Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS NEEDS TO STRENGTHEN REGULATORY REQUIREMENTS FOR MEDICARE PART B OUTPATIENT CARDIAC AND PULMONARY REHABILITATION SERVICES TO ENSURE PROVIDERS FULLY MEET COVERAGE REQUIREMENTS

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Office of Inspector General

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

CMS Needs to Strengthen Regulatory Requirements for Medicare Part B Outpatient Cardiac and Pulmonary Rehabilitation Services to Ensure Providers Fully Meet Coverage Requirements

Why OIG Did This Audit

Previous OIG work identified Medicare claims for cardiac and pulmonary rehabilitation services that did not comply with Federal requirements. Preliminary work reviewing one provider's compliance identified broader, significant concerns with Centers for Medicare & Medicaid Services (CMS) regulations; therefore, we determined that an audit of CMS's Medicare cardiac and pulmonary rehabilitation programs could identify potential areas for improvement and reduce provider errors as well as result in monetary savings.

Our objective was to determine whether CMS regulatory requirements contained sufficient information to ensure that claims for outpatient cardiac and pulmonary rehabilitation services complied with Medicare coverage requirements.

How OIG Did This Audit

We selected for review the third highest-paid provider in the country in combined Medicare reimbursement for both outpatient cardiac and pulmonary rehabilitation services. We reviewed a random sample of 100 beneficiary-days. We submitted 10 beneficiary-days to an independent medical review contractor and evaluated all 100 beneficiary-days for compliance with applicable requirements and to determine whether services complied with Medicare coverage and documentation requirements.

What OIG Found

CMS regulatory requirements related to Medicare outpatient cardiac and pulmonary rehabilitation services did not contain sufficient information to ensure that claims for these services met Medicare coverage requirements. Specifically, the requirements lacked details related to what patient-specific information should be contained in a beneficiary's medical record and how this information should relate to their individualized treatment. As a result, for all 100 sampled beneficiary-days, we determined that medical record documentation obtained from the selected provider did not contain sufficient evidence to support whether Medicare coverage requirements for reimbursement of cardiac and pulmonary rehabilitation services were met. On the basis of our sample results, we estimated that $2.7 million in Medicare payments made by CMS to the selected provider for outpatient cardiac and pulmonary rehabilitation services may not have met Medicare coverage requirements, as intended. Further, based on our review, we believe that Medicare payments totaling approximately $626 million made by CMS to all providers for outpatient cardiac and pulmonary rehabilitation services during our audit period may not have met the requirements.

What OIG Recommends and CMS Comments

We recommend that CMS revise its regulations to provide sufficient guidance to ensure that providers meet coverage requirements for outpatient cardiac and pulmonary rehabilitation services.

In written comments on our draft report, CMS stated that, in March 2021, it updated subregulatory guidance in two of its manuals to more closely reflect regulatory text. CMS also stated that it will consider our recommendation when determining appropriate next steps regarding the regulations on outpatient cardiac and pulmonary rehabilitation services.

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INTRODUCTION

WHY WE DID THIS AUDIT

Previous Office of Inspector General (OIG) work identified Medicare claims for cardiac and pulmonary rehabilitation services that did not comply with Federal requirements.[1] In addition, a Medicare Administrative Contractor conducted reviews of cardiac and pulmonary rehabilitation services that identified significant errors related to providers' documentation supporting the medical necessity of these services.[2] Based on these findings, we determined that audits of providers' compliance with Medicare requirements were warranted. Preliminary work reviewing one provider's compliance identified broader, significant concerns with Centers for Medicare & Medicaid Services (CMS) regulations; therefore, we determined that an audit of CMS's Medicare cardiac and pulmonary rehabilitation programs could identify potential areas for improvement and reduce provider errors as well as result in monetary savings.

OBJECTIVE

Our objective was to determine whether CMS regulatory requirements contained sufficient information to ensure that claims for outpatient cardiac and pulmonary rehabilitation services complied with Medicare coverage requirements.

BACKGROUND

The Medicare Program

The Medicare program, established by Title XVIII of the Social Security Act (the Act), provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the Medicare program.

Medicare Part B provides supplementary medical insurance for medical and other health services, including outpatient cardiac and pulmonary rehabilitation services. CMS contracts with Medicare contractors to process and pay Part B claims. Federal law precludes payment to any provider of Medicare services or other person without information necessary to determine the amount due the provider.[3]

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[1] *Englewood Hospital and Medical Center Claimed Unallowable Medicare Part B Reimbursement for Outpatient Cardiac and Pulmonary Rehabilitation Services* (A-02-14-01013) December 9, 2015.

[2] CGS Administrators, LLC, "Outpatient Services for Pulmonary Rehabilitation (HCPCS G0424) – Ohio – Discontinued" and "Cardiac Rehabilitation (HCPCS Code 93798): Complex Medical Review – Kentucky and Ohio--Continue." Available online at https://www.cgsmedicare.com/parta/pubs/news/2014/0714/cope26189.html and https://www.cgsmedicare.com/parta/pubs/news/2017/08/cope4121e.html. Accessed on August 24, 2020.

[3] Section 1833(e) of the Social Security Act. (the Act).

Medicare Part B provides for coverage of items and services furnished under cardiac and pulmonary rehabilitation programs (sections 1832(a), 1861(s)(2)(CC), (eee)(1), and (fff)(1) of the Act).[4] For these services to be covered, they must be medically necessary, include an individualized treatment plan, a physician-prescribed exercise (i.e., activity), and a psychosocial assessment.

Cardiac and Intensive Cardiac Rehabilitation Program

The standard of care prior to widespread adoption of cardiac rehabilitation was bedrest and inactivity after heart attacks. In the 1970s, cardiac rehabilitation developed into highly structured, physician-supervised, electrographically monitored[5] exercise programs that consisted almost solely of exercise. Over subsequent years, cardiac rehabilitation was expanded to include lifestyle changes such as lowering blood pressure, reducing stress, smoking cessation, diet change, and weight loss.

Currently, cardiac rehabilitation is a physician-supervised program intended to help people recover from heart attacks, heart surgery, and percutaneous coronary intervention[6] procedures such as stenting and angioplasty. Cardiac rehabilitation programs provide, among other things, education and counseling services to help beneficiaries increase physical fitness, reduce cardiac symptoms, improve health, and reduce the risk of future heart problems, including heart attack. For cardiac patients requiring more frequent services, intensive cardiac rehabilitation provides a physician-supervised program that furnishes oftentimes more rigorous cardiac rehabilitation services.

Pulmonary Rehabilitation Program

Pulmonary rehabilitation began in 1999 as a program of care for patients with chronic respiratory impairment. The program is individually tailored and designed to optimize an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Similar to the goals of the cardiac and intensive cardiac rehabilitation programs, the main goal of the pulmonary rehabilitation program is to empower and facilitate the ability of beneficiaries to exercise independently.[7] Exercise is combined with other training and support mechanisms to encourage long-term adherence to a treatment plan.

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[4] 42 CFR §§ 410.47 and 410.49. CMS provides additional guidance clarifying the Medicare requirements for outpatient cardiac and pulmonary rehabilitation services in chapter 15 of CMS's *Medicare Benefit Policy Manual* (Pub. 100-02) and in chapter 32 of its *Medicare Claims Processing Manual* (Pub. 100-04).

[5] Electrocardiographic recordings are used to diagnose a wide range of heart disease and other conditions that manifest themselves by abnormal cardiac electrical activity.

[6] This is a non-surgical procedure that uses a catheter (a thin flexible tube) to place a small structure called a stent to open blood vessels in the heart.

[7] 74 Federal Register 61738, 61880 (Nov. 25, 2009).

HOW WE CONDUCTED THIS AUDIT

We selected for review the third highest-paid provider in the country in combined Medicare reimbursement for both outpatient cardiac and pulmonary rehabilitation services during the period April 2016 through March 2018 (audit period).[8] Our audit covered $2,741,884 in Medicare payments made to the selected provider for 26,408 beneficiary-days[9] of outpatient cardiac and pulmonary rehabilitation services.

We selected a random sample of 100 beneficiary-days.[10] We submitted documentation related to the first 10 sampled beneficiary-days to an independent medical review contractor to assess whether services were allowable in accordance with Medicare's medical necessity, documentation, and coding requirements. The medical review contractor identified issues with all 10 sampled beneficiary-days. We then reviewed the remaining 90 sampled beneficiary-days to determine whether there were issues with documentation similar to those identified by the independent medical review contractor.

After discussing our preliminary findings with the independent medical review contractor and CMS, we shifted the focus of our audit from the provider to CMS. Specifically, we found that although the provider generally complied with Medicare coverage requirements, it did not meet the intent of the requirements. Therefore, we determined that the larger issue was whether CMS's regulatory requirements were sufficient to ensure providers complied with the intent of the Medicare coverage requirements.

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 the details of our audit scope and methodology, Appendix B contains our statistical sampling methodology, Appendix C contains our sample results and estimates, and Appendix D contains our summary of errors for each sampled beneficiary-day.

[8] The selected provider was a hospital located in Florida. The top two highest-paid providers did not provide any pulmonary rehabilitation services during the audit period.

[9] For the purpose of this audit, a "beneficiary-day" is defined as all cardiac and pulmonary rehabilitation services provided to a beneficiary during 1 day.

[10] The 100 sampled beneficiary-days were composed of 74 beneficiary-days for cardiac rehabilitation, 10 beneficiary-days for intensive cardiac rehabilitation, and 16 beneficiary-days for pulmonary rehabilitation.

FINDINGS

CMS regulatory requirements related to Medicare outpatient cardiac and pulmonary rehabilitation services did not contain sufficient information to ensure that claims for these services met Medicare coverage requirements. Specifically, the requirements lacked details related to what patient-specific information should be contained in a beneficiary's medical record and how this information should relate to their individualized treatment. As a result, for all 100 sampled beneficiary-days, we determined that medical record documentation obtained from the selected provider did not contain sufficient evidence to support whether Medicare coverage requirements for reimbursement of cardiac and pulmonary rehabilitation services were met.[11] Specifically, we determined that:

- For all 100 sampled beneficiary-days, individualized treatment plans were incomplete or missing essential content.

- For 75 sampled beneficiary-days, documentation did not support that an adequate psychosocial assessment was performed.

- For 61 sampled beneficiary-days, the beneficiary's individualized treatment plan did not indicate that education and counseling services were tailored to meet the associated beneficiary's specific needs.

We note that CMS's requirements related to cardiac and pulmonary rehabilitations services generally present many complexities and differ from requirements for other Medicare-eligible services in that they do not include enough details related to what providers must document in beneficiaries' medical records.

CMS REQUIREMENTS WERE NOT SUFFICIENT

CMS requirements for providers regarding Medicare conditions of coverage were not sufficient to ensure providers maintained adequate evidence in beneficiaries' medical records. As a result, the selected provider may not have clearly understood what documentation was necessary to provide evidence—from a medical perspective—that Medicare coverage requirements were met. Subsequently, the insufficient CMS requirements could result in Medicare payments being made by CMS to <u>all</u> providers for outpatient cardiac and pulmonary rehabilitation services that may not have fully met the requirements. Medicare paid $626 million for these services.[12]

[11] The total exceeds 100 because 80 beneficiary-days contained multiple errors.

[12] The total paid was $626,032,892.

Requirements Lacked Detail to Ensure That Individualized Treatment Plans Were Complete and Contained Essential Content

Federal regulations describe cardiac, intensive cardiac, and pulmonary rehabilitation programs as physician-supervised programs that furnish rehabilitation for beneficiaries with cardiac and pulmonary disease (42 CFR §§ 410.49 and 410.47).

Cardiac and intensive cardiac rehabilitation programs must include a written individualized treatment plan that must be established, reviewed, and signed by a physician every 30 days (42 CFR § 410.49). Similarly, pulmonary rehabilitation programs must include an individualized treatment plan that must be established, reviewed, and signed every 30 days by a physician involved in the beneficiary's care and who has knowledge related to the beneficiary's condition (42 CFR § 410.47). For each of these rehabilitation programs, the individualized treatment plans must describe (1) the beneficiary's diagnosis; (2) the type, amount, frequency, and duration of the items and services under the plan; and (3) the goals set for the individual under the plan.

Cardiac and intensive cardiac rehabilitation programs must include physician-prescribed exercise, including aerobic exercise combined with other types of exercise (e.g., stretching) as determined to be appropriate (42 CFR § 410.49). Pulmonary rehabilitation programs must include physician-prescribed and supervised exercise, including techniques such as exercise conditioning, breathing retraining, step, and strengthening exercises. Some aerobic exercise must be included in each pulmonary rehabilitation session (42 CFR § 410.47).

CMS requirements lacked enough information and detail to ensure providers maintained sufficient evidence of compliance with Medicare coverage requirements. Specifically, the requirements do not clearly explain what providers are required to document in an individualized treatment plan to ensure that a beneficiary's specific medical needs are adequately addressed. For all 100 sampled beneficiary-days, the medical record documentation contained an individualized treatment plan with fillable boxes.[13] Although the plans had fillable boxes for modality, time, and intensity of exercise for rehabilitation services, they did not contain sufficient evidence—from a medical perspective—that these components were individualized for each beneficiary's specific needs and goals. Additionally, other boxes did not contain sufficient evidence that the plan was established in coordination with the beneficiary. For example, for elements such as "Family history," "Attended hypertension class," and "Medication compliance," boxes were checked or left blank. Specifically:

- **Individualized treatment plans lacked evidence of physician supervision and were not tailored to meet beneficiaries' specific medical needs.** For all 100 sampled beneficiary-days, the individualized treatment plan lacked essential detail and failed to indicate whether a physician was involved in supervising the beneficiary's care or

[13] Individual treatment plans contained boxes that were fillable and could contain either a checkmark, a number denoting frequency, or a word for the type of modality.

explain how rehabilitation program components were tailored to the beneficiary's specific medical needs. We also noted that individualized treatment plans for all 100 sampled beneficiary-days displayed similar remarks regarding the beneficiary's treatment, goals, and progress. Similar wording and standardized checkmarks were used for all 100 sampled beneficiary-days and did not detail how components were utilized for each beneficiary. In fact, goals appeared to have been derived from American College of Cardiology rehabilitation guidelines with no adaptation to individual needs, diagnosis, or functional status.[14]

- **Individualized treatment plans did not include descriptions of beneficiaries' diagnoses.** For all 100 sampled beneficiary-days, the individualized treatment plan did not contain a detailed description of the beneficiary's diagnosis to support the prescribed treatment. For 51 beneficiary-days, although a diagnosis appeared on the individual treatment plan, there was not a description of the diagnosis, as required by regulation. For the remaining 49 sampled beneficiary-days, the beneficiary's diagnosis was not indicated on the individualized treatment plan. The regulation does not describe the purpose of including the description of the diagnosis and how it is to be incorporated when developing the individualized treatment plan for a beneficiary. Without a detailed description of the diagnosis, beneficiaries may have an individualized treatment plan developed to receive services that may not have been tailored to their diagnosis.

- **Individualized treatment plans signed after date of service or not signed.** Most of the 100 sampled beneficiary-days were signed by a physician every 30 days, per CMS requirements. However, for 23 of the sampled beneficiary-days, the individualized treatment plan was established prior to the date of service but signed by a physician after the date of service.[15] Placing a beneficiary on a treatment plan prior to having the plan reviewed and signed by a physician potentially places the beneficiary's health and safety at risk.

Requirements Lacked Detail to Ensure That Documentation Supported That Adequate Psychosocial Assessments Were Performed

Cardiac and intensive cardiac rehabilitation programs must include an evaluation of a beneficiary's mental and emotional functioning as it relates to their rehabilitation, including an assessment of those aspects of a beneficiary's family and home situation that affects their rehabilitation treatment. These programs must also include a psychosocial evaluation of the beneficiary's response to and rate of progress under the treatment plan (42 CFR § 410.49).

[14] The medical review contractor noted that language in beneficiary's treatment plans mirrored language from an American College of Cardiology report.

[15] The individualized treatment plans were signed by the physician 2 to 78 days after the date of service. For example, for one sampled beneficiary-day, the date of service was January 18, 2017, and the treatment plan was signed on February 28, 2017.

Similarly, pulmonary rehabilitation programs must include an assessment of those aspects of a beneficiary's family and home situation that affects the beneficiary's rehabilitation treatment and a psychosocial evaluation of the beneficiary's response to and rate of progress under the treatment plan (42 CFR § 410.47).

CMS Medicare coverage requirements were not adequate to ensure that providers maintained sufficient evidence in beneficiaries' medical records. Specifically, the requirements do not clearly explain how to document (e.g., maintain written physician notes) that an evaluation of a beneficiary's mental and emotional status and an assessment of the beneficiary's family and home situation were conducted. As a result, the selected provider may not have clearly understood what documentation was required to support that an adequate psychosocial assessment was performed.

For 75 of the 100 sampled beneficiary-days,[16] the medical record documentation did not support—from a medical perspective—that an adequate psychosocial assessment was performed. We determined that the medical record documentation was inadequate and did not contain enough information on the beneficiary's mental and emotional functioning and aspects of their home and family situations that are crucial to planning, patient participation, and monitoring. Specifically:

- For 75 sampled beneficiary-days, a section within the individualized treatment plan titled "Psychosocial Intervention" conveyed minimal information relating to the beneficiary's mental and emotional situation and progress within the program. For 27 of these sampled beneficiary-days, the only comment noted in the section was "coping well."

- For 39 sampled beneficiary-days, the psychosocial assessment included only a numerical score related to the beneficiary's mental and emotional functioning and aspects of their home and family situations without any supporting reports or assessments. Further, the psychosocial assessment did not include details to support how the numerical score was determined or how the score factored into the beneficiary's rehabilitation services.[17]

- For 16 sampled beneficiary-days, a yes/no checkbox for "family support" was ticked without any other information. This checkbox alone lacks essential detail to explain those aspects of individuals' home and family situations that might have been important to planning, patient participation, and monitoring.

[16] The 75 sampled beneficiary-days were composed of 54 beneficiary-days for cardiac rehabilitation services, 7 beneficiary-days for intensive cardiac rehabilitation services, and 14 beneficiary-days for pulmonary rehabilitation services.

[17] The provider stated that it uses survey tools to develop numerical scores for its psychosocial assessments, including quality-of-life and depression surveys. For the 39 sampled beneficiary-days, the beneficiary's medical record included only a numerical score (i.e., not the associated surveys).

Requirements Lacked Detail to Ensure That Education and Counseling Services Were Tailored to Beneficiary's Individual Needs

Cardiac and intensive cardiac rehabilitation programs must include cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the beneficiary's individual needs (42 CFR § 410.49). Pulmonary rehabilitation programs must include education or training closely and clearly related to the beneficiary's care and treatment tailored to the beneficiary's needs. Education includes information on respiratory problem management and, if appropriate, brief smoking cessation counseling. In addition, any education or training prescribed must assist in achievement of individual goals towards independence in activities of daily living, adaptation to limitations and improved quality of life (42 CFR § 410.47).

CMS Medicare coverage requirements were not adequate to ensure that providers maintained sufficient evidence in beneficiaries' medical records. Specifically, the requirements do not clearly explain what supporting documentation must be included to ensure education and counseling services were tailored to meet the beneficiaries' needs.

For 61 of the 100 sampled beneficiary-days,[18] the medical record did not support that education and counseling services were tailored to meet the beneficiary's specific needs. Specifically, the medical record contained fillable boxes indicating whether education and counseling were provided to the beneficiary; however, the documentation did not contain an assessment indicating that the provider evaluated the beneficiary's individual needs for these services.

CONCLUSION

Cardiac, intensive cardiac, and pulmonary rehabilitation services are individually tailored to empower beneficiaries to achieve their goals towards independence in activities of daily living and improved quality of life. CMS requirements were inadequate to ensure that providers maintained sufficient documentation in beneficiaries' medical records to support that the care provided was individually tailored to their circumstances. As a result, the selected provider may not have clearly understood what patient-specific information should be contained in beneficiaries' medical records to comply with Medicare coverage requirements. Not ensuring that beneficiaries' medical records are complete (i.e., sufficient to document compliance with coverage requirements) may result in care that is not tailored to beneficiaries' medical needs, thereby placing their health and safety at risk.

[18] The 61 sampled beneficiary-days were composed of 46 beneficiary-days for cardiac rehabilitation services, 6 beneficiary-days for intensive cardiac rehabilitation services, and 9 beneficiary-days for pulmonary rehabilitation services.

On the basis of our sample results, we estimated that CMS made Medicare payments totaling $2.7 million[19] to the selected provider for outpatient cardiac and pulmonary rehabilitation services that may not have met Medicare coverage requirements, as intended. Further, based on our review, we believe that Medicare payments made by CMS to all providers for outpatient cardiac and pulmonary rehabilitation services during our audit period may not have met the requirements. Medicare paid $626 million for these services during our audit period.

RECOMMENDATION

We recommend that the Centers for Medicare & Medicaid revise its regulations to provide sufficient guidance to ensure that providers meet coverage requirements for outpatient cardiac and pulmonary rehabilitation services.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS stated that, in March 2021, it updated subregulatory guidance within its *Medicare Benefit Policy Manual* and *Medicare Claims Processing Manual* regarding the coverage requirements for outpatient cardiac and pulmonary rehabilitation services to more closely reflect the regulatory text. CMS also stated that revising regulations requires notice and comment rulemaking and that it will consider our recommendation when determining appropriate next steps regarding regulations on cardiac and pulmonary rehabilitation services.

We commend CMS on its efforts to ensure that providers meet coverage requirements for outpatient cardiac and pulmonary rehabilitation services as it plans its next steps. CMS also provided separate technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix E.

OTHER MATTERS: POST-PROCEDURE TIMEFRAMES NOT SPECIFIED FOR CERTAIN REHABILITATION SERVICES

Medicare covers cardiac rehabilitation services for beneficiaries that have experienced an acute myocardial infarction within the preceding 12 months (42 CFR § 410.49). However, the regulation does not specify timeframes during which a beneficiary may receive cardiac rehabilitation services after the occurrence of other covered conditions (i.e., coronary artery bypass surgery, heart value repair or replacement, percutaneous transluminal coronary angioplasty or coronary stenting, or heart or heart-lung transplant). CMS could improve the overall quality of the Medicare program as it relates to determining whether

[19] Our actual estimate is $2,733,202 in Medicare payments for services that may not have met Medicare coverage requirements. The 90-percent confidence interval for the Medicare payments associated with this estimate ranges from $2,377,601 to $2,741,884.

cardiac rehabilitation services are reasonable and necessary if it specified timeframes related to these other covered conditions in 42 CFR § 410.49.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

During the period April 2016 through March 2018 (audit period), Medicare made payments totaling $626 million to providers for outpatient cardiac and pulmonary rehabilitation services. We selected for review the third highest-paid provider in the country in combined Medicare reimbursement for both outpatient cardiac and pulmonary rehabilitation services during the audit period. During this period, the selected provider claimed Medicare reimbursement for 26,408 beneficiary-days of outpatient cardiac and pulmonary rehabilitation services totaling $2,741,884.

We selected a random sample of 100 beneficiary-days. We submitted documentation related to the first 10 sampled beneficiary-days to an independent medical review contractor to assess whether services were allowable in accordance with Medicare's medical necessity, documentation, and coding requirements. The medical review contractor identified issues with all 10 sampled beneficiary-days. We then reviewed the remaining 90 sampled beneficiary-days to determine whether there were issues with documentation similar to those identified by the independent medical review contractor.

After discussing our preliminary findings with the independent medical review contractor and CMS, we shifted the focus of our audit from the provider to CMS. Specifically, we concluded that although the provider did not meet the intent of CMS documentation of coverage requirements, the larger issue was the insufficiency of CMS regulatory requirements.

We determined that a review of CMS's internal controls was not significant to accomplishing our audit objective. We established reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file but did not assess the completeness of the file.

We conducted our audit from September 2018 through February 2021.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws and regulations;
- interviewed CMS program officials to obtain an understanding of the Medicare requirements related to outpatient cardiac and pulmonary rehabilitation services;
- interviewed provider officials to gain an understanding of the provider's policies and procedures related to providing and billing Medicare for outpatient cardiac and pulmonary rehabilitation services;

- obtained from CMS's NCH file all Medicare payments for outpatient cardiac and pulmonary rehabilitation services made to the selected provider during our audit period;

- created a sampling frame of 26,408 beneficiary-days of outpatient cardiac and pulmonary rehabilitation services totaling $2,741,884;

- reviewed data from CMS's Common Working File and other available data for the services for the sampled beneficiary-days to determine whether any of the service lines had been canceled or adjusted;

- selected a random sample of 100 outpatient cardiac and pulmonary rehabilitation beneficiary-days from the sampling frame;

- obtained medical records and other supporting documentation from the provider for the 100 sampled beneficiary-days;

- used an independent medical review contractor to review medical records and other documentation for 10 sampled beneficiary-days and reviewed the remaining 90 sampled beneficiary-days to determine whether services provided were allowable in accordance with Medicare medical necessity, documentation, and coding requirements;

- estimated the total amount of Medicare payments made to the selected provider for outpatient cardiac and pulmonary rehabilitation services that may not have met Medicare coverage requirements;

- discussed our preliminary findings with the independent medical review contractor and CMS, and, based on these discussions, redirected the focus of our audit from provider-specific to CMS-focused;

- determined whether CMS requirements were adequate to ensure that the provider maintained sufficient documentation in the beneficiaries' medical records; and

- discussed the results of our review with CMS program 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.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our target for this audit was all beneficiary-days of service (beneficiary-days) for which the selected provider received Medicare reimbursement for outpatient cardiac and pulmonary rehabilitation services provided during the period April 1, 2016, through March 31, 2018. A beneficiary-day is defined as all cardiac and pulmonary rehabilitation services for one beneficiary for 1 day.

Our sampling frame was an Access database of 26,408 beneficiary-days totaling $2,741,884 from CMS's NCH for which the provider received Medicare reimbursement for outpatient cardiac and pulmonary rehabilitation services during the period April 1, 2016, through March 31, 2018.[20]

SAMPLE UNIT

The sample unit was a beneficiary-day.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

We selected a sample of 100 beneficiary-days.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We sorted the sampling frame by Health Insurance Claim number (a beneficiary identification number) and date of service. We then consecutively numbered the sample units from 1 to 26,408. After generating 100 random numbers, we selected the corresponding frame items for review.

[20] We originally obtained an Access database of 26,585 beneficiary-days totaling $2,747,017 from CMS's NCH file for which the selected provider received Medicare reimbursement for outpatient cardiac and pulmonary rehabilitation services during the period April 1, 2016, through March 31, 2018. We removed 117 beneficiary-days totaling $5,133 for which Medicare was not the primary payer and 60 beneficiary-days for which the provider was paid $0.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of Medicare payments that were at risk made to the selected provider for outpatient cardiac and pulmonary rehabilitation services that may not have met Medicare coverage requirements. We calculated a point estimate and a two-sided 90-percent confidence interval for the estimate.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Sample Results

Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Number of Beneficiary-days with Errors	Value of Beneficiary-days with Errors
26,408	$2,741,884	100	$10,350	100	$10,350

Estimated Value of Beneficiary-Days With Errors
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$2,733,202
Lower limit	$2,377,601
Upper limit	$2,741,884[21]

[21] The upper limit calculated using the OIG/OAS statistical software was $3,088,802. The estimate was adjusted downward based on the known value of the sampling frame.

APPENDIX D: SUMMARY OF ERRORS FOR EACH SAMPLED BENEFICIARY-DAY

Legend

Error	Description
1	Individualized treatment plan incomplete or missing essential content
2	Documentation did not support that an adequate psychosocial assessment was performed
3	Education and counseling services not tailored to beneficiary's individual needs

Office of Inspector General Review for the 100 Sampled Beneficiary-days

Sample Number	Error 1	Error 2	Error 3	No. of Errors
1	X	X	X	3
2	X	X	X	3
3	X	X	X	3
4	X	X	X	3
5	X	X	X	3
6	X	X	X	3
7	X	X	X	3
8	X	X	X	3
9	X	X	X	3
10	X	X	X	3
11	X			1
12	X	X	X	3
13	X	X		2
14	X	X	X	3
15	X	X		2
16	X	X		2
17	X			1
18	X		X	2
19	X	X		2
20	X	X	X	3
21	X			1
22	X	X	X	3
23	X			1
24	X	X	X	3

Sample Number	Error 1	Error 2	Error 3	No. of Errors
25	X			1
26	X	X	X	3
27	X	X	X	3
28	X	X	X	3
29	X	X	X	3
30	X	X		2
31	X	X	X	3
32	X		X	2
33	X			1
34	X	X	X	3
35	X	X	X	3
36	X	X	X	3
37	X			1
38	X	X	X	3
39	X	X	X	3
40	X	X	X	3
41	X	X	X	3
42	X			1
43	X	X	X	3
44	X		X	2
45	X	X	X	3
46	X	X	X	3
47	X	X	X	3
48	X	X	X	3
49	X	X	X	3
50	X	X	X	3
51	X			1
52	X	X	X	3
53	X			1
54	X	X	X	3
55	X	X	X	3
56	X	X	X	3
57	X	X	X	3
58	X	X	X	3
59	X	X	X	3
60	X	X	X	3
61	X	X		2

Sample Number	Error 1	Error 2	Error 3	No. of Errors
62	X	X	X	3
63	X	X	X	3
64	X			1
65	X			1
66	X	X	X	3
67	X			1
68	X	X	X	3
69	X	X	X	3
70	X	X	X	3
71	X			1
72	X	X		2
73	X	X	X	3
74	X			1
75	X			1
76	X	X		2
77	X	X		2
78	X	X		2
79	X	X		2
80	X			1
81	X	X		2
82	X	X		2
83	X	X		2
84	X	X	X	3
85	X	X		2
86	X	X		2
87	X	X	X	3
88	X	X	X	3
89	X			1
90	X	X	X	3
91	X	X		2
92	X	X		2
93	X			1
94	X	X		2
95	X		X	2
96	X	X	X	3
97	X		X	2
98	X			1

Sample Number	Error 1	Error 2	Error 3	No. of Errors
99	X	X	X	3
100	X	X	X	3
Total	**100**	**75**	**61**	**236**

APPENDIX E: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: April 23, 2021

TO: Amy J. Frontz
Deputy Inspector General for Audit Services
Office of Inspector General

FROM: Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS Needs to Strengthen Regulatory Requirements for Medicare Part B Outpatient Cardiac and Pulmonary Rehabilitation Services (A-02-18-01026)

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

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 amended section 1861 of the Social Security Act to establish coverage, including conditions for coverage, for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation programs. In the Calendar Year (CY) 2010 Physician Fee Schedule (PFS) final rule with comment period, CMS implemented these provisions, consistent with the statutory requirements.[1] The regulations specify each of the required components for the various programs, including physician-prescribed exercise, psychosocial assessment, outcomes assessment, individualized treatment plan, and education or training or cardiac risk factor modification.

In 2014, CMS issued a National Coverage Determination that expanded the indications for coverage for cardiac rehabilitation to beneficiaries with stable, chronic heart failure.[2] In 2018, section 51004 of the Bipartisan Budget Act (BBA of 2018) amended section 1861(eee) of the Social Security Act to expand the covered indications for intensive cardiac rehabilitation to include beneficiaries with stable, chronic heart failure. In the CY 2020 PFS final rule with comment period CMS updated 42 CFR 410.49 to codify this expansion of coverage.[3]

CMS recognizes the importance of continuing to provide Medicare beneficiaries with access to medically necessary services and, at the same time, working to protect the Medicare Trust Funds from improper payments. CMS uses a robust program integrity strategy to reduce and prevent

[1] 74 FR 61872-61886 and 62002-62003 (pulmonary rehabilitation) 62004-62005 (cardiac rehabilitation/intensive cardiac rehabilitation); 42 CFR 410.47 (pulmonary rehabilitation) and 410.49 (cardiac rehabilitation/intensive cardiac rehabilitation)
[2] https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=359&ncdVer=1
[3] 84 FR 62897-62899 and 63188

Medicare improper payments, including automated system edits within the claims processing system, and conducting prepayment and postpayment reviews. For example, CMS's Recovery Audit Contractors were approved to begin medical necessity and documentation requirement reviews of cardiac rehabilitation and intensive cardiac rehabilitation services in January 2019, and pulmonary rehabilitation services in March 2019.[4] As part of this strategy, CMS recovers identified overpayments in accordance with agency policies and procedures.

Additionally, CMS has taken action to prevent improper Medicare payments by educating health care providers on proper billing. CMS educates health care providers on Medicare billing through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services revise its regulations to provide sufficient guidance to ensure that providers meet coverage requirements for outpatient cardiac and pulmonary rehabilitation services.

CMS Response

CMS updated the subregulatory guidance within the Medicare Benefit Policy Manual and Medicare Claims Processing Manual regarding the coverage requirements for outpatient cardiac and pulmonary rehabilitation services to more closely reflect the regulatory text in March 2021.[5] Revisions to the regulations require notice and comment rulemaking. CMS will consider this recommendation when determining appropriate next steps regarding the regulations for outpatient cardiac and pulmonary rehabilitation services.

[4] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0135-Cardiac-Rehabilitation; https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0140-Pulmonary-Rehabilitation

[5] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf; https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf