimed battery lives for nonrechargeable devices would generally exceed several years.

## **The Food and Drug Administration**

FDA is the Federal agency tasked with approval of medical devices, including implantable medical devices such as neurostimulators. FDA also monitors adverse event reports regarding medical devices, which it receives via its Medical Device Reporting (MDR) system. The MDR system is one of the postmarket surveillance tools FDA uses to monitor device performance, detect potential medical device-related safety issues, and contribute to benefit-risk assessments of these products. Mandatory reporters (manufacturers, device user facilities,<sup>5</sup> and importers) are required to submit to FDA certain types of reports for adverse events and product problems involving medical devices. In addition, FDA also encourages health care professionals, patients, caregivers, and consumers to submit voluntary reports about adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

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<sup>4</sup> CMS, *Medicare Financial Management Manual*, Pub. No. 100–06, chapter 7, § 10.1.2.

<sup>5</sup> A device user facility is defined by FDA as a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician’s office.

Although FDA has determined that these devices are safe, it has received reports of shocks, burns, bruising, skin irritation, and pain associated with the use of some implantable medical devices. Some of these injuries required hospital treatment. FDA data indicate that 262,748 adverse event reports for neurostimulators were received during the period of January 1, 2010, through June 1, 2019. Of these adverse event reports, 262,457 (99 percent) indicated event types such as malfunction (89,906), serious injury (169,795), or death (2,756).

## Medicare Coverage of Neurostimulators

Medicare National Coverage Determinations (NCDs) are nationwide determinations of whether specific medical items, services, treatment procedures, or technologies are covered under Medicare.<sup>6</sup> The NCDs are published in the *Medicare National Coverage Determinations Manual* (NCD Manual) and will be revised based on the most recent medical and other scientific and technical evidence available to CMS. NCD decisions regarding coverage are generally based on section 1862(a)(1) of the Social Security Act unless otherwise specifically noted. Table 1 below includes the NCDs associated with surgically implanted neurostimulators.

**Table 1: NCDs Associated With Neurostimulators\***

Number	Title
NCD 160.2†	Treatment of Motor Function Disorders with Electric Nerve Stimulation
NCD 160.7	Electrical Nerve Stimulators
NCD 160.18	Vagus Nerve Stimulation
NCD 160.24	Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease
* NCD Manual, Pub No. 100–03 ch. 1, part 2.	
† We did not have any findings related to NCD 160.2, but we included it to provide a complete list of NCDs applicable to neurostimulator implantation surgeries.	

## Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for hospital outpatient services furnished on or after August 1, 2000. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each

<sup>6</sup> *Medicare National Coverage Determinations Manual* (NCD Manual), Pub. No. 100–03, ch.1, part 1, Forward–Purpose for *National Coverage Determinations Manual*. Although some Medicare contractors have issued Local Coverage Determinations (LCDs) regarding neurostimulators, we did not use those LCDs when conducting this audit because those LCDs applied only to the specific Medicare contractor jurisdictions that issued them and are not applicable nationwide.



APC group.<sup>7</sup> All services and items within an APC group are comparable clinically and require comparable resources. Table 2 describes the three HCPCS codes associated with neurostimulator implantation surgeries covered by our audit.

**Table 2: HCPCS Codes Associated With Neurostimulator Implantation Surgeries**

<b>HCPCS Code</b>	<b>Description</b>
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

### **Medicare Requirements 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.<sup>8</sup>

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.<sup>9</sup>

### **HOW WE CONDUCTED THIS AUDIT**

Our audit covered \$1.4 billion in Medicare payments to providers for 58,213 beneficiaries who had at least one neurostimulator implantation surgery during calendar years 2016 and 2017 (audit period). We identified beneficiaries as having a neurostimulator implantation surgery if a Medicare claim was submitted with HCPCS codes 61885, 61886, or 63685. We reviewed a

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<sup>7</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

<sup>8</sup> The Social Security Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>9</sup> 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.

stratified random sample of 106 beneficiaries associated with 124 Medicare claims with payments totaling \$3.4 million. These 124 claims were submitted by 102 providers.<sup>10, 11</sup>

We requested medical records from providers associated with the beneficiaries in our sample to determine whether the providers that performed the surgeries had the documentation in the patients' medical charts supporting the conditions for coverage as applicable to their diagnoses. We provided the supporting documentation for the sampled beneficiaries received from the providers to an independent medical review contractor (independent contractor). The independent contractor determined whether the claims for neurostimulator implants met Medicare requirements.<sup>12</sup>

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.

Appendix A contains details of our audit scope and methodology. Appendix B contains our statistical sampling methodology. Appendix C contains our sample results and estimates. Appendix D contains the NCD criteria. Appendix E contains a glossary of terms used in this report.

## **FINDING**

More than 40 percent of the health care providers covered by our audit did not comply with Medicare requirements when they billed for neurostimulator implantation surgeries. Specifically, we determined that medical records for 58 of the 106 sampled beneficiaries (associated with 56 providers) contained support that providers met Medicare requirements when billing for neurostimulator implantation surgeries; however, medical records for 48 of the sampled beneficiaries (associated with 46 providers) did not contain support that providers met Medicare requirements. On the basis of our sample results, we estimated that during calendar years 2016 and 2017 providers received \$636 million in unallowable Medicare payments associated with neurostimulator implantation surgeries and beneficiaries paid \$54 million in

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<sup>10</sup> A total of 104 physicians performed the surgeries at the 102 provider facilities.

<sup>11</sup> These 124 Medicare claims were for both initial and replacement implantations. Fourteen beneficiaries had more than one claim submitted during the 2-year audit period. We did not review claims for initial neurostimulator implantation surgeries that occurred before our 2-year audit period.

<sup>12</sup> Delays in the completion of our fieldwork were caused by delays in receiving provider medical records and the time it took the independent contractor to complete medical reviews.

related unnecessary coinsurance amounts.<sup>13</sup> These unallowable payments occurred because providers did not include sufficient documentation in the medical records to support that Medicare coverage requirements were met. Additionally, in some limited instances providers stated that they did not fully understand these Medicare coverage requirements. Furthermore, claims for neurostimulator implantation surgeries did not require prior authorization and are not subject to prepayment review. After the completion of our field work, CMS published a final rule that requires prior authorizations for implanted spinal neurostimulators effective for services provided on or after July 1, 2021.<sup>14</sup> This final rule does not include claims for neurostimulator implantation surgeries for Parkinson’s disease or seizure disorders.

## **PROVIDERS DID NOT ALWAYS COMPLY WITH MEDICARE REQUIREMENTS FOR NEUROSTIMULATOR IMPLANTATION SURGERIES**

The NCD Manual contains the requirements that providers must meet for neurostimulator implantation surgeries to be covered by Medicare. Providers must include sufficient documentation in the Medicare beneficiaries’ medical records to demonstrate that the providers met these coverage requirements (NCD Manual, chapter 1, part 2, §§ 160.7, 160.18, and 160.24 and the Social Security Act § 1833(e)). Appendix D contains the requirements from these applicable NCDs.

We analyzed CMS’s neurostimulator claims data for our 106 sampled beneficiaries and found that 87 of them received neurostimulators for chronic pain, 4 for seizures, and 13 for essential tremors and Parkinson’s disease. Two of the beneficiaries received neurostimulators with investigational device exemptions.

Our independent contractor subsequently reviewed the providers’ medical records for the 106 sampled beneficiaries and determined that the medical records for 48 of the 106 sampled beneficiaries (49 percent) did not indicate providers’ compliance with the NCD Manual documentation requirements.<sup>15</sup> The 46 providers associated with these 48 sampled beneficiaries received \$1,205,654 in Medicare payments and \$115,206 in beneficiary coinsurance amounts for 54 neurostimulator implantation surgery claims. (See Table 3 on the next page for the complete results of the independent contractor’s review.)

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<sup>13</sup> The estimated Medicare overpayments were \$636,498,547, and the estimated beneficiary unnecessary coinsurance amounts were \$54,041,129.

<sup>14</sup> 85 Fed. Reg. 85866, 86248, and 86303 (Dec. 29, 2020) (revising 42 CFR § 419.83(a)).

<sup>15</sup> The result of 49 percent rather than 45 percent is due to the stratification of the sample.

**Table 3: Independent Contractor Results**

<b>Applicable Criteria and Diagnosis</b>	<b>Number of Beneficiaries for Whom Documentation Was Missing in Medical Records</b>	<b>Number of Beneficiaries With Complete Medical Records</b>	<b>Total</b>
NCD Manual § 160.7, Chronic Pain	36	51	87*
NCD Manual § 160.18, Vagus Nerve Stimulator for Seizures	3	1	4
NCD Manual § 160.24, Deep Brain Stimulation for Essential Tremor and Parkinson's Disease	9	4	13
Humanitarian Device Exemption†	0	2	2
<b>Total</b>	<b>48</b>	<b>58</b>	<b>106</b>
<p>* This total includes a sample item that was billed for a temporarily implanted electrode, or trial neurostimulator, but did not receive a permanent neurostimulator device during our sample period. The independent contractor reviewed the associated medical records and determined that the sample item complied with Medicare requirements.</p> <p>† The devices were categorized by FDA as Humanitarian Device Exemptions subject to 21 CFR part 814, subpart H, for rare conditions or rare subsets of common conditions.</p>			

For beneficiaries who had neurostimulator implantation surgeries due to chronic pain (authorized by NCD § 160.7), the following types of documentation were missing from the medical records:

- documentation that other treatment modalities have been tried and did not prove satisfactory or were judged to be unsuitable or contraindicated for the patient (7 beneficiaries),
- documentation that the patient underwent a multidisciplinary screening (2 beneficiaries),
- documentation that the multidisciplinary screening included a psychological evaluation (34 beneficiaries), and
- documentation that the patient demonstrated pain relief with a temporarily implanted electrode prior to permanent implantation (8 beneficiaries).<sup>16</sup>

<sup>16</sup> Because some beneficiaries had multiple types of missing documentation, the number of beneficiaries in this list is greater than our total of 36.

For beneficiaries who had neurostimulator implantation surgeries due to seizures (authorized by NCD § 160.18), the following types of documentation were missing from the medical records:

- documentation that the patient did not have medically refractory partial onset seizures with failed or not recommended surgery (2 beneficiaries) and
- documentation that the claim included a diagnosis code listed in the *Medicare Claims Processing Manual* as required (1 beneficiary).

For beneficiaries who had neurostimulator implantation surgeries due to Parkinson's disease or essential tremor (authorized by NCD § 160.24), the following types of documentation were missing from the medical records:

- documentation that the diagnosis was based on kinetic tremors of the hands without other neurologic signs or a diagnosis of idiopathic Parkinson's disease (1 beneficiary),
- documentation of a marked disabling tremor on an appropriate scale (3 beneficiaries), and
- documentation of advanced idiopathic Parkinson's disease using an appropriate scale (7 beneficiaries).<sup>17</sup>

#### **A Representative Example of Insufficient Documentation**

A beneficiary had a neurostimulator implanted for the treatment of chronic pain in 2016. Medicare reimbursed the provider \$22,139 for the neurostimulator implantation surgery. The beneficiary paid \$1,288 in copayments for the surgery. The independent contractor determined that the beneficiary's medical record did not contain the following items as required: (1) documentation that supported that other treatments had been tried and failed or were contraindicated, (2) documentation that a psychological evaluation of the beneficiary had been conducted, and (3) documentation that a trial neurostimulator had been used with demonstrated pain relief. The provider was given numerous opportunities to supply the missing documentation but did not provide it. Therefore, we determined the Medicare payment of \$22,139 and the beneficiary's copayment of \$1,288 were unallowable.

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<sup>17</sup> Because some beneficiaries had multiple types of missing documentation, the number of beneficiaries in this list is greater than our total of nine.

At the time of this audit's publication, these overpayments include some claims that are outside the 4-year period for reopening for good cause (the 4-year reopening period).<sup>18</sup> Notwithstanding, providers can request that a Medicare contractor reopen those claims for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period.

## CONCLUSION

These unallowable payments occurred because providers did not include sufficient documentation in the medical records to support that Medicare coverage requirements were met. Additionally, in some limited instances providers stated that they did not fully understand these Medicare coverage requirements. Furthermore, claims for neurostimulator implantation surgeries did not require prior authorization and are not subject to prepayment review, and there is currently no edit in the CMS software that could initiate such a review. On the basis of our sample results, we estimated that providers received \$636,498,547 in unallowable Medicare payments and beneficiaries paid \$54,041,129 in related unnecessary coinsurance amounts.

After the completion of our fieldwork, CMS published a final rule that requires prior authorizations for implanted spinal neurostimulators effective for services provided on or after July 1, 2021.<sup>19</sup> This final rule does not include claims for neurostimulator implantation surgeries for Parkinson's disease or seizure disorders. We believe CMS should take immediate action to address the high error rate associated with provider claims for neurostimulator implantation surgeries because of the significant financial impact these claims have on the Medicare Trust Funds and Medicare beneficiaries.

## RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services instruct the Medicare contractors to:

- recover the portion of the \$1,205,654 in identified Medicare potential overpayments from the 46 providers for the 54 incorrectly billed claims attributed to 48 sampled beneficiaries that are within the 4-year reopening period;
- instruct the 46 providers identified with the 54 incorrectly billed claims to refund \$115,206 in coinsurance amounts that have been incorrectly collected from the 48 sampled beneficiaries, or from someone on their behalf, for claims within the 4-year reopening period;

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<sup>18</sup> 42 CFR §§ 405.980(b)(2) and 405.980(c)(2).

<sup>19</sup> 85 Fed. Reg. 85866, 86248, and 86303 (Dec. 29, 2020) (revising 42 CFR § 419.83(a)).

- determine which of the remaining 58,107 claims in our sampling frame were incorrectly billed, recover the portion of the estimated \$636,498,597 in potential Medicare overpayments that are within the 4-year reopening period, and instruct the providers identified with the incorrectly billed claims to refund \$54,041,129 in beneficiary coinsurance amounts; and
- based on the results of this audit, notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments), so they can 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.

We also recommend that the Centers for Medicare & Medicaid Services:

- conduct provider outreach and education regarding the Medicare coverage requirements for neurostimulator implantation surgeries and
- require prior authorization for neurostimulator implantation surgeries for Parkinson's disease and seizure disorders.

#### **CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, CMS concurred with our recommendations and provided details about the actions it has taken or plans to take. CMS said that it uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system and prepayment and postpayment medical reviews.

To address the recommendations, CMS said that it will:

- direct the MACs to recover overpayments made to providers and refund any deductible or coinsurance amount paid by beneficiaries,
- review the sampling frame for potential overpayments that occurred during the 4-year reopening period, and
- analyze OIG's data to determine which providers may have received an overpayment, then have the MACs contact these providers and track any returned overpayments made in accordance with the 60-day rule.

CMS stated that it has educated providers about the new prior authorization requirement through a Medicare Learning Network (MLN) newsletter in June 2021 to coincide with the timing of the effective date of that rule on June 1. CMS said that it will also continue to conduct

provider outreach and education regarding the Medicare coverage requirements for neurostimulator implantation surgeries through various channels including the MLN. Lastly, CMS said that it will review the impact of the new prior authorization requirement but that its prior authorization authority does not extend to inpatient services, such as implantation surgeries for Parkinson's disease and seizure disorders.

CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix F.

We acknowledge the significant number of actions CMS has taken or plans to take to improve the claims processing controls for preventing and detecting overpayments for neurostimulator implantation surgeries. Also, by requiring prior authorization, CMS helps ensure that applicable coverage, payment, and coding requirements are met before the services are rendered. However, CMS's inability to implement this control for inpatient claims, such as those for patients with Parkinson's disease or seizure disorders, leaves this area vulnerable to future overpayments.<sup>20</sup>

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<sup>20</sup> Our recommendation specifically referred to neurostimulator implantation surgeries with neurostimulator defined as a battery-powered electronic device enclosed in a small metal container that is surgically implanted under a patient's skin and connected to wires called leads. The neurostimulator sends low levels of electrical energy through the leads to nerve fibers. (See appendix E for a glossary of terms.) CMS billing procedures state that implantation of the pulse generator, or neurostimulator, is allowed as an outpatient procedure, and the implantation of the electrodes currently must be performed as an inpatient procedure.



## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$1.4 billion in Medicare payments to providers for 58,213 beneficiaries who had received at least one neurostimulator implantation surgery during calendar years 2016 and 2017 (audit period). We reviewed Medicare claims for beneficiaries who received neurostimulator implants indicated with HCPCS codes 61885, 61886, and 63685 during our audit period to determine whether the procedures complied with Medicare coverage requirements. We reviewed hospital claims with paid amounts greater than \$1,000 (per claim) and that were not included in a previous or ongoing audit.<sup>21</sup> Our sampling frame consisted of 44,812 outpatient hospital claims and 16,313 Part B ambulatory surgery center (ASC) claims for a total of 61,125 claims with a Medicare paid amount of approximately \$1.4 billion.

Our audit objective did not require an understanding or assessment of CMS's complete internal control structure. We limited our review of internal controls to obtaining an understanding of the controls that CMS had in place to ensure the accuracy of the payments.

We conducted our audit from December 2018 to June 2021.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- requested and obtained from FDA the MDR records and other information associated with adverse events and product problems involving neurostimulators during the period January 1, 2010, through June 1, 2019;<sup>22</sup>
- analyzed the MDR records and other information received from FDA to identify safety issues associated with excessive multiple neurostimulator implantation surgeries caused by premature battery depletion;
- obtained from the CMS National Claims History file all paid Medicare outpatient hospital and Part B ASC claims that: (1) included HCPCS code 61885, 61886, or 63685 and a line

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<sup>21</sup> For outpatient hospital claims, we included claims with paid amounts greater than \$1,000. For ASC claims, we included claims in which the line item containing the desired HCPCS code had a provider payment amount greater than \$1,000. In addition, we checked with CMS's Recovery Audit Contractor to ensure that these claims were not subject to a previous or ongoing audit.

<sup>22</sup> We requested information for a time period greater than our audit scope so that we could review the history of adverse events for a time period similar to the time period for which CMS had noted an increase in neurostimulator implantation surgeries to see if there was a trend.

provider payment amount greater than \$1,000, (2) was not included in a previous or ongoing audit, and (3) had dates of service during the period January 1, 2016, through December 31, 2017;

- created our sampling frame by grouping the 61,125 Medicare claims by unique beneficiary identification number to get 58,213 beneficiaries;
- selected a stratified random sample of 106 beneficiaries from our sampling frame (see Appendix B);
- requested and obtained from providers the medical records associated with the 106 sampled beneficiaries' surgeries;<sup>23</sup>
- analyzed the medical records received from providers noting the brand of neurostimulator provided, whether or not the neurostimulator was rechargeable, and the physician who conducted the surgery;
- submitted the medical records for all 106 sampled beneficiaries to an independent contractor;
- requested any additional provider documentation required by the independent contractor to complete its review;
- reviewed the independent contractor's determination letters to ensure accuracy and consistency as well as to determine how much, if any, of the total amount Medicare paid for each neurostimulator claim was unallowable;
- estimated the dollar amount of overpayments CMS made for Medicare claims for neurostimulator implantation surgeries and the dollar amount of beneficiary coinsurance associated with these overpayments; and
- discussed the results of the audit with CMS officials.

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.

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<sup>23</sup> For some sample items, during the process of obtaining these records either over the phone or via email, providers expressed confusion regarding the regulations. We documented when this happened as well as the person we spoke with at the facility. We did not explicitly ask providers or medical professionals about the regulations.

## APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

Our target population for this audit was paid Medicare Part B outpatient hospital and ASC claims with dates of service in calendar years 2016 and 2017 for neurostimulator implants.

The sampling frame consisted of 61,125 outpatient hospital and ASC claims with payments totaling \$1,407,297,242. It included services with dates of service during the period January 1, 2016, through December 31, 2017, billed with one of three HCPCS codes (61885, 61886, and 63685), paid amounts greater than \$1,000,<sup>24</sup> and claims which were not identified within the Recovery Audit Contractor Data Warehouse as having been included in a previous or ongoing audit.

### SAMPLE UNIT

The sample unit was a beneficiary.

### SAMPLE DESIGN AND SAMPLE SIZE

Our sample design was a stratified random sample containing six strata as follows:

Stratum	Dollar Range of Stratum	Number of Beneficiaries	Sample Size	Dollar Value of Medicare Payments
1	\$1,004–\$23,995	32,733	47	\$663,682,169
2	\$24,001– \$117,844	22,709	43	\$618,040,014
3	\$5,119–\$108,114	2,755	8	\$124,360,441
4	\$8,072–\$27,812	10	2	\$338,317
5	\$121,309–\$175,638	5	5	\$761,779
6	No Range	1	1	\$114,522
<b>Total</b>		<b>58,213</b>	<b>106</b>	<b>\$1,407,297,242</b>

### SOURCE OF THE RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General (OIG), Office of Audit Services (OAS) statistical software.

### METHOD OF SELECTING SAMPLE ITEMS

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<sup>24</sup> For outpatient hospital claims, we included claims with paid amounts greater than \$1,000. For ASC claims, we included claims in which the line item containing the desired HCPCS code had a provider payment amount greater than \$1,000.

We consecutively numbered the frame items from 1 to 32,733 for stratum 1, 1 to 22,709 for stratum 2, 1 to 2,755 for stratum 3, and 1 to 10 for stratum 4. After generating random numbers for each of these strata, we selected the corresponding frame items for review. We also selected all frame items in strata 5 and 6.

## **ESTIMATION METHODOLOGY**

We used the OIG, OAS statistical software to estimate the dollar value of overpayments made by CMS and beneficiaries for Medicare claims for neurostimulator implantation surgeries as well as replacement devices. Estimates are contained in Appendix C.

## APPENDIX C: SAMPLE RESULTS AND ESTIMATES

### SAMPLE RESULTS

#### Sample Items With Incorrectly Billed Claims—Medicare Payments

Stratum	Frame Size (Beneficiaries)	Value of Medicare Payments in Frame	Sample Size	Value of Medicare Payments in Sample	Number of Beneficiaries With Incorrectly Billed Claims	Value of Overpayments by Medicare in Sample
1	32,733	\$663,682,169	47	\$968,345	25	\$490,730
2	22,709	618,040,014	43	1,157,504	20	535,232
3	2,755	124,360,441	8	349,180	1	34,258
4	10	338,317	2	79,932	1	30,912
5	5	761,779	5	761,779	0	0
6	1	114,522	1	114,522	1	114,522
<b>Totals</b>	<b>58,213</b>	<b>\$1,407,297,242</b>	<b>106</b>	<b>\$3,431,262</b>	<b>48</b>	<b>\$1,205,654</b>

#### Sample Items With Incorrectly Billed Claims—Beneficiary Coinsurance

Stratum	Frame Size (Beneficiaries)	Value of Beneficiary Coinsurance in Frame	Sample Size	Value of Beneficiary Coinsurance in Sample	Number of Beneficiaries With Incorrectly Billed Claims	Value of Overpayments by Beneficiaries in Sample
1	32,733	\$77,343,438	47	\$102,375	25	\$51,816
2	22,709	48,568,838	43	97,158	20	32,166
3	2,755	12,118,668	8	45,261	1	2,632
4	10	113,341	2	20,391	1	7,886
5	5	13,589	5	13,589	0	0
6	1	20,706	1	20,706	1	20,706
<b>Totals*</b>	<b>58,213</b>	<b>\$138,178,580</b>	<b>106</b>	<b>\$299,479</b>	<b>48</b>	<b>\$115,206</b>

\*Numbers may not add up precisely due to rounding.

### ESTIMATES

#### Estimated Value of Overpayments for Incorrectly Billed Claims in the Sampling Frame (Limits Calculated at the 90-Percent Confidence Level)

	<u>Medicare Payments</u>	<u>Beneficiary Coinsurance</u>
Point Estimate	\$636,498,547	\$54,041,129

Lower Limit	\$522,294,038	\$40,896,543
Upper Limit	\$750,703,056	\$67,185,715

#### **APPENDIX D: NATIONAL COVERAGE DECISIONS RELATED TO NEUROSTIMULATORS**

##### **NCD Manual, chapter 1, part 2, § 160.2, Treatment of Motor Function Disorders with Electric Nerve Stimulation**

The NCD indicates that while electric nerve stimulation has been employed to control chronic intractable pain for some time, its use in the treatment of motor function disorders, such as multiple sclerosis, is a recent innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no Medicare payment may be made for the stimulator or for the services related.

##### **NCD Manual, chapter 1, part 2, § 160.7(B)(2), Electrical Nerve Stimulators**

The NCD indicates that no payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all the conditions listed below have been met:

- The implantation of the stimulator is used only as a late resort (if not last resort) for patients with chronic intractable pain.
- With respect to the first condition, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory or are judged to be unsuitable or contraindicated for the given patient.
- Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation (such screening must include psychological, as well as physical evaluation).
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and followup of the patient (including that required to satisfy the third condition) must be available.
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

##### **NCD Manual, chapter 1, part 2, § 160.18 (B) and (C), Vagus Nerve Stimulation**

The NCD indicates that VNS is reasonable and necessary for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.

VNS is not reasonable and necessary for all other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.<sup>25</sup>

**NCD Manual, chapter 1, part 2 § 160.24, Deep Brain Stimulation for Essential Tremor and Parkinson's Disease**

This NCD indicates that Medicare will cover unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation for the treatment of essential tremor and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus or globus pallidus interna (GPi) deep brain stimulation for the treatment of Parkinson's disease if conditions are met. Devices will be considered reasonable and necessary if they are FDA-approved devices for deep brain stimulation or devices used in accordance with FDA-approved protocols governing Category B IDE deep brain stimulation clinical trials.

For thalamic VIM deep brain stimulation to be considered reasonable and necessary, patients must: (1) be diagnosed with essential tremor based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson's disease (presents of at least two cardinal Parkinson's disease features (tremor, rigidity, or bradykinesia)) which is of a tremor-dominant form; (2) have a marked disabling tremor of at least three or four on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy; and (3) be willing and able to cooperate during conscious operative procedure, as well as during postsurgical evaluations and adjustments of medications and stimulator settings.

For subthalamic nucleus or GPi deep brain stimulation to be considered reasonable and necessary, patients must: (1) be diagnosed with Parkinson's disease based on the presence of at least two cardinal Parkinson's disease features (tremor, rigidity, or bradykinesia); (2) have advanced idiopathic Parkinson's disease as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale part III motor subscale; (3) be L-dopa responsive with clearly defined "on" periods; (4) have persistent disabling Parkinson's disease symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy; and (5) be willing and able to cooperate during conscious operative procedure, as well as during postsurgical evaluations and adjustments of medications and stimulator settings.

Deep brain stimulation is not reasonable and necessary and is not covered for essential tremor or Parkinson's disease patients with any of the following: (1) nonidiopathic Parkinson's disease or "Parkinson's Plus" syndromes; (2) cognitive impairment, dementia or depression which

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<sup>25</sup> Effective for services performed on or after February 15, 2019, Medicare will cover FDA-approved VNS devices for treatment resistant depression through Coverage with Evidence Development when offered in a CMS-approved trial that meets certain requirements. As this became effective after the end of our audit period and we did not have any claims involving treatment-resistant depression, we did not consider this criterion during our audit.

would be worsened by or would interfere with the patient's ability to benefit from deep brain stimulation; (3) current psychosis, alcohol abuse or other drug abuse; (4) structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder; (5) previous movement disorder surgery within the affected basal ganglion; and (6) significant medical, surgical, or neurologic orthopedic comorbidities contraindicating deep brain stimulation surgery or stimulation.



## APPENDIX E: GLOSSARY OF TERMS<sup>26</sup>

**adverse event:** Defined by the FDA as any undesirable experience associate with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is: death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly or birth defect, required intervention to prevent permanent impairment or damage, or other serious events that may not fit the other outcomes but may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes.

**deep brain stimulator:** A device that uses implanted electrodes and electrical stimulation to treat movement disorders associated with Parkinson’s disease, essential tremor, dystonia, and other neurological conditions. The device is implanted under the person’s collarbone and connected to leads implanted inside the brain where continuous pulses of electric current from the neurostimulator pass through the leads and into the brain.

**device user facility:** Defined by FDA as a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician’s office.

**dystonia:** A disorder that affects the way the body moves. It causes the muscles to contract, which makes them move involuntarily or get stuck in an abnormal position. Dystonia can affect the entire body or a certain part, and the movements can sometimes cause pain.

**essential tremor:** A neurological condition that causes the hands to shake rhythmically. The head, trunk, and voice might also be involved, but hand shaking is most prominent. The cause is not known, but it is often passed down from a parent to a child.

**generator:** The part of the neurostimulator that contains the battery and device information.

**lead:** Also known as an electrode, a part of a neurostimulator that connects the generator to the nerve or nerves that are being stimulated.

**malfunction:** Defined by FDA as the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.

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<sup>26</sup> The terms and definitions in this glossary come from various sources, including Federal regulations, CMS guidance, and publications for medical professionals. They may not be universally the same across all sources. The terms and definitions expressed here are for the purposes of this report only.

**neurostimulator:** A battery-powered electronic device enclosed in a small metal container that is surgically implanted under a patient's skin and connected to wires called leads. It sends low levels of electrical energy through the leads to nerve fibers.

**obsessive-compulsive disorder:** A common anxiety disorder. It causes unreasonable thoughts, fears, or worries. A person with obsessive-compulsive disorder tries to manage these thoughts through rituals.

**Parkinson's disease:** A progressive, neurodegenerative disorder, typically affecting people older than 65 years of age, that gradually strips away motor abilities and may cause a slow and awkward gait, rigid limbs, tremor, shuffling, and a lack of balance.

**postmarket surveillance:** A system that monitors devices after they have been approved by FDA and are on the market for use by physicians. It includes requirements and regulations such as tracking systems; reporting of device malfunctions, serious injuries, or deaths; and registering the establishments where devices are produced or distributed.

**provider:** Under 42 CFR § 400.202, *provider* means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services. *Supplier* means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare. For our audit, we use the term *provider* to refer to both providers and suppliers to include hospitals and ambulatory service centers.

**serious injury:** Defined by FDA as an injury or illness that: (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

**spinal cord stimulator:** An implanted device that sends low levels of electricity directly into the spinal cord to relieve pain. It consists of thin wires called electrodes placed between the spinal cord and the vertebrae and a generator placed usually near the buttocks or abdomen.

**vagus nerve:** Also known as the tenth cranial nerve that transmits information to or from the surface of the brain to tissues and organs in the body. It is responsible for the digestive tract, respiration, and heart rate functioning as well as sensory and motor functions in the throat, heart, lungs, and abdomen.

**vagus nerve stimulator:** A device used to interrupt disorganized electrical signals that bring on seizures. It consists of a pulse generator implanted in the chest that creates low-energy electrical signals and leads that carry those signals to the vagus nerve.

## APPENDIX F: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES


Centers for Medicare & Medicaid Services

*Administrator*

Washington, DC 20201

**DATE:** August 4, 2021

**TO:** Christi A. Grimm  
Principal Deputy Inspector General  
Office of Inspector General

**FROM:**   
Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services

**SUBJECT:** The Office of Inspector General (OIG) Draft Report: Medicare Overpaid More Than \$636 Million for Neurostimulator Implantation Surgeries (A-01-18-00500)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS recognizes the importance of providing Medicare beneficiaries with access to medically necessary services, and, at the same time, working to prevent improper payments. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system and prepayment and postpayment medical reviews. During the OIG's audit period of calendar years (CY) 2016 and 2017, claims for neurostimulator implantation surgeries were not subject to prepayment review and did not require prior authorization. Prior authorization ensures that applicable coverage, payment, and coding requirements are met before services are rendered. As part of CMS's responsibility to protect the Medicare Trust Funds, CMS continually analyzes data to determine if there are outpatient services that are exhibiting unnecessary increases in volume for which prior authorization would be appropriate. As a result of this analysis, CMS began requiring prior authorization for implanted spinal neurostimulators for dates of service on or after July 1, 2021, per the CY 2021 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule.<sup>1</sup>

Additionally, CMS has taken action to prevent improper Medicare payments by educating health care physicians and nonphysician practitioners on proper billing. CMS educates health care providers on Medicare billing through various channels including the Medicare Learning Network (MLN), weekly electronic newsletters, and quarterly compliance newsletters. Accordingly, CMS released a MLN Connects Newsletter Message to providers on June 10, 2021, reminding providers of the new prior authorization requirement set to begin on July 1, 2021.<sup>2</sup> Additionally, CMS released guidance to the Medicare Administrative Contractors (MACs) to conduct provider education about this new requirement.<sup>3</sup> CMS is also exploring opportunities to improve claim

<sup>1</sup> CY 2021 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule. <https://www.cms.gov/files/document/12220-opps-final-rule-cms-1736-fc.pdf>

<sup>2</sup> MLN Connects Newsletter Message. [https://www.cms.gov/outreach-and-education/outreachffsprovpartprogprovider-partnership-email-archive/2021-06-10-mlnc#\\_Toc74047354](https://www.cms.gov/outreach-and-education/outreachffsprovpartprogprovider-partnership-email-archive/2021-06-10-mlnc#_Toc74047354)

<sup>3</sup> Change Request 12214. <https://www.cms.gov/files/document/r10720otn.pdf>

processing controls to prevent and detect the types of overpayments identified in the OIG's audit in the future and will provide any relevant provider education to further address the issues the OIG identified moving forward.

OIG's recommendations and CMS' responses are below.

#### **OIG Recommendation**

We recommend that CMS instruct the Medicare contractors to recover the portion of the \$1,205,654 in identified Medicare potential overpayments from the 46 providers for the 54 incorrectly billed claims attributed to 48 sampled beneficiaries that are within the 4-year reopening period.

#### **CMS Response**

CMS concurs with OIG's recommendation. CMS will direct its MACs to recover the identified overpayments consistent with relevant law and the agency's policies and procedures.

#### **OIG Recommendation**

We recommend that CMS instruct the 46 providers identified with the 54 incorrectly billed claims to refund \$115,206 in coinsurance amounts that have been incorrectly collected from the 48 sampled beneficiaries, or from someone on their behalf, for claims within the 4-year reopening period.

#### **CMS Response**

CMS concurs with OIG's recommendation. CMS will instruct its Medicare Administrative Contractors to recover the identified overpayments consistent with relevant law and the agency's policies and procedures. As part of this process, the Medicare Administrative Contractors will instruct providers to refund any deductible or coinsurance amounts that may have been incorrectly collected from beneficiaries or from someone on their behalf.

#### **OIG Recommendation**

We recommend that CMS instruct the Medicare contractors to determine which of the remaining 58,107 claims in our sampling frame were incorrectly billed, recover the portion of the estimated \$636,498,597 in potential Medicare overpayments that are within the 4-year reopening period, and instruct the providers identified with the incorrectly billed claims to refund \$54,041,129 in beneficiary coinsurance amounts.

#### **CMS Response**

CMS concurs with OIG's recommendation. CMS will review the OIG's sampling frame and determine if any additional review is possible considering the 4-year reopening period. If CMS notes the claims in the sampling frame to be beyond the 4-year reopening period, CMS will conduct reviews on providers included in the sampling frame with more recent timeframes.

#### **OIG Recommendation**

We recommend that CMS instruct the Medicare contractors to, based on the results of this audit, notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments), so they can 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.

**CMS Response**

CMS concurs with OIG's recommendation. CMS will analyze the OIG's data to identify appropriate providers to notify of potential overpayments. Within CMS's policies and procedures, CMS will then instruct its MACs to notify the identified providers of OIG's audit findings. CMS will track any returned overpayments made in accordance with this recommendation and the 60-day rule.

**OIG Recommendation**

We recommend that CMS conduct provider outreach and education regarding the Medicare coverage requirements for neurostimulator implantation surgeries.

**CMS Response**

CMS concurs with OIG's recommendation. As stated above, in June 2021, CMS educated providers about the new prior authorization requirement through a MLN Newsletter Message and directed the MACs to conduct further education to providers. CMS will continue to conduct provider outreach and education regarding the Medicare coverage requirements for neurostimulator implantation surgeries through various channels including the MLN, weekly electronic newsletters, and quarterly compliance newsletters.

**OIG Recommendation**

We recommend that CMS evaluate the impact of its new prior authorization requirement and, if appropriate, consider extending the requirement to neurostimulator implantation surgeries for Parkinson's disease and seizure disorders.

**CMS Response**

CMS concurs with OIG's recommendation. CMS will review the impact of the new prior authorization requirement. However, regarding neurostimulator implantation surgeries for Parkinson's disease and seizure disorders, these surgeries are currently on the inpatient only list. CMS's prior authorization authority does not extend to inpatient services.